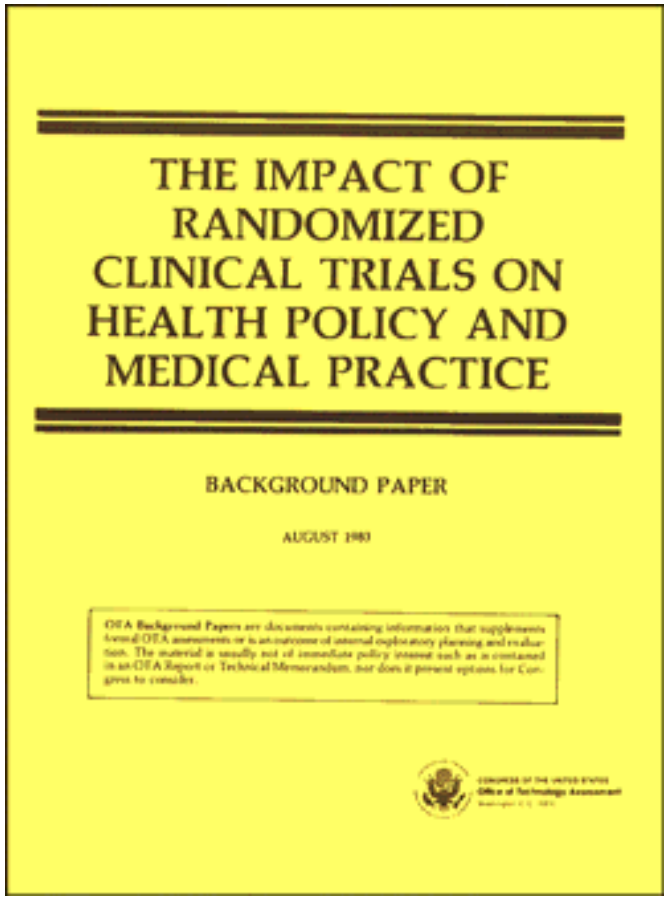
The Impact of Randomized Clinical Trials on Health Policy and Medical Practice

August 1983

NTIS order #PB84-114560



Recommended Citation:

The Impact of Randomized Clinical Trials on Health Policy and Medical Practice: Background Paper (Washington, D. C.: U.S. Congress, Office of Technology Assessment, OTA-BP-H-22, August 1983).

Library of Congress Catalog Card Number *83-600575*

For sale by the Superintendent of Documents,
U.S. Government Printing Office, Washington, D.C. *20402*

Preface

Rational decisions at all levels in health care—from Federal Government policymaking to the treatment of a single patient by a physician—require sound information. Randomized clinical trials (RCTS), a family of clinical experimental designs, provide the highest quality of evidence for the efficacy and safety of medical technologies.

The Office of Technology Assessment (OTA) has a longstanding interest in the tools of medical technology assessment and decisionmaking. Previous OTA reports focusing on the information necessary and available for these activities have discussed the role of RCTS in particular. RCTS fill an obvious need for information yet their impact in health care has remained largely undocumented. This background paper was initiated by OTA to bring together the literature and current views about the actual and potential role of RCTS in decisionmaking about medical technologies.

OTA background papers are prepared by OTA staff and drafts are reviewed by interested individuals and organizations. This paper was written by Hellen Gelband. Thomas Chalmers and Henry Sacks prepared an annotated bibliography that provided material for chapter .5. The Health Program Advisory Committee reviewed the draft; those individuals acknowledged in appendix B either provided information during the course of the study, reviewed the draft report, or did both.

Health Program Advisory Committee

Sidney S. Lee, Committee *Chair*
Michael Reese Hospital and Medical Center

Stuart H. Altman*
Florence Heller School
Brandeis University

Carroll L. Estes
Department of Social and Behavioral Sciences
School of Nursing
University of California, San Francisco

Rashi Fein
Department of Social Medicine and Health Policy
Harvard Medical School

Melvin A. Glasser
Health Security Action Council
Committee for National Health Insurance

Patricia King
Georgetown Law Center

Joyce C. Lashof
School of Public Health
University of California, Berkeley

Margaret Mahoney
The Commonwealth Fund

Frederick Mosteller
Department of Health Policy and Management
School of Public Health
Harvard University

Mitchell Rabkin*
Beth Israel Hospital
Boston, Mass.

Dorothy P. Rice
Department of Social and Behavioral Sciences
School of Nursing
University of California, San Francisco

Richard K. Riegelman
School of Medicine
George Washington University

Walter L. Robb
Medical Systems Operations
General Electric
Milwaukee, Wis.

Frederick C. Robbins
Institute of Medicine

Rosemary Stevens
Department of History and Sociology of Science
University of Pennsylvania

● Until April 1983.

OTA Staff for The Impact of Randomized Clinical Trials on Health Policy and Medical Practice

H. David Banta, *Assistant Director, OTA*
Health and Life Sciences Division

Clyde J. Behney, *Health Program Manager*

Hellen Gelband, *Project Director*

Virginia Cwalina, *Administrative Assistant*

Ann Covalt, *Editor*

Jennifer Nelson, Secretary

Mary Walls, *Secretary*

Contractors

Thomas C. Chalmers and Henry Sacks
The Mount Sinai Medical Center
Annotated Bibliography on the Impact of RCTS on Medical Practice

OTA Publishing Staff

John C. Holmes, *Publishing Officer*

John Bergling Kathie S. Boss Debra M. Datcher Joe Henson
Glenda Lawing Linda Leahy Donna Young