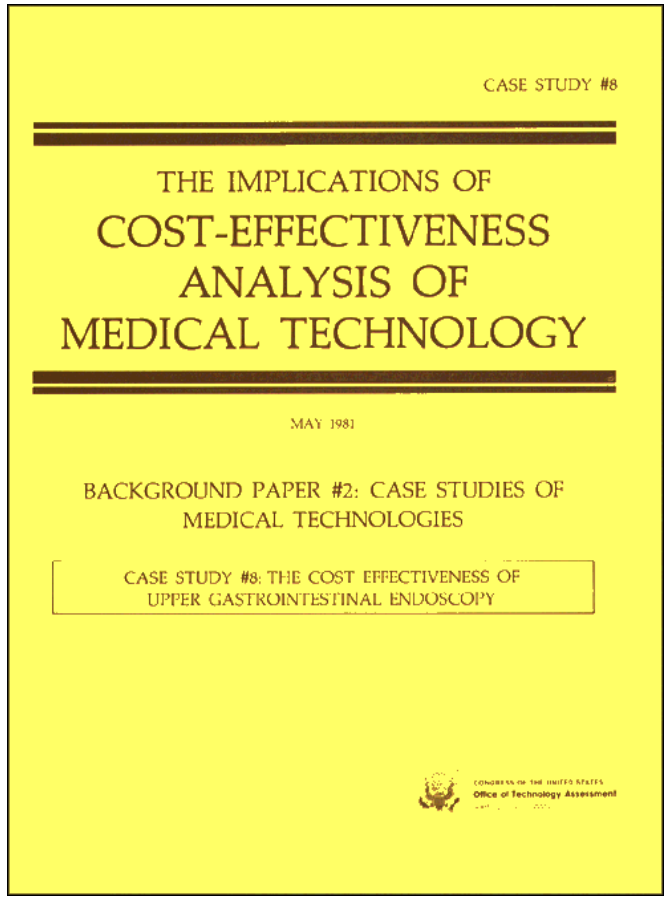
The Cost Effectiveness of Upper Gastrointestinal Endoscopy

May 1981

NTIS order #PB81-221814





THE IMPLICATIONS OF COST-EFFECTIVENESS ANALYSIS OF MEDICAL TECHNOLOGY

MAY 1981

BACKGROUND PAPER #2: CASE STUDIES OF MEDICAL TECHNOLOGIES

CASE STUDY #8: THE COST EFFECTIVENESS OF UPPER GASTROINTESTINAL ENDOSCOPY

Jonathan A. Showstack, M.P.H.
Senior Research Associate

and

Steven A. Schroeder, M.D.
Professor of Medicine

Health Policy Program, University of California, San Francisco

With Commentary by the American Society for Gastrointestinal Endoscopy

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.

CONGRESS OF THE UNITED STATES
Office of Technology Assessment
Washington D C 20510

Library of Congress Catalog Card Number 80-600161

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

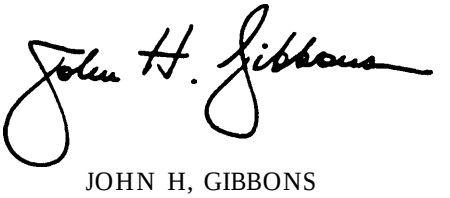
Foreword

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.

Because of particular circumstances regarding this case study on gastrointestinal endoscopy, a commentary by the American Society for Gastrointestinal Endoscopy is presented immediately following the case study. The case study authors' response is presented after the commentary.

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.



JOHN H, GIBBONS
Director

Advisory Panel on The Implications of Cost= Effectiveness Analysis of Medical Technology

John R. Hogness, *Panel Chairman*
President, Association of Academic Health Centers

Stuart H. Altman
Dean
Florence Heller School
Brandeis University

James L. Bennington
Chairman
Department of Anatomic Pathology and Clinical Laboratories
Children Hospital of San Francisco

John D. Chase
Associate Dean for Clinical Affairs
University of Washington School of *Medicine*

Joseph Fletcher
Visiting Scholar
Medical Ethics
School of Medicine
University of Virginia

Clark C. Havighurst
Professor of Law
School of Law
Duke University

Sheldon Leonard
Manager
Regulatory Affairs
General Electric Co.

Barbara J. McNeil
Department of Radiology
Peter Bent Brigham Hospital

Robert H. Moser
Executive Vice President
American College of Physicians

Frederick Mosteller
Chairman
Department of Biostatistics
Harvard University

Robert M. Sigmond
Advisor on Hospital Affairs
Blue Cross and Blue Shield Associations

Jane Sisk Willems
VA Scholar
Veterans Administration

OTA Staff for Background Paper #2

Joyce C. Lashof, *Assistant Director, OTA*
Health and Life Sciences Division

H. David Banta, *Health Program Manager*

Clyde J. Behney, Project *Director*

Kerry Britten Kemp, * *Editor*
Virginia Cwalina, *Research Assistant*
Shirley Ann Gayheart, *Secretary*
Nancy L. Kenney, *Secretary*
Martha Finney, * *Assistant Editor*

Other Contributing Staff

Bryan R. Luce Lawrence Miike Michael A. Riddiough
Leonard Saxe Chester Strobel*

OTA Publishing Staff

John C. Holmes, *Publishing* Officer

John Bergling* Kathie S. Boss Debra M. Datcher
Patricia A. Dyson* Mary Harvey* Joe Henson

● OTA contract personnel.

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 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, 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, 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 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, Mowed 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 was 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 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 #8

The Cost and Effectiveness of Upper Gastrointestinal Endoscopy

Jonathan A. Showstack, M.P.H.
Senior Research Associate

and

Steven A. Schroeder, M.D.
Professor of Medicine

Health Policy Program
University of California, San Francisco

AUTHORS' ACKNOWLEDGMENTS

We would like to thank David Altman, M. D., Andrew Lipton, M. D., Anne Scitovsky, Lois Myers, Michael Matsumoto, and our colleagues at the University of California Health Policy Program for their comments and criticisms of an earlier draft of this paper. **We also thank Howard Steinberg, M. D., for allowing us to use his unpublished data, Judy Schwartz for her assistance in data collection, Elizabeth Afshari for her secretarial support and assistance in data collection, and Blue Shield of California for making available data on endoscopies reimbursed through the programs it administers.**

All opinions and conclusions expressed in this paper **are those** of the authors.

Contents

	Page
Preface	3
Introduction	3
Clinical Effectiveness	5
Cost of Endoscopy	7
Clinical Cost (Morbidity and Mortafity)	7
Economic Cost	8
Issues in Studying the Benefits and Costs of Endoscopy	11
Discussion	12
Summary	15
References	15
Commentary by the American %ciety for Gastrointestinal Endoscopy	18
Authors Response to ASGE Commentary	20

LIST OF TABLES

Table No.		Page
l.	Most Common Diagnoses for a Sample of Endoscopies Billed to California Medicare, Medicaid, CHAMPUS, and BlueShield Standard Policies, 1976	5
2.	Selected Endoscopic Procedures Billed to California Medicare, Medicaid, CAMPUS, and BlueShield Standard Policies During 1977	9
3.	One Year Cost Assumptions	9
A-l.	Estimate of Overall Costs and Recurring Costs per Procedure in Physician's Office	19

Case Study #8:
The Cost and Effectiveness of Upper Gastrointestinal Endoscopy

Jonathan A. Showstack, M.P.H.
Senior Research Associate

and

Steven A. Schroeder, M.D.
Professor of Medicine

Health Policy Program
University of California, San Francisco

PREFACE

Upper gastrointestinal endoscopy is only one of many relatively new diagnostic and therapeutic technologies that are in widespread use in the medical care system. Examples of others are coronary angiograms, renal hemodialysis, and fetal monitoring. Few new technologies are evaluated thoroughly before they become part of "standard practice." Evaluating their worth and attempting to make their use as efficacious as possible, therefore, presents many formidable problems. This report presents an analysis of the cost and efficacy of the current use of upper gastrointestinal endoscopy. However, the analyses and conclusions reached have parallels in many other medical technologies already in current use in a wide variety of medical specialties in many different settings.

INTRODUCTION

For more than 100 years, physicians have been able to see the mucosa of the stomach through the use of a rigid gastroscope. In the 1930's, the viewing technique became relatively safe with the introduction of the semirigid gastroscope (37). Because this instrument lacked flexibility, it frequently did not allow viewing of major portions of the stomach (6). It was not until the introduction of the flexible fiberoptic endoscope in 1957 that endoscopy came to be widely used as a diagnostic procedure.

Upper gastrointestinal endoscopy is the generic term for all types of visualization of the upper gastrointestinal tract that use the fiberoptic endoscope. This report discusses the most common and basic use of an endoscopy —visualization of the upper gastrointestinal tract from the esophagus to an upper portion of the small intestine. Although there are also several complex procedures that use an endoscope (e.g., endoscopic retrograde cholangiopancreatography), the report does not discuss these.

The fiberoptic endoscope consists of two bundles of glass fibers that transmit light in a coherent manner. The placement of lenses at each end of one of the bundles allows an image of an object illuminated at one end of the bundle to be seen at the other end; clear images are

transmitted by the bundle even when the fibers are bent or curved. The other glass-fiber bundle transmits light from a source outside the patient to illuminate the viewed object. Additional channels are included to inject air through the endoscope to inflate the stomach and duodenum to aid viewing, and to provide water to clean the lens. One or more hollow channels are included to allow passage of miniature forceps and snares to take biopsies of suspicious material or grasp small foreign objects.

Generally, the physician-endoscopist is assisted by a nurse during the procedure, although the procedure can be performed on an emergency basis without assistance. Preparation for an endoscopy is generally limited to three steps: The patient is briefed on the procedure; a mild anesthetic is sprayed into the patient's pharynx; the patient is then given a tranquilizer (usually intravenous diazepam). The patient, generally lying on his or her left side and sometimes strapped onto the examining table, is awake but drowsy during the procedure. Most patients remember little of the experience.

The physician passes the endoscope past the hypopharynx and is able to see the esophagus on a viewing screen at the end of the endoscope. (A second, "training," viewpiece can be attached for a second observer or a camera.) The endoscope is moved forward and back by simply pushing or pulling the tube. The tip of the endoscope can be moved from side to side or turned back on itself (up to a 180° turn) by moving a lever on the controls. This allows the endoscope to be directed to or through any area that the physician wishes. In this way, the endoscope can be passed through the stomach, into and through the duodenum, and into the proximal small intestine.

One potential problem for the endoscopist is getting "lost" in the stomach. The image that the physician sees is distorted, from back to front, by the wide-angle objective lens. The light source and field of view of the endoscope allow detailed, clear vision only 1 or 2 inches in front of the lens. This limitation, plus the lack of "markers" in much of the upper gastrointestinal tract, make it possible for an inexperienced endoscopist to lose track of where the tip of the endoscope is in relation to the patient. Furthermore, because of the distortion and lack of depth perception created by the wide-angle lens, it often takes multiple attempts at biopsies to obtain samples of mucosa from the exact area desired.

An endoscopy of the esophagus, stomach, and duodenum generally takes less than 30 minutes from initial medication to removal of the endoscope (32). An additional 10 minutes may be spent by the physician dictating notes concerning the procedure. The difference between exploring the stomach only and exploring the duodenum as well is possibly 5 more minutes of examination. Biopsies of a suspicious area in the duodenum might take another 5 minutes. Waye states that a complete endoscopic examination should take no more than 15 minutes (47). A nurse may assist during the procedure by helping to keep the patient in place on the examining table. The nurse also assists with the orientation and premeditation of the patient, and with the use of forceps.

Training in the use of an endoscope is a standard part of residency programs for gastroenterologists (2). Present guidelines suggest that the trainee should perform 50 to 100 upper gastrointestinal endoscopies under supervision (19). There has been some debate over this emphasis in training programs. Some claim that gastroenterological clinical trainees devote too much time to training in procedures, while others argue that not only should gastroenterologists receive intensive training in the technique, but also training should be made available to all physicians interested in using an endoscope in their practices (13,23). In fact, any physician (not just gastrointestinal specialists) can perform and be reimbursed by health insurers for performing an endoscopy—no matter what type of formal training in the procedure, if any, the physician has undergone. Physicians can use the equipment in hospital facilities or can purchase the equipment for about ***$10,000*** (affordable to most) for use in their private offices. There is no additional malpractice premium in California resulting from use of the procedure.

Endoscopies are generally performed to document a condition, such as the size of a hiatal hernia or the site of an upper gastrointestinal hemorrhage. Table 1 lists the most common diagnoses for which all endoscopies, and esophagoscopies and gastroscopies only, were billed to Blue Shield of California during 1976 (43). These diagnoses were determined as the result of a procedure and are not necessarily the same as indications for performing the procedure. In addition to hiatal hernia and upper gastrointestinal bleeding, the most common diagnoses obtained from performing an endoscopy included gastritis, duodenitis, and stomach ulcers. All types of primary cancer of the upper gastrointestinal tract accounted for 9 percent of all diagnoses. Similar results are documented by Fisher, et al. (17).

CLINICAL EFFECTIVENESS

The clinical value of endoscopy is twofold. First, by allowing physicians to see the mucosa of the upper gastrointestinal tract, endoscopy can provide valuable information in certain cases. Second, by enabling physicians to obtain specimens of mucosal tissue through biopsy and cytology, it can provide confirmatory diagnostic information.

In a well-documented discussion of endoscopy, Waye lists the indications, therapeutic uses, and contraindications for endoscopy (47). The three primary indications he lists for the use of endoscopy are upper gastrointestinal hemorrhage, pathologic lesion on X-ray, and symptoms unexplained by X-ray (e.g., gastritis). The therapeutic uses of endoscopy Waye lists are rupture of esophageal mucosal rings, removal of foreign objects in the esophagus and stomach, and stopping of gastrointestinal bleeding by electrocoagulation or other means. The only contraindication Waye lists is an uncooperative patient. Waye points out that a patient can inflict severe damage on a fiberoptic endoscope by biting the instrument.

Colcher lists a wide variety of indications for performing endoscopy (10). He also notes that it is important to examine the esophagus, stomach, and duodenum simultaneously. Among the many indications based on radiologic diagnosis Colcher lists are presence of a gastric ulcer, gastric carcinoma or lymphoma, benign tumors, "large folds, " deformed antrum, pyloric-channel obstruction, and postoperative inspection of the stomach. Two of the many indications based on the clinical manifestations he lists are acute upper gastrointestinal tract bleeding and "postoperative problems. " Some of the therapeutic procedures Colcher lists are management of benign esophageal strictures, webs or rings, and polypectomy.

It is clear that Waye's, Colcher's, and others' lists of indications for endoscopy are quite broad and inclusive. The lack of specific indications is illustrated by Belber in *Gastrointestinal Disease* (a standard textbook): "Indications are really so broad that we could summarize by saying that whenever we suspect the upper gastrointestinal tract may be the site of disease, symp-

Table 1 .—Most Common Diagnoses for a Sample of Endoscopies Billed to California Medicare, Medicaid, CHAMPUS, and Blue Shield Standard Policies, 1976

Total endoscopies (N = 5,515)	Esophagoscopies (N = 536)	Gastroscopies (N = 851)
1. Hiatal hernia (13%)	1. Hiatal hernia (14%)	1. Upper gastrointestinal bleed (18°/0)
2. Upper gastrointestinal bleed (12°76)	2. Caustic substance (9°/0)	2. Hiatal hernia (12°/0)
3. Gastritis and duodenitis (10°/0)	3. Obstruction of the esophagus (8°/0)	3. Stomach ulcer (1 10/0)
4. Stomach ulcer (10%)	4. All other (69°/0)	4. All other (59°/0)
5. Upper gastrointestinal cancer (90/.)		
6. All other (46°/0)		

SOURCE: H. Steinberg. University of California, San Francisco, Calif. unpublished data, 1978.

tomatic or nonsymptomatic, we feel it is advisable to have a look" (6). Belber goes on to list only three absolute contraindications to endoscopy: an unwilling or uncooperative patient, the probability that a viscus (internal organ) is perforated, or a patient in shock. Sullivan *(46)* and Colcher (11) list similar contraindications. Thus, almost all patients with even minor upper gastrointestinal symptoms are potential candidates for an endoscopy.

Ultimately, criteria for use of any diagnostic tool must be based on improvement in patient outcome or increased efficiency of care as a result of administration of the diagnostic test or procedure. Studies on the diagnostic value of endoscopy generally fall into two categories: a general category of studies of clinical indications for endoscopy, and a separate category of studies of endoscopy's value in the specific case of upper gastrointestinal hemorrhage.

In the broadest published study of the value of endoscopy for nonbleeding patients, Cameron and Ott *(9)* reported the results of 1,360 *ex*aminations. All patients had been previously examined by upper gastrointestinal X-ray. The question that Cameron and Ott asked is, "For symptomatic patients, what information is provided by endoscopy in addition to that provided by the upper gastrointestinal X-ray series?" To limit their study to major conditions, the authors specifically excluded as significant findings: hiatal hernia, gastric and duodenal scarring, gastritis, and gastric erosion. Overall, endoscopy altered the diagnosis in 18 percent of the examinations, and yielded additional findings of possible clinical significance in another 7 percent. In cases where X-ray results were negative, endoscopy produced significant positive findings 11 percent of the time,

As a diagnostic tool, endoscopy can provide excellent new information in some cases (e. g., locating the site of an upper gastrointestinal hemorrhage not seen on X-ray), while adding confirmatory information in other cases (e. g., ruling out peptic ulcer disease in favor of gastritis). Perhaps a key to evaluating the clinical effectiveness of upper gastrointestinal endoscopy is the current lack of effective treatments for the most common upper gastrointestinal diseases. In many cases, the major treatment decision for upper gastrointestinal diseases is whether to perform surgery. However, in almost all cases, this decision is based on clinical, rather than morphologic, criteria. The diagnostic yield from an endoscopy, therefore, may add very little to the decisionmaking process once an adequate clinical picture is obtained. E.g., in the case of peptic ulcer disease, the major indications for surgery are perforation, organic obstruction, intractable bleeding, and refractoriness to medical therapy (41). None of these requires the performance of an endoscopy for confirmation.

Gastric cancer presents another example of a condition for which endoscopy may provide useful additional information but rarely affects the decision of whether to perform surgery, An X-ray will reveal a gastric abnormality in approximately *90* percent of symptomatic patients, but will fail to differentiate between benign and malignant lesions about **25** percent of the time (26). Primarily because of its ability to provide directed biopsies of suspicious tissue, an endoscopy can help to rule out gastric cancer. The reassurance this provides to the patient may be one of the largest benefits of endoscopy. However, it is very difficult to quantify this reassurance value. This may cause cost-effectiveness equations to have an artificially low-effectiveness value. Ruling out gastric cancer may also prevent unnecessary exploratory surgery.

In a study of patients with confirmed gastric cancer, Olearchyk (32) states that an upper gastrointestinal X-ray series was positive in 95 percent of 206 patients who underwent this test, while an endoscopy with biopsy was positive in 69 percent of the 70 patients who underwent the latter procedure (although a true-positive rate approaching 95 percent for an endoscopy with biopsy is at last theoretically possible). Others point out the need for biopsies when viewing early gastric cancer or chronic gastritis (18,40).

The definitive diagnosis of gastric cancer by endoscopy (as opposed to ruling out the disease) provides little benefit to the patient because of the current lack of adequate treatment for this

condition and poor 5-year survival rates. In fact, the decision to operate in the case of gastric cancer is based almost entirely on how widely metastasized the disease is. An endoscopy provides little or no additional information to answer this question.

In the specific case of upper gastrointestinal hemorrhage, it seems clear that endoscopy leads to increased diagnostic accuracy, but there is little evidence that it changes morbidity or mortality rates. The improved diagnostic accuracy afforded by endoscopy has been shown in several studies (12,21,28,44,45). However, a lack of difference in outcome for bleeding patients who undergo a diagnostic endoscopy has been documented by a variety of controlled prospective studies.

Sandlow, et al. (35), studied 150 patients who were randomly assigned to a group that underwent an emergency endoscopy followed by barium-contrast X-ray or to a group that underwent the same studies delayed until 1 week after admission. The patients in the first group fared either no better or even worse than the patients in the latter group. A study by Allan, et al. (l), assigned patients to either immediate endoscopy or to an initial barium-contrast examination after which endoscopy was performed on only 34 percent of the cases for particular clinical indications. There was no difference in outcome between these two groups. In a study by Dronfield, et al. ***(14), 322*** patients were randomly assigned to either endoscopy or radiology. The diagnostic yield was higher in the endoscopy than the radiology group, but there was no difference between the two groups in management or survival. Two other prospective studies also document similar findings of increased diagnostic yield but no difference in outcome (22,31). Thus, while endoscopy clearly increases the diagnostic yield for certain patients, there is little evidence that outcome has been improved by performing an endoscopy in addition to an upper gastrointestinal X-ray series. In a review of several of the aforementioned studies, Eastwood asks, "Unquestionably, the sooner endoscopy is performed after a bleeding episode, the greater the diagnostic yield, but is that better for the patient?" (15). He goes on to state that, "Although it seems reasonable, the necessity of a definite diagnosis before therapy for active upper gastrointestinal bleeding has not been proved. "

However, a caveat must be noted here for the case of upper gastrointestinal hemorrhage and gastric carcinoma. The results cited above are for the diagnostic uses of endoscopy. Therapeutic methods under development for the control of gastrointestinal hemorrhage through the use of an endoscope may alter this picture for some specific causes of hemorrhage *(36),* It also should be noted that, while having little positive effect on patient outcome, an endoscopy to document a healing ulcer or to rule out gastric cancer may substitute for an upper gastrointestinal X-ray series. Of course, if both endoscopy and an upper gastrointestinal series are performed, the diagnostic effect of the combined procedures may be marginal, while the higher cost is substantial. In current practice, either or both procedures are performed for many different types of upper gastrointestinal disease.

COST OF ENDOSCOPY

Clinical Cost (Morbidity and Mortality)

Because of the instrument's flexibility and ease of handling, endoscopy with a flexible fiberoptic endoscope produces a relatively low rate of complications ***(20,25,30,42).*** The American Society for Gastrointestinal Endoscopy (ASGE) surveyed its members in 1974 to determine rates of morbidity and mortality associated with various types of gastrointestinal endoscopy *(42).* Of the *642* questionnaires that ASGE sent to its members, ***404 (64*** percent) were returned. Almost all the respondents *(86* percent) were gastroenterologists.

The reported examinations had an overall complication rate of 1.3 per 1,000 cases. Absolute numbers of complications in this series of

211,000 examinations were as follows: perforation, 70; bleeding, 63; cardiopulmonary complications, 129; and infection, 17. There were an additional 228 miscellaneous complications, which were attributed primarily to medication reactions (hives, thrombophlebitis). If the latter are included, the overall complication rate becomes *2.3* per 1,000 examinations. There were 13 fatalities in this series. Perforations accounted for five fatalities, bleeding accounted for two, and cardiopulmonary complications for six.

Two-thirds of the perforations occurred in the esophagus; the rest occurred primarily in the stomach. Of the *63* cases of bleeding that were attributable to the endoscopic procedure, approximately one-third were the result of biopsies (although there was no indication of the severity of the bleed). Cardiopulmonary complications of the endoscopic procedure were primarily caused by severe respiratory depression or arrest secondary to intravenous diazepam (tranquilizer) or to aspiration. There were an additional three cases of respiratory arrest secondary to pharyngeal anesthesia. Thus, perforation occurred in approximately 1 out of *3,300* examinations, bleeding in approximately 1 out of *3,500,* and cardiac and pulmonary complications in approximately 1 out of *1,600.*

In another report, Hafter (20) discusses data on approximately 400,000 endoscopies, of which 211,000 were from the Silvis study cited above (42). Hafter reports an overall perforation rate of approximately 1 per 3,000 examinations, an aspiration rate of slightly less than 1 per 1,000 examinations, and an overall mortality rate of approximately 1 per 20,000 examinations. He also reports a comparison between semirigid and flexible instruments used in endoscopy. The data for the semirigid endoscope show a perforation rate of approximately 2 per 1,000 and a mortality rate of approximately 1 per 5,000. Thus, it seems that the introduction of the flexible fiberoptic endoscope has reduced the rate of serious complications and deaths resulting from this procedure by a factor of approximately four. However, Silvis notes that the decrease in perforation has been offset by an increase in complications due to bleeding related to the introduction of biopsy techniques (42). Further, Silvis notes, "If bleeding and perforation are combined, the complications from mechanical problems remain approximately the same [between semirigid and flexible instruments] at 0.6 per 1,000 cases. "

An additional potential hazard of endoscopy, transmission of an infectious organism (Salmo*nella typhimurium),* has been documented by Beecham, et al. (5). This presumably rare event was attributed to inadequate disinfection of the endoscopic equipment.

Thus, while complications secondary to this procedure are relatively rare, they are not insignificant when one considers the number of endoscopies that are being performed in this country. As described below, at least 500,000 endoscopies per year are performed in the United States. Thus, over 650 patients may suffer serious complications, and approximately 25 patients may die as a result of the procedure each year.

Economic Cost

In the assessment of the cost effectiveness of upper gastrointestinal endoscopy, two central questions emerge: What does it cost physicians to perform an endoscopy? and, What do doctors charge for an endoscopy? Since many, if not most, endoscopies are done in hospitals, hospital charges for the examination room and anesthesia are often added to physician charges. The data reported below on the incidence and charges for endoscopy in California, obtained from Blue Shield of California, reflect only physician charges. Since they do not include hospital charges, these data underestimate the true overall cost of endoscopy to society.

To administer the Northern California Medicare Program, Blue Shield of California collects billing data from a variety of programs, including Blue Shield standard policies, Northern California Medicare, California Medicaid, and California CHAMPUS (the programs that Blue Shield of California administers directly). Blue Shield also collects data from Occidental Life Insurance Co., which administers Southern California Medicare. As a result, Blue Shield data

cover approximately 25 percent of the health insurance market in California.

During 1977, more than 12,735 endoscopies were billed to the aforementioned programs, which represent about 5 million potential beneficiaries (see table 2). The median charge was approximately *$240.* The most common procedure was an esophagogastroduodenoscopy, which had a statewide median charge of approximately *$250;* performing one or more biopsies adds approximately *$30* to this charge. The median charge for esophagoscopy and gastroscopy alike is approximately *$200;* a biopsy adds $45 to the charge for esophagoscopy and *$40* to the charge for gastroscopy.

An overall estimate of national costs in *1977* may be made if it is assumed that endoscopies were performed at the same rates and charges for the entire population of the United States as for the *25* percent of the California population that Blue Shield's data represent. Under these assumptions, the total number of endoscopies performed in the United States during 1977 would have been approximately **510,000,** for total aggregate physician charges of approximately ***$122*** million. [1] (An unknown proportion of endoscopies are performed in hospital facilities, for which there is an additional charge.)

On the individual level, endoscopies are quite lucrative, given that they rarely take more than 45 minutes to perform. However, the quotation of what doctors charge for a service does not answer the question of what the service costs to perform. The following hypothetical cost analysis should shed some light on this matter.

The basic assumption in this example is that the doctor spends his or her entire time actually performing endoscopies; i.e., there **are no other** clinical procedures being charged for during this time. An additional assumption is that the optimal charge (and reimbursement) for a procedure should be set at an efficient level of operation.

In this example, a gastroenterologist is hired full-time by a physician group practice to perform endoscopies. In order to support this work, a nurse is hired full-time, and a secretary devotes approximately 50-percent time to the appropriate paperwork (see table 3). Also included in this example are costs for four rooms (one examining room, two offices, and one supply room); the endoscope (depreciated over 5 years); and general overhead costs of ***20*** percent (fringe benefits, insurance, telephone, etc.).

Table 2.—Selected Endoscopic Procedures' Billed to California Medicare, Medicaid, CHAMPUS, and Blue Shield Standard Policies During 1977

Type of procedure (1974 CRVS No.[b])	Number of procedures	Approximate median charge
Esophagoscopy (40100)	'-1,063	**$200**
Esophagoscopy, with biopsy (40105)	932	245
Gastroscopy (40160)	1,614	**200**
Gastroscopy, with biopsy (40165)	1,351	240
Esophagogastroduodenoscopy (40140)	4,027	250
Esophagogastroduodenoscopy, with biopsy (40145)	1,153	280
Others (40102, 40120, 40125)	2,595	240
Total	12,735	$240

[a] Procedures billed without modifiers
[b] California Medical Association, 1974 *Revision of the* 1969 California Relative Value *Studies* (San Francisco: Sutter Publications, 1975)

Table 3.—One-Year Cost Assumptions

Gastroenterologist (full-time, net income)	= $65,000
Nurse (full-time, net income)	= 15,000
Secretary (@ $10,000 per year, half-time net income)	= 5,000
4 rooms (370 ft² @ $1.50/ft² per month) 1 examining room, 10 x 10 2 offices, 10' x 10 1 supply room, 10 x 7'	= 6,660
Equipment (depreciated at 20% per year, plus 10°/0 per year interest expense) Endoscope = $10,000 Table = 1,500	= 3,450
Subtotal	$95,110
Overhead @ 20% (fringe benefits, telephone, insurance, supplies, etc.)	19,022
Total	$114,132

[1] Data reported by Mendenhall, et al, (28), Indicate that gastroenterologists alone may account for this many procedures. It is likely that Blue Shield of California data overestimate the percentage of elderly patients and children due to the majority of the data coming from medicare and medicaid billings. This inaccuracy may reduce the generalizability of these data and lead to an overestimate when projected to a national age distribution An unknown number of other procedures and procedures billed with modifiers are excluded from the Blue Shield data reported.

As can be seen in table 3, the cost of maintaining a full-time endoscopist is approximately $114,000 per year. The "cost" of performing an endoscopy should then be, on average, $114,000 divided by the yearly number of procedures. Assuming a 230-day working year (5 days per week for 46 weeks), three examples of yearly volume and average cost per endoscopy are:

40 minutes/endoscopy (12/day) =
2,760/year = $41/endoscopy
60 minutes/endoscopy (8/day) =
1,840/year = $62/endoscopy
80 minutes/endoscopy (6/day) =
1,380/year =$83/endoscopy

Even the lowest volume shown (six per day) still results in a cost barely more than a third of the typical charge for endoscopies billed through Blue Shield of California. This not only assumes some slack-time, but also does not include any additional revenue generated during this time. Note also that to affect the cost per endoscopy, the itemized costs listed in table 3 would have to be changed greatly. For example, if one were to double the costs in table 3 (i. e., pay the physician a net l-year income of $130,000), the cost per endoscopy, even at the lowest volume, would still be far below the typical charge for the procedure.

Note that the charge for use of an examining room is built into the above figures. Therefore, it is more lucrative for the physician to perform an endoscopy in a facility provided by a hospital than to perform the procedure in his or her own office. In the hospital, the physician does not have to absorb the costs of the examining room, equipment, and other indirect office costs. For instance, the University of California, San Francisco Hospital charges a patient $140 for the use of its endoscopy facilities. The doctor then charges the patient an additional fee for professional services, generally the same fee as would be charged for a procedure performed in the physician's office.

The most realistic example is probably 60 minutes per endoscopy (at a cost of **$62),** with 40 minutes per endoscopy ($41) being optimal (i.e., the true average cost of performing an endoscopy with little slack time and no other income during this time). Thus, physician charges for endoscopy are from three to six times the actual cost of performing the procedure. For the physicians, endoscopies may be economic "winners" that make up for economic "losers" such as being reimbursed at a much lower rate for performing a complete history and physician examination. The fact that there are winners and losers is also true of most other clinical specialties, where technological care is reimbursed more highly than consultative care (39).

As Petersdorf stated in an editorial in the *Annals of Internal Medicine (34):*

> The fee for endoscopy, no matter how simple, is several times that for a complete history and physical examination that leads to a brilliant diagnosis, or for a life-saving maneuver that does not involve the use of a hollow tube, a knife, or electrocautery.

A more specific question related to the economics of endoscopy asks how much money gastrointestinal specialists typically earn from endoscopies. Using data from a national survey of gastroenterologists by Mendenhall, et al. (29), we estimate the mean yearly number of endoscopies performed by gastroenterologists in the United States in 1976 to be 275. This figure is approximately the same as that reported for the members of ASGE who responded to ASGE's survey of complications of endoscopy (42). If this yearly number of endoscopies is multiplied by $240, which is the median physician charge billed to Blue Shield of California during 1977, $66,000 (275 X $240) is the approximate mean annual gross *charges* by gastroenterologists in the United States for the physician services component of performing endoscopies. This figure excludes other charges to the same and other patients (e.g., for consultative, diagnostic, and therapeutic services).

One further note on the cost of performing an endoscopy: The cost described above generally refers to routine, scheduled procedures. Performance of an emergency endoscopy (e.g., in the middle of the night on an acutely bleeding patient in a hospital emergency room) requires great skill and incurs several different types of

costs not figured into the above calculation. However, it is likely that only a small minority of endoscopic procedures are done under such difficult circumstances.

ISSUES IN STUDYING THE BENEFITS AND COSTS OF ENDOSCOPIES

The goal for any diagnostic technology is to improve the diagnostic process so that the outcome will be better than that which would have resulted without the use of the technology. One way a better outcome can result is through the definitive diagnosis of a condition while it is still in an early, treatable stage. A second, though much less valuable, goal for the use of a technology is to lead to a definitive diagnosis even though the diagnosis will not directly benefit the outcome. It is possible that the result of a definitive diagnosis in such an instance will be better management of the condition (even without improved outcome). A final goal of a diagnostic technology is to replace other, less definitive, technologies and/or to improve diagnostic efficiency.

There are very few data in the literature to substantiate a claim that upper gastrointestinal endoscopy leads to either better outcome or reduced use of other similar technologies. Endoscopy does approach the less valuable goal of improved diagnosis leading to better management of some conditions (e. g., upper gastrointestinal bleeding) without confirmed better outcome.

One would think that the value of a technology that allows a physician to see a part of the body that could otherwise not be seen without surgery or X-ray would be easy to document. However, in the case of endoscopy this documentation would take expensive, time-consuming randomized controlled trials. The best outcome from these trials would be a set of criteria to define when endoscopy should be performed, by whom, and how often.

Definitive data are unlikely for several reasons. First, in order to say definitively when a diagnostic procedure should be used, one should have an expectation of an improved outcome through the use of the procedure. It does not seem that this will be true in the near future for the major conditions for which endoscopy is now used (i. e., upper gastrointestinal bleeding, gastritis, and hiatal hernia). Second, in the case of a life-threatening condition, such as gastric cancer, it is highly unlikely that a randomized controlled trial of endoscopy could be performed ethically, because such a trial would involve withholding this commonly accepted clinical procedure. Third, aside from obtaining directed biopsies, the ability of the endoscopist to make judgments based on visual evidence is the critical research question. A randomized controlled trial would give information only on a small set of endoscopists in a few settings. The assumption that these data can apply to other endoscopists in other settings is questionable. Fourth, randomized controlled trials are extremely expensive. In an era of increased competition for resources, it is unlikely that large trials would be funded for a technology such as endoscopy that has such low morbidity and relatively low individual costs.

Cost-effectiveness and cost-benefit studies of clinical diagnostic and therapeutic procedures are limited in their usefulness because of great difficulties in assessing benefits. Each of the many steps taken by a physician, including both physical examinations and diagnostic tests, add incrementally to the knowledge needed to diagnose a condition. At what specific point is a particular question asked or procedure done? Since the process is cumulative, procedural order may be "correct," but the marginal benefit from the increased information will be different, depending on when the procedure is done or question is asked. **A** protocol that would specify exactly when an endoscopy should be performed in the process of working-up the patient for a particular condition is conceivable, but given the rather eclectic process that most physicians use to reach a diagnosis, it seems unlikely that such a protocol would be used often.

Endoscopy does not provide a number that either defines or rules out a condition when compared to a standard range of numbers. The results of an endoscopy must be compared with, and added to, other clinical information. The assessment of benefits of an endoscopy, therefore, would require studying the incremental benefits accrued from performance of the procedure at different points in the diagnostic workups of many patients and conditions. Then these benefits would have to be weighed against the marginal costs associated with each endoscopy. Though theoretically possible, it is unlikely that current measures of cost and benefit are sensitive enough to provide an accurate assessment of the relative benefits of endoscopy that would be useful to the clinician or to third-parties that must decide whether to pay for the performance of an endoscopy.

DISCUSSION

The literature abounds with enthusiastic endorsements for endoscopy. Upper gastrointestinal endoscopy is a procedure that is simple and easily performed. It is also well-tolerated by the patient and has relatively low rates of morbidity and mortality. An endoscope is clearly a technological marvel, enabling physicians to see and obtain tissue samples from areas of the body that were previously out of reach. The endoscopic procedure is easily learned and can be performed on an outpatient basis. Furthermore, the procedure is "invasive" only in the sense that the instrument enters an orifice of the patient; an endoscopy does not penetrate tissue and does not inject or deposit foreign substances into the body. Clinical information about the cause of the patient's gastrointestinal symptoms is often improved as the result of the performance of the procedure.

These positive factors run up against society's need to allocate medical care resources efficiently—a need that implies that choices have to be made with respect to which patients need what types of medical care. Clearly, the cost to both the individual patient and society would be enormous if all patients with upper gastrointestinal symptoms were to undergo endoscopy. Three factors are particularly relevant when considering the relative benefits of endoscopy: 1) the lack of documented improved outcome as a direct result of endoscopy, 2) the individual and social costs of the procedure, and 3) the implications of the widespread use of endoscopy for the organization and delivery of medical care.

Endoscopy provides additional information and may help make a diagnosis more precise, but it is not at all clear that many patients benefit from this information. Even in the case of upper gastrointestinal bleeding, where endoscopy has been shown to provide more precise diagnosis than other techniques, there is no documented evidence that endoscopy improves outcome. By enabling the physician to perform directed biopsies of suspicious tissue, endoscopy also helps to confirm or rule out gastric cancer. However, there is no evidence that given available therapies, 5-year survival rates are altered by such early detection. While it is possible that endoscopic diagnosis of gastric cancer alters therapy, such as by preventing surgery, data documenting the extent of this effect are not available. Endoscopy is useful to document the postoperative patient's condition, to search for bleeding sites not found by X-ray, to examine patients with upper gastrointestinal symptoms in the absence of other positive findings, and to remove mucosal polyps. Most, if not all, patients would progress satisfactorily without these endoscopic findings and procedures.

The economic costs of endoscopy seem out of proportion to the clinical value of the procedure. Current financial and professional incentives encourage performance of endoscopies, while they discourage cognitive processes such as complete histories and physical exams (39). The incentive to perform endoscopies is not limited to gastroenterologists, but applies to all types of physicians. Surgeons and general internists also commonly perform endoscopies. The

same physician who orders an endoscopy can also perform the procedure in his or her own office for a minimal investment in time and equipment.

Procedures often become associated with medical specialties (38). New specialties are formed as new procedures are developed—e.g., a new specialty society has been formed for physicians who are endoscopists, the ASGE. As endoscopy has become a major part of the practice of gastroenterology, there has been concern expressed about the increasing procedural orientation of the specialty and the ability of society to support the rapidly expanding pool of gastroenterologists (7,27). (The American Board of Internal Medicine subspecialty exam in gastroenterology certified 20 physicians in 1966, 215 in 1973, and 557 in 1977 (27).) Fred Kern, in his 1976 presidential address to the American Gastroenterological Association, observed (24):

> . . . we are in serious danger of becoming technicians rather than consultants and teachers. Our medical and surgical colleagues call upon us for our technical skills, not for our wise advice. Furthermore, our enthusiastic and often uncritical acceptance of endoscopic procedures and the nearly open-ended list of indications for their use are troublesome.

Kern also wondered "whether smaller fees (for the procedure) would lead to fewer endoscopies."

More recently, Kern has discussed the problem of gastroenterologists spending a disproportionate amount of time performing procedures during training rather than in consultation and learning clinical skills. He has even called for the training of "non-M. D. assistants" to perform endoscopies under the supervision of a gastroenterologist (23). Thus, it appears that the reimbursement for and ease of performance of endoscopy provides incentives not only for procedural care over consultative care, but also for specialty care over primary care.

Medical procedures that can be performed on an ambulatory basis present complex problems for those concerned with the regulation of the process of medical care and reduction in the overall cost of medical care. The cost of the equipment falls well below any certificate-of-need regulatory limits. While often performed by gastroenterologists on a consultative basis, endoscopy is also performed by other types of physicians, especially internists and general surgeons. Direct regulation of this procedure appears to be an impossible task, but it seems reasonable to lessen the financial incentive to perform the procedure by lowering reimbursement for the procedure to a level that more closely approximates the cost of performing the procedure. However, we would note that a unified approach to adjusting relative reimbursement must be taken by both public and private third-party payers. If only the public payers (primarily medicare and medicaid) reduce payment for an endoscopy, a two-class system of medical care would be reinforced, with patients able to pay being more likely than others to receive a needed procedure. Once relative reimbursement is changed, studies should be performed to determine how often the procedure is used, by whom, and for what types of patients and clinical indications. With this additional information, more directed regulatory efforts might be possible.

Another adjustment that can be made in the reimbursement structure for endoscopy is the reduction of the number of descriptions of the procedure from the current three or more to a single overall description. There is very little difference in the true cost of performing what is now called an esophagoscopy with either a gastroscopy or a duodenoscopy. The descriptions of these procedures should be combined into one, that of esophagogastroduodenoscopy (or just plain "endoscopy"), with a small additional charge permitted in the case of performance of a biopsy, cytology, polypectomy, or other diagnostic or therapeutic additions to the basic procedure.

A physician may be certified as a gastroenterological subspecialist, a certification that requires that the physician be competent in the use of an endoscope (2), but there is no other specific certification in endoscopy. Any physician can perform and be reimbursed for performance of an endoscopy. Even if hospitals were to require

some such certification to use their endoscopic equipment, the physician could simply purchase the equipment and perform the procedure in his or her own office. Any measure of systemwide benefits of endoscopy must assume a baseline competence in performing the procedure. Data we have obtained from Blue Shield of California indicate that there are more nongastroenterologists performing endoscopies than gastroenterologists and that nongastroenterologists rarely perform more than so procedures per year. In fact, we estimate that the median number of endoscopies performed by a nongastroenterologist is approximately ***20*** per year. This seems far too low to maintain competence in the procedure.

We agree with Kern, Petersdorf, et al., who worry that physicians are becoming too procedure-oriented, and specifically, that gastroenterologists are being considered more as endoscopists than as subspecialists in internal medicine. Clearly, competence in endoscopy has become critical to the job prospects of gastroenterologists (16). Most subspecialties in medicine and surgery face the same problem, e.g., cardiology with its catheterizations and angiograms, pediatrics with its neonatal intensive care units, and nephrology with its renal dialysis units.

We would like to reemphasize the problem of quantifying benefits for diagnostic procedures. Even though population studies may not detect either clinically or statistically significant differences in outcome that can be attributed to the use of a diagnostic procedure, there is always the possibility that there are specific cases for which knowledge gained from performance of a procedure may be extremely beneficial. When grouped with a larger number of cases, these particular cases may get lost. Because of this potential for benefit to individual patients, it is important to perform studies to determine which endoscopically obtained diagnostic information is associated with better prognosis. As our understanding of the disease processes of the upper gastrointestinal tract improves, it may become possible to delineate specific, discrete conditions and indications for which a diagnostic or therapeutic endoscopy should be performed.

Given our present understanding of upper gastrointestinal disease, perhaps it is inevitable that many endoscopic procedures need to be performed to ensure that those few will be done that clearly benefit patients undergoing the procedure. The public policy question then becomes: What price, both financial and clinical, and what effect on the medical care system are we willing to absorb to support current use of endoscopy and analogous technological procedures? The issue is not just whether upper gastrointestinal endoscopy is useful now or will become more so in the future, but whether current financial and other incentives that encourage the use of endoscopy should be continued in light of our current knowledge of the effectiveness of the procedure.

One of the ways to provide for the most effective use of a technology such as endoscopy is for the subspecialty societies, regulators, third-party payers, and physicians who either perform or refer their patients for performance of an endoscopy to agree to specific definitions of levels of competence and to discrete, limited a priori indications for performing the procedure. Guidelines for the use of endoscopy in the management of patients with esophagitis and patients with duodenal ulcer have recently been issued jointly by the American Gastroenterological Association, the American College of Gastroenterology, and ASGE (3,4). Unfortunately, these guidelines are so broad that they are unlikely to lead to more efficacious use of endoscopy. Another way to decrease unnecessary use of the procedure is to lower reimbursement by health insurers for the procedure to a level that is closer to the actual cost of providing the procedure. These are generic issues for most medical technologies. They are more complex for a technology such as endoscopy where benefits are so difficult to measure and so easy to assume. The real and potential costs to patients and society mandate that these issues be dealt with as soon as possible.

SUMMARY

Upper gastrointestinal endoscopy is an easily performed diagnostic procedure that is well-tolerated by patients. Although the majority of endoscopies are done by general internists and gastroenterologists, the procedure is performed by physicians in many specialties.

Indications for upper gastrointestinal endoscopy are very broad, and there are few clinical contraindications to the use of the procedure. It is difficult, at best, to document improved outcome as a result of performance of an endoscopy, although the procedure does provide additional diagnostic information in many cases. The ability to obtain biopsies of suspicious tissue is one of the main values of endoscopy. The reassurance to the patient that he or she does not have cancer is a valuable, if difficult to measure, result of the procedure.

The cost of performing an endoscopy is relatively low, Given an efficient production process, the estimated cost to a physician group practice is approximately ***$41*** to $83 per endoscopy, depending on volume. The median charge in California in 1977 for the physician services component of the procedure was approximately $240. Thus, charges are from three to six times the cost of performing the procedure. It is estimated that at least 500,000 endoscopies are performed each year in the United States, for total annual physician charges of at least $122 million.

The value of an upper gastrointestinal endoscopy is generally limited by our current understanding of and lack of effective treatments for the major disease processes of the upper gastrointestinal tract. As our understanding increases and treatments become more effective, so may the value of an endoscopy increase. However, existing financial and clinical incentives undoubtedly encourage the performance by physicians of many more endoscopies than can be clinically justified at this time. Physicians, health insurers, and regulators must define discrete a priori indications for performance of the procedure, levels of competence to perform the procedure must be established, and perhaps most importantly, relative reimbursement for performance of an endoscopy must be lowered to more closely approximate the cost of performing the procedure (and possibly to take into account the circumstances under which the procedure was performed, such as routine or emergency). Without such changes, physicians may continue to perform endoscopies on many patients with upper gastrointestinal symptoms—for most of whom there will be little or no direct benefit.

REFERENCES

1. AlIan, R., and Dykes, P., "A Comparison of Routine and Selective Endoscopy in the Management of Upper Gastrointestinal Hemorrhage," *Am. J.Gastroenty.*61:154, 1974.
2. American Board of Internal Medicine, "Guidelines for the Training of Gastroenterologists," *Gastroenty.* 73:382, 1977.
3. American Society for Gastrointestinal Endoscopy, American Gastroenterological Association, American College of Gastroenterology, "The Role of Endoscopy in the Management of Esophagitis: Guidelines for Clinical Applications," revised, July 22, 1978.
4. _____ "The Role of Endoscopy in the Management of Patients With Duodenal Ulcer," revised, 1978.
5. Beecham, H. J., 111, et al., "Salmonella Typhimurium: Transmission by Fiberoptic Upper Gastrointestinal Endoscopy," *J. A.M.A.* 241 :1013, 1979.
6. Belber, J. P., "Gastroscopy and Duodenoscopy," in *Gastrointestinal Disease*, M. H. Sleisenger and J. S. Fordtran (eds.) (Philadelphia: W. B. Saunders Co., 1978).
7. Benson, J. A., Jr., "Enough is Enough, and More is Less," *Gastroenty.*75:353, 1978.

8. California Medical Association, *1974 Revision of the 1969 California Relative Value Studies* (San *Francisco:* Sutter Publications, **1975).**
9. Cameron, A. J., and Ott, B. J., "The Value of Gastroscopy in Clinical Diagnosis: A Computer-Assisted Study, " Mayo *Clin. P.* 52:806, 1977,
10. Colcher, H., "Current Concepts—Gastrointestinal Endoscopy, " *N. Eng. J. Med.* 293:1129, 1975.
11. _____, "Endoscopy of the Stomach and Duodenum," in *Gastroenterology*, H. L. Bockus (cd.) **(Philadelphia:** W. B. Saunders Co., 1974).
12. Cotton, P. B., et al., "Early Endoscopy of Esophagus, Stomach, and Duodenal Bulb in Patients With Haematemesis and Melaena, " *Br. Med. J.* 2:505, 1973.
13. Dagradi, A. E., "State-of-the-Art: The Training of a Gastrointestinal Endoscopist, " *Am. J. Gastroenty.* 71:224, 1979.
14. Dronfield, M. W., et al., "A Prospective, Randomised Study of Endoscopy and Radiology in Acute Upper-Gastrointestinal-Tract Bleeding, " *Lancet*, 1:1167, 1977.
15. Eastwood, G. L., "Does Early Endoscopy Benefit the Patient With Active Upper Gastrointestinal Bleeding?" *Gastroenty.* 72:737, 1977.
16. Falkenstein, D. B., et al., "Endoscopy: A Dominant Influence in the Gastroenterology Job Market, " N. *Eng. J. Med.* 297:116, 1977.
17. Fisher, J. A., et al., "Upper Gastrointestinal Endoscopy—A GP Service, " *Br. J. Med.* 2:1199, 1977.
18. Fung, W, P., et al., "Endoscopic, Histological and Ultra-Structural Correlations in Chronic Gastritis, " *Am. J. Gastroenty.* 71:269, 1979.
19. *Guidelines for Training in Endoscopy* (Boston: Federation of Digestive Disease Societies, Inc., 1979).
20. Hafter, E., "The Risk of Oesophagoscopy and Gastroscopy," SC. *J. Gash-y.* 12 (suppl. 47):12, 1977.
21. Katon, R. M., and Smith, F. W., "Panendoscopy in the Early Diagnosis of Acute Upper Gastrointestinal Bleeding, " *Gastroenty.* 65:728, 1973,
22. Keller, R. T., and Logan, G. M., Jr., "Comparison of Emergent Endoscopy and Upper Gastrointestinal Series Radiography in Acute Upper Gastrointestinal Hemorrhage, " *Gut* 17:180, 1976.
23. Kern, F., Jr., "Clinical Training in Gastroenterology: A Proposal for Restoring Balance, " *Gastroenty.* 6:1489, 1979.
24. _____ "Gastroenterology, 1976: Good News and Bad News, " *Gastroenty.* 71 :537, 1976.
25. Mandelsteam, P., et al., "Complications Associated With Esophagogastroduodenoscopy and With Esophageal Dilation, " *Gastrointest. Endose.* 23:16, 1976.
26. McDonald, W. C., and Rubin, C. E., "Cancer, Benign Tumors, Gastritis, and Other Gastric Diseases, " in *Harrison Principles of Internal Medicine*, 8th cd., G. W. Thorn, et al. (eds.) (New York: McGraw-Hill Book Co., 1977).
27. McGill, D. G., "Manpower in Gastroenterology, " *Gastroenty.* 72:1345, 1977.
28. McGinn, F. P., et al., "A Prospective Comparative Trial Between Early Endoscopy and Radiology in Acute Upper Gastrointestinal Hemorrhage, " *Gut* 16:70, 1975.
29. Mendenhall, R. C., et al., "Gastroenterology Study Report, " USC/DRME D-1067 (Los Angeles: University of Southern California School of Medicine, Division of Research in Medical Education, 1977).
30. Meyers, M. A., and Ghahremani, G. G., "Complications of Diagnostic Endoscopy: 1—Esophagoscopy and Gastroscopy, " Radio. 115:293, 1975.
31. Morris, D, W., et al., "Prospective, Randomized Study of Diagnosis and Outcome in Acute Upper-Gastrointestinal Bleeding: Endoscopy vs. Conventional Radiography, " *Am. J. Dig. Dis.* 20:1103, 1975.
32. Myren, J., "The Cost of Gastroenterological Examinations, " *Scand. J. Gastroent.* 12(suppl. 47): **33, 1977.**
33. Olearchyk, A. S., "Gastric Carcinoma: A Critical Review of 243 Cases, " *Am. J. Gastroenty.* 70: 24, 1978.
34. Petersdorf, R. G., "Internal Medicine 1976: Consequences of Subspecialization and Technology, " *Ann. Intern. Med.* 84:92, 1976.
35. Sandlow, L. J., et al., "A Prospective Randomized Study of the Management of Upper Gastrointestinal Hemorrhage," *A rn. J. Gastroenty.* 61:282, 1974.
36. Schapiro, R. H., "The Visible Vessel: Curse or Blessing?" N. *Eng. J. Med.* 300:1438, 1979.
37. Schindler, R., *Gastroscopy (New* York: Hatner Publishing Co., 1966).
38. Schroeder, S. A., and Showstack, J. A., "The Dynamics of Medical Technology Use: Analysis and Policy Options, " in *Medical Technology: The Culprit Behind Health Care Costs?* proceedings of the Sun Valley Forum, S. Altman and R. Blendon (eds.), DHEW publ. No. (PHS) 79-3216 (Washington, 13. C.: U.S. Government Printing Office, 1979).
39. _____, "Financial Incentives to Perform Med-

ical Procedures and Laboratory Tests: Illustrative Models of Office Practice," *Med. Cure* 16:289, 1978.

40. Seifert, E., et al., "Diagnosis of Early Gastric Cancer," *Am. J. Gastroenty.* 71:563, 1979.
41. Silen, W., "Peptic Ulcer," in *Harrison Principles of Internal Medicine*, 8th ed., G. W. Thorn, et al. (eds.) (New York: McGraw-Hill Book Co., 1977).
42. Silvis, S. E., et al., "Endoscopic Complications: Results of the 1974 American Society for Gastrointestinal Endoscopy Survey," *J. A. M. A.* 235: 928, 1976.
43. Steinberg, H., University of California, San Francisco, Calif., unpublished data, 1978.
44. Stevenson, G. W., et al., "Prospective Comparison of Double-Contrast Barium Meal Examination and Fiberoptic Endoscopy in Acute Upper Gastrointestinal Hemorrhage," *Br.* Med. *J.* 2:723, 1976.
45. Sugawa, C., et al., "Early Endoscopy: A Guide to Therapy for Acute Hemorrhage in the Upper Gastrointestinal Tract," *Arch. Surg.* 107:133, 1973.
46. Sullivan, B. H., "Part II: Esophagoscopy and Biopsy," in *Gastroenterology*, H. L. Bockus (cd.) (Philadelphia: W. B. Saunders, 1974).
47. Waye, J. D., "The Current Status of Esophagoscopy, Gastroscopy, and Duodenoscopy," *Mt. Sinai J. Med.* 42:57, 1975.

COMMENTARY BY THE AMERICAN SOCIETY FOR GASTROINTESTINAL ENDOSCOPY

Bergein F. Overholt, M.D.
Chairman, Ad Hoc Committee on Government Relations
American Society for Gastrointestinal Endoscopy
Manchester, Mass.

In defining costs of performing an upper gastrointestinal endoscopy (EGD), a more realistic cost analysis would include all costs of space, drugs, supplies, depreciated equipment costs, repair costs for instruments, and realistic personnel costs.

The Showstack/Schroeder paper does not contain some of these costs, and consequently their estimates appear erroneous. Also, their paper includes the physician's fee, which we feel should not be considered in estimating actual costs of the procedure, Of course, the physician's fee is variable, depending on experience, geographic location, type of practice, etc., and so we have not included it in our procedural costing data.

Of particular concern is the lack of inclusion of the real instrument costs, including a more realistic 2-year depreciation because of the remarkable advances in equipment; the large instrument repair bills occasioned by the kind of wear attendant to this particular procedure; the necessity for backup instruments; the necessity for equipment for resuscitation in the event of emergency; accessory equipment, electrosurgical power sources, disposable supplies, and realistic personnel costs.

A true cost incorporating similar personnel and space figures as Showstack and Schroeder detail and assuming only 5&percent utilization of facilities and personnel is presented in table A-1. Assuming only *50* percent of personnel and space costs and incorporating actual costs per procedure, one can readily figure accurate and true costs of an office EGD assuming a yearly 46-week working experience.

Although Showstack and Schroeder state the average number of EGDs performed in 1976 was 275/year/endoscopist, a more realistic range today would be *368* to 690/year *(8* to 15/week). This results in the incorporation of only 50 percent of personnel and space expenses in the cost analysis, as these resources would be free for other uses when not being utilized for EGDs.

8 procedures/week x 46 weeks = 368 procedures 'year
10 procedures/week x 46 weeks = 460 procedures/year
12 procedures/week x 46 weeks = 552 procedures/year
15 procedures/week x 46 weeks = 690 procedures/ year

With personnel, space, and depreciated equipment costs of *$41,401.20* and with recurring per procedure costs of $29.70 per EGD, the following range of true per procedure costs in the physician's office can be obtained by the following formula:

$$\frac{\text{Total fixes costs}}{\text{Number of EGDs/year}} + \text{recurring costs/EGD} = \text{true cost/EGD}$$

Fixed costs	/ FGSs	[A vi	= cost FGD +	recurring cost	= True cost (-). / per FGD
41, 401.	20 -	368	= 112.50 +	29.70	= 142.20
41. 401.	20 -	460	= 90.00 +	29.70	= 119.70
41. 401.	20 –	552	= 7500 +	29.70	= 104.70
41. 401.	20 –	690	= 60.00 +	29. 70	= 89.70

It must be realized that when 16 or more procedures are done per week, full-time nurse, and space expenses must be included because procedure set-up time, cleaning time, etc., become a reality. Thus, if 25 procedures per week were performed with full-time R.N. and space expenses included, cost per EGD is figured at $79.70. However, added to this would be the necessity for an additional examining room, table, cart, endoscope, light source, suction machine, oxygen, etc., which would bring the cost above the $100 range.

Finally, it is reemphasized that these figures represent realistic costs for an EGD performed in the physician's office and do not incorporate the physician's fee.

Table A-1.—Estimate of Overall Costs and Recurring Costs per Procedure in Physician's Office (not including physician's fee)

Personnel		
Nurse ($15,000/yr; ½-time, net income)		$7,500.00
LPN ($10,000/yr; ½-time, net income)		5,000.00
Secretary ($10,000/yr; ½-time, net income)		5,000.00
Space (585 ft² @ $1.50/ft²/mos; 50% utilization)		5,265.00
1 examining room ..... 12'x10 = 120 ft²		
2 offices ..... 10'x12 = 240 ft²		
1 supply room ..... 10'x1O = 100 ft²		
½ waiting room area ..... ½ — 10'x20 = 100 ft²		
1 dressing room ..... 5 'x5 = 25 ft²		
Equipment		
A. 2 endoscopes	($14,800)	
1 light source	($1 ,000)	
1 electrosurgical power supply	($1 ,000)	
Items in A are depreciated over 2 years]		8,400.00
B. 1 mechanical table	($4,500)	
1 patient cart	($350)	
1 endoscopic equipment cart	($350)	
1 suction machine	($200)	
1 tank oxygen	($200)	
Emergency equipment (ambu bag; defibrillator, drugs)	($6,000)	
[Items in B are depreciated at 20% per year over 5 years + 10% per year interest expense]		2,436.00
C. Endoscopic accessory equipment:		
3 biopsy forceps	($450)	
1 snare	($150)	
2 cytology brushes	($200)	
[Items in C have 1 year depreciation]		900.00
Subtotal		34,501.00
Overhead @ 20% (light, electricity, heating, fringe benefits, telephone, insurance, etc.)		6,900.20
Total		$41,401.20
Recurring costs per procedure		
A. Drugs(valium, demerol, dyclone, narcan)		$5.00/procedure
B. Disposable items		
1 glove	$0.10	
4 syringes	0.40	
2 needles	0.10	
1 scalp vein	0.50	
Alcohol sponge, band aid, cotton ball	0.05	
Five 4 x 4 sponges	0.05	
1 disposable gown	0.90	
1 trash bag	0.05	
1 charge bill (triplicate)	0.50	
Emesis basin, tissues Iubrifax	1.00	
Cleaning solution (glutaraldhyde, alcohol)	1.00	
Instruction and permit sheet	0.05	4.70/procedure
C. Instrument repair cost		20.00/procedure
Total recurring costs per procedure		$29.70/procedure

AUTHORS' RESPONSE TO ASGE COMMENTARY

We appreciate the opportunity to review the comments of Dr. Bergein Overholt, M. D., of the American Society for Gastrointestinal Endoscopy (ASGE) concerning the report that we prepared for the Office of Technology Assessment, The "Cost and Effectiveness of Upper Gastrointestinal Endoscopy. "

In responding to the ASGE concerns, we would like to point out that our data on charges as well as our cost estimates were for 1977. As such, they would need to be adjusted if one wished to judge the cost in 1980 of an upper gastrointestinal endoscopy. According to Blue Shield of California, the median physician charge in California in 1979 (the most recent year for which data are available) for an esophagogastroduodenoscopy was approximately *$275* **(as** compared to a median charge in 1977 of approximately *$250).*

We describe below some specific issues that we can see in the ASGE estimate of 1980 total yearly costs, but the overall problem with their analysis relates to using the wrong number as the denominator in the equation:

$$\frac{\text{Total yearly cost}}{\text{Yearly volume}} = \text{Average cost per procedure}$$

Our analysis is based on a theoretical yearly volume of procedures and the associated yearly cost. ASGE, in general, estimates total yearly costs, but uses current actual (low) volume figures that have no direct relationship with costs —e.g., our cost estimates are based on an endoscopic procedure taking between 40 and 80 minutes, whereas ASGE estimates that the costs of an endoscopy should be amortized over only 8 to 15 procedures per half week, that is, approximately 2 hours and 30 minutes down to 1 hour and *20* minutes per endoscopy. The ASGE estimate assumes that the costs incurred are not volume-dependent, i.e., that the nurse, secretary, rooms, etc., are not engaged in any other activities while waiting for the next endoscopy to take place. In contrast, our model assumes little or no slack-time. We estimate the cost per procedure, not the cost to an endoscopist of maintaining the facilities to perform endoscopies even at low volume. (Note that we quote in our paper a statement by Waye that an endoscopy should take no more than 15 minutes. Surely, even our time estimates are generous!)

This volume estimate is central to the ASGE argument, as is shown by the following analysis using the ASGE (half-time) *1980* cost estimates ($41,401 fixed costs per year and $30 per procedure) and our estimates of (half-time) volume (we have also added the cost of a half-time endoscopist @ $50,000 per year net):

80 minutes /endoscopy = 690/½ year = $162/procedure
60 minutes /endoscopy = 920/½ year = $129/procedure
40 minutes/endoscopy = 1,380/½ year = $96/procedure

Thus, even if one accepts the ASGE 1980 cost estimates, the costs are still only approximately 35 percent to 60 percent of the typical 1979 charges for the procedure. The point that we make in our paper regarding the difference between costs and charges for endoscopies in 1977 still holds. Note also that, using 1979 charge data, if endoscopists perform between 368 and 690 procedures a year, as the ASGE estimates, the average annual gross charges by endoscopists in California for endoscopies alone is between approximately $101,200 to $189,750 (368 x $275; 690 X $275).

Of course, the cost per endoscopy computed above used ASGE estimates of 1980 costs, We question several cost assumptions made by ASGE. Most importantly, ASGE estimates that there is a $20 "equipment repair cost" (included in their "recurring costs") per endoscopy. Since $20 times the ASGE estimates of volume *(368* to *690* procedures per year) equals between $7,360 and $13,800 per year, one has to wonder why an endoscopist repairs equipment rather than replaces equipment. None of the endoscopists to whom we have spoken has experienced repair bills that even approach the ASGE estimates. In addition, most other ASGE cost estimates are for 1980 and are somewhat generous—e.g., one might question the inclusion of an L.P.N. as well as the amount of time allocated for a secretary (is a half-time secretary really necessary for barely more than one endoscopy per day?). Finally, ASGE does not account for the fact that many endoscopies are done in hospitals

for which the physician does not incur many of the overhead costs estimated by the ASGE.

In general, we feel that the ASGE cost estimates actually support the point that we make in our paper: Charges for an endoscopy are relatively high compared to the cost of performing the procedure.

U. S. GOVERNMENT PRINTING OFFICE 1981 341-844/ 1005