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CATARACT SURGERY

Patient-Reported Data on Appropriateness and Outcomes

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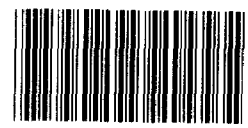

Dear Mr. Chairman and Members of the Committee:

I am pleased to be here today to present the results of a study we conducted at the request of this committee. The specific topic is cataract surgery, but I believe that GAO's findings in this relatively narrow area also have relevance to the broader field of health care reform. As the nation struggles with mounting costs and concerns over diminishing quality, the data I will present this morning show that opportunities exist for reducing the costs of health care while simultaneously improving its quality.

This morning we are releasing a report on our study that provides more details than I can present in the context of this statement. Instead, what I will give here today is an overview of the study and its objectives, methods, and findings.

OVERVIEW

A cataract is a clouding of the lens of an eye that typically develops slowly as people get older. Depending on what part of the lens is most affected, and how far along the process has gone, the effect on vision can range from minimal to catastrophic. In most cases, surgical removal of the obscured natural lens, usually combined with the insertion of an artificial lens implant, is the only treatment option available.

Whereas cataract surgery was once invariably a procedure performed on an inpatient basis, the overwhelming majority of cataract surgeries are now performed as outpatient procedures, either in hospital outpatient departments or in free-standing ambulatory surgical centers.

The shift of the locale for surgery from the hospital to the ambulatory setting has raised concerns regarding the mechanisms by which quality of care is monitored. Based on these concerns, this committee requested that we conduct a study evaluating quality assurance mechanisms under the Medicare program. The study, which focuses on cataract surgery, has a number of components, the most innovative of which is a survey of patients who have undergone cataract surgery. The objective of this survey was to gather information directly from patients on their experiences. We did this for two reasons. The first was because patients leave the ambulatory setting shortly after their surgery and there is no other systematic source of information on the extent of morbidity (pain, swelling, infection, and so on) or benefit (improvements in vision) resulting from the procedure. Second, even if there were another source, patients have the greatest awareness and the most complete knowledge of the symptoms and functional impairments they have themselves experienced.

We sent our survey to 1,964 patients in California,

Massachusetts, Pennsylvania, and Texas. We obtained usable responses from 1,488, or 76 percent. This rate is calculated from the total set of cases included in the random selection. Therefore, nonresponse includes all those for whom no survey results were obtained for any reason (death, mental infirmity, inaccurate mailing address, and so on).

For criteria for medical necessity, we used guidelines issued by the American Academy of Ophthalmology (AAO). These guidelines emphasize the importance of assessing both the effect of the cataract on the patient's usual activities and the clinical measurement of visual acuity in weighing the likely benefits of surgery against the risks of serious adverse outcomes. According to the guidelines, surgery is not appropriate unless there is evidence that the cataract has led to both clinically measured limitations in visual acuity and functional impairment perceived by the patient in his or her daily life.

Further, on February 25 of this year, the Agency for Health Care Policy and Research (AHCPR) announced a new guideline for the clinical management of cataracts in adults. This guideline, similar to AAO's, makes it clear that intervention is appropriate only when a functional impairment exists (that is, when some facet of daily living is constrained because of the cataract). Further, the guideline states that a "patient must understand the

likely benefits and potential risks of undergoing cataract surgery." The data from our survey speak to each of these important issues and allow us to address two specific questions:

-- To what extent do patients undergoing cataract surgery experience positive results?

-- To what extent do surgeries meet the criteria established for medical necessity?

I will discuss our findings on each of these questions in turn.

OUTCOMES FROM CATARACT SURGERY

Although in individual cases other long-term outcomes may ensue, the central issue in outcomes measurement for cataract surgery is how much better patients can see once they have recovered from the operation. We addressed this issue by examining how much change was reported by our patient respondents in terms of both symptoms and functions. Tables 1 and 2 show the proportion of patients reporting that their functional capabilities and symptoms improved, stayed the same, or got worse. (Change in this analysis represents any increase or decrease in the extent to which a patient had difficulty with a functional activity or was bothered by a symptom.)

Table 1: Proportion of Patients Who Reported Their Visual Functioning Improved, Stayed the Same, or Worsened After Surgery

Activity	Better	Same	Worse
Watching TV			
Seeing picture at all	36.1%	60.6%	3.2%
Seeing colors	30.2	67.2	2.6
Recognizing people	44.4	51.9	3.7
Reading words on screen	62.3	33.3	4.4
Reading			
Headlines	32.0	65.7	2.3
Large print	24.1	73.9	2.0
Standard text	56.2	38.4	5.4
Telephone books	59.6	35.9	4.4
Driving			
Short distances in daytime	34.1	64.2	1.8
Long distances in daytime	47.0	48.9	4.1
Short distances at night	61.9	33.9	4.3
Long distances at night	61.1	35.7	3.1

Table 2: Proportion of Patients Who Reported Their Eye Symptoms Improved, Stayed the Same, or Worsened After Surgery

Symptom	Better	Same	Worse
Blurred vision	77.8%	18.8%	3.4%
Sensitivity to glare	53.1	35.8	11.1
Double vision	21.8	75.6	2.6
Itching	34.1	58.8	7.1
Floaters	44.8	50.8	4.5
Feeling of something in eye	37.9	55.8	6.2

As can be seen from the tables, a majority of patients reported an improvement in 5 of the 12 functional activities. The largest improvement was noted in reading words on television and driving at night, followed closely by reading telephone books and standard-sized text. Most of those who did not indicate improvement in a given activity remained unchanged, but between 2 and 5 percent said that they got worse after the surgery.

Much the same pattern emerged for symptoms. Improvement was most striking for blurred vision, where over three quarters said they got better. A little over half reported less sensitivity to glare, and somewhat less than half indicated improvement with "floaters." While most of the rest remained unchanged, between 3 and 11 percent reported getting worse. Sensitivity to glare was the symptom most likely to worsen after surgery.

Patients may improve in some symptoms or functions and worsen in others. To get a sense of how symptoms and functional abilities changed overall, we divided our respondents into four groups:

-- those reporting clear improvement (one or more items improved with none worsening),

-- those who experienced no change (no items either improving or worsening),

-- those reporting a clear deterioration (one or more items worsening with none improving), and

-- those with mixed results (some items improved and others worsened).

The distribution for functions alone, symptoms alone, and functions and symptoms together is shown in table 3.

Table 3: Cumulative Change in Symptoms and Functions: Cataract Patients Who Experienced Improvement, No Change, Worsening, or Mixed Outcomes

	Better	No change	Worse	Mixed
Functions	74.1%	9.7%	4.6%	11.7%
Symptoms	71.4	5.3	5.0	18.3
Functions and symptoms	65.9	1.7	2.4	30.0

Again, our data show that the results of cataract surgery were clearly favorable for a substantial majority of patients. In terms of change in visual functioning, symptoms, and both taken together, about three fourths to two thirds of the patients responding to our survey indicated some level of improvement with no offsetting worsening on another symptom or function. The next largest group, between 12 and 30 percent, improved in some areas and worsened in others. Uniformly adverse outcomes were limited to between 4 and 5 percent of patients for functions and symptoms and only a little more than 2 percent considering functions and symptoms together. Another 1.7 percent indicated no change for any symptoms or functions.

MEDICAL NECESSITY FOR CATARACT SURGERY

The guidelines issued by AAO on when cataract surgery should be performed specify three criteria as necessary:

-- the patient should perceive a visual disability, relative to the types of activities that he or she otherwise would normally undertake;

-- the patient's vision must be impaired (that is, the clinically measured best correctable visual acuity

should be 20/50 or worse on the Snellen scale);[1]

-- the patient should have been informed of the risks and benefits of surgery and should have made his or her own decision that the benefits outweigh the risks.[2]

Although our survey did not measure the frequency with which patients were involved in the decision to have cataract surgery (the third AAO criterion), we did collect data on the extent to which patients experienced symptoms and functional impairment prior to surgery. I will begin with the results reported by patients on the nature and extent of their presurgery symptoms.

Symptoms Prior to Surgery

Table 4 shows the proportion of patients who reported having each of the 6 symptoms we asked about immediately prior to their cataract surgery and the extent to which they were bothered by them.

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[1]Or 20/40 or worse with a patient's complaints of disabling glare.

[2]American Academy of Ophthalmology, "Cataract in the Otherwise Healthy Eye," September 16, 1989, p. 6.

Table 4: Extent of Presurgery Eye Symptoms Reported by Patients

Symptom	Patient did not have symptom	Patient had symptom and was bothered			
		Not at all	A little	Moderately	Severely
Blurred vision	12.0%	5.2%	23.7%	31.7%	27.4%
Sensitivity to glare	23.4	6.0	25.4	26.3	18.8
Double vision	75.5	3.2	9.9	7.7	3.8
Itching	55.0	8.2	20.2	12.2	4.4
Floaters	40.3	15.4	24.1	14.4	5.7
Feeling of something in eye	52.5	6.9	20.8	13.1	6.7

Blurred vision and excessive sensitivity to glare were, as expected, the two most common presurgery symptoms reported by our respondents. They appeared in 88 and 77 percent of these patients, respectively. However, the extent to which these symptoms affected patients varied markedly. A few, 5 to 6 percent, had these symptoms but were not bothered by them at all. Another 25 percent, approximately, experienced little bother. Fifty-nine percent had moderate to severe difficulty with blurred vision, 45 percent with glare.

Table 5 presents the pattern when one looks for the most extreme presurgery symptom reported across all 6 possible symptoms. The intent is to show the proportion of patients who experienced different levels of "bother" because of their

cataract-related symptoms. The table also shows the greatest degree of bother for just the three classic cataract symptoms--blurred vision, sensitivity to glare, and double vision.

Table 5: Highest Level of Presurgery Eye Symptoms Reported for Any of Six Symptoms[a]

Symptom	Patient did not have symptom	Patient had symptom and was bothered			
		Not at all	A little	Moderately	Severely
Most severe response among all 6 symptoms	3.0%	6.2%	20.9%	34.9%	35.1%
Most severe response among blurred vision, glare, and double vision	6.0	5.6	21.5	33.6	33.3

[a]The 6 symptoms are blurred vision, sensitivity to glare, double vision, itching, floaters, and a feeling of something in the eye.

As the table shows, only 3 percent of patients reported having no symptoms. However, almost 10 percent reported either not having had symptoms or not being bothered by them at all (3 plus 6.2 percent).

Functional Impairment Prior to Surgery

Let us turn now to functional impairment, the primary criterion for defining appropriate surgery in the AAO guidelines and in the more recent guideline from AHCPR. Both sets of

guidelines are in accord that if daily life is not changed by the presence of a cataract, then surgery to remove the cataract is not justified. The reason for this is that although cataract surgery is usually safe, it does carry some risks, similar to most forms of surgery. This can be seen from our data in tables 1 and 2, showing that some patients did report getting worse after the surgery. In instances in which the surgery is unlikely to improve daily functioning, therefore, the logic is that these risks are not worth taking.

The data from our survey allow us to comment on the extent of functional impairment before surgery reported by patients undergoing cataract surgery. The responses to these questions, shown in table 6, indicate two overall patterns. First, except for the visually most stressful activities, the majority of patients reported relatively unimpaired eye function. Those experiencing little or no difficulty substantially outnumbered those having moderate to great difficulty in 8 of the 12 activities. For 2--reading words on television and driving short distances at night--about as many reported moderate to great difficulty as little or none. Only for reading telephone books and driving long distances at night did the group experiencing moderate to great difficulty clearly predominate.

Table 6: Extent of Presurgery Impaired Visual Functioning Reported by Patients

Activity	Amount of difficulty				Not applicable
	None	Little	Moderate	Severe	
Watching TV					
Seeing picture at all	57.1%	21.6%	14.0%	5.3%	2.0%
Seeing colors	63.8	16.8	10.7	7.2	1.5
Recognizing people	45.2	25.1	19.3	8.9	1.5
Reading words on screen	23.2	24.6	27.7	21.5	3.0
Reading					
Headlines	61.1	14.9	10.7	9.6	3.7
Large print	64.1	13.1	8.7	4.3	9.8
Standard text	29.1	26.3	20.7	18.6	5.3
Telephone books	16.0	24.5	20.9	32.9	5.6
Driving					
Short distances daytime	41.5	13.1	7.9	3.0	34.5
Long distances daytime	24.6	16.7	10.2	5.4	43.0
Short distances at night	11.4	15.0	10.9	15.6	47.1
Long distances at night	5.7	9.0	10.9	18.5	55.8

As with our analysis for symptoms, we looked across all measures of functional impairment to see the highest level reported by patients in any of the 12 measures. Table 7 presents these results.

Table 7: Highest Level of Presurgery Visual Impairment Reported by Patients for Any of Twelve Functional Activities[a]

	Amount of difficulty			
	None	Little	Moderate	Severe
Greatest difficulty reported for any of 12 functions	6.0%	18.0%	25.4%	50.5%
Greatest difficulty reported for any of 10 functions[b]	9.7	22.3	29.0	39.1

[a]The 12 activities are listed in table 1.

[b]Excludes driving long distances at night and reading telephone books.

As can be seen from table 7, 6 percent of patients reported having no functional impairment prior to their cataract operations. Importantly, if these patients in fact did not have any limitations in their daily living resulting from their cataracts, then they did not meet an essential criterion in both the AAO and AHCPR guidelines on when surgery is appropriate. Further, if one expands the category of "questionable" surgeries to include those on patients who report having only "slight impairment," then 24 percent of the surgeries covered by our sample fall into this category.

CONCLUSIONS AND IMPLICATIONS

What, then, do all these numbers I have presented mean? Are things going well with cataract surgery, or is there reason for

concern? At the most general level, it seems that the news reported by patients is both good and bad. On the positive side, it seems clear that few patients (between 4 and 5 percent) experience uniformly negative changes with either symptoms or functions and even fewer (about 2 percent) experience uniformly negative outcomes for both symptoms and functions taken together. In addition, the majority of patients (approximately two out of three) report improvements in both symptoms and functions after their operations.

However, it is clear that some patients do report negative outcomes, which means that efforts at monitoring quality of care in this area remain important. As I mentioned, the data from cataract surgery patients is only one component of a larger study of quality assurance under the Medicare program. Our report from the full project, due this summer, will address the needs for quality assurance in greater detail.

The most important immediate message from our data, however, regards medical necessity. Although inappropriateness has not been clearly defined, our survey results show different amounts of questionable surgery based on different criteria for appropriateness.

If we adopt the criterion that any level of problem with either symptoms or functions (even those the patient considers

slight) is sufficient to warrant surgery, our study shows that very few surgeries (2.5 percent) were inappropriate. But if the criterion we choose is functional impairment--the one adopted by both the AAO and AHCPR guidelines--then 6 percent of surgeries in our study were inappropriate. (This is based on the proportion of patients who indicated they had no limitations in any of the 12 functional activities included in our survey before their cataract surgeries.)

If we escalate the criterion for inappropriateness from "no problem" to "slight problem," then 16 percent of our respondents' surgeries were questionable. (This corresponds to the proportion of patients who indicated they had no more than "slight" problems with either symptoms or functions prior to surgery.)

Finally, if the criterion is one of substantial functional impairment, almost a quarter of our respondents (24 percent) would have had inappropriate surgery, reporting to us that they had no more than slight problems with visual function before their surgeries.

Because of the magnitude of total Medicare expenditures for cataract surgery, even small changes in the rate of inappropriate surgery could have notable financial implications. Exactly how much money would be "saved" on a continuing basis by reducing inappropriate cataract surgeries is difficult to estimate. That

figure would require, at a minimum, knowledge of how many cataracts would later progress to a point at which they did cause functional impairment (and when that occurred), trends in the incidence of cataracts in coming years, and changes in the costs of the procedure. However, to provide a sense of how much was spent in a recent year on potentially inappropriate surgery for cataracts, we did the following:

-- we hypothesized that the data from the four states were not unrepresentative of current practice in the nation as a whole,

-- we applied the permissive criterion that for the surgery to be considered inappropriate, a patient must have reported no functional impairment, and

-- we calculated that every 1 percent of cataract surgeries represented approximately $34 million in expenditures for the Medicare program as a whole.[3]

In this scenario, given 6 percent of patients who experienced no functional impairment, Medicare would have spent approximately $200 million in 1991 for inappropriate cataract

[3]Medicare expenditures for cataract surgery in 1991 were estimated to total $3.4 billion. Denis M. O'Day et al., Cataract in Adults: Management of Functional Impairment (Rockville, Md.: U.S. Department of Health and Human Services, Agency for Health Care Policy and Research, February 1993), p. 21.

surgery.

The actual expenditure on unnecessary cataract surgery in 1991 is thus uncertain, as is the true long-range savings that could be obtained through a decline in inappropriate cataract surgery over time. Our findings, however, are provocative in that they describe a policy situation in which expenditure reduction enhances the quality of care. In effect, if the volume of inappropriate surgeries could be reduced, not only might financial savings be realized but health services to individuals with cataracts would improve. At a time when health care reform is often viewed as a "zero sum game" (where all situations have both winners and losers), the situation with cataract surgery is one in which mechanisms for reducing inappropriate care improve both the health of patients and that of the health care system.

This concludes my statement today. I would be happy to answer any questions you may have.

METHODOLOGY

The questionnaire used to collect the information presented in this testimony was developed over the course of the initial phases of this project. Discussions were held with cataract patients, clinicians who deal with cataracts, and experts in the measurement of clinical outcomes to ensure that the instrument provided both valid and reliable responses. Once the questionnaire was completed, it was pretested on a random sample of 144 cataract patients.

The survey was sent to a random sample of patients in California, Massachusetts, Pennsylvania, and Texas. The focus on states to define the sampling frame was necessary because quality assurance under the Medicare program is a state-based activity. We intentionally picked four relatively large states, so that we could be assured of having a reasonably large number of patients in the study.

The questionnaire had four main sections. One asked for general information about the patients (age, gender, and so on). The three other sections focused specifically on items related to the basis for, and outcomes of, cataract surgery. The first of these sections asked patients to describe the nature and extent of the symptoms and functional impairment they were experiencing

prior to their surgery. Specifically with respect to symptoms, we asked the patients whether they had experienced any of the following 6 symptoms in the 4 weeks prior to their surgery and, if so, how much they were bothered by them on a scale ranging from not at all to severely:

-- fuzzy, blurred, or clouded vision;

-- vision restricted by glare or excessive sensitivity to light;

-- double vision;

-- itching or burning in the eye;

-- floaters (small visual obstructions);

-- a feeling of something in the eye.

With respect to functional impairment, the questionnaire asked the extent to which the patients' daily lives were affected by limited vision. The survey assessed visual functioning through a set of questions that asked respondents to describe their difficulty prior to surgery in watching television, reading, and driving. Respondents could choose among four levels

of difficulty: no, little, moderate, and great, plus a "not applicable" category for those who did not engage in the specified activity.

The third section of the survey instrument asked about short-term outcomes. Examples of short-term outcomes include pain, swelling, and infection. These are discussed more fully in our report and I will not present any findings in this statement regarding them.

The final section of the instrument was concerned with long-term outcomes. As with our questions on the condition of the patient prior to surgery, this section also focused on how symptoms and functions changed after the surgery and, in fact, employed the same 6 symptoms and 3 dimensions of function. Our interest in questions on long-term outcomes was to see whether, and the extent to which, patients improved along all items.

The emphasis placed in the AAO guidelines on the significance of visual functional impairment as perceived by the patient underscores the particular relevance of patient-reported data when assessing the appropriateness of cataract surgery. However, there may still be concerns about the accuracy with which patients would recall, after the surgery, what their perceived limitations were before it took place. While memory

can certainly fade over time, we concluded that the data we collected, almost all of which were gathered in a 5-to-10-month window after surgery (median 7.3 months), provided strong evidence of actual patient perceptions for the following reasons:

-- how well one sees after a cataract operation, compared to before it was performed, is a highly salient question to anyone who has undergone the procedure;

-- the type of information we requested concerned patient experiences directly over an extended period of time;

-- there is no stigma attached to the information we sought and therefore more or less unconscious distortion may not be as likely as with more sensitive topics;

-- the slowness with which cataracts often develop means that patients' assessments of their own visual impairments prior to the surgery may be better grounded after the surgery than before it. It is only after the cataract has been removed and recovery from the surgery is largely complete that the patient can experience what he or she had been missing visually beforehand. This expectation was borne out in a small-scale pilot

test that we conducted, in which we compared patient reports from before cataract surgery with the recollection of those same patients several months after surgery.

Therefore, we concluded that the use of patient assessments of presurgical visual impairments collected after the surgery has occurred is not only legitimate but preferred, to improve accuracy, despite the somewhat greater risk of blurred recall.

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