

Department of Health and Human Services
**OFFICE OF
INSPECTOR GENERAL**

**OUTPATIENT SURGERY
MEDICAL NECESSITY
AND QUALITY OF CARE**



Richard P. Kusserow
INSPECTOR GENERAL

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OFFICE OF INSPECTOR GENERAL

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OEI-09-88-01000

EXECUTIVE SUMMARY

PURPOSE

This report compares the medical necessity and quality of care of selected outpatient surgeries rendered to a 1988 sample of Medicare beneficiaries in ambulatory surgical centers (ASCs) and hospital outpatient departments (OPDs).

This report is the second in a series on outpatient surgery. The first report, issued December 1989, discussed beneficiary satisfaction.

BACKGROUND

Over the past 8 years, the most common setting for surgery has shifted from the inpatient department of the acute care hospital to the OPDs and ASCs. In part, this shift has resulted from advances in medical technology (which have made the ambulatory setting a safer surgical environment), improvements in anesthesia techniques and decreases in the length of postoperative care.

Although most outpatient surgery continues to be performed in OPDs, the number of ASCs and their share of the outpatient surgery market are increasing. From 1984 through 1989, the number of ASCs increased over 300 percent. Between 1988 and 1989 alone, the number of free-standing ASCs increased by 27 percent. As of April 1990, there were 1,177 Medicare-certified ASCs. The rapid ASC growth presented hospitals with a business challenge, to which they responded by increasing the number of OPDs providing outpatient surgery. Although the hospitals perform more outpatient than inpatient surgeries, they are losing their outpatient surgery market share to ASCs. The hospital share has decreased from 89 percent in 1984 to about 76 percent in 1989.

Prior to 1985, outpatient quality of care was not under review by peer review organizations (PROs). Subsequently, several legislative bills expanded the PRO authority to include outpatient quality of care review. In April 1989, the PROs completed implementation of 100 percent preprocedure and 5 percent retrospective review of at least 10 nonemergency inpatient or outpatient surgical procedures. The surgeries selected for this inspection were performed before the national implementation of PROs' preprocedure review.

METHODOLOGY

For this inspection, we selected 4 high-volume Medicare outpatient surgical procedures from 10 States and reviewed the appropriateness of setting, medical necessity and quality of care for each surgery. We selected cataract surgery with intraocular lens (IOL) implant, upper gastrointestinal (GI) endoscopy, colonoscopy and bunionectomy. We identified the 10 States that had the highest number of ASCs and selected a random sample of 1,170 Medicare

beneficiaries, half of whom had their surgeries in ASCs and half in OPDs. Since there were only eight bunionectomies in our sample, we excluded them from the analysis and have not included any information about them in this report. All procedures were performed between January and March 1988. We collected the medical records from both the surgeons and the facilities and used an independent medical review contractor to review the records. The contractor used physician specialists to develop the procedure-specific criteria. The physicians then reviewed each record for appropriateness of outpatient setting, medical necessity and quality of care. In addition, we interviewed several professional medical associations and a sample of ASC and OPD physicians in each specialty to identify currently acceptable standards for medical necessity and quality of care.

Based on information we received from Medicare carriers, we identified 84 ophthalmologists who received more than \$1 million in 1987. We compared the medical necessity and quality of care for their patients with the patients of non-high volume ophthalmologists.

FINDINGS

➤ ***The Outpatient Setting Was Appropriate.***

The medical reviewers determined that the outpatient setting was appropriate for 99.5 percent of the surgeries and inappropriate for only 0.5 percent.

➤ ***While Most Surgeries Were Medically Necessary, Reviewers Questioned More Than 23 Percent Of Upper GI Endoscopies.***

The reviewers determined that 23.3 percent of the upper GI endoscopies, 7.7 percent of the colonoscopies and 1.7 percent of the cataract cases were medically unnecessary.

➤ ***Approximately 14 Percent Of The Beneficiaries Had Poor Or Questionable Care.***

The reviewers determined that 85.6 percent of the beneficiaries had adequate care, 2.7 percent had poor care and 11.7 percent had questionable care.

➤ ***High Volume Ophthalmologists Are More Likely To Provide Medically Unnecessary Services And Render Poor Or Questionable Care.***

High volume ophthalmologists (i.e., those who earn at least \$1 million annually) have almost twice the rate of medically unnecessary surgery and questionable care as non-high volume ophthalmologists.

RECOMMENDATIONS

- ***The HCFA Should Add Upper GI Endoscopies To The PRO Review List Of Recommended Procedures.***

Our study revealed that more than 23 percent of the upper GI endoscopies were medically unnecessary and almost 6 percent of the endoscopy patients had poor care. Therefore, we recommend that HCFA should add upper GI endoscopy to the PRO preprocedure review list of recommended procedures.

- ***The HCFA Should Intensify Review Of High Volume Ophthalmologists.***

By intensifying review of high volume ophthalmologists, HCFA could more easily identify both questionable practice patterns and ophthalmologists who are providing unnecessary services or render poor quality cataract surgery.

AGENCY COMMENTS

The HCFA disagreed with the draft report's recommendations to (1) include upper GI endoscopy on the mandatory PRO preprocedure review list and (2) intensify the review of high volume ophthalmologists. According to HCFA, it would not be cost effective to mandate PRO review of upper GI endoscopies. The HCFA suggested adding the procedure to the recommended review list rather than the mandatory review list. According to HCFA, intensified review of high volume ophthalmologists is not necessary because the current preprocedure mandatory review of cataract surgery is sufficient.

The complete text of the comments is contained in appendix D.

OFFICE OF INSPECTOR GENERAL RESPONSE

Based on HCFA's comments, we have modified our recommendation concerning upper GI endoscopies. Our recommendation now states that upper GI endoscopies should be included on the recommended preprocedure review list rather than the mandatory list.

We continue to be concerned about high volume ophthalmologists and believe that a more intensive review of their services is warranted. This could be accomplished in any of a number of different ways, including (1) a preprocedure PRO review that is more intensive than currently conducted, (2) a postprocedure PRO review, (3) establishment of carrier screens that trigger pre- or postprocedure carrier review or (4) a combination of any of the above or similar methods.

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INTRODUCTION

BACKGROUND

Over the past 8 years, the most common setting for surgery has shifted from the inpatient department of the acute care hospital to the outpatient department of the hospital (OPD) and ambulatory surgical center (ASC). In part, this shift has resulted from advances in medical technology (which have made the ambulatory setting a safer surgical environment), improvements in anesthesia techniques and decreases in the length of postoperative care. The 1983 changes in Medicare inpatient reimbursement under the prospective payment system (PPS) also contributed to the shift to the outpatient setting.

Although most outpatient surgery continues to be performed in OPDs, the number of ASCs and their share of the outpatient surgery market is increasing. Since the Health Care Financing Administration (HCFA) first certified ASCs to receive Medicare reimbursement under the Omnibus Budget Reconciliation Act (OBRA) of 1980, the number of ASCs increased 300 percent from 1984 through 1989. Between 1988 and 1989 alone, the number of free-standing ASCs increased by 27 percent.¹ As of April 1990, there were 1,177 certified ASCs in the Medicare program. The rapid ASC growth presented the hospitals with a business challenge. They responded by increasing the number of OPDs providing outpatient surgery. Although the hospitals perform more outpatient than inpatient surgeries, they are losing their outpatient surgery market share to ASCs. The hospital share has decreased from 89 percent of the market in 1984 to 76 percent in 1989.²

Medicare regulations do not specifically define medical necessity or quality of care. The concepts are characterized as providing adequate care according to the practices of the medical community. Section 1862(a)(1)(A) of the Social Security Act states that no payment may be made under part A or part B for services that are not reasonable and necessary. In recent years, many professional organizations, such as the American Academy of Ophthalmology, have issued guidelines to their members outlining medical necessity criteria and suggesting standards of care.

Prior to 1985, the peer review organizations (PROs) were not responsible for reviewing outpatient quality care. Several legislative bills expanded the PRO authority since that time, including the Consolidated Omnibus Reconciliation Act (COBRA) of 1985 and the Sixth Omnibus Budget Reconciliation Act (SOBRA) of 1986. The COBRA authorized PROs to deny payment for questionable care while SOBRA mandated PROs to review quality care in postacute and ambulatory care settings, including OPDs and hospital-affiliated ASCs. In April 1989, the PROs completed implementation of 100 percent preprocedure review of at least 10 nonemergency inpatient or outpatient surgical procedures. The PROs were given this authority under Section 9401 of Public Law 99-272. Cataract extraction is one of two mandatory procedures. The PROs can choose 8 other procedures from a recommended list of 11 surgeries, or they can select other procedures based on historical data. In addition, HCFA requires the PROs to review retrospectively the medical records for 5 percent of their preprocedure requests on a quarterly basis. The purpose of retrospective review is to verify their

determinations of medical necessity. The surgeries selected for this inspection were completed before the national implementation of PRO preprocedure review.

PURPOSE

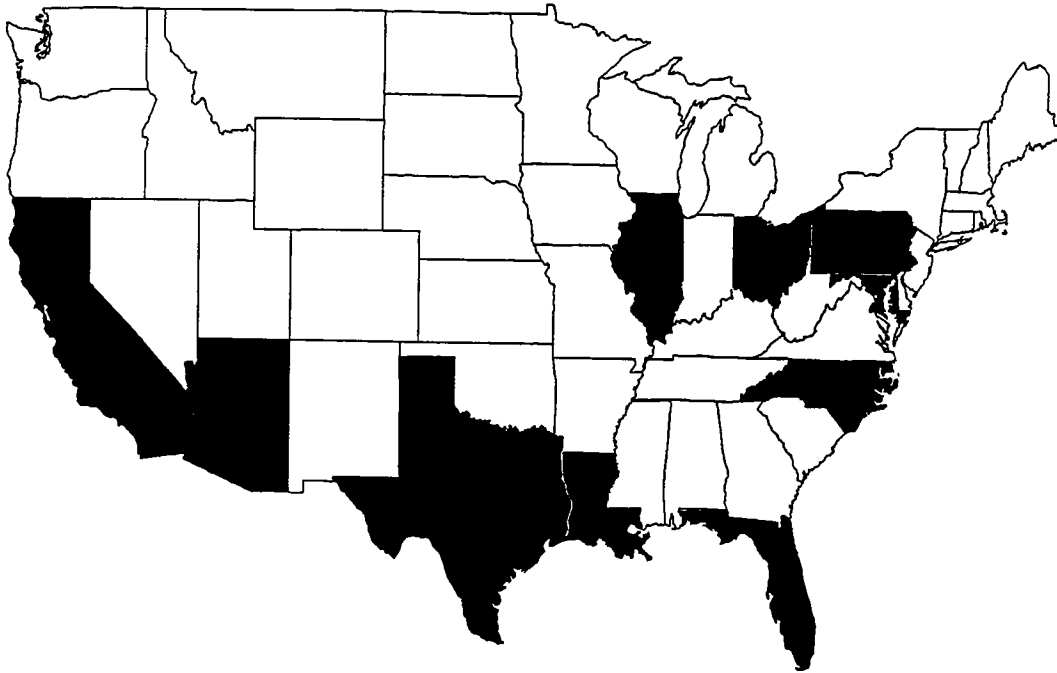
This report compares the medical necessity and quality of care of selected outpatient surgeries rendered to a 1988 sample of ASC and OPD Medicare beneficiaries. This report is the second in a series on outpatient surgery. The first report, issued December 1989, discussed beneficiary satisfaction.

METHODOLOGY

For this inspection, we selected four high-volume Medicare outpatient surgical procedures—cataract extraction with intraocular lens (IOL) implant, upper gastrointestinal (GI) endoscopy, colonoscopy and bunionectomy. Cataract extraction, the highest volume Medicare outpatient procedure, is the surgical removal of a lens that has become cloudy or opaque. The lens is most commonly replaced by an artificial lens (the IOL). Upper GI endoscopy is the visual inspection of the esophagus, stomach and small intestine using a flexible, fiberoptic tube inserted through the mouth. Colonoscopy is the visual inspection of the colon, which is a part of the large intestine, using a flexible, fiberoptic tube inserted through the rectum. A bunionectomy corrects the great toe displacement generally by surgically removing a bone wedge and realigning the toe.

The universe consisted of 172,615 outpatient surgeries that were performed in 10 States between January and March 1988. These were the States with the highest number of Medicare-certified ASCs in February 1988.

10 STATES WITH THE MOST ASCs



We selected a random sample of 1,170 Medicare beneficiaries, half of whom had their surgeries in ASCs and half in OPDs. We chose this sample size to satisfy specific statistical testing criteria which are detailed in appendix A. Due to the small number of bunionectomies, we excluded these cases from all analyses leaving a universe of 1,162 cases. Appendix A includes the details of the sample selection.

We collected the medical records from both the surgeons and the facilities and used an independent medical review contractor to review the records. The contractor used physician specialists to develop the procedure-specific criteria for appropriateness of setting, medical necessity and quality of care. Members of the American Academy of Ophthalmology and the American Society for Gastrointestinal Endoscopy reviewed these criteria, and their suggestions were incorporated. The criteria for each procedure are included in appendix B. The medical reviewers then utilized the criteria and completed a narrative assessment for each record. In addition, we interviewed representatives of several professional medical associations and a sample of ASC and OPD physicians in each specialty to identify currently acceptable standards for medical necessity and quality of care.

Based on information we received from Medicare carriers, we identified 84 ophthalmologists in our sample who received more than \$1 million in 1987. We compared the medical necessity and quality of care of their patients to the patients of non-high volume ophthalmologists.

FINDINGS

THE OUTPATIENT SETTING WAS APPROPRIATE

For the 90.1 percent (1,047 of 1,162 cases) that included documentation, the reviewers assessed the outpatient setting as appropriate for 99.5 percent (1,042 of 1,047 cases) of all procedures and inappropriate for 0.5 percent (5 of 1,047 cases). (See appendix A for detail concerning documented and undocumented records.) Physicians are not required to document in the medical record why they chose the ASC or OPD. However, the patient's history and physical test results will be the basis for determining if a patient should be hospitalized. For our sample, the medical reviewers determined if the outpatient setting was appropriate using objective criteria for each surgical procedure. The criteria included assessing the anesthesia category and the patient's level of illness.

The outpatient setting was inappropriate for five beneficiaries (0.5 percent)—one cataract and four upper GI endoscopy patients. The medical review comments included the following:

The patient has numerous medical problems. She was advised to discontinue her aspirin and Persantine, whether that was done with medical consultation is not clear from the chart, and this could have been dangerous in a person who has had carotid surgery three times. It is likely that this is not a good candidate for an outpatient setting. (ASC cataract patient)

I am not certain that this outpatient setting, if the patient was this fragile, was correct, particularly since she was transferred to a hospital after the procedure.... (ASC upper GI patient)

Overall, there was no statistically significant difference between the ASC and OPD sites for the inappropriate cases.

There were no major differences between OPD and ASC patients in sex and average age. The breakdown by sex for each site was similar—35 percent male and 65 percent female in ASCs and 36 percent male and 64 percent female in OPDs. The average age was 75.8 years for ASC patients and 76.0 years for OPD patients.

The OPD patients in our sample were no sicker than the ASC patients. Sicker patients frequently have concomitant conditions, such as diabetes, hypertension or arrhythmias. If such conditions exist, physicians exercise additional medical precaution when determining if the patient is a good outpatient candidate. Even though 31 percent of all sampled patients had concomitant conditions, the medical reviewers found no differences in the outcomes for these patients. Of the five patients who should have been inpatients, only two of them had concomitant conditions.

There has been much publicity and concern expressed by the American Association of Retired Persons (AARP) and others that patients were being forced to the outpatient setting when they

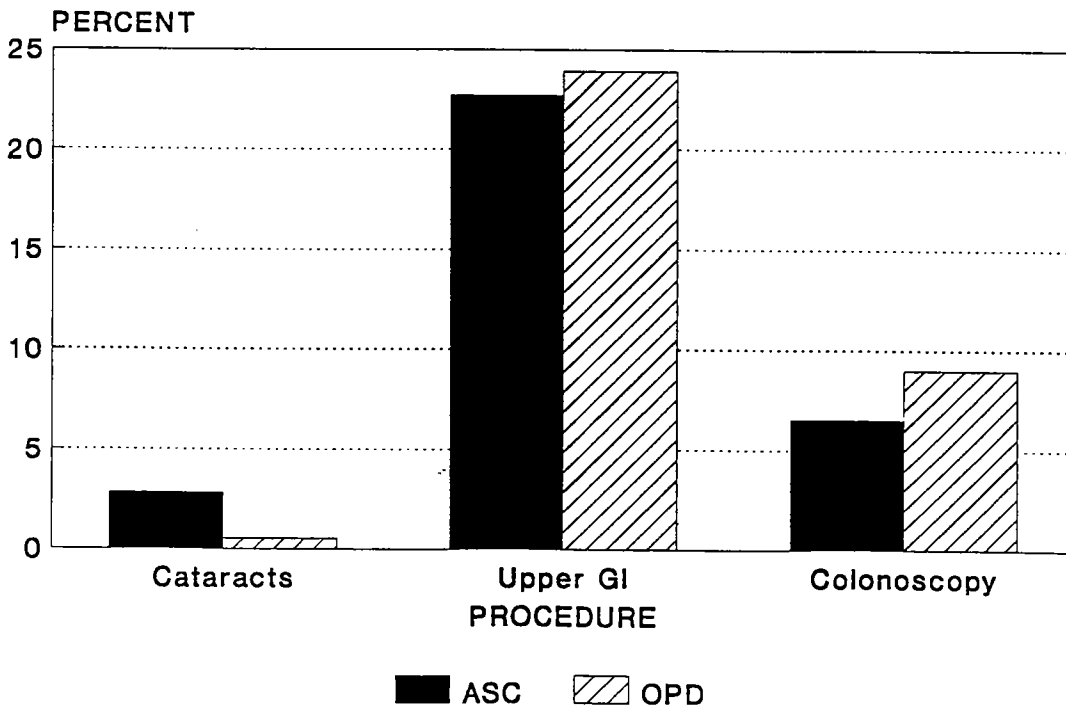
preferred to be hospitalized or should have been admitted because of their medical condition. In our telephone survey, 72 of 837 beneficiaries told us they would have preferred to stay in the hospital overnight. Of the 72 cases, 22 were ASC patients and 50 were OPD patients. According to the medical reviewers, none of the patients' physical conditions warranted their admission as inpatients.

WHILE MOST SURGERIES WERE MEDICALLY NECESSARY, REVIEWERS QUESTIONED MORE THAN 23 PERCENT OF UPPER GI ENDOSCOPIES

For the 96.6 percent (1,122 of 1,162 cases) with documentation, medical reviewers deemed 93.9 percent (1,053 of 1,122 cases) of the surgeries medically necessary and 6.1 percent (69 of 1,122 cases) unnecessary. The medical reviewers analyzed the cases and determined whether the need for surgery was appropriately and adequately substantiated. The reviewers based their decisions on such factors as (1) the decrease in visual acuity caused by the presence of an opacity for cataract surgery, (2) upper GI distress which persists despite an appropriate trial of therapy for upper GI endoscopy or (3) an abnormality identified by barium enema for colonoscopy.

Reviewers determined that 23.3 percent (44 of 189 cases) of the upper GI endoscopies, 7.7 percent (12 of 155 cases) of the colonoscopies and 1.7 percent (13 of 777 cases) of the cataract cases were not medically necessary.

MEDICALLY UNNECESSARY SURGERIES
Distribution by Procedure



The 44 unnecessary upper GI endoscopies were evenly divided between ASCs and OPDs. The usual symptoms which would necessitate the procedure include upper GI bleeding, difficulty in swallowing, persistent vomiting, persistent heartburn or a history of growths (polyps). The most common reasons why the surgeries were found to be medically unnecessary were (1) substantiation for surgery was inadequate (29.5 percent) and (2) symptoms did not justify the procedure (15.9 percent). Inadequate substantiation included cases where the patient did not have a trial of medical therapy prior to the procedure. Inappropriate symptom cases included ones where the endoscopy was used as a routine follow-up for a previously documented noncancerous condition. Our finding of more than 23 percent unnecessary endoscopies is higher than the 17 percent reported in a Rand Corporation study of Medicare patients who had diagnostic upper GI endoscopies in 1981.³ Approximately 77 percent of the cases were performed by gastroenterologists and 23 percent were performed by general surgeons and internists.

The 12 medically unnecessary colonoscopies were almost evenly divided between ASCs and OPDs. Common reasons for performing a colonoscopy include rectal bleeding (technically called occult bleeding), chronic bowel disease, a history of chronic polyps or unexplained anemia. In our sample, the most common reason for medically unnecessary colonoscopies was that the symptoms did not justify the procedure (66.7 percent). For example, if the patient did not exhibit occult blood in a stool sample and there were no other symptoms, the reviewers deemed the procedure as medically unnecessary.

While the overall rate for unnecessary cataract surgery was low (1.7 percent), the rate for the 13 medically unnecessary cases varied between the sites—2.7 percent for ASCs and 0.5 percent for OPDs. While this difference is statistically significant, the numbers are too small for any further analysis which adjusts for other factors such as age, sex or initial visual acuity.

We found that medical necessity could not be determined solely on the beneficiary's reported symptoms. Of 113 upper GI endoscopy patients who reported symptoms such as heartburn and ulcers, medical reviewers determined that only 86 of their endoscopies were medically necessary. For the cataract cases, 3 percent of the beneficiaries did not report symptoms, yet medical reviewers found that their surgeries were necessary. In addition, of 179 beneficiaries who said that their cataracts did not hinder their daily activities, the reviewers found that 177 of the surgeries were medically necessary.

APPROXIMATELY 14 PERCENT OF THE BENEFICIARIES HAD POOR OR QUESTIONABLE CARE

For the 93.4 percent (1,085 of 1,162 cases) of surgeries with documentation, 85.6 percent of the beneficiaries (929 of 1,085 cases) had adequate care, 2.7 percent (29 of 1,085 cases) had poor care and 11.7 percent (127 of 1,085 cases) had questionable care. Poor care is defined as care which does not meet the acceptable standards of the medical community. Two examples of poor care for cataract surgeries include (1) a case where the surgery was performed on the beneficiary's better eye and the surgery caused worse vision in that eye, and (2) a case where more than 2 months after surgery, the beneficiary had poor vision (Snellen test of 20/100). In the

latter case, the medical record indicated no reason for the poor vision, and no tests were performed to assess the cause of the problem. Questionable care was defined as some aspect of care which the reviewers did not find within acceptable standards, e.g., if a cataract patient did not have the basic preoperative screens or if follow-up care was not rendered in a timely manner.

Although ASCs had more cases of poor and questionable care than the OPDs, the difference between the sites was not statistically significant. The quality of care rates for each procedure follow:

Quality of Care Rates by Procedure						
PROCEDURE	ASC		OPD		OVERALL	
	N	%	N	%	N	%
CATARACTS						
poor	8	2.2	5	1.3	13	1.8
questionable	61	16.6	47	12.5	108	14.5
adequate	299	81.3	324	86.2	623	83.7
SUBTOTAL	368	100.1	376	100.0	744	100.0
UPPER GI ENDOSCOPY						
poor	7	7.4	4	4.4	11	5.9
questionable	8	8.4	7	7.6	15	8.0
adequate	80	84.2	81	88.0	161	86.1
SUBTOTAL	95	100.0	92	100.0	187	100.0
COLONOSCOPY						
poor	2	2.6	3	3.9	5	3.3
questionable	1	1.3	3	3.9	4	2.6
adequate	74	96.1	71	92.2	145	94.2
SUBTOTAL	77	100.0	77	100.0	154	100.1
TOTAL	540	49.8	545	50.2	1085	100.0

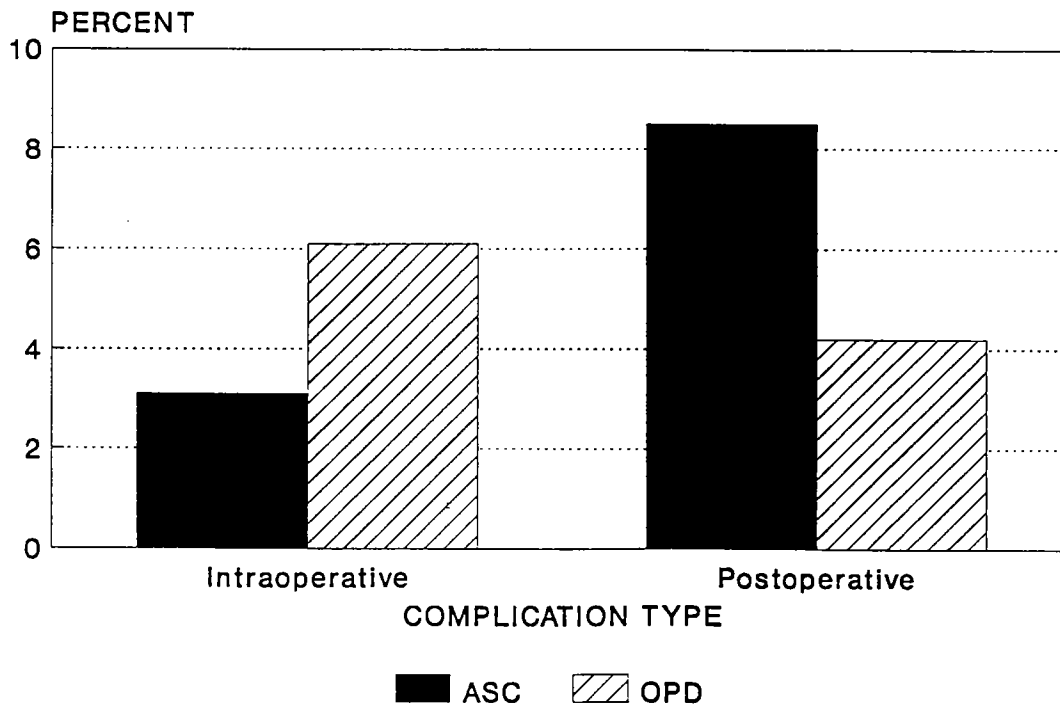
The upper GI endoscopies had the highest rate of poor care in both sites, 7.4 percent of ASC and 4.4 percent of OPD cases.

Intraoperative and Postoperative Complications

The overall OPD intraoperative complication rate for the sample was over twice the ASC rate (2.4 percent versus 1.0 percent), which is statistically significant. Cataract intraoperative complications in our sample included vitreous loss from a posterior capsule tear and iris prolapse from the patient moving on the operating table. Complications during cataract surgery occurred in 3.1 percent of ASC and 6.1 percent of OPD cases. All intraoperative complications in both sites were resolved appropriately.

Postoperative complication rates ranged from 0.5 percent (1 of 202 cases) for upper GI endoscopies to 6.1 percent (49 of 802 cases) for cataracts. There were only 2 endoscopy complications out of 360 upper GI and colonoscopy cases. During the cataract postoperative period, reactions may occur which range from the expected (e.g., mild pain) to the severe (e.g., extreme pain from germ infection). The patient can minimize the expected reactions by using nonprescription pain medication. The severe reactions can lead to serious infection or permanent loss of eyesight, if they are not treated in a timely manner with antibiotics or other medications. Medical literature does not contain many well-established or accepted cataract complication rates for different reactions. A few studies cited rates of 0.04 to 5.7 percent for the retention of large amounts of fluid in the cornea (corneal edema), less than 2 percent for inflammation of the eye cavities (endophthalmitis) and 2 to 3 percent for separation of the thin lining at the back of the eye from the hard shell (retinal detachment).

CATARACT COMPLICATION RATES
By Site



In our study, 6.1 percent of cataract cases had postoperative complications, including protrusion of the colored part of the eye through a corneal wound (iris prolapse), hemorrhage within the anterior chamber (hyphema) and elevated ocular pressure. We found that the postoperative complication rate for the sampled ASC patients was 8.5 percent for cataract cases, while the rate for sampled OPD patients was 4.2 percent, which is statistically significant. Adjustments for age, sex and initial visual acuity had no effect on the complication rate.

Cataract Cases Involving Questionable Care

There were 127 questionable care cases. The highest number (108 of 127 cases) involved cataract surgeries. There are two main reasons why cataract cases were considered questionable:

- Inadequate preoperative tests—About 44 percent (48 of 108 questionable care cases) of surgeries were questioned because the medical record did not include documentation of basic preoperative tests, e.g., A-scan, funduscopy or tonometry.
- 60-day preoperative screening—About 35 percent (38 of 108 cases) of questionable cases did not have preoperative ophthalmic screens completed within 60 days prior to surgery. The medical review criteria specified 60 days as the outside limit in order to have the most current data before surgery. In one case, the biometric data used to measure the IOL power was documented to have occurred 5 years before the surgery.

Of 32 patients who had surgery in both eyes, 17 had the surgeries within 30 days. Surgeons generally do not operate on both eyes within such a short time span. The waiting period should allow healing in the first eye and sufficient time to rule out complications, such as infection. An ASC patient is 3 times more likely to have both cataract surgeries within 30 days than an OPD patient (6 percent versus 2 percent). This practice was prevalent among a few physicians. These cases did not have higher rates of medically unnecessary surgery or quality of care problems than the rest of the sample.

About 9.1 percent of beneficiaries did not have visual acuity improvement. We found that patients with poor or questionable care were less likely to have visual improvement than the patients with adequate care. There is a significant difference by site in the visual acuity improvement of the beneficiaries. This difference may be accounted for by the difference in age and initial visual acuity. As the patients' age increases, they were 1.4 times more likely to have the same or worse postoperative visual acuity. Older patients were almost five times as likely to have the same or worse postoperative vision if the initial visual acuity was 20/40 or better.

In our beneficiary survey, 11 percent (55 of 522 cases) of cataract patients reported their vision was the same or worse after surgery. The medical reviewers, however, found that 25 percent of this group (14 of 55 cases) had no improvement in visual acuity.

HIGH VOLUME OPHTHALMOLOGISTS ARE MORE LIKELY TO PROVIDE MEDICALLY UNNECESSARY SERVICES AND RENDER POOR OR QUESTIONABLE CARE

About 22 percent (178 of 802 cases) of our sampled cataract patients had their surgery performed by high volume ophthalmologists, or ophthalmology groups. These providers received at least \$1 million from Medicare in 1987. Of the 255 ophthalmologists the OIG identified as high volume providers nationally, 84 were in our sample. Sixty-four percent of the 84 physicians are solo practitioners, and 36 percent are group practitioners. We conducted further analysis to determine whether the quality and medical necessity of the surgeries performed by high volume ophthalmologists differed from non-high volume ophthalmologists.

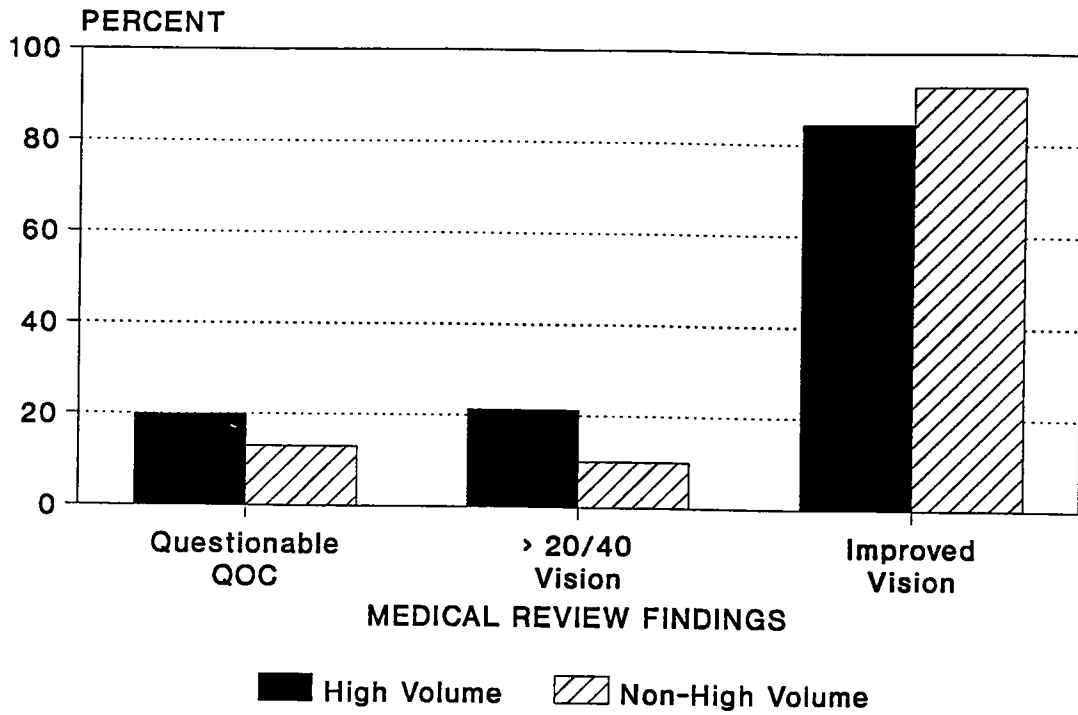
While high volume physicians do not affect the differences between OPDs and ASCs, they do have a higher percentage of medically unnecessary, poor and questionable care cases. Within the OPD sample, they have a higher percentage of poor and questionable care than non-high volume ophthalmologists. Within the ASC sample, they are responsible for a greater percentage of medically unnecessary surgeries. In addition, ASC high volume ophthalmologists operate on patients with better preoperative visual acuity.

Compared to non-high volume ophthalmologists, the surgeries performed by high volume ophthalmologists were:

- twice as likely to be medically unnecessary (2.9 percent versus 1.3 percent—not statistically significant),
- twice as likely to be of poor quality (3.0 percent versus 1.4 percent—not statistically significant),
- more likely to be of questionable quality (19.9 percent versus 13.0 percent—statistically significant),
- less likely to have intraoperative complications (2.9 percent versus 5.3 percent—not statistically significant),
- more likely to have postoperative complications (8.6 percent versus 5.7 percent—not statistically significant),
- twice as likely to be performed on patients with a visual acuity of 20/40 or better (21.4 percent versus 10.1 percent—statistically significant) and
- based on changes between pre- and postoperative visual acuity only, more likely to have the same or worse visual acuity (15.6 percent versus 7.3 percent—statistically significant).

COMPARISON OF CATARACT PROVIDERS

High Volume versus Non-High Volume



NOTE: QOC = Quality of Care

RECOMMENDATIONS

THE HCFA SHOULD ADD UPPER GI ENDOSCOPIES TO THE PRO REVIEW LIST OF RECOMMENDED PROCEDURES

Currently, the peer review organizations review 10 inpatient or outpatient surgical procedures on a preprocedure and retrospective basis for quality of care. Cataract surgery is one of two mandatory procedures. Our study revealed that more than 23 percent of the upper GI endoscopies were medically unnecessary and almost 6 percent of the endoscopy patients had poor care. Therefore, we recommend that HCFA add upper GI endoscopy to the PRO review list of recommended procedures.

THE HCFA SHOULD INTENSIFY REVIEW OF HIGH VOLUME OPHTHALMOLOGISTS

By intensifying review of high volume ophthalmologists, HCFA could more easily identify both questionable practice patterns and ophthalmologists who are providing unnecessary or poor quality cataract surgery.

AGENCY COMMENTS

The HCFA disagreed with the draft report's recommendations to (1) include upper GI endoscopy on the mandatory PRO preprocedure review list and (2) intensify the review of high volume ophthalmologists. According to HCFA, it would not be cost effective to mandate PRO review of upper GI endoscopies. The HCFA suggested adding the procedure to the recommended review list rather than the mandatory review list. According to HCFA, intensified review of high volume ophthalmologists is not necessary because the current preprocedure mandatory review of cataract surgery is sufficient.

The complete text of the comments is contained in appendix D.

OFFICE OF INSPECTOR GENERAL RESPONSE

Based on HCFA's comments, we have modified our recommendation concerning upper GI endoscopies. Our recommendation now states that upper GI endoscopies should be included on the recommended preprocedure review list rather than the mandatory list.

We continue to be concerned about high volume ophthalmologists and believe that a more intensive review of their services is warranted. This could be accomplished in any of a number of different ways, including (1) a preprocedure PRO review that is more intensive than currently

conducted, (2) a postprocedure PRO review, (3) establishment of carrier screens that trigger pre- or postprocedure carrier review or (4) a combination of any of the above or similar methods.

ENDNOTES

1. John A. Henderson, "Surgery centers continue making inroads," *Modern Healthcare*, May 21, 1990, p. 99.
2. *Ibid.*, p. 99.
3. "Abstracts—Upper GI Endoscopy: Is It Overused?" *Geriatrics*, February 1989, p. 98.

APPENDIX A

METHODOLOGY

The purpose of the study was to compare the medical necessity, quality of care and cost of selected Medicare outpatient surgical procedures in two settings—ambulatory surgical centers (ASCs) and hospital outpatient departments (OPDs). We identified the 11 States that had the highest number of ASCs—Arizona, California, Florida, Illinois, Louisiana, Maryland, North Carolina, Ohio, Pennsylvania, Texas and Washington. These States had 61 percent of the ASCs certified by the Health Care Financing Administration (HCFA) in February 1988. We identified several high volume outpatient procedures on the basis of (1) the 1985 Part B Medicare Annual Data (BMAD), (2) HCFA's 1986 ASC survey, (3) interviews with ASC administrators and (4) input from the academic community and several medical societies. We selected four procedures—cataract extraction with intraocular lens (IOL) implant, upper gastrointestinal (GI) endoscopy, colonoscopy and bunionectomy.

To establish the universe of outpatient surgeries performed between January 1 and March 31, 1988, we requested procedure code printouts from the 12 Medicare carriers that process Part B claims for the 11 States. (We chose the first quarter of 1988 to allow the intermediaries, which pay OPD claims, sufficient time to convert their claims processing systems to incorporate the same billing codes used by the carriers, which pay ASC claims.) We manually counted ASC and OPD surgeries for the four procedures from the printouts. We eliminated Washington from the sample because the carrier printouts did not distinguish the specific outpatient site (ASC or OPD) for three of the four procedures—upper GI endoscopy, colonoscopy and bunionectomy. The universe of surgeries for the selected quarter are distributed by site as follows:

PROCEDURE	ASC		OPD		TOTAL	
	N	%	N	%	N	%
Cataracts	44299	85.1	74121	61.5	118420	68.6
Upper GI Endoscopy	4093	7.9	25712	21.3	29805	17.3
Colonoscopy	3287	6.3	19938	16.5	23225	13.5
Bunionectomy	357	0.7	808	0.7	1165	0.7
TOTALS	52036	100.0	120579	100.0	172615	100.1

To determine our sample size, we used HCFA's 5-percent threshold for peer review organization (PRO) review of outpatient quality of care. We assumed the same threshold and set a power of 80 percent to determine a two-fold difference between ASCs and OPDs. We had an 80 percent chance to determine if significant positive or negative differences existed, e.g., if poor ASC quality of care exceeded 10 percent or if it fell below 2.5 percent when the OPD rate for poor care was 5 percent. Using this criterion, we selected 585 surgeries in each site. We used a computer program to generate random numbers and identified a total of 1,170 surgeries. We selected a proportionate number of surgeries from each State based on the summed distribution of all outpatient surgeries in that State. Table 2 includes the State sample distribution.

TABLE 2										
Distribution of Procedures Among States										
	PROCEDURE GROUP									
	Cataracts		Upper GI Endoscopy		Colonoscopy		Bunionectomy		TOTAL	
	N	%	N	%	N	%	N	%	N	%
STATE										
Arizona	34	4.2	10	5.0	2	1.3	0	0.0	46	3.9
California	160	20.0	68	33.7	64	40.5	6	75.0	298	25.5
Florida	170	21.2	12	5.9	22	13.9	2	25.0	206	17.6
Illinois	58	7.2	0	0.0	0	0.0	0	0.0	58	5.0
Ohio	60	7.5	20	9.9	12	7.6	0	0.0	92	7.9
Louisiana	32	4.0	12	5.9	4	2.5	0	0.0	48	4.1
Maryland	20	2.5	8	4.0	6	3.8	0	0.0	34	2.9
North Carolina	46	5.7	16	7.9	8	5.1	0	0.0	70	6.0
Pennsylvania	64	8.0	30	14.9	24	15.2	0	0.0	118	10.1
Texas	158	19.7	26	12.9	16	10.1	0	0.0	200	17.1
TOTALS	802	100.0	202	100.1	158	100.0	8	100.0	1170	100.1

We requested beneficiary payment histories from the carriers to (1) identify the surgeons and the facilities where surgeries were completed and (2) determine all procedures associated with the entire episode of care, including preoperative tests and postoperative services rendered by September 30, 1988. We then requested medical records from both the surgeons' offices and the facilities (ASCs or OPDs). The medical data included, at a minimum, a record of both pre- and postoperative care rendered by physicians during office visits, preoperative test results, copies of the operative reports, anesthesia reports, x-ray interpretations and any related paperwork completed during the surgery.

We identified all services associated with the surgeries, e.g., preoperative ophthalmic tests, and entered the frequencies and costs into a dBase III+ program for further SAS statistical analysis. For those OPD surgeries where IOLs were not billed to Part B through the carrier, we contacted fiscal intermediaries to obtain copies of the claims submitted by the hospitals. When the IOLs were included in medical supplies or sterile supplies rather than a separate cost center, we called the hospitals to obtain the billed and allowed amounts.

An independent medical review contractor used physician specialists to develop procedure-specific criteria. Members of the American Academy of Ophthalmology and the American Society for Gastrointestinal Endoscopy reviewed the criteria, and their suggestions were incorporated. The medical reviewers utilized the criteria and completed a narrative assessment for each record. The reviewers assessed each record for medical necessity, appropriateness of the outpatient setting and quality of care.

First, we eliminated the bunionectomies from all analyses due to the small number included in the sample. For some of the remaining cases, assessment was impossible when the medical records were (1) incomplete due to missing information from the surgeon or the facility or (2) inadequate due to illegible or poor documentation. For these undocumented records, the medical reviewers were unable to assess 9.9 percent (115 of 1,162 records) for appropriateness of the outpatient setting, 3.5 percent (41 of 1,162 records) for medical necessity and 6.6 percent (77 of 1,162 records) for quality of care.

Based on information we received from Medicare carriers, we identified ophthalmologists who received more than \$1 million in 1987. Out of 255 ophthalmologists, 84 performed 178 surgeries in our sample. We analyzed this subset further to identify any differences between the surgeries completed by the high volume ophthalmologists versus the non-high volume ophthalmologists in our sample. Table 3 describes demographic data about the sampled ASC and OPD patients.

In addition, we interviewed representatives of several professional medical associations and a sample of ASC and OPD physicians in each specialty to identify currently acceptable standards for medical necessity and quality of care.

Table 3 describes demographic data about the sampled ASC and OPD patients.

TABLE 3				
Demographic Information for Sample				
CHARACTERISTIC	ASC		OPD	
	N	%	N	%
AVERAGE AGE (years)	75.8	N/A	76.0	N/A
AGE GROUP				
0-64 years	14	2.4	19	3.2
65-69 years	83	14.2	88	15.0
70-74 years	167	28.5	136	23.2
75-79 years	142	24.3	156	26.7
80-84 years	122	20.9	120	20.5
85+ years	57	9.7	66	11.3
TOTAL	585	100.0	585	99.9
SEX				
Female	380	65.0	375	64.1
Male	205	35.0	210	35.9
TOTAL	585	100.0	585	100.0
RACE				
White	130	22.2	357	61.0
Black	6	1.0	30	5.1
Asian	2	0.3	4	0.7
Other	3	0.5	14	2.4
Not documented	444	75.9	180	30.8
TOTAL	585	99.9	585	100.0

APPENDIX B

MEDICAL REVIEW CRITERIA

APPENDIX C

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APPENDIX D

AGENCY COMMENTS

APPENDIX E

AMERICAN SOCIETY FOR GASTROINTESTINAL ENDOSCOPY LETTER