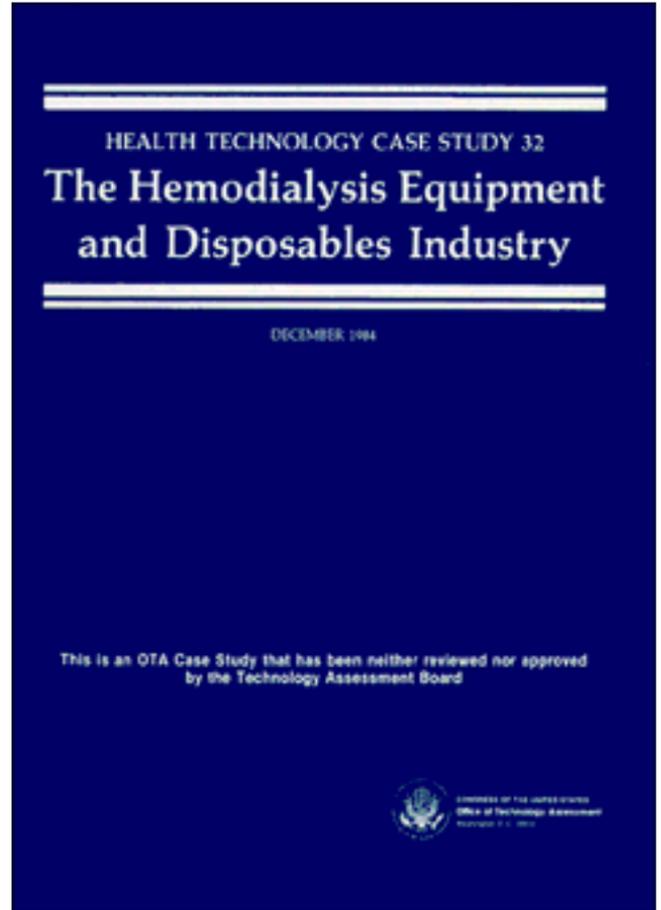


*The Hemodialysis Equipment and
Disposables Industry*

December 1984

NTIS order #PB85-154953



HEALTH TECHNOLOGY CASE STUDY 32

The Hemodialysis Equipment and Disposable Industry

DECEMBER 1984

This case study was performed as part of OTA's Assessment of
Federal Policies and the Medical Devices Industry

Prepared for OTA by:
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OTA Case Studies are documents containing information on a specific medical technology or area of application that supplements formal OTA assessments. The material is not normally of as immediate policy interest as that in an OTA Report, nor does it present options for Congress to consider.

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Preface

The Hemodialysis Equipment and Disposable Industry is Case Study 32 in OTA's Health Technology Case Study Series. This case study has been prepared in connection with OTA's project on *Federal Policies and the Medical Devices Industry*, which was requested by the Senate Committee on Labor and Human Resources and endorsed by the Senate Committee on Veterans' Affairs. A listing of other case studies in the series is included at the end of this preface.

OTA case studies are designed to fulfill two functions. The primary purpose is to provide OTA with specific information that can be used in forming general conclusions regarding broader policy issues. The first 19 cases in the Health Technology Case Study Series, for example, were conducted in conjunction with OTA's overall project on *The Implications of Cost-Effectiveness Analysis of Medical Technology*. By examining the 19 cases as a group and looking for common problems or strengths in the techniques of cost-effectiveness or cost-benefit analysis, OTA was able to better analyze the potential contribution that those techniques might make to the management of medical technology and health care costs and quality.

The second function of the case studies is to provide useful information on the specific technologies covered. The design and the funding levels of most of the case studies are such that they should be read primarily in the context of the associated overall OTA projects. Nevertheless, in many instances, the case studies do represent extensive reviews of the literature on the efficacy, safety, and costs of the specific technologies and as such can stand on their own as a useful contribution to the field.

Case studies are prepared in some instances because they have been specifically requested by congressional committees and in others because they have been selected through an extensive review process involving OTA staff and consultations with the congressional staffs, advisory panel to the associated overall project, the Health Program Advisory Committee, and other experts in various fields. Selection criteria were developed to ensure that case studies provide the following:

- examples of types of technologies by func-

tion (preventive, diagnostic, therapeutic, and rehabilitative);

- examples of types of technologies by physical nature (drugs, devices, and procedures);
- examples of technologies in different stages of development and diffusion (new, emerging, and established);
- examples from different areas of medicine (e.g., general medical practice, pediatrics, radiology, and surgery);
- examples addressing medical problems that are important because of their high frequency or significant impacts (e. g., cost);
- examples of technologies with associated high costs either because of high volume (for low-cost technologies) or high individual costs;
- examples that could provide information material relating to the broader policy and methodological issues being examined in the particular overall project; and
- examples with sufficient scientific literature.

Case studies are either prepared by OTA staff, commissioned by OTA and performed under contract by experts (generally in academia), or written by OTA staff on the basis of contractors' papers.

OTA subjects each case study to an extensive review process. Initial drafts of cases are reviewed by OTA staff and by members of the advisory panel to the associated project. For commissioned cases, comments are provided to authors, along with OTA's suggestions for revisions. Subsequent drafts are sent by OTA to numerous experts for review and comment. Each case is seen by at least 30 reviewers, and sometimes by 80 or more outside reviewers. These individuals may be from relevant Government agencies, professional societies, consumer and public interest groups, medical practice, and academic medicine. Academicians such as economists, sociologists, decision analysts, biologists, and so forth, as appropriate, also review the cases.

Although cases are not statements of official OTA position, the review process is designed to satisfy OTA's concern with each case study's scientific quality and objectivity. During the various stages of the review and revision process, therefore, OTA encourages, and to the extent possible requires, authors to present balanced information and recognize divergent points of view.

Health Technology Case Study Series^a

Case Study Series No.	Case study title; author(s); OTA publication number ^b	Case Study Series No.	Case study title; author(s); OTA publication number ^b
1	Formal Analysis, Policy Formulation, and End-Stage Renal Disease; Richard A. Rettig (OTA-BP-H-9(1)) ^c	16	The Costs and Effectiveness of Nurse Practitioners; Lauren LeRoy and Sharon Solkowitz (OTA-BP-H-9(16))
2	The Feasibility of Economic Evaluation of Diagnostic Procedures: The Case of CT Scanning; Judith L. Wagner (OTA-BP-H-9(2))	17	Surgery for Breast Cancer; Karen Schachter Weingrod and Duncan Neuhauser (OTA-BP-H-9(17))
3	Screening for Colon Cancer: A Technology Assessment; David M. Eddy (OTA-BP-H-9(3))	18	The Efficacy and Cost Effectiveness of Psychotherapy; Leonard Saxe (Office of Technology Assessment) (OTA-BP-H-9(18)) ^d
4	Cost Effectiveness of Automated Multichannel Chemistry Analyzers; Milton C. Weinstein and Laurie A. Pearlman (OTA-BP-H-9(4))	19	Assessment of Four Common X-Ray Procedures; Judith L. Wagner (OTA-BP-H-9(19)) ^e
5	Periodontal Disease: Assessing the Effectiveness and Costs of the Keyes Technique; Richard M. Scheffler and Sheldon Rovin (OTA-BP-H-9(5))	20	Mandatory Passive Restraint Systems in Automobiles: Issues and Evidence; Kenneth E. Warner (OTA-BP-H-15(20)) ^f
6	The Cost Effectiveness of Bone Marrow Transplant Therapy and Its Policy Implications; Stuart O. Schweitzer and C. C. Scalzi (OTA-BP-H-9(6))	21	Selected Telecommunications Devices for Hearing-Impaired Persons; Virginia W. Stern and Martha Ross Redden (OTA-BP-H-16(21)) ^g
7	Allocating Costs and Benefits in Disease Prevention Programs: An Application to Cervical Cancer Screening; Bryan R. Luce (Office of Technology Assessment) (OTA-BP-H-9(7))	22	The Effectiveness and Costs of Alcoholism Treatment; Leonard Saxe, Denise Dougherty, Katharine Esty, and Michelle Fine (OTA-HCS-22)
8	The Cost Effectiveness of Upper Gastrointestinal Endoscopy; Jonathan A. Showstack and Steven A. Schroeder (OTA-BP-H-9(8))	23	The Safety, Efficacy, and Cost Effectiveness of Therapeutic Apheresis; John C. Langenbrunner (Office of Technology Assessment) (OTA-HCS-23)
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		32	The Hemodialysis Equipment and Disposables Industry; Anthony A. Romeo (OTA-HCS-32)

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^bOriginal publication numbers appear in parentheses.

^cThe first 17 cases in the series were 17 separately issued cases in *Background Paper #2: Case Studies of Medical Technologies* prepared in conjunction with OTA's August 1980 report *The Implications of Cost-Effectiveness Analysis of Medical Technology*.

^dBackground Paper #3 to *The Implications of Cost-Effectiveness Analysis of Medical Technology*.

^eBackground Paper #5 to *The Implications of Cost-Effectiveness Analysis of Medical Technology*.

^fBackground Paper #1 to OTA's May 1982 report *Technology and Handicapped People*.

^gBackground Paper #2 to *Technology and Handicapped People*.

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