Compassionate ethics for clinics

Biomedical ethicists and clinical practitioners both champion the good of the patient, but sometimes their approaches diverge. The harmony of the ideal and the real is our utmost goal, but we often confront situations where theory falls apart in practice. A neonatal study performed by several noted institutions that is being audited by the US Office for Human Research Protections (OHRP) is a case in point.

Prematurely born infants have underdeveloped lungs that need an intentional oxygen supply. However, too much oxygen carries other risks. Thus, to determine the optimal oxygen level within the range of levels allowed in the current clinical guidelines, researchers at 23 well-known academic institutions carried out a US government-financed study, the Surfactant Positive Airway Pressure and Pulse Oximetry Randomized Trial (SUPPORT), from 2004 to 2009. According to their article in the *New England Journal of Medicine* (2010; 362:1959-1969), infants receiving the lower oxygen concentration, which was 85 to 89 percent, showed a higher mortality rate than those in the higher oxygen concentration group, who received 91 to 95 percent. This result fundamentally changed the treatment guidelines for premature infants.

The OHRP, however, has noted that the researchers did not properly notify the subjects that their babies could have faced differing risks of either death or developing serious ocular problems according to the treatment protocol randomly assigned to them. While the principle investigator of SUPPORT, Dr. Neil Finer at the University of California at San Diego, has argued that at the time of the study design, there was no basis in the literature for attributing a greater risk of death to the lower oxygen level, the OHRP has identified pub-

lished research on the greater risk of blindness with the higher oxygen level. The OHRP acknowledges the value of the research objective of the SUPPORT group, but in a March 2013 letter, they suggested that the consent form for SUPPORT was not clearly written, such that the research institutions failed to warn the participants about these risks.

Shades of the Tuskegee syphilis experiment in the 1930s come to mind, but the current case is not so cut and dried. Before drawing a hasty conclusion, the experience of Dr. Dan Brock, who is an ethics philosopher at Harvard Medical School, is worth considering. When he got cancer, he was forced to confront the interface between theory and practice. In *Malignant: Medical Ethicists Confront Cancer*, he described the mental anguish of trying to choose a treatment path alone when his physicians, following best practices, did not push him to pursue one treatment over another because definitive research evidence was lacking.

When infants are treated, clinical practitioners usually make careful decisions based on the physical condition of the patients in consultation with their parents. This approach was taken in the SUPPORT study, given that the oxygen levels of all of the participants were within the standard range of the American Academy of Pediatrics' guideline.

We await the outcome of the careful deliberations between the SUPPORT group and OHRP. Meanwhile, let our ethical standards be practical and compassionate and our clinical practice be theoretically sound. Both are equally vital in the treatment of our patients.

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