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Measuring the Clinical Appropriateness of the Use of a Procedure

Can We Do It?

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Increasing attention is being paid to data on geographic differences in population-based rates of use of medical and surgical procedures. To understand these differences and to determine what level of use is appropriate, a method is needed to judge the clinical appropriateness of services. We recently developed and tested such a method in two large, urban geographic areas. Eighty-one medical records from a randomly selected sample of 30 billing entities (46 physicians) who performed upper gastrointestinal endoscopy (UGIE) on Medicare patients were abstracted. Ninety-four percent of physicians who were asked agreed to participate. Reliability testing showed 99% agreement on items abstracted from a subset of records independently reviewed by two abstractors. Based on the abstractions, each patient could be assigned at least one (mean 2.2) specific clinical indication for which UGIE was performed. Using ratings derived from a previously held panel meeting, it was possible to evaluate the appropriateness of the indications for each UGIE. Key words: upper gastrointestinal endoscopy; clinical appropriateness. (*Med Care* 1988; 26:415-422)

Increasing attention is being paid to differences in population based rates of use of medical and surgical procedures.¹⁻⁶ The reasons for these differences have become a subject of current debate. Since the clinical characteristics of patients may contribute to variations in use rates, a methodology for

assessing the appropriateness of the indications for use of a procedure is necessary. In an attempt to understand the contribution of clinical factors to variations in use rates, we developed a method for retrospectively evaluating the appropriateness of performing a medical procedure. The purpose of this paper is to describe a method for obtaining physician cooperation and for abstracting information required from the medical record so that appropriateness of performing a procedure can be evaluated.

While this method is being used to evaluate indications for both medical and surgical procedures (upper gastrointestinal [UGI] endoscopy, coronary angiography, and carotid endarterectomy), this paper presents only

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results of a study of upper gastrointestinal endoscopy.⁷⁻⁹ Upper gastrointestinal endoscopy was selected because it is a frequent procedure that is performed with variable rates across geographic regions on both inpatients and outpatients who span the disease spectrum from well to critically ill. If the method is satisfactory in identifying the indication(s) for use of endoscopy, it is likely that it can identify indications for other procedures that are performed on more homogeneous groups of patients.

Method

Sample Patients and Physicians

A list of names of individual physicians or groups of physicians who were reimbursed for performing UGI endoscopy on at least five Medicare patients in two PSRO regions in the 9-month period August 1, 1982, through April 30, 1983 was acquired. In addition, a list of patients on whom the procedure was performed was also obtained. From the 62 billing entities (individual physicians or groups of physicians), 30 were randomly selected. The probability of selecting a billing entity was proportional to the number of UGI endoscopies performed.

Six gastroenterologists, each considered a leading medical figure in the locality from which the study sample was drawn, were invited to participate as members of the study's steering committee. These physicians asked six additional gastroenterologists to serve as liaison physicians. Each liaison physician, after being trained in a 2-hour session, was asked to contact up to eight of the billing entities in the sample and ask these endoscopists to cooperate with the study.

The requests made by the liaison physicians to each performing physician were:

1. To allow the office medical record of three patients to be abstracted. The three patients had received their UGI endoscopy at the end of the study period.
2. To sign a letter granting us access to the hospital records for those patients who were

inpatients at the time that endoscopy was performed.

3. To sign a letter asking the referring physician, if any, to allow us to abstract data from his or her office record.

4. To permit x-ray, endoscopic, surgical, and pathologic reports to be reproduced from the office and hospital record.

Once the performing physician agreed to participate, he was sent information that confirmed participation, further explained the study, and described the formal support for the study that had been expressed by the American Medical Association, the American Gastroenterological Association, and the American Hospital Association. A member of the research team then called each performing physician's office to confirm patient chart selection and to schedule appointments for abstracting.

In summary, the method of enlisting physician cooperation depended upon a fanning-out process in which steering committee member physicians recruited liaison physicians who, in turn, enlisted the participation of performing endoscopists, who then invited participation, where necessary, from referring physicians (Fig. 1). Physicians were assured that all data would remain strictly confidential and that the patient, the physician, and the hospital could not be identified. The liaison, performing, and referring physicians were given honoraria of \$300, \$100, and \$100, respectively.

Data Collection and Materials

Two data collectors were trained to abstract the medical records. For each performing physician, one data collector abstracted all of the patient records. Of the three patient records abstracted for each performing physician, two were designated as study cases, and the third was designated as a reliability record. In the case of reliability records, the performing physician's record was the only chart abstracted. The latter was abstracted independently by both data collectors.

To facilitate hospital cooperation, we also prepared a hospital introductory letter, assembled the previously mentioned letters of support, and maintained a copy of an oath of confidentiality that was signed by the data collector who abstracted the medical records. This packet was sent to the director of the medical records department at each hospital and was followed by a telephone call to confirm participation and to arrange for an appointment to abstract the appropriate records.

Abstraction forms, developed by a team consisting of physicians and social scientists, included detailed information about the patient's gastrointestinal problems and comorbid conditions. The information permitted us to select for each study patient one or more of the previously developed indications for use of endoscopy.⁷ This list had been generated by a panel of physicians that included gastroenterologists, primary care physicians, surgeons, and radiologists with diverse geographic backgrounds.¹⁰ The abstraction form required data collectors to respond to approximately 1,000 items. For 79 questions, the data collectors had to justify these answers by copying exact words from the medical record. The broad categories of topics covered in the abstraction form were demography (53 questions); general medical problems (133); past and present gastrointestinal signs, symptoms, and evaluations (586); endoscopy result and postprocedure management (99); and medications (158).

Assigning Indications and Appropriateness Ratings for the Endoscopy

To assign indications for use of endoscopy, each abstraction form was independently reviewed by an experienced data collector and by a physician member of the research team. In addition, a random sample of records and records in which indications were difficult to assign were reviewed by a second physician from the research team. A set of rules was used to relate the

information available from the abstraction form to the list of indications.

For each indication, an appropriateness rating that was designated by the expert panel was assigned. When more than one indication for the use of endoscopy was present, the indication with the higher rating was assigned. Appropriateness was defined by the panel as the condition where the expected health benefit (i.e., increased life expectancy, relief of pain, reduction in anxiety, improved functional capacity) exceeded the expected negative consequences of performing the procedure (i.e., mortality, morbidity, anxiety of anticipating the procedure, misleading or false diagnoses, pain produced by the procedure, time lost from work) by a sufficiently wide margin that the procedure was worth performing. A nine-point integer scale was used. Median ratings by the panel of 1, 2, or 3 were designated as inappropriate and median ratings of 7, 8, or 9 as appropriate. Indeterminate use was defined as median ratings of 4, 5, or 6 or as indications that were rated as inappropriate (i.e., 1, 2, or 3) by at least three panelists *and* as appropriate (i.e., 7, 8, or 9) by at least three panelists.

Results

Abstracting the Medical Record

Of the 30 billing entities (46 physicians) who were invited to participate, 27 billing entities including 43 physicians (94%) did; 100% of the referring physicians participated. Medical records for 81 patients from 27 billing entities were abstracted; 27 of these were used only to assess reliability. The average time required to abstract information from the hospitals', the endoscopists', and the referring physicians' record was 45, 60, and 30 minutes, respectively.

For patients hospitalized at the time of their endoscopy, the hospital record was as complete as the endoscopists' office record. For one patient each, however, the record of a GI consultation, a saline loading test, a

TABLE 1. New Information About Indications for Use of Endoscopy Obtained From the Review of a Referring Physician's Record

New Clinical Information Obtained by Reviewing the Referring Physician's Record	Type of Changes in Indications	Effect of Change in Indications on Appropriateness Ratings
Symptoms of anorexia	Adds (1) new indication	0 points
Symptoms of nausea, vomiting, abdominal pain	Adds (1) new indication	0 points
Past history of peptic disease	Changes (1) indication	0 points
UGI series report states radiologist questions malignancy and recommends endoscopy	Adds (1) new indication	+5 points
UGIs normal (vs. not done)		0 points
Adequate medical therapy vs. inadequate medical therapy (5 weeks vs. 2 nonconsecutive weeks)	Changes (2) indications	+6 points
Prior history of peptic disease	Changes (2) indications	0 points
UGI series report states "further evaluation with endoscopy suggested if clinically warranted"; (vs. UGI series done, no report)	Adds (1) new and changes (1) indications	+6 points
Prior history of peptic disease	Changes (1) indication	0 points

prior UGI endoscopy, and a prior UGI series (all of which had been performed within the year prior to the marker procedure) were missing from the hospital record. The data from these additional tests did not affect the appropriateness score assigned to the endoscopy.

Of the 24 patients whose endoscopies were performed as outpatients, 12 (50%) had both a referring and performing physician who did not share a common office or group record. For 8 of these 12 patients, the information obtained from the referring physician's record added information about the indications for the endoscopy (Table 1). For three of these patients, subsequent change in the appropriateness of the designated rating was striking, changing the rating by 5 or 6 points on the 9-point scale.

The endoscopy report was available for review in all 81 patients. There was a mean of 2.6 diagnoses listed per report with as many as 6 diagnoses listed for two patients. For no patient was the endoscopic examination described as normal. The most common diagnoses were esophagitis (15 patients), hiatal hernia (19 patients), gastric ulcer (17 patients), and gastritis (21 patients).

Reliability Between Data Collectors

Eighteen inpatient and eight outpatient records were reviewed by both data collectors. Because 1,029 data items were collected from each record, 26,754 items were evaluated for reliability. One hundred eighty discrepancies between data collectors were noted (including omitted data). Overall, 99.4% of items of information were identical with discrepancies distributed as follows: demographics, 1.7% (n = 1,378 items); general medical problems 1.8% (n = 3,458 items); past and present gastrointestinal signs, symptoms, and evaluations, 0.5% (n = 15,236 items); endoscopy result and postprocedure management, 0% (n = 2,574 items); medications, 0.2% (n = 4,108 items).

Indications for the Endoscopy

Patients were assigned as many as five separate indications for their endoscopy with a mean of 2.2 indications per patient (Table 2). A patient with peptic symptoms and hematochezia (i.e., bright red blood per rectum) who required more than two transfusions would be assigned one indication

TABLE 2. Indications for Use of Endoscopy in 54 Patients by Clinical Category

Group of Clinical Indications	Total Number of Indications Assigned	Total Number of Patients Who Satisfy an Indication ^a	Patients With an Indication for This Group as the Most Appropriate ^b
Asymptomatic patients at risk for cancer	0	0	0
Follow-up to prior endoscopy	10	4	4
Follow-up to prior UGI series	14	9	9
UGI bleed or melena in patient without portal hypertension	12	12	9
UGI bleed or melena in patient with portal hypertension	4	4	4
Stool positive for occult blood	5	5	3
Hematochezia	0	0	0
Peptic symptoms	38	34	27
UGI obstruction	1	1	0
Dysphagia or odynophagia in normal host	7	7	3
Dysphagia or odynophagia in immunocompromised or diabetic host	1	1	1
Unexplained chest pain	1	1	1
Miscellaneous (anorexia, weight loss, early satiety)	10	10	7
Total	103	88	68

^a The total number of patients who satisfy an indication in a group is less than the total number of indications for the group because one patient may satisfy more than one indication per group.

^b The total number of patients in this column exceeds the total number of 54 studied patients because some patients had a tie in their most appropriate rating.

from the group describing peptic symptoms and a second indication from the group describing clinical scenarios associated with hematochezia. While 40% of the patients had indications for endoscopy that were in only 1 of 13 possible clinical groups of indications, 43% of the patients had indications from 2 of the 13 groups, and 17% had indications from 3.

Using the appropriateness rating developed by the expert panel, each indication for endoscopy was rated. Clinical scenarios describing one patient assigned an appropriate rating and one patient assigned an inappropriate rating are described below.

Inappropriate Use of Endoscopy. A 77-year old man developed angina 2 years after coronary artery bypass surgery; the new angina was controlled medically. His first endoscopy was 6 months ago when, while using naproxen, he was noted to have a duodenal ulcer with bleeding. Two months ago, he again was endoscoped for

recurrence of bleeding from his duodenal ulcer while using aspirin. The latter was stopped and the patient was treated with cimetidine with prompt and complete resolution of his symptoms. A third endoscopy (the procedure evaluated for this study) was performed to evaluate healing of the duodenal ulcer despite the absence of continuing symptoms or signs.

Appropriate Use of Endoscopy. A 66-year-old woman with known arthritis, cardiomyopathy, chronic atrial fibrillation, and chronic stable angina was admitted with a 3-day history of increasing nausea, anorexia, vomiting, and epigastric pain. She gave a 4-week history of epigastric pain, a 12-week history of nausea, and a chronic history of alcohol abuse and pancreatitis. Her medications included ibuprofen, cimetidine, and antacid which she took for 8 weeks prior to admission. One month ago, she had a UGI series that was normal except for a slight prominence of folds in the car-

diaphragmatic junction, unchanged from a prior study 2 years earlier. Endoscopy was performed to evaluate the etiology of the epigastric pain, which persisted despite the use of cimetidine and antacids.

Appropriateness Ratings

For 24% of the endoscopies in this pilot study, the most appropriate indication for the procedure was rated as inappropriate (i.e., median rating = 1, 2, or 3) on the nine-point integer scale. For 11% of procedures, the highest-rated indication was indeterminate (i.e., median rating = 4, 5, or 6 or indication with disagreement regardless of the median rating). For 65% of procedures, the highest-rated indication was appropriate (i.e., median rating = 7, 8, or 9). Table 2 lists the frequency with which the most appropriate indications for each procedure was assigned to each group of clinical indications. Adjustment of the appropriateness rating by patient comorbidity did not significantly ($P > 0.05$) change the ratings despite 11% of the patients being described as having high comorbidity.

Discussion

The reasons for population-based variations in use rates of medical procedures have become an important concern. As interest in this area grows, so does the need for a methodology for assessing the appropriateness of clinical reasons for performing a procedure. The excellent rate of physician participation, the high levels of reliability, the wide range of clinical reasons for the use of endoscopy, and the ability to distinguish levels of appropriateness demonstrate that such a methodology is feasible. Credence is given to the concept that community-based research involving randomly selected physicians and the medical records of their patients can be performed. This study was successful because hospitals, endoscopists, and referring physicians cooperated. Abstraction forms were designed and used to generate reliable information that was sufficiently

detailed to allow us to establish the clinical reason for the performance of the endoscopy. When endoscopy was performed on an inpatient, the hospital record contained the information necessary to assign an indication for its use. It was necessary, however, to supplement the endoscopist's records with information from the referring physician's record if endoscopy was performed on an outpatient; the additional information obtained from the referring physician's office changed the appropriateness rating of the procedure for a few patients.

The small sample size studied does not permit us to generalize from the distribution of appropriateness ratings. It is encouraging, however, to discover that sufficiently detailed clinical information exists so that this question could be answered by a larger national study.

The methodology presented in this paper was designed to collect information about the indications for performing endoscopy in the community and the clinical appropriateness of the indications. After the methodology was used to collect information about why procedures were performed, a separate step assigning the appropriateness rating to the indications was applied. In the current study, we used appropriateness ratings assigned to the indications by a panel of physicians who were diverse both clinically and geographically. Since it is possible that indications rated as inappropriate by one group of raters may be rated as appropriate by another, it is important to note the mixed composition of the panelists who rated the indications for endoscopy assigned in this study.¹⁰ A strength of the methodology presented here is that it allows collection of information about the reason for the procedure to be separated from the assignment of the appropriateness rating. In this way, the methodology can be applied after different raters assign appropriateness ratings to the indications. In addition, the current methodology allows indications for the procedure to be assessed not only in terms of appropriateness but also in terms of the degree

of agreement or disagreement about the appropriateness rating. We have previously described the methods by which agreement regarding appropriateness ratings has been assessed.^{10,11}

Using the methods for measuring the clinical appropriateness of endoscopy, as described in this paper, is expensive. As data using this method accumulate, we anticipate the critical items that determine appropriateness of indications will become apparent. Instruments for data collection can then be refined, as can the best sources for obtaining certain pieces of data (e.g., hospital's or performing physician's or referring physician's record). Currently, there is no secondary data base in the United States (e.g., Medicare data) that provides sufficient clinical data to assess the clinical appropriateness for a procedure. It is, however, conceivable that after sufficient clinically detailed medical record data about appropriateness and quality of care have been collected and analyzed, the foundations for such a meaningful data base could be developed.

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