Soc. Sci. Med. Vol. 35, No. 9, pp. 1079–1091, 1992
Printed in Great Britain.

0277-9536/92 $5.00 + 0.00

ETHICS ARE LOCAL: ENGAGING CROSS-CULTURAL VARIATION IN THE ETHICS FOR CLINICAL RESEARCH

NICHOLAS A. CHRISTAKIS*

Robert Wood Johnson Clinical Scholar, Department of Sociology, Section of General Internal Medicine, Leonard Davis Institute of Health Economics, University of Pennsylvania, Philadelphia, PA 19104, U.S.A.

Abstract—Relatively little consideration has heretofore been given to the interaction between Western clinical research ethics and non-Western ethical expectations. How should any conflict that might arise when a biomedical investigator and a research subject come from different cultural settings and have different ethical expectations be addressed? Which ethics should govern such trans-cultural clinical research? The answers to these questions are of increasing importance because many countries of the developing world are presently sites of field testing of biomedical agents sponsored and administered by countries of the developed world, especially in the context of the AIDS pandemic. Drawing mainly on examples from Asian medical systems and settings, I elucidate four possible ethical models to guide the conduct of transcultural biomedical research. Two assume that research ethics are culturally relative and two assume that a unified, universalistic conceptualization of research ethics is possible. All four, however, are problematic and are to a large extent deficient. The cause of the deficiencies of these models lies, I argue, in the way that ethics are ordinarily conceived. The proper approach to ethical conflict recognizes that culture shapes (1) the content of ethical precepts, (2) the form of ethical precepts, and (3) the way ethical conflict is handled. Medical ethics may be viewed in cross-cultural perspective as a form of 'local knowledge', and any differences in such knowledge between cultures—since such differences will not conveniently disappear—must be engaged and negotiated.

Key words—medical ethics, cross-cultural comparison, Asia, clinical research, AIDS

INTRODUCTION

Despite the cultural specificity of Western medicine—product that it is of a particular cultural tradition—it has been extraordinarily widely diffused throughout the world. In non-Western settings, Western biomedicine typically comes to form one part of a heterogeneous collection of medical systems and competes for patients with the others [1]. Usually, Western, 'cosmopolitan', medicine itself undergoes a transformation under the influence of local culture, making it profoundly indigenous and Western at the same time [2]. Much has been written about the interaction of values, norms, and expectations when cosmopolitan medicine comes to be practiced in non-Western settings, often in conflict or in parallel with other medical systems. There has been very little consideration, however, of the interaction of the exogenous Western tradition of medical research with indigenous medical practice and local culture. More particularly, there has been almost no study of the local impact and local perception of the guiding *ethics* of Western medical research in non-Western settings. Yet, as with the transposition of medical systems themselves, attempts to transpose systems of clinical research ethics will likely be only partially successful.

*Address for correspondence: 338 Fitzwater Street, Philadelphia, PA 19147, U.S.A.

By 'biomedical research' I mean critical and exhaustive investigation that has at least two aims: (1) the discovery of new facts about the human body through systematic observation or experimentation, and (2) the correct interpretation of these facts and the testing of new hypotheses about health and disease. Here, I shall only be concerned with research that involves living human beings, that is, *clinical* biomedical research. Clinical research includes trials of new pharmaceutical agents or surgical techniques, epidemiological research, systematic collection of clinical observations, study of normal and abnormal processes in living humans, and related activities.

A fundamentally rational and experimental science, modern Western medicine holds research in very high esteem and bases its power upon it. Indeed, in the wake of the therapeutic nihilism of the early 19th century, Western medicine has come to be founded in a very essential way upon research on human beings. This basis of Western medicine upon research stands in contradistinction to certain non-Western medical traditions whose foundation is principally textual or traditional. For example, the literate Asian medical traditions (Ayurveda and Traditional Chinese Medicine) look backwards to their basic texts for knowledge, whereas Western medicine looks forward, through research, for knowledge [3]. While 'traditional' thought has been characterized as trying to annul the passage of time, 'scientific' thought often

seems to be frantically trying to hurry it up by devising artificial situations, experiments, that would otherwise take a long time to take place naturally [4]. The epistemology of Western as compared with these non-Western contemporary medical systems is often fundamentally different.

In the conduct of clinical research, ethical rules specify how research scientists ought to behave towards their research subjects [5]. Ethical rules govern the proper, moral, and desirable conduct of an individual or a profession; they have prescriptive, explicative, protective, and creative functions. Ethical rules are generally based upon profound religious and philosophical beliefs held by a given people, and, thus, the ethics regarding research with human subjects might, *a priori*, be expected to vary cross-culturally. Conflicts over research ethics may be expected to exacerbate the traditional conflicts that arise when the Western medical tradition is transposed into a non-Western cultural setting. Clinical research ethics might therefore provide an arena for 'medico-cultural conflict' [6].

Conflict is especially likely to emerge in situations where there is direct contact between potentially different ethical systems, as in the conduct of transcultural biomedical research, where the researcher and subject come from different cultural backgrounds (usually Western and non-Western respectively). The psychiatrist and anthropologist Arthur Kleinman has argued:

> Clinical investigations in developing societies must be understood as taking place within the particular contexts of practical, everyday beliefs, values, and power relationships that constitute local cultural systems and [must be understood] as creating potential conflicts between these non-Western systems and the Western cultural conceptions and norms that are a usually unrecognized part of clinical research projects and the expectations and behaviors of clinical researchers .... Clinical investigations [result in problems] because of different and often conflicting cultural constructions of what clinical research is, how it is conducted, and what is to be gained from it [7].

An incomplete fit between the ethical expectations of researchers and subjects raises an important question: Is it possible to formulate ethical rules governing the conduct of investigators from one cultural background performing research on subjects from another? At the heart of this question is the problem of ethical universality vs relativity—the belief that the ethical principles governing the conduct of research are the same wherever research is conducted versus the contention that, since ethics are socially constructed, they will vary according to the cultural setting in which they are formulated. Because it brings investigator and subject together across a cultural boundary in a real-life situation, the conduct of transcultural clinical research will raise important practical issues for the theoretical tension between universalistic and relativistic perceptions of research ethics.

Peter Kunstadter, of the University of Hawaii, has remarked that

> Although the issue of 'universalistic' vs 'relativistic' nature of medical ethics has been raised, the range of relative differences which has generally been considered is extremely narrow. Medical ethics today are almost exclusively Western (Judeo-Christian), and based largely on the technocratic culture of the practitioners, not the patients .... Most studies of medical ethics have been made in Western societies within the context of orthodox Western medicine and have assumed rather than [examined] the underlying basis of ethical or moral choices [8].

Given that biomedical research itself is characteristically Western, the paucity of studies of non-Western clinical research ethics, though troubling, is not surprising. The lack of serious consideration of cross-cultural clinical ethics is unfortunate, however, because of the pivotal position of ethics in mediating between the technical and socio-cultural aspects of healing. If biomedical research is seen as the figurative endpoint in a progressive dehumanization of medical practice, a point where human beings are treated as means and not as ends, then one of the major functions of research ethics is to countervail this tendency.

The lack of consideration of cross-cultural medical ethics is also unfortunate given three current trends in the practice of Western medicine: (1) the worldwide salience of Western medicine and its ever increasing spread into non-Western settings, (2) the increasing movement of Western medical investigators across cultural boundaries, and (3) the increasing application of Western research methodologies (by both Western and non-Western physicians) to medical problems in the developing world. These trends all bring Western investigators into greater contact with non-Western research subjects and highlight the importance of a cross-cultural perspective on clinical research ethics.

These trends are especially manifest in the confrontation of the AIDS pandemic. This pandemic has called into question a universalistic conceptualization of clinical research ethics based on a Western model because, here, the same dangerous disease (and research upon it) occurs throughout the world in disparate socio-cultural settings; it invariably raises ethical questions, but does not invariably yield the same answers [9]. AIDS research of various kinds by Western investigators in non-Western settings, such as epidemiological studies, vaccine trials, and drug trials have all raised difficult problems for research ethics. The importance of sensitivity to local culture in general and local ethics in particular has been brought to the fore, and the necessity of local community involvement has been stressed by many AIDS researchers. Difficulties have arisen in satisfying conflicting ethical expectations.

For example, Michele Barry, a physician at Yale University, described a situation wherein the ethical expectations of the investigators' and subjects'

cultures clashed in a Tanzanian research project. The project was a seroprevalence study that involved sampling maternal and infant blood upon birth and testing for HIV antibodies. Her home Institutional Review Board, in accord with traditional Western research ethics and as part of its approval, had required that subjects give informed consent to participate and that subjects be informed of their test results. Tanzanian authorities, however, had a conflicting set of requirements: worried that the results could cause counterproductive alarm among the subjects, and cognizant of the fact that no meaningful care was available for HIV-positive individuals in Tanzania, they insisted that the Western researchers not tell their subjects that their blood was being tested nor what the outcomes of the tests were. The study was abandoned because of this conflict [10].

Problems have arisen as well with placebo usage, which has heretofore been regarded as a settled matter within Western research ethics. Certain research protocols that are unacceptable in the West may be seen as acceptable in non-Western countries. For example, a Brazilian investigator recently proposed comparing the drug dideoxycytidine with placebo in order to assess the efficacy of this drug in prolonging survival in HIV-infected patients; an additional goal of the trial was to determine if an investment by the Brazilian government in this drug would be worthwhile. The study raises two major problems when seen from the perspective of orthodox Western research ethics: Is it ethical to conduct a placebo-controlled trial when efficacious therapy for HIV infection (namely, AZT) exists? And, is it ethical to design a clinical study to answer an economic question? [11]. From a Brazilian perspective, the answer to these questions is affirmative.

Thus, the basic problem that confronts us is: which ethics should govern transcultural clinical research? By 'transcultural' I mean generally the situation that arises when the investigator and the subjects in biomedical research come from different cultural settings. But more particularly, I mean the relatively frequent situation in which the investigator is Western and the subject is non-Western.

I wish to consider four possible practical solutions to the problem of which ethics should govern transcultural biomedical research. Two assume that research ethics are culturally relative and two assume that a unified, universalistic conceptualization of research ethics is possible. All four, I will argue, are to a greater or lesser extent unsatisfactory, largely because of the way that the question itself is configured. This fact militates for a fundamental shift in the way the problem of cross-cultural ethical differences is approached.

NO TRANSCULTURAL BIOMEDICAL RESEARCH

One solution to the problem of which ethics should govern clinical investigation when researchers from one culture use subjects from another is simply to avoid (or prohibit) such research. This essentially specious solution eliminates the discrepancy between the ethical expectations of different cultures by eliminating the contact between cultures.

There are two fundamental problems with this model. The first one arises from the worldwide ascendancy of Western biomedicine, accepted, as it is, as the official medicine in most countries. Since clinical research itself is generally conducted by physicians who practice Western medicine, the ethics that come to govern such research are largely those of Western biomedicine. This is exacerbated by the fact that physicians in the developing world often identify more with the culture of cosmopolitan medicine than with their own. For example, according to Dr V. Ramalingaswami, formerly Director of the All India Institute of Medical Sciences, "physicians in developing countries become estranged from their own people in the course of their training" [12]. Much more so than in the West, physicians in the developing world form part of a social elite, and this fact, coupled with the frequent use of English in training, compounds the cultural distance between doctor and patient, between investigator and subject [13]. The system of medical training in much of the developing world is such as to foster identification with Western norms and expectations regarding such things as specialty choice, language of instruction, patient care, career advancement, and, in all likelihood, research ethics.

Thus, allowing the research ethics of the investigators to prevail in a particular cultural setting will not necessarily solve the problem of appropriate ethics because, arguably, the subject and the investigator will still come from different cultures. The ethics guiding the conduct of clinical research will thus not truly be *local* in the sense that they are not indigenous to the research subjects.

The second problem with this model, as with the next model discussed below, is that—as an essentially relativistic ethical model—it does not *evaluate* the ethical systems involved. May the members of a given society adhere to a system of clinical research ethics that, by some other standard, is inappropriate?

TRANSCULTURAL RESEARCH SHOULD SATISFY BOTH ETHICAL SYSTEMS

An alternative model is to require transcultural research independently to meet the ethical requirements of the two cultures involved (that is, the culture of the investigator and of the subject). This would entail a commendable respect for the beliefs of the subjects' culture. In addition, it would ordinarily involve adopting a relativistic position towards ethics: no assessment of the ethical systems is made: all are considered to be inherently satisfactory.

The basis for such relativistic thinking about ethics is the contention that nothing is inherently right or wrong, that no moral principles are inherently

legitimate. Such thinking supposes that actions are defined as right or wrong by given peoples in specific cultural contexts at specific times and that behavior is culturally relative. As a result, ethical relativity contends that value judgments should be forsworn in assessing foreign systems of belief. Moreover, ethical relativity contends that the impossibility of objectively determining moral action obliges *tolerance* towards other cultures.

Several practical problems are raised by this position. If research is designed so that it independently meets the ethical expectations of both the subjects and the investigators, then the research, in this model, is perforce ethical and permissible. Yet, it is possible to imagine that research meeting the ethical criteria of both the investigator and the subjects might, under some third standard, be considered unethical. Does this mean that all clinical research projects should meet all possible ethical standards for research, or only the two standards of the involved researchers and subjects? Moreover, this model provides no guidance for resolving conflicting ethical expectations: if neither system is superior and the two conflict, to which one should there be recourse? If the resolution of the conflict is in favor of the subject and is antithetical to the investigator, is the investigator relieved of his ethical duty? Can the research then proceed? If no resolution between conflicting ethics is possible, what is to be done if both societies perceive the research to be essential? Or, if no resolution between conflicting ethics is possible—and the research is therefore impermissible—may the investigators conduct it elsewhere? Finally, to meet the ethical prescription of this model requires a knowledge of local ethical expectations. Who should decide when 'all' ethical expectations have been met? A paternalistic feeling on the part of the investigator that the ethical expectations of the subjects have been met would presumably not be enough.

Aside from the foregoing practical problems with this solution, there is a significant theoretical problem as well. The notion of tolerance, to which ethical relativism is linked, is subject to criticism. Ethical relativism is *not* value-free, for a value judgment is contained in its call for tolerance: it asserts that we *ought* to respect other value systems. The problem here is that the evidence regarding cross-cultural variation in basic moral beliefs does not in itself justify tolerance. Though on liberal, humanistic grounds tolerance has some appeal, critics of relativistic thinking, such as Elvin Hatch, have pointed out that tolerance should not be extended beyond its limits [14]. At what point should tolerance stop? Noting that ethical guidelines for judging across cultural boundaries are insufficiently refined, Hatch proposes a 'humanistic principle' to address ethical standards cross-culturally. This principle includes two basic assertions: (1) people ought to enjoy a reasonable level of material existence, and (2) human suffering is bad. If these criteria are met, however, other moral principles or other (non-moral) portions of a people's cultural inventory should not be morally evaluated and should be tolerated. Unfortunately, these alone are insufficient guidelines for clinical research. Indeed, if these were the only standards to evaluate the ethics of clinical research, much that is now considered unethical by present standards (at least Western ones) would be deemed ethical.

ETHICS GOVERNING MEDICAL RESEARCH SHOULD BE ABSTRACTED CROSS-CULTURALLY

Thus, a theoretically developed, fundamental, universal principle to guide research could be the humanistic standard. An alternative, empirically based approach would be to examine systems of medical ethics cross-culturally in an effort to identify universal principles. In this manner, an absolutist system of ethics could presumably be developed around the observed common themes. As examples, let us consider the literate Asian medical traditions of Ayurveda and Traditional Chinese Medicine, both of which contain a significant number of explicit ethical rules. Both of these traditions are more ancient than the Hippocratic tradition and they together are used by nearly two billion people. The general goal of this model of ethics to govern transcultural biomedical research would be to develop a universal standard through cross-cultural analysis of disparate systems of medical ethics.

Ayurveda

Ayurveda has a quite elaborate set of rules of right conduct [15]. The rules delineate actions for the physician that are proper—medically, personally, and professionally—but not moral *per se*. That is, the ethical precepts of Ayurveda are principally about such mundane matters as student selection, medical practice, and professional demeanor. The ethical principles outlined below are abstracted from the Ayurvedic texts and not from modern clinical transactions. Though there is considerable reason to believe that there would be a difference between theory and practice, the texts nevertheless spell out what are considered ideals by contemporary practitioners [16]. Of the major texts of Ayurveda, two, the *Caraka Samhita* and the *Sushruta Samhita*, form the sources for the material that follows [17].

Many Ayurvedic ethical precepts concern who would make a good physician: detailed requirements of initiates (including such things as physical appearance and dress) and specific rites of initiation are prescribed. One section of the *Sushruta Samhita* notes, for example:

> A physician, who is well versed in the science of medicine and has attended to the demonstrations of surgery and medicine, and who himself practices in the healing art, and is clean, courageous, light-handed, fully equipped with supplies of medicine, surgical instruments and appliances,

and who is intelligent, well-read, and is a man of ready resources, and one [who] commands a decent practice, and is further endowed with all moral virtues, is alone fit to be called a physician [18].

The stress on technical proficiency and expertise in the definition of good physicians is not surprising, especially in view of the harmful potential of medical practice that is recognized in the Ayurvedic texts. The texts betray considerable concern regarding the practice of medicine by the untutored or by quacks, and they seek to provide guidelines to avoid problems. *The Sushruta Samhita* states that

[A] physician, experienced in his art but deficient in the knowledge of Ayurveda, is condemned by all good men as a quack, and deserves capital punishment at the hands of the king .... A physician, ignorant of the science and art of surgery and emollient measures Sneha-karma, etc. is but a killer of men out of cupidity, and ... is allowed to carry on his nefarious trade only through the inadvertence of the king [19].

Physicians are therefore instructed to read the texts and to practice their techniques—but not on human beings; rather, the texts specify that physicians are to practice on vegetables, dead animals, and dolls.

Though there is no mention of practice, as such, on human beings, there is, nevertheless, an emphasis on learning from clinical experience: "The wise doctor should not adhere exclusively to what is written in the books, but use his own discretion and reasoning" [20]. But while Ayurvedic medicine is significantly experiential, it is not quite experimental. This observation is important in addressing the issue of whether a research tradition—or something akin to it—exists in Ayurveda and whether, therefore, some portion of the texts might reasonably be expected to address the ethical conduct of this activity. Debiprasad Chattopadhyaya, an Indian philosopher, has argued that Ayurvedic medicine, during its inception, fought hard for the status of a science. Part of this effort was to "raise mere empirical knowledge to the status of scientific principles. The technical word they use for this intellectual discipline is *yukti*. It is a key concept of Indian medicine and it roughly means rational application. Among other things, what it requires is the knowledge of how a number of causes combine to produce an effect" [21]. The texts assert that "rational application [*yukti*] is the ultimate foundation of [therapeutic] success. A physician accomplished in rational application is always superior to one with the mere empirical knowledge of the substances" [22]. But rational application was nevertheless limited to the observation of Nature, not intervention and manipulation in the way required by experimentation. Despite an emphasis on observation and experience, there is, in fact, no tradition of research as such in Ayurveda [23].

In treating patients, Ayurvedic physicians have a number of further ethically relevant injunctions to heed. The Ayurvedic texts stress that careful observation is essential to proper treatment and that treatment is bound to fail if the diagnosis is wrong. Physicians are encouraged to discriminate manageable from unmanageable cases in order to avoid assuming responsibility for terminal patients. And the texts stipulate that no harmful therapy should be adopted and that treatment should be administered 'until the last breath.'

In addition, there is an ethical tradition of deception in the Ayurvedic texts, of which there are several examples. In the care of the dying, the texts state: "Even after having noticed the signs of impending death, the doctor should not tell that to the patient; instead, constant reassurance should be given" [24]. A further example of deception is that of deliberately misleading patients regarding the nature of the food being given to them (since the prescription of animal meats would likely provoke disgust and noncompliance in Hindu patients) [25]. These examples indicate that the model doctor is sometimes supposed to assume a paternalistic posture with respect to the patient and occasionally lie.

Traditional Chinese medicine

As in the Ayurvedic texts, the Chinese medical texts that deal with ethics are principally concerned with the proper behavior of a professional physician [26]. In *Medical Ethics in Imperial China*, Paul Unschuld, a scholar of Chinese medicine, translates and compiles every statement regarding medical ethics in the Chinese medical texts dating from the seventh to the nineteenth centuries A.D. [27]. These medical texts still constitute an important source for the practitioners of traditional Chinese medicine but, as with Ayurveda, there is surely a discrepancy between textual ethics and clinical practice. However, once again, the texts articulate what contemporary practitioners acknowledge to be ideal and will form the basis for the description that follows.

A number of ethical themes may be identified in the Chinese texts. Most of the ethical material is directed at developing the status of physicians as elite professionals. The effort to develop professional status involved ethical precepts that encouraged physicians to avoid criticism of colleagues and to forswear undue monetary or sexual rewards for services rendered. For example, the scholar Chang Kao (fl. A.D. 1210) in a collection of anecdotes entitled 'Retribution for Medical Services', describes several cases where greed is punished and refusal of money or sexual favors is rewarded. Hsü Yen-tso (fl. A.D. 1895), in his critique of the medical profession, 'Admonitions with Regard to Physicians and Drugs', remarks that "The intentions of physicians are twofold. One consists in preserving human life, the other consists in making a profit. Should we not be cautious in view of these contrary tendencies?" [27, p. 110].

As part of the efforts towards professionalization, the texts articulate a differentiation of enlightened physicians' ('*ming-i*') from 'common physicians'

('*yung-i*'). Kung Hsin (A.D. 1600) in his 'Warning Words to Enlightened Physicians' observes:

> The enlightened physicians of today cultivate humaneness and righteousness in their attitude. Their study is extensive and embraces all of the writings in their entirety. For this reason they are well versed in theoretical medicine and its practical use. They know *yin* and *yang*, and understand the macroscopic phases [*yün*] and the types of climate [*ch'i*] . . . . They ponder over the best procedures, are [flexible] in their treatments and do not cling mechanically to any formulas. . . . Enlightened physicians who act in this way will be remembered for their virtue in all eternity [27, p. 69].

Sun Szu-miao (A.D. 581?–682), the first Chinese author to have directly treated questions of medical ethics, also spends a significant portion of his important treatise 'On the Absolute Sincerity of Great Physicians' on issues of the truly professional practice of medicine. For example, he states:

> [A] great physician [*ta-i*] should possess a clear mind, in order to look at himself; he should make a dignified appearance; neither luminous nor somber. It is his duty to reduce diseases and to diagnose sufferings and for this purpose to examine carefully the external indications and the symptoms appearing in the pulse [of the patient]. He has to include thereby all the details and should not overlook anything. In the decision over the subsequent treatment with acupuncture or with medicaments nothing should occur that is contrary to regulations [27, p. 31].

This need for careful attention and thought is similar to the emphasis on observation and careful diagnosis seen in the Ayurvedic texts. As in the Ayurvedic texts, the dangerous potential of medical practice is recognized in the Chinese texts.

An important ethical theme that is developed in the Chinese medical texts is that of 'humaneness' (*jen-shu*), a trait felt to be inherent in a professional physician. Lu Chih (A.D. 754–805) describes humaneness thus:

> The sentiments of the physicians are focused on living men; hence it is said: 'Medicine is practised humaneness'. When someone suffers from a disease and seeks a cure, this is no less important than if someone facing death by fire or by drowning calls for help. Physicians are advised to practice humaneness and compassion. Without dwelling on [externals such as] tresses and a cap that fits, they have to hasten to the relief of him who asks for it. This is the proper thing to do. Otherwise accidents such as burning or drowning take place. How could a man who is guided by humaneness calmly tolerate such a happening? [27, p. 35].

Humaneness is also interpreted as compassion by Sun Szu-miao:

> Whoever suffers from abominable things, such as ulcers or diarrhea, will be looked upon with contempt by people. Yet even in such cases, this is my view, an attitude of compassion, of sympathy, and of care should develop; by no means should there arise an attitude of rejection [in regard to the afflicted person] [27, p. 31].

In sum, humaneness encompasses the notions of beneficence towards the ill and the duty to treat those in need. It is an obligation to do good to sick people. And it involves the injunction to treat others as one would oneself. Chang Kao noted that "Physicians should remember: When another person is ill, it is as though I myself [am ill]" [27, p. 52]. This formulation of humaneness within medicine is reflective of the more general Chinese idea of ethics as based upon a paradigm of goodness resulting not from a system of prescriptive and proscriptive rules, but rather from the behavior of good individuals. A *ming-i*, in other words, would perforce conduct himself ethically.

Problems with this model

Hence, in this model of ethics to govern trans-cultural biomedical research, the ethics of Ayurveda and Traditional Chinese Medicine, along with other systems of medical ethics from throughout the world —such as the Western ones discussed below—would be studied in an effort to develop a universal, cross-cultural standard based on common concerns. A significant problem arises, however, with this familiar cross-cultural approach of looking for universals. Both research and research ethics are singularly Western. Largely because the very notion of clinical research on human subjects is rare, if not absent, in other medical systems, systems of biomedical research ethics *as such* do not exist in any medical system other than Western biomedicine. The systems of medical ethics found in the literate Asian medical traditions, for example, are, as we have seen, largely professional ethics that include precepts regarding respect for the texts, loyalty to the profession, and commitment to the craft. Where they treat demeanor towards patients, they are largely motivated by a desire to enhance professional credibility. Do the essentially professional ethics of Ayurveda and traditional Chinese medicine permit extension to the case of subjects of research? Can an absolutist conceptualization of biomedical research ethics, based on more general medical ethics, be formulated?

Some aspects of these professional ethics truly *are* relevant to the conduct of human research. The Asian texts generally recognize a special responsibility or duty that physicians have with respect to the sick. The texts recognize that, in addition to a commitment to the discipline of medicine, doctors must be committed to their patients. When the commitment to patients conflicts with the commitment to the texts or to the profession, the resolution is generally, but not always, in favor of the patient. The texts recognize the inherent conflicts sometimes seen in medical practice, between devotion to the profession and desire to help a patient or between a desire for profit and a concern for therapy. Perhaps in response to such conflicts, or perhaps in order to enhance professional status, all the texts articulate that doctors should be 'good' or 'moral' in some culturally specific way; the texts state that physicians should be held to higher standard than the rest of society. These concepts could provide a basis for the development of a special code of ethics when the patient happens also to be a research subject; towards such an individual, it could be argued, special commitment must exist. Indeed, the injunction

to put oneself in the patient's place would be especially applicable in the case of research.

Beyond this articulation of the special status of physicians because of their special responsibility, the two literate Asian systems of medical ethics tend to articulate a principle of humaneness or beneficence. Akin to the humanistic principle that suffering is bad, this basic principle may also provide a foundation for research ethics. Moreover, the texts recognize the potential for harm inherent in medical practice. They betray a concern for the well-being of the patient often to the point of articulating a paternal posture for the physician.

Aside from the two foregoing themes, however, a cross-cultural analysis is *unlikely* to yield many constant precepts. Indeed, quite a few of the ethical expectations in the literate Asian traditions would be difficult to reconcile with the conduct of modern biomedical research. Comparison of alternative forms of therapy, use of risky invasive procedures, informed consent without deception, use of placebos, tolerance of some risk to the subject for a greater good of society: all these might be differently construed in different ethical traditions. Indeed, the words for, and meanings of, these concepts may be expected to vary significantly across cultures.

In sum, this model of ethics to govern transcultural clinical research—that of abstracting a universal system of ethics from cross-cultural analysis—is imperfect on two accounts: (1) the lack of a research tradition in non-Western systems of medicine results in a lack of explicit research ethics, and (2) the concerns raised in systems of professional ethics, though sometimes germane to patient care and research subjects, are not always relevant to the issues raised in the conduct of modern clinical research.

WESTERN RESEARCH ETHICS SHOULD APPLY UNIVERSALLY

Since non-Western medical systems lack an experimental tradition involving the use of human subjects, should we not therefore use a Western conceptualization of research ethics in conducting transcultural clinical research, a conceptualization which, after all, has been developed to contend with the Western tradition of human experimentation? Such use is supported by the fact that biomedical research is unique to the West and also by the fact that, in some sense, research ethics are *an integral part of research*, shaped and modified by the characteristic features of clinical research such as randomization, placebos, life supportive technologies, and so forth. This fourth model for transcultural biomedical research ethics generally contends that Western ethics should be the universal standard. But, as we shall see, the straightforward application of Western ethics across cultural barriers is problematic.

In 1947, after the Second World War and the revelations of human experimentation in Nazi concentration camps, the allied nations promulgated the Nuremberg Code [28]. This code came rapidly to be recognized as an authoritative, 'international' statement of the rights of research subjects. The reason for this is partly the fact that one basis for the claim of jurisdiction by the International Military Tribunal was the notion of a natural, universal law to which all individuals could be held accountable, notwithstanding the specific laws of the jurisdiction under which their criminal behavior occurred. The Nuremberg Code, which emerged from the trials, attempted to set forth a legal framework that would justify research involving human subjects provided that it was 'within reasonable, well-defined bounds' and satisfied certain 'moral, ethical, and legal concepts'. The Declaration of Helsinki, which was first adopted by the World Medical Assembly in 1964 and was revised in 1975, 1983 and 1989, adapted the principles of the perhaps excessively legalistic and theoretical Nuremberg Code to fit the empirical realities of biomedical research; for example, it provides for the authorization through proxy consent of the participation of less than fully autonomous subjects [29].

The Nuremberg Code and the Helsinki Declaration gradually assumed an aura of universality and came to be applied to a wide variety of culturally, clinically, and economically specific settings. There was a gradual recognition, however, that Nuremberg and Helsinki were not appropriate for all research settings. Consequently, a new set of guidelines was developed and promulgated jointly by the Council for International Organizations of Medical Sciences (CIOMS) and the World Health Organization in 1982 [30]. These guidelines have emerged as the leading articulation of ethical standards for specifically transcultural research.

According to the CIOMS guidelines, when research is conducted by investigators of one country on subjects of another, "the research protocol should be submitted for ethical review by the initiating agency. The ethical standards applied should be no less exacting than they would be for research carried out within the initiating country" [30, p. 32]. Nevertheless, the stated purpose of these guidelines is to amend the principles of the Declaration of Helsinki in order "to suggest how they may be applied in the special circumstances of many technologically developing countries". In other words, there is a tension in the guidelines between a desire for culturally relevant application of ethical principles on the one hand and the belief that "the ethical implications of research involving human subjects are identical in principle wherever the work is undertaken" on the other.

Western codifications of biomedical research ethics, including the CIOMS guidelines, are generally founded, implicitly or explicitly, upon three principles: respect for persons, beneficence, and justice [31]. Application of these principles, however, will be greatly influenced by the cultural setting of the

research in a number of critical ways, only some of which are directly addressed in the guidelines.

Respect for persons incorporates a deontologic conception of human beings as ends unto themselves and gives rise to the necessity for informed consent; this involves: (1) providing subjects with information about the risks and benefits of research participation, and (2) ensuring that subjects participate in the research of their own free will. A very fundamental problem arises, however, in the application of the respect for persons principle because of cross-cultural variation in the definition of personhood. Western societies stress the individualistic nature of a person and put much emphasis on the individual's rights, autonomy, self-determination, and privacy. But this is at variance with the more relational definitions of a person found in many non-Western societies which stress the embededness of the individual within society and define a person by means of his relations to others [32].

From this variation in the definition of a person arise important practical implications. Since the notion of persons as individuals is undermined, the consent of the individual may be viewed as non-essential in certain cultural settings. Indeed, the focus of the consent process may shift from the individual to the family or to the community; for example, in the People's Republic of China, consent for a procedure might first be elicited from relatives who would in turn persuade the individual of the virtue of the proposed intervention [33]. Similarly, in Taiwan, doctors are often expected to withhold information from patients and direct their remarks to their families; such behavior is viewed by neither the patients nor the practitioners as presenting an ethical dilemma [1, p. 281]. Thus, in the context of research, it may initially be necessary to secure the consent of a subject's family or social group instead of or in addition to the consent of the subject himself.

Variations in the definition of personhood between societies may also find expression in who precisely is deemed able to give informed consent for others. This is acknowledged in the CIOMS Guidelines: "Where individual members of a community do not have the necessary awareness of the implications of participation in an experiment to give adequately informed consent directly to the investigators, it is desirable that the decision whether or not to participate should be elicited through the intermediary of a trusted community leader" [30, pp. 26–27]. This is phrased as if it is an unavoidable and lamentable compromise in an otherwise essential ethical principle. However, this is not necessarily the case since different societies may have different standards, standards that permit such proxy consent. There will be considerable variation by culture as to who is acknowledged to be a 'community leader' and whether such an individual will meet a Western investigator's expectation regarding who can appropriately give consent for another adult. The principle of community leader consent, however, may be the only alternative, albeit unsatisfactory by Western standards, to individual consent in many cases where beneficial research is essential. But this alternative may not necessarily be disturbing within the society of which the research subject is a member. Clear requirements for this type of consent, however, are that the community leader be acting in good faith on behalf of his or her constituents and with their approval [34].

In the context of human subjects research, beneficence is the obligation to protect research subjects from harm and to maximize possible benefits and minimize possible harms. The principle of beneficence thus mandates an appropriate risk/benefit ratio. A relational or expansive definition of personhood of the kind described above may result in ethical decisions that, by Western standards, unduly favor the interests of society-at-large at the risk of the individual. Western ethical standards generally accord considerable import to the welfare of the individual in the conduct of research. For example, the Declaration of Helsinki states that "concern for the interests of the subject must always prevail over the interest of science and society" [29, section I.5]. The *Belmont Report*, an American standard of research ethics, more explicitly acknowledges the difficulties in balancing the rights of the individual vs those of society; while stating that the "risks to subjects [should] be outweighed by the sum of both the anticipated benefit to the subject, if any, and the anticipated benefit to society", the *Belmont Report* nevertheless notes, that "in balancing these different elements, the risks and benefits affecting the immediate research subject will normally carry special weight" [31, p. 7].

The calculus of such balancing will be different in different socio-cultural settings. In some situations, cultural expectations may be that the anticipated benefit to society or to one's community will justifiably outweigh the anticipated risk to the individual. Societal values may be such that the interests of the subject are not perforce precedent over the interests of society. Thus, furthering the interest of society-at-large may not necessarily compromise the rights and interests of the individual research subject, within the particular value system that the subject holds. Even more fundamentally, a developing world research subject may find it "difficult to see how the interests of the subject conflict with the interests of the society except, of course, if the society is not his own" [35]. In this view, the interests of the subject and of the society or the community are necessarily congruent. Problems arise only if the values and expectations of a society of which the individual is *not* a member are imposed.

Considerations of beneficent treatment of research subjects also may be modified by specific practical and social concerns. Moreover, the assessment of the acceptability of a particular medical intervention will differ in developed as compared with developing countries as a result of different patterns of illness and

different medical and economic constraints acting upon the population. Different cultural settings may well lead to different decisions [36].

It is thus clear that a simple, straightforward application of Western biomedical research ethics in non-Western settings is problematic. A refined object of this model might therefore be to take a Western standard and *modify* it in a culturally sensitive way, in recognition of the problems outlined above, rather than apply it as is. But this too is problematic: even if the Western standard is modified to accord with local cultural expectations, the danger of imposing Western perceptions of what is appropriate to consider in ethical decision-making, of stipulating in advance which aspects to emphasize, still remains. Indigenous peoples may have ethical concerns about biomedical research that are difficult for Westerners to appreciate, let alone anticipate or validate. These concerns might not fit easily within the framework of Western codifications, or worse, might escape recognition altogether.

ENGAGING ETHICAL DIFFERENCES

Each of the four models of ethics to govern transcultural clinical research that have been considered is thus inadequate. Eliminating ethical conflict by prohibiting contact between researchers (usually Western) and subjects (usually non-Western) across cultural boundaries is unsatisfactory because non-Western investigators in other societies have often already been inculcated with Western ethical notions or are often otherwise significantly alienated from indigenous ethical beliefs. Moreover, in this relativistic model, no thoughtful *assessment* of either ethical system takes place. This lack of assessment is also a problem with the second model considered (that of having the research meet the ethical expectations of both the researcher and the subject). The second model fails to provide guidance in eliminating conflict between ethical expectations and, like the first model, this model is based on the potentially troublesome moral value of tolerance.

The absolutist ethical models are also imperfect. Abstracting a system of research ethics through cross-cultural examination of systems of medical ethics is complicated by the lack of other research traditions. Where present, other systems of medical ethics are largely professional in nature and, in a fundamental way, do not speak to the concerns of the Western tradition of clinical research. The problem with the fourth model (the use of Western research ethics as a standard) is that, conversely, it does not speak to non-Western ethical expectations. Moreover, such an outright application of Western research ethics is confounded by serious cultural variation in the interpretation of certain essential ideas (such as personhood, disease causation, and so forth), and, finally, this model suffers from the problem of imposing external ethical categories upon indigenous ethical precepts.

The inadequacy of these four models has three causes; all of which have to do with the influence of culture upon the problem itself. This influence is quite profound: culture shapes (1) the content of ethical precepts, (2) the way ethics as a concept is configured (that is, the form of ethical precepts), and (3) the interaction between conflicting ethical expectations (that is, the way ethical conflict is handled). Addressing the first problem (how culture shapes ethical rules) requires careful analysis of indigenous ethical expectations. We have seen some examples of this type of analysis in our consideration of Ayurvedic and Chinese medical ethics and in our examination of the outright attempt to apply Western research ethics in certain non-Western settings.

Addressing the latter two problems (how culture shapes our idea of what ethics is and our idea of how to resolve ethical conflict), however, is more difficult: it requires the development of a special perspective on ethical systems. That is, traditional Western bioethical approaches may well be inadequate to contend not only with the manifest variability in ethical norms across cultures but also with the other two causes of the inadequacies in the models. These models break down in part because they treat ethics in a philosophically orthodox fashion and look for the answer through what *ought* to be done rather than through what is done. Configuring ethics solely as a set of prescriptive and proscriptive rules, and not also as a cultural system of thought that has explicative and creative functions is inadequate. This inadequacy on the one hand is highlighted by the conduct of transcultural clinical research—which, by its nature, brings into direct contact potentially discrepant ethical expectations—and on the other hand must be rectified because of the pressing need for international medical research.

All four models fail to address the culturally defined meaning of ethical systems in that they assume a non-interpretive posture with respect to the concept of ethics. Medical ethics is not the same kind of thing in all cultures. Sociologists Renée Fox and Judith Swazey have argued, for example, that the Chinese 'medical morality' is *not* equivalent to Western 'bioethics' [37]. Writing of Karl Mannheim's struggle to develop a "non-evaluative concept of ideology", the cultural anthropologist Clifford Geertz has observed that a paradox arises when conceptualizing systems of ideas because of the realization that "socio-political thought does not grow out of disembodied reflection but it is always bound up with the existing life situation of the thinker" [38]. The solution to this problem, Geertz argues, lies in a more adroit handling of socio-political thought—including ethics, I believe—by conceptualizing it as an ordered system of cultural symbols.

That is, it is not the ethical rules themselves which are so important, it is their *meaning*. The rules, in a

sense, may be taken to reflect how a given culture perceives that human beings should be treated by others, how investigator and subject should communicate, or how medical knowledge is to be acquired. Ethics do not just regulate behavior, they construe it. Like law, ethics have "imaginative, or constructive, or interpretive power, a power rooted in the collective resources of culture rather than in the separate capacities of individuals" [39]. In this respect, ethics has something in common with ideology. Though the two are admittedly different, ideological and ethical systems are similar in that both are templates for the organization of social processes. Indeed, systems of biomedical research ethics may be seen as ideologies of a sort, for "whatever else ideologies may be—projections of unacknowledged fears, disguises for ulterior motives, phatic expressions of group solidarity—they are, most distinctly, maps of problematic social reality and matrices for the creation of collective conscience" [38, p. 220].

Medical ethics may be different things in different cultures in part because of the activity ethics are viewed as appropriately governing. For example, the distribution of resources that maintain or restore health is configured as necessarily a moral problem within contemporary Western medical ethics. Yet, in other societies, the distribution of such resources might not be configured as a moral issue at all, and the distribution of health-related resources may be seen as requiring no more attention to ethical precepts than the distribution of food [40].

A culturally sensitive perspective on systems of medical ethics has a further consequence. According to the prevailing view, medical ethics, as part of a positivist tradition in Western philosophy, consists of rules and principles directed at what ought to be the case. An alternative, contextualist, view of medical ethics, however, focuses on accounting for the *phenomena* of medical ethics. It seeks to understand the practice of medical ethics by locating its cultural context [41]. A contextualist perspective on morality offers a way out of the thorny methodologic and substantive issues raised by a positivist—and culturally myopic—perspective on morality, issues brought to the fore by the conduct of transcultural clinical research.

A contextualist approach also contributes to a solution to the problem of which ethics should govern transcultural research by broadening the philosophical basis of research ethics. Part of the problem with the foregoing four models—even from a Western point of view—is that the full richness of Western philosophy itself has not been tapped. As Fox and Swazey have argued,

> the paradigm of values and beliefs, and of reflections on them, that has developed and been institutionalized in American bioethics is an impoverished and skewed expression of our society's cultural tradition. In a highly intellectualized but essentially fundamentalistic way, it thins out the fullness of that tradition and bends it away from some of the deepest sources of its meaning and vitality [37, p. 358].

Bioethics has, until very recently, based itself almost exclusively on Anglo–American analytic philosophical thought and largely ignored other Western philosophical traditions, such as phenomenology, virtues theory, existentialism, social ethics, and so forth.

Hence, present concepts of medical ethics are too detached from the clinical reality in which ethics come into play. A significant source of ethical meaning is the particular situation in which ethical issues are raised. Clinical research ethics have a concrete existence, expressed in each research setting. Ethical rules such as those pertaining to clinical research, like other socio-political and religious thought, are constructed, fashioned, made. And since both the maker and the situation in which they are applied vary, so will the product. In order to resolve the troubling problems raised by the conduct of transcultural clinical research, an ethnography of the practice of morality in medical contexts in general and in transcultural clinical research in particular will be needed, and social scientists can contribute meaningfully in this respect.

Such a casuistic view of medical ethics has practical implications: it means that understanding the specific, relevant ethical expectations of indigenous peoples will be a prerequisite of transcultural clinical research. It is not the existence of moral standards that varies cross-culturally, it is their form and content. Could we not ask members of a given society a series of ethnographic questions: Is it right for a doctor to try a new or untested therapy on a patient in order to see what happens? How is knowledge acquired in a given medical system? Can doctors do anything other than *treat* a patient? Can doctors misbehave when interacting with patients, and if so, how? How is participation in medical research viewed? How do Western research ethics come to be indigenized? The study of the answers to such questions might provide a strong foundation for evaluating the assumptions underlying what is considered to be ethical care of patients and research subjects in the relatively homogeneous medical system of American culture.

Indeed, the Western system of research ethics is itself a recent creation, largely articulated since World War II. It rests on a medical ethic that was exclusively doctor/patient oriented and which, under pressure of the research endeavor, was expanded to accommodate the investigator/subject relationship. Western medical ethics, that is, were at the outset based on the Hippocratic tradition, and, akin to the Asian medical ethics considered above, were largely professional in nature. The concept of essential patient rights which in themselves create obligations for professionals is alien to the Hippocratic ethical tradition. This concept found its first important expression in the West in the Nuremberg Code. The code abandoned the notion that experimental subjects are protected by professional standards and replaced it with the notion that

subjects intrinsically have self-determination and autonomy.

In short, there has been an evolution in medical ethics—in response to the existence of research and to the abuse of research subjects in certain settings—in the West. The indigenous ethics of non-Western cultures, as they apply to professional etiquette or clinical care, are also capable of evolution. Of course, the form of research ethics that such systems of non-Western medical ethics ultimately achieve might be quite different from Western research ethics.

But the emergence of non-Western systems of clinical research ethics, such as they might be, must be expected and understood. Indeed, we are at the initial stages of a proliferation of biomedical research in the developing world, a proliferation that includes many collaborative efforts between developed and developing countries. In view of the importance and ubiquity of such research, an understanding of the emergence of research ethics in non-Western countries is of enormous practical significance. As traditional and biomedical practice converges around much of the world [42], clinical research ethics will be under increased pressure to adapt to local circumstances and local cultures.

Thus, culture shapes both the content and form of ethical systems. It can also be seen to shape how the existence of conflicting ethical expectations is construed and handled. In the United States in particular, we often seem to expect that a solution to ethical problems is indeed possible, if only we were clever or persuasive or patient enough. The expectation, tempered by our culture, is that ethical dilemmas have a solution. However, not all conflicts, especially in such a complex area as research ethics, are resolvable. Resolving ethical dissonance is apt to be especially unlikely when non-casuistic, systematic solutions—those divorced from actual, clinically and culturally specific situations—are applied. The four models considered above are problematic on this account. American bioethics has an inherent bias in that there is an expectation that final and transcendent resolution of ethical disputes is indeed possible. By 'transcendent' I mean that there is the idea that a solution divorced from, and uninformed by, the particular local cultural setting in which the dispute is framed is possible. And by 'final' I mean that there is the expectation that no rough and unseemly edges will remain after resolution of a particular conflict. In the United States, we seem to hesitate to accept inherent ethical irresolvability.

Ethical systems, however, do not exist in order to eliminate ethical discourse. Instead, they provide a framework for such discourse—a framework for the confrontation of particular situations that pose ethical dilemmas. A discourse between ethical systems requires mutual understanding—not only of the ethical expectations that are being contested and discussed, but also of the very meaning of what ethical systems are and what their function is.

Such a discourse can address which ethics should govern transcultural clinical research. This approach to the problem is similar to the second solution outlined above. But it is different from that solution in four critical respects: (1) an ongoing *dialogue* between ethical systems is inherent in it; (2) a *negotiation* between ethical systems about *a particular situation* takes place; (3) proponents of both the dissonant ethical systems *assess and examine* themselves and each other; and (4) a rationale for *tolerance* is thus provided, namely, that ethical conflict is sometimes irresolvable but must nevertheless be handled.

The kind of negotiation between equals that this approach entails would admittedly be difficult to attain in many settings in the developing world where research is conducted—if for no other reason, because of the tremendous difference in education, literacy, wealth, and power between investigators and subjects. The difficulty in achieving such a cross-cultural dialogue, however, does not mean that efforts should be abandoned. Moreover, in such a discourse, the involved parties must accept the existence of alternative ethical systems, and, while not forswearing assessment of the other systems, must still negotiate with them. Such negotiation and mutual understanding also provides the practical advantage of providing a mechanism for dispute resolution [43]. Thus, the hallmarks of such an approach are ethical *pluralism* and humility rather than either ethical relativism or universalism.

Ethics may be viewed as a form of 'local knowledge', which Geertz has described as "local not just as to place, time, class, and variety of issue, but as to accent—vernacular characterizations of what happens connected to vernacular imaginings of what can" [39, p. 215]. As a consequence of such a perspective, the comparative study of research ethics cannot be a matter of reducing concrete differences to abstract commonalties, nor of locating identical phenomena masquerading under different names. Rather, in the thick of ethical differences, the goal should be to *engage* rather than *abolish* ethical conflict. Indeed, in seeking to abolish ethical conflict we might delude ourselves into thinking that there is more commonalty of belief than really exists.

We must navigate, in short, between the simplicity of ethical universality and the evasion and complexity of ethical relativism, between intellectual hubris and moral paralysis. We should not ask 'Is there a single model for research ethics?' but rather 'Can there be?' We must face and accept the indeterminacy of ethical variability. That medical ethics cannot be separated from the behavior they are intended to govern in the cultural setting in which they are to govern it means that the search for a single model of transcultural research ethics would be fruitless. Instead of such a search, the varieties of ethical expectations should be turned into commentaries one upon

the other, the one illuminating what the other obscures.

Acknowledgements—I am very grateful to Professors Renée C. Fox, Arthur M. Kleinman and Robert J. Levine for helpful critiques of earlier versions of this manuscript. This work was completed while the author had support as a Robert Wood Johnson Foundation Clinical Scholar.

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