In “The Real Problem with Equipoise”, Winston Chiong (2006) rejects “the equipoise requirement” as a standard for determining ethically acceptable research. He locates his rejection within the dichotomy, suggested by Franklin Miller and Howard Brody (2002, 2003), of the difference and similarity positions. In contrast to Miller and Brody, who adopt the difference position while rejecting equipoise, Chiong advocates for the similarity position while also rejecting the equipoise requirement. On my view, Chiong’s endorsement of the similarity position and his rejection of the equipoise requirement are both mistaken.

First, he seems to have fallen victim to a false dichotomy. Even though I agree with him that the difference position is mistaken, the similarity position is not the best alternative. Specifically, Chiong does not recognize the disparate aims of clinical research and clinical care that illustrate the inadequacy of the similarity position. This is illustrated neatly by his parallel between medical education and clinical research. If we avoid the false dichotomy, we can see that equipoise provides an important standard for evaluating medical research.

Second, Chiong’s rejection of the equipoise requirement is mistaken because the equipoise requirement is best understood in the context of the history of clinical research and not simply as an extension of the principles governing clinical care. Indeed, the
equipoise requirement fulfills exactly the utilitarian values (despite the Kantian face he puts on them) that drive Chiong’s standard for evaluating research.

The Space Between

Chiong advocates for the similarity position instead of the difference position. In brief, these positions are distinguished by the respective views of the obligations owed patients and research subjects by clinical practitioners and clinical researchers. Proponents of the similarity position suggest the obligations owed patients and research subjects are the same, while proponents of the difference position suggest these two groups are owed entirely distinct obligations. Chiong notes that on his view even though “clinical research should be governed by the same principles that guide clinical practice, I reject the uncompromising account of these principles that underlies the equipoise requirement.” (3-4) Instead, the physician’s obligations according to Chiong’s similarity position follow from a “Kantian standard for the reasonable priority that doctors—including doctors in ordinary practice settings as well as clinical investigators—should show towards their patients.” (4) Specifically, he rejects the “traditional view that doctors should offer treatments that are in the best interests of the individual patient, without regard for the welfare of third parties.” (4) In turn this leads Chiong to claim that, “the pertinent question is not whether the two treatments are in equipoise, but instead whether the potential benefits to third parties are sufficient in this case to justify the less-than-optimal care given to some of the patients in the study.” (6)
The difference position is grounded by the claim that clinical research and clinical care have distinct aims. Chiong infers that this claim arises from the fact that clinical research is not designed to produce optimal research subject care. He explains: “Here again [in claiming the distinct aims of clinical research and clinical care] these authors seem to presume that, if clinical research is not organized so as to provide optimal medical care to individual patients, then the therapeutic obligation does not properly apply. Yet this argument would seem to prove too much.” (12) To illustrate this point Chiong uses the aim of medical education, and compares it to the aim of medical research.

As Chiong notes, “medical education requires compromises for the sake of perpetuating the medical profession by teaching new doctors.” Taking clear aim at the difference position, he suggests that, “this [set of compromises for the sake of medical education] doesn’t yet give us grounds for dividing these aims between two different activities.” (14) If medical education and medical research were similar enough, this would be a powerful argument. However, it seems a mistake to confound medical education and medical research.

The mistake may come from Chiong’s use of “optimal patient care” in his discussion. He describes both medical research and medical education as “contexts where some activity is not organized to provide optimal care.” (12) True enough, but the parallel ends there. The aims of medical research and medical education are too disparate to support analogous obligations. The primary aim of medical care performed by interns and residents in the course of their education is still the care of the patient. The primary
outcome is the patient’s health, and the education of the intern or resident happens along the way. The primary aim of medical research is the production of a generalizable conclusion. The primary outcome is the denial or confirmation of a hypothesis, and the care of the subjects happens along the way. Neither will produce optimal care. However, in medical education, the “less-than-optimal” care of the patient remains the primary aim, and in medical research, the care of the subject is a secondary aim.

Accordingly, clinical researchers have obligations that arise from the aim to produce a generalizable conclusion. Once this aim has been abandoned (i.e., a protocol is no longer sustainable), the care of the research subject no longer follows the research protocol and the attendant obligations and course of treatment revert to those of all patients in similar conditions. Clinical practitioners (including interns and residents) have obligations that are defined first by the care of this particular patient. Even if a resident must be relieved of performing a laparoscopic appendectomy, the course of treatment for the patient remains the same (or, in the some cases, is modified to address any mistakes made by the resident). Indeed, even this “failure” is usually part of the education process.

The above makes clear why I, along with proponents of the difference position, hold the similarity position to be untenable. However, I’m quite sure the difference position is mistaken as well. As Chiong so clearly explains, the proponents of the difference position exclude care of the research subject (even as a secondary focus) from the obligations of medical researchers. They offer only an amorphous “non-exploitation” principle. But this goes too far. Yes, clinical care and clinical research are different, but they share the focus
on patient care (be it a present or future patient). Moreover, the difference position ignores the fact that most research subjects were patients first and are often motivated, not by altruism, but by the therapeutic possibilities of clinical research.

I here propose that we split the difference between these two positions. On this view, the therapeutic obligation in medical research is an attenuated version of the obligation in medical care. Instead of the obligation to provide optimal or good enough care that exists in the clinic, the therapeutic obligation that exists in medical research (and it does exist) is indirect: researchers have a responsibility to pursue only those conclusions that have a reasonable expectation of improving patient care. In clinical care, a physician breaches his therapeutic obligation when he performs/offers treatment that has no reasonable expectation of benefit for this patient. In clinical research, a researcher breaches her therapeutic obligation when she takes part/designs a clinical trial that has no reasonable expectation of improving patient care in the long term.

On this view of the therapeutic obligation in medical research, the equipoise requirement does not seem so out of place. We only want to perform those clinical trials that have a reasonable expectation of improving patient care; that is, we should test only those experimental interventions that we think will be at least as good as the existing evidence based standard of care. These experimental treatments could improve on the standard of care (1) through improved effectiveness at treating the disease, (2) through diminished side-effects, or (3) through decreased cost. The equipoise requirement allows for a generalizable conclusion while requiring that conclusion hold the promise of improving
upon existing medical practice. Notably, when no evidence-based standard of care exists, this view can also accommodate the use of placebo controls, but excludes a placebo-control when an evidence-based standard of care does exist.

**Repeating History**

The equipoise requirement can be best understood as a corrective to past practices in medical research rather than as a means to extending the principles of medical care to medical research. Given the aim of medical research (e.g., producing a generalizable conclusion), the equipoise requirement also serves an indispensable constraint on medical research. In terms of Chiong’s critique, equipoise is best understood as an attempt to ensure the inclusion of research subject interests rather than an attempt to exclude third-party interests. The aim of medical research already includes third-party interests (those who will be able to take advantage of the generalizable conclusion) and the equipoise requirement balances these with research subject interests. By requiring a reasonable expectation of improved patient care in the long run, it keeps us from exposing research subjects to diseases that we have known treatments for. For example, the horrors of Tuskegee include the fact that the research subjects with syphilis were not offered Penicillin even though it was a proven treatment of syphilis for the last 20 years of the study. For similar examples of abuses in medical research before the introduction of equipoise as a guiding principle, see Henry Beecher’s (1966) classic expose on 22 ethically suspect clinical trials.

**Kantian Consequentialism**
Finally, we should recognize that the equipoise requirement serves the purposes that Chiong’s “Kantian” principle aims to serve. His “Kantian” principle serves to answer the following question: “What compromises in the care offered to patients in a clinical trial can be justified by the potential benefits to third parties?” (22) Aside from the fact that this is decidedly utilitarian standard (measuring the good vs. the harm to justify a course of action), the equipoise requirement provides us with a two standard responses to this question. First, any compromise in patient care is minimized because the research subjects are still offered the standard of care. Nonetheless, the rigidity of clinical trial often precludes any the patient-specific modeling of treatment that may prove beneficial. Second, equipoise provides a general answer to the question above: “The compromises in the care of research subjects can be justified by a reasonable expectation of improving patient care in the long run.”

REFERENCES


