This claim that clinicians are not in a position to know their patients' best interest may still shock some more traditional Hippocratic physicians. Most analysts of the ethics of clinical trials are probably willing to acknowledge that clinicians are not in the best position to project the possible outcomes from administration of various treatments of experimental agents. They can, however, learn these from investigators. They should be skilled at communicating the possible outcomes to potential subjects. The real problem is that, even if we assume we have an accurate account of those possible outcomes and their relative probabilities, we still cannot assign utilities to them. In fact, investigators and clinicians cannot even determine for individual patients or subjects whether the anticipated outcome should count as a benefit or a harm. That an agent may make the subject drowsy is a significant risk for a truck driver, but may be a benefit for a retired insomniac. Knowing how seriously to take the drowsiness is simply beyond the skill of the clinician. Knowing whether the drowsiness is justified in the light of the other potential effects is something only the subject can know.

The problem is made more severe by the fact that the utilities or disutilities of treatment agents must be assessed in the light of the nonmedical beliefs and values of the potential subject. A wealthy person deeply committed to the trial under consideration may easily take a day off work to protect against the risks of the drowsiness; a low-income single mother may find that option very unattractive.

The critical problem is that the variables that must be considered before the potential subject can know whether he or she is indifferent enough between two treatments to volunteer to be randomized are normally well beyond the expertise or knowledge of the clinician. They involve the subject's cultural commitments and his or her economic, legal, religious, familial and aesthetic interests, all of which are beyond the expertise of the clinician. Thus the clinician is in a poor position to determine whether the potential subject's values—including many nonmedical values—would lead the subject to be near enough to equipoise to be willing to volunteer. It is not unrealistic to conclude that the clinician cannot establish whether the potential subject is in equipoise. It is even more unrealistic to believe that an investigator could make this judgment. Because Chiong argues effectively that these players do not have to establish equipoise in the first place, discovering that they do not have the skills to do this does not present an insurmountable problem. ■

REFERENCES

Chiong, W. 2006. The real problem with equipoise. *American Journal of Bioethics* 6(4): 37–47.

Miller, F. G., and H. Brody. 2003. A critique of clinical equipoise. *Hastings Center Report* 33(3): 19–28.

Veatch, R. M. 2002. Indifference of subjects: An alternative to equipoise in randomized clinical trials." *Social Philosophy & Policy* 19(2): 295–323.

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Physicians as Researchers: Difficulties with the "Similarity Position"

David Wasserman, University of Maryland Deborah S. Hellman, University of Maryland Robert Wachbroit, University of Maryland

Chiong raises the important question of "what compromises in the care offered patients in a clinical trial can be justified by the potential benefits to third parties" (2006, 37)—a question that cannot even be raised under the equipoise standard. But, he is mistaken, we believe, in assuming that this question must have the same answer for researchers and physicians. That assumption would be warranted if clinical research and medicine were different aspects of the same profession, governed by the same rules. That, however, is

just what is denied by proponents of what Chiong calls "the difference position." On this view, it is at least theoretically possible that a study could satisfy all the requirements to make knowing and voluntary participation acceptable—addressing an important question in a way likely to yield a valuable answer, and offering a reasonable balance of benefits to risks—and yet still involve too great a departure from the standard of care for a physician to ethically recommend it to her patients. This could be so even if the

physician were not committed to absolute priority for her patients—an extreme stance Chiong rightly urges us to reject. For proponents of the difference position, the qualified priority that the physician should accord her patients might still compel her to withhold her recommendation from a study that satisfied the researcher's more limited duty toward those individuals.

The fact that one of Chiong's principle arguments against the difference principle is that it would not "serve the interests" of patients shows the strength of his assumption that research and treatment share the same therapeutic, patient-centered orientation. But the defender of the difference position would insist that determining whether role differentiation serves patients' interests hardly settles the issue. The difference position takes the primary goal of the researchers to be the acquisition of "generalizable knowledge" that may or may not serve the (medical) interests of her present subjects. The researcher must treat her subjects with respect and may have duties to them that she would not have to strangers. But their interests are not paramount in the way they are for the treating physician.

Chiong obscures the possible divergence between researcher's and physician's duties by his formulation of the physician's duty as one of offering "good enough" care. Choing concedes that this standard "requires the exercise of judgment," but he does not even suggest the considerations on which that judgment is to be based. In leaving the content of "good enough" care underspecified, Chiong misses the real and important possibility that both the treating physician and the researcher have duties to the patient or participant that lie in between the poles of complete partiality and nonpartiality but that differ in content nonetheless. Chiong's use of Kantian universalizability does not help to clarify the content of the physician's or researcher's role. He is surely correct that most of us would not will that physician-researchers be prohibited from conducting studies that imposed some medical burdens or risks on participants (to call them either patients or subjects at this point may beg the question). He also is correct that most of us would find it unacceptable for physician-researchers to impose extreme or unnecessary burdens or risks on participants. But these thought experiments hardly show that we would will that researchers display the same degree of partiality toward their subjects that physicians display toward their patients. For proponents of the difference principle, the researcher, whether she has a medical, nursing, or social work degree, or a doctorate, acts in a different role than the treating physician, and the constraints we would will on one may be different than the constraints we would will on the other. Because of the difference in their roles, what is "good enough" for one might not be good enough for another.

In the examples Chiong offers to illustrate his universalizability test, the researcher is conducting studies with participants for whom he has, presumably, never served as a treating physician. For the proponent of the difference position, the fact that he happens to be an M.D. has less relevance to the moral rules under which he must operate than the fact that he has never served as a physician to the individuals who will be his research subjects. A proponent of the similarity position like Chiong would insist that those individuals became his patients as well as subjects when they enrolled in his research. But that again assumes the role identity for which Chiong needs to argue. And the case against that identity is reinforced by considering whether, or how, the existence of a prior physician—patient relationship would constrain a physician—researcher.

Thus, most of us would agree with Chiong that a researcher arriving in an impoverished, AIDS-stricken country could conduct a study that randomly assigned pregnant, HIV-positive women to long and short courses of zidovudine (AZT). The harder question—building on Chiong's use of that controversy—is whether most of us would also agree that a physician already treating a group of pregnant, HIV-positive women who had the resources to give them all the long course of AZT could instead offer them a 50% chance of a long or short course as subjects in a clinical trial. Thus, imagine that a physician with a large practice in an impoverished East African country were offered a choice by a donor: a supply of AZT sufficient to put all her pregnant HIV-positive patients on the long course or a supply of AZT sufficient to run the kind of long- versus short-course trial of which Chiong would approve. We suspect most people would regard her as obliged to take the former in her capacity as physician. Either donation would be a windfall, but the physician would be obliged to pick the one with greater expected benefit to her patients. In contrast, a researcher offered the means to either treat X number of individuals who had not been his patients with long course, or run a clinical trial with those individuals testing short course against long course would not be similarly constrained. Having acquired no duty to those individuals to give them the best care he could, he would be ethically permitted choose the research over the treatment option, although it gave those individuals less than the best expected

At the same time, Chiong is surely correct that the physician's duty to each patient is not to provide the absolutely best care—a standard that, as at least one commentator has pointed out, would lead every physician but the best to refer as many of their patients to the best physician as the latter could (best) handle. A physician's duty is only to do the best she can, above some vague, shifting threshold of competence. Moreover, her duty to any one patient is qualified by her duties to her other current patients, and

by the constraints imposed by law, especially those that impose rationing. Thus, although the East African physician has a duty to provide long-course treatment for all her patients rather than subject them to long/short randomization, rationing considerations might justify her in choosing to provide enough short-course treatment for all of them, rather than a more limited supply of long-course treatment, that would leave some of her patients with no treatment at all. Or, consider another example. Suppose the country adopts a law requiring that patients receive only short-course treatment and that any additional AZT must be turned over to public hospitals to treat other patients, except when long-course treatment is administered in the context of a clinical trial. In that case, the physician might be justified in offering his patients the trial instead of the short course. This would depend on whether the greater expected benefit of the trial made it acceptable for the physician to treat his patients as subjects—an issue we cannot resolve

The difference between the physicians' and researcher's role is further reflected in the array of duties that should be imposed on the researcher, according to several recent commentators (e.g., Emanuel, Wendler and Grady 2000;

London 2005), but which would arguably be inappropriate for a (treating) physician: to healthy volunteers, to the host community, to the health-care infrastructure of the host country, etc. While Chiong could respond that the physician merely takes on additional duties in acting as a researcher without losing his primary duties to his patient-subjects, the nature of the former duties again suggests that clinical research is a fundamentally different enterprise from clinical treatment, and the roles of researcher and physician fundamentally different.

REFERENCES

Chiong, W. 2006. The real problem with equipoise. *American Journal of Bioethics* 6(4): 37–47.

Emanuel, E. J., D. Wendler, and C. Grady. 2000. What makes clinical research ethical? *Journal of the American Medical Association* 283: 2701–2711.

London, A. J. 2005. Justice and the human development approach to international research. *Hastings Center Report* 35(1): 24–37.

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Equipoise and the Ethics of Clinical Research Revisited

Franklin G. Miller, National Institutes of Health¹

The orthodox dogma of clinical equipoise no longer reigns uncontested. I am happy to see the thoughtful and incisive target article by Chiong (2006) and welcome another ally in the struggle to free research ethics from the grip of equipoise—a doctrine that is erroneous in theory and practice. Also welcome is his revisionist conception of clinical medical ethics as encompassing legitimate departures by physicians from an absolute therapeutic obligation to patients.

In critiquing proponents of clinical equipoise, my colleagues and I have argued that they attempt unsuccessfully and incoherently to make clinical research fall within a traditional understanding of clinical medical ethics (Brody and Miller 2003; Miller and Brody 2003; Miller and Rosenstein 2003). To replace this misguided "similarity position," we have advanced a "difference position." Clinical research, by

virtue of being aimed at producing generalizable knowledge, adopting methods foreign to medical care (e.g., randomization, masked treatment assignment, and the use of placebo controls), and including procedures that carry risks to research participants that are not justified by medical benefits to them, should be understood as governed by ethical norms distinctive from those that apply to clinical medicine. Chiong rejects equipoise and the difference position. Instead, he argues that when medical ethics is properly understood, the obligations of physicians to patients can be fulfilled in clinical research. However, Chiong's attack on the difference position is wide of the mark and his novel version of the similarity position remains difficult, if not impossible, to square with the enterprise of legitimate clinical research.

In previous work I have suggested a meta-principle for applied ethics that the normative framework appropriate for a given, legitimate professional activity needs to reflect an accurate understanding of the nature of that activity (Miller and Brody 2003). Although this may appear to be a truism, it has been routinely violated in work on the ethics

^{1.} The opinions expressed are those of the author and do not necessarily reflect the position or policy of the National Institutes of Health, the Public Health Service, or the U.S. Department of Health and Human Services.