



ASC Quality Collaboration

August 28, 2009

VIA ELECTRONIC DELIVERY

Michael Rapp, MD, JD, Director
Quality Measurement and Health Assessment Group
Office of Clinical Standards and Quality
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Blvd
Mail Stop S3-02-01
Baltimore, MD 21244

Re: CMS QMIS; Cataract Surgery Measure ID 100207

Dear Dr. Rapp:

On behalf of the ASC Quality Collaboration, a cooperative effort of organizations and companies interested in ensuring ambulatory surgical center (ASC) quality data is appropriately developed and reported, please accept the following comments regarding the Quality Measures Management Information System (QMIS) Measure ID 100207 pertaining to cataract surgery. The ASC Quality Collaboration's stakeholders include ASC corporations, the ASC industry association, professional societies, and accrediting bodies. Please see Appendix A for a list of the ASC Quality Collaboration's participants.

Recognizing that Medicare beneficiaries have a choice of providers and settings for many of the most common outpatient surgical services, we look forward to the time when direct comparisons between equivalent surgical care delivered in hospital outpatient departments and ASCs will be possible. We continue to encourage CMS to apply the same facility-level quality measures to all settings offering outpatient surgery in order to expand the points of comparison available to Medicare beneficiaries and to improve transparency among different facility providers. It is in this context that we offer the following comments on the cataract surgery measure currently under development for the hospital outpatient department.

I. The measure is not supported by clinical practice guidelines for outpatient surgical facilities

Our review of existing clinical practice guidelines did not identify any guideline indicating that facilities offering a site of service for cataract surgeries are to include an assessment of the Activities of Daily Vision Scale or a cataract surgery index (CSI) in their care of cataract surgery patients.

The measure justification states the measure is consistent with a clinical practice guideline from the American College of Eye Surgeons, but we were not able to find support for the measure specifications within that document. Specifically, we find no recommendation or evidence base for facility involvement in prognostication of the outcome of cataract surgery.

II. The measure is not supported by the scientific evidence presented

The measure specifications appear to rely heavily on evidence from one study by Naeim et al¹. However, we do not believe this study provides sufficient evidence to establish the scientific acceptability of the measure for a number of reasons.

First, the study does not provide evidence for a facility role in the evaluation of predicted probability of improvement from cataract surgery. Our reading of the study indicates the evaluations were performed for patients recruited from ophthalmologist's offices, rather than from outpatient surgical facilities.

Though the study was a randomized trial, its scope was small. The study enrolled 250 patients, of which 33 withdrew. Participants were from the Los Angeles areas and primarily white females, which limits the extent to which the study results can be generalized.

As noted by the authors, this small sample size limited the ability to evaluate lesser functional benefits. Significantly, the authors note that the "study shows [cataract surgery] is also cost-effective for 75% of patients who were previously estimated to have a small probability (<30%) of benefiting from the procedure" and conclude that "the highly significant change in visual functioning supports the notion that there might have been an overall utility benefit from cataract surgery had this study been designed and powered to test this outcome." We note that the authors were appropriately cautious when stating that "[t]here may be a subgroup of patients, CSI > 11, for whom a strategy of watchful waiting may be equally effective and considerably less expensive" (emphasis added). In short, this study does not allow one to conclude that a CSI > 11 identifies patients who would not derive functional benefit from cataract surgery, but rather that additional study is needed for this subgroup.

No other study referenced in the measure justification appears to provide support for the measure specifications. Establishing a quality measure based on such a limited evidence base is inappropriate.

Notwithstanding the lack of an appropriate evidence base for this measure, we are also concerned that the measure was not tested for reliability and validity prior to being presented for public evaluation and comment. We believe that such testing would demonstrate flaws in the measure specifications, particularly with respect to the exclusions.

¹ Naeim A, Keeler EB, Gutierrez PR, Wilson MR, Reuben D, Mangione CM. Is cataract surgery cost-effective among older patients with a low predicted probability for improvement in reported visual functioning? *Med Care*. 2006 Nov;44(11):982-9.

III. The measure is not a facility-level measure

We believe that measures for the evaluation of outpatient surgical facility quality should reflect processes or outcomes of care that are directly attributable to the facility itself - its staff, equipment, environment of care, and its roles in the delivery of patient care - and for which the facility, by virtue of its specific functions in patient care, may reasonably be held accountable. This tenet goes to the core of the concept of “controllability” or “accountability” in quality measurement – the extent to which the outcomes related to the proposed measure are under the control of the entity being measured.

The decision for cataract surgery, as for any other surgery, is one made by the patient in consultation with and based on the guidance of their physician. This measure proposes to attribute control of that decision to the facility, yet this is not a role that facilities play in the delivery of health care. Specifically, a facility does not predict the probability of improvement, nor is this data generated concurrent with, or as a byproduct of, facility processes during the cataract surgery procedure.

IV. Shared concerns

We note that several other technical and process concerns regarding this measure have been raised by the ophthalmic community. We echo these concerns and fully support the comments submitted by these organizations.

In summary, we find the proposed facility-level cataract surgery measure to be significantly flawed in its construction. It fails to meet accepted standards for multiple evaluation criteria and therefore we urge the agency to withdraw the measure. Thank you for considering these comments.

Sincerely,



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On behalf of the ASC Quality Collaboration
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Appendix A

Current Participants in Activities of the ASC Quality Collaboration

Accreditation Association for Ambulatory HealthCare
Ambulatory Surgery Foundation
Ambulatory Surgical Centers of America
American College of Surgeons
American Osteopathic Association, Healthcare Facilities Accreditation Program
AmSurg
Association of periOperative Registered Nurses
Hospital Corporation of America, Ambulatory Surgery Division
National Surgical Care
Novamed
Nueterra Healthcare
Surgical Care Affiliates
Symbion
The Joint Commission
United Surgical Partners International