

ABSTRACT

International Network on Feminist Approaches to Bioethics (FAB) 2008 meeting in Croatia

Wendy Rogers
Associate Professor, Medical Ethics and Health Law
Department of Medical Education
Flinders University

Angela Ballantyne
Dr, Visiting Scholar, Interdisciplinary Bioethics Center
Yale University

Exclusions from research: when is sex-specific research appropriate?

In response to the well-recognised historical exclusions of women from research, there has been increased attention directed towards fairness or sex equity amongst research participants. Proper consideration of sex and gender in research requires attention to both ethical and scientific dimensions. This presentation draws on original empirical and ethical analysis of the rates of inclusion of women in Australian clinical research in order to explore the question of appropriateness in relation to sex-specific research.

We conducted a comprehensive analysis of 400 Australian clinical research studies published 2003-2006 to determine when and where women were excluded or included. Of the 400 studies, 36 were male-only (30,528 participants), 78 were female-only (257,651 participants) and 286 were non sex-specific (258,645 participants). In our analysis of the male or female-only studies, we worked with the concept of biological necessity in order to classify the research as appropriately or inappropriately sex-specific. When determining biological necessity, we considered sex-specific anatomy, the condition under investigation and any sex-specific outcome measures such as clinically significant levels of sex hormones.

The majority of sex-specific research involving women was strongly linked to biological (reproductive) function. For sex-specific research involving men, the pattern varied, with fewer studies linked to reproductive function. Forty three studies (approximately 35% of the sex-specific studies) were research into phenomena that were not directly associated with sex-related biological function. In 39 of these studies (23 involving men and 16 women), there was no justification for the exclusion of the other sex. Amongst the studies, there was considerable heterogeneity regarding the potential influence of sex or gender. In some studies sex and/or gender could be expected to play a major role, for example skin cancer screening in older men; whereas in other studies there was no obvious reason for excluding one sex, for example a trial of a fruit and vegetable extract on heart disease that was conducted exclusively with men. There were some familiar patterns: 6 of the 7 sex-specific cardiovascular studies involved men only; whilst research into physical interventions were aimed at protection in old age for women compared with increasing sporting prowess for men.

In our discussion we focus upon the challenges of defining appropriate sex-specific research using examples from our data set, and relate these to the regulatory requirements in Australia and at the NIH for fair and appropriate (respectively) inclusion of women and men as research participants.