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Autonomy, Humane Medicine, and Research Ethics: An East Asian Perspective

David Kum-Wah Chan

Do principles of bioethics differ between cultures? In the United States, bioethics has become an important subject in the last forty or so years, and autonomy has been enshrined as one of the key principles of medical ethics, alongside beneficence, nonmaleficence, and justice.[1] In recent years, the paternalistic model in the physician–patient relationship has been completely replaced by a model that stresses the patient's informed consent before treatment by the physician.

Since the concept of autonomy has for centuries played an important role in Western philosophy, as well as in the rise of liberal democracy, its role in medical ethics has been long overdue. But the concept of autonomy is not found in many non-Western societies, and has only arrived on the scene there as an imported Western idea. It evidently is not found in the philosophy of the ancient Chinese sage Confucius that has deep historical roots in East Asian countries. Confucian ethics articulates an authoritarian and hierarchical system both for the state and in the family, and the community's interests are valued above the individual's. It is thus difficult to envisage the principles that developed in Anglo-American bioethics as universalistic if such principles are to include autonomy. If an Asian bioethics based on ancient Confucian ideas could not incorporate a principle of autonomy, could it develop a non-Western alternative that could serve East Asian societies where modern medicine has gained common acceptance?

This chapter describes the basic values of medical practice according to ancient Chinese medical ethics, and examines whether an ethics based on the ideas of Confucius can sufficiently guide physicians in their relationship with patients. I suggest that in the arena of research, a recent case in Singapore illustrates how traditional medical ethics in East Asian societies

is inadequate and needs to be supplemented by a principle of autonomy. Therefore, where research ethics is concerned, the principle of autonomy may well have validity across cultures, and autonomy will become an important value as biotechnology spreads to countries in East Asia.

ANCIENT CHINESE MEDICAL ETHICS

Confucian thought has influenced every aspect of Chinese life for more than two thousand years. This philosophy spread to neighboring countries in East Asia through Chinese imperial power, the spread of Chinese culture, and later by way of Chinese migrants who settled in Southeast Asia. Today, Confucian ideas continue to be studied and taught in Taiwan, South Korea, Hong Kong, and Singapore, countries that became known as the "Asian tigers" for their accelerated economic growth and development. Rapid modernization in these East Asian societies has included provision of modern health care modeled on Western medicine. There has, however, been great suspicion concerning Western ideas of democracy and individual autonomy.

Western-educated physicians in East Asia, like their counterparts in America or Britain, have some exposure to the subject of biomedical ethics. However, as in many places in the West, their training in ethical thinking is often inadequate. Unlike in the West, physicians in East Asia have also to integrate Western bioethics with Confucian values found in their own society. In addition, Confucian ethics has not been systematically applied to moral problems in medicine. Ancient Chinese medical ethics has been preserved in the form of codes and rules of conduct that were compiled by various Confucian medical scholars in earlier times. It is likely that aspects of Confucian ethics have surfaced in medical practice due to the cultural background of medical practitioners in East Asian societies rather than to the study of these historical texts.

Awareness in Western countries of an Asian bioethics has derived from infrequent attempts at cross-cultural comparisons that question the universalistic aspirations of Western bioethics.[2] The earliest available Chinese text on the duties of physicians to their patients was written by Sun Szu-Miao in the seventh century. Sun emphasized compassion and humaneness as the basic values of medical practice. Almost a thousand years later, a similar emphasis was repeated in Kung Hsin's maxim of 1556: "The good physician of the present day cherishes humaneness and righteousness. . . . His beneficence is equal to that of Providence."[3] The idea of humaneness is at the heart of Confucian ethics and is the defining virtue of the ideal Confucian man:

> It was widely accepted that a physician's saving his patients' lives and promoting their welfare was as respectable as a Confucian scholar's realizing his moral and political aspirations through ruling the states and bringing peace and pros-

> perity to people. The well-known saying: "The achievement equals that of a good prime minister," frequently used by Chinese people to praise a successful physician, reflects this concept exactly. . . . The practice of medicine is the realization of humaneness.[4]

The virtue of humaneness is realized in the practice of medicine through an attitude of kindness and benevolence. The principles laid down in the ancient texts instruct physicians to diligently master the skills of their profession, to be selfless and devoted to their patients, to treat rich and poor equally, and to be modest, dignified, and respectful. Emphasis is placed on the value of life and the patient's welfare, not the physician's own glory and self-aggrandizement. However, there is no requirement for the physician to respect the wishes of the patient. Given that individual autonomy is not valued for its own sake in Confucian ethics, this is unsurprising. Firstly, there is a larger role for the family or community to make medical decisions for the individual. Secondly, the hierarchical system of authority places the educated physician above the common person.

Without concern for autonomy, physicians guided by humaneness will do their best to look after their patients in a paternalistic manner. Ancient Chinese medical ethics is characterized as beneficence-oriented in contrast to the autonomy-oriented medical ethics found in Western countries.[5] But paternalistic practices are not alien to Western medicine, as the Hippocratic oath at the foundation of Western medical ethics does not require physicians to respect the wishes of patients. Even today, the balance between beneficence and autonomy is debated in Western countries. Beneficence is thus a value that is recognized in more than one cultural context, and ethical physicians in both East Asian and Western societies are guided by beneficence in their conduct toward their patients.[6] The absence of a principle of autonomy in ancient Chinese medical ethics allows physicians to be more paternalistic than their Western counterparts, but this is culturally acceptable in traditional East Asian societies and not necessarily unethical.

PRINCIPLES OF RESEARCH ETHICS

Medical progress requires the development of new drugs and treatments. Research is necessary to discover how the body works, what illness does to the body, and how the patient responds to treatment. Since it is humans who would be treated, testing has to be done on humans to find out a treatment's effectiveness as well as side effects. The history of medicine is replete with examples of patient well-being and lives being sacrificed for the sake of science. What is clearly reprehensible about these examples is how human beings are treated as objects and used to serve the purpose of the

researcher. Impetus for a code of research ethics for human experimentation came at the end of World War II, during the trial of German scientists who had experimented with a callous disregard for the suffering they inflicted on their human subjects. The Nuremberg Code of 1948 emphasized the centrality of voluntary consent. Its first article states: "The voluntary consent of the human subject is absolutely essential." Such research must be absolutely necessary (Article 2), and all unnecessary suffering and injury must be avoided (Article 4).

The main ethical problem for physicians who conduct experiments on patients is that they are violating the principle of nonmaleficence in deliberately risking harm to the patient, and the principle of beneficence in withholding treatment of patients in a control group. The Declaration of Helsinki, adopted by the World Medical Association in 1964, distinguishes between therapeutic research where subjects of research stand to benefit if the treatment on trial works, and nontherapeutic research where there is no such benefit for the test subject. Therapeutic research derives some moral justification from the principle of beneficence, whereas nontherapeutic research cannot be justified except on the ground that the subject voluntarily and knowingly assumed the risk. Thus, the informed consent requirement is more stringent in the latter case.[7]

Research on humans is now part and parcel of medical science in Western countries. The dual role of physician and researcher clearly changes the physician–patient relationship. Physicians would not have a moral basis for using (or allowing for use) their patients for research without an ethics of informed consent. A physician is justified in limiting the duties of beneficence and nonmaleficence only because patient autonomy is respected.

Medical research has spread beyond Western centers of research for a number of reasons. Scientific expertise is being tapped in non-Western countries. The development of treatments needs to take into account different responses from different test populations. And scientific validity may well depend on a large enough population of test subjects that cannot be found in Western countries alone. All of these factors are applicable to what is perhaps the most important medical research in human history: research in human genetics.

Non-Western countries embarking on medical research are included under the Declaration of Helsinki. They need to observe the requirement of informed consent for experimentation on human subjects. Can this requirement be adopted if individual autonomy is not traditionally valued in these countries? What needs to be done for research to be carried out ethically in East Asian countries where Confucian values still form the basis of traditional ethics and where autonomy is an imported moral concept? Answers to these questions are not yet fully available, but lessons can be learned from the experience of Singapore.

A CASE STUDY

Since the early 1990s, Singapore has embarked on a project of becoming a world biotechnology center. The country was already known for its high standard of health care. As a former British colony, its doctors are trained in Western medicine and its medical specialists are accredited to British professional institutions and colleges. With a well-educated population, the country's universities can be counted on to produce scientific researchers, many of whom undergo postgraduate training in the United States and Britain. In addition, the government built infrastructure and offered tax incentives to attract biotech companies and top scientists from Western countries. Moreover, the National Medical Ethics Committee has served to ensure high ethical standards for Singapore's medical professionals. In the year 2000, the Bioethics Advisory Committee was appointed by the government to propose legal and ethical guidelines for biotechnology research in Singapore, modeled on Western precedents. In its first term, the Committee produced a report after examining issues relating to both stem cell research and research in human genetics.

On January 19, 2003, the people of Singapore were shocked to read a story in their local newspaper regarding a possible breach of ethics in the conduct of a research project that was headed by the director of the National Neuroscience Institute (NNI). The details that came to light after a thorough investigation by an inquiry panel of independent experts are summarized here.[8]

The NNI had been set up in March 1998. Besides patient care services, it has a research arm with facilities for neuroscience research. In December 2000, British Professor Simon Shorvon was appointed director of NNI. Shorvon obtained a grant from the Singapore Biomedical Research Council (BMRC) for a research project he was conducting to identify genes that influenced susceptibility to Parkinson's disease (PD), epilepsy, and tardive dyskinesia, and also genes that influenced responsiveness to drug treatment. The method of research involved collecting blood samples from subjects with the neurological diseases (and from persons without these diseases as a control group), extracting DNA from the blood, and lab analysis of the DNA. In October 2001, Shorvon's Ph.D. student, Dr. Ramachandran, was appointed project manager to work under Shorvon's supervision.

The complaints that surfaced after November 2002 concerned the way in which patients with PD were identified, contacted, and tested. Shorvon needed blood samples from 750 PD patients by July 2003. By July 2002, only twelve volunteers had been recruited through their neurologists. Shorvon and Ramachandran obtained a list of PD patients directly from hospital records and without their neurologists' knowledge. They also devised a procedure to confirm that the patients indeed suffered from PD, a procedure

that involved taking patients off their usual medication for at least twelve hours, observing their movement disorders, and then administering a "standard" dose of L-Dopa to observe their reactions. They had obtained neither approval from ethics committees nor informed consent from the PD patients for the procedure, while the patients' own neurologists were kept in the dark. Moreover, testing was performed in patients' homes or at NNI, without these patients being admitted to a clinical center for proper care and medical attention. Some patients had adverse reactions to the procedure due to omission of their normal medication or due to the administration of a different dose of L-Dopa during the testing.

The inquiry panel appointed by NNI concluded in its report of March 21, 2003, that the research project had been unethical in four areas: breach of confidentiality, lack of ethics committee approval, compromise of patient well-being and safety, and failure to obtain informed consent. It held Shorvon and Ramachandran clearly responsible for ethical misconduct.[9] In describing the procedure used in the project, the panel stated that PD patients had been treated for the purpose of research as "experimental subjects without any rights" (paragraph 73), in a manner "unacceptable in any civilized country" (paragraph 344).

ANALYSIS AND COMMENTARY

The inquiry panel in Singapore had done a superb job in a very short time to gather evidence on the case and document the ethical violations of the research carried out by Shorvon and Ramachandran. In presenting this case study, my purpose is to draw out some cross-cultural issues in research ethics. One possibility is that there is no such issue here: the case is one of a simple failure to follow universal guidelines for experimentation on human subjects. The Declaration of Helsinki had made patient consent obligatory for nontherapeutic research, and also mandated ethics committee approval for all research on human subjects. In Singapore, the National Medical Ethics Committee had also published guidelines that reflect those in the declaration. Shorvon is a British doctor who should have been aware of the ethics of human experimentation.

One issue that does arise in the case is whether the ethical lapses in the research project could have happened in the West. With respect to accessing patient confidential data through hospital records, Professor Burgunder, a coprincipal investigator of the project, told the panel that this would "never have been allowed in Switzerland" (paragraph 105). The list of hospital patients suffering from Parkinson's disease was obtained by Ramachandran from the pharmacies of two hospitals, after he stated that the research study was of "national interest." Furthermore, Shorvon had authorized the appli-

cation for information, falsely giving an assurance that release of confidential patient information had ethics committee approval. The panel mentioned that the application had "obviously carried greater weight because he was Director of NNI" (paragraph 83).

With respect to the failure to obtain informed consent from PD patients who were used as test subjects, patients interviewed by the inquiry panel stated that they were under the mistaken impression that the testing was done with the approval of their treating neurologists (paragraph 266). None of them were aware of the risks associated with the tests performed on them, and none were given explanations as to the nature of the L-Dopa tests. It never occurred to them to question the authority of Ramachandran or the justification for having their medication modified. In fact, they had omitted their medication prior to testing after receiving a phone call request to do so from one of two persons working for Shorvon, neither of whom were qualified medical professionals.[10]

Both the violation of patient confidentiality and the failure to obtain informed consent reflect a breach of the principle of respect for autonomy. Shorvon had knowingly neglected his duty to patients and had acted unethically. But what made it easier for him to engage in ethical misconduct was the failure of a number of people to protect the autonomy of patients. Those in the hospitals who were impressed by Shorvon's status as director of NNI failed to protect confidential patient information. Those who worked for Shorvon failed to raise critical questions.[11] Most surprising of all was the failure of the patients or their family members to ask what the tests were about and whether there were risks to the patients. Yet the mere assumption that their own neurologists knew about the tests should not render informed consent unnecessary.

It is entirely possible that these failures to protect patient autonomy are due to the fact that the concept of individual autonomy is absent from East Asian values in general, and from ancient Chinese medical ethics in particular. Even though health care and the medical profession in Singapore have a Western orientation, it does not seem that the imported value of individual autonomy has been fully integrated into the nation's medical professionals' and patients' practices and attitudes.[12] Another aspect of Confucian ethics is respect for those in authority and for those with high educational qualifications. Thus, patients did not find it necessary to ask questions about what was being done to them. Those under Shorvon did not question his authority.

As described above, ancient Chinese medical ethics is beneficence-oriented. Physicians are expected to place patient well-being over the physician's own interests. Humaneness is a virtue that characterizes the life of every person who exemplifies Confucian ideals. Traditionally, education in China included training in Confucian ethics, and appointment to important posts was based on success in examinations. There was an assumed link between

virtue and position. So another reason that the actions of those in authority are not questioned is the belief that such persons are motivated by benevolence. In Shorvon's case, this assumption proved to be completely mistaken.

In ethical lapses of enormous gravity, he and Ramachandran used a procedure that varied PD patients' medication in ways that endangered their well-being and safety. The inquiry panel described their "callous disregard for the PD Subjects' welfare" (paragraph 200). PD patients were instructed to omit their medication even though the resultant movement disabilities would cause them discomfort and make it difficult for them to get out of bed. Some of them were asked to travel to NNI even though they risked falling down. Omission of medication could bring about high fever, kidney failure, hyperthermia, and intense spasms. The increased dosage some patients were given during the testing could cause their tongues or limbs to become twisted. One patient (identified by patient folder number as PD10) experienced a fall in blood pressure from 140/100 to 100/70 within fifteen to twenty minutes of receiving a test dose that was four times his usual dosage (paragraph 202). Another patient (identified as PD 196) "suffered dyskinesia in both lower limbs, dystonia in his left hand and a marked systolic blood pressure fall of 50" (paragraph 202). The panel found that no assessment was made as to whether the test subjects could skip medication or travel to NNI, and no provision was made to admit subjects into clinics, leaving them at home without medical attention while they skipped their medication.

Such utter disregard for the test subjects' well-being and safety is a violation of ethical principles in both Western bioethics and ancient Chinese medical ethics. In the West, however, a failure to fulfill the duty of beneficence (or nonmaleficence) may not be quite so damaging because physicians are expected to respect patient autonomy by obtaining informed consent. The absence of a duty to respect patient choice in traditional medical ethics in East Asia leaves open the possibility that patients, who do not expect to be asked for informed consent, can be harmed by physicians who take advantage of their authority. Physicians such as Shorvon who come from Western countries may be tempted to do things that they would not do back home.[13] Where research, especially the nontherapeutic kind, is concerned, failure to ensure that test subjects are volunteers leaves them vulnerable to risks that are taken only to serve the interest of researchers. It seems clear that ancient Chinese medical ethics is not quite equipped to guide ethical research.

CHALLENGES AND ALTERNATIVE VIEWS

There are two ways in which my analysis of the Shorvon case may be challenged. First, it may be said that there is no ethical system that can guarantee that physicians act ethically. Shorvon and Ramachandran acted unethi-

cally because they were willing to disregard ethical rules. If they had been concerned about their test subjects' well-being, as required by the traditional ethical standards of East Asia, they would not have exposed them to danger, and would not even have accessed their records without the patients' own neurologists' knowledge. Adding a principle of respect for patient autonomy to ancient Chinese medical ethics would not alter the unethical conduct of researchers who do not care about ethical rules that require informed consent from their subjects.

But my point in discussing the Shorvon case specifically concerns research ethics. It is in the nature of research that the benefits accrue to others and not just, if at all, to the patient. It is also part and parcel of research that test subjects have to bear risks of harm, the existence of which the researchers aim to discover. Thus, physicians who are guided only by beneficence and nonmaleficence toward their patients cannot possibly find it ethical to use them as test subjects. The only ethical justification for conducting research on patients is the fact that the patients have voluntarily agreed to participate in the research with full knowledge of the procedures and the dangers. In the absence of informed consent, research on human subjects cannot be ethical. Of course, Shorvon and Ramachandran are unethical by the standard of ancient Chinese medical ethics. But relying on that standard, no research on humans could be ethical. It is by appeal to the principle of respect for autonomy that the difference between ethical research and the kind of research carried out by Shorvon and Ramachandran can be articulated.

A second challenge to my analysis comes from those with the view that the ethics of the Shorvon case can be interpreted entirely in terms of Western medical ethics. The problem is not that the concept of patient autonomy has not been fully absorbed into the culture, but that there are different ideas about what informed consent means in Shorvon's research. Disputes about what counts as informed consent have often given rise to ethical problems in Western countries.[14] If this interpretation is right, then no cross-cultural issue is raised by this case.

Shorvon had attempted to defend himself before the inquiry panel by suggesting that the form used to obtain consent from PD subjects, which had been submitted for ethics committee approval, covered the procedure of L-Dopa testing, since it included the line: "You will also be asked for information on yourself and your condition" (paragraph 275). The panel was swift and devastating in demolishing this explanation: "No one can seriously suggest that the phrase 'information on yourself and your condition' covered the L-Dopa responsiveness testing, which involved omitting and varying medication." It is important to note that the PD subjects did not assume that they were consenting to something else, but that they had cooperated with the testing without having signed any consent form. None of them asserted a right to an explanation of the test procedure, purpose, and risks, nor were

they initially aware that they were participating in research as test subjects.[15] Thus, different ideas about what constituted informed consent were not the issue here. Rather, it was the absence of any expectation on the part of PD subjects that the physician is duty-bound to obtain informed consent from his or her patient or subject before proceeding with treatment or research.

LESSONS TO BE LEARNED

The universality of American bioethics has been challenged by cultural pluralists, who perceive that "bioethics is dominated by the West and by the Western ethos of liberal individualism."[16] Ancient Chinese medical ethics provides an alternative model of the doctor–patient relationship that is beneficence-oriented. But this model does not seem suitable for an ethics of research. In research, physicians have to restrict the application of principles of beneficence and nonmaleficence toward their patients. The difference between ethical and unethical research is whether human test subjects have given informed consent. The principle of respect for patient autonomy may well have valid application across cultures wherever research is done.

The case study discussed here entitles us to say something stronger. In moving into biotechnological research, Singapore has also recognized informed consent as an essential ethical requirement. This did not prevent the unethical research that Shorvon engaged in. It is true that no set of ethical principles can prevent abuse by unethical individuals who disregard them. But those who worked with Shorvon and in the hospitals, and the patients themselves, did not value patient autonomy sufficiently. These parties did not expect patients to have a right to informed consent. To change this, it is not enough to use informed consent for safeguarding against unethical research. Respect for patient autonomy must become part of the entire culture of medicine in the country. For any country that joins the global enterprise of medical research, respect for autonomy becomes a universal ethical principle not only in research but in the practice of medicine in general.

NOTES

1. Tom L. Beauchamp and James F. Childress, *Principles of Biomedical Ethics*, 5th ed. (New York: Oxford University Press, 2001). This has been a highly influential textbook in which the four-principle approach to biomedical ethics is articulated.

2. Tao Lee, "Medical Ethics in Ancient China," in *Cross Cultural Perspectives in Medical Ethics: Readings*, ed. Robert M. Veatch (Boston: Jones & Bartlett, 1989); Daniel Fu-Chang Tsai, "Ancient Chinese Medical Ethics and the Four Principles of Biomedical Ethics," *Journal of Medical Ethics* 25 (1999): 315–321.

3. According to Tao Lee, "Medical Ethics in Ancient China," the complete maxim has been used as a motto in the baccalaureate service of the Peiping Union Medical College since 1939.

4. Tsai, 316–317.

5. Tsai, 320.

6. I take beneficence here to include nonmaleficence, since looking after the patient's well-being includes both benefiting them and not harming them.

7. The Declaration of Helsinki allows proxy consent on behalf of legally incompetent patients for the purpose of therapeutic research only.

8. The report of the Inquiry Panel has been published on the website of the National Neuroscience Institute, which can be found at www.nni.com.sg.

9. Ramachandran fled Singapore just as the ethical issues became public knowledge and refused to cooperate with the inquiry panel. The panel criticized Shorvon for changing his story during the inquiry, but he subsequently accepted the panel's report in a letter dated March 31, 2003.

10. Of the two persons, one had no medical qualifications and the other was a nurse. Both were employed for clerical and administrative work. In addition, a man who assisted Ramachandran in his testing of patients had previously worked as a security guard and had no prior experience in the medical profession.

11. Professor Burgunder claimed in his testimony before the panel that he was uncomfortable with the procedures and against accessing patient confidential information and bypassing the patients' own neurologists. But he did not bring his concerns to the attention of authorities. The panel felt that he had a share of responsibility for the ethical lapses of the project.

12. My claim here is supported by some of the data from a study that I collaborated on, and that has been published in D. Chan and L.G. Goh, "The Doctor–Patient Relationship: A Survey of Attitudes and Practices of Doctors in Singapore," *Bioethics* 14 (2000): 58–76.

13. When asked during the inquiry about his failure to obtain approval from the relevant ethics committees for accessing confidential medical records and testing patients by varying their L-Dopa medication, Shorvon claimed that his approach to obtaining ethics approval was "perfectly okay" by U.K. ethical standards. The panel however found this difficult to accept, as the Helsinki Declaration is a universal standard for research ethics (paragraph 176).

14. For instance, can a patient who is emotionally upset provide informed consent? And what is the status of unwritten wishes regarding the withholding of life-saving treatment?

15. They were only asked to sign a consent form (approved by an ethics committee) for the extraction of blood after the L-Dopa test procedure had been carried out (paragraph 67).

16. Segun Gbadegesin, "Bioethics and Cultural Diversity," in *A Companion to Bioethics*, ed. Helga Kuhse and Peter Singer (Oxford: Blackwell, 1998), 25.