

"Inclusion: The Politics of Difference in Medical Research"

Steven Epstein, 2007, 413 pages, University of Chicago Press, \$19.00

Review by Norman M. Goldfarb

"Inclusion: The Politics of Difference in Medical Research" is a fascinating, well-researched, densely argued, and balanced study of complex social policies that both reflect and drive larger social trends. It should be required reading for anyone who wants to set public policy for — or spout off about — patient rights in clinical research.

The book tells the story of how, since the mid-1980s, advocacy groups and other social and political movements have been transforming the "standard human" of clinical research — a middle-aged, white, middle-class, American male — into a multiplicity of standard humans of different genders, races, ethnicities, ages, etc.

The author postulates an evolving paradigm of "inclusion and difference." In other words, let's invite everyone to the party and study the differences. The adoption of this paradigm addresses the problem of exclusion of underserved groups from clinical research. In other words, if my group is not studied, how will I know whether a new medical treatment works for me?

However, adopting the paradigm also opens a Pandora's box of issues, such as the following:

- A focus on racial, gender and age categories distracts from what may be more useful categories, such as economic status and actual biological differences.
- The statistics of sub-group analysis, especially comparing (often non-existent) treatment effects across sub-groups, require much larger and more expensive clinical studies and therefore allow fewer studies.
- Government requirements for diversity create temptations to cross ethical boundaries when recruiting scarce study subjects from certain sub-groups.
- The politics of inclusion can divert resources from the needy to the politically effective.
- The focus on human categories (including quotas for study populations) reinforces subgroup stereotypes and fosters a divisive sense of separateness in society.

Like all juicy social policy issues, there are no simple answers, just tradeoffs with (often unintended) consequences. Public health policy is currently caught in a whirlwind of contradictions. For example, evidence-based standardization of care (ideally, one standard treatment with one standard generic drug) struggles to accommodate developments in personalized medicine that require a multiplicity of expensive, boutique treatments and drugs.

It is challenging to both include and protect vulnerable groups. The irony is that increasing inclusion means that the subgroup of middle-aged, white, middle-class, American males will no longer serve as the world's guinea pigs.

The book includes 14 chapters:

- Introduction: Health Research and the Remaking of Common Sense
- How to Study a Biopolitical Paradigm
- Histories of the Human Subject

- The Rise of Resistance: Framing the Critique of the Standard Human
- The Path to Reform: Aligning Categories, Targeting the State
- Opposition to Reform: Controversy, Closure and Boundary Work
- Formalizing the New Regime
- From the Standard Human to Niche Standardization
- Counts and Consequences: Monitoring Compliance
- The Science of Recruitmentology and the Politics of Trust
- To Profile or Not to Profile: What Difference Does Race Make?
- Sex Differences and the New Politics of Women's Health
- Whither the Paradigm?
- Conclusion: Identity, Difference, Disparities and Biopolitical Citizenship

The book is available in bookstores.

Reviewer

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