The Artificial Heart: Costs, Risks, and Benefits

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BACKGROUND PAPER #2: CASE STUDIES OF MEDICAL TECHNOLOGIES

CASE STUDY #9: THE ARTIFICIAL HEART: COST, RISKS, AND BENEFITS

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OTA Background Papers are documents containing information that supplements formal OTA assessments or is an outcome of internal exploratory planning and evaluation. The material is usually not of immediate policy interest such as is contained in an OTA Report or Technical Memorandum, nor does it present options for Congress to consider.
Foreword

This case study is one of 17 studies comprising Background Paper #2 for OTA’s assessment, The Implications of Cost-Effectiveness Analysis of Medical Technology. That assessment analyzes the feasibility, implications, and value of using cost-effectiveness and cost-benefit analysis (CEA/CBA) in health care decisionmaking. The major, policy-oriented report of the assessment was published in August 1980. In addition to Background Paper #2, there are four other background papers being published in conjunction with the assessment: 1) a document which addresses methodological issues and reviews the CEA/CBA literature, published in September 1980; 2) a case study of the efficacy and cost-effectiveness of psychotherapy, published in October 1980; 3) a case study of four common diagnostic X-ray procedures, published in April 1982; and 4) a review of international experience in managing medical technology, published in October 1980. Another related report was published in September 1979: A Review of Selected Federal Vaccine and Immunization Policies.

The case studies in Background Paper #2: Case Studies of Medical Technologies are being published individually. They were commissioned by OTA both to provide information on the specific technologies and to gain lessons that could be applied to the broader policy aspects of the use of CEA/CBA. Several of the studies were specifically requested by the Senate Committee on Finance.

Drafts of each case study were reviewed by OTA staff; by members of the advisory panel to the overall assessment, chaired by Dr. John Hogness; by members of the Health Program Advisory Committee, chaired by Dr. Frederick Robbins; and by numerous other experts in clinical medicine, health policy, Government, and economics. We are grateful for their assistance. However, responsibility for the case studies remains with the authors.

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This case study is one of 17 that comprise Background Paper #2 to the OTA project on the Implications of Cost-Effectiveness Analysis of Medical Technology. The overall project was requested by the Senate Committee on Labor and Human Resources. In all, 19 case studies of technological applications were commissioned as part of that project. Three of the 19 were specifically requested by the Senate Committee on Finance: psychotherapy, which was issued separately as Background Paper #3; diagnostic X-ray, issued as Background Paper #5; and respiratory therapies. The other 16 case studies were selected by OTA staff.

In order to select those 16 case studies, OTA, in consultation with the advisory panel to the overall project, developed a set of selection criteria. Those criteria were designed to ensure that as a group the case studies would provide:

- examples of types of technologies by function (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 (such as general medical practice, pediatrics, radiology, and surgery);
- examples addressing medical problems that are important because of their high frequency or significant impacts (such as 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 informative material relating to the broader policy and methodological issues of cost-effectiveness or cost-benefit analysis (CEA/CBA); and
- examples with sufficient evaluable literature.

On the basis of these criteria and recommendations by panel members and other experts, OTA staff selected the other case studies. These 16 plus the respiratory therapy case study requested by the Finance Committee make up the 17 studies in this background paper.

All case studies were commissioned by OTA and performed under contract by experts in academia. They are authored studies. OTA subjected each case study to an extensive review process. Initial drafts of cases were reviewed by OTA staff and by members of the advisor panel to the project. Comments were provided to authors, along with OTA's suggestions for revisions. Subsequent drafts were sent to OTA for numerous experts for review and comment. Each case was seen by at least 20, and some by 40 or more, outside reviewers. These reviewers were from relevant Government agencies, professional societies, consumer and public interest groups, medical practice, and academic medicine. Academicians such as economists and decision analysts also reviewed the cases. In all, over 400 separate individuals or organizations reviewed one or more case studies. Although all these reviewers cannot be acknowledged individually, OTA is very grateful for their comments and advice. In addition, the authors of the case studies themselves often sent drafts to reviewers and incorporated their comments.

These case studies are authored works commissioned by OTA. The authors are responsible for the conclusions of their specific case study. These cases are not statements of official OTA position. OTA does not make recommendations or endorse particular technologies. During the various stages of the review and revision process, therefore, OTA encouraged the authors to present balanced information and to recognize divergent points of view. In two cases, OTA decided that in order to more fully present divergent views on particular technologies a commentary should be added to the case study. Thus, following the case

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studies on gastrointestinal endoscopy and on the Keyes technique for periodontal disease, commentaries from experts in the appropriate health care specialty have been included, followed by responses from the authors.

The case studies were selected and designed to fulfill two functions. The first, and primary, purpose was to provide OTA with specific information that could be used in formulating general conclusions regarding the feasibility and implications of applying CEA/CBA in health care. By examining the 19 cases as a group and looking for common problems or strengths in the techniques of CEA/CBA, OTA was able to better analyze the potential contribution that these techniques might make to the management of medical technologies and health care costs and quality. The second function of the cases was to provide useful information on the specific technologies covered. However, this was not the major intent of the cases, and they should not be regarded as complete and definitive studies of the individual technologies. In many instances, the case studies do represent excellent reviews of the literature pertaining to the specific technologies and as such can stand on their own as a useful contribution to the field. In general, though, the design and the funding levels of these case studies were such that they should be read primarily in the context of the overall OTA project on CEA/CBA in health care.

Some of the case studies are formal CEAs or CBAs; most are not. Some are primarily concerned with analysis of costs; others are more concerned with analysis of efficacy or effectiveness. Some, such as the study on end-stage renal disease, examine the role that formal analysis of costs and benefits can play in policy formulation. Others, such as the one on breast cancer surgery, illustrate how influences other than costs can determine the patterns of use of a technology. In other words, each looks at evaluation of the costs and the benefits of medical technologies from a slightly different perspective. The reader is encouraged to read this study in the context of the overall assessment’s objectives in order to gain a feel for the potential role that CEA/CBA can or cannot play in health care and to better understand the difficulties and complexities involved in applying CEA/CBA to specific medical technologies.

The 17 case studies comprising Background Paper #2 (short titles) and their authors are:

- Artificial Heart: Deborah P. Lubeck and John P. Bunker
- Automated Multichannel Chemistry Analyzers: Milton C. Weinstein and Laurie A. Pearlman
- Bone Marrow Transplants: Stuart O. Schweitzer and C. C. Scalzi
- Breast Cancer Surgery: Karen Schachter and Duncan Neuhauser
- Cardiac Radionuclide Imaging: William B. Stason and Eric Fortess
- Cervical Cancer Screening: Bryan R. Luce
- Cimetidine and Peptic Ulcer Disease: Harvey V. Fineberg and Laurie A. Pearlman
- Colon Cancer Screening: David M. Eddy
- CT Scanning: Judith L. Wagner
- Elective Hysterectomy: Carol Korenbrot, Ann B. Flood, Michael Higgins, Noralou Roos, and John P. Bunker
- End-Stage Renal Disease: Richard A. Rettig
- Gastrointestinal Endoscopy: Jonathan A. Showstack and Steven A. Schroeder
- Neonatal Intensive Care: Peter Budetti, Peggy McManus, Nancy Barrand, and Lu Ann Heinen
- Nurse Practitioners: Lauren LeRoy and Sharon Solkowitz
- Orthopedic Joint Prosthetic Implants: Judith D. Bentkover and Philip G. Drew
- Periodontal Disease Interventions: Richard M. Scheffler and Sheldon Rovin
- Selected Respiratory Therapies: Richard M. Scheffler and Morgan Delaney

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