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

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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

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. Wave points out that a patient can inflict severe damage on a fiberoptic endoscope by biting the instrument.

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).

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, pyloricchannel 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)
 Hiatal hernia (13%) Upper gastrointestinal bleed (12°76) Gastritis and duodenitis (10°/0) Stomach ulcer (10%) Upper gastrointestinal cancer (90/.) All other (46°/0) 	1. Hiatal hernia (14%) 2. Caustic substance (9°/0) 3. Obstruction of the esophagus (8°/0) 4. All other (69°/0)	 Upper gastrointestinal bleed (18°/0) Hiatal hernia (12°/0) Stomach ulcer (1 10/0) All other (59°/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 examinations. 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 (Salmonella 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. '(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 op-

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

Type of procedure (1974 CRVS No.°)	Number of procedures	mean
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) Esophagogastroduodenoscopy,	4,027	250
with biopsy (40145)	1,153	280
Others (40102, 40120, 40125)	2,595	240
Total	12,735	\$240

[®]Procedures billed without modifiers

*California Medical Association, 1974 Revision of the 1969 California Relative Value Studies (San Francisco: Sutter Publications, 1975)

timal 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 3.—One-Year Cost Assumptions

Gastroenterologist (full-time, net income) = \$65,000
Nurse (full-time, net income)
Secretary (@ \$10,000 per year,
half-time net income)
4 rooms (370 ft ² @ $1.50/ft^2$ per month) = 6,660
1 examining room, 10 x 10
2 offices, 10' x 10
1 supply room, 10 x 7'
Equipment (depreciated at 20% per year,
plus 10°/0 per year interest expense) = 3,450
Endoscope = \$10,000
Table = 1,500
Subtotal \$95,110
Overhead @ 20% (fringe benefits, telephone,
insurance, supplies, etc.)
Tatal \$114.122
Total

⁶ Datareported by Mendenhall, et al. (28), Indicate that gastroenterologists alone may account for this many procedures. It a likely that Blue Shield of California data overestimate the percentage of elderly patients and children due to the majority of the data coming trommedicare and medicate billings. This inaccuracy may reduce the genera lizability of these data and lead to an overestimate when projected to an attonal aged is tribution An u nk now n 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 1-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 in-

come 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 *An*-nals 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-ofneed 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, thirdparty 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.