

## CLINICAL ETHICS

# How medical ethical principles are applied in treatment with artificial insemination by donors (AID) in Hunan, China: effective practice at the Reproductive and Genetic Hospital of CITIC-Xiangya

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This paper investigates the efficiency of application of medical ethics principles in the practice of artificial insemination by donors (AID) in China, in a culture characterised by traditional ethical values and disapproval of AID. The paper presents the ethical approach to AID treatment as established by the Reproduction and Genetics Hospital of CITIC-Xiangya (CITIC Hunan-Yale Approach) in the central southern area of China against the social ethical background of China and describes its general features. The CITIC-Xiangya Approach facilitates the implementation of ethical relations between clinicians and patients participating in AID treatment procedures in Hunan-Yale.

Hunan-Yale Medical School for research into sterility and genetics. The Hunan-Yale Medical School itself was established in 1914 by Hunan Yuqun Association in China and the Yale-China Association. It has become one of the leading medical centres in China over the past 90 years. The Clinic of Sterility and Genetics initiated China's earliest research on anthropic oogenesis, in vitro fertilisation (IVF), embryo transfer, and in vivo maturation in 1980; set up China's first frozen sperm centre in 1981; produced China's first baby by means of artificial fertilisation from frozen sperm in 1983; and delivered China's first test-tube baby from donative embryo transfer in 1988.<sup>1,2</sup> It has since added achievements in the fields of preimplantation genetic diagnosis, intracytoplasmic sperm injection (ICSI), embryo freezing, and blastula culture.

Chinese civilisation and culture has a long history. The ancient civilisations of China had a patriarchal clan system and an economy based on scattered farming and animal husbandry. Consequently, many Chinese moral values differ from those of some Western countries. Many people adhere to the old, traditional, and conservative moral values about procreation and the family. Although the first test-tube baby in China was born in 1988, ethical principles in relation to assisted reproductive technologies (ARTs) were only recently introduced to provide regular guidance in clinical procedures. The Ministry of Public Health of China issued the first medical guidelines for ART, *Ethical Principles for ART* (in Chinese), in 2001. It has not, however, been routinely applied to supervise clinical procedures and influence the behaviour of clinicians.

How can medical ethical principles be implemented during ART by hospitals or clinicians in China? The answer can be found in the practice of medical treatment with artificial insemination by donor (AID) at the Reproductive and Genetic Hospital of CITIC-Xiangya, which has made great efforts and progress in this field. The hospital was established as a joint venture by CITIC (China International Trust and Investment Corporation) and Hunan-Yale (Xiangya) Medical School in 2002. However, its history can be traced back to the clinic that was set up by China's famous geneticist Dr Lu Huiling (1900–97) and his successor Dr Lu Guangxiu (the current director the hospital) as a part of the

Over the past 23 years, the hospital has paid a lot of attention to the moral aspects of the practice of ART. Under the direct leadership of the Ministry of Public Health of China, the first symposium on ART and social ethical problems was held by the hospital in 1988, when it was agreed that the guiding principles of medical ethics should be upheld both in clinical services and in research related to ART in China. The Hunan-Yale Ethical Committee for Reproductive Medicine was established and set to work in 2001. In line with the social and ethical background of China's AID patients, a man who suffers from sterility and his spouse shall participate in AID treatment under the provisions of the *Minimum Standards for the Management of Sperm Banks* (in Chinese) and *Practice Criteria for Assisted Reproduction Technologies* (in Chinese) issued by the Ministry of Public Health of China in 2001. The hospital of CITIC-Xiangya has been exploring ways to safeguard the benefits and rights of AID patients and offer better AID services to them. On the basis of its success in the development of the clinical aspects of AID service, it has also gradually set up its own approach to ethical regulation of clinicians' behaviour in AID treatment services, referred to as the CITIC-Xiangya Approach.

### CULTURAL AND ETHICAL BACKGROUND OF THE CITIC-XIANGYA APPROACH

According to China's traditional ethical values, the fundamental purpose of marriage is procreation. In AID, the role of the donor's sperm seems to challenge the tie between marriage and

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family, and raises moral concerns about the relationship between the social father, the biogenic father (donor), and the child. As a result, there is an argument about whether AID treatment is acceptable or not according to traditional morals relating to marriage. People who insist on traditional ethics regard those using AID as immoral and discriminate against children born through AID. An ethical background survey on artificial fertilisation showed that 67.57% of the people included in the survey were against the use of AID.<sup>3</sup> Furthermore, an important feature of traditional Chinese ethics is that it advocates collectivism. For example, respect for family relationships emphasises the importance of the whole. Filial piety suggests that offspring show much respect to their parents. Individual rights may have to be relinquished for the benefit of other members of the family. Indeed, filial duty has been an essential moral value in traditional China,<sup>4</sup> and Dong Zhongshu (179–104 BC), a famous Confucian scholar of the Han Dynasty, said, “A son’s disobedience against his parents’ will is the most serious crime worthy of punishment by the whole society”.<sup>5</sup> Since the time of the Sui-Tang Dynasties, disregard of filial duties had been stipulated as one of the “ten evils” in some of China’s ancient social laws.<sup>6</sup> For the benefit of the family, procreation has been regarded as an important aspect of filial piety. Such interpretations of filial piety have been profoundly influencing Chinese society for several thousand years. Even now, a number of people, specially in rural areas of China, still adhere to these ancient values and moralities of human relationships: “Three things prove one’s unfilialness, among which no posterity hits the top line”.<sup>7</sup>

Against this ethical and social background, and the influence of the social pressures for begetting offspring for continuation of the family line, the patients coming to our hospital express a strong desire for having a child by mean of ART. However, they also worry about being discriminated against by others who reject AID. A questionnaire issued by the Hunan-Yale Ethics Committee for Reproductive Medicine in 2002 to AID patients in the central southern region of China showed that 78% of patients felt uneasy about being discriminated against.<sup>8</sup>

The number of men suffering from sterility in China has doubled,<sup>9</sup> and, under pressure from traditional views about marriage and reproduction, most of them will seek AID treatment. They have an awkward position in society because of their reproductive handicap and they suffer from psychological pressures. For the sake of fairness and justice, they deserve more consideration and help from society.

Although there has been a gradual increase in levels of AID treatment in China since the 1980s, some medical practitioners and hospitals in a few areas provide AID solely for the sake of commercial gain.<sup>10</sup> Some clinicians do not pay enough attention to patients’ benefits and rights and others do not give patients sufficient information about AID treatment. For example, some doctors fail to enquire about the patient’s family situation and do not help the couple understand the possibility of social discrimination and do not make an attempt to match the donor’s appearance and physical characteristics with the husband in order to minimise possible dispute later. Some have indicated that they would disclose the patient’s participation in AID, which subsequently leads to legal litigation.<sup>11</sup>

In 1984, the first litigation regarding AID treatment in China took place in Shanghai. A woman, holding an 11 day old baby in her arms, asked for legal protection from the court. Her husband had been previously diagnosed as having sperm abnormality and the couple had received AID treatment in a local hospital without the knowledge of the husband’s parents. Unfortunately, the baby was noticeably different in appearance from the husband. Under pressure

from the husband’s brother, the truth was disclosed by the couple. The husband regretted the treatment and the whole family was strongly opposed to it. Consequently, the wife and the newborn baby were expelled from the family and she proceeded with litigation.<sup>12</sup> As the market economy of China is gradually undergoing modernisation, patients are beginning to recognise their rights and are requesting hospitals to help establish a good medical ethical relationship between the clinicians and themselves. They also want better medical services and humane treatment, claiming their due rights. For example, patients request the hospital to give them further information about the particulars of AID treatment and demand that their interview with the clinician should be in private. Some request a greater involvement in the selection of donors and improved success rate.<sup>8</sup> The CITIC-Xiangya Approach was set up to accommodate the particular social and ethical background of the Chinese patients.

## ETHICAL CONTENT OF THE CITIC-XIANGYA APPROACH

In 2001, the Ministry of Public Health of China announced the seven fundamental ethical principles for ART treatment in the *Ethical Guidelines for ART and Sperm Banks* (in Chinese):

- Respect for patient autonomy and of value to patients
- Informed consent
- Protection and safeguarding the interests of offspring
- The common good
- Respect for patients’ privacy
- Prevention of commercialisation
- Ethical regulation

As matter of fact, the Reproductive and Genetic Clinic of Xiangya (the predecessor of the Reproductive and Genetic Hospital of CITIC-Xiangya) was foremost among hospitals in China in initiating the application of the relevant ethical principles in all ART treatment procedures. Since 1983, it has followed the concepts of autonomy, informed consent, protection of identity of patients’ and so on.

The CITIC-Xiangya Approach in general adheres to the seven principles given above and actually extends the application of the ethical principles to all stages of AID treatment in China. The ethical content of each stage is described below.

### Stage 1: Counselling

- Give potential patients a kind reception and allow them to give a full explanation of their problems and conditions.
- Give patients a clear explanation about AID treatment so that they are well informed, in particular about the treatment period and procedures—for example, IVF consists of ovarian stimulation to induce growth of multiple eggs in the ovaries; ultrasound guided retrieval of the eggs; fertilising the eggs with the partner’s semen; possible ICSI procedure; transferring the resulting embryo(s) into the uterus; and establishment of pregnancy. Explain potential benefits, treatment options, details of costs involved, and potential physical and psychosocial risks of ART procedures, for example, medication related risks during IVF treatment, possible allergic reactions and long term risks. All counselling should be given with full consideration of patients’ cultural backgrounds and degree of literacy.
- Carefully enquire about the case history and health status of the patients and establish the possible aetiology and the appropriate treatment protocol.
- Encourage patients to ask questions so as to make sure that they have completely understood the clinician’s

explanation about AID treatment. If they appear confused, repeat the explanation until they indicate full understanding. Counselling support should continue throughout treatment, and doctors should give accurate and objective answers to patients' questions at all times.

### Stage 2: Diagnosis

- Clinicians should confirm that potential patients have been correctly diagnosed and have clear indications for AID treatment, and that they will not respond to other forms of medical treatment and are incapable of natural reproduction. It should be strictly stipulated that any person capable of natural reproduction cannot be diagnosed as infertile, either due to the doctor's neglect or with a commercial motive.
- ART treatment should be strictly avoided in the presence of any of the six contraindications to AID listed in *Practice Criteria for Artificial Reproductive Techniques* (2001).
- Clinicians should hold qualifications awarded by the relevant organisations. They should conduct a careful and thorough examination with proper equipment. Consent should be acquired before any examination that involves touching the patient's body.

### Stage 3: Signing the Agreement of Informed Consent

- The patients should be well informed about the details of AID treatment, including:
  - the purpose, procedures, method, relevant success and failure rates, alternative modes of treatment
  - possible pain or discomfort
  - duration of treatment and expected benefit
  - potential risks (including any adverse outcomes for the potential offspring, and possible short and long term physical or psychosocial risks) and side effects of the proposed treatment
  - choice between domestic and imported medicines (usually costlier) and details of costs involved in each treatment cycle
  - clinicians' obligation to see and talk with the patients at any moment when required. For example, clinicians will inform the patient of the success rate of the AID treatment (which is 30–35% for each cycle in the hospital), the accompanying risks of multiple pregnancies, complications of pregnancy including miscarriage, genetic defects, birth defects or stillbirth through the AID, etc.
  - to inform the patients that offspring born through such treatment will have the same legal rights and obligations as those of natural born children.
- Give patients detailed oral explanation about every item of the Informed Consent Agreement in plain, intelligible language. For example, clinicians should inform the patients that they are only allowed to accept frozen sperm provided by a licensed sperm bank, and pregnancy by this means does not rule out the possibility of a miscarriage, premature delivery or teratogenesis. The patient should attend for the required examinations once she is pregnant. One copy of the written agreement should be given to the patients. Allow patients sufficient time to reflect before and after making a decision.
- Only after the patients confirm that they have fully understood the significance of the agreement, and that they are quite willing to accept all possible adverse results, should they be allowed to sign the consent agreement. The

agreement should be obtained and documented in writing. The Form of Informed Consent includes the information given by the clinicians, and declaration and signatures of the patient and their spouse. Usually the patients' declaration is as follows: "Our clinicians have described in language we can understand, the proposed treatment, the medically significant risks involved, and the alternative course of treatment or non-treatment, including the respective risks of each. Our signatures indicate that we have read and understand the above information, and that we authorise Dr Lu and her associates to perform the ovarian stimulation, egg retrieval, fertilisation of the eggs, possible ICSI, embryo transfer, and any additional services as may be deemed reasonable and necessary, and give our written consent to the proposed procedure".

- The patients should also be informed that they have the right to withdraw from the treatment at any time—for example, they may terminate hospitalisation because of personal or other reasons including financial, mental, physiological, or physical issues and so on, without any effect on their future healthcare needs.

### Stage 4: Planning the treatment protocol

- Clinicians should discuss all options and every step with the patients in great detail and give the patients a detailed account of the proposed treatment protocol and advantages and disadvantages. Let the patients choose the donor and the method of insemination (intrauterine, intracervical, vaginal).
- Carefully listen to the patients' views on the operation protocol that they want to follow.
- Clinicians should advise the most appropriate AID treatment protocol for each couple. The protocol should fully consider individual couples' requirements and the indications of medical treatment and cost effectiveness for the respective patients. It should consider decreasing the number of operations and period of treatment in order to reduce expenses and risks.
- The final AID treatment protocol should be decided by the patients. However, it may still be changed and improved during the treatment period according to the requirements of the patients.

### Stage 5: The operation stage

- The hospital will provide the patients with good facilities for ART treatment as prescribed in *Practice Criteria for ART*, such as suitable medical treatment facilities with qualified clinicians and nurses, under appropriate ethical management.
- Clinicians should inform patients in advance about what they will be doing during the operating stage. A signed consent form should be obtain from the patients. For instance, clinicians should inform the patients that their ovarian stimulation progress will be monitored by ultrasound and oestrogen blood levels, and will require a single injection of the human chorionic gonadotrophin hormone. For egg retrieval under ultrasound guidance, a thin aspiration needle will be passed through the top of the vagina and into the cul de sac (a space behind the uterus) to enter the ovarian follicles and aspirate the follicular fluid.
- There should be provision of strict screening procedures for sperms so as to ensure that the chosen sperm will meet the patients' requirements. Moreover, clinicians must observe strict avoidance of inbreeding in AID treatment.

- Regular AID treatment should be offered strictly according to the planned protocol and standard techniques. Efforts must be made to prevent any avoidable harm to the patient and to achieve the best operative result.
- Any psychological and physiological changes in the patients must be considered carefully during the treatment procedure. Provide psychological counselling at all appropriate times.

### Stage 6: Follow up

- Inform the patients well in time about all possible events that may occur to minimise factors that can adversely influence the success rate; the importance of the follow up after the treatment; and that the follow up will be conducted by a designated doctor.
- Provide patients with counselling or support services as necessary, and maintain an up to date and ongoing record of the couple's condition—for example, the designated doctor will pay attention to physiological changes or psychosocial effects and provide consultation for the patients when they require it.

### Maintaining confidentiality

Any information about the patients and donors that could identify them should be retained as confidential records within the hospital. Clinicians are responsible for any disclosure of the patients' or donors' identities. The donors, recipients, offspring, and doctors participating in an AID operation must not be known each other. For example, the identity of the sperm donor should be coded. No donor has a right to access the personal data of the recipient and the offspring. Nor do recipients and clinicians providing AID treatment have a right to refer to the donor's personal data.

No-one who has access to personal information about the patients and donors is an exception to the principle of maintaining confidentiality. Any person accessing the information will be required to sign a Confidentiality Undertaking which has been approved by the chief of hospital. They must do everything necessary to keep the confidential information secret and may use this information only to the extent necessary for a permitted purpose.

### DISCUSSION

The CITIC-Xiangya Approach fully considers the social and ethical background in China. A large number of people are still influenced by traditional views on marriage and procreation, and they argue against AID and discriminate against AID patients and their offspring. Hence all patients have the right to claim strict privacy about their participation in AID treatment.<sup>8</sup> The approach complies with the "triple blind principle"—that is, three relations between people: the recipients and the donors, the offspring and the donors, the clinicians participating in the AID treatment and the donors. All are unaware of each other's personal information.<sup>13</sup> Moreover, supervisory measures are taken to code the donor's identity and medical record. Any doctor breaking the confidence of an AID patient should face disciplinary measures.

Many Chinese people desire to have several children in the hope that this will bring them more blessings. However, rapid population growth can result in serious social problems. Thus it is necessary and reasonable to implement family planning. Considering that China is a developing country with insufficient natural resources per capita and already has a large population, the Approach conforms with Chinese family planning laws. According to these only married couples who suffer from sterility are allowed AID treatment. Unmarried

women may be not be provided AID treatment in the hospital.

The Approach respects local moral beliefs and individual patients' wishes. This is in accord with the ethical principle of autonomy. Any treatment advised by the clinicians must follow the principle of beneficence and they should try to achieve the best results at the most reasonable cost to the patients. It adheres to the principle of informed consent and expects clinicians to give patients essential information in detail and the importance of postoperative follow up in order for them to make a decision. AID treatment can only be initiated after the patients have signed the informed consent agreement voluntarily. The Approach has to be assured that patients will be fully informed about all advantages and disadvantages of the treatment proposed by the clinician. The psychological and physical integrity of the patients should be respected by the clinicians in the hospital, and all patients should be provided comprehensive treatment, not only for their physical disease but also for their mental health so as to release them from psychological pressure and physical discomfort. For example, a consultation clinic on psychology and ethics has been established and counselling is regularly offered in the hospital for patients and clinicians.

The approach consistently adheres to the accepted international ethical principles for ART:

- It protects and respects the rights of the patients during the process of procreation and health care via informed consent and privacy. For example, efforts are made to help each couple in hospital to give birth to a child as best as possible. In this approach, informed consent is not just a process for obtaining a signature but an opportunity for patients to express their free will—so that they can request to stop the treatment at any time in the cycle without any effect on future treatment. Besides ethical obligations during clinical treatment, the doctor involved in providing the medical service must bear in mind and have respect for human dignity.<sup>14</sup> Clinicians who do not show respect to their patients are required to offer an apology to the patient and can even face disciplinary measures.
- It acknowledges and follows the principle that sperm from a single donor should provide impregnation for no more than five women. This helps to reduce the potential risk of consanguinity and/or incest.<sup>15</sup>
- It also abides by the principle to protect the offspring's and society's interests. For example, it forbids human reproductive cloning as well as sexual selection for non-medical purposes. It affirms the obligation to terminate AID treatment if required to avoid potential harm to the offspring.
- It monitors the ethical regulation and evaluation of the ART treatment procedures.

The Ethics Committee of the Reproductive and Genetic Hospital of CITIC-Xiangya has been set up and the entire AID medical procedure is conducted under the supervision and guidance of the abovementioned ethical principles.

### CONCLUSIONS

The CITIC-Xiangya Approach has been established to accommodate traditional Chinese ethical values and patients' demands. The implementation of this approach has continuously improved the quality of medical service. As a result of its application, the hospital has had a record of no medical malpractice litigation during the past 23 years. Thus it has earned a good reputation among the patients and nationwide experts in the field of ART. According to the questionnaire survey undertaken by the ethics committee in 2003, the rate of satisfaction among inpatients is 92%. The number of

patients is steadily increasing, for instance, over 12 000 patients were admitted to the hospital in 2003. The patients come from provinces from all over China and even from abroad. The Approach has actually had a positive and instructive influence on the implementation of the principles of medical ethics and has improved relations between clinicians and patients in the ART treatment process in the Hunan province and other parts of China. In 2002, Yu Xiucheng, head of the inspection group of medical experts of the Ministry of Public Health of China, stated, "The hospital's experience is recommendable and instructive to other hospitals in the field all over China". This article presents the evidence behind this statement.

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Xiangya is the pinyin of Hunan-Yale.

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