Cost Benefit/Cost Effectiveness of Medical Technologies: A Case Study of Orthopedic Joint Implants

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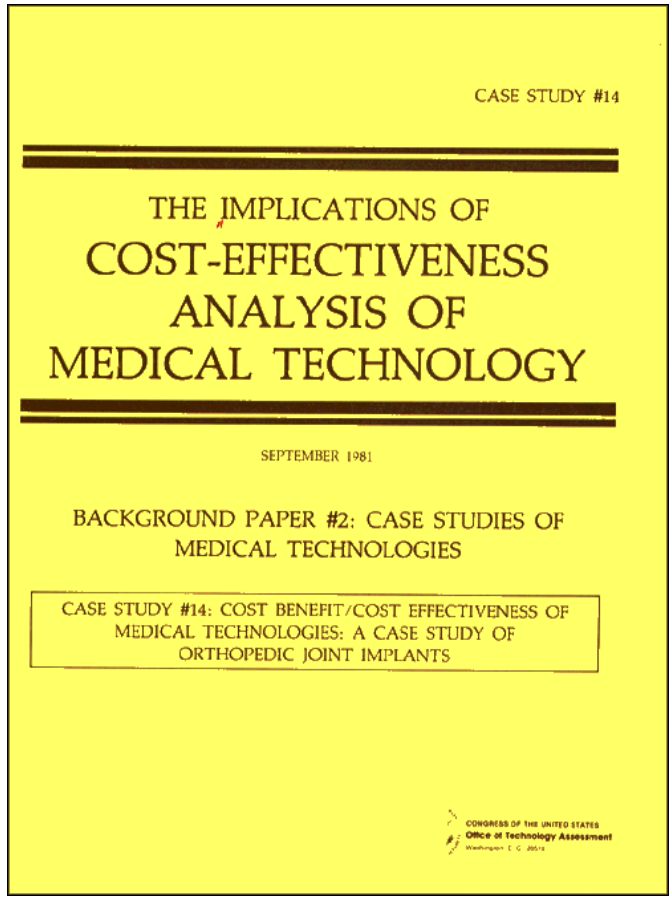

CASE STUDY #14

THE IMPLICATIONS OF COST-EFFECTIVENESS ANALYSIS OF MEDICAL TECHNOLOGY

SEPTEMBER 1981

BACKGROUND PAPER #2: CASE STUDIES OF MEDICAL TECHNOLOGIES

CASE STUDY #14: COST BENEFIT/COST EFFECTIVENESS OF MEDICAL TECHNOLOGIES: A CASE STUDY OF ORTHOPEDIC JOINT IMPLANTS

Judith D. Bentkover, Ph. D.

and

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Arthur D. Little, Inc., Cambridge, Mass.

OTA Background Papers are documents that contain information believed to be useful to various parties. The information undergirds 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.

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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, to be published in summer 1981; and 4) a review of international experience in managing medical technology, published in October 1980. Another related report was published in September of 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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Preface

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 a]], 19 case studies of technological applications were commissioned as part of that project. Three 01 the 19 were specifically requested by the Senate Committee on Finance: psychotherapy, which was issued separately as Background Paper #3; diagnostic X-ray, which will be issued as Background Paper #.5; and respiratory therapies, which will be included as part of this series. The other 16 case studies were selected by OTA staff.

In order to select those 16 case studies, OTA, i n 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 o t her 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 advisory panel to the project. Comments were provided to authors, along with OTA's suggestions for revisions. Subsequent drafts were sent by OTA to 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

*Office of Technology Assessment, U.S. Congress, *The Implications of Cost Effectiveness Analysis of Medical Technology* (GPO stock No. 052-003-00765 7 (Washington, D.C.: U.S. Government Printing Office, August 1980).

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 forma] 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 feeling 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

These studies will be available for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. Call OTA's Publishing Office (224-8996) for availability and ordering information.

Case Study #14

Cost Benefit/Cost Effectiveness of Medical Technologies: A Case Study of Orthopedic Joint Implants

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AUTHORS' ACKNOWLEDGMENT

The authors would like to thank Don Shepard at Harvard University for his helpful comments on earlier drafts of this case study.

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STATEMENT OF PURPOSE, SCOPE, AND APPROACH

The purpose of this study is the assessment of the feasibility and potential usefulness of undertaking cost-effectiveness/cost-benefit analysis *(CEA/CBA)* of orthopedic joint prostheses. The two specific questions that we address are the following:

- Is it feasible to carefully and completely evaluate the orthopedic joint implant technology within a CEA/CBA framework?
- How could such an evaluation be useful in formulating public policy (e.g., regarding reimbursement practices, research and development funding, safety and efficacy regulation, capital controls, and medical manpower distribution)?

To investigate these issues, we first examine technical feasibility by surveying what is known about orthopedic joint implants and identifying what must be ascertained in order to apply a CEA/CBA framework. We gauge technical feasibility by examining answers to the following questions:

- Is it possible to describe the present state of orthopedic joint implant technology?
- Is it possible to define the target population?
- Is it possible to identify and quantify the costs associated with the diffusion of this technology?
- Is it possible to determine (and quantify, in the case of CBA) the benefits associated with the diffusion of this technology?
- What are the limitations and constraints of CEA/CBA of orthopedic joint implants?

Next, we investigate the issue of usefulness of CEA/CBA of orthopedic joint implants. The analysis of this issue answers questions such as the following:

- How are policies regarding orthopedic joint implants currently developed?
- How do the limitations and constraints of CEA/CBA affect its use in the formulation of public policy directed towards orthopedic joint implants?
- In view of the answers to the foregoing questions, what is the feasibility of expanding and integrating the use of CEA/CBA of orthopedic joint implant technology in existing public policy decisionmaking systems?

Finally, we identify useful directions for future policy research efforts.

Our approach to investigating the topics listed above included a review of the literature, personal communication with selected medical

specialists with relevant experience, and conversations with representatives of the orthopedic prosthesis industry. Although our foci were the feasibility and potential usefulness of CEA/CBA of orthopedic joint implants, our efforts often resulted in our answering specific questions that in themselves are components of a CEA/CBA study. In discussing our results, we include this information, because it provides interesting and valuable insight and obviously supports our conclusions regarding feasibility. We recognize, however, that the result is a certain implied emphasis on topics for which information is readily available. Therefore, we caution the reader to keep this in mind.

TECHNICAL FEASIBILITY OF CEA/CBA OF ORTHOPEDIC JOINT IMPLANTS

Overview of Orthopedic Joint Implant Technology

The current state of the art and the chronological development of orthopedic joint implant technology are well documented and extensively described in the literature. Considered as an entity, orthopedic joint implant technology is thought to be fairly well developed. Specific prostheses and implant procedures associated with some joints (e.g., hips), however, are more advanced than others (e.g., elbows). The salient features of orthopedic joint implant technology and the history of its development are briefly reviewed below.

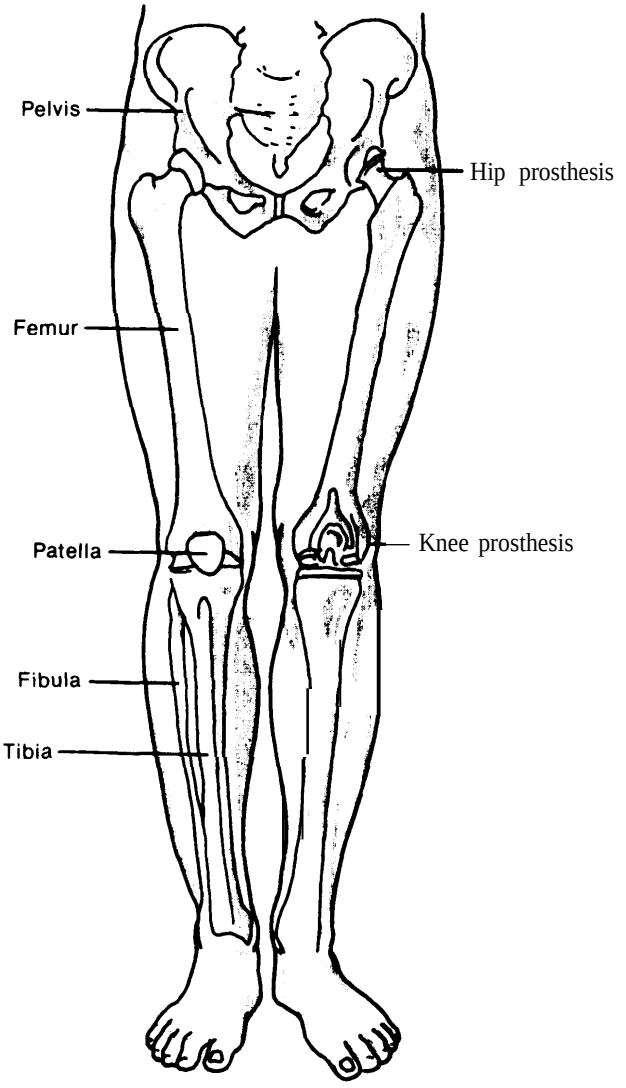
Description of the Technology

Orthopedic joint implants replace with artificial components one or more of the essential elements of a joint—namely, the two ends of the articulating bones and the antifriction pad between them. Muscles, tendons, and ligaments are attached to various remaining natural structures, so that the joint can function with only minor restrictions. Figure 1 shows the location of hip and knee prostheses. Sketches of artificial hip and knee joints appear in figures 2 and 3, respective y.

At the time of this writing, the Food and Drug Administration's (FDA) Orthopedic Panel has identified 28 types of orthopedic implants (see table 1). Depending on their complexity and potential for doing harm, medical devices are classified into one of three groups:

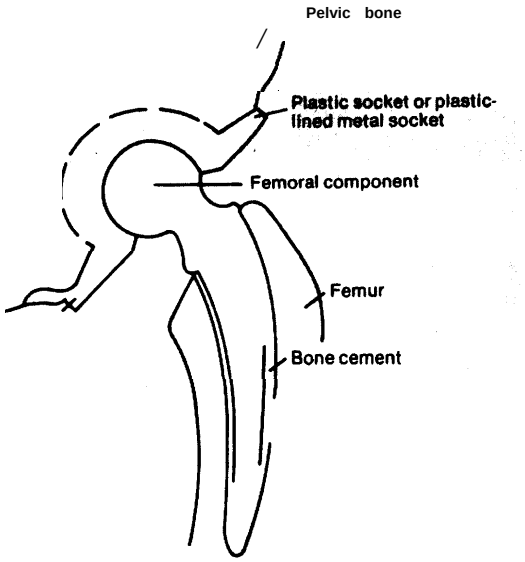
Class 1: Those requiring only general controls (e.g., adherence to good man-

Figure 1.— Location of Hip and Knee Prostheses



SOURCE: *Scientific American,* January 1978.

Figure 2.—Detail of Hip Prosthesis



SOURCE Arthur D Little, Inc

ufacturing practices.

Class II: Those subject to performance standards.

Class III: Those requiring premarket approval from FDA in the manner of drugs.

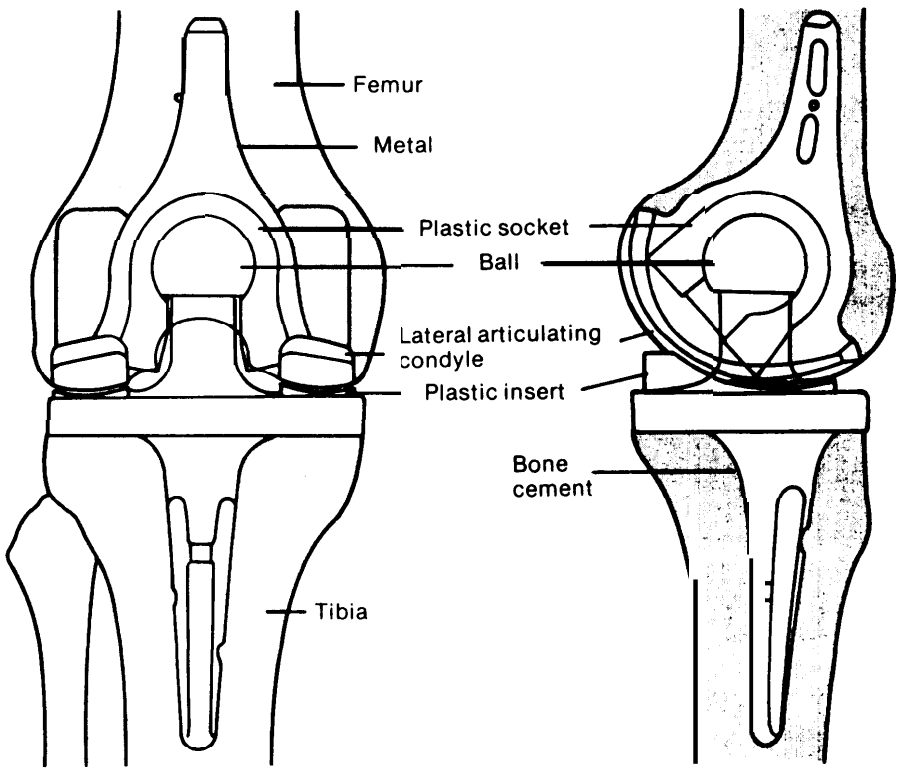
All of the 28 types of implants identified in table 1 are Class II devices, except the shoulder prosthesis, which is considered a Class III device.

Orthopedic joint implant procedures are major operations which last several hours and are done under total anesthesia. Such operations are performed both to relieve arthritic pain, which is often severe, unremitting, and incapacitating, and to restore function of a joint impaired by various kinds of arthritis, bone disease, or trauma.

History of the Technology

The modern era of orthopedic joint prostheses began in 1962 in England. In that year, Sir

Figure 3.— Detail of Knee Prosthesis



SOURCE *Scientific American*, January 1978

Table 1.—Types **of Joint Implant Prostheses**

Ankle, 2-part metal on plastic articulation, semiconstrained carpal
Diaphysis, custom
Elbow, constrained
Elbow, nonconstrained, unipolar
Elbow, semiconstrained
Finger and toe
Hip, met stem-ceramic self-locking ball-ceramic or PE cup
Hip, acetabular component, metal cemented
Hip, acetabular component, nonpolyethylene
Hip, acetabular mesh
Hip, cement restrictor
Hip, femoral component, cemented, metal
Hip, 4-part plastic-metal-plastic-metal, trunnion bearing type
Knee, constrained (metal-polyethylene)
Knee, hinged (metal-metal)
Knee, metallic plateau
Knee, mold arthroplasty
Knee, nonconstrained (metal-polyethylene)
Patellar (metal)
Posterior patellar surface, plastic
Shoulder
Tendon, passive
Upper femoral
Upper humeral
Wrist, polysiloxane
Wrist, 2-part metal-plastic articulation, semiconstrained
Wrist, 3-part metal-plastic-metal articulation, semi constrained

SOURCE Arthur D Little Inc Cambridge, Mass 1980

John Charnley introduced techniques for total hip replacement using a metal component inserted in the medulla of the femur and a polyethylene cup replacing the acetabulum or femoral socket. Both components were held in place with methyl methacrylate, which behaves as a cement and distributor of stresses.

Since 1962, the hip replacement operation has undergone considerable development. In addition to the use of new materials, modified designs, and different techniques, there has been a refinement of the indications for the operation. There has also been a proliferation of orthopedic surgeons trained in the technique. Until 1971, hip implantations performed in the United States were largely experimental and done only in teaching centers. However, after FDA released methyl methacrylate as an acceptable substance in this application, the number of hip implantations performed annually increased about 20 percent per year. Currently, it is estimated, at least 100,000 total hip replacements are done in the United States each year, many of them at community hospitals (2).

Stimulated by the success of the hip operation, orthopedic surgeons and engineers have recently addressed replacement of other joints with similar prosthetic devices. They have met with considerable success in the use of knee prostheses in the past 5 years or so, and it is estimated that perhaps 50,000 knee replacements are now done annually in the United States (2). Prostheses for the elbow, shoulder, wrist, fingers, and toes exist, but replacements of these joints are much less common (12,000 per year) than those of the hip or the knee, partly because the afflictions they relieve are much less debilitating than those of the hip or knee (33).

As the oldest and most common orthopedic joint operation, hip replacement is the most completely characterized. There is voluminous literature discussing several attributes of the hip operation, including comparisons of material, mechanical design, indications, contraindications, epidemiology, costs, success rates, failure modes, failure rates, techniques, etc. The techniques and results of the operation are still vigorously discussed, but it is widely agreed that total hip replacements done by skilled surgeons in properly equipped facilities on properly selected patients have a high (85 to 90 percent) probability of success in relieving pain and restoring the hip to full functional capacity for the normal activities of middle-aged and elderly adults.

Although Charnley's original approach to hip implantation has remained, various improvements in details of design have been made. These include the use of other metals (e.g., cobalt steel and titanium) in place of stainless steel and other polymers for the joint. Techniques used to prepare bones for prostheses have been the subject of considerable experimentation. Methods for avoiding complications have been developed as complications have been discovered. In the early days, infection rates sometimes ran as high as 10 percent, Now, however, through the strict adherence to sterile procedures, infection rates, at least in some centers, have been held to 1 percent. There is

some hope that impregnating the methyl methacrylate with antibiotics such as gentamycin can reduce infections still further. This technique is used in Europe, but FDA has not yet approved it for use in the United States. Techniques to prevent loosening of implants have been explored, but loosening remains the most common failure, Though sometimes asymptomatic, such loosening is believed to be the precursor to most mechanical failures. Mechanical failures have been reduced through better engineering design of prostheses.

Arriving at the current state of knowledge about hip implants has required considerable experimentation and experience. Some of this has been supported by Federal agencies such as FDA and the National Institutes of Health (NIH) in the United States and similar agencies abroad. Much of it, however, has been undertaken at the initiative of orthopedic surgeons and biomedical engineers in academic settings and elsewhere. Approximately nine commercial firms in the United States supply the parts and instruments used in hip implant surgery (see table 2). These firms have contributed some of the knowledge concerning materials, manufacturing, and finishing. In particular, industry has been responsible for developing manufacturing techniques for these devices. [1]

The state of knowledge about joint prostheses other than hip is relatively less advanced. Knee implants are the second most common type, but less experience has been accumulated with these than with hip implants. Furthermore, failures of knee implants are more frequent, in part because the mechanics of the knee are more complicated than those of the hip. (There are now over 80 different knee designs, indicating that the field is by no means so well established as that for hips.) Prostheses for other joints (e.g., finger, toe) are much less common, and relatively little clinical experience with them has been gained.

[1] Design of orthopedic prostheses is something of an art, since their engineering properties, in terms of the forces to which they will be subjected and the stresses they will impart to adjacent bone and ligament, are somewhat unpredictable. For this reason, various orthopedic surgeons have created their own designs: successful designs, associated with the surgeon's name, are often the basis of a manufacturer's product line.

Table 2.— Profile of the Orthopedic Joint Implant Industry

Company	Estimated sales of joint implants in the United States in 1980 ($ millions)
Zimmer(owned by Bristol Meyers)	$45
Howmedica (owned by Pfizer)	35
DePuy (owned by Biodynamics)	12
Richards (owned by Rorer)	5
Dow Corning Wright (owned by Dow Corning)	4
Cintor(owned by J & J)	3
Orthopedic Equipment Co.	3
3M (Minnesota Mining and Manufacturing)	2
U.S. Surgical Corp.	1
All others	4
Total	$114

SOURCE Arthur D Little, Inc , Cambridge, Mass , 1980

In general, orthopedic joint implant technology can be characterized as being relatively mature. Fairly detailed literature pertaining both to the nature of the operations and the original development of the technique of joint replacement is available.

Orthopedic joint implant technology may illustrate many of the features of applying CEA/CBA to a rehabilitative technology (e.g., target population, nature of the benefits, public policy implications). Nevertheless, it is important to remember that orthopedic joint implant technology includes a variety of procedures at various stages of development. In this case study, an attempt is made to provide general information about orthopedic joint implants; where it is necessary to illustrate a specific point, the appropriate specific prosthesis or set of prostheses is discussed. Since the focus of the study is on issues inherent in the application of CEA/CBA to orthopedic joint implant technology, no attempt is made to analyze exhaustively the technology associated with the implant of any single limb.

Identification of the Target Population

Aggregate Data

The literature and readily accessible aggregate data do not reveal the orthopedic joint implant target population per se. As discussed below,

however, there are data that permit pertinent inferences.

Orthopedic joint implants are used to relieve various arthritic conditions, so the prevalence of arthritis and rheumatism provide an upper limit to the number of persons who could be candidates for joint replacement. Orthopedic joint implant procedures are major operations, carrying some risk of mortality or aggravated morbidity, however, so it is not likely that persons with mild arthritic conditions or arthritis of joints that does not create significant impairment would undergo surgery.

According to the National Health Interview Survey (46) of the National Center for Health Statistics (NCHS), the number of people with limitation of activities due to chronic arthritis and rheumatism in the United States in 1974 was 4,500,000. Of these individuals, 800,000 suffered limitation of activities other than major activity; 2,600,000 suffered limitation in amount or kind of major activity; and 1,100,000 were unable to carry on their major activity. Individuals with arthritis and rheumatism account for 15 percent of all persons with activity limitation and 16 percent of all persons unable to perform their major activities.

Among individuals 65. years and over, arthritic and rheumatic conditions account for 23 percent of all persons with limitation of activity. They are the second leading cause of activity "limitation, exceeded only by heart conditions (24 percent). Among white persons, the same trend is apparent. Arthritic and rheumatic conditions are the second leading cause of activity limitation (15 percent), exceeded only by heart conditions (16 percent). Among nonwhites, arthritis and rheumatism account for 17 percent of persons with activity limitation. These conditions are more debilitating among nonwhites than they are among whites.

Thus, arthritis and rheumatism are leading causes of activity limitation for both a substantial proportion of the population-at-large and several specific population cohorts. As the population ages, the number of persons limited in activity by arthritis and rheumatism can be expected to increase.

Disaggregate Data

The literature and existing disaggregate data are disappointing in that the target populations for specific types of orthopedic joint implants are not explicitly identified. However, future definition of relevant population cohorts may be possible by considering the indications and contraindications for joint implant surgery vis-a-vis discharge abstract data containing diagnostic information. Indications and contraindications are briefly reviewed below.

- *Indications.* —The principal conditions amenable to joint replacement are osteoarthritis, rheumatoid arthritis," ankylosing spondylitis, other arthropathies, and sequelae of trauma, neoplastic destruction, and other pathology of the joints. Pain is usually the primary reason for operating, but limited range of motion and gait disturbances may also be important. There is obviously room for judgment about the degree of pain or limits of motion as indications for the operation.
- *Contraindications.* —Existing infection of the joint is generally a contraindication, though some success has been reported abroad with gentamycin-impregnated cement. Excessive damage may make success improbable, as in the case when osteoporosis has progressed too far for the bones to hold the prosthesis reliably. The presence of other disease making it. difficult for the patient to withstand a major operation may also be a contraindication.

Data on the Frequency of Joint Implant Operations

Additional insight into the identification of target populations is provided by data depictin$_g$ the frequency of previous implant operations. The frequency of joint implant operations has been estimated to be 100,000 hip replacements per year, 50,000 knee replacements, and 12,000 replacements of other joints (2).

A review of the literature on orthopedic joint implants reveals that the total number of joint replacement procedures performed annually in the United States has never been reported. How-

ever, to compute an estimate of this number, data can be obtained from a number of sources and then aggregated.

The Office of Research and Statistics, Division of Health Insurance Studies, Health Care Financing Administration (HCFA), has statistics consisting of a 20-percent sample of medicare recipients who were discharged from a short-stay hospital (a hospital where the average length of stay is 30 days or less). These data indicate when an orthopedic joint implant procedure was the major surgical procedure being performed. By multiplying the number of orthopedic joint implants derived from these data by a factor of five, one can produce an estimate of the total number of operations for patients 65 and over.

The number of artificial hip implants for patients of various ages is available for a sample (33 to 42 percent, depending on the year) of U.S. hospitals from the Commission on Professional and Hospital Activities (CPHA) in Ann Arbor, Mich. These data can be extrapolated to national totals by multiplying the published Professional Activities Survey (PAS) data by the reciprocal of the percentage of the national total of patient discharges that PAS hospitals constitute. Then, the ratio between patients of all ages receiving total hip implants v. patients older than 65 receiving these implants can be derived. The estimated total of patients age 65 and over (as calculated above) can be multiplied by this ratio in order to compute the estimated total number of patients receiving total hip implants. Unfortunately, since PAS data do not identify implant procedures for joints other than the hip, it is not possible to estimate the frequency of all orthopedic joint implants in the same manner.

The number of artificial hip implants performed in Veterans Administration (VA) hospitals can be obtained from the VA central office and added to the medicare total to give an estimate of the national total of hip implants each year. To the extent that patients eligible for but not taking advantage of medicare are not included, this total is likely to slightly underestimate the actual total.

Prior to 1971, the cement methyl methacrylate was regulated by FDA as an investigational new drug, so all cases in which it was used were reported to FDA, and there was an accurate record of the frequency of implant procedures. Since that time, however, the amount of reporting has not been growing rapidly, although the literature reveals that the number of operations on hips and knees has. According to industry sources, in 1978, some 200,000 prostheses were sold annually.

At present, there are about 11,000 board-certified orthopedic surgeons in the United States. As this number increases (and orthopedic joint implants remain the most efficacious long-run means of alleviating the limitations imposed by arthritis), the frequency of orthopedic joint implants and perhaps the number of persons comprising the target population may increase. Also, as the prostheses and surgery become more refined, the number of contraindications may diminish and similarly promote a larger target population.

The Emergency Care Research Institute, in Philadelphia, is about to complete a study for FDA based on a survey of experience at approximately nine representative hospitals. This study will provide additional data on the frequency with which joint implant procedures are undertaken.

Specification of an Analytical Framework

CEA and CBA are both useful, widely applied analytical techniques, but CEA is more amenable than CBA to assessing the technology of orthopedic joint implants. There are two reasons. First, although both these techniques require the identification and quantification of costs, only CBA necessitates placing a value on the benefits associated with the reduction in pain, suffering, and impairment—the improvement in quality of life—for a predominantly nonworking population. Second, CBA usually involves the consideration of systemwide effects. Thus, for example, CBA would require assigning value to the effect on the economy of having a less impaired, older population.

Although economists have long been considering the problems associated with the valuation of these benefits in connection with CBA and other analyses, to date, no solutions have been developed. In this section, therefore, we develop a cost-effectiveness analytical framework within which the technology of orthopedic joint implants can be assessed in accordance with the present state of knowledge. (For the sake of completeness, benefits are described, although not quantified, in a subsequent section.)

Cost-effectiveness ratios (C/E) for orthopedic joint implants, expressing the *net* medical expenditure per year of healthy life gained by an individual undergoing an orthopedic joint implant procedure, can be computed with the following formula:

$$C/E = (C_{oji} - C_a + C_c) / (E_m - E_c)$$

where:

C/E = net cost-effectiveness ratio
C_{oji} = costs associated with orthopedic joint implant procedures
C_a = costs associated with the treatment of arthritic and other individuals that would be prevented by orthopedic joint implant procedures
C_c = costs associated with the treatment of complications of orthopedic joint implant procedures
E_m = quality-adjusted life years of morbidity prevented by orthopedic joint implant procedures
E_c = quality-adjusted life years of morbidity and mortality associated with complications of orthopedic joint implant procedures

Separate cost-effectiveness ratios can be calculated for different types of orthopedic joint implants and for population cohorts of various ages as bases for evaluating alternative courses of action in relation to investment in different research projects and reimbursement policy formulation.

The cost-effectiveness ratios that are generated by using the equation cited above depend on the assumptions that are made about the value of several cost and effectiveness variables. Note, for example, that the effects of orthopedic joint implants are expressed in a single-index, quality-adjusted life years (QALYs).[2] To compute QALYs, different disability/impairment states are assigned rankings along a continuum which ranges from death, on the one extreme, to full functioning, on the other. The measure of net effectiveness in the equation above incorporates both the notion of the expected gains associated with increased functional status and the concept of potential risk. The determination of weights or various values for different disability states poses a problem for the researcher, Another problem associated with the use of QALYs are the distributional effects implied by attributing the same value to years of disability-free life gained by individuals of different ages. Obviously, younger persons would necessarily have better cost-effectiveness ratios than older persons.

Both of these problems have been discussed in the literature, and solutions, albeit imperfect ones, can be found there. Weighings for different health states were derived by Bush, Chen, and Patrick (13) and used by OTA (48). Shepherd (60) and Larson (36) designed methods for assessing the results of hip surgery. The Shepherd system is difficult to use because it does not integrate function with motion and does not assign a single overall value; thus, interpersonal and intertemporal comparisons are difficult. The Larson system yields a single value, but has been criticized as lacking sensitivity y.

Another weighting scheme to evaluate the results of hip implants integrates pain, function, range of motion, and the absence of deformity was developed by Harris (30). This method, which integrates pain, function, range of motion, and the absence of deformity, has much intuitive appeal and is likely to be adaptable to the analysis of the results of other orthopedic joint implant procedures. On the premise that pain and functional capacity constitute the indications for surgery in the vast majority of patients, Harris devised a point scale with four categories and a maximum of 100 points: pain (44 points), function (47 points), range of motion (5 points), absence of deformity (4 points).

Within each category, gradations are possible. Thus, for example, “slight” pain (defined as “occasional ache or awareness of pain of low grade, no compromise of activities”) is allotted 40 points; “marked” pain (described as severe at

[2] QALYs were developed by Zeckhauser and Shepard (72) and have been used in much subsequent public policy research.

times, but not precluding ambulation) is allotted 10 points. Similarly, function is broken down into two series: daily activities (14 points) and gait (33 points). Motion is described in accordance with an index based on preference and value; based on the assumption that the first 450 arc of flexion is of more value than the arc from 900 to 13$0^{0}$, the former receives a higher index value. Finally, the 4 points given for the absence of deformity are all eliminated in accordance with a set of predetermined criteria (e.g., permanent flexion contracture greater than 300, fixed adduction of more than 10 O).

Further research might incorporate another similar benefit measure, the sickness impact profile (SIP), a health status indicator reflecting social interaction, ambulation, sleep, nutrition, usual daily work, household management, mobility, body movement, communication activity, leisure, intellectual functioning, family interaction, emotions, and personal hygiene (8). The use of the SIP measure would have to be undertaken via surveys in order to assess the benefits of orthopedic joint implant patients.

Identification and Quantification of costs

As is fairly common in economic cost studies, it is useful to classify costs associated with the diffusion of orthopedic joint implants into two categories: direct and indirect.

Direct Costs

Direct costs include expenditures for materials and services associated with orthopedic joint implants. Since specific data quantifying the total direct costs of various types of orthopedic joint implants do not exist in a convenient format, one would probably employ a "bottom-UP" (aggregative) approach to estimate these costs. [3]

Such an approach involves three steps:

1. Ascertain utilization of specific services and supplies.
2. Determine unit costs for each resource identified in the first step.
3. Multiply quantities of resources utilized by their unit costs to determine resource expenditures; then aggregate similar expenditure components to obtain categorical totals.

The utilization of specific services (e.g., number of days of hospitalization) often varies with patient age and perhaps sex, so utilization estimates should be developed with specific regard to patient age group and sex. Direct costs projected to occur at future time periods should be appropriately discounted (discussed later), and all such future follow-on costs should be adjusted for patients' survival probabilities. The identification of resources utilized (both type and quantity) can be largely accomplished by reviewing the literature identified in the bibliographic references at the end of this case study. (Professional judgment can be employed for further clarification or to fill any gaps.)

Unit cost data could be compiled so as to reflect geographically representative prices. Pertinent regional data exist in the American Hospital Association's *Guide Issue* and *Hospital Statistics* (hospital costs); *Medical Economics* (physician fees); California Relative Value Scale (physician fees); Medicare Survey published in New *England Journal of Medicine*, May 13, 1976 (physician fees); HCFA's *Invoice-Level Price Survey* (drug costs); IMS American, Ltd., National Prescription Audit (drugs); the Na-

[3] The other method used in estimating the direct costs, the "top-down" (disaggregative) approach, begins with aggregate total expenditure estimates by type of expenditures (e. g., hospital, physicians' services). For each type of expenditure, the total is then distributed, by diagnosis, by using utilization and cost estimates from various sources. This method of calculating direct costs is most common in studies whose primary purpose is to estimate aggregate costs of illness by broad diagnostic category. Excellent expositions of this method and examples of its use are found in Rice *(54)* and Cooper and Rice (17).

As one might imagine, the major difficulties with this approach arise from the quality of available data used to distribute total expenditures related to a given diagnosis. For example, it would be necessary to distribute diagnostic-related expenditures (for arthritis) in accordance with the frequency of surgical v. medical treatment. The availability of data necessary to implement this approach is not readily apparent. Furthermore, although associated conditions or multiple diagnoses do affect length of stay, diagnostic distribution of days of hospital care is based on primary diagnosis. Also, several different data sources are often used in distributing hospital care expenditures by diagnosis depending on the particular type of hospital in which patients receive care (e. g., Federal, long-term, non-Federal)

tional Ambulatory Care Survey of NCHS (outpatient followup and chronic care costs).

In the event that long-term nursing home care or home care is identified as a relevant resource for a particular population cohort, pertinent cost information can be obtained from available Federal documents (e.g., 11). Finally, the cost of the prosthesis can be obtained from industry data. (The procurement of hospital charges associated with various orthopedic joint implant procedures from the Social Security Administration's 20-percent sample of medicare recipients, CHAMPUS, NCHS, or PAS discharge abstract data is worthy of future investigation.)

In order to demonstrate the aggregative costing methodology just described, we generate a very crude estimate of the initial direct cost of a hip, knee, ankle, shoulder, or elbow joint implant below. This estimate is based on resource needs identified in the literature and typical values.

Surgeon's fee	$1,000
Operating room fees	500
Anesthesiologist's fee	200
Prosthesis	500
20-day stay at $200 per day	4,0004
Miscellaneous	400
Total initial direct cost	$6,600

A toe or finger joint implant requires a shorter hospital stay, so the total initial direct cost would be slightly lower,

Other pertinent direct cost components include the cost of followup and, occasionally, rehabilitation therapy. The resource needs associated with these cost components would probably have to be estimated by medical experts and costed out by using existing hospital and provider data. Hospital and provider data must be derived from a variety of sources. The use of these data implies the necessity of having to deal with the inconsistencies imposed by differences between costs and charges as well as by variations in reporting techniques. Consequently, a well-defined, consistent set of assumptions is necessary in order to "merely aggregate costs. "

[4]It should be noted that the unit cost estimate reflects charges, which do not represent true cost estimates.

Direct costs must include the expected value of a complication and thereby account for the necessity of patients' having further medical treatment. This value can be calculated on the basis of data that present the frequency of various complications (by population cohort) and the direct cost of such complications.

Indirect Costs

Indirect costs associated with orthopedic joint implants include productivity losses that result from patients' spending time in the hospital and recuperating at home and from the patients' family and friends spending time visiting in the hospital, etc. Typically, such time is valued by lost earnings and lost household production data. These data are readily available in a study by Mushkin, et al. (45). Earnings foregone due to premature death also comprise indirect costs. These data, too, are available in the Mushkin study.

Complications

Both direct and indirect costs must include costs of any lack of safety and resulting presence of complications associated with orthopedic joint implants. Expected values of the direct and indirect costs associated with complications must be included in the estimate of total cost.

The literature suggests that much is known about safety of joint implants. The materials—metal, plastic, and cement—now have a long period of use behind them and only mild evidence of toxicity, quite commensurate with the benefits. Cemented bones sometimes resorb (dissolve) for reasons that are not well understood. Delayed infections are thought by some to be the consequence of sepsis (infection) originating elsewhere in the body, but most believe it is the consequence of bacteria introduced at the time of operation. Followups must be long-term—2 or 3 years is not long enough—and later occurring infections have been known to arise after 8 years. However, most failures, except infections and ultimate loosening of the implant, become evident in the early months.

Complications with hip replacement are well documented, and means for avoiding them are

well established. Nevertheless, even the "best centers" have not succeeded in eliminating these complications entirely. In addition to facing the risks associated with any major operation, patients with hip replacements have a higher incidence of thromboembolitic problems, although mortality from this cause is only about 1 percent. Deep wound infection occurs in 1 to 2 percent of patients (and may occur very late—cases up to 8 years after the operation have been reported). Loosening of the femoral component is relatively common—estimates run as high as 20 percent of all patients—though in many cases the patient remains asymptomatic. Occasionally, the femoral component itself fails. Other complications of joint replacement include loosening, dislocation, neurovascular deficits, periarticular calcification, nonunion of cut bone, malposition of components, fractures, and discrepancy in limb lengths. Reoperations are often, but not always, possible.

It should be noted that R&D costs are not and should not be included in the specification of relevant costs. R&D costs are already sunk costs; they are not incurred as the given technology diffuses.

Determination of Benefits

The benefits that accrue to patients successfully undergoing orthopedic joint implantation include intangible personal gains in terms of increased self-esteem and decreased pain and suffering, as well as economic savings realized by increased income and reduced illness-related expenditures. It is convenient to categorize benefits in the same way as costs: direct and indirect.

Direct Benefits

Benefits pertaining to the relief of pain have been described by Harris **(29).** He compared the preoperative and postoperative prevalence of five categories of pain, ranging from severe to none, among 124 patients with hip implants. Fifty of the 124 reported severe pain preoperatively; only 1 of them (with pain secondary to a sciatic palsy) complained of severe pain after the operation. Preoperatively, only 1 patient reported no pain; 106 patients claimed no pain postoperatively.

Examining functional status, Harris (29) compared the preoperative and postoperative overall evaluation ratings of the 124 hips with followup periods of 6 months or longer. The average preoperative score was 44.3 and the average postoperative score was 92.3, substantial change. In fact, all but a single patient reported a significant improvement. In terms of support required, the number of individuals requiring no support increased from 23 preoperatively to 114 postoperatively. In terms of distance walked, preoperatively, 15 individuals claimed the ability to walk an unlimited number of blocks; postoperatively, 114 individuals asserted the same ability. Finally, in terms of having a limp, **50** patients classified their limp as severe preoperatively, and only 1 patient complained of this problem postoperatively.

In order to ascertain monetary benefits, it is necessary to take account of the heterogeneity of the population undergoing surgery. On the basis of several sources (Charnley in 1972 and Ring in 1974, as described by Taylor (65)), we can separate the population into three groups: 1) persons under 60 years (30 percent); 2) persons aged 60 to 70 (42.5 percent); and 3) and persons aged 70 or older (27.5 percent). The most significant economic benefits based on earnings accrue to those individuals in the preretirement group (i. e., the first group and half of the second group), although there is an underestimation of the savings accruing to females. If we use income data that value household production and take account of labor force participation rates, productivity increases, and mortality trends (45), we can obtain a fairly good estimate of the benefits accrued as a result of alleviating disabled and handicapped persons.

Benefits paid to those incapacitated with rheumatism and arthritis are transfer payments and therefore should not be measured as part of the real (resource) cost to the economy. However, they do merit consideration as an indication of the amount of economic assistance society is offering potential recipients of orthopedic joint implants. These benefits include appropriate payments under the following programs: Old Age, Survivors, and Disability Insurance;

Aid to the Permanently and Totally Disabled; Veterans Administration Annual Compensation and/or Pension.

Indirect Benefits[5]

Indirect benefits associated with joint implants primarily consist of the savings that result from averted expenditures on caring for the individuals who without an implant would have been handicapped by their arthritis. They also include additional savings that result from averted drug and equipment expenditures associated with arthritis. Data concerning these can be derived from information contained in a study of the economics of arthritis by Nuki, Brooks, and Buchanan (47). More recent information can be found in unpublished and published data from the Health Interview Survey of NCHS.

Success and Efficacy

Both direct and indirect benefits must take account of both the expected success of the implant procedure and the efficacy of the orthopedic joint implant.

It has been observed, though not reliably documented, that success rates are higher with surgical teams who do joint implantations frequently, and who presumably, therefore, have more skill and experience (4). Because deep infections are a more frequent and severe complication in joint implantation operations than in others, adherence to rigorous standards of asepsis is very important. Adherence to such standards requires properly equipped facilities and properly trained staff, and these requirements are sometimes used as arguments to support confining joint implantation operations to selected centers.

Hip implants are said to be efficacious—that is, to yield good to excellent results in relieving pain and restoring nearly normal function—in 85 to 90 percent of the cases undertaken (26, 27). Knee implants have almost as good a record—relief of pain in 90 percent of the cases, deep infections in O to 7 percent, and an overall failure rate of 7 to 22 percent after 2 years (18).

The aforementioned figures are drawn from review articles, which in turn are the product of long series of results. Charnley is still active in the field, and his early patients provide the longest term data. Many of the clinical trials of orthopedic joint implants are simply voluntary submissions by surgeons of a long series of their patients. As a result, it is often difficult to identify the sources of differences in outcome among different groups.

Focus on Average Rather Than Marginal Effectiveness

The focus of CEA/CBA of orthopedic joint implants is on average effectiveness, a measure which assumes that benefits and/or effectiveness are equally distributed among all persons included in the computation of a single ratio, Marginal effectiveness, a concept which refers to the benefit and/or effectiveness derived from the last orthopedic joint implant recipient, is likely to be less than average effectiveness, because the people who are likely to derive the greatest benefit from orthopedic joint implants are likely to receive prostheses earlier than others for whom the potential benefit is not as great.

In order to remove this constraint from the analysis, it would be worthwhile to perform CEA/CBA separately for different population cohorts.

Regression to the Mean

Another limitation inherent in CEA/CBA of orthopedic joint implants is the complication of the interpretation of the results due to the regression-towards-the-mean phenomenon. This phenomenon is the tendency exhibited by pain or functional status indicators that are selected for a group of patients on the basis of extreme values that may reflect a fluctuating component. Thus, the actual fluctuation of pain and functional status may obscure the difference between preoperative true v. observed values. For example, if there are substantial ranges

[5] In the cost-effectiveness framework described above, these indirect benefits offset (and are therefore subtracted from) the cost of the orthopedic joint implant procedure.

associated with the definition of two health status disability or functional impairment categories, incorrect inferences would result from a comparison of the higher boundary of the low range with the lower boundary of the higher range. This situation is likely to occur when arthritis victims experience both pain-free, unimpaired days and painful, disabled days. Obviously, a before-and-after comparison yields results that are very dependent on the value assigned to the before period.

Shepard and Finison (58) review methods of removing the effect of regression towards the mean. Many of these have practical—often ethical—difficulties. From a theoretical point of view, the best procedure is to identify a randomly assigned control group of patients who would not be offered orthopedic joint implants. A more ethically acceptable, albeit more costly, method is to obtain a series of measurements and average them. Shepard and Finison suggest an alternative approach that builds on systematically collected data from large samples of longitudinal research studies. Their work suggests that it is possible to derive estimates of statistical regression and thereby obtain a meaningful baseline indicator to determine the effects of orthopedic joint implants.

Placebo Effect

The interpretation of benefits might be further obscured by the placebo effect. In particular, it is possible that the benefits of orthopedic joint implants are overstated by the value of benefits equivalent to the value of those which are associated with any "treatment" (e.g., a bone scraping).

USEFULNESS OF CEA/CBA OF ORTHOPEDIC JOINT IMPLANTS

Present Policy Formulation

At the present time, orthopedic joint implant technology is regarded in much the same manner as other surgical procedures. Since it does not require a substantial investment ($150,000) in capital equipment, it is not affected by capital controls, except to the extent that the building of additional operating room facilities are affected. In most cases, there are operating rooms fairly well equipped to handle orthopedic joint implant procedures; hence, the marginal cost associated with this procedure is very low. The materials and devices used in the procedures are subject to FDA regulation.

Effect of Limitations and Constraints of CEA/CBA on Its Usefulness in Public Policy Formulation

Imperfect Substitutability of Alternatives to Orthopedic Joint Implants

The alternatives to joint implantation are analgesics and other drugs, aids to ambulation, and physical therapy. Rheumatoid arthritis can be treated with a variety of drugs, none of them very satisfactory. Osteoarthritis in its early stages can be relieved by analgesics, but there are no effective medical treatments for its advanced stages. Arthritis of all kinds tends to become progressively worse with time, so conservative medical treatment is almost always appropriate at first. Eventually, however, patients with these afflictions become candidates for surgery. The stage at which surgery is appropriate depends on many factors—age, general health, lifestyle, degree of impariment, response to analgesics, etc. Surgeons emphasize the matter of staging (particularly with rheumatoid arthritis, which is a systemic disease)—not operating on a hip, for instance, until problems with the knee and ankle have been brought under control.

Thus, although there are short-run alternative treatments, in the long-run, only orthopedic joint implants restore functional and pain-free status. Consequently, unless the analytical time horizon (i.e., short-run v. long-run) is specified, the policy implications of CEA/CBA results are not clear and may even be misleading.

Arbitrary Selection of a Policy Decision Rule

Another limitation on the usefulness of CEA/CBA in public policy development, applying in the case of orthopedic joint implants as well as other applications of such analysis, is that imposed by the arbitrary selection of a policy decision rule.

Feasibility of Expanding and Integrating the Use of CEN/CBA in Public Policy Formulation

Typically, the overwhelming problem precluding CEA/CBA is the lack of adequate data. Although an optimal set of data to allow quick and precise estimation of the costs and benefits of all orthopedic joint implants does not exist, further study in the area of CEA/CBA of orthopedic joint implant technology is feasible, because the necessary cost, incidence, prevalence, and outcome data can be assembled from existing data and the literature. Furthermore, such study would be useful, because or thopedic joint implants have the potential of becoming a widespread technology and could affect more than 900,000 arthritis patients who are unable to engage in work, housekeeping, or school activities.

Close study of the hip implant appears to be particularly worthwhile, because research on this would provide insight into future funding decisions for other orthopedic joint prostheses. Because the prostheses are at different stages of development and address problems of different degrees of severity, the prostheses for each joint must be discussed separately. Although hip joint replacements, in the great majority of cases, are an accepted therapy to relieve pain and restore the important function of mobility, the same cannot be said of replacements of other joint Whether or not to undertake replacement is much more of an issue in the case of other joints, and selection of patients remains a policy issue about which the results from a current CEA/CBA of hip joint implants could provide valuable insights.

A prerequisite to the incorporation of CEA/CBA of orthopedic joint implants in the process of public policy development is the use of additional material to supplement such analysis. The choice of which technologies' development and/or diffusion should be encouraged depends on society's welfare function, a weighted combination of values of the constituency, Although CEA/CBA does provide a convenient means of organizing and considering information about orthopedic joint implants, results from such analysis must be considered in conjunction with relevant political realities and legal and ethical issues.

Another prerequisite to the incorporation of CEA/CBA of orthopedic joint implants in public policy formulation is the use of current analyses. Policies developed on the basis of outdated data and discount rates are not very useful and can be misleading.

If these prerequisites are met, then CEA/CBA of orthopedic joint implants could be a useful input into policy decisions regarding reimbursement practices, R&D funding, safety and efficacy regulation, capital controls, and medical manpower distribution.

USEFUL DIRECTIONS FOR FUTURE POLICY RESEARCH

In this study, we have indicated that CEA/CBA is a feasible means of providing an objective, systematic, and useful analysis of public policy issues relating to the diffusion of orthopedic joint implant technology. Performed correctly, the technique provides a convenient method of comparing two or more alternatives by arraying and quantifying costs and benefits for each.

Although CEA/CBA has intrinsic limitations as an analytical technique (e.g., failure to provide a unique, nonarbitrary criterion for choice; failure to account for rapidly evolving techno-

logical advancements; possible dominance of an unknown factor, for instance, the discount rate), these limitations are not sufficient to preclude future CEA/CBA studies related to the medical technology of orthopedic joint implants.

It has been pointed out that the costs of orthopedic joint implants can be more easily measured than the benefits. As a result, it is easy to overemphasize the costs associated with such procedures. Furthermore, there is a danger of underestimating benefits by inadvertently discounting the value of relieving pain and restoring functional ability to a predominantly nonworking population. Therefore, it might be suggested that studies of othopedic joint implant technology should focus on the efficiency and cost effectiveness of alternative investments related to orthopedic joint implants.

A CEA study of the artificial hip would be a particularly worthwhile future research endeavor. Since the necessary data are available, it would be possible to complete the study relatively quickly, easily, and inexpensively. Because arthritis affects so many persons and in most cases eventually affects the hip joint, a CEA study of the artificial hip to answer questions such as those listed below would be of widespread interest.

- What are the costs of artificial hip implants?
- For which population cohorts is it most cost effective to adopt this technology?
- How do cost-effectiveness ratios computed for investments in orthopedic joint implants compare with similar ratios computed for investments in regional arthritis and rheumatism nonsurgical rehabilitation centers?
- What are the necessary data that must be collected in order to conduct similar studies for other orthopedic joints?
- What are meaningful criteria to adopt in order to screen new and other existing orthopedic joint implant technologies?

In conclusion, the value of undertaking a future CEA/CBA of artificial hip implants is that the application of such analysis would force one to be explicit about a technology that potentially may affect many people. Also, it would furnish a tested framework for evaluation of other more controversial medical technologies (e. g., other prostheses and devices used to restore function to malfunctioning organs and other parts of the body). Finally, the application of CEA/CBA to the technology of hip implants would illustrate a methodology realistically adapted to available data. Such information would be greatly useful to Federal policy makers and to consumers. It would also be useful to health systems agency boards, to health maintenance organization administrators, and to other health planning agencies with the responsibility for allocating resources for research and capital expenditures. The information might also be valuable to industrial concerns that must estimate the orthopedic equipment market and to educational institutions that must know where training emphasis should be placed.

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