SIXTH FRAMEWORK
PROGRAMME

Ethical Governance of Biological and Biomedical Research: Chinese-European Co-operation

1st WORKSHOP REPORT

Informed consent in reproductive genetics and stem cell technology and the role of Ethical Review Boards

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Introduction: general guiding questions and expectations

The first BIONET workshop, held in Beijing in April 2007, provided an opportunity for European and Chinese BIONET members, together with invited experts, to begin the work of "mapping" the normative frameworks and practices concerning informed consent, good governance and best practice in research and clinical contexts, with an initial focus on reproductive medicine.

Participants from each region began with a wish to develop their knowledge of the situation of informed consent in the other. In addition, we wished to develop our experience of working together, in order to confirm the feasibility of open ethics debate and communication between the different languages and cultures involved and explore the possibilities of increasing our understanding of the current situation and the challenges that were being faced, both in Europe and in China .

The workshop was not only an opportunity for learning and understanding, but it was also a point of departure for the entire BIONET project. To achieve this goal, the main problems, concerns, ethical ideas and solutions were introduced from different professional and national perspectives. Participants discussed the experience of different established ethics systems, and in the policymaking process. Our common goal was, jointly, to explore ways of improving regulation, governance and practice according to shared ethical and scientific standards. From the European, side, there was particular interest in determining the best forms of governance of European research activities in China, based upon a more accurate understanding of the situation on the ground. From the Chinese side, there were specific interests in learning more about European standards and creating a momentum to support related developments in China.

The long-term plan of the BIONET is to provide a solid basis to develop advice and policy for the governance of Sino-European research projects in the life sciences, in the form of evidence based best-practice guidance. In the process, BIONET will support network building, towards a sustainable quality infrastructure for consultation and co-operation on matters related to the ethics of life sciences research between Europe and China. The process of preparation for this first workshop had already initiated networking and cooperation, within China and Europe, and across the continents.

The workshop was also intended to inform BIONET partners about the requirements, the limitations and challenges in access to information about bioethical governance, the diverging opinions and experiences about normative values and procedures or cultures, and about practical obstacles for understanding. These explorations and learning activities were informed by our empirical approach towards the issues, as a basis for the long-term purpose of mapping of bioethical governance, and the preparation of policy advice. The outcomes from the first workshop will be crucial for the preparation of the BIONET conferences in 2008 and 2009.

Reproductive medicine: the rise of ART in Europe and China

Assisted Reproductive Technologies (ART) comprise a range of biomedical technologies that have been extensively developed and widely applied in Europe and in China in the last three decades, including in vitro fertilisation (IVF), intracytoplasmic sperm injection (ICSI), artificial insemination by donor (AID) and pre-implantation genetic diagnosis (PGD). By their very nature they relate to the emotions, well-being and dreams of humans, but are also surrounded by political/ideological or socio-economic factors and cultural understandings of fertility/infertility. They rely on an environment that supports the procurement, storage, manipulation and assessment of gametes and embryos from human subjects in ART centres. As such, these technologies raise a range of ethical, policy, regulatory, legal, social and medical issues, and have implications for professional conduct, the rights of patients, and individual and population welfare.

In many European countries, IVF and other forms of assisted reproductive technology have become routine. The principled right to found a family, guaranteed by the European Convention on Human Rights, has in many countries been translated into fully or partly-subsidised infertility treatment programmes for those unable to conceive 'naturally'. In a country like Denmark, as many as 3.7% of all births are ART babies. And although fundamental moral issues have not been settled, ethical debates have moved away from initial concerns about the artificial medicalisation of a 'fact of life' (namely that some couples are not able to conceive), towards very practical deliberations about a maximum age for IVF treatment, whether or not donor anonymity should be upheld in cases of artificial insemination by donor (AID), whether single and/or lesbian women should be allowed to undergo ART treatment, limits on embryo selection and whether or not 'designed' saviour siblings or certain procedures of pre-gestational selection should be allowed. Since the world's first IVF baby, Louise Brown, was born in the United Kingdom in 1978, country after country has adopted national legislation to govern the practice of ART, including the United Kingdom (Human Fertilisation and Embryology Act of 1990), Germany (Embryo Protection Act of 1990) and Denmark (Act on Artificial Fertilization from 1997). There are many national differences in these European regulations, in terms of ethical principles and stakes as well as in the characteristics of the respectively adapted policy, with some countries allowing surrogacy and others prohibiting it, some permitting embryo selection for 'saviour siblings' or to prevent "serious disease" in contrast to those that ban any form of selection. In some countries, the interests of the (potential) child can take priority over a couple's right to a family (e.g. when a couple's perceived lack of parental abilities is used as justification to deny infertility treatment), and in others the only requirement for being accepted for treatment is a couple's (or single woman's) unfulfilled desire to have children. And, with recent attention on human embryonic stem cell research and therapeutic cloning, ethical debates that emerge at the "IVF-stem cell interface" have also become central to legislative initiatives to govern research on gametes, embryos and stem cells.

In China, the first 'test tube baby' was born in Beijing in March 1988. Ever since the demand for and supply of assisted reproductive technologies has grown rapidly. While

accurate statistics are difficult to obtain, it is estimated that infertility rates are creeping towards 10% of all couples in China, with the ill effects that fast-paced modernisation has brought in its wake – unhealthy urban lifestyles, pollution, improper use of contraceptive medicines, etc. – often cited as major factors behind this increase. A particular factor that has been mentioned to explain the increasing demand for infertility treatment among women older than 35 in China is that their condition is often caused by various abortions that are still used as the major remedy for unwanted pregnancies and birth control. In Beijing alone, over 10,000 couples have sought treatment for infertility since IVF became available from the early 1990s, and over 3,000 IVF babies have been born while sperm banks throughout the country are in constant shortage of donors.

China has a long-standing history of ethical codes of medical practice dating back to the 4th century BC. In more recent times, the medical profession, and in particular those working in the field of reproductive healthcare, have come to be strictly regulated under the "Law of the People's Republic of China on Medical Practitioners" (1999), the "Law of the People's Republic of China on Maternal and Infant Health Care" (1995) as well as the "Regulations on the Administration of Medical Institutions" (2002). Yet, it is clear that new technologies and developments in the life sciences raise new ethical concerns. As put by Prof. Lu Guangxiu of the Hunan Institute of Reproductive and Stem Cell Engineering, "the implementation of ART technologies, which have changed the natural process of child bearing by separating it from sex and marriage, has initiated a series of ethical dilemmas". Moreover the rapid uptake of these new technologies in the 1990s meant that by the turn of the millennium, over 200 hospitals and health centres (some estimates put it at 400) were thought to be providing ART treatment in China, although, importantly, not according to a consistent standard of practice. Indeed, so extensive was the growth in the provision of ART treatment that Dr. Li Zheng of Shanghai's Renji Hospital suggested in 2001 that "the passage of legislation has fallen behind the rate of IVF activity in China".

Yet, this state of affairs would undergo radical changes in the very same year, as the Ministry of Health issued its first set of "Ethical Principles for Human Assisted Reproductive Technology & Sperm Banks" in February 2001 (revised in July 2003). Upon launching these new principles, which made it obligatory for any institution or individual providing ART treatment to get official authorisation to do so as well as introduced binding practice guidelines, Yu Xiucheng of the Ministry of Health argued that "the market [for ART treatment] must be regulated; otherwise the technology could be abused and the market may grow out of control, causing many social, ethical and legal problems". As a direct result of these new regulations, the number of approved ART centres has fallen to 88 and sperm banks to 10 (as of December 2006). Notwithstanding

these important developments, a number of challenges remain in China. A “grey zone” of an uncounted number of unauthorized private clinics persists as some individuals are prepared to risk punishment by providing ART services without a license, lured by an ever-growing demand for ART services and the potential of “huge business profits” (Yu Xiucheng). Moreover, as patients have become more aware of ART, clinics have experienced a rise in ethically challenging cases where patients use their knowledge of ART techniques to seek treatment for ‘infertility’ when in fact they are hoping for multiple births (as a way to circumvent China’s one-child policy) or are attempting ‘sex selection’ with the aim of having a boy child. Also, ethical debates have been prominent in many national news media where, for example, the wife of a prisoner on death row requested ART with semen from her jailed husband as well as in cases of requests for surrogacy. And finally, ethical debates about embryo and gamete donation for stem cell research have also begun in China with calls for ethical review boards to closely monitor such donation with a special view on protecting women from exploitation or harm.

Workshop setting

It was against this background that European and Chinese experts met in Beijing for the first BIONET workshop on “Informed consent in reproductive genetics and stem cell technology and the role of Ethical Review Boards”. About 50 participants gathered at the Peking University Health Science Centre from 1 to 5 April 2007 to discuss and exchange experiences around issues of informed consent and ethical review of ART treatment and research. While the second workshop will be focussing particularly on research in the area of regenerative medicine, the first workshop concentrated on ART clinical practice, and its interface with research, as a means to understand how issues of informed consent and ethical governance come into play, because clinical practice in infertility clinics is almost inevitably the starting point and material source for almost all research into reproductive medicine and stem cells.

The workshop adapted a combination of communication tools and methods, in order to take advantage of the interdisciplinary, multi-national and cross-cultural diversity of contributors, with a variety of experiences and skills. In the absence of one general scientific framework for such a project, the discussion in various formats methodically engaged a change of perspectives. Formats ranged from keynote presentations to semi-structured case discussions, small group work and open debate, as well as a change of location for on-site visits and discussions in a reproductive clinic and a genome research centre (see programme).

Delegates came not only from academia, clinical and research professions, but also from different ministries, administrations, and from the two Chinese journals specializing in medical ethics (Zhongguo yixue lunlixue / Chinese Medical Ethics and Yixue yu zhexue / Medicine and Philosophy). European delegates from the UK Medical Research Council's CURE project (China-UK Research Ethics) participated as active observers. Moreover, two local patient representatives took part in the discussion. In terms of gender, participation was fairly distributed.

In addition, the inter-generational dimensions of the research materialized through contributions from BIONET's newly formed group of junior researchers, with special presentations and very active participation, making a significant impact on the event. Presentations were arranged in the way of a dialogue, with consecutive Chinese and European contributions, cases from China and Europe and shared chairing responsibilities. There was ample time for open debate, in response to speakers and in the plenum, with a reasonable minimum of structural constraint.

Interaction was facilitated through socializing events, such as a scenic banquet and a visit to the botanical garden. After three days of intensive work as a full group, a number of participants had to return to their regular professional activities. For this group of participants, 5 days proved too long.

Discussions were summarized and presentations and materials were made available to participants (on CD). Further results will be published on the open access point of the BIONET website. In addition to workshop discussions, the BIONET Expert Group was formally constituted (after informal preparations during and since the kick-off meetings) and set out to work towards a scientific agenda, under the chairmanship of Professor Christoph Rehmann-Sutter. The first results were introduced to the participants and discussed during the workshop.

In sum, the structure worked out well and was generally approved by the participants. In particular , the changes of perspective proved to be inspiring, the 'pairing' of Chinese with European presentations was successful and the interdisciplinary design encouraged spirited debate. When required the organisers adapted flexibly by modifying the programme in order not to restrict the lively discussions. Finally, participants said that they felt they had learned and benefited a lot from the workshop and were now able to see more clearly the characteristics of the ethical and challenges as well as the starting points for constructive collaborations. The organisers also learned from strengths and weaknesses, and this will feed into the design of future workshops. To facilitate this, an evaluation form has been sent out to all participants.

A look into the debate: key issues

Over the course of five days, participants at the workshop addressed the particular concerns of different groups: patients and research subjects, biomedical research institutions (hospitals and research units), policymakers, law enforcement officials, educators, as well as Chinese experts in ethics and culture. In the following, some of the key issues to have arisen are summarised.

The condition of bioethics

In his introductory note, Officer Yu Xiucheng (Ministry of Health) stated that, “Bioethics is not well developed in China”, and that it is not mature enough to contribute as much as desired to the political goal of sustaining a “harmonious society”. Mr. Yu identified a great need to develop bioethics as an integrated approach to applied ethics, bringing together and mending gaps between the different professions, the natural and social sciences, strata in society, physicians and patients, traditional wisdom and modern challenges, on the basis of state of the art scholarship. This is still an open task for China, urging the state to connect bioethics with a modernised social science infrastructure. Mr. Yu pointed out that it will not suffice for China merely to follow and assimilate the standards of international bioethics, but that it needs to develop the culture’s humanistic resources and make a reflected contribution to the domestic and global quest to good practice.

The conceptual frameworks and terminological standards and institutions resulting from this situation in China differ from those in Europe, not only regarding the basis for the development of normative theory (ethics and law) but also due process. Moreover, they are crucial as tools for analysis, argument and communication, and thus have to be accounted for when engaging in cross-cultural, international and interdisciplinary exchange. If not properly accounted for, these differences can lead to avoidable misconceptions, jeopardizing the multilateral relationships and the prospects of establishing best practice in European-Chinese collaborations.

Also, it follows from the short history of bioethical regulation in China that there are still only relatively few properly educated bioethics experts (who could, for example, serve on review boards or as advisors in institutions), and those few are not supported by an adequate academic environment (such as in a social sciences context). In addition, most of those experts have received education in bioethics with a strong orientation towards the USA system. In the light of differences between US-bioethics and European bioethics

and intra-European diversity, this poses additional difficulties to Chinese-European understandings.

Through the discussions, significant diversities of understanding were observed regarding a number of issues. For example, there were varied definitions of stakes; e.g., what is a human being, what is an embryo, can the state approve of killing, when a “balanced approach” is required, who defines the extremes and according to which standards? Whereas the debate about the moral status of the embryo is still ongoing in China (disregarding the legally accepted 14-days deadline), participation is limited. Prof. Wang Yanguang and Prof. Cong Yali noted that recent pilot studies on attitudes towards abortion indicate a development in the direction to paying more attention and developing a climate of sympathetic and considered debate with a diversity of opinions.

There are different and overlapping conceptions of morality, ethics, law and political ideology. The differences and connections between the related practices of governance are also somewhat unclear, for example the relative scope of governance by law, regulation, opinion leadership, or propaganda. Participants from all countries shared some confusion about questions such as “can ethics or law establish the right to a desired outcome?” (such as a right to having a child, or a right to begetting a son when desired). Such questions that have been discussed in Europe for many years, are new and heatedly debated in China. There was also intense debate about the proper interpretation of due process as well as of participation in and the content and structure of legislation. In China, significant aspects of the process are non-transparent. The debate illustrates that China is in early stages of introduction of a culture of law and making it practical.

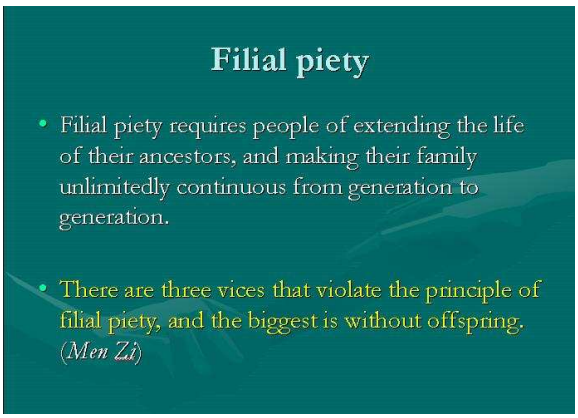
In China, it was argued, people are not yet used to debating fundamental developments in public before they take place (Yang Huanming, referring to the introduction of IVF in China). Developments in science, and in biomedicine, and their applications, often take place without discussion. Prof. Propping, discussing the invention and use of ICSI, which took place without any ethical oversight, shows how this also applies to Europe. The Chinese government has targeted the problem by setting up a system of oversight and by boosting the image of societal responsibility and “good science” and encouraging public debate of bioethics, through various means. But the extent of debate remains variable, and, both in China and in Europe, public debate often follows the revelation of scandals.

Because of the largely top-down approach to policy making in China, the transparency of the process of developing and enforcing ethical standards and legislation is sometimes questioned. In China, the debate is mostly limited to experts, officials and lawyers; whereas in Europe significant contributions come from independent media, churches, NGOs and other civil society organizations. These civil society organizations are less established and active in China, especially in bioethics debates. There are emerging tendencies among patients and clients to organise self-help groups and offer advice, information and support services to the citizens. Yet it remains difficult to have productive debate when the empirical situation is unclear and a reliable research and evidence base is lacking. An inadequate evidence base can lead to misleading conclusions, and even generate inappropriate policy measures.

Moreover, there is still much truth in the traditional and popular Chinese saying that, "The sky is high, and the emperor is far away". Even the best intended policy measures at the central or provincial government levels lose their grip when local authorities or professionals do not comply, and participants in the workshop were of the view that such lack of compliance is widespread across China. Strategic responses were discussed such as further improving general education, targeting the education of relevant professional groups, increasing the implementation of the licensing and monitoring system and developing the awareness of patients' and citizens' rights while providing more qualified legal experts (e.g. medical lawyers).

Cultural concepts of fertility/infertility

In China, deep-rooted social practices and cultural understandings about family lineage and ancestors have been a crucial factor in the continually growing demand for ART. This became clear through many of the clinical cases that were distributed to participants and discussed in group sessions. A case was presented where a woman and her parents-in-law pleaded for Artificial Insemination by Husband (AIH) following a car accident that left the husband in a coma. The overriding concern of this woman and her parents-in-law was framed in the language of the classical Confucian saying, that "having no descendants is one of the most unforgivable and unfilial deeds". The importance of family lineage is also apparent in cases of Artificial Insemination by Donor (AID). While they might disclose that they are undergoing ART treatment, couples will rarely inform even the closest of relatives if they require AID. It became clear in the discussion, that underneath the surface of references to "culture", there is a huge variety of different motivations and conceptualizations of the meaning and the perceived problems in ART and especially in AID, for example frustrated males' self-esteem when seen as an "incapable" husband, equating AID with adultery, or the participation of third parties (namely medical professionals) in the intimate acts of procreation.



In another case presented, a couple that had undergone AID successfully but the father fell terminally ill shortly afterwards: conflict arose with his parents after he disclosed to them that his child was conceived with the help of donor sperm. The parents subsequently rejected the child's inheritance rights upon the death of their son, in disregard or ignorance of the legal situation. Finally, certain conceptions of lineage also play a big role in the fact that adoption is rarely an option for infertile couples in China. As summarized by Professor Qiu Renzong in a presentation on the 'Philosophical concept of reproduction and its cultural transformation with technological advancement', in China it is expected that "gentlemen (*jun zi*) pay

great attention to marriage that unites two families into one in order to serve ancestors in the temple of the family and to extend the family to future generations". Filial piety, said Professor Qiu, requires people to extend the life of their ancestors continuously from generation to generation. In a multi-cultural and modernizing society such as China, however, the outlooks on family and reproduction are obviously difficult to standardize.

In his talk, Professor Qiu also described Chinese conceptions of infertility as growing out of ancient Confucian, Taoist and Buddhist teachings. Through these teachings, which affected mostly the upper strata of society, infertility was primarily viewed as a female problem resulting from an abnormal structure of female sex organ, an abnormal uterus, the eating of poisonous herbs, inbreeding, excessive sex and also serious diseases suffered by the husband. In her presentation, Professor Qiao Jie of the Third Hospital of the Peking University Health Science Centre, argued that "in China, the burden of infertility most often falls on the woman and in the past, couples who could not conceive either adopted or divorced". Indeed, as Professor Qiu pointed out, social implications of infertility included individual unhappiness, disharmony in families, stigmatization of infertile women as violators of filial piety, domestic violence and divorce.

Rongchuan Yi, one of the patient representatives attending the workshop on the fourth day, explained to participants how a diagnosis of infertility was disconcerting; was it a disease, what had caused it, what implications did it have, could it be helped? She actually questioned the definition of infertility as a disease. She also expressed the view that patients' rights include full information, treating the patient as a mature client and leaving the final decisions up to them. At present, she argued, clinics are not adequately prepared to spend enough time on counselling. She pointed out that patients should be supported when trying to form self-help and support organisations, because, "Only patients have patience". Here would also lie an important sector for the engagement and education of specialized social workers. For patients, ART signified hope; hope that they could fulfil their desire to have children after they had been told that they could not do this on their own. Taking these considerations into mind, it is hard to see the demand for ART in China either diminish or decelerate at this stage. It is obvious, though, that interactions between patients and professionals will more often take the form of legal disputes. Ethics has a great responsibility and some capacity to prevent and alleviate conflicts, by establishing standards that support due process, good practice and better awareness of the medical and social intricacies of IVF procedures.

In Europe, as pointed out earlier, many forms of ART have become routine. In most countries, infertility is no longer considered an acceptable impediment to a couple's right to found a 'natural' family. National health insurance schemes often partially or fully finance a limited number of IVF cycles for infertile couples. And as French Professor Dominique Memmi argued in her presentation on 'Professional experiences and ethical issues in ART from a European Perspective' that there was a split between those European countries which stipulated that there "must be a therapeutic reason for ART treatment" and those that allowed ART in all cases "to help a woman bear a child". In the latter case, single women and lesbians, for example, would be allowed to undergo ART. Dr. Ayo Wahlberg showed how Denmark had in recent years gone from legally

stipulating the former towards the latter following an amendment of their national Act on Artificial Fertilization in 2006. This change, however, had now initiated a discussion as to whether the national health insurance system should only pay for ART in cases where there was a therapeutic reason, leaving single women and lesbians to pay for ART themselves.

Another key ethical debate in Europe, as UK Professor Genevra Richardson pointed out in the discussions following Professor Memmi's presentation, was that of an age limit for ART, a debate which was informed by a similar questioning of whether infertility for women over 40 could be classified as a "therapeutic condition". It was clear from discussions that the concept of infertility was undergoing transformations in many European countries but often with different outcomes.

Regulation and "the grey zone"

One of the liveliest and most heated debates followed after a number of presentations from Chinese partners suggested that numerous Chinese realities exist, with different standards and practices. While it appeared that, in general, the situation in larger ART centres is well organised and monitored, with great efforts being made to develop a best practice regime, there were other clinics where this was not the case. The workshop facilitated the establishing of contacts for co-operations between Chinese centres. It remained an open challenge, though, how to engage those clinics and research institutions of lower achievements, and how to deal with those, especially private ones, which do not comply with the regulations.

More lively discussions ensued in discussions about how best to ensure that regulation was sufficient and/or effective. What emerged from many of the presentations and comments during discussion was that both in Europe and in China there were different forms of regulations, rules, guidelines and laws. Indeed, Chinese and European experts at the very final session evaluating the workshop suggested that in future workshops time was devoted to discussing the concept of 'governance' as this word, with its newly acquired significance in political science and debates over regulation, could not at present be easily or appropriately translated into Chinese.

In a presentation on "Informed Consent in Genetic Research and Diagnostics", Professor Peter Propping, from Germany, explained how in Germany there were many different instruments used for the ethical supervision of research. The Declaration of Helsinki functioned as a general rule, as in most countries including China, which ensured that considerations related to the well-being of the individual in principle should take precedence over the interests of science and society. Further to this there are national laws, professional regulations of the Federal Board of Physicians, recommendations of National Ethics Council (which law makers took into consideration), concrete statements on projects by Ethical Committees at medical faculties and not at least the ethical requirements of public or private funding institutions, as well as other regulatory bodies. In discussions afterwards, Prof. Richardson pointed out that it was often the funders and

international science journals who played a key role in ensuring ethical compliance as researchers would always make sure that they lived up to their requirements, otherwise they would risk losing their income or career opportunities. In particular, funding agency ethical guidelines had 'teeth' as she put it.

In China, when it came to ART clinical practice, there is a similar heterogeneity of laws, rules and regulations. First of all, there are national laws which are approved by the National Executive. These include the "Law on Medical Practitioners", the "Law on Maternal and Infant Health Care" and the "Marriage Law". As Li Rong of the Third Hospital (and one of BIONET's student exchange candidates) showed in her presentation, ART centres are obliged to strictly adhere to national population and family-planning legislation and policies, as stipulated on the level of state regulations. Since 2001, they must also be authorised and certified to practice by the Ministry of Health according to "The regulation on Assisted Reproductive Technology" as well as "The regulation on the Administration of Medical Institutions". Once approved, a Centre receives a certificate from the Ministry of Health which is its licence to operate and must provide necessary documents and annual reports to the Ministry of Health. Hence it is often regulations and in particular the licensing requirements that have the most 'teeth' in China as Centres do not want to risk losing their licence to operate. ART centres are also required to follow "Ethical Principles for Human Assisted Reproductive Technology & Sperm Banks" which were revised by the Ministry of Health in July 2003. There appeared to be a consensus among the Chinese participants that the ethical standards and protocols, to the drafting of which she had contributed substantially, are relatively advanced and exemplarily adhered to in Prof. Lu's clinic and research institute, as compared with other locations in China. And finally, authorised ART centres are required to carry out routine self inspection in accordance with their own rules.

Professor Feng Yun of the Reproductive & Medicine Centre, Ruijin Hospital in Shanghai welcomed these latest regulatory initiatives from the Ministry of Health. Yet at the same time he pointed out how regulations and guidelines did not always provide answers to individual cases on a day-to-day basis in the clinic. For example, some patients who travel to ART clinics in urban centres from rural areas in order to receive state of the art treatment only have 3-day permits to be in the city, which leads to a demand for implantation of fresh embryos. This in turn is in conflict with guidelines to keep embryos for 6 weeks, so as to be able to perform relevant quality controls and embryo assessments, before implantation. Also, with so many people travelling from many different areas, it is very difficult sometimes to know what the status of frozen gametes are when these people return to their homes without leaving sufficient contact details behind. And finally, while commercialisation is strictly forbidden, ART techniques such as cryo preservation cost considerable amounts, how should appropriate

levels of costing be calculated internally within clinics? Similarly, while compensation for travel costs and time off work was allowed for donors, what was an appropriate level and kind of compensation? In other words, Prof. Feng highlighted the practical gaps between regulations and guidelines on the one hand and clinical realities on the other, indicating a vast grey area of uncertain implementation of and compliance with the medical and ethical standards.

Professor Huang Yuanhua of the Hainan Reproductive Medicine Centre discussed what he saw as one of the key priorities in China today, namely the accreditation and assessment of ART centres. Prior to the 2001 regulations, there were over 200 centres (others have estimated 350 or 500!) offering ART services and many of them were practicing according to questionable standards, for example advertising obviously fictitious success rates of 70 to 80%. Now that new regulations had been introduced it was important to ensure that they were enforced through regular audits of ART centres. Ethical review boards were also an important tool as a kind of self-auditing institution. Moreover, auditing efforts should not only target authorised centres, but should also identify and map out the extent of a continuing "grey zone". Regulations and guidelines could be an effective way to ensure that licensed centres operated ethically, but they did not reach those remaining individuals operating without authorisation. First of all, they require proper training and support of ethics committee members and medical personnel.

In sum, the discussion on regulation showed how a heterogeneity of forms of regulation prevail or are in different stages of development and implementation, in both Europe and China. In Europe, this diversity encouraged to some extent 'fertility tourism' as there were many cases where nationals of one country that had, for example, an age limit on IVF or a ban on PGD, simply travelled to another European country where it was legal. In China, as Professor Lu pointed out, there was a diversity of ART centres, ranging from the top clinics which had much to offer in terms of best practice, to the medium and also to the lower standard clinics, not to mention the 'grey zone'. It was reported that frequently patients whose request for treatment had not been approved or who felt dissatisfied with the course of events would turn to places of lower reputation, and, given sufficient financial means or social pressure - they would receive the demanded services,. The regulations and guidelines on ART introduced by the Ministry of Health were necessary steps in a process of national harmonisation but they were not sufficient in themselves as they had to be followed up with audit procedures as well as enforcement, education and general public awareness.

Affordability, commercialisation and the socio-economic context of ART

In both Europe and China there is a market for infertility treatment, which raises issues of public health policy. Prof. Paul Unschuld argued in his presentation on 'Some thoughts on the historical roles of European physicians in reproductive medicine', that in today's globalizing world "health and disease are economically valuable" and that "health and disease have become figures in a market economy". His argument was that while in the

past the health of a nation's population had been a key priority of the European States, and in contrast to China, in terms of ensuring a strong labour force as well as national army to defend itself and to compete economically with other countries, this pressure to keep an entire population healthy was giving way to a marketization of healthcare where the patient becomes customer. He argued that the historical shaping of the identity of the medical profession as custodians of the state's interests and as guardians for their patients, with the resulting powerful social, scientific, political and economic position of physicians, could not be transferred to the Chinese context. However, concerns about a global development towards marketization and commercialization of healthcare were universal and were very familiar to Chinese participants. Together with regulation, commercialization was one of the most keenly debated topics at the workshop. It was noted that the relative position, status and financial standing of the physicians in society in China differs from that in European countries. To some extent, this lower status in China explains the relative weakness of the medical profession and the limited political influence of medical ethics.

In Europe, the ethical basis of the relationship between doctor or researcher and patient is the expressed permission of the latter to engage in specific activities that would otherwise be regarded as criminal violations of a person's integrity: as Dr. Döring pointed out, "As soon as the doctor touches the patient, it is an offence, unless the patient expressly permits it". Chinese participants were less certain that this basic principle underpinned relevant policies and practices in China.

As pointed out earlier, in Europe, some countries offer ART services via national health insurance systems while in others patients have to pay for it. Cost is very often an important consideration in all countries, especially when patients seek IVF via private clinics. As is the case with most health-related issues, there is inequality and it is often the more well-off who have better access to IVF treatment. There is considerable inequality not just between European countries (e.g. Denmark provides 2,000 cycles per million people compared to 600 cycles per million people in the United Kingdom) but also within countries as cycles per patient are often higher in more affluent areas of a country (in the UK this is referred to as the "postcode lottery"). In the UK, one fertility treatment cycle is estimated to cost about €4,400 or RMB 44,000.

In China, the questions of affordability, commercialization, access and equality are among the most important in ART, especially considering wide socio-economic disparity in such a vast country. There is no public health insurance system that would cover ART treatment. To begin with, authorized ART treatment centres are often located in urban centres meaning that people living in rural areas have to travel sometimes quite far to get access to treatment which adds to already very substantial costs for ART treatment when compared to average annual incomes. In Beijing, assisted insemination (with donor sperm) can cost anywhere between 3,000 to 5,000 RMB (€300-500) while in vitro fertilization costs 4 to 5 times more at 20,000 to 30,000 RMB (€2,000-3,000), and all of this has to be viewed against an assisted conception success rate of about 25-33% which is often difficult to communicate to patients. These are great costs in a country where average annual income per capita is roughly 12,000 RMB (€1,200).

Dr. Liqing Fan, head of the sperm bank affiliated with the Institute of Reproductive & Stem Cell Engineering in Changsha, discussed the question of commercialization in his presentation. He asked the question of whether or not sperm is a commercial product, whether it should have price and if so what should the basis for sperm quality be – intelligence, social status, motility of the sperm? In China, there is a chronic shortage of sperm donors as demand constantly outstrips supply and there are many factors behind this shortage including: misinformation about the legal responsibilities of the donor towards any children conceived; considerably lower costs of assisted insemination with donor sperm compared to IVF; a high rate of non-qualifying donor applicants (70-80% were excluded after assessment in Changsha according to Fan, although the reasons for such a high exclusion rate were not clarified); and finally, cultural understandings about family lineage and filial bonds could also be a barrier.

In his presentation on ART-related research and commodification in Denmark, Dr. Ayo Wahlberg showed how a Danish company called Cryos had in recent years marketed itself globally as "meeting the demand for Scandinavian sperm". Sperm was definitely a commercial product in Denmark and this factor had played a role in Danish lawmakers' recent decision to uphold the anonymity of donors, as business would suffer otherwise. Cryos priced its sperm according to biological quality criteria (primarily sperm motility), however, patients could search the anonymous donor database according to criteria like educational background, ethnicity and age. In China, the relevant regulations clearly stipulate that gametes cannot be commercialized or traded.

Commercialisation was also debated during one of the case discussions on egg donations, which was chaired by patient representatives Rongchuan Yi and Xiaohong Zhou. The case concerned an advertisement that had been placed in a Beijing university campus: "An infertile couple is seeking an ovum. The desired egg donor should be: age 20 to 29 years old, with at least an undergraduate diploma, no family medical history, good looking, regardless of the marriage status. The reward will be above ten thousand yuan." The case underlined how both in China and Europe, prospective parents were always anxious about the personal history of the people who donate the gametes they rely on to have children. In this particular case, Xiaohong Zhou asked "if men could donate sperm for compensation then why shouldn't women be able to donate eggs?" To this, Prof. Peter Propping replied that the risks for women donating eggs were much higher than for men donating sperm, as they had to take fertility drugs and undergo an invasive procedure.

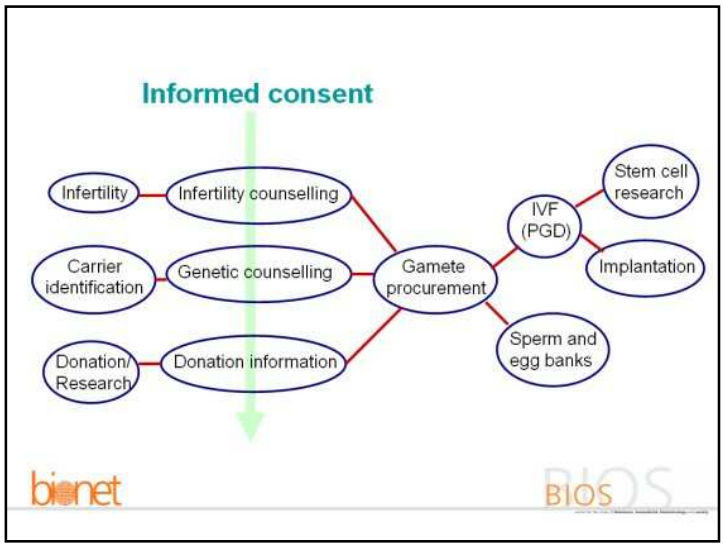
The question of commercialization and the lacking awareness of the illegal nature of such activities also came up in Joy Zhang's (PhD student at LSE and one of BIONET's student exchange candidates) presentation on surrogacy, as she showed how potential surrogate

mothers could easily be found on the internet, on a legal website, despite restrictions and prohibitions. This, Ms. Zhang argued, has meant that in China surrogacy has in fact gone from an object of prohibition to one of recognition, while it is still legally banned and the question remains open whether China will eventually follow, e.g. the UK's route to making legislative proposals on surrogacy.

In sum, commercialization of the ART process – gamete procurement/donation, gamete storage, fertility counselling, ART cycles, follow up – was a fact in both Europe and China raising numerous ethical challenges. In both contexts, donation was seen as an altruistic act and any compensation was to be based solely on any particular inconveniences for the donor related to the act of donation. Opening up gamete donation to market forces it was argued would leave many people open to exploitation, especially women. At the same time, ART treatment was expensive and had to be financed in some way, whether through health insurance plans or by the patient as private customer. In China, the most pressing governance problem in this regard is implementation of legal and ethical standards, resulting from the striking difference between regulation on the one hand and public awareness and compliance on the other.

Time and care – institutionalisation of informed consent

One of the key topics of the first workshop was informed consent and how this comes into play in ART treatment as well as related biomedical research. Informed consent has been legally required for hospitals since 1982, as reported by Dr. Zhuo Xiaoqin, a lawyer from Beijing, and it has since gradually gained greater ethical and regulatory salience through legislation, education and public debate. Discussants emphatically emphasized that the moral reasoning underpinning this concept needs to be distinguished from the legal form, and that both needed to be strengthened in order to improve the patient-doctor relationship (Professor Li Benfu). Chinese and Europeans in principle agreed that the informed consent signature should be regarded as a minimal formal condition for interventions into the body, expressing a subjects' permission to the doctor or researcher to invade his or her private sphere. Moreover, all participants shared a growing awareness of the shortcomings of the existing informed consent regimes, both in Europe and in China. This goes beyond the question of political or social limitations, for example, where adoption is not offered as an option in the informed consent process in IVF: while this is



routine in European countries, there is a significantly underdeveloped practice of adoption in China.

In particular, the importance of additional interaction between professionals and the subject, with alertness towards his or her social situation, was acknowledged: there was shared dissatisfaction with a narrow model of giving information to patients and subjects, and this was giving way to a more adequately considered model of communication-centred and context-sensitive informed consent. Participants agreed that this would help to move from "informed consent as merely a piece of paper" (Wang Yanguang) towards an ethically meaningful process. On the other hand, alongside the view that the patient/the family should make their own decision according to their own best judgement, there remains a strong paternalistic opinion that counselling during informed consent procedures should include as assessment of the reasonableness of the patients will. The tension between these two positions remains, and is difficult to overcome.

Another critical issue is the language of 'rights' in bioethics. Chinese participants often emphasized the need to balance individual rights, responsibility and the social good. There were significant tensions between this approach and conflicting notions of 'rights' that tend to be prevalent in Europe and the United States: for example, the self-centred individual rights approach and the traditional liberal autonomy approach that regards rights and duties as two sides of the same coin. As Prof. Yang Huanming explained, the Chinese model of patients rights has been taken from the USA, but implemented in a political top-to-down direction. He suggested that this was problematic, because it tends to reduce moral, economic and emotional claims to legal matters. For example, when patients need a convincing explanation of a failure, (such as non-delivery of a healthy baby after IVF), they should be offered options other than filing lawsuits. An improved informed consent practice would be expected to protect the patient, sustain a harmonious doctor-patient relationship, re-assure society of the moral integrity of the medical and research professions. The growing incidence of legal disputes, on the other hand, can be in welcomed as an expression of the development of a state of law in China and the emerging of highly educated patients who demand their rights, but at the same time has the potential to create a public climate of disharmony and to foster what has been refer to elsewhere as "a culture of compensation".

When it came to operationalising informed consent, it is fair to say that a common concern in both a European and a Chinese context was ***time to care***! How was one able to ensure that sufficient time and appropriate care was taken in very busy and often stressful working environments to make sure that patients were given the time necessary to understand risks and benefits, and to avoid a situation where informed consent is just a formality? How to ensure that informed consent is organized as a process and not just a signature? What is more, there were many different forms of informed consent that were to be taken into consideration depending on whether it was ART treatment, biomedical research or donation in question.

Prof. Tu Ling gave a comprehensive presentation of the informed consent process at the Reproductive and Genetic Hospital of Changsha, which is headed by Prof. Lu Guangxiu.

Prof. Lu and her team have implemented a pioneering programme of ethical governance in their ART hospital, which includes the setting up of an ethics committee with a secretariat, training of staff members on ethical issues and informed consent procedures and an informed consent process for patients seeking treatment. With such a great and rising demand for ART treatment at their hospital, it was decided to organize a lecture programme for potential patients (once per week), patients who were about to commence treatment (three times per week) and for inpatients (twice per week). In 2005, over 120 lectures had been hosted and over 10,000 patients had participated in them. The purpose of these lectures, which were very much appreciated by patients, according to Prof. Tu, was to offer general information in preparation of the individual interviews with clients and couples, to make efficient use of the scarce time of clinicians, as patients who attended such lectures were well prepared and much better informed when they then went on to an individual consultation with an ART clinician. The hospital also had a customer evaluation element, in the form of a feedback programme where patients were asked to fill out questionnaires asking, for example, whether they felt that they had "complete", "partial" or "no" knowledge of the ART process, procedures and expenses.

In a European context, Prof. Genevra Richardson gave an overview of some of the dilemmas and challenges when it came to informed consent at the interface of ART and stem cell research. The key ethical questions concerned timing (at what point in time should different forms of consent be obtained), independence (ART clinician and researcher should be fully independent of each other as should their respective informed consent processes, treatment should in no way be affected by a decision not to participate in research), confidentiality (including patient privacy and donor anonymity issues) and inducements (how should donors be compensated without making them vulnerable to exploitation and undue risks?). In discussions, Prof. Nikolas Rose pointed out that sociological research had shown that the ideal of 'non-directive' counselling was often very hard to put into practice: doctors often made their own opinions known in subtle ways, and these influenced a patient's decisions. Prof. Dominique Memmi pointed out that in a clinical setting, informed consent provided a kind of 'permission to be touched' from the patient, as fertility treatment requires invasive procedures to be carried out, especially on women.

The distinction between informed consent and informed decision making was also raised in many presentations as was the "principle of individual autonomy", with its various and inconsistent interpretations and practices. While it was generally agreed that families play a very important role in China when it comes to decisions about the healthcare of family members, in case discussions it was also apparent that when it came down to decisions about ART treatment, the couple should be the ones making all decisions and not their parents or other family members. However, given the fact that, in most cases, in China

“an individual’s illness is a family’s illness”, because of the ways medical care and expenses are in the hands of the family, it would be impractical to reduce the considerations in the decision making process to the interests of the individual patient. It was pointed out that in the Changsha case, family members often attended the lectures given together with prospective patients, as an act of moral and social support and shared responsibility, but that it was the couple, who legally had to sign informed consent forms.

One of the key conclusions to arise from these discussions as well as from the Chinese and European examples was how important it was to institutionalize informed consent processes so that they were a regular and fixed part of any treatment process, not just in terms of securing a signature, but in terms of organising clinical processes such that the issues of time and care for informed consent were factored into operational considerations. Prof. Genevra Richardson added that the same went for any ART-related biomedical research; informed consent should be protocolled with sufficient time when any trials or research were designed.

There was another challenging aspect to the question of informed consent in a Chinese ART context; namely what to do in cases where patients’ desires conflicted with existing regulations and laws or with their own safety. Many of the participating practitioners recounted cases where patients utilized their knowledge of ART to try and achieve a desired yet not necessarily legally accepted result. For example, in one of the cases presented to participants a patient misleads doctors about a past birth of a ‘Down’s Syndrome’ child in order to get a prenatal chromosome screening, when her true motive was to discover the sex of the child - non-medically indicated sex-diagnosis is illegal in China. Prof. Propping informed the workshop that, in early 2007, following the development of techniques that would allow foetal sex determination at an early age through analysis of blood samples taken from the mother, the European Society for Human Genetics urged legislators to expressly ban sex determination through blood tests. A Chinese case was also recounted where a patient requested sex selection to avoid transmitting colour blindness to a daughter, but colour blindness did not fall under the category of “serious hereditary disease” that is required by law before sex selection - which is otherwise illegal - can be approved.

Another central problem is multifoetal pregnancies. In the experience of Chinese participants, as it has proven very difficult to convince some women, especially those from the countryside, to return to the clinic for foetal reduction when multiple foetuses have been implanted, despite the fact that multifoetal pregnancies carry high risks. European participants noted that such “reduction” operations did not seem to be considered as medically and emotionally problematic, even when they were highly invasive and risky. However in China, this is also a problem outside clinics as fertility drugs are available over the counter leading some people to use them without proper information about risks. In the discussion it was clarified that there was no reliable evidence as to the motives for such non-compliance. However, it was agreed that these problems illustrate the challenges that arise when ideals of informed consent clash with those of the professional responsibility to act in the best interests of the patient. This is illustrated in cases of the use of ART for sex selection, where public policy interests clash

with individual or and socio-economic preferences for a particular sex. It is also illustrated in the case of multifoetal pregnancies, where professional assessments of risk clash with the strong desire to have children and preserve family lineage even at the cost of potential complications or even death to the mother. One of the patient representatives at the workshop made this latter point very emphatically. These challenges underlined the importance of clear and good quality information about risks and benefits for patients in the informed consent process. They also raise the questions of medical risk assessment and highlight the need for further dialogue between Chinese and European practitioners on these matters.

Ethics committees & review boards

Experiences from Europe and China have shown how a key element for ART as well as other biomedical technologies is good governance and the implementation of the ideals of best practice, which centrally concerns questions of ethics. Perhaps as a natural consequence, ethics committees have become an increasingly important component in both clinical and research settings in China and Europe. In a presentation on 'Ethics Committees and Involving of Non-Experts from an European Perspective', Professor Christoph Rehmann-Sutter proposed a typology of ethics committees and argued that ethics committees "are necessarily a part of a bureaucracy and hence, there is a threat that they might be sucked up by formal duties and lose their primary objectives".

Three structural types of ethics commissions and their main functions:

1. Research ethics commissions	Protoct health, rights and dignity of human research participants while acquiring generalisable knowledgne in research studies.
2. Clinical ethics committees	Advise health care personnel in difficult situations to find the ethically best possible decision or procedure in individual patient care (plus: internal practice guidelines, teaching etc.).
3. Policy making or advisory committees	Provide sound ethical arguments as basis for science and health policies (state legislation, government decisions, guidelines of professional associacions etc.)

In China, participants suggested that some of the first ethics committees that had been constituted in the context of ART had been exactly too bureaucratic and often consisted of members from hospital administration departments. Moreover, there was no adequate training and education of the committee members and no clear definition of the ethical or otherwise governing purpose of these bodies. As such these committees rarely had time to go through all the issues required of them. In discussions, Prof. Cong Yali argued that the training of ethics committee members was a key priority in China so that such committees were not merely seen as add-ons but were actually qualified, independent and integral to decision making processes in hospitals.

Since these first committees were constituted, newer 'second generation' ethics committees were beginning to emerge as has been the case at Peking University's Third Hospital as well as at the Reproductive and Genetic Hospital in Changsha, and these have developed much better practices. During a site visit to the Third Hospital Prof. Qiao Jie and the clinical ethics committee's chairman, Dr. &&, explained that in 2006 a new ethics committee had been constituted consisting of epidemiologists, ethicists, lawyers,

laymen, clinicians, psychologists as well as a patient representative. And in Changsha the ethics committee had ethicists, reproductive specialists, nurse representative, clinicians and administrators on their ethics committee. In both cases time was an issue as members of ethics committees had other duties to take care of, but in Changsha a secretariat had been established to help deal with the workload.

A presentation of real cases decided by the ethics committee of the Beijing Third Hospital raised the discussion about the purpose and range of legitimacy of such an institution. A case was presented were a consanguineous married couple had requested AID, because they feared that the natural course of insemination (by husband) would be highly risky (in this context the figure of 41% risk of foetal malformation was quoted as the accepted standard, however many experts disputed the accuracy of this risk estimate). The Ethics Committee had noted that all formal requirements were fulfilled (marriage certificate, a permission to have a baby, healthy condition of parents and normal social status of the family). However, the committee noted that this was a case of an illegal marriage because the couple were cousins (of an unspecified degree). The committee considered reporting this to the authorities, but decided against this, but they also rejected the couple's request for AID, because of the unclear status of the marriage. This case illustrated the difficult and uncertain position and self-perception of an ethics committee, between medical considerations, ethical obligations towards the patients and a felt moral obligation to support state policies.

It became clear in discussion that there are different expectations of the role and the style of review boards and the ways in which they should use ethical norms. The European experience suggested that, whenever feasible, ethics advice should not be given in the form of an imperative, but formulated in terms of orientations for action for example through the prediction of different scenarios resulting from following different courses of action. The objective of this approach was that ethics advice should not take away responsibility from the key actors, but rather should reinforce their own responsibility for the decision. It was noted that areas of uncertainty are inescapable, and indeed are the proper working ground of ethics (in contrast to law and morality, where a certain degree of definiteness is expected).

In Europe, a key issue for ethical review boards is that of the independence between clinical practice on the one hand and biomedical research on the other. Just as there should be different processes of informed consent in the two cases so too should there be different ethical review boards and processes. In Prof. Rehmann-Sutter's typology the distinction is between Research Ethics Committees (which tend to meet on a regular basis) and Clinical Ethics Committees (which can also meet regularly but may also have to meet ad hoc at short notice if an urgent ethical case arises). Such a division could be seen in some of the practices in Chinese ART centres, e.g. according to regulations there must be a laboratory responsible person and a clinic responsible person for ART treatment, and these two should not be the same person. However, most Chinese ethics committees currently dealt with both research and clinical practice issues. This highlighted again the importance of the institutionalization of ethics committees and training of ethics board members to ensure awareness of this distinction between ethical

practice in the clinic and in the laboratory. Institutionalisation implied such steps as establishing a secretariat, but bearing in mind the warning that bureaucratization had its dangers.

Professor Stephen Lam from the Department of Health, Hong Kong gave a presentation on the history and the ethical debates among as well as the social engagement measures taken in order to formulate the Hong Kong Code of Practice on Reproductive Technology and Embryo Research, explaining the structure of the Council on Human Reproductive Technology , the Secretariat, Ethics Committee, Inspection Committee, Investigation Committee as well as working groups, and the new developments in reproductive technology and PGD. The ethics committee operated according to guiding principles including respect for human life in all forms, welfare of the child, personal autonomy, community values (responsible parenthood, parental love, and the family) and balance between individual and collective interests to protect vulnerable parties from harm or exploitation. They also operated according to discourse guidelines:

- Every member has right to judge in accordance with own conscience
- Careful and disinterested analysis of recommendations may reduce likelihood of serious moral mistakes
- Open and rational debate to find common ground for resolutions promoting healthy coexistence of different values and opinion
- Desirable to arrive at consensus, but dissenting opinions will be duly recorded and appended to committee's resolutions
- When necessary, seek public's view, to ensure that distinction between public and private morality is upheld and justified, taking in account the culture and context of Hong Kong Society

Based on Professor Lam's presentation there was discussion about how to balance the interest of parents to have children and the welfare of future children. The important conclusion from his talk was that it was not sufficient to have formalized rules of constitution and membership but that there should also be rules of discourse and guiding principles for ethics committees as well. The example of Hong Kong is particularly relevant for the BIONET project because it shows one model to integrate European (namely UK) and Chinese standards in terms of well considered practice.

Research collaborations

Regarding the international dimensions of BIONET, the delicate question of the borderline between the invited sharing of expertise, observations and concerns, on the one hand, and undue interference on the other was debated frequently in the workshop. This tension can obviously not be fully dissolved, but the workshop created an atmosphere of trust and frankness that mitigated it. Some Chinese experts insisted that this should not be a point to worry about. For example, Prof. Huanming Yang argued that the example of the notorious eugenics debate during the second half of the 1990s confirmed that the strategy of openness could be constructive, and a contribution to the

improvement of science and ethics on all sides. Some charges of "undue interference" were undoubtedly misplaced, but at the same time, it was clear that a partnership could never be productive if it assumed that only one partner had something to learn.

In the final presentation of the workshop Professor Wolfgang Hennig highlighted some European concerns about research co-operations with Chinese partners. He articulated concerns about the applicability of European standards, in particular regarding data security, quality of data, reliability of drugs, scientific and ethical protocols, under conditions where the Chinese governments admits difficulties in implementing domestic standards and monitoring practice. Prof. Hennig emphasised that European researchers and ethicists were not seeking to teach good practice to China or criticise Chinese governance. The European interests are limited to making sure that European researchers and European funds conformed to European standards no matter where the related activities take place, and that researchers were conforming to all international laws and regulations concerning the conduct of research. If there was to be significant European investment in research in China, it was crucial that those funding and undertaking such research fully understood the details of the practices and the system in China. Prof. Hennig suggested that there was a need for the institutionalisation of data gathering and monitoring of research practice undertaken by European biomedical researchers in China especially as regards data security and the quality of data.

In the discussions that followed it was argued that Europe and China should make efforts to create a win-win situation, based on mutual respect, learning and understanding, and high quality co-operation in bioethics and the life sciences. State of the art scientific standards would provide a key to good practice. It is also in the best interest of China to avoid being any association with scientific scandals and bioethical irregularities, whereas Europe needs to make efforts to avoid the charge that it is operating with double standards between research within and outside Europe. Participants felt that systematic networking among Chinese and European institutions would produce synergetic effects and would help overcome the current situation of poorly co-ordinated local institutions. BIONET could help provide relevant information, build trust and encourage good governance even under conditions of competitiveness that can be adverse to the principles of science. European and Chinese bioethics, life sciences and governments have to respond to similar challenges, and these common interests could be used to advance standards and practice for the benefit of all.

Findings

The debate that took place at the first BIONET workshop should be appreciated as an end in itself. It was successful as a process of critical and problem-oriented work. As Prof. Cong Yali explained to the workshop participants, "Bioethics does not offer definite answers to all questions. Practitioners should help ethicists in doing a good job, we should gradually learn more about this approach." Among the concrete findings were:

- Chinese participants suggested that a standardized informed consent protocols should be developed, that would be generally valid and adaptable according to specific requirements in given situations, combining universal ethical convictions and room for diversity of strategies to contextualise them properly. In addition to providing examples of model informed consent forms, such a protocol would detail the steps of the full process, going beyond the conveying of information and communication and establishing a model of participation. Such protocols are required not just for ART treatment, but also for ART-related research activities as well as for gamete donation. Care should be taken to avoid the discussed legal, intellectual and/or scientific biases, which are still present in many informed consent forms and in the language.

- It was also recommended that special certified training programmes should be developed and offered to practitioners, such as physicians and nurses in order to qualify them to counsel patients in informed consent, and to systematically include social workers services. In clinical practice, sufficient time and standardised informed consent procedures should be introduced into daily hospital routines – informed consent procedures should be institutionalised while also allowing for individual particularities and care. It was appreciated that practitioners alone could not overcome the major obstacles towards improved informed consent regimes. They require protection and support from the state, from professional organizations and from visible examples of good practice. Due process depends on adequate subsidies, not only in terms of finances and education but also sufficient time to care for patients and clients.

- European participants suggested that in the context of European-Chinese research collaborations, these same considerations about informed consent should be carefully protocolled into research designs as well as into agreements between partners so that adequate time and resources for good quality informed consent procedures could be guaranteed.

- Chinese ART practitioners highlighted that while the Ministry of Health's revised ethical guidelines on ART are very welcome, they were nevertheless confronted on an almost daily basis with ethical dilemmas which could not be resolved by recourse to these guidelines (e.g. whether to allow AID in cases where the husband was in a vegetative state). This suggested a need for strengthening clinical ethics committees as well as ensuring that these committees had sufficient

resources, training and mandate to be able to meet on an ad hoc basis to address such dilemmas.

- Where research ethics committees were concerned, Chinese participants described how 'first generation' ethics committees which consisted mainly of hospital and institutional administrators were gradually being replaced by 'second generation' ethics committees (institutional review boards or IRBs) with much wider representation from clinicians, lawyers, nurses and patients. However, one of the take home messages for Chinese participants was that a separation of institutional ethics review boards from Research Ethics Committees was necessary and that they should be independent of each other. Moreover, the issue of the training of ethics committee members was highlighted as crucial to ensure that ethics was not seen as an add-on.

- From the European point of view, when it came to research collaborations what was at stake was making sure that European researchers and European funds were accountable to European standards while also adhering to national requirements no matter where the research activities take place.

- On a more general level, it appeared that participants shared the idea of good practice, and criticised unethical, unscientific and dishonest activities in ART related medicine and life sciences research on the grounds of similar ethical and scientific concerns. The globalised trends toward open and hidden forms of commercialization and a general tendency to accept economic/market capitalist rationales in medicine pose serious ethical problems and challenges to the character of medicine that Chinese and European participants were jointly concerned about.

Media response

A press conference was held on the final day of the workshop with invited journalists. A press release concerning the formation of the BIONET Expert Group was prepared in both Chinese and English (see below). The workshop was also featured on the front page of the LSE website and a story was prepared for the University of Basel website as well.

Some of the media response is included here:

Science Times:
http://sciencetimes.com.cn/sbhtmlnews/20074923464881217 6846.html

Popular Science News
http://www.cpst.net.cn/dzkjb/2007/0412/default.htm

Chinese Radio English Service (interviews with Christoph Rehmann-Sutter and Cong Yali)
http://english.cri.cn/4026/2007/05/14/44@226563.htm

LSE:
http://www.lse.ac.uk/collections/pressAndInformationOffice/newsAndEvents/archives/2007/BIOSBIONET.htm
http://www.lse.ac.uk/collections/pressAndInformationOffice/newsAndEvents/archives/2007/EthicsEuropean-ChineseBioResearchCollab.htm

University of Basel:
http://www.unibas.ch/index.cfm?uuid=DF665EC13005C8DEA311B22AF4E806BB&type=search&show_long=1

Media Release

April 6, 2007

Ethics of European-Chinese biomedical research collaborations

This week in Beijing, a new European and Chinese Expert Group on ethics of research in biomedicine and biotechnology has been set up. The international committee, composed of 10 members from the fields of medicine, ethics, law, political science and social science will work towards guidelines for best practice in ethical governance of collaborative research between China and Europe, foster mutual understanding and provide opportunities to learn from each other. Results are to be expected within less than 3 years.

The new Ethical Expert Group is part of BIONET, a Coordinated Action Project, funded by the European Union research framework program 6. BIONET is a 21-partner European-Chinese collaboration on ethical governance in the life sciences, coordinated by the London School of Economics and involving leading Chinese institutions such as Hunan Institute of Reproduction and Stem Cell Engineering (Changsha), Peking University Health Science Centre, Union Medical College (Beijing) and the Chinese Academy of Social Sciences (Beijing).

Two cultures working together to tackle some of the most sensitive issues in biomedical research ethics, such as the latest developments in reproductive medicine, genomics, biobanking, and stem cell research. It shall provide an opportunity for mutual learning. The group works on the assumption that an exchange process can provide better solutions for both sides. A series of conferences and workshops to be held in Beijing, Shanghai, Changsha and other places in China and Europe are planned, the first of which was hosted by Peking University Health Care Centre in the week of 1-6 April. It's special focus were questions of informed consent and ethical review boards in assisted reproductive technologies and biomedical research. The workshop was attended by 20 experts from Europe and about 27 clinical practitioners and bioethicists from China. Exchange was substantial and fruitful as participants at the final session said.

The Expert Group is chaired by Christoph Rehmann-Sutter, a Professor of bioethics at the University of Basel/Switzerland and also President of the Swiss National Advisory Commission on Biomedical Ethics. Trained both in molecular biology and in philosophy he is a specialist for communication in bioethics and biopolitics. The Expert Group is co-chaired by Professor Qiu Renzong of the Chinese Academy of Social Sciences and includes Professor Lu Guangxiu, Professor Zhai Xiaomei and Professor Cong Yali from China and Professor Herbert Gottweis, Professor Wolfgang Hennig, Professor Genevra Richardson and Dr. Ole Döring from Europe.

“Communication, based on listening to the concerns of others in different cultural contexts, is a root from which ethics can grow. It is itself an ethical act,” said Prof. Rehmann-Sutter.

“Though bioethics emerged a little late in China, in recent years our government has made great efforts to develop bioethics working with scholars in related fields. Now with the support of the government and efforts of scholars, we have seen how bioethics has really provided guidance in biomedical research and practice. I believe BIONET will improve mutual communication and help to standardise practice so that we can protect the interests of common people,” said Professor Lu Guangxiu.

Interviews can be requested and information is available through the secretariat of the Expert Group at BIOS centre, London School of Economics in Europe and through Prof. Cong Yali, Peking University Health Science Centre in China.

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Appendixes

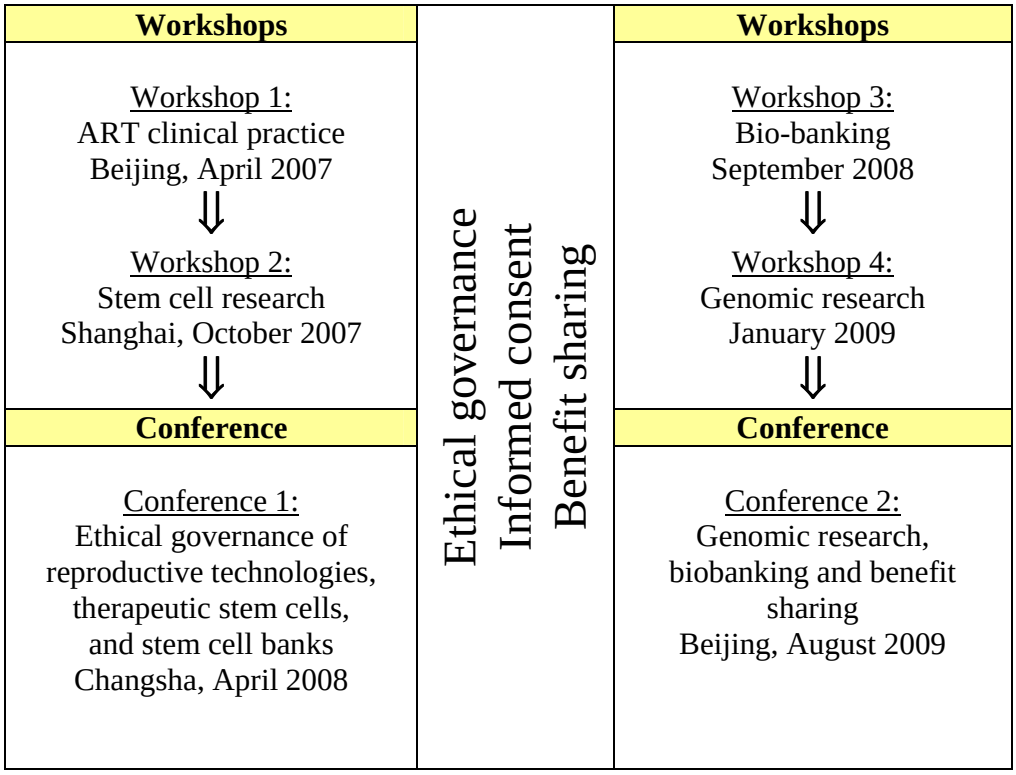
List of members of Expert Group:

- Professor Lu Guangxiu, Institute of Human Reproduction and Stem Cell Engineering, Changsha
- Professor Professor Qiu Renzong, Chinese Academy of Social Sciences (co-Chair)
- Professor Cong Yali, Peking University Health Science Centre
- Professor Zhai Xiaomei, Peking Union Medical College, Research Centre for Bioethics, Beijing
- Dr. Ole Döring, Institute of Asian Affairs, Hamburg, Germany
- Professor Herbert Gottweis, Department of Political Science, University of Vienna, Austria
- Professor Wolfgang Hennig, Institute of Genetics, University of Mainz, Germany & CAS-MPG Partner Institute for Computational Biology, Shanghai, China
- Professor Genevra Richardson, School of Law, King's College, United Kingdom

Chairman: Professor Christoph Rehmann-Sutter, Unit for Ethics in the Biosciences, University of Basel, Switzerland

BIONET workshop objectives

The most important component of the BIONET collaboration is a series of 6 workshops and conferences. Four workshops have been designed to feed into two overall conferences which are scheduled to be held in April 2008 and August 2009. It is on the basis of these workshops and conferences that BIONET will be able to gather an evidence base which can be useful for policy makers, researchers, bio-ethicists and others interested in the ethical governance of research in the life sciences. The workshops and conferences will focus on three key areas – reproductive medicine, genomic research into disease susceptibility and treatability and biobanking – and will in particular look at how issues of ethical governance, informed consent and benefit sharing come into play around these forms of research and practice in China and Europe.



Workshops have a number of objectives the most important of which is to foster mutual understanding of cultural particularities and differences not just between Europe and China but also within these two vast regions. The particular aims of the first workshop were:

- To provide a platform for scholars with different cultural and academic backgrounds to improve understanding

- To provide capacity building for a range of professionals across China who are involved in research, research ethics and decision making in these areas, including members of ethics review boards
- To explore differences in approaches, and current themes around, ethical review and regulation, particularly around informed consent
- To enhance understanding of the strengths and weaknesses of different approaches to the regulation of biomedical research and practice
- To gather evidence of problems, cases and practices in the ethical governance of research in this area, as they are experienced on the ground by different professional groups in different regions in relation to different issues.
- To define lines of future studies in the clinics of doctor/patient relationships, and on other issues which may arise
- To facilitate the development of evidence based social scientific research on ethics, and awareness of the need to research the experience and views of patients and research subjects.
- To learn from each other about the ethical governance of ART.

Rather than focus solely on plenary lectures, workshops are organised so as to promote maximum discussion among participants by ensuring plenty of time for questions and debate after plenary presentations, and also by organising break out groups where particular case studies are presented for discussion. Site visits to clinics and laboratories are also organised to give participants a chance to learn about the practical context of the issues discussed in the workshop. The workshops also provide BIONET's network of junior researchers a place to share their research as well as to learn from and participate in discussion.

List of participants

The workshop will be attended by representatives from different sectors and disciplines. Participants in the workshop will include (1) scientists/physicians including those who are practitioners in research and clinical settings; (2) ethics committee members; (3) philosophers/bioethicists; (4) science and technology administrators/regulators; (5) sociologists and lawyers. Attendance will be limited to 50, including 10 from Europe, to ensure opportunities for discussion among the participants Among the Chinese participants, there will be 20 ART experts, 2-3 legal scholars, 2 government officers and 6 ethicists.

Name	**Position and work institute**
Nikolas Rose	BIOS Centre, London School of Economics and Political Science
Christoph Rehmann-Sutter	Unit for Ethics in the Biosciences, University of Basel, Switzerland
Ole Döring	Institute of Asian Affairs
Herbert Gottweis	Department of Political Sciencem, University of Vienna
Michael Barr	Research Council UK Academic Fellow PEALS
Dominique Memmi	Director of Research, Centre National de la Recherche Scientifique
Prof.Peter Propping	Institut fuer Humangenetik, Universitaetsklinikum
Genevra Richardson	School of Law, King's College
Margaret Sleeboom-Faulkner	Department of Social Anthropology, Sussex University
Paul U. Unschuld	Medizinische Fakultät, Institut für Geschichte der Medizin
Ayo Wahlberg	Research Fellow, BIOS Centre, London School of Economics
Amanda Dickens	Global Biopolitics Centre, UEA
David Warrell,	emeritus Professor Tropical Medicine,
Catherine Elliott	MRC Head office, UK
Tony Peatfield	MRC Head office, UK
Thomas Streitfellner	Department of Political Science, University of Vienna
Xiaoning Xu	Senior research fellow
Stephen TS Lam	Department of Health, Hong Kong SAR
Guangxiu Lu	President, Reproductive and Genetic Hospital of Citic-Xiangya, Institute of Reproductive & Stem Cell Engineering, Central South University
Benfu Li	Chair of Chinese medical ethics association (CMEA)
Renzong Qiu	Chinese Academy of Social Sciences
Huanming Yang	Beijing Genomic Institute
Guijin Zhu	Tongji Hospital of Tongji Medical College of Huazhong University of Science & Technology
Jie Qiao	Head of Ob/Gyn Depatement and Reproductive Centre, Peking University Third Hospital
Wenli Zuo	Ob/Gyn Department, Peking University First Hospital
Guoning Huang	Vice President of Chongqing Obsterics and Gynecology Hospital Assosiate Chief Physician, Chongqing Reproduction and Genetics

Jiayin Liu	Professor of Medicine, Chief Physician
Chunliang Fan	Researcher, Institute of Policy and Management, Chinese Academy of Sciences
Huan Shen	Head of Centre of Reproductive Medicine, Peking University, People's Hospital
Yun Feng	Professor, Chief Physician, Reproductive & Medicine Centre Director
Yihua Yang	Master Student, Ruijin Hospital, Shanghai Jiaotong University, School of Medicine
Xiaoming Zhu	Reproductive Endocrinology Specialist
Yuanhua Huang	Professor of Ob/Gyn Medicine, Chief Physician, Director of Hainan Reproductive Medicine Centre
Xiucheng Yu	Surveillance Officer, China's Ministry of Health
Zhaodai Bai	Associate Professor
Canquan Zhou	Reproductive Medicine Centre, Zhongshan Medical School
Jie Li	Reproductive Medicine Centre
Liqing Fan	Vice President, Reproductive and Genetic Hospital of Citic-Xiangya, Institute of Reproductive & Stem Cell Engineering, Central South University
Wei Liu	Reproductive and Genetic Hospital of Citic-Xiangya, Institute of Reproductive & Stem Cell Engineering, Central South University
Ling Tu	Reproductive and Genetic Hospital of Citic-Xiangya, Institute of Reproductive & Stem Cell Engineering, Central South University
Yan Wang	Doctor, Reproductive Medicine Research Centre, Shangdong University
Ginny He	Reproductive and Genetic Hospital of Citic-Xiangya
Jiaen Liu	President, Beijing Jia En De Yun Hospital
Pei Li	Secretary of Ethical Committee, Beijing Jia En De Yun Hospital
Xiaoqin Zhuo	Lawyer
Yinliang Liu	Director, Research Centre of Biotechnology Law, China University of Politics and Law
Mingjie Zhao	Vice Chief Editor, Medicine and Philosophy Magazine
Tan Li	Infertility Clinic, Datun Hospital
Rong Li	Peking University Third Hospital
Joy Zhang	BIOS Centre, London School of Economics and Political Science
Yeyang Su	Beijing Genomic Institute
Xiuyun Yin	Peking University Health Science Centre
Xiaonong Li	Peking University Health Science Centre
Rongchuan Yi	Patient representative
Xiaohong Zhou	Patient representative
Yu Wang	Associate Professor of Ob/Gyn Medicine, Associate Chief Physician
Suli Sui	Bioethics Centre, Peking Union Medical College
Xinqing Zhang	Associate Professor
Xiaoting Shi	Journal of Chinese Medical Ethics
Ruipeng Lei	Huazhong University of Science and Technology
Yali Cong	Deputy director of medical ethics program of PUHSC
Jianhua Lin	Public Relation and External Cooperation Office, Huashan Hospital of Fudan University

Workshop programme

Date/Time	Topic	Speaker	Chair
Day 1 Sunday 1 April	**The State of ART in China and Europe: The Context**		
12:30 – 14:00	**Welcome Lunch** (Bi Xiang Ge Restaurant, Second floor)		
14:00-14:30	Welcome Ceremony	Nikolas Rose, Xu Baiyu/Zhang Daqing Lu Guangxiu /Qiu Renzong	
14:30-14:45	Introduction of the programme	Ole Döring, CongYali	
14:45 – 16:15	Plenary Session: The Context		
14:45 – 15:10	Presentation: The General condition of ART in current China	Yu Xiucheng (MOH)	Rose Lu
15: 10 - 15:35	Presentation: Professional experiences and ethical issues in ART, from a European view	Dominique Memmi	
15:35-16:15	Presentations: Research Findings on Regulations and Practices in Europe and China-the view from BIONET exchange students	Thomas Streitfellner Joy Zhang, Rose Li	
16:15 – 16:30	**Coffee/Tea Break**		
16:30 – 17:45	Introduction of Participants General Discussion of key ethical and governance concerns in China and Europe: Potential topics may include but not limited: ➢ The legal frameworks ➢ National , local and regional variations ➢ Composition and role of ethics committees ➢ Resource and health service issues and implications	Mediators: Qiu Renzong Nikolas Rose	
17:45 – 18:00	Summary and overview of day	Ole Döring, CongYali	Rose Lu
18:00 – 19:30	**Reception and Workshop Dinner**	Bi Xiangge	

Day 2 Monday 2 April	Morning: Social and Ethical Debates in ART Afternoon: Informed Consent in Clinical Practice	Speaker	Chair
9:00 – 12:30	Social and ethical debates in ART		Li Benfu Christoph
9:00 - 9:30	Presentation Some Thoughts on the Historical Role of Physicians – Current Challenges	Paul Unschuld	
9:30 - 10:00	Presentation: Philosophical concept of reproduction and its cultural transformation with technology advancement --Confucian's perspective	Qiu Renzong	
10:00 - 10:40	Questions to speakers and open discussion related to topics, but not limited: ➢ Role of different technologies: PGD, ICSI, enhancement ➢ Interests of different stakeholders and conflict resolution ➢ Medical and social indications, multi-foetal reduction, paternity/maternity in gamete donation, prevention of infertility ➢ Cultural meanings of reproduction and infertility in Europe and China		
10:40 - 11:00	**Coffee/Tea Break**		
11:00 - 12:30	Workshop Session for Group Discussions (two parallel groups)		
11:00-12:00	Group 1: Ethical and social issues of sperm banks	Speaker: Fan Liqing Chair: Bai Zhaodai	
	Group 2: The role of ethical committee: Ethics committees and involving of non-experts from a European perspective	Speaker: Christoph Rehmann-Sutter Chair: Li Benfu	
12:00-12:30	Summary and reports from group discussion	Rapporteurs Lei Ruipeng Tu Ling and Li pei	
12:30 - 13:30	**Lunch Break**		
13:30 - 16:30	Informed consent in clinical practice: Ethical Dilemmas		
13:30 - 14:00	Informed Consent in Chinese Practice	Qiao Jie	Zhu Yimin Ayo Wahlberg
14:00 – 14.30	Regulating consent in an area of ethical uncertainty: the case of embryo donation in Europe	Genevra Richardson	
14:30 – 15: 30	Questions to speakers and open discussion related to topics: ➢ the common issues of informed consent, the file of informed consent in		

	practice ➢ PGD, etc.		
15:30 - 15:45	**Coffee/Tea Break**		
15:45 - 16:45	Case Discussion in Two Parallel Groups		Liu Jiaen Ole
16.45 – 17.15	Report back from Groups	Rapporteurs Group 1: Wang Yan Group 2: Li Rong	
Evening	BIONET Expert Group Meeting		Christoph

Day 3 Tuesday 3 April	Informed Consent in Practice: Dilemmas in Clinical and Research Practice	Speaker	Chair
9:00 - 12:30	Informed consent in biomedical research		
9:00 - 10:15	Plenary Session: Informed consent in biomedical research Four brief presentations, two from China, two from Europe on key issues in informed consent in biomedical research "Informed consent in biomedical research in Europe" and casesnd discussions.(peter) ➢ Meaning of informed consent in research contexts ➢ Donation, of gametes and embryos/Storage of gametes and embryo ➢ Procurement and storage ➢ Commodification and commercialisation	Feng Yun Peter Propping Huang Yuanhua Ayo Wahlberg	Yang Huanming Michael Barr
10.15: 10:30	**Coffee/Tea Break**		
10:30 - 11:30	Case Discussion in Two Parallel Groups		Huang Guoning Liu Jiaen
11:30 – 12:30	Report back from groups	Rapporteurs Group 1: Zhu Guijin Group 2: Zhou Canquan	
12:30 - 13:30	**Lunch Break**		
13: 45 – 18:00	Visit to Plant Garden Departure on 13:45 at gate of Conference Center		
Evening	BIONET Expert Group Meeting		

Day 4 Wednesday ,4 ,Apr.	Regulation of ART and issues of social justice and welfare: governmental and patient perspectives	Speaker	Chair
9:00 – 12:30	Implementation of the regulation on ART		
9:00 - 9:30	Presentation: ethical governance on ART	Lu Guangxiu	Herbert Gottweis **Feng Yun**
9:30 -10:00	Presentation: Implementation of informed consent in ART: Hong Kong experience	Stephen Lam	
10:00 - 11:30	Questions to speakers and topics for general discussion related to: ➢ Problems of implementation ➢ Prohibited and unacceptable practices ➢ Sanctions and incentives for bad and good practice ➢ Managing local and regional variations ➢ Regulating private ART clinics ➢ Licensing, evaluation and oversight ➢ Monitoring - from ART to offspring	Mediators: Amanda Dickens Huang Wenyuan	
11:10 - 11:30	**Coffee/Tea Break**		
11:30 - 12:30	Case Discussion in Two Parallel Groups	Mediators: Liu Yinliang / Unschuld. Rapporteurs Zuo Wenli/Wang Shuyu	
12:00 - 13:30	**Lunch Break**		
13:30 - 14:00	Report back from Groups One is law case One is EU case		
14:00 - 16:30	Public and Patient Perspectives on ART		
14:00 – 14:20	Consultation from public	Li Benfu	Rose Cong
14:20 - 14:40	Presentation	Wolfgang Hennig	
14:40 – 15:30	Plenary Session: Patient perspectives on the availability and use of ART Potential topics: ➢ Consent – the patient's view (two patient representatives) ➢ Patient demands and pressures ➢ Satisfaction and dissatisfaction ➢ Cost, payment, affordability, resources ➢ Confidentiality and access to information	Mediators: Qiu Renzong Patient representative	
15:30 - 16:00	**Coffee/Tea Break**		

16:00 - 17:00	Case Discussion in Two Parallel Groups		Zhuo Xiaoqin Zhao Mingjie
17:00 - 17:30	Report back from Groups		
17:45	Dinner in Chinese Tradition Restaurant (plan)		
Evening	BIONET Steering Committee Meeting		

Day 5 Thursday 5 April	Site Symposium and BIONET Meetings	Facilitator
9.00 – 10.00	BIONET Expert Group Meeting	Christoph Rehmann-Sutter
10.00 - 12:30	Site Symposium at third hospital of PUHSC Discussions with practitioners	Qiao Jie
12.30 – 1.30	**Lunch Break**	
13:30 – 14:45	Closing Session for Workshop Summary, review and evaluation of the workshop	Nikolas Rose
15:00 - 19:00	Site visit, followed by dinner at Huada Jiyin Zhongxin	Yang Huanming

Day 6 Friday 6 April	BIONET Meetings (BIONET PARTNERS ONLY)	Facilitator
9:00-11:00	Expert Group presentation to BIONET partners	Christoph Rehman Sutter
11:00 – 11:30	Coffee Break	
11:30 – 1:00	BIONET Consortium Meeting To review workshop and for forward planning	Nikolas Rose
1:00	**CLOSE**	