Considering usual medical care in clinical trial design

September 29 2009

In this week's *PLoS Medicine*, Liza Dawson (National Institutes of Health) and colleagues discuss the scientific and ethical issues associated with choosing clinical trial designs when there is no consensus on what constitutes usual care.

For example, in 2002 a clinical trial designed to evaluate the best way of ventilating patients with a severe lung condition called acute respiratory distress syndrome sparked a major controversy.

Critics charged that management of the condition in the different arms of the study did not adequately reflect usual medical care, and alleged that it was essential for scientific and ethical reasons to have a usual care comparison arm in the study. The controversy over trial design enmeshed the National Institutes of Health (NIH), the Office for Human Research Protections (OHRP) and the critical care research community.

The trial was put on hold and reviewed by two independent expert panels. Experts pointed to the need for further analysis of the scientific and ethical issues involved in choosing trial designs when there is no consensus on standard of care. Dawson and colleagues discuss these issues in their policy paper. They enumerate five factors that make consensus on these issues particularly difficult, and recommend specific criteria for assessing proposed study designs.

More information: Dawson L, Zarin DA, Emanuel EJ, Friedman LM, Chaudhari B, et al. (2009) Considering Usual Medical Care in Clinical

Trial Design. PLoS Med 6(9): e1000111.
doi:10.1371/journal.pmed.1000111