Development of Research Ethics in China

ÇİN'DE ARAŞTIRMA ETİĞİNİN GELİŞİMİ

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Özet

The author briefly describes the condition of development of research ethics in China, especially address the serious situation of human subjects protection and scientists' behaviors. The aim is to point out some ethical issues related to the system establishment and several aspects need attention in the process of research ethics capacity building in China.

Key Words: Research ethics, ethical Issues, China

Abstract

Yazar, özellikle deneklerin korunmasına ve bilimadamlarının davranışlarının önemine yönelik olarak kısaca Çin'de araştırma etiğinin gelişim durumunu tanımlamaktadır. Amaç, sistemin kuruluşu ile ilgili bazı etik sorunlara ve Çin'de araştırma etiğinin yapılanması sürecinde dikkat gereken birkaç açıya işaret etmektir.

Anahtar Kelimeler: Araştırma etiği, etik sorunlar, Çin

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1. The Serious and Complex Situation Related to Research Ethics in Current China

With more and more biomedical research and clinical trials experimented in China within last two decades, China has become a country with the largest population of human subjects now. So, it is necessary to look back the history of research ethics briefly.

In early 1990s, some researchers of big international cooperation didn't know how to translate "informed consent" into Chinese, so, it is not surprising if informed consent wasn't implemented well in some projects. Gradually, informed consent was emphasized, not only because it is required by international cooperation projects, but also by 'regulations for medical work' issued by Ministry of Health early in 1994 and the GCP in 1999. But, a signed consent form was often replaced by oral consent in late 1980s and early 1990s.[1]

The first law suit case related to human subject happened in 1998. Changrong Ge, who was a government employee, sued two hospitals in Beijing for being taken as an experiment subject while in physical examination once a year (it was about an evoked potential test by magnetic irritation through head, which was not a regular item of physical check) without informed. This case challenged such kind of research behavior for the first time which was regarded as "common" in clinical practice.

It is reported that more than 800 new drugs need experiment,[2] that's why a special "community or group" who mainly live on testing new medicine, emerged within these five years. Usually they are called "professional medicine tester" in Chinese. The constitution of this community is a little complex, but college students are preferred.

The discussion on stem cell in mainland China started from an experiment by a professor, about the fusion of a nuclear of a 7-year-old-boy's skin cell with the enucleation egg of a rabbit in 2001 in former Zhongshan Medical University, Guangzhou. The report said the more than 100 "human embryo" got by above way was the pioneer in the filed of therapeutic cloning.[3] Two sides formed since then, support and against. The side of support means to do such research in the basic period, not allowed in clinic. Another scientist and her team in Shanghai also created "hybrid" stem cell almost in the same time. In mainland China, this similar experiment didn't raise the same debate, but outside China, it created a buzz after rumors of it circulated in the scientific community and were reported in The Wall Street Journal in March 2002.[4]

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It was reported that a Japanese patient came to Beijing to accept treatment in summer of 2004 by using the stem cell from aborted fetus.[5] In fact, many others have been treated or apply to doctor to accept treatment. Not sharp ethical issues are raised within China, but not the case abroad. A foreign correspondent argued that the doctor (who did the surgery for Japanese patient) was forging ahead without first testing the technique's safety or scientific basis in clinical trials with independent review.[6] Another hot topic is the ethical issues of brain surgery for drug addict.

Truly speaking, the most serious situation of research ethics is related the system, about 20 of 25 biggest multinational pharmacy companies had branch in China, and it is estimated by experts that 60 multinational drug companies are being involved into about 100 phase one experiments.[2] One typical case related to HIV testing happened in Ditan Hospital in Beijing in 2004 April has raised much controversy in China and also in abroad, which just reflects many issues of system construction of research ethics.

2. The Brief Description of Possible Reasons for Above Phenomenon

Firstly, not only the medical researcher, but also the common people didn't have a strong sense of individual right, "informed consent" was still an unfamiliar concept. Why western scientists and researchers raised sharp ethical questions to Chinese researchers' behaviors (especially about the hybrid making in the basic research period) involves the second reason, maybe the intrinsic one. For the different values towards the concept of "human being", "person", "fetus", "embryo", "abortion", etc. the Chinese society, including the group of scientists don't take "embryo", "hybrid", "stem cell come from fetus" as seriously as that in the western. It is a complex issue if we deepen the understanding of these basic concepts. One project about this is being done by the author under the support of Ministry of Education, P.R. China.

It is also the true point where Chinese Bioethics and research ethics different with others.

Thirdly, involves the system related to biomedical research. In China, only if a new drug has passed the gate of registration, it is relatively easy to get the allowance to put into production by China's SFDA (State of Food and Drug Administration), however, it is relatively loose to register, but rather strictly to be allowed to put into production, which is key to the economic management for many foreign drug companies. Relatively much lower cost is another main reason for foreign drug companies to transfer to the drug market in China. The Ditan HIV case happened in Beijing 2004 April showed that there existed many leaks in the system construction of research ethics, such as the administrative procedures of clinical trial, the informed consent, etc. The biggest leak here is the procedure which surprised many people-- this clinical trial is illegal for having not been registered. But, how this illegal clinical trial could be done implies many ethical issues and involve some people's interest.

3. The Condition of Research Ethics Capacity Building and its Special Issues Needed Attention in the Near Future

Generally speaking, capacity development has a three-level meaning: level one is the individual researcher, the primary actor of capacity development; level two is the institution in which the researcher will operate; and the level three is the central administration itself, its organization and mode of operation, which is also the policy level.[7] In China, all these three levels are urgent to be raised, and the bottleneck is the system!

Fortunately, China has begun the capacity building, though there is a long way to it. Peking University Health Science Center has held two research ethics training workshops under the support of China Medical Board of New York in 2004 February and November. Till now the seeds (participants are regarded as seeds of the field of research ethics) have reached 130. From the feedback of the trainees, the problem is not the establishment of IRB, but how IRB works, and the capacity of IRB members to do ethical review to protocols. This is also a system problem, because according to GCP (this regulation was issued by SFDA in 1999 and revised in 2003), in Chapter three, there mention that IRB must be established in basic pharmacological base, it is required at least 5 members in IRB, including experts from drug, non-drug, law, and other unit. So, it does not address ethicist, and most IRBs would prefer lawyer rather ethicist for the former can provide direct benefit for the pharmacological bases! It is no doubt that the moral justification of the IRB's review remains a question. Optimistically speaking, the situation is becoming better for some IRB members have been trained by research ethics workshops.

A special issue, which maybe the unique one in the world, is the system of "maintaining the running of treatment by medicine sale". Since 1950s, healthcare system has been reflecting the planned economic, the price of treatment is relatively low for the social welfare. But the condition changed while the reform of healthcare system began in early 1980s. when government couldn't provide enough money to hospital for its running, but allowed to compensate the income of hospital by medicine sale (it is one way of several methods to keep hospital's economic running), naturally, common people can hardly pay the medicine for the higher and higher price. At this point, new drug research and medical treatment connect closely, hospitals, physicians and drug companies usually become a

union of interest. Even some serious adverse event happen in the clinical trial, being the researcher and at same time the physician of "subject", some the them maybe tend to protect drug company instead of subjects, under the circumstances that the monitoring system is not developed. E.g. they will not report to SFDA or other related institution the adverse event, or don't informed the subject they have the right to get compensate, or don't deal with the compensation in the legal way but secretly. Related to the economic condition, some poor patients would like to participate the phase Ⅱ if they needn't pay for new drug.

4. Conclusion

In early 1990s, "informed consent" was still unfamiliar to the whole society, but in 21st Century, being a concept, informed consent has been familiar by both researchers and human subjects. The problem in current China is not the establishment of IRBs, but how IRB works, how to do informed consent, what's the role of family member in clinical trial, esp. when related to the children subjects, etc. Similar to the condition of clinical ethics, family member plays an important role in the process of informed consent, so does in the clinical trial. For the not developed insurance system, there exist some factors not good to informed consent, e.g. some clinical trials needn't pay, which is already an economic lure for some poor patients, let alone some trials will pay participants (in phase □) some amount of money; on the other hand, for those patients, who can still enjoy free medical service, will not "trust" the research if they are informed they needn't pay anything, or can even be paid.

Being a discipline, research ethics began to emerge in the beginning of 21st Century. For the special culture background, research ethics in China will develop in a special way, but should share the similar basic issues, such as how to protect the interest of so large community of human subjects, how to regulate the research behaviors, even how to supervise the ethical review of IRB, etc.

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