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**Searching for Advances in  
Biomedical Ethics in China: Recent Trends**

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## Searching for Advances in Biomedical Ethics in China: Recent Trends

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### Introduction

The fact that the domains of biotechnology, biomedical research and advanced clinical medicine in China are still seriously underdeveloped in infrastructural, legal and ethical terms has prompted different explanations. Some argue that this lag can be understood as expressing the need for reforms, supporting Chinese efforts to implement a policy of modernisation (Döring 2003a). Others refer to a "technological imperative" that is deeply ingrained in China's politics and ideology, especially in the areas of population policy and biomedicine (Dikötter 1998). Others go as far as to claim, in the context of discussions of biopolicy in the West, that human cloning, including reproductive cloning and positive embryo selection, would be performed anyway, "if not America, China will do it inevitably" (Gregory Stock, <http://research.mednet.ucla.edu/pmts/Stock.htm>). In spite of such biased assumptions, Chinese policy makers have adopted a view that regards a sound system of legal regulations and ethical guidelines as a strategic advantage in the competitions of the global and regional markets of biomedicine.

In this light, the introduction of ethical regulations in medicine in China might seem at odds with the country's social and moral reality. Chinese bioethicists find themselves torn between the necessity to re-create a fully-fledged modern health-care system that would also accommodate China's culture and aspirations to become global players in the biomedical sciences. The result is a top-down approach in medical ethics, created on behalf of the people. Despite its introduction, there are concerns about whether China is prepared to embrace the standards it claims to have adopted. Reports about China are frequently flavoured with superlatives, struggling with the limits of our ability to imagine the enormity and momentum of the country's ambitions and problems. In fact, the leaders of the People's Republic hope that the biotech revolution — now shaking the formerly isolated communist nation — will have similar effects to those induced by the Soviet Union's legendary Sputnik space programme, bringing the country to the world's attention.

Since China's involvement in the Human Genome Project and its completion of the sequencing of the rice genome, China is establishing a prominent place in genetics and genomics. (Normile et.al. 2002, Dennis 2002) At the same time, the ideological profile of the Chinese Communist Party, having opened her arms to welcome the ranks of successful entrepreneurs as party members in 2001, is getting blurred. The new policy of encouraging scientific creativity seems to tolerate intellectual diversity and freedom as long as they do not openly challenge the political establishment. Although all countries need to develop up-to-date bioethics, China is unique in also having to deal with social, institutional and economic reforms, and the introduction of a modern system of education, technical and legal international standards at the same time. More fundamentally, it not only needs to re-examine its bioethical values, but also to clarify and to establish the related moral and legal frame-

works in the first place. Biotechnology functions as a catalyst in the dynamic processes for the building of a modern Chinese culture in the 21<sup>st</sup> century.

This is particularly relevant in medical genetics. A significantly lower level of standards in biomedical regulation, or a weakness in enforcing the related legislation, has the potential to lure researchers to conduct experiments in China that contradict bioethical standards. Can the often-alleged cultural differences between China and 'the West' be used as an excuse for the current situation? More dramatically, will such differences push global bioethics into the spiral of compromising and downsizing standards? Will the impact of China's new role in the world fuel the global cultural antagonisms and ideologies of cultural ethical relativism?

Notwithstanding her still largely rural population, China is transforming into an urban society with individualistic, utilitarian and competitive features, threatening to leave ideas of solidarity and social justice behind. This development is disturbing in the context of medical genetics. The state is making efforts to provide for a system of (very) basic accessible services and a sketch of medical ethics as a safety net, the accomplishments of which remain to be seen. Provisions, such as the principle of informed consent in the clinic and research, have been announced. Although those statements might be well intended, and the only feasible option for improvement, they need to be accepted by the population in general to be ethically convincing and culturally meaningful. Also they need to be embedded in a policy of public health and social justice.

Here, I provide an overview of the recent move towards a new style and new priorities in policies on medical genetics, referring to examples from human embryo research. I discuss medical ethics, elaborating on examples from genetic counselling and informed consent. The present conceptual, legal and practical challenges of medical ethics are outlined in some detail, with a special focus on the principle of informed consent. Can informed consent, on the basis of respect for autonomy, be culturally accepted in China? This is discussed with reference to two prominent proposals for the regulation of research on human embryos (cloning and stem cells) that have recently been submitted for national legislation.

## **Background**

Until the first wave of reforms in 1979, China had been subject to the whims of the Communist Party. Whereas scientific work was often defamed as being bourgeois, genetics was ruled by a largely unpredictable policy of campaigns and commands. Structures and institutions of a civil state that would express and legitimize moral opinions representing cultural or social groups were actively repressed. Since then, China has been trying to form a reliable legal state, triggered in particular by joining the World Trade Organization in 2001. On the domestic level, a set of new laws and ethical regulations was promulgated. Higher standards in protecting patients, consumers and donors, legal security and reliability for scientists and doctors, building up the health-care sector and providing a regulative framework for biomedical research were promised. The measures include, among others, a revision of the Patient and Consumer Protection Act of 1993 which now regulates the physicians' liability, Professional Standards for General Practitioners and Family Doctors (1999), a new Pharma Law (2001, Reim 2001). They relate to the Decree to Reform and Develop the Health Care Sector of 1997. While working out legal and ethical regulations, the authorities attempted to elucidate the principal purpose of medicine in society. In March 1998, the Ministry of Public Health (MOH) published a Five-Point Declaration on cloning, banning all trials to clone humans, with no exception of therapeutic cloning. Even the controversial Maternal and Infant Health Care Law of 1995, in article 19, recognizes the principle of informed consent (Doering 1998, Bobrow 1995). The Minister of Public Health issued a moral statement to remind doctors to care for the patients' benefit and protection first (Xinmin 1999, Doering 1998, Bobrow 1995).

In its international contributions to biopolitics and bioethics regulations, China has been active in contributing to the setting up of international standards. In an act for the Protection of Genetic Resources from 1998, China stipulates that biological material may be used only on the basis of full informed consent by donors, and reserves claims for all benefits deriving from international biomedical research using Chinese sources (Dickson 1998b).

China has engaged in formulating, and has eventually accepted, the main relevant international declarations and guidelines in bioethics and medical ethics, including the World Medical Association's Helsinki Declaration (2000), documents by WHO and UNESCO (Human Rights and Biotechnology) (UNESCO 2001a and 2001b), the WTO (Agreement on Trade Related Intellectual Property Rights: TRIPS, patenting; Liu 2001), and others.— these documents form the basis for domestic biopolicy-making and for engaging in the global markets. In this way, China attempts to build the new regulations based on a universal common ground — yet with 'Chinese particularities' — to honour the special features of China's culture and society.

The explicit acknowledgement of the international responsibilities of China's bio-policies deviates from the clumsy efforts to maintain a defensive and isolated strategy that dominated until the mid-1990s, when the focus lay mainly on defending China's population and eugenics policies (Rich 1995). This old approach culminated in a large-scale campaign to boycott the 18th World Congress of the International Genetics Federation in Beijing, in 1998 (Rich 1995, Masood 1995). Permission by Chinese authorities to openly discuss eugenics during the congress, and the fact that a successful debate actually took place, marked a turning point for a constructive and worldly attitude in Chinese bio-politics (Dickson 1998a). China has reduced incidences of open interference in many spheres of social life on political grounds, for example, in implementing its population policy, and has invested more confidence in the ability of the young generations of highly educated specialists to build a state-of-the-art biotechnological research system, together with a modern health-care system (Jiang 2000). The government encourages private engagement and joint ventures in establishing biomedical research (Normile 2002, Swinbanks 1999). The tenth Five-Year-Plan (2001–2005) includes ~US\$ 600 million of direct public investment, and venture capital is invited to share the optimism for growing profits, especially in applied genetics. The authorities have, in fact, given away some of their power, leaving strategic decisions and company policies to the discretion of scientific experts and entrepreneurs outside the political centre (Boeschén & Döring 2001).

Obviously, this orchestrated strategy toward bioethical laws and regulations can have a special bearing on those areas which are to be governed through licensing and adjustment of the flow of public funds, such as in biomedical research. Recent news from China indicates a growing alertness concerning global issues in bioethics. On 22 October 2001 at a round-table conference in Paris, Cheng Jinpei, the Chinese Vice Minister of Science and Technology, made clear China's support of stem-cell research with human embryos for therapeutic and preventative reasons and its opposition to any human reproductive cloning experiments. In the absence of effective domestic regulation, Cheng emphasized that cloning technology should not violate international rules on bioethics. China would support the setting-up of an international convention for the banning of human cloning (People's Daily 2001).

## **Ethics standards in practice**

### *Biotechnology*

Bio-policy makers in China seem to recognize the importance of establishing ethical and technical standards throughout the vast country. A growing request among the population to benefit from biomedical progress creates markets and opportunities — especially amongst new parents or parents-to-be, who demand to enhance the odds of biological fitness for their single child. New con-

trols are being introduced to repel commercial medical institutes from offering poor quality and low-standard services that would jeopardize consumers' health or delude lay persons into subscribing to pointless products and services. In late 2001, the Ministry of Public Health approved the first five Chinese medical institutions for research on human-assisted reproduction and for operating human sperm banks. It was announced that China is installing a strictly controlled system of assisted reproduction and sperm-bank technology in order to rule out substandard practices. A government survey found that 44 sperm banks, 175 institutes that performed in vitro fertilization (IVF) research, 126 institutions that carried out artificial insemination from unknown donors and 214 that used husband-artificial insemination had already been operating without valid licenses (Xinhuanet 2001). These findings probably represent only the tip of an iceberg.

Established Chinese scientists have frequently demanded effective laws to make sure that ethical principles are observed in practice and that foreseeable violation of these principles can be prevented. For example, although human cloning is rejected explicitly by most governments and international organizations (HUGO 1999), the discovery of hidden experiments is reported from time to time (Mann 2003). Chen Renbiao, a senior medical geneticist of Shanghai's Second Medical University, argues that it is not enough to object to them — instead, we should be prepared by making appropriate laws in advance (Xinhua 2001).

#### *Research and clinical practice*

Although the general trend in the regulation of biotechnology seems to justify optimism, research and clinical practice gives reason for continued concern. Not all domestic and foreign research institutes honour the fact that some people, especially in rural China, are not qualified to be requested to consent to certain kinds of medical experiment (McManus & Saywell 2001). Disturbing cases of international medical research in China — such as the collecting of blood for pharmaceutical research by an American team in the impoverished province of Anhui, where proper informed consent procedures seem to have been neglected (Dembner 2000, Lawler 2002) — indicate that it can be inconvenient for researchers to abstain on ethical grounds from medical research that has the potential for high profits, given a reasonable chance of not being found out (Pomfret & Nelson 2000). Moreover, scandals of blood contamination, as reported in 2001 from underdeveloped provinces such as Henan, indicate that blood donation can be ethically problematic in China due to safety problems, notwithstanding the standards set up by Chinese law (here, the Blood Donation Law of 1998). In this case, donated blood had been pooled without sufficient examination and was subsequently re-infused, thereby spreading HIV, hepatitis and other infections among trusting patients (Gill & Palmer 2001a and 2001b, Lederer 2001). 'Health workers' who perform such services in rural areas are often without education about informed consent, and are often ill-equipped, re-using syringes and ignoring basic standards of hygiene. Moreover, they have received no adequate education about informed consent, or the ethical dilemmas of medicine and protecting human subjects in medical research.

#### *Family planning*

Transforming China gives rise to new concerns about the emerging individualized 'liberal eugenics', in line with the current model of utility and commercialism in reproductive technology and the related prenatal counselling (Habermas 2001). Social pressure and the desire of parents to have a 'perfect baby' are understandably high under the conditions of birth limitations (Coghlan 1998). The urban population is generally allowed to have only one child per couple; women are encouraged to give 'late birth' (around the age of 30), and to delay the second birth, if any is granted, for as long as possible. These regulations are enforced with the help of incentives, such as access to higher-quality housing and support for schooling. However, peasants and members of ethnic-minority groups are exempted from these restrictions. Marriage licenses require a medical check-up to ensure healthy offspring. Doctors are expected to direct would-be parents to avoid or terminate a problematic pregnancy. Parents of a handicapped child are allowed to have a second baby, a meas-

ure that has recently been applied in rural areas to parents whose first child was female. However, often the harsh social conditions and poor facilities make it undesirable for parents to carry a handicapped fetus to term. In general, Chinese propaganda seems to be obsessed with ideals of mental and physical competitiveness. This is mixed with lack of general education and irrational expectations from medicine, even among intellectuals (Yang 2002). A tendency to regard genetic screening as a way to ensure ‘a good birth’ and to choose abortion as the solution to a ‘failed pregnancy’ is obvious, given the absence of a critical debate about eugenics in China (Wertz 1999, Döring 1997). China is about to organize the legal framework and practice of informed consent and counselling. Hence, it would be premature for observers to offer an actual description of the Chinese attitudes and current patterns of behaviour. Some Chinese bioethicists, such as Nie Jingbao of the Bioethics Centre in Otago, have argued that the moral concept and the ideal of informed consent are applicable in China according to Chinese culture but need to be reinterpreted in the light of modern conditions and issues (Nie 2001).

### *Social and cultural patterns*

Sociological studies can provide useful information about the real mindset and preferences of a selected target group. In 1998, results from the first survey of its kind that gathered responses from 255 providers of genetic services throughout China were published (Wertz 1999, Nippert 1999). The findings show a strong tendency towards paternalism and directive counselling — Chinese geneticists would counsel more directly and more pessimistically after prenatal diagnosis identified a fetus with a genetic disorder than would geneticists elsewhere (Wertz 1999, Qiu 1999). It also transpired that Chinese geneticists were more likely than their colleagues from elsewhere to use the law to try to enforce ‘healthy’ behaviour. So, overall in China, the health of the future child seems to override the wishes or the ‘rights’ of the parents.

These results reflect China’s preoccupation at that time with improving population quality while reducing its growth. Now, almost 10 years later, the situation has changed — policy makers have redefined priorities from directing to encouraging, patients and consumers have adopted new habits by demanding the protection of their rights, and a new generation of genetics service providers have gradually come to be in charge. Moreover, parent groups have been formed that demand respect and support for disabled children. The former patronizing attitudes of doctors towards their patients are declining (Wertz 1999), but new surveys are required to assess what doctors and patients in China believe, prefer and aspire to.

Bioethicists with a background in philosophy and medicine have argued that more attention should be paid to cultural issues in this debate (Veatch 1989) — a reasonable assessment of China’s culture might help to predict relevant preferences and behaviour of Chinese people. A Hong-Kong-based Chinese bioethicist, Fan Ruiping, claims that a special ‘family autonomy’ in China favours collective decision-making over respecting the will of individual patients, and regards paternalism as being supported by Confucian culture (Fan 1997). Chinese people in general are purportedly driven by an interest in what is good rather than by what is right (Fan 1997).

The alleged cultural peculiarity might be seen as an excuse for the downgrading of ethical standards in China. But Nie Jingbao believes that the “cultural difference argument is founded on some serious misunderstandings of Chinese culture and medical moralities, Western culture, and informed consent” (Nie 2001). Further cultural analyses and empirical studies would be extremely welcome to sort out the facts from the fiction in ascribing certain culturalistic patterns to Chinese morality. Both China’s diversity of old moral traditions, and the absence of state-independent moral institutions — that could be compared in this function with the Christian churches — should remind us not to rush to general conclusions and cultural stereotypes. For now, however, the lack of a deep understanding of culture and ethics does not inhibit practical efforts towards progress in medical ethics in China. How can a valid understanding of the present ‘cultural factor’ be achieved? Paediat-

ric medical geneticist Stephen Lam, from Hong Kong, recommends focusing on real communities, with a clear methodological and topical approach when we try to scrutinize a culture in medical ethics. According to Lam, “informed consent is just one of the facets that need to be addressed in genetic counseling”(Lam 2002). Doctors need to learn from both the parents and children to understand the real complexities of bioethical issues.

Preliminary results from my own research project support the general picture of China as a transforming society with an emerging new culture with unique and unpredictable patterns. Chinese culture is revisited as a reservoir of reflected moral experience from the past. However, what impact it might eventually gain, and how it will be interpreted in today’s medical ethics, is subject to speculation. Unpublished findings of small-scale studies in several regions in China, as well as numerous affidavits from scientists, doctors and ethicists, seem to indicate that, for example, Chinese patients share a tendency to prefer to be informed about their medical condition. In fact, sinologist Paul U. Unschuld has pointed out that Chinese doctors used to add an undisclosed diagnostic description to the recipe which was to be presented at the pharmacy, or to other physicians (Unschuld 1973). This indicates that the adherence of contemporary China to simple-minded medical paternalism cannot be explained in terms of cultural inclination, but by analysing the power relationship between doctor and patient in their respective socio-economic environments. On the other hand, culturally, an ethical imperative to respect the patient, and the special obligation of the doctor to tell the truth, has been corroborated by re-investigations of Confucian ethics (Nie, no date) (see below for further discussion). However, wishing to be treated with honesty as a patient and accepting informed consent does not imply that certain given interpretations and forms of informed consent are suitable for China.

### **Informed Consent: Conceptual Puzzles**

Given the recent political history, it is no surprise that China has not developed a tradition of proper informed consent. Those traditions are relatively young even in Europe and North America (Faden & Beauchamp 1986, Degen 2002). In contemporary China, below the surface of the political signals that demand respect for patients and subjects in medicine and research, it is difficult to estimate the extent to which counselling in medical practice is directive, fair or built on moral principles, and how the relevant concepts, such as respect of autonomy, non-malice and justice, are understood.

Articles on the impact of culture on the emerging medical practice in China provide different or even contradictory opinions as to whether informed consent is practical in China. This is because of the controversial concept of ‘autonomy’. There seems to be a consensus that the importance of self-determination and free individual decision-making, in accord with China’s self-esteem, must be assessed together with other principles in medical ethics, such as ‘justice’, ‘doing no harm’ and ‘beneficence’. Even if it would not relate to China’s ethical traditions, the demand to respect patients’ and human subjects’ rights would still be an ‘Asian issue’, just because today Asian ethicists regard it as such (Fan 1997). The interesting question is not whether or not China’s culture supports informed consent, but rather, by what means and in the terms of what conceptual language this support is phrased.

For example, Edwin C. Hui (Xu Zhiwei) of the University of British Columbia, explains that abstractness and a-historicism are the causes of the failure of ethical ‘western’ principles to guide moral decision-making about real problems in specific social settings in China. He argues that there is no good reason to assume that all moral standards are deducible from a unitary set of principles (Hui 2002) Still, Hui maintains that the individual should be respected and protected according to Chinese ways. To illustrate his favoured model of contextualism, Hui refers to the one-child-per-family policy of China that can be justified given China’s historical and sociological realities.

Before its implementation, argues Hui, a fertile Chinese female bore, on average, 6.1 children, but “this number has been reduced to 1.4 by 1995 through policies that may be seen in the West as an unjustifiable infringement of reproductive freedom”<sup>41</sup>. Despite this marked reduction, the Chinese population reached 1.3 billion by the end of the twentieth century, whereas the optimum would have been 0.7 billion. Given these demographics, social disasters seem inevitable. “The Chinese believe in the importance of individual autonomy, but they also believe that this right of autonomy is guided by social needs”, reported Hui (Hui 2002).

According to Confucian tradition, a person is never seen in isolation. Instead, they are at the centre of relationships. A person exists in a social context in order to fulfil their social responsibilities, and a person’s nature manifests itself only through human relatedness. Therefore, this, (according to Hui), ‘Western’ idea of individual autonomy might not be appropriate for considering reproductive rights in the Chinese context (Hui 2002) This ‘extended autonomy’ — seeing a person in the context of their family — has curious relevance in genetics as, after all, we share our genes with our family. If we know that we carry a mutation, should we tell our family?

Preliminary surveys seem to confirm such a sense of obligation towards the family, especially on the part of medical geneticists (Wertz 1999). However, reports about families rejecting a child that was created by IVF that involved sperm from an unknown donor, and the traditional practice of adopting unrelated children, on the other hand, seem to indicate an incoherent practice (Qiu 2002). Medical ethicist and family doctor, Daniel Fu-chang Tsai from Taipei (Taiwan), supports this view — according to him, a Chinese doctor sees his patient in the context of his family, his community and his social history.

However, Tsai warns that priorities should not be blurred in attempts to harmonize. “Chinese health care practitioners should be aware of how to protect their patients from being manipulated or coerced by the collectivist pressure (mostly from their families) and promote their autonomy without despising their traditional family values” (Tsai 2001).

Geneticist Chen Renbiao articulates in moral terms a conservative view from the Chinese mainland, recognizing China’s particular social needs that have been shaped by recent history. “As a developing country, our broad masses remain poor in elementary knowledge of medicine, even in the big cities, not to mention the border areas” (Chen et.al. 2002). So, informing patients appropriately is desirable but more difficult in China than in developed countries, even for those who have medical training. Indeed, in the light of general education, open controversial debate and alertness to social issues in medicine, China remains a developing country. Ethics in medical education is a complex problem (Du 2002). A crucial point is that sometimes it is difficult for doctors to differentiate between undue paternalism and what they feel are scientifically sound and reasonable suggestions.

Beijing geneticist Yang Huanming emphasizes that medical geneticists should educate the public about the true purpose of genetic information and genetic measures, which should be used for prediction, prevention, diagnosis and treatment of diseases only — not for eugenics (Doering 2002b). Nothing that violates informed consent should be done to anybody in the name of the law, because all relevant laws require informed consent, argues Yang, “The same applies to science (because science should never be imposed on anybody). Likewise for the society (because society calls for protection of individual choice), and the future should not be formed (because the future is not made by those people who claim to know more than others), without informed consent even if we have the best intentions to help” (Yang 2002). Individual geneticists should take responsibility for the abuse or misuse of genetic information and genetic measures, not laws or the society. Whether, and how, Chinese scientists and doctors are going to live up to these standards depends on encouragement. At present, the prospects are not too good. Just recently, the Honorary President of the Chinese Association of Medical Ethics, Du Zhizheng (Dalian), has spoken up for significant reform

of medical education, propagating ethics as a strategy to ensure that doctors understand and respect patients by practising confidentiality, equal treatment and informed consent (Du 2002).

### **The near future**

After successful contributions to the Human Genome Project (Cyranoski 2001) and the Rice Genome Project (Normile & Pennisi 2002), China now finds itself, for the first time, on the threshold of openly engaging in a policy-making controversy at the core of biomedical ethics. The common practice of abortion as a means of family planning in China has fuelled a general impression that early human life receives relatively low esteem. Accordingly, China could be expected to promise low ethical standards and huge quantities of biological material for human embryo research. This judgement is certainly premature and unfair, as far as it presupposes a positive decision in favour of killing an embryo or a fetus (Nie 1999). Yet, confidence in efficient action for the protection of early human life is untimely, too, although Shanghai philosopher Chen Rongxia has recently called for more sense of awe of the “miracle of life” as a common universal moral core in the face of practices such as human cloning (Chen R. 2002). China’s leading bioethicist, Qiu Renzong, has explained that China advocates the peculiar value of a human embryo. The destruction, even of an early human life form, needs to be justified by high-ranking medical purposes, which are not expected to be achievable otherwise (Qiu 2000).

The present situation is inconvenient for responsible policy-makers. Chen Zhu, a medical geneticist and haematologist, and Vice-President of the Chinese Academy of Sciences, had been taken aback by the reports of the experimental creation, by Chen Xigu in Guangzhou, of human–rabbit hybrids in 2001. Chen was quoted in *Nature*, saying, “It is of great importance for a large country like China for this kind of work to be under strict regulation” (Abbott & Cyranoski 2001). Confronted with deficient regulations and monitoring, many scientists and ethicists urge for ethical guidelines for genomic and stem-cell research, including the full informed consent of donors as a basic requirement.

China has a history in somatic and cord blood stem-cell research, with a current fashion of storing cord blood in private banks for stem-cell research. According to official sources, in 2001, more than 2,500 families from different places in China have signed agreements with a Tianjin-based cord-blood stem-cell bank — the first in China to store cord blood for the expected future benefit of their babies (People’s Daily 2001). The diversity of stem-cell research approaches might facilitate another boom in China’s biomedical sciences, albeit meeting a more sober-minded economy (Dennis 2002). Given the past history of stem-cell-related research, strict and legally binding regulations are required.

In 2001, two proposals have been submitted with the aim of advising China’s legislators about formulating scientifically and ethically satisfactory regulations. In their Ethical Principles and Management Proposals on Human Embryonic Stem-Cell Research, an interdisciplinary advisory group of leading scientists and ethicists from Beijing proposed a draft for the Ministry of Health and the Ministry of Science and Technology.

The document highlights the principles of general respect for human life at all stages, informed consent, safety and effectiveness, encouragement of biomedical research and a ban on “any form of gamete, embryo or fetus tissue trade” (Article 2) (Ethical Principles... 2001). The document proposes that all institutions that are involved in human embryonic stem-cell research must be approved by the government, and must submit to an Institutional Review Board and offer ethics training to staff members. It requires the government to enact professional and ethical standards in the qualification of personnel and technical standards for facilities. A Human Genetic Resources Man-

agement Office will be created to be in charge of the licensing and monitoring of researchers and institutions.

### **Draft Provisions on Embryo Research**

Ethical Principles and Management Proposals on Human Embryonic Stem-Cell Research drafted for the Ministry of Health and the Ministry of Science and Technology in 2001 (excerpt).

These provisions specify (Article 4) that it must be strictly forbidden to:

- implant a research-used embryo into human or animal uterus;
- combine the human gamete with animal gametes, and research on combining human somatic-cell nuclei with animals is to be placed under close supervision, and the result of such combination must not be re-implanted into a human body;
- use an embryo older than 14 days;
- add a gene from alien sources to the embryo or replace the cell nucleus in the embryo with a human or animal-cell nucleus;
- coerce or lure others into becoming pregnant and then choosing abortion or manipulate the method and time of abortion.

Source: *Ethical Principles 2001*.

The second relevant document written at about the same time, the Ethical Guidelines for Human Embryo Stem-Cell Research, is a draft by the Bioethics Committee of the Southern China National Human Gene Research Center, Shanghai (Bioethics Committee 2001). The Shanghai draft emphasizes the importance of encouraging research, but the ultimate purpose of the law remains vague — protection of embryos or donors, or providing a predictable legal framework for research — as does the administrative character of the institution that is to be monitoring ethics. The contents of the two documents, however, are quite similar — a consensus can be seen in the general esteem of human life, in pointing out informed and voluntary donation, the 14 day dead-line for the permissible destruction of an embryo and the ban on re-implanting an embryo from research into a human uterus. Also, both documents reject cloning for reproductive purposes but allow it for therapy.

The Shanghai guidelines seem to reflect issues of risk control in contrast to the more fundamentally ethical view of the Beijing guidelines. Interestingly, the Shanghai guidelines state that “research combining human gamete with animal gamete is not allowed, but fundamental research may be permitted” (Article 13.4). Here, the cross-species recombinant in vitro experiments are permitted, which are designed to support Shanghai’s local researchers who are engaged in such projects.

Furthermore, “‘Human–animal’ cell-merging, if it is only for non-clinical fundamental research and if it meets the above three requirements, might be allowed. But any combination of human cells with animal cells for clinical purpose — for example, for the purpose of being implanted into the human body — is strictly prohibited” (Article 14.4). According to this article, the creation of cross-species hybrids is allowed if it is conducted strictly in vitro — provided, in addition, that donation occurred voluntarily, that embryo production took place in vitro and that only ‘spare embryos’ are used.

Both guidelines explicitly prohibit coercion of others into becoming pregnant and then choosing abortion, or into manipulating the method and time of abortion. Here, ethics advisors obviously react to a current malpractice, which seriously violates the concept of informed consent. As far as ethical priorities are concerned, it is evident that donors — in this case, women — enjoy relatively greater attention than the protection of early human lives. This probably indicates the emergence of a moral culture that would be in favour of informed consent, but does not pay as much attention to

the moral status of an embryo. These two points express a tension between real practice and the aims of ethical regulations in China.

## Conclusion

As long as institutions are too weak and too few to effectively monitor biomedical researchers and implement ethics regulations, it is unclear whether China can manage to ensure a medical practice that would soothe the serious worries about protection and respect of patients and donors. In recognition of cultural self-esteem and political effort, it is not true that there would be no place for informed consent and other high ranking internationally established ethical standards in bioscientific research and medical counselling in China.

At the same time, it is far from clear how good practice can be achieved. The size of such a task is overwhelming, especially in the rural areas. Certainly, the state and ethicists alone cannot stimulate such a process. Ordinary people need to be educated and encouraged to claim their rights as patients and donors. As indicated by the health administrative crisis exposed by SARS, the social and public health system needs to be reformed in a way that assigns greater responsibility to accountable administrators (Döring 2003a). Will China be successful in strengthening the common people and enhancing the educational level? Will the forthcoming institutional and law reforms merit confidence in the legal practice? Will society find a balance between commercial necessity and the social virtues that define a vital civilization?

These questions indicate that discussing cultural issues in medical ethics in China merely on the level of 'Chinese culture' does not suffice and oversimplifies the real complexities of cultural values in China's medical ethics. Both the normative bearings of culture and the real lives of people must be considered. The open China of today invites much closer scrutiny and, perhaps, more sympathy from ethicists than in the past.

How the cultural fabric affects moral standards in biomedicine cannot be predicted solely on the basis of what we know about the past. Instead, it is a challenge for our interactions, indicating new efforts to interpret normative reasoning and decision-making in the different communal contexts inside China, and to cooperate with Chinese colleagues in doing so. It is in the best interest of medical ethics to benefit from international and interdisciplinary cultural studies, by limiting stereotypes and biases, and learning through this concrete example about the real range of living cultures in China, and their guiding values.

It is unlikely that, by its peculiar culture, China will contribute to the downgrading of international ethical standards. Instead, it might stimulate a more desirable transformation, so that universal principles can become more effective, especially in preventing patients and donors from harm and underprivileged groups from injustice. As China is not an island, cooperation creates exciting opportunities to support China's, and therefore the world's, bioethical culture.

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