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Further analyses of Medicare procedures provided in multiple ambulatory settings: An introduction

Technological advances in medical procedures, drugs, and devices have made it possible to deliver in a variety of ambulatory settings many medical services that were once limited to inpatient hospital care. For example, cataract surgery can be provided in both hospital outpatient departments (OPDs) and ambulatory surgical centers (ASCs). Medicare's payment rates for the same service usually vary across settings. Is that appropriate? Should payment rates for the same service vary based on cost differences among settings or should the rates be uniform across sites of care, adjusting for differences in patient mix?

To begin addressing these policy issues, the Commission contracted with RAND Health to conduct two studies to explore the following analytical questions:

- Do the types of patients who receive a service differ systematically by setting?
- Does the nature of a service vary based on the setting in which it is provided?
- Does quality of care vary by setting?

In its first study, RAND conducted a literature review and convened expert panels of physicians to identify patient and adverse outcome measures for three high-volume services performed in multiple ambulatory settings: cataract surgery, colonoscopy, and magnetic resonance imaging (MRI) of the head, neck, and brain. RAND also explored the feasibility of using Medicare claims data to measure the indicators. This study is available at http://medpac.gov/publications/contractor_reports/Oct04_ASC_Rpt_intro.pdf.

RAND conducted a second study of the same three procedures to address two questions:

1. Are certain settings more likely to have patients with characteristics that might increase the cost of performing the procedure?
2. Are there significant differences among settings in the risk-adjusted rates of adverse outcomes following the procedure?

To examine the first question, RAND selected clinical experts to help identify patient characteristics that might increase the facility cost of each procedure (i.e., the non-professional portion of the service). For example, it may take longer (and therefore cost more) to obtain consent from and explain post-surgical care to patients with dementia. These characteristics were not formally evaluated by large panels of clinical experts, nor did RAND quantify the relationship between each characteristic and cost differences. To explore the second question, RAND selected adverse outcomes for each procedure based on their incidence, preventability, severity, and whether they could be differentiated from a patient's pre-existing condition. Rates of adverse outcomes in each setting were adjusted for several patient factors, including demographic characteristics and comorbidities.

Based on the three services examined, the study makes the following conclusions:

- Rates of most patient characteristics that might increase the cost of performing one of the three services were very low in all settings; the vast majority of characteristics were present in fewer than 10 percent of patients.
- Looking across all three services and settings, no single setting had consistently higher rates of characteristics that might increase the cost of the procedure. Where

statistical differences existed, OPD patients had higher rates of characteristics than ASC patients for cataract surgery and colonoscopy, but patients treated in physician offices and testing facilities had higher rates of certain characteristics for MRI of the head, neck, and brain.
- Rates of adverse outcomes were very low in all settings, and the magnitude of significant differences among settings was quite small.

Because the study examined only three procedures, it is difficult to draw general conclusions. Nevertheless, this study demonstrates that claims data can be used to evaluate differences among sites of care and is thus an important step in addressing whether payment variations among settings are appropriate. The final report follows.

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Further Analyses of Medicare Procedures Provided in Multiple Ambulatory Settings

A study conducted by staff from Rand Health for the Medicare Payment Advisory Commission

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Further Analyses of Medicare Procedures Provided in Multiple Ambulatory Settings

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Preface

Technological advances such as improved anesthesia and pain management coupled with health care financing changes have produced a shift in many services from inpatient to outpatient settings. As a result, both the volume and complexity of procedures provided in ambulatory settings have increased. Very little is known, however, about the effect of the shift from inpatient to ambulatory care on quality of care and how patient and procedure characteristics vary among ambulatory settings.

In this report, we conduct empirical analyses of three high-volume medical procedures, each of which is performed frequently in two or more ambulatory settings. The study population consists of Medicare patients having one of the three procedures in an ambulatory setting during 2001. The three procedures, selected as part of a previous study, are cataract surgery, colonoscopy, and magnetic resonance imaging of the head, neck, and brain. The ambulatory settings of interest are the hospital outpatient department, the ambulatory surgical center, the physician office, and the independent diagnostic testing facility.

As a followup to a previous study, the Medicare Payment Advisory Commission (MedPAC) asked RAND to conduct further analyses on these three procedures. First, they requested a comparison across settings of patient characteristics that might increase the facility cost of performing the procedure. In addition, they requested that a set of adverse outcomes meeting certain criteria be selected and analyzed to evaluate how risk-adjusted outcome rates vary by the setting in which the service is provided. These analyses are useful for evaluating quality and policy issues such as the appropriateness of site-of-service payment differentials across ambulatory settings for the same procedure.

The report should be of interest to those concerned with issues related to Medicare reimbursement policy, quality of care, and ambulatory health care, including those interested in health policy and in the field of health services research. This research was sponsored by MedPAC under Contract E4015950.

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Summary

The research described in this report focuses on three medical procedures performed frequently in multiple ambulatory settings in the Medicare population. The study procedures (cataract surgery, colonoscopy, and magnetic resonance imaging of the head, neck, and brain) were selected in a previous study based on having high volume in two or three settings in addition to potential safety concerns. The current study was designed to answer two questions. First, are there significant differences between ambulatory settings in the characteristics of the Medicare patients having these three high-volume procedures that might be expected to increase the facility cost? Second, are there significant differences between the settings in risk-adjusted rates of adverse outcomes following the three procedures?

Overview of Methods. We addressed these questions by selecting and analyzing a set of characteristics and outcomes using enrollment and claims data for a 5 percent sample of Medicare beneficiaries for calendar year 2001. To address the first question above, we consulted a few clinical experts to help select a subset of patient characteristics for each procedure that might increase the facility cost (i.e., the non-physician portion of the service). The measures were then compared across settings with statistical testing. It is important to note that the characteristics were not formally evaluated by a large panel of clinical experts, nor did RAND quantify the relationship between each characteristic and actual cost. To investigate the second question above, we selected outcomes for each procedure based on input from a few clinical experts, frequency of occurrence, and formal ratings of preventability and severity from a large expert panel (conducted as part of a previous study). Conditions that were considered by our clinical advisors to be possible indications for having the procedure were eliminated. For each outcome, we constructed multiple logistic regression models to calculate risk-adjusted rates for each setting.

Cataract Surgery. We analyzed data for 77,294 patients who underwent cataract surgery in 2001. Of these, 47 percent were performed in an OPD and 53 percent in an ASC. A set of 22 patient characteristics was selected based on clinical expert opinion, including general medical and ophthalmologic comorbidities, that might increase the facility cost of performing cataract

surgery in an outpatient setting. Two-thirds of the characteristics, including all nine of the eye-related conditions, occurred rarely with rates of less than 5 per 1000. Of the 22 characteristics, 18 were more common among OPD patients than ASC patients, 11 of which were significantly more common (age over 85 years, dementia, acute episode of COPD, prescription drug dependence, alcohol abuse, schizophrenia, tremor, pseudoexfoliation of lens capsule, progressive high myopia, dislocation of lens, and posterior synechiae).

From the list of 30 possible adverse outcomes following cataract surgery that was assembled during the Phase 1 study, we selected four conditions for further analysis. In the current study, all four of the adverse outcomes occurred infrequently following cataract surgery, with risk-adjusted rates ranging from less than 0.1 per 1,000 (iris prolapse) to 1.6 per 1,000 (endophthalmitis). The rate of endophthalmitis was significantly higher in the 30 days after cataract surgery among patients in the OPD than in the ASC. The rates of the other three outcomes (cataract fragments, persistent corneal edema, and iris prolapse) were slightly but not significantly higher in the OPD patients.

Colonoscopy. We analyzed data for 90,890 patients who had a colonoscopy in 2001. Of these, 70 percent were performed in an OPD, 26 percent in an ASC, and 4 percent in a physician office. A set of 18 patient characteristics was selected based on clinical expert opinion, including general medical and gastrointestinal (GI) comorbidities that might increase the facility cost of performing colonoscopy in an outpatient setting. Most of the medical characteristics (excluding age) occurred infrequently with rates of less than 10 per 1000 while the four GI conditions were found somewhat more often. Of the 18 characteristics, 10 (7 medical and 3 GI) were found significantly more often among OPD patients than ASC patients (age over 85 years, recent unstable angina, dementia, acute episode of COPD, acute episode of cardiomyopathy/heart failure/pulmonary edema, malignant hypertension, prescription drug dependence, past bowel obstruction, past colorectal cancer, and melena). Four characteristics were significantly more common among OPD patients than office patients (age over 85 years, acute episode of COPD, prescription drug dependence, and allergy to analgesic agent). The office rates were significantly higher than OPD and ASC rates for 4 characteristics (recent unstable angina, malignant hypertension, past colorectal cancer, and melena). In addition, the office rate was significantly higher than the ASC for cardiomyopathy/heart failure/pulmonary

edema and inflammatory bowel disease, and the ASC rate was significantly higher that the office rate for allergy to analgesic agent.

From the list of 20 conditions assembled during the Phase 1 study, we selected two conditions for further analysis as possible adverse outcomes following colonoscopy. One of the two, splenic rupture, was dropped because there were no cases. The other outcome, perforation, occurred at a rate of less than 2 per 1000 within 30 days of colonoscopy in all the settings and subgroups. ASC patients had significantly higher rates of perforation among all, RBC, and non-RBC colonoscopies than the OPD patients, and somewhat higher rates than the office patients. (RBC refers to a subset of colonoscopies that entail removal, biopsy, or control of bleeding.)

MRI of the head, neck, and brain. We analyzed data for 40,497 patients who had an MRI (brain) in 2001. Of these, 52 percent were performed in the OPD, 36 percent in the office, and 11 percent in the IDTF. A set of 11 patient characteristics was selected based on clinical expert opinion, including general medical and neurological conditions that might increase the cost of performing an MRI (brain) in an outpatient setting. For 5 characteristics, the rates among office patients were significantly higher than among OPD and IDTF patients (age over 70 years, recent unstable angina, orthopnea, dementia, and tremor). Office patients also had a significantly higher rate of anxiety than OPD patients. The only characteristic for which the OPD rate was significantly higher than the office rate was cerebral edema. Compared to patients in the OPD, rates among patients in the office and IDTF combined were similar for most characteristics. However, office/IDTF patients had a significantly higher rate than OPD patients for three characteristics (age over 70 years, dementia, and tremor) and a significantly lower rate for cerebral edema. However, the magnitudes of all of the differences between settings, including those that were statistically significant, are small.

From the list of 19 conditions assembled during the Phase 1 study, we selected one condition, anaphylaxis/anaphylactoid reaction, for further analysis as a possible adverse outcome following MRI (brain). Only 3 cases of anaphylaxis, one per setting, were identified on claims with dates of service within 7 days of the procedures. Two of the 3 cases of anaphylaxis occurred in patients who had an MRI without contrast. This finding might indicate an error in coding on the claim, meaning the code on the claim was for an MRI without contrast, but the

procedure was actually an MRI with contrast. Another explanation might be that the patient had a reaction to another allergen (e.g., peanuts or bee sting) during the same time frame.

Conclusion. Our study extends research on the topic of differences among ambulatory settings in the characteristics and outcomes of the three study procedures in two ways. First, we incorporated clinical expertise into the selection of patient characteristics and outcomes. Second, we assessed differences between the settings using appropriate statistical methods, allowing us to evaluate the results in a more scientifically rigorous manner and, therefore, to assign more weight to the conclusions.

Using claims data to examine potential differences in quality and processes of care across ambulatory settings has several advantages, including they are routinely collected, relatively inexpensive to analyze, and available relatively quickly. However, outcomes can be difficult to measure using administrative data because coded diagnoses are vague with no indication of the severity of a condition. In addition, attributing an outcome to a particular procedure is often problematic and it might be difficult to distinguish a potential complication of the procedure from the symptoms that created the need for the procedure.

We conclude the following:

- Observed rates for most characteristics thought to affect the cost of performing the three study procedures are very low in all settings.
- Looking across all three services and all settings, no single setting had patients with consistently higher rates of characteristics that might increase the cost of performing the service. The characteristics we examined were not formally evaluated by a large panel of clinical experts, nor did RAND quantify the relationship between each characteristics and actual cost.
- Observed rates for adverse outcomes are also very low in all settings, so that the magnitudes of significant differences between settings are quite small.

Although there are some significant differences between the settings, both in terms of the type of patients who are treated in the setting and in the outcomes following cataract surgery and colonoscopy, the lack of consistent patterns across the three study procedures might make it

difficult to draw general conclusions about differences in care provided in the various ambulatory settings. The study, however, still contributes useful information that will inform policy decisions related to this topic.

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We are grateful to the Medicare Payment Advisory Commission (MedPAC) for funding this research. We appreciate the valuable input we received throughout the project from our Project Officer at MedPAC, Ariel Winter, and from Sarah Thomas, also of MedPAC. Ariel arranged for access to the data and offered helpful suggestions on every aspect of the research as well as on a draft of this report. We are also grateful to the three clinical consultants, Dr. Christopher Chang, Dr. Irene Kuo, and Dr. Kenneth Ong, for the time and effort spent to help us understand important clinical issues related to performing colonoscopy, cataract surgery, and magnetic resonance imaging of the head, neck, and brain, respectively, in the various ambulatory settings. We would also like to express our appreciation to Arlene Turner of Social and Scientific Systems, Inc., for creating the files containing the variables related to the risk score.

List of Abbreviations

Abbreviation	Definition
AICD	Automatic implantable cardioverter defibrillator
AMI	Acute myocardial infarction
APC	Ambulatory Payment Classification
ASC	Ambulatory surgical center
CMS	Centers for Medicare and Medicaid Services
COPD	Chronic obstructive pulmonary disease
CRNA	Certified Registered Nurse Anesthetist
DRG	Diagnosis-related group
HCC	Hierarchical Condition Category
OPD	Hospital outpatient department
ICD-9-CM	International Classification of Disease, 9th Revision, Clinical Modification
IDTF	Independent diagnostic testing facility
MedPAC	Medicare Payment Advisory Commission
MRI	Magnetic resonance imaging
MTUS	Miles, Time; Units, Services Count
RBC	Removal, biopsy, or control of bleeding
SAF	Standard Analytical File
SSS	Social and Scientific Systems, Inc.

1. Introduction

Technological advances such as improved anesthesia and pain management coupled with health care financing changes have produced a shift in many services from inpatient to outpatient settings. As a result, both the volume and complexity of procedures provided in ambulatory settings have increased. Very little is known, however, about the effect of the shift from inpatient to ambulatory care on quality of care and how patient and procedure characteristics vary among ambulatory settings.

In 2003-2004, RAND conducted a study for the Medicare Payment Advisory Commission (MedPAC) to provide them with information on this topic. The objectives of the earlier study (referred to as the Phase 1 study) were to identify high-volume services provided in multiple ambulatory settings and to examine the feasibility of using administrative data to analyze how the nature of a service, the patient characteristics, and outcomes vary by the setting in which the service is provided. We have described the results of this study in a previous report (Wynn et al., 2004).

Overview of Phase 1 Study

In the Phase 1 study, RAND, in conjunction with MedPAC and Social and Scientific Systems, Inc., used 2001 Medicare Part B claims data for a 5% beneficiary sample to identify high volume procedure groupings provided in at least two of four ambulatory settings: ambulatory surgical center (ASC), hospital outpatient department (OPD), physician office (office), and independent diagnostic testing facility (IDTF). MedPAC, in consultation with RAND, then reviewed the high volume procedures to select three procedures for further study. The high volume procedures that were considered potential candidates for further study met two basic criteria:

- the procedure was performed in at least two sites of care (>10% of total volume in each site); and,
- the procedure was among the top 25 multi-site procedures in terms of total volume or expenditures.

The objective was to choose a diverse set of high volume study procedures that vary by type (e.g., surgical vs. non-surgical), that have potential safety concerns, and to include at least the three ambulatory care settings in the study.

Three high-volume procedures were selected: cataract surgery, colonoscopy, and magnetic resonance imaging of the head, neck, and brain. Together, the procedures account for about 2.4 percent of the volume and 17.0 percent of payments for diagnostic and therapeutic procedures in ambulatory settings[1] (Wynn et al., 2004).

Cataract removal surgeries are among the most common surgeries performed in the United States (National Eye Institute, 2003). Most cataract removal surgeries are uncomplicated and lead to improved visual acuity and patient satisfaction. In some cases, however, postoperative complications related to the eye arise. In other cases, complications occur from the sedation or anesthesia used during the procedure, as well as from the local (injected) anesthesia (Shugarman et al., 2004).

Colonoscopies are commonly performed procedures used to screen for colorectal cancer, but they are also used to diagnose the causes of unexplained changed in bowel habits, which may be caused by cancer or some other disease/condition. Therapeutic colonoscopies can be performed to remove polyps and to treat bleeding in the colon. Generally, the procedure is performed under some level of sedation and/or with pain medication. Most colonoscopies are uncomplicated and effectively diagnose and treat various gastrointestinal conditions. However, intra-operative and post-operative complications might arise, including some conditions related to the colon and others unrelated to the colon but associated with sedation (Shugarman et al., 2004).

Magnetic resonance imaging of the head, neck and brain (referred to as MRI (brain)) is generally considered to be a non-invasive procedure used for diagnostic purposes. Cranial and spinal MRI may be performed with or without contrast agents. Contrast agents are used to help providers to detect and characterize lesions. In general, performing MRI (brain) is associated with few adverse outcomes. Certain subgroups of patients are at higher risk of complications,

1 This calculation does not include evaluation and management services, professional anesthesia services, outpatient rehabilitation therapy services and laboratory tests, DME, drugs and medical supplies, and outpatient dialysis and accounts only for professional and facility services provided in physician offices, ASCs, OPDs, and IDTFs.

including those with certain types of cardiac pacemakers, metallic vascular aneurysm clips, ferromagnetic devices, and metallic fragments in the orbit, as well as those with claustrophobia (Shugarman et al., 2004). Because of safety concerns, MRI (brain) is contraindicated for some patients with metallic foreign bodies or implants. In general, however, patients without contraindications undergo non-contrast MRI (brain) without experiencing adverse events. Patients undergoing contrast-enhanced MRI (brain) also have few adverse reactions.

As part of the Phase 1 study, we conducted three expert panel meetings, one for each of the selected procedures. Panelists were asked to rate the study procedure on several dimensions: the preventability and severity of selected adverse outcomes, patient characteristics that might affect where care is delivered, and procedure characteristics that might affect the appropriateness of furnishing the services in particular settings to patients at different risk levels. During Phase 1, the panel ratings were used to select a subset of the patient characteristics and outcomes for analysis using administrative data. Focusing on this subset of measures, we tested the feasibility of using 2001 claims data for Medicare fee-for-service beneficiaries to measure differences among the ambulatory settings. We compared patient characteristics (i.e., demographics, Medicare status, and comorbidities) among ambulatory settings that might affect the resources required to perform the procedure. The rationale for these analyses was that performing a diagnostic or surgical procedure on a medically complex patient or patient with a particular condition such as dementia may require more facility resources. We also compared outcome rates among ambulatory settings. However, we did not control for differences in patient characteristics across settings such as age and specific comorbidities (e.g., diabetes) that might affect the risk of a post-procedure complication. It was recognized at the time that these analyses should be conducted with risk adjustment before any conclusions were drawn concerning differences in complication rates across ambulatory settings.

Objectives of Current Study

As a followup to the Phase 1 study, MedPAC requested that RAND conduct a study to perform more in-depth analyses related to patient characteristics and adverse outcomes. As part of the current study, MedPAC requested that RAND:

- Identify patient characteristics that would be expected to increase the facility cost of performing the three procedures and test for significant differences in the rates across the settings.

- Recommend a set of outcome measures for the three procedures for further analysis using risk adjustment.

- Conduct analyses for the selected outcomes that would allow comparison of risk-adjusted outcome rates among the ambulatory settings for each procedure.

These analyses are considered prerequisites for evaluating quality and policy issues such as the appropriateness of site-of-service payment differentials across ambulatory settings for the same procedure.[2]

Organization of This Report

This report consists of four sections. Section 2 describes the study methods, including how the outcomes and patient characteristics were selected, data sources, file construction, the analytic samples, and the statistical methods used to conduct the analyses of the Medicare claims data. Section 3 provides the results of the claims analyses, including a comparison across settings of the percentage of patients with selected characteristics and comorbidities that might be expected to increase the facility cost of performing the procedure and of the risk-adjusted rates of adverse outcomes and. Section 4 discusses the overall findings and conclusions from the study. Following these sections, we provide appendices containing the background of the clinical consultants, the diagnosis and procedure codes used to identify the procedures, patient characteristics, and outcomes, and detailed results of the analysis.

2 While the issue of when care is provided appropriately in an inpatient vs. outpatient setting remains an important issue, the study focus is on the variations in procedures performed in ambulatory settings. Medicare site of service payment differentials for ambulatory procedures may adversely affect beneficiary access to appropriate care or the efficient delivery of needed health care services.

2. Methods for Selection and Analysis of Study Measures

Using 2001 administrative data for Medicare beneficiaries, we studied selected patient characteristics and outcomes of three high-volume procedures that are commonly performed in multiple ambulatory settings. The three study procedures are cataract surgery, colonoscopy, and MRI (brain). The objectives of these analyses were to:

- Identify patient factors that are likely to increase the facility cost of performing the three study procedures. Examine whether the percentage of patients with these factors varies by setting.
- Refine the outcome measures for the three study procedures developed by RAND in the Phase 1 study. Select measures that represent adverse events, rather than the patient's underlying condition, and select tools to adjust the outcome measures for patient characteristics.
- Calculate rates of adverse outcomes for the three study procedures for each ambulatory setting in which they are provided. The rates should be adjusted for differences in the characteristics of patients treated in each setting.

Below we describe the methods employed to accomplish these objectives. We first explain how we selected both the outcomes for risk adjustment and patient characteristics that might increase the facility costs of performing the procedure. We then describe the data sources, construction of the analytic files, the sample definition, and calculation and statistical analysis of the measures. The results of the empirical analyses of the patient characteristics and the outcomes are presented in Section 3 for the three study procedures.

Selection of Measures

Use of Clinical Consultants

To ensure the project was guided by sound medical expertise, three clinical consultants were recruited to be advisors throughout the project. One specialist for each of the three procedures was selected: an ophthalmologist for cataract surgery, a gastroenterologist for

colonoscopy, and a neuroradiologist for MRI (brain).[3] The project physician (internal medicine) coordinated the input from the three consultants throughout the selection of outcomes and patient characteristics.

At the beginning of the project, the consultants were provided with an overview of the project and its objectives. They were assigned four tasks related to the project objectives. The first task was to identify patient characteristics that might increase the facility costs of performing the procedure. The second task was to assist in the selection of outcomes. The third task was to select patient characteristics (i.e., covariates) that should be used for risk-adjustment in the multivariate analysis of the outcomes. The final task was to comment on the proposed followup periods for each outcome to be used in the claims analysis. To facilitate each of these tasks, the consultants were asked to provide written comments in a spreadsheet generated specifically for this purpose. This process is described in more detail below.

Selecting Patient Characteristics Related to Facility Costs

MedPAC asked RAND to identify patient characteristics and comorbidities that might increase the facility cost of delivering the three procedures. We developed a list of possible measures based on the characteristics on the rating sheets used during the three Phase 1 panel meetings and information from the clinical expert panel discussion in the report by Wynn et al. (2004). The clinical consultants reviewed the list of patient characteristics for the procedure within their area of expertise and indicated whether each patient characteristic might increase the facility cost of performing the procedure.[4] It is important to note that the characteristics were not formally evaluated by a large panel of clinical experts, nor did RAND quantify the relationship between each characteristic and actual cost. The Phase 1 lists for cataract surgery, colonoscopy, and MRI (brain) contained 61, 54, and 45 characteristics, respectively. The consultants provided written comments explaining why they thought the facility cost would increase if a patient had the condition or characteristic (see Appendix C). They also indicated whether or not each characteristic was likely to appear in claims data (i.e., to be coded on a claim by a clinician).

3 We describe the backgrounds of the three clinical consultants in Appendix A.

4 The project physician also reviewed the lists for the three procedures. In addition to providing this information, the clinical consultant for cataract surgery also included characteristics that might increase the physician cost.

Selecting Adverse Outcomes for Risk Adjustment

MedPAC also requested that RAND recommend between four and seven outcome measures for each of the three procedures for further analysis using risk adjustment. The selection process began with the project physician and clinical consultants reviewing a list of adverse outcomes that could be indications for having the procedures. The project physician reviewed the lists for all three procedures. The consultants reviewed the list of outcomes for the one procedure within their specialty. The outcome lists that they reviewed had been generated for the expert panel during the Phase 1 study. The consultants considered each outcome to identify which can be indications for (i.e., reasons for having) the procedure. They were also asked to indicate which outcomes would be likely to be coded in medical claims data. Based on this information, we selected a subset of outcomes from each list that are not indications for the procedure. Any condition on the outcome list that can be an indication for the procedure was eliminated from consideration as a measure for further analysis. This step was necessary because, based on claims data, it is not possible to determine conclusively whether an outcome occurred for the first time following the procedure, or whether the outcome was a pre-existing condition that was the reason the procedure was performed.

We selected outcome measures for further analysis on the basis of several factors. We attempted to identify adverse outcomes that are severe, preventable, and occur frequently enough to produce stable estimates. To facilitate this process, we created a table for each procedure containing rows representing the outcome measures and columns representing:

- the preventability scores,
- the severity scores,
- the incidence of the outcome (per 1000 procedures), and
- whether the outcome could be an indication for the procedure.

The preventability and severity scores in the tables were derived from the rating sheets completed by the members of the three expert panels conducted during the Phase 1 study. Outcome rates used in this process were derived from the results in the Phase 1 report (Wynn et al., 2004). We used the information in these tables together with the clinical input from the project physician and the clinical consultants as the basis for recommending outcome measures for further analysis.

As part of reviewing the outcome measures, each clinical consultant also reviewed a list of patient characteristics and comorbid conditions for the one procedure within their specialty. The purpose of the review was to identify covariates to be used in the multivariate analyses. The lists that they reviewed had been generated for the expert panel during the Phase 1 study. For each patient characteristic, the consultant was asked to comment on whether it would increase the likelihood of any of the outcomes occurring, and to provide details about the association between the characteristic and the outcome. They also indicated whether or not the characteristic was likely to appear in claims data (i.e., to be coded on a claim by a clinician). The list of possible covariates included demographic characteristics (e.g., age, gender, and race), Medicaid eligibility, and disability status as well as comorbidities (e.g., diabetes) that might affect the occurrence of a particular adverse outcome.

For each outcome, each consultant assessed whether 7 or 30 days following the procedure would be a more appropriate timeframe for identifying each outcome in the claims data based on the likelihood of the outcome being the result of the procedure. Information from the Phase 1 panel discussions was also considered in determining the most appropriate time frame for measuring each outcome.

Analysis of Administrative Data

Data Sources

For these analyses, the enrollment and demographic variables for Medicare beneficiaries were derived from the Centers for Medicare and Medicaid Services (CMS) 5% Denominator File. All variables related to inpatient and outpatient utilization (e.g., indicators based on diagnosis and procedure codes) were derived from Medicare Part A and Part B claims. The variables related to utilization of inpatient and outpatient care by Medicare beneficiaries were extracted from claims represented in the 5% Physician/Supplier Standard Analytical File (SAF), the 5% Hospital Inpatient SAF, and the 5% Hospital Outpatient SAF. Social and Scientific

Systems, Inc. (SSS) assigned Hierarchical Condition Categories (HCC) risk scores and other variables related to the HCC for 2001 using 2000 administrative data.[5]

Analyzing claims data has several advantages, including they are routinely collected, inexpensive to analyze, and available quickly (Wynn et al., 2004). However, comorbidities and outcomes can be difficult to measure using administrative data because clinical detail is lacking and data elements not directly related to payment might be unreliable. ICD-9-CM diagnosis codes may be vague (e.g., heart failure, unspecified) and contain symptoms (e.g., fatigue) as well as diseases. In addition, the nomenclature provides only limited indicators of the severity of a condition. This makes identifying specific clinical outcomes following a procedure challenging. In addition, attributing outcomes to particular procedures is often problematic. Some conditions of interest are also unlikely to be coded or coded incompletely on claims. The limitations of claims data do not mean that they should not be used for clinically-based measures; however, they should be used with some caution.

One issue that might affect the claims data for services furnished in ambulatory settings is the rules used to define inpatient hospital services under the prospective payment system (PPS) for acute care hospitals (CMS, 2006).[6] As a result of these rules, analyses using OPD claims data do not include sicker patients who received a service as an outpatient but whose conditions necessitated a hospital admission that led to the study procedure being redefined as an inpatient service. The policies are most likely to impact the MRI analyses, assuming patients are more likely to be admitted following an MRI. However, they might also affect findings comparing patient characteristics and outcomes across settings for colonoscopies and to a lesser extent cataract surgeries. However, because our study is focused on the services that are covered under Medicare Part B, it is appropriate that the comparisons exclude those who are defined as inpatients for payment purposes.

5 The HCC model assigns a risk score based on a beneficiary's expected service use relative to that of the national average beneficiary, given their demographic characteristics (e.g., age and gender) and medical conditions. It can be used to identify patients who are likely to have complex medical needs. Such patients might be at higher risk for complications than other patients and may require closer monitoring throughout a surgical procedure and recovery.

6 Diagnostic services provided to a beneficiary by the admitting hospital (or by an entity wholly owned or operated by the hospital) within 3 days prior to the date of the beneficiary's admission for a covered inpatient stay are deemed to be inpatient services and included in the PPS payment (CMS, 2006). MRI procedures are defined as diagnostic procedures for purposes of this provision. Therefore, there are no OPD claims for beneficiaries who receive an MRI as an outpatient and are subsequently admitted within 3 days to the same hospital. Moreover, non-diagnostic outpatient services that are furnished by the same hospital during the 3 days immediately preceding the patient's admission and are related to a patient's hospital admission are similarly defined as inpatient services. Further, any outpatient services, regardless of whether they are related to the admission, are considered inpatient services if the patient is admitted to the same hospital before midnight of the following day.

File Construction

The analytic files for our study contained enrollment data and claims for care (inpatient and outpatient) provided during calendar year 2001 (CY2001) to Medicare beneficiaries who had one of three study procedures between January 1 and December 31, 2001.[7] The three procedures, which we refer to as index procedures, were: MRI (brain) (BETOS I2C), cataract removal/lens insertion (BETOS P4B), and colonoscopy (BETOS P8D). The CPT codes included in each procedure grouping are listed in Appendix B. To be included in the sample, beneficiaries must have had the procedure performed in one of four ambulatory settings:

- Hospital outpatient department (OPD)
- Ambulatory surgical center (ASC)
- Physician office (Office)
- Independent diagnostic testing facility (IDTF)

Social and Scientific Systems, Inc. (SSS) created extract files containing all records from the 5% Denominator file, the 5% Physician/Supplier SAF, the 5% Inpatient SAF, and the 5% Outpatient SAF for the beneficiaries with one of the three procedures. From these files, we created four mutually exclusive files for each of the three index procedures. The four files were:

1. Index Procedure File: A standardized record for each index procedure performed during CY2001. Each record in this file represents one index procedure and related services received on the same date as the index procedure and includes variables from the Denominator File and variables that relate to the index procedure from the various SAFs, including diagnoses, provider specialties, and other procedures.
2. Physician/Supplier Claim File: All physician/supplier claims for care received in any setting during CY2001 for beneficiaries with an index procedure performed during CY2001.
3. Inpatient Claim File: All facility claims for care received in an inpatient hospital during CY2001 for beneficiaries with an index procedure performed during CY2001.
4. Hospital Outpatient Claim File: All facility claims for OPD care received during CY2001 for beneficiaries with an index procedure performed during CY2001.

The claims in Files 2 through 4 do not include the care (i.e., anesthesia and all other care) in the index procedure file. In addition, the care in these files is not necessarily related to the index

7 We used administrative data for 2001 because the data files were built in 2003 for the Phase 1 analyses.

procedure (e.g., MRI (brain)). Claims for durable medical equipment, skilled nursing facilities, home health agencies, and hospice are not included in these analyses.

The index procedure file contains a single fixed length record for each index procedure with a standardized set of variables, regardless of which ambulatory setting the procedure was performed in. A beneficiary can have more than one record in the index procedure file if s/he had more than one index procedure (MRI (brain), cataract surgery, or colonoscopy) on different dates in 2001. The three index files include records for all procedures with the HCPCS (CPT) codes included in the BETOS categories for MRI (brain) (BETOS I2C), cataract removal/lens insertion (BETOS P4B), and colonoscopy (BETOS P8D) (Appendix B). In addition, the cataract file included one other code, CPT 66820, which is in BETOS P4E (Eye procedure-other) based on clinical input.[8] All variables in the index procedure file record were derived from one or more claims for the index procedure.

For index procedures performed in an ASC or IDTF, the record generally contains variables from a physician/supplier SAF claim for the facility service and from a physician/supplier SAF claim for the related physician services. For index procedures performed in the OPD, the record generally contains variables from an outpatient SAF claim (i.e., facility) and from a physician/supplier SAF claim. For index procedures performed in a physician office, the record only contains variables from a physician/supplier SAF claim. Claims for anesthesia services furnished in conjunction with the index procedure in any of the sites were identified in the physician/supplier file and added to the index procedure record.

Variables in the index procedure files included diagnosis and procedure codes from the facility and physician claims, as well as the date of service, modifier codes, and provider specialty for each procedure. The 2001 HCC risk score (based on 2000 data) for each beneficiary was merged onto the record from a file created by SSS prior to this project. Separate variables for diagnosis and procedure codes, modifier codes, and provider specialty were created for anesthesia-related services. In addition, variables for the length of anesthesia time were included for each anesthesia code.

8 CPT code 66820 is defined as "Discission of secondary membranous cataract (opacified posterior lens capsule and/or anterior hyaloid); stab incision technique (Ziegler or Wheeler knife)."

Analytic Samples

We restricted the sample to beneficiaries who were enrolled in both Part A and Part B of Medicare and were in traditional fee-for-service Medicare for at least one month during CY2001. We excluded beneficiaries who were enrolled in a Medicare managed care organization because utilization data for their inpatient and outpatient care are not available. In calculating each measure, we included all beneficiaries who were enrolled in Medicare fee-for-service for at least one month following the procedure (the period used in these analyses to measure most of the adverse outcomes). [9]

The cataract analytic sample included all cataract surgeries that were performed on Medicare fee-for-service patients in two ambulatory settings (OPD and ASC) during 2001. We excluded cataract surgeries that were performed in physician offices because they comprise a small percentage of the procedures. [10]

The colonoscopy analytic sample included all colonoscopies that were performed on Medicare fee-for-service patients in three ambulatory settings (OPD, ASC, and physician office) during 2001. We first analyzed all colonoscopies. We then categorized the colonoscopies into two subgroups based on the HCPCS codes: those with some lesion removal, biopsy, or control of bleeding (RBC) and those without RBC (non-RBC) and analyzed these two subsamples separately. [11]

The MRI analytic sample included all MRIs (brain) that were performed in three ambulatory settings (OPD, physician office, and IDTF) during 2001. We first analyzed all MRIs (brain). We then separated them into two categories based on HCPCS codes: those with a contrast agent and those without a contrast agent and analyzed these two subsamples separately. [12]

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9 For procedures performed in December, we searched for the outcome through December 31, 2001.

10 During 2001, only 278 of 77,572 cataract surgeries among Medicare fee-for-service patients were performed in a physician office (Wynn et al., 2004).

11 The HCPCS codes for RBC colonoscopy are 44389, 44391, 44392, 44393, 44394, 45379, 45380, 45382, 45383, 45384, 45385, and 45387. The HCPCS codes for "non-RBC" colonoscopy are 44388, 45378, and G0105.

12 The HCPCS codes for MRI with contrast are 70541, 70542, 70543, 70545, 70546, 70548, 70549, 70552, and 70553. The HCPCS codes for MRI without contrast are 70544, 70547, and 70551.

Analysis of Patient Characteristics

We constructed algorithms to define each patient characteristic that might affect facility costs, specifying the measure in terms of diagnosis (ICD-9-CM) or procedure codes (CPT, HCPCS, and ICD-9-CM), and the time frame identifying the characteristic (see Appendix C for the specifications for the patient characteristics). We searched claims for all care received during 2001 in all settings of care (inpatient, outpatient, ASC, IDTF, and office) to identify each patient characteristic. In addition, we used variables representing individual medical conditions that were generated by the HCC risk score program. Each of these (0, 1) variables indicated whether a particular diagnosis code or set of codes appeared on a patient claim during calendar year 2000. HCCs representing specific conditions (e.g., diabetes) are assigned based on diagnoses from the following sources: principal hospital inpatient, secondary hospital inpatient, hospital outpatient, physician, and clinically trained non-physician (e.g., psychologist) (Pope et al., 2004). These HCC dummy variables for specific conditions are calculated as part of the program that assigns the predicted expenditures for the patient in the following year.

For each patient characteristic, we calculated a rate per 1,000 based on the number of procedures for patients with a particular characteristic divided by the total number of procedures. In comparing differences in patient characteristics among settings, the rates were estimated for each setting separately (OPD and ASC for cataract surgery; OPD, ASC, and office for colonoscopy; and OPD, office, and IDTF for MRI (brain)). In addition, the MRI rates were also estimated for IDTF and office combined because these two settings are paid under the same payment system (physician fee schedule). We calculated a single set of rates based on all cataract surgeries. However, for colonoscopy, we repeated the analysis for three samples (all, RBC, and non-RBC). Similarly, we conducted analyses on three samples for MRI (brain) (all, with contrast, and without contrast). We then conducted The Fisher's exact test was used to determine if the differences between settings were significantly different.[13] If we found this to be significant, we tested all of the pair-wise comparisons using frequency tables in SAS® Version 8.2 (SAS Institute, Inc., 2002).

13 The Fisher's exact test provides the exact P value rather than the approximate P value that results from the chi-square test (Afifi and Azen, 1979), It is used when the number of cases is small.

Analysis of Outcomes

For each outcome measure, we constructed algorithms to describe each outcome measure, specifying the outcome in terms of diagnosis or procedure codes (ICD-9-CM, CPT, and HCPCS), and the time frame following the procedure within which the outcome occurred (see Appendix J for the specifications for the outcome measures). We calculated the rate of all except one measure based on outcomes occurring within 30 days following each procedure.[14] We searched for the outcome on claims for all settings of care (inpatient, outpatient, ASC, IDTF, and office). We calculated the outcome rates as the number of procedures with a particular adverse outcome within the specified time period divided by the number of procedures expressed as a rate per 1000 procedures.

We analyzed the rate of each adverse outcome occurring within 30 days using multiple logistic regression methods.[15] We used logistic regression because each outcome measure can be represented by a dichotomous variable. The unit of analysis is the individual procedure. The form of the logistic regression was

$$\ln(odds) = a + b_1 X_1 + b_2 X_2 + \ldots + b_N X_N$$

where ln is natural log, X_1 to X_N are a set of N independent predictor variables, a is the intercept, and b_1 to b_N are the logistic regression coefficients. The odds are defined specifically as

$$odds = \frac{P_z}{1 - P_z}$$

where P_Z is the probability of having some characteristic, z. The equation can be written in terms of P_Z as follows:

$$P_z = \frac{1}{1 + \exp\left[-\left(a + b_1 X_1 + b_2 X_2 + \ldots + b_N X_N\right)\right]}$$

14 For "anaphylaxis/anaphylactoid reaction," we analyzed the outcome measure using two different time frames, within 7 and 30 days of the MRI (brain).

15 We analyzed "anaphylaxis/anaphylactoid reaction" using two different time frames, within 7 and 30 days of MRI (brain).

where exp is the constant, e, raised to the power of the expression shown. This equation is called the logistic regression equation. Logistic regression models control for other differences at the individual level that might mask the true differences between the settings.

We included the same demographic and entitlement dummy variables in the analyses of all outcomes. Dummy variables representing age (under 65, 75-84 and 85 and over), gender, race (African-American, other), disability as original reason for entitlement, and one or more months of Medicaid eligibility in 2001 were included in every model. Dummy variables representing comorbiditiess that might alter the risk of the outcome occurring were also included. It is necessary to control for these differences because they may be related to risk of developing a particular outcome. By controlling for these factors statistically, we were able to measure differences in the outcome rate among the settings independent of these other factors. Controlling for numerous covariates in the multivariate analysis improves precision. In addition, dummy variables representing each ambulatory setting were also included in each regression equation:

INASC=1 if the procedure was performed in an ASC

=0 for all others

INOPD=1 if the procedure was performed in an OPD

=0 for all others

INIDTF=1 if the procedure was performed in an IDTF

=0 for all others

INOFF=1 if the procedure was performed in an office

=0 for all others

These dummy variables represent the effect on the outcome rate of having the procedure performed in a particular setting.

The outcome rates were estimated for each setting separately (OPD and ASC for cataract surgery; OPD, ASC, and physician office for colonoscopy; and OPD, physician office, and IDTF for MRI (brain)). In addition, the MRI outcome rates were also estimated for IDTF and office combined because these two settings are paid under the same payment system (physician fee schedule). For each cataract surgery outcome, we estimated the parameters of one logistic

regression model. For the colonoscopy outcome (i.e., perforation), we estimated three logistic regression models (all colonoscopies, RBC colonoscopies, and non-RBC colonoscopies). For the MRI (brain) outcome (i.e., anaphylaxis/anaphylactoid reaction), we also estimated three logistic regression models (all MRIs, MRIs with contrast, and MRIs without contrast).

The results presented in Tables 3.5, 3.6, 3.11, and 3.14 in Section 3 of this report are risk-adjusted rates generated from the multiple logistic regression models described above. We used an approach that simulates what rates that would be expected if the same set of patients had the procedure performed in different settings (i.e., everything was the same except the setting). To calculate the risk-adjusted rates for an outcome, we first estimated the logistic regression equation for that outcome. We then used the parameter estimates from the equation (i.e., the intercept and regression coefficients) to predict the probability of the outcome occurring for each individual in the sample. For each outcome, a separate predicted probability was calculated for each setting. To generate a predicted probability for each setting, the dummy variable(s) for the setting(s) was (were) set equal to zero or one to simulate the values *in a particular setting*. For example, when we predicted rates for endophthalmitis (an outcome for cataract surgery), we calculated the predicted probability for OPD for each case in the sample by setting the dummy variable for ASC to zero (i.e., by "turning it off"). We then calculated the predicted probability for the second setting, ASC, by setting the dummy variable for ASC to one (i.e., by "turning it on"). We calculated these two predicted probabilities, one for OPD and one for ASC, for each record in the cataract surgery sample. The risk-adjusted rates presented in the Section 3 tables are the means of the predicted probabilities for each setting.

Statistical significance of differences in the risk-adjusted rates between the settings is based on the chi-square test for the logistic regression coefficient for the dummy variable representing a particular setting. The statistical test was performed using the LOGISTIC procedure in SAS® Version 9.1.2 (SAS Institute, Inc., 2002-2003). For example, the statistical test for the difference between the risk-adjusted perforation rates for the OPD and the ASC is based on the chi-square statistic for the ASC dummy variable from the model.

3. Results of Selection Process and Data Analysis

In this section, we report the results of our analyses of CMS administrative data for a 5 percent sample of Medicare beneficiaries who had at least one of the three study procedures in 2001. We examined whether the rates of patients with characteristics that might increase the facility cost of performing the three study procedures vary by setting. We present the results for 22 characteristics for cataract surgery, 18 for colonoscopy, and 11 for MRI (brain).

We also determined risk-adjusted rates for the outcome measures for the three procedures by setting. We used multiple logistic regression models to adjust for covariates that might affect the rate of the outcomes (i.e., risk adjustment). We present the results for four outcome measures for cataract surgery, one outcome for colonoscopy, and one outcome for MRI (brain).

Comparison of Patient Characteristics Across Settings

As described in Section 2, we selected a subset of the patient characteristics for the claims analysis on the basis of the expert opinions of the project physician and the three clinical consultants. They were asked to identify a subset of patient characteristics that might increase the facility cost of performing the procedure by reviewing a list from the Phase 1 study.

Cataract Surgery

Based on the input of the project physician and the clinical consultant for cataract surgery, we selected 22 patient characteristics that might increase the facility cost of performing cataract surgery.[16] Of the 22 characteristics, 13 relate to medical conditions unrelated to eyes (e.g., dementia) (first 13 measures in Table 3.1) and 9 relate to ophthalmologic conditions (e.g., subluxation of lens) (last 9 measures in Table 3.1). Each characteristic was identified using all

16 We selected 23 patient characteristics for cataract surgery, but one characteristic (history of ruptured globe) could not be tested in the claims analysis because we were unable to identify ICD-9-CM diagnosis codes for the algorithm.

Table 3.1 Characteristics of Cataract Surgery Patients By Setting, Medicare Fee-for-Service, 2001

	OPD		ASC		Fisher's exact
	Number	Rate*	Number	Rate*	p-value
All cataract surgeries	36,623	--	40,671	--	
Age > 85 years	4229	115.5	4030	99.1	**0.000**[§]
Dementia	1711	46.7	1585	39.0	**0.000**[§]
Chronic obstructive pulmonary disease (COPD) with hospitalization or emergency department visit within past one year	842	23.0	815	20.0	**0.005**[§]
Bronchietasis with acute exacerbation	12	0.3	10	0.2	0.529
Barbiturate, chlordiazepoxide, diazepam, glutethimide, meprobamate, or methaqua-lone dependence or Opioid type dependence	153	4.2	121	3.0	**0.005**[§]
Alcohol abuse	951	26.0	878	21.6	**0.000**[§]
Personal history of allergy to anesthetic agent	6	0.2	4	0.1	0.533
Personal history of allergy to narcotic agent	75	2.0	74	1.8	0.511
Personal history of allergy to analgesic agent	50	1.4	50	1.2	0.617
History of shock due to anesthesia in which correct substance was properly administered	1	0.0	0	0.0	0.474
Anxiety	279	7.6	283	7.0	0.289
Schizophrenic disorder	248	6.8	182	4.5	**0.000**[§]
Essential, benign, or drug-related tremor/ abnormal head movements, fasciculations, spasms or tremor not otherwise specified	208	5.7	156	3.8	**0.000**[§]
Subluxation of lens	12	0.3	7	0.2	0.177
Recession of chamber angle	0	0.0	0	0.0	--
Pseudoexfoliation of lens capsule	40	1.1	6	0.1	**0.000**[§]
Progressive high (degenerative) myopia/malignant myopia	7	0.2	1	0.0	**0.031**[§]
Dislocation of lens	13	0.4	2	0.0	**0.003**[§]
History of open wound of adnexa	0	0.0	0	0.0	--
Endothelial corneal dystrophy, including combined corneal dystrophy, cornea guttata, and Fuch's endothelial dystrophy	65	1.8	77	1.9	0.737
Posterior synechiae	19	0.5	4	0.1	**0.001**[§]
History of vitrectomy	140	3.8	176	4.3	0.284

[§] Comparisons in bold are significant at $p<0.05$.

*Per 1,000 procedures.

Source: RAND analysis of the 5 percent Standard Analytical Files of Medicare claims, 2001.

claims for care received by the cataract surgery patients in any inpatient or outpatient setting at any time during 2001 unless otherwise stated in the definition of the characteristic.[17]

The rates of these 22 characteristics are shown in Table 3.1 for the two settings in which cataract surgeries are most commonly performed, OPD and ASC.[18] Two-thirds of the characteristics, including all of the eye-related conditions, occurred infrequently in both settings with rates of less than 5 per 1000. Of the others, only four of the characteristics occurred at a rate of more than 10 per 1000 (i.e., one percent); these are age greater than 85, dementia, COPD, and alcohol abuse.

For 11 of the 22 characteristics, the rates are significantly higher among OPD patients having cataract surgery than ASC patients. This means that patients having cataract surgeries in OPDs are more likely than ASC patients to be over 85 years of age, have dementia, an acute episode of COPD, prescription drug dependence, alcohol abuse, schizophrenia, tremor, pseudoexfoliation of lens capsule, progressive high myopia, dislocation of lens, and posterior synechiae. For another 7 characteristics, the OPD rates are higher, but not significantly higher, than ASC rates. For two characteristics, the ASC rate is somewhat (but not significantly) higher than the OPD rate. For two of the characteristics (recession of chamber angle and history of open wound of adnexa), there were no patients in either setting with those conditions coded on a claim during 2001.

Colonoscopy

Based on input from the project physician and the clinical consultant for colonoscopy, we selected 18 patient characteristics that might increase the facility cost of performing colonoscopy.[19] Of the 18 characteristics, 14 relate to other medical conditions (e.g., unstable angina) (first 14 measures in Table 3.2) and 4 relate to gastrointestinal conditions (e.g., history of partial or complete bowel obstruction) (last 4 measures in Table 3.2). Each characteristic

17 See Appendix C for definitions of each patient characteristic for cataract surgery.

18 As described in the Methods section, cataract surgeries performed in physician offices were excluded from these analyses.

19 We selected 19 patient characteristics for colonoscopy, but one characteristic (mechanical heart valve) could not be tested in the claims analysis because we were unable to find diagnosis codes to uniquely identify it.

Table 3.2 Characteristics of Colonoscopy Patients By Setting, Medicare Fee-for-Service, 2001

	OPD		ASC		Office		Fisher's exact p-value		
	Number	Rate*	Number	Rate*	Number	Rate*	OPD vs. ASC	OPD vs. Off	ASC vs. Off
All colonoscopies	63372	--	23503	--	4015	--			
Age > 70 years	42756	674.7	15844	674.1	2670	665.0	0.864	0.199	0.252
Age > 85 years	3568	56.3	1131	48.1	181	45.1	**0.000**[§]	**0.002**[§]	0.423
Unstable angina in last 3 months	355	5.6	82	3.5	39	9.7	**0.000**[§]	**0.002**[§,b]	**0.000**[§]
MI (>30 days but fewer than 6 months)	1	0.0	0	0.0	0	0.0	1.000	1.000	1.000
Dementia	2201	34.7	658	28.0	131	32.6	**0.000**[§]	0.504	0.112
Chronic obstructive pulmonary disease (COPD) with hospitalization or emergency department visit within past year	1022	16.1	255	10.8	33	8.2	**0.000**[§]	**0.000**[§]	0.153
Asthma with hospitalization or emergency department visit within past one year	0	0.0	0	0.0	0	0.0	--	--	--
Bronchietasis with acute exacerbation	15	0.2	5	0.2	3	0.7	1.000	0.088[c]	0.098[c]
Cirrhosis	500	7.9	157	6.7	33	8.2	0.071	0.783	0.301[c]
Cardiomyopathy/heart failure/ pulmonary edema with hospitalization or emergency department visit in past year	7291	115.1	2209	94.0	440	109.6	**0.000**[§]	0.307	**0.002**[§]
Malignant hypertension	482	7.6	106	4.5	184	45.8	**0.000**[§]	**0.000**[§]	**0.000**[§]
Barbiturate, chlordiazepoxide, diazepam, glutethimide, meprobamate, or methaqualone dependence or opioid type dependence	331	5.2	78	3.3	11	2.7	**0.000**[§]	**0.029**[§,a,b]	0.653
Personal history of allergy to anesthetic agent	4	0.1	2	0.1	0	0.0	0.665	1.000	1.000
Personal history of allergy to analgesic agent	102	1.6	37	1.6	1	0.2	1.000	**0.033**[§,a,b]	**0.036**[§,a,b]
History of partial/complete bowel obstruction	2246	35.4	669	28.5	124	30.9	**0.000**[§]	0.133	0.386
History of colorectal cancer	1587	25.0	316	13.4	154	38.4	**0.000**[§]	**0.000**[§]	**0.000**[§]
Inflammatory bowel disease	1128	17.8	379	16.1	103	25.7	0.095	**0.001**[§]	**0.000**[§]
Melena	1553	24.5	275	11.7	229	57.0	**0.000**[§]	**0.000**[§]	**0.000**[§]

[§] Comparisons in bold are significant at $p<0.05$.

*Per 1,000 procedures.

Source: RAND analysis of the 5 percent Standard Analytical Files of Medicare claims, 2001.

[a] Not significant for RBC colonoscopy (see Table D.1 in Appendix D).

[b] Not significant for non-RBC colonoscopy (see Table D.2 in Appendix D).

[c] Significant for non-RBC colonoscopy (see Table D.2 in Appendix D).

was identified using all claims for care received by the colonoscopy patients in any inpatient or outpatient setting at any time during 2001 unless otherwise stated in the definition of the characteristic.[20] Among the colonoscopy patients, there was only 1 patient in any of the three settings with an "MI in more than 30 days but less than 6 months during 2001." For one characteristic ("asthma with hospitalization or emergency department visit within past one year"), there were no patients in any of the three settings with the condition coded on a claim during 2001. Most of the characteristics are uncommon with rates of less than 10 per 1000 (i.e., 1 percent). The three most frequent characteristics are age greater than 70, age greater than 85, and an acute episode of cardiomyopathy/heart failure/pulmonary edema.

The rates of these 18 characteristics are compared in Table 3.2 for the three settings in which colonoscopy is provided (OPD, ASC and office). For 10 of the 18 characteristics, the rates are significantly higher among OPD patients having colonoscopy than ASC patients. This means that patients having colonoscopies in OPDs are more likely than ASC patients to be over 85 years of age, have recent unstable angina, dementia, an acute episode of COPD, an acute episode of cardiomyopathy/heart failure/pulmonary edema, malignant hypertension, prescription drug dependence, past bowel obstruction, past colorectal cancer, and melena[21]. There is no consistent pattern among these characteristics for office patients compared to OPD or ASC patients; rates are sometimes higher in the office setting and sometimes higher in the other settings. The OPD rates for 4 characteristics are significantly higher than office rates (over 85 years, an acute episode of COPD, prescription drug dependence, and allergy to analgesic agent). The office rates are significantly higher than both OPD and ASC rates for 4 characteristics (recent unstable angina, malignant hypertension, past colorectal cancer, and melena). In addition, the office rate is significantly higher than the ASC for cardiomyopathy/heart failure/pulmonary edema and inflammatory bowel disease, and the ASC rate is significantly higher that the office rate for allergy to analgesic agent.

The patterns of patient characteristics by setting for all colonoscopies (Table 3.2) are similar to the patterns we found for the two subsets of colonoscopies (RBC and non-RBC) (see Appendix D). All significant differences between settings for the RBC and non-RBC

20 See Appendix C for definitions of each patient characteristic for colonoscopy.
21 Melena is defined as "presence of blood in the stool" (Hensyl, 1990).

colonoscopies are in the same direction as those for all colonoscopies. Any differences in the significant results between this table and the tables for RBC and non-RBC are indicated in the footnotes on Table 3.2.

MRI (Brain)

Based on input from the project physician and the clinical consultant for MRI (brain), we selected 11 patient characteristics that might increase the facility cost of performing this procedure. Of the 11 characteristics, 6 relate to general medical conditions (e.g., unstable angina) (first 6 measures in Table 3.3) and 5 relate to conditions that might directly affect performing the MRI (e.g., history of claustrophobia) (last 5 measures in Table 3.3). Each characteristic was identified using all claims for care received by the MRI (brain) patients in any inpatient or outpatient setting at any time during 2001 unless otherwise stated in the definition of the characteristic.[22]

All except three of these characteristics are found in less than 50 per 1000 (i.e., 5 percent) of the MRI (brain) patients (Table 3.3). The three most common characteristics are age greater than 70, age greater than 85, and dementia. For one characteristic (MI within past 7 days during 2001), there were only 2 patients in the office setting with the condition coded on a claim during 2001 and none in the other two settings. For another characteristic (MI in more than 7 days but fewer than 30 days during 2001), there was only one patient in the office setting. We, therefore, consider the pattern of results for the remaining 9 characteristics below.

The rates of these 9 characteristics are compared in Table 3.3 for the three settings in which MRI (brain) is provided (OPD, office, and IDTF). For five characteristics, the rates among office patients are significantly higher than among OPD and IDTF patients. This means that patients having MRI (brain) in the office setting are more likely than OPD and IDTF patients to be over 70 years of age, have recent unstable angina, orthopnea[23], dementia, and tremor. The significantly higher percentage of patients over 70 years of age in the office, however, probably has little clinical or cost significance, given the broad range of ages included in the category, and

22 See Appendix C for definitions of each patient characteristic for MRI (brain).

23 Orthopnea is defined as "discomfort in breathing which is brought on or aggravated by lying flat" (Hensyl, 1990).

Table 3.3 Characteristics of MRI (Brain) Patients By Setting, Medicare Fee-for-Service, 2001

	OPD		Office		IDTF		Fisher's exact p-value		
	Number	Rate*	Number	Rate*	Number	Rate*	OPD vs. Office	OPD vs. IDTF	Office vs. IDTF
All MRI (brain)	21233	--	14712	--	4552	--			
Age > 70 years	14279	672.5	10393	706.4	3081	676.8	**0.000**[§]	0.589	**0.000**[§,a]
Age > 85 years	1745	82.2	1167	79.3	359	78.9	0.335	0.474	0.950
Unstable angina in last 3 months	142	6.7	130	8.8	19	4.2	**0.022**[§,a]	**0.049**[§,a,b]	**0.001**[§]
Myocardial infarction within past 7 days	0	0.0	2	0.1	0	0.0	0.168	0.168	1.000
Recent myocardial infarction (> 7 days but fewer than 30 days)	0	0.0	1	0.1	0	0.0	0.409	0.409	1.000
Orthopnea	27	1.3	36	2.4	2	0.4	**0.010**[§,a]	0.149	**0.006**[§,a,b]
Dementia	1917	90.3	1699	115.5	365	80.2	**0.000**[§]	**0.029**[§,b]	**0.000**[§]
Anxiety	201	9.5	172	11.7	42	9.2	**0.044**[§,a,b]	0.933	0.195
History of claustrophobia	9	0.4	7	0.5	4	0.9	0.805	0.264	0.301
Essential, benign, or drug-related tremor/abnormal head movements, fasciculations, spasms, or tremor not otherwise specified	449	21.1	728	49.5	79	17.4	**0.000**[§]	0.106	**0.000**[§]
Cerebral edema	69	3.2	15	1.0	6	1.3	**0.000**[§]	**0.032**[§,a,b]	0.608

[§] Comparisons in bold are significant at $p<0.05$.

*Per 1,000 procedures.

Source: RAND analysis of the 5 percent Standard Analytical Files of Medicare claims, 2001.

[a] Not significant for MRI (brain) with contrast (see Table E.1 in Appendix E).

[b] Not significant for MRI (brain) without contrast (see Table E.2 in Appendix E).

the proportion of patients over 85 years of age does not differ (Table 3.3). Office patients also have a significantly higher rate of anxiety than OPD patients. The only characteristic for which the OPD rate is significantly higher than the office rate is cerebral edema. OPD and IDTF rates are similar for most characteristics, but OPD patients have a significantly higher rate than IDTF patients for three characteristics (recent unstable angina, dementia, and cerebral edema).

The patterns of patient characteristics by setting for all MRIs (brain) (Table 3.3) are similar to the patterns we found for the two subsets of MRI (brain) (with and without contrast) (see Appendix E). All significant differences between settings for the subsets of MRIs with and

without contrast are in the same direction as those for all MRIs (brain). The differences in the significant results between this table and the tables for MRI (brain) with and without contrast are indicated in the footnotes on Table 3.3.

Because services provided in offices and IDTFs are paid under the same payment system (physician fee schedule), we also assessed whether OPD patients differ from a combined group of office and IDTF patients. OPD patients have significantly lower rates than the combined group for three characteristics (over 70 years of age, dementia, and tremor) and a significantly higher rate for cerebral edema (Table 3.4). As mentioned above, the significantly higher percentage of patients over 70 years of age in the office/IDTF probably has little clinical or cost significance, given the broad range of ages included in the category and the proportion of patients over 85 years of age does not differ (Table 3.4). The finding of the OPD patients having significantly lower rates is somewhat unexpected. However, because ICD-9-CM codes do not indicate the severity of these conditions, we were not able to determine whether there are differences in the severity of cases with these conditions across the settings. In an effort to understand this finding, we discuss three other possible explanations.

The first possible explanation for this finding relates to Medicare's hospital outpatient payment rules. The rules define as inpatient services any outpatient diagnostic services provided by a hospital within three days prior to admission and, therefore, are included in the PPS payment (see Methods section for a description of the rules related to PPS payment) (CMS, 2006). The effect of the policies is that patients who had an MRI (brain) and were subsequently admitted to the hospital are not in our sample. Because they comprise a subgroup that is likely to be more ill than patients who were not admitted and are thus in our sample, this also might result in the observation that office patients have higher rates of the characteristics of interest than the OPD patients. Because of these rules regarding outpatient diagnostic services preceding hospital admissions, the outpatient claims for patients who are admitted within 3 days are not in our sample of MRIs, and we are, therefore, not able to study them directly.

The rules regarding outpatient diagnostic services prior to admission might also affect the characteristics of the office/IDTF patients. If a hospital is not going to be reimbursed for an MRI if the patient is admitted, and the patient is likely to be admitted to a hospital, the physician

might order the test to be performed in another setting. If this were true, this subgroup of patients (i.e.,

Table 3.4 Characteristics of MRI (Brain) Patients By OPD and Office/IDTF Combined, Medicare Fee-for-Service, 2001

	OPD		Office/IDTF		Fisher's exact
	Number	Rate*	Number	Rate*	p-value
All MRI (brain)	21233	--	19264	--	
Age > 70 years	14279	672.5	13474	699.4	**0.000**[§,a]
Age > 85 years	1745	82.2	1526	79.2	0.273
Unstable angina in last 3 months	142	6.7	149	7.7	0.217
Myocardial infarction within past 7 days	0	0.0	2	0.1	0.226
Recent myocardial infarction (> 7 days but fewer than 30 days)	0	0.0	1	0.1	0.476
Orthopnea	27	1.3	38	2.0	0.083
Dementia	1917	90.3	2064	107.1	**0.000**[§]
Anxiety	201	9.5	214	11.1	0.103
History of claustrophobia	9	0.4	11	0.6	0.513
Essential, benign, or drug-related tremor/abnormal head movements, fasciculations, spasms, or tremor not otherwise specified	449	21.1	807	41.9	**0.000**[§]
Cerebral edema	69	3.2	21	1.1	**0.000**[§]

[§] Comparisons in bold are significant at p<0.05.

*Per 1,000 procedures.

[a] Not significant for MRI (brain) without contrast (see Table E.4 in Appendix E).

Source: RAND analysis of the 5 percent Standard Analytical Files of Medicare claims, 2001.

those who had an MRI performed in an office or an IDTF and were then admitted to a hospital as an inpatient) would be expected to be more ill than other office/IDTF patients.

To test this, we compared the characteristics of two subgroups of patients who had MRIs in the office/IDTF: those who were admitted as an inpatient within three days of the MRI, and those who were not admitted. First, we found that only a small percentage of patients having MRIs in the IDTF or office were subsequently admitted. Of the 19,264 patients who had MRIs

in the IDTF or office, only 1.6 percent (307/19,264) were admitted to a hospital within 3 days. Among patients with an office or IDTF MRI who were admitted within 3 days, the rates of the characteristics of interest were not consistently higher than those who were not admitted (data not shown). We were not able to analyze data on OPD MRI patients who were admitted within 3 days. However, the lack of differences in the rates among the office/IDTF MRI patients who were admitted and not admitted within 3 days provides no support for assuming OPD MRI patients who were admitted within 3 days exhibited higher rates of the characteristics of interest than those who were not admitted. In conclusion, the effect of the outpatient rule regarding procedures performed in the OPD prior to admission to the same hospital does not seem to explain the higher rates in the office/IDTF.

A second possible explanation for this finding is that MRIs (brain) are performed in different settings in different regions of the United States. In the Phase 1 study, we observed, for example, that a much lower percentage of outpatient MRIs in the Middle Atlantic region[24] are performed in an OPD than in the rest of the geographic regions combined (31 percent vs. 57 percent, respectively) (Wynn et al., 2004).

To test the hypothesis related to regional differences, we compared the rate of the three characteristics of interest (dementia, tremor, and cerebral edema) between those who had an MRI in an OPD and those who had an MRI in an office or IDTF by region. For dementia, the rates were higher among the office/IDTF patients than the OPD patients in all nine regions of the United States (significantly higher for four regions). For tremor, the pattern was similar with higher rates in the office/IDTF in all nine regions (significantly higher for eight regions). For cerebral edema, the rates in the OPD were higher than in the office/IDTF in six of nine regions (one significant). In conclusion, because the office/IDTF rates are consistently higher (or lower) than the OPD rates across the regions, the overall differences in rates are not likely explained by differences in specific regions.

A third possible explanation for this finding is that the group of patients having MRIs in the OPD might be largely comprised of those with injuries (e.g., falls) who come in through the emergency department (ED) and, therefore, might actually be "healthier" (i.e., have fewer chronic conditions) than those having an MRI in another setting. To test this, we compared two

groups of OPD patients with an MRI: those with ED charges within two days of the OPD visit and those without such ED charges. Of the 21,233 patients who had MRIs in the OPD, 1.6 percent (340/21,233) had ED charges (data not shown). If the proposed hypothesis were true, the OPD patients with ER charges would be expected to have lower rates. Instead, we found higher rates of six patient characteristics among the OPD/ED patients, of which one was significant.[25] Based on this, we conclude that the higher rates observed in the office/IDTF patients are not explained by healthier patients coming into the OPD through the ED.

In conclusion, we tested three hypotheses that might explain the higher rates of dementia and tremor in the office/IDTF. However, none of the three appear to explain the finding that office/IDTF patients having MRI had significantly higher rates of dementia and tremor.

Comparison of Outcome Measures Across Settings

We recommended seven outcomes to MedPAC for further analysis using risk adjustment methods, four for cataract surgery, two for colonoscopy, and one for MRI. As explained above in Section 2, the outcome measures for the three procedures were selected on the basis of their preventability and severity ratings, frequency of occurrence after the procedure, and assurance from our clinical experts that they are not conditions that could be indications for having the procedure. Below we describe the rationale for selecting each of these outcomes based on the selection criteria. A detailed description of the entire process of selecting these from the complete list of outcomes for each procedure is described in Appendix F, including information on all four selection criteria for all of the outcomes that were considered.

For each of the six outcome measures, we generated risk-adjusted rates using a multiple logistic regression model to adjust for patient characteristics that might affect the risk of the outcome occurring after the procedure. By controlling for these characteristics, differences in the outcome rates can be attributed to differences between the settings rather than to differences in other patient characteristics that might affect the rates. The results presented in Tables 3.5, 3.10, 3.12, and 3.13 are risk-adjusted rates generated from the multiple logistic regression models described in the Methods section. Below we discuss the covariates included in these

24 The Middle Atlantic region includes New Jersey, New York, and Pennsylvania.

models and the results of analysis with regard to differences in the risk-adjusted outcome rates among the various ambulatory settings.

Cataract Surgery

In selecting the outcome measures for cataract surgery, we considered a list of 30 measures, including the initial set of 27 that were rated and discussed as part of the Phase 1 panel process, plus three outcomes that were added during or after the Phase 1 panel meeting. We recommended to MedPAC that four of these measures be analyzed further using risk adjustment. They are endophthalmitis, cataract fragments in eye, persistent corneal edema, and iris prolapse.

Of the cataract surgery outcomes not considered for further analysis, three were dropped because they can be indications for having cataract surgery; these are persistent cystoid macular edema, retinal break, and retinal detachment. Four additional outcome measures (capsule rupture or posterior capsule tear, new or worsening heart failure, wound dehiscence, and wound leak) were eliminated because there are no ICD-9 codes that can be used to identify the conditions in claims data.

Endophthalmitis is an inflammation (often from infection) of the vitreous or aqueous humor of the eye that might occur following cataract surgery. Endophthalmitis was considered to be severe (6 of 6 panelists rating it 8 or 9) and preventable (5 of 5 panelists rating it 5 or 7) by the Phase 1 cataract surgery panel[26] (Wynn et al., 2004). We recommended it for further analysis because it is a severe condition that can be prevented.

Cataract fragments in eye describes a medical condition in which a part of the cataract falls into a particular part of the eye. Although the Phase 1 panel did not rate this outcome, the clinical consultant for cataract surgery for the current study informally rated it a 4 on the severity scale and a 7 on the preventability scale. We recommended it for further analysis because the Phase 1 panel thought it was important enough to add it to the list of outcomes.

Persistent corneal edema is the prolonged swelling of the corneal tissues beyond the normal healing period for cataract surgery. Persistent corneal edema was considered to be

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[25] The rates of six characteristics (age over 85 years, unstable angina, orthopnea, dementia, anxiety, and tremor) were higher among the OPD patients with ED charges than among the OPD patients without such charges. Of these, the rate of dementia was significantly higher.

[26] In Phase 1, the cataract surgery panel consisted of 7 members, but only 5 and 6 members rated severity and preventability, respectively, of endophthalmitis.

moderately severe (all 6 panelists rating it 5 or 7) and preventable (5 of 6 panelists rating it 7 or 8) by the Phase 1 cataract surgery panel (Wynn et al., 2004). We recommended it for further analysis because it is a severe condition that can be prevented.

Iris prolapse is a condition in which a portion of the pigmented part of the eye sags into the eye. It is considered to be a complication of cataract surgery. Iris prolapse was considered to be somewhat severe (4 of 6 panelists rating it 5 or 7) and preventable (5 of 6 panelists rating it 8) by the Phase 1 cataract surgery panel (Wynn et al., 2004). We recommended it for further analysis because it is a somewhat severe condition that can be prevented.

Results of Outcome Analyses. Accounting for differences in patient characteristics, the risk-adjusted rate of endophthalmitis within 30 days of cataract surgery was significantly higher among OPD patients than among ASC patients (Table 3.5). This result is based on 61 cases of endophthalmitis occurring among 36,622 cataract surgeries in the OPD and 42 cases among 40,665 ASC surgeries.[27] The risk-adjusted rates of the other three outcomes did not differ between patients having cataract surgery in the two settings. Cataract fragments were diagnosed within 30 days at a predicted rate of 0.94 and 0.90 cases per 1,000 in the OPD and ASC, respectively.[28] Corneal edema was coded on claims within 30 days of surgery at a slightly, but not significantly, higher risk-adjusted rate in the OPD than the ASC (0.76 vs. 0.62 per 1,000).[29] Iris prolapse was coded very infrequently on claims in the 30 days after surgery, with only 3 and1 cases among OPD and ASC patients, respectively.[30] Appendix G shows the percentage of the cataract surgery sample for each dummy variable in the four cataract surgery models.

27 There are 103 cases of endophthalmitis the current study compared to 113 cases in the Phase 1 study. The difference is explained by two factors. First, we excluded one case that occurred in a patient with cataract surgery performed in the office setting. Second, 9 patients had two cataract surgeries performed and a single diagnosis of endophthalmitis that fell within 30 days of both procedures. In the current study, we counted this as only one outcome for each beneficiary while in Phase 1 it was counted as two outcomes.

28 There are 71 cases of cataract fragments in the current study compared to 92 cases in the Phase 1 study. The difference is explained by two factors. First, we excluded two cases that occurred in patients with cataract surgery performed in the office setting. Second, 19 patients had two cataract surgeries performed within a short period of time and a single diagnosis of cataract fragments that fell within 30 days of both procedures. In the current study, we counted this as only one outcome for each beneficiary while in Phase 1 it was counted as two outcomes.

29 There are 63 cases of persistent corneal edema in the current study compared to 54 cases in the Phase 1 study. The difference is explained by two factors. First, we excluded one case that occurred in a patient with cataract surgery performed in the office setting. Second, we included ten more cases identified as having keratoplasty on an inpatient or outpatient basis.

30There are 4 cases of iris prolapse in this model compared to 62 cases in the Phase 1 study. The difference is explained by two factors. First, the ICD-9-CM codes that were used to identify cases were changed between the two studies. In the current study, we use 364.75 to identify cases while 364.7x was used in the Phase 1 study. Second, two patients had two cataract surgeries performed and a single diagnosis of iris prolapse that fell within 30 days of both procedures. In the current study, we counted this as only one outcome for each beneficiary while in Phase 1 it was counted as two outcomes.

Table 3.5 Risk-Adjusted Rates* of Selected Outcomes Occurring Within 30 Days Following Cataract Surgery By Setting, Medicare Fee-for-Service, 2001

	OPD		ASC		Chi-Square p-value
	Number	Rate**	Number	Rate**	
All cataract surgeries	36,623	--	40,671	--	
Endophthalmitis	61	1.64	42	1.05	**0.026**[§]
Cataract fragments in eye	35	0.94	36	0.90	0.827
Persistent corneal edema	28	0.76	25	0.62	0.435
Iris prolapse	3	0.07	1	0.03	0.415

[§] Comparisons in bold are significant at $p<0.05$.

*Each risk-adjusted rate is calculated based on the logistic regression model (see Methods section for details).

**Per 1,000 procedures.

Source: RAND analysis of the 5 percent Standard Analytical Files of Medicare claims, 2001.

Note: Cataract surgeries performed in the office setting were excluded because of small numbers.

As described above in the Methods section, multiple logistic regression models were used to estimate the risk-adjusted rates for the four cataract surgery outcomes that are shown in Table 3.5. The model parameters (regression coefficients, standard errors, and p-values) for each of these models are shown in Tables 3.6-3.9. The model coefficients for endophthalmitis (Table 3.6) indicate that being older and having the procedure performed in an OPD significantly increased the probability of having a diagnosis of endophthalmitis within 30 days of cataract surgery. Older beneficiaries were increasingly more likely to have endophthalmitis as indicated by significant positive coefficients that increase in magnitude with increasing age. The remaining model coefficients were not statistically significant.

Based on the coefficients for the cataract fragments model (Table 3.7), increasing age also significantly increased the probability of having a diagnosis of cataract fragments within 30 days of cataract surgery. The coefficients for the rest of the model variables, including the dummy variable for the ASC setting, were not statistically significant.

Table 3.6 Parameter Estimates from Logistic Regression for Endophthalmitis within 30 Days of Cataract Surgery, Medicare Fee-for-Service, 2001

Variable*	Parameter Estimate	Standard Error	p Value
Intercept	**-6.781**	**0.267**	**<.0001**[§]
age_under_65	-0.105	0.815	0.8971
age_75_84	**0.551**	**0.244**	**0.0237**[§]
age_85p	**1.156**	**0.296**	**<.0001**[§]
female	-0.313	0.202	0.1217
race_afam	0.677	0.347	0.0509
race_other	0.690	0.439	0.1164
disabled	0.000	0.421	0.9997
medicaid	-0.290	0.346	0.4019
diabetes	0.048	0.223	0.8298
arth_lupus	0.393	0.370	0.2881
cancer_leuk	0.521	0.587	0.3748
inasc	**-0.449**	**0.201**	**0.0257**[§]

[§] Parameters in bold are significant at $p<0.05$.

*Two variables representing AIDS and tremor were dropped from the model based on initial results indicating the coefficients were insignificant and unstable because of small numbers.

In the models for persistent corneal edema and iris prolapse (Tables 3.8 and 3.9, respectively), none of the variables were statistically significant, including the dummy variable for the ASC setting. This means that the variables represented in the two models did not significantly increase or decrease the probability of either persistent corneal edema or iris prolapse within the 30 days after cataract surgery.

Table 3.7 Parameter Estimates from Logistic Regression for Cataract Fragments within 30 Days of Cataract Surgery, Medicare Fee-for-Service, 2001

Variable*	Parameter Estimate	Standard Error	p Value
Intercept	**-7.542**	**0.334**	**<.0001**[§]
age_under_65	0.305	0.709	0.6673
age_75_84	**0.682**	**0.301**	**0.0235**[§]
age_85p	**1.212**	**0.371**	**0.0011**[§]
female	-0.060	0.247	0.8096
race_afam	-0.772	0.728	0.2891
race_other	0.471	0.537	0.3798
disabled	0.688	0.406	0.0900
medicaid	-0.025	0.388	0.9478
history_vitrectomy	-10.773	428.700	0.9800
tremor	1.033	1.010	0.3064
inasc	-0.052	0.238	0.8272

[§] Parameters in bold are significant at p<0.05.

*Two variables representing pseudoexfoliation and pupillary abnormalities were dropped based on initial results indicating the coefficients were insignificant and unstable because of small numbers.

Table 3.8 Parameter Estimates from Logistic Regression for Persistent Corneal Edema within 30 Days of Cataract Surgery, Medicare Fee-for-Service, 2001

Variable*	Parameter Estimate	Standard Error	p Value
Intercept	**-7.441**	**0.369**	**<.0001**[§]
age_under_65	0.226	0.890	0.7998
age_75_84	-0.202	0.294	0.4912
age_85p	-0.513	0.544	0.3459
female	0.581	0.322	0.0709
race_afam	0.332	0.540	0.5384
race_other	0.575	0.621	0.3543
disabled	-0.079	0.584	0.8926
medicaid	-0.306	0.473	0.5176
diabetes	-0.052	0.317	0.8692
inasc	-0.215	0.276	0.4353

*A variable representing tremor was dropped from the model based on initial results indicating the coefficient was insignificant and unstable because of small numbers.

[§] Parameters in bold are significant at p<0.05.

Table 3.9 Parameter Estimates from Logistic Regression for Iris Prolapse within 30 Days of Cataract Surgery, Medicare Fee-for-Service, 2001

Variable*	Parameter Estimate	Standard Error	p Value
Intercept	-21.196	143.900	0.8829
age_under_65	0.783	1.538	0.6108
age_75_84	0.083	1.441	0.9542
age_85p	1.582	1.481	0.2852
female	10.674	143.900	0.9409
race_afam	1.979	1.091	0.0697
race_other	-10.050	463.800	0.9827
disabled	1.830	1.323	0.1667
medicaid	0.606	1.141	0.5958
inasc	-0.945	1.159	0.4147

*Four variables representing pseudoexfoliation, history of vitrectomy, pupillary abnormalities, and tremor were dropped from the model based on initial results indicating the coefficients were insignificant and unstable because of small numbers.

Colonoscopy

In selecting the recommended outcome measures for colonoscopy, we considered a list of 20 outcome measures, including the initial set of 19 that were rated and discussed as part of the Phase 1 panel process, plus one outcome that was added after the Phase 1 panel meeting. We recommended to MedPAC that two of these measures, perforation and splenic rupture, be analyzed further using risk adjustment. However, there were no cases of splenic rupture, within the 30-day window of the colonoscopies in our sample.[31] Therefore, splenic rupture could not be used as an outcome for colonoscopy. Perforation became the only outcome to be studied for colonoscopy.

Of the colonoscopy outcomes not considered for further analysis, five were dropped because they can be indications for having a colonoscopy; these are abdominal pain, hemorrhage, abdominal distension, sepsis and other infections, and hypotension. One outcome measure (post-

polypectomy syndrome) was eliminated because there are no ICD-9 codes that can be used to identify the condition in claims data.

Perforation (i.e., colonic perforation) is a tear of the large intestine, which occurs very infrequently during colonoscopy. Perforation may lead to bleeding and leakage of the contents of the large intestine into the abdominal cavity. This is problematic because the large intestine contains bacteria that should not be in the abdominal cavity, and might result in a severe infection. Perforation was considered to be severe (8 of 9 panelists rating it 6, 8 or 9) and moderately preventable (6 of 9 panelists rating it 5 or 8) by the Phase 1 colonoscopy panel (Wynn et al., 2004). Perforation was selected because it is a severe condition that can usually be avoided.

Results of Outcome Analyses. Based on all colonoscopies, perforation occurred within 30 days of the procedure at a significantly higher predicted rate (i.e., adjusted for differences in patient characteristics) among ASC patients than among OPD patients (1.67 vs. 0.76 per 1,000, respectively) (Table 3.10). We repeated the logistic regression runs on the subset of colonoscopies with lesion removal, biopsy, or control of bleeding (RBC) and those without RBC. Among both RBC and non-RBC colonoscopies, the predicted perforation rates were also significantly higher in the ASC than in the OPD (Table 3.10). The predicted rate of perforation among office colonoscopies did not differ significantly from OPD and ASC for any of the three

Table 3.10 Risk-Adjusted Rates* of Perforation Occurring Within 30 Days Following Colonoscopy By Setting, Medicare Fee-for-Service, 2001

Colonoscopy Sample	OPD		ASC		Office		Chi-Square p-value		
	Number	Rate**	Number	Rate**	Number	Rate**	OPD vs. ASC	OPD vs. Office	ASC vs. Office
All colonoscopies	63372	--	23503	--	4015	--			
All	49	0.76	37	1.67	3	0.75	**0.000**§	0.982	0.180
RBC	28	0.80	20	1.63	0	0.00	**0.016**§	0.975	0.960
Non-RBC	21	0.71	17	1.73	3	1.37	**0.007**§	0.285	0.715

§ Comparisons in bold are significant at $p<0.05$.

31 Between Phase 1 and Phase 2, we changed the ICD-9-CM diagnosis codes used to identify splenic rupture cases. In Phase 1, ICD-9-CM codes 789.2 and 865.1 were used and, in Phase 2, ICD-9-CM codes 865.0 and 865.1 were used.

*Each risk-adjusted rate is calculated based on the logistic regression model (see Methods section for details).
**Per 1,000 procedures.
Source: RAND analysis of the 5 percent Standard Analytical Files of Medicare claims, 2001.

samples of colonoscopies (all, RBC, and non-RBC). These predicted rates are based on a total of 89 cases (49, 37, and 3 cases of perforation in the OPD, ASC, and office, respectively).[32] Appendix H shows the percentage of the colonoscopy sample in each category of the dummy variables in the models and the parameters from each perforation logistic regression (regression coefficients, standard errors, and p-values). The model parameters (regression coefficients, standard errors, and p-values) for the perforation model are shown in Table 3.11. In the perforation model, having the procedure performed in the ASC increased the probability of having a diagnosis of perforation within 30 days of having a colonoscopy (as discussed above). None of the remaining variables, including the dummy variable for the office setting, were statistically significant. This indicates that the rest of the variables did not significantly increase or decrease the probability of a perforation diagnosis within the 30 days following a colonoscopy.

Table 3.11 Parameters from Logistic Regression for Perforation within 30 Days of All Colonoscopies, Medicare Fee-for-Service, 2001

Variable	Parameter Estimate	Standard Error	p Value
Intercept	**-7.512**	**0.235**	**<.0001§**
age_under_65	-0.878	0.577	0.1281
age_75_84	0.189	0.231	0.4132
age_85p	0.402	0.412	0.3289
female	0.009	0.218	0.9681
race_afam	-0.019	0.409	0.9636
race_other	-0.690	0.732	0.3459
disabled	0.269	0.383	0.4818
medicaid	**0.825**	**0.313**	**0.0085§**
bowel_obstruct	**1.158**	**0.345**	**0.0008§**
colorectal_cancer	0.782	0.472	0.0972
inflam_bowel_disease	0.638	0.591	0.2804

32 There are 89 cases of perforation in the current study compared to 73 cases in the Phase 1 study. The difference is explained by the fact that we included more cases identified with additional ICD-9-CM codes for perforation. In Phase 1, we included only 998.2, and in the current study, we include 998.2, E870.4, and 569.83.

melena	0.742	0.516	0.1500
inasc	**0.796**	**0.220**	**0.0003**[§]
inoff	-0.014	0.597	0.9817

[§] Parameters in bold are significant at $p<0.05$.

MRI (Brain)

In selecting the recommended outcome measures for MRI (brain), we considered a list of 19 outcome measures, including the initial set of 18 that were rated and discussed as part of the Phase 1 panel process, plus one outcome that was added after the Phase 1 panel meeting. We recommended to MedPAC that only one of these measures, anaphylaxis/anaphylactoid reaction, be analyzed further using risk adjustment.

Of the MRI outcomes not considered for further analysis, eight outcomes were dropped because they can be indications for having an MRI (brain); these are altered mental status, dizziness, headache, ocular injury, paresthesia, seizure, syncope, and vasospasm. One additional outcome measure, vasodilatation, was eliminated because there are no ICD-9 codes that can be used to identify the condition in claims data.

Anaphylaxis/anaphylactoid reaction is an immediate and potentially life-threatening allergic reaction involving the entire body due to a massive release of mediators from special cells. It can result in difficulty breathing and, in rare cases, death. It would occur as a result of an allergic reaction of the patient to the contrast media used in some MRIs. This outcome was considered to be very severe (all 7 panelists rating it 7, 8, or 9) by the Phase 1 MRI panel (Wynn et al., 2004). However, anaphylaxis was not considered to be preventable by most of the Phase 1 MRI panel, with only 2 of 7 panelists rating it 4 or higher. It is included despite the fact that it occurs very infrequently and might not be predictable, because there are no other reasonable outcome measures for MRI (brain).

Results of Outcome Analyses. Anaphylaxis was an extremely infrequent event among patients who had MRI (brain) with or without a contrast agent. Only three cases of anaphylaxis were identified from claims in the first 7 days after an MRI (brain), only one of which occurred in a patient having MRI (brain) with a contrast agent (top of Table 3.12). Finding anaphylaxis cases among those having an MRI (brain) without contrast was unexpected, because the assumption was that exposure to the contrast agent would trigger the anaphylactic reaction. However, this finding might have occurred due to a coding error in which the MRI was coded as "without contrast" when it was actually conducted "with contrast." Another possible explanation

Table 3.12 Risk-Adjusted Rates* of Anaphylaxis/Anaphylactoid Reaction Occurring Within 7 and 30 Days Following MRI (Brain) in OPD, Office, and IDTF, Medicare Fee-for-Service, 2001

	OPD		Office		IDTF		Chi-Square p-value		
MRI (Brain) Sample	Number	Rate**	Number	Rate**	Number	Rate**	OPD vs. Office	OPD vs. IDTF	Office vs. IDTF
All MRI (brain)	21233	--	14712	--	4552	--			
Within 7 days									
All	1	0.04	1	0.08	1	0.17	0.653	0.336	0.608
With contrast	1	0.08	0	0.00	0	0.00	0.953	0.971	0.998
Without contrast	0	0.00	1	0.19	1	0.36	0.932	0.928	0.662
Within 30 days									
All	6	0.28	3	0.21	2	0.44	0.660	0.582	0.407
With contrast	5	0.37	1	0.13	1	0.42	0.356	0.906	0.420
Without contrast	1	0.13	2	0.28	1	0.46	0.536	0.365	0.689

*Each risk-adjusted rate is calculated based on the logistic regression model (see Methods section for details).
**Per 1,000 procedures.
Source: RAND analysis of the 5 percent Standard Analytical Files of Medicare claims, 2001.

is that the anaphylaxis could result from other conditions or situations that might not be coded (i.e., undercoded) in claims (e.g., ingestion of peanuts or a bee sting in an allergic patient).

Although we ran a logistic regression model for the three cases that occurred with 7 days of an MRI, there is little that can be concluded from such a small sample, other than the predicted rates of anaphylaxis are zero or very small and there are no significant differences among the settings. We tested the sensitivity of the finding to the length of the followup period, by extending it to 30 days (bottom of Table 3.12). We found 11 cases of anaphylaxis occurred within the 30-day period, with 7 among those with contrast MRIs (brain) and 4 among those with non-contrast MRIs (brain).[33] None of the differences in predicted rates (i.e., adjusted for patient characteristics) among settings were significant based on the 30-day model.

Because services provided in offices and IDTFs are paid under the same payment system (physician fee schedule), we also constructed models to test for differences between OPD patients and a combined group of IDTF and office patients. Based on predicted rates from these models, we conclude that the 7-day and 30-day rates are not significantly different between the

33 The 11 cases identified within 30 days of an MRI in the current study are the same as those in the Phase 1 study.

Table 3.13 Risk-Adjusted Rates* of Anaphylaxis/Anaphylactoid Reaction Occurring Within 7 and 30 Days Following MRI (Brain) in OPD and IDTF and Office Combined, Medicare Fee-for-Service, 2001

	OPD		IDTF and Office		Chi-Square
	Number	Rate**	Number	Rate**	p-value
All MRI (brain)	21233	--	19264	--	
Within 7 days					
All	1	0.04	2	0.11	0.446
With contrast	1	0.08	0	0.00	0.941
Without contrast	0	0.00	2	0.25	0.904
Within 30 days					
All	6	0.28	5	0.26	0.913
With contrast	5	0.37	2	0.20	0.477
Without contrast	1	0.13	3	0.32	0.423

*Each risk-adjusted rate is calculated based on the logistic regression model (see Methods section for details).
**Per 1,000 procedures.
Source: RAND analysis of the 5 percent Standard Analytical Files of Medicare claims, 2001.

OPD and the other two settings in the entire MRI (brain) sample and in the subgroups of procedures with and without contrast (Table 3.13).

The model parameters (regression coefficients, standard errors, and p-values) for the anaphylaxis model based on all MRIs (brain) are shown in Table 3.14. In the anaphylaxis model, none of the variables were statistically significant, including the dummy variable for the IDTF

Table 3.14 Parameters from Logistic Regression for Anaphylaxis within 7 Days of All MRIs (Brain) for Three Settings, Medicare Fee-for-Service, 2001

Variable*	Parameter Estimate	Standard Error	p Value
Intercept	-20.062	144.900	0.8899
age_under_65	-1.713	1.415	0.2261
age_75_84	-10.711	189.800	0.9550
age_85p	-10.798	406.200	0.9788
female	-0.223	1.233	0.8566
race_afam	-10.852	318.000	0.9728
disabled	0.894	1.412	0.5267
medicaid	12.807	144.900	0.9296
history_anaph_shock	-9.767	1001.300	0.9922
inidtf	1.363	1.417	0.3363
inoff	0.636	1.416	0.6532

*Two variables representing "other race" and personal allergy to radiographic dye were dropped from the model based on initial results indicating the coefficients were

insignificant and unstable because of small numbers.

and office settings. This indicates that the variables represented in the two models did not significantly increase or decrease the probability of an anaphylaxis diagnosis within the 30 days after having a MRI (brain). Appendix I shows the percentage of the MRI (brain) sample in each category of the variables in the models, and the parameters from anaphylaxis logistic regression models (regression coefficients, standard errors, and p-values) for MRIs (brain) with and without contrast for the three-setting comparison, and for all MRIs, as well as with and without contrast for the two-setting comparison.

4. Summary and Discussion

The research described in this report focuses on three procedures performed frequently in multiple ambulatory settings on Medicare patients. The study procedures (cataract surgery, colonoscopy, and MRI (brain)) were selected in Phase 1 of this study based on having high volume in two or three settings in addition to potential safety concerns. The current study was designed to answer two questions. First, are there significant differences between ambulatory settings in the characteristics of the Medicare patients having these three high-volume procedures that might be expected to increase the facility cost? Second, are there significant differences between the settings in risk-adjusted rates of adverse outcomes following the three procedures? We addressed these questions by analyzing selected characteristics and outcomes using enrollment and claims data for a 5 percent sample of Medicare beneficiaries for calendar year 2001.

Summary of Findings

Cataract Surgery. All cataract surgery patients exhibited low rates of most characteristics that might increase facility costs. However, significantly more OPD patients had several of the characteristics than those in the ASC (age over 85 years, dementia, acute episode of COPD, prescription drug dependence, alcohol abuse, schizophrenia, tremor, pseudoexfoliation of lens capsule, progressive high myopia, dislocation of lens, and posterior synechiae). In addition, we observed that after risk adjustment, all four outcomes (endophthalmitis, cataract fragments, corneal edema, and iris prolapse) occurred more frequently in the OPD. However, for only one of the outcomes, endophthalmitis, was the rate significantly higher.

Colonoscopy. All colonoscopy patients displayed low rates of most characteristics possibly related to increased facility costs, but OPD patients had somewhat higher rates than ASC patients (age over 85 years, recent unstable angina, dementia, acute episode of COPD, acute episode of cardiomyopathy/heart failure/pulmonary edema, malignant hypertension, prescription drug dependence, past bowel obstruction, past colorectal cancer, and melena).

There was not a consistent pattern of these characteristics for OPD or ASC patients compared to office patients; rates were sometimes higher in the office setting and sometimes in the other two settings. Using logistic regression, we investigated one outcome following colonoscopy, perforation. The risk-adjusted rates of perforation were low in all three settings, but significantly higher in the ASC than in the OPD, and not higher than in the office setting. The same pattern also held for rates of perforation following RBC and non-RBC colonoscopies.

MRI (Brain). Rates were low among patients having an MRI (brain) for most characteristics that might increase facility costs. Of those with such characteristics, office patients showed significantly higher rates than patients in the OPD and IDTF (age over 70 years, recent unstable angina, orthopnea, dementia, and tremor). OPD and IDTF patients had similar rates for most characteristics. Anaphylaxis was the only outcome selected for further analysis using risk adjustment. The risk-adjusted rates for anaphylaxis within 7 days of the procedure were extremely low and not significantly different across settings. These results did not change when the followup period was extended to 30 days.

Discussion

The report from the Phase 1 study concluded that the "preliminary analyses for the three procedures suggest that with further refinement the administrative data can be used to reach a number of policy-relevant conclusions" (Wynn et al., 2004). Our study incorporates some of the refinements discussed in the Phase 1 study as necessary before any conclusions are made concerning differences across ambulatory settings. First, we incorporated clinical expertise into the selection of a set of patient characteristics that might increase facility costs, and then employed statistical tests to assess the likelihood of the differences between settings being due to chance. It is important to note that the patient characteristics analyzed in this study were not formally evaluated by a large panel of clinical experts, nor did RAND quantify the relationship between each characteristic and actual cost. Second, we carefully selected a set of outcomes that met specific criteria and then utilized multiple logistic regression to risk-adjust for covariates and to test for differences between settings. These methods allow us to evaluate the results in a more scientifically rigorous manner and, therefore, to strengthen the conclusions.

In interpreting these findings, it is important to keep in mind that most of the observed rates for the patient characteristics are very low, and therefore, the differences between the rates in the different settings are very small (see Tables 3.1—3.4). For cataract surgery, the most frequent patient characteristic was being over 85 years of age, with the rate in the OPD significantly higher than the ASC rate (Table 3.1). All of the other characteristics for cataract surgery occur much less frequently, with some OPD rates significantly higher than ASC. For colonoscopy, the rates of the patient characteristics are also low, with some OPD rates significantly higher than ASC and some office rates significantly higher than OPD (Table 3.2). For MRI, most of the patient characteristic rates are low with three significantly higher in the IDTF/office than OPD and only one significantly higher in the OPD than IDTF/office (Tables 3.3 and 3.4).

Similarly, the adverse outcomes occur very infrequently in all settings. We found significant differences between settings for two outcomes, endophthalmitis following cataract surgery and perforation following colonoscopy. Endophthalmitis occurred at a rate of 1.64 and 1.05 per 1000 procedures in the OPD and the ASC settings, respectively, with a difference of 0.59 per 1000 (see Table 3.5). Perforation occurred even less frequently with rates of 0.76, 1.67, and 0.75 per 1000 procedures in the OPD, ASC, and office settings, respectively, with differences between the settings of less than 1 per 1000 (see Table 3.10). Although the differences are significant, the magnitude of these rates should be considered when the policy significance of the differences between the various settings is contemplated.

Selection of Measures

We attempted to identify 4 – 7 adverse outcome measures for each procedure as MedPAC had requested. However, given that the study procedures are relatively safe with a low rate of complications, identifying this number of meaningful outcome measures was not possible. A large number of conditions that might occur as a result of the three procedures were eliminated because they were also considered to be indications for having the procedure. In addition, several outcomes were excluded from consideration because there was not an ICD-9-CM code suitable for identifying them in claims data.

Of the remaining conditions, we tried to identify outcomes that are severe, preventable, and frequent, and can reasonably be assumed to have occurred as a result of the procedure. We focused primarily on outcomes related to the organ affected by the procedure, because it would be more difficult to establish that the general medical outcomes occurred as a result of the procedures, especially using claims data as supporting evidence. This issue arises because it is impossible to tell from claims data when a condition was diagnosed. Conducting a similar study using medical records might allow the use of some of the conditions that were excluded as outcomes because it might be possible to determine the sequence of events more accurately.

Limitations of Administrative Data

Using claims data to examine potential differences in quality and processes of care across ambulatory settings has several advantages (Wynn et al., 2004). Medicare claims data are routinely collected and relatively inexpensive to analyze. They are available relatively quickly – there is a lag of seven months between the end of a calendar year and the release of Standard Analytical Files (SAF) of Medicare claims from CMS.[34] Thus, measures based on claims data can be calculated in a somewhat timely fashion. The availability of claims data on an ongoing basis allows periodic evaluation crucial to identifying emerging trends and evaluating the impact of policy. However, outcomes can be difficult to measure using administrative data because clinical detail is lacking and data elements not directly related to payment might be unreliable.

There are concerns about using claims data for condition-specific analyses because identifying clinical subgroups of patients with ICD-9-CM codes might be problematic (Wynn et al., 2004). These concerns fall into two categories: 1) the ICD-9-CM diagnostic nomenclature, and 2) the use of ICD-9-CM diagnostic codes (Iezzoni, 1990). The ICD-9-CM nomenclature contains many ambiguities. Codes may be vague (e.g., heart failure, unspecified) and contain codes for symptoms (e.g., fatigue) as well as codes for diseases (e.g., lung cancer). In addition, the nomenclature provides only limited indicators of the severity of a condition. This makes identifying specific clinical outcomes following a procedure difficult.

The way in which diagnoses are coded in individual settings and overall might create artifactual differences (Wynn et al., 2004). For example, in searching for a patient characteristic

or an outcome, finding it on an inpatient claim might be more likely because multiple diagnoses are coded for each admission. In contrast, most outpatient claims contain at most a few diagnostic codes. In addition, certain ICD-9-CM codes are also more likely to be coded on inpatient claims because hospital payment based on DRGs has introduced a pecuniary bias into coding practices known as "DRG creep" (Simborg, 1981). In studies to validate ICD-9-CM codes with chart-based reviews, substantial inaccuracies and unexplained geographic variation have been uncovered (IOM, 1980). The degree of inaccuracy, however, depends greatly on the condition and algorithm used to detect the condition (Quam et al., 1993).

In the Phase 1 study, we noted that attributing outcomes to particular procedures often requires making questionable assumptions (Wynn et al., 2004). In the current study, we have addressed this issue in two ways. First, we have limited the analyses to outcomes that are not considered to be indications for having the procedure. Therefore, when we find an outcome coded on a claim during the period following the procedure, we know that it was not the reason for having the procedure. Second, we have limited the outcomes to conditions that are specific to the body system involved in the procedure (e.g., perforation of the colon for colonoscopy).

One of the objectives of the Phase 1 study was to determine whether administrative data could be used to study differences among settings in the patient characteristics that might increase the facility resources needed to perform the procedure (Wynn et al., 2004). In the current study, we have used clinical expert opinion to select a subset of characteristics that might affect the medical complexity of a patient. Although we did not analyze data to answer this question directly, the clinical experts and the project physician provided us with information about the likelihood of the procedure requiring more facility resources. The underlying assumption is that performing a diagnostic or surgical procedure on a medically complex patient or on a patient with a particular condition such as dementia may require more resources. In Phase 1, the MRI panel indicated a patient with claustrophobia might be more time-consuming and might require sedatives. Patients with dementia and those with monocular vision were identified by the colonoscopy and cataract panels, respectively, as likely to require more time. However, because claustrophobia is likely to be "undercoded" on claims, the rates of claustrophobia reported in the current study (see Tables 3.3 and 3.4) are probably

34 We used 2001 data for these analyses because the files were created for the Phase 1 study which started in 2003.

underestimated. Codes are not available for identifying monocular vision in claims, so we were not able to calculate a rate for this condition.

The overall limitations of claims data and of specific variables used in our analysis do not mean that claims data should not be used for clinically-based measures, though confirmation with more clinically detailed methods such as chart review would be desirable.

Conclusion

In this study of three high-volume outpatient procedures, we compared patient characteristics and outcomes in multiple settings using Medicare administrative data. We conclude the following:

- Observed rates for most characteristics thought to affect the cost of performing the three study procedures are very low in all settings.
- Looking across all three services and all settings, no single setting had patients with consistently higher rates of characteristics that might increase the cost of performing the service. The characteristics we examined were not formally evaluated by a large panel of clinical experts, nor did RAND quantify the relationship between each characteristic and actual cost.
- Observed rates for adverse outcomes are also very low in all settings, so that the magnitudes of significant differences between settings are quite small.

Although there are some significant differences between the settings, both in terms of the type of patients who are treated in the setting and in the outcomes following cataract surgery and colonoscopy,[35] the lack of consistent patterns across the three study procedures might make it difficult to draw general conclusions about differences in care provided in the various ambulatory settings. The study, however, still contributes useful information that will inform policy decisions related to this topic.

35 The outcome for MRI, anaphylaxis/anaphylactoid reaction, did not vary significantly by setting.

Appendices

Appendix A. Background of Clinical Consultants

The clinical consultant for colonoscopy, Christopher Chang, M.D., Ph.D., is an Assistant Professor of Medicine in the Division of Gastroenterology at UCLA Medical Center. He completed his fellowship in gastroenterology at UCLA Medical Center. He has clinical experience working in the inflammatory bowel disease clinic and also is involved in a variety of research activities related to Campylobacter (a pathogen that causes gastrointestinal illnesses).

The clinical consultant for cataract surgery, Irene C. Kuo, M.D., is Assistant Professor of Ophthalmology at the Wilmer Eye Institute, and Medical Director of the Wilmer Eye Institute at White Marsh, Maryland. A corneal specialist and board-certified ophthalmologist, Dr. Kuo has clinical expertise in laser refractive surgery, corneal disease and surgery, corneal transplant and cataract surgery, and uveitis. Dr. Kuo is involved in a variety of research activities, including wound healing after keratorefractive procedures and the evaluation and treatment of infectious keratitis. She completed her residency at the University of Southern California—Doheny Eye Institute, and her fellowship in cornea, refractive surgery, and uveitis at the University of California at San Francisco and the Proctor Foundation.

The clinical consultant for MRI (brain), Kenneth Ong, M.D., is a neuroradiologist in private practice in San Jose, CA. He completed his fellowship in neuroradiology at University of California, San Francisco. He is in a group practice with 12 other radiologists. The group covers two hospitals, runs an outpatient radiology office, and provides readings for a nearby imaging center.

Appendix B. HCPCS/CPT Codes for Study Procedures

Table B.1 BETOS P4B: Eye procedure—Cataract Removal/Lens Insertion

CPT Code	CPT Description
66820*	Discission of secondary membranous cataract (opacified posterior lens capsule and/or anterior hyaloid); stab incision technique (Ziegler or Wheeler knife).
66830	Removal of secondary membranous cataract (opacified posterior lens capsule and/or anterior hyaloid) with corneo-scleral section, with or without iridectomy (iridocapsulotomy, iridocapsulectomy).
66840	Removal of lens material; aspiration technique, one or more stages.
66850	Removal of lens material; phacofragmentation technique (mechanical or ultrasonic) (e.g., phacoemulsification), with aspiration.
66852	Removal of lens material; pars plana approach, with or without vitrectomy.
66920	Removal of lens material; intracapsular.
66930	Removal of lens material; intracapsular, for dislocated lens.
66940	Removal of lens material; extracapsular (other than 66840, 66850, 66852).
66982	Extracapsular cataract removal with insertion of intraocular lens prosthesis (one stage procedure), manual or mechanical technique, (eg, irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (eg, iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage
66983	Intracapsular cataract extraction with insertion of intraocular lens prosthesis (one stage procedure).
66984	Extracapsular cataract removal with insertion of intraocular lens prosthesis (one stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification).
66985	Insertion of intraocular lens prosthesis (secondary implant), not associated with concurrent cataract removal.
66986	Exchange of intraocular lens.

*Although the CPT code 66820 falls in BETOS category P4E (Eye procedure - other), it was included in the analysis.

Table B.2 BETOS P8D: Endoscopy—colonoscopy

CPT Code	CPT Description
44388	Colonoscopy through stoma; diagnostic, with or without collection of specimen(s) by brushing or washing (separate procedure).
44389	Colonoscopy through stoma; with biopsy, single or multiple.
44390	Colonoscopy for foreign body
44391	Colonoscopy through stoma; with control of bleeding, any method.
44392	Colonoscopy through stoma; with removal of tumor(s), polyp(s), or other lesion(s) by hot biopsy forceps or bipolar cautery.
44393	Colonoscopy through stoma; with ablation of tumor(s), polyp(s), or other lesion(s) not amenable to removal by hot biopsy forceps, bipolar cautery or snare technique.
44394	Colonoscopy through stoma; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique.
44397	Colonoscopy w/stent
45355	Surgical colonoscopy
45378	Colonoscopy, flexible, proximal to splenic flexure; diagnostic, with or without collection of specimen(s) by brushing or washing, with or without colon decompression (separate procedure).
45379	Colonoscopy, flexible, proximal to splenic flexure; with removal of foreign body.
45380	Colonoscopy, flexible, proximal to splenic flexure; with biopsy, single or multiple.
45382	Colonoscopy, flexible, proximal to splenic flexure; with control of bleeding, any method.
45383	Colonoscopy, flexible, proximal to splenic flexure; with ablation of tumor(s), polyp(s), or other lesion(s) not amenable to removal by hot biopsy forceps, bipolar cautery or snare technique.
45384	Colonoscopy, flexible, proximal to splenic flexure; with removal of tumor(s), polyp(s), or other lesion(s) by hot biopsy forceps or bipolar cautery.
45385	Colonoscopy, flexible, proximal to splenic flexure; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique.
45387	Colonoscopy, flexible, proximal to splenic flexure; with transendoscopic stent placement (includes predilation)
G0105*	Colorectal screen; high risk individual

*Level II HCPCS code.

Table B.3 BETOS I2C: Advanced imaging—MRI: head, neck, and brain

CPT Code	CPT Description
70541	Magnetic resonance angiography, head and/or neck, with or without contrast material(s).
70542	MR (e.g., proton) imaging, orbit, face, and neck; with contrast material
70543	MR (e.g., proton) imaging, orbit, face, and neck; without contrast material, followed by contrast material(s) and further sequences.
70544	MR angiography, head; without contrast material(s)
70545	MR angiography, head; with contrast material(s)
70546	MR angiography, head; without contrast material, followed by contrast material(s) and further sequences.
70547	MR angiography, neck; without contrast material(s)
70548	MR angiography, neck; with contrast material(s)
70549	MR angiography, neck; without contrast material, followed by contrast material(s) and further sequences.
70551	Magnetic resonance (e.g., proton) imaging, brain (including brain stem); without contrast material
70552	Magnetic resonance (e.g., proton) imaging, brain (including brain stem); with contrast material(s).
70553	Magnetic resonance (e.g., proton) imaging, brain (including brain stem); without contrast material, followed by contrast material(s) and further sequences.

Appendix C. Patient Characteristics: ICD-9-CM Codes and Clinical Expert Comments for Three Procedures

Cataract Surgery Patient Characteristics

Characteristic for Cataract Surgery	ICD-9-CM Codes	Reason for increased facility cost (according to clinical expert)
Age > 85 years	---	takes longer/dense cataract
Dementia	If hcc049 = 1 or if any diagnosis code on any claim in any setting **during all 12 months of 2001** = 290.0 Senile dementia, simple type 331.0 Alzheimer's disease 331.82 Dementia with Lewy bodies (includes Dementia with Parkinsonism) 331.1 Frontotemporal dementia	spend more time to consent for Sx; more tech time to explain tests; more time to explain meds, care, f/u
Chronic obstructive pulmonary disease with hospitalization or emergency department visit within past one year	if any diagnosis code on any claim in any **inpatient or hospital outpatient** setting **during all 12 months of 2001** = 491 Chronic bronchitis 491.21 With (acute) exacerbation 492 Emphysema 416.9 Chronic pulmonary heart disease, unspecified Chronic cardiopulmonary disease, Cor pulmonale (chronic) NOS	takes longer chair time if lugging O2 canister, may take time to position on op. table
Bronchietasis with acute exacerbation	if any diagnosis code on any claim in any setting **during all 12 months of 2001** = 494.1 Bronchiectasis with acute exacerbation	takes longer chair time if lugging O2, may take time to position on op. table
Barbiturate, chlordiazepoxide, diazepam, glutethimide, meprobamate, or methaqualone dependence or Opioid type dependence	if HCC052 = 1 OR IF any diagnosis code on any claim in any setting **during all 12 months of 2001** = 304.1 Barbiturate and similarly acting sedative or hypnotic dependence 304.0 Opioid type dependence	more time and effort by anesthesiologist to sedate and for nurses and MDs to recover postoperatively

Characteristic for Cataract Surgery	**ICD-9-CM Codes**	**Reason for increased facility cost (according to clinical expert)**
Alcohol abuse	If hcc053=1 or if any diagnosis code on any claim in any setting **during all 12 months of 2001** = 305.0, 303, 303.0, 303.00, 303.01, 303.02, 303.9, 303.90, 303.91, 303.92 **305.0 Alcohol abuse** **303 Alcohol dependence syndrome** **303.0 Acute alcoholic intoxication** **303.9 Other and unspecified alcohol dependence** The following fifth-digit subclassification is for use with category 303: 0 unspecified 1 continuous 2 episodic 3 in remission (we should not include "in remission" patients)	more time and effort by anesthesiologist to sedate and for nurses and MDs to recover postoperatively
Personal history of allergy to anesthetic agent	if any diagnosis code on any claim in any setting **during all 12 months of 2001** = V14.4 Anesthetic agent	Different meds may be needed
Personal history of allergy to narcotic agent	if any diagnosis code on any claim in any setting **during all 12 months of 2001** = V14.5 Narcotic agent	Different meds may be needed
Personal history of allergy to analgesic agent	if any diagnosis code on any claim in any setting **during all 12 months of 2001** = V14.6 Analgesic agent	Different meds may be needed
History of shock due to anesthesia in which correct substance was properly administered	if any ICD-9-CM code on any claim in any setting **before the procedure date** during 2001 = 995.4 shock due to anesthesia	Different meds may be needed
Anxiety	If hcc059 = 1 or if any diagnosis code on any claim in any setting **during all 12 months of 2001** = 300.0 Anxiety states	longer time with tech, more time to explain procedure, to sedate
Schizophrenic disorder	If hcc054 = 1 or if any diagnosis code on any claim in any setting **during all 12 months of 2001** = 295 Schizophrenic disorder **V11.0 Schizophrenia**	longer time with tech, more time to explain procedure

Characteristic for Cataract Surgery	**ICD-9-CM Codes**	**Reason for increased facility cost (according to clinical expert)**
Essential, Benign, or Drug-Related Tremor/ Abnormal head movements, Fasciculations, Spasms or Tremor Not Otherwise Specified	if any diagnosis code on any claim in any setting **during all 12 months of 2001** = 781.0 or 333.1. Please check all 2001 claims, both before and after the procedure date.	takes longer to obtain measuremts of eye, may be more difficult to obtain good view thruout surgery
Subluxation of lens	if any ICD-9-CM code on any claim in any setting **before the procedure date** during 2001 = 379.32 Subluxation of lens	takes longer and longer chair time to explain risks of surgery
Recession of chamber angle	if any ICD-9-CM code on any claim in any setting **before the procedure date** during 2001 = 364.77 Recession of chamber angle	takes longer and longer chair time to explain risks of surgery
Pseudoexfoliation of lens capsule	if any ICD-9-CM code on any claim in any setting **before the procedure date** during 2001 = 366.11 Pseudoexfoliation of lens capsule	takes longer and longer chair time to explain risks of surgery
Progressive high (degenerative) myopia/malignant myopia	if any ICD-9-CM code on any claim in any setting **before the procedure date** during 2001 = 360.21 Progressive high (degenerative) myopia Malignant myopia	takes longer and may need to special order intraocular lens implant (which takes time)
Dislocation of lens	if any ICD-9-CM code on any claim in any setting **before the procedure date** during 2001 = 379.33 Anterior dislocation of lens 379.34 Posterior dislocation of lens	takes longer and longer chair time to explain risks of surgery
History of ruptured globe	No codes available	takes longer and longer chair time to explain risks of surgery

Characteristic for Cataract Surgery	**ICD-9-CM Codes**	**Reason for increased facility cost (according to clinical expert)**
History of open wound of adnexa	if any ICD-9-CM code on any claim in any setting **before the procedure date** during 2001 = 870 Open wound of ocular adnexa	takes longer (should be okay)
Endothelial corneal dystrophy, including combined corneal dsystrophy, cornea guttata, and Fuch's endothelial dystrophy	if any ICD-9-CM code on any claim in any setting **before the procedure date** during 2001 = 371.57 endothelial corneal dystrophy	takes longer need extra tests (corneal specular microscopy), longer chair time to explain risks of surgery
Posterior synechiae	if any ICD-9-CM code on any claim in any setting **before the procedure date** during 2001 = 364.71 Posterior synechiae	takes longer and longer chair time to explain risks of surgery
History of vitrectomy	if any HCPCS/CPT code on any claim in any setting **before the procedure date** during 2001 = 67005, 67036, **67108 (NOTE: code added since Phase 1),** 67010, 67040, 67038, 67039	may take longer if complications, and longer chair time to explain risks of surgery

Colonoscopy Patient Characteristics

Characteristic for Colonoscopy	ICD-9-CM Codes	Reason for increased facility cost (according to clinical expert)
Age > 70 years	---	Takes longer; colon redudancy, longer to recover from sedation, less mobile and slower in general
Age > 85 years	---	Takes longer; colon redudancy, longer to recover from sedation, less mobile and slower in general
Unstable angina in last 3 months	if any diagnosis code on any claim in any setting **during 3 months preceding procedure** = 411.1 Intermediate coronary syndrome 411.89 Other Coronary insufficiency (acute), Subendocardial ischemia	there may be increased facility costs secondary to having procedure done at bedside, or requiring anesthesia assist. For MI 0 to 30 days, colonoscopy would probably be deferred except in LGIB requiring hemostasis, for at least 30d post-MI.
MI (>30 days but fewer than 6 months)	if any diagnosis code on any claim in any setting **during 31-180 days preceding procedure** = 410 Acute myocardial infarction	there may be increased facility costs secondary to having procedure done at bedside, or requiring anesthesia assist.
Dementia	If hcc049 = 1 or if any diagnosis code on any claim in any setting **during all 12 months of 2001** = 290.0 Senile dementia, simple type 331.0 Alzheimer's disease 331.82 Dementia with Lewy bodies (includes Dementia with Parkinsonism) 331.1 Frontotemporal dementia	takes longer. Dementia itself shouldn't make procedure last longer as long as sedation works properly. If pt is uncooperative or family/caregivers are not present, this will likely increase non-MD staff time.
Chronic obstructive pulmonary disease with hospitalization or emergency department visit within past one year	if any diagnosis code on any claim in any **inpatient or hospital outpatient** setting **during all 12 months of 2001** = 491 Chronic bronchitis 491.21 With (acute) exacerbation 492 Emphysema 416.9 Chronic pulmonary heart disease, unspecified Chronic cardiopulmonary disease, Cor pulmonale (chronic) NOS	probably key issue is whether their pulm dis is well controlled at time of procedure. If pulmonary status is fragile, then anesthesia assist is good idea and risk of pulm compllications, e.g. hypoxia or hypercapnia, increases. Procedure may take longer as well.
Asthma with hospitalization or emergency department visit within past one year	if any diagnosis code on any claim in any **inpatient or hospital outpatient** setting **during all 12 months of 2001** = 493.2 Chronic obstructive asthma	probably key issue is whether their pulm dis is well controlled at time of procedure. If pulmonary status is fragile, then anesthesia assist is good idea and risk of pulm compllications, e.g. hypoxia or hypercapnia, increases. Procedure may take longer as well.
Bronchietasis with acute exacerbation	if any diagnosis code on any claim in any setting **during all 12 months of 2001** = 494.1 Bronchiectasis with acute exacerbation	probably key issue is whether their pulm dis is well controlled at time of procedure. If pulmonary status is fragile, then anesthesia assist is good idea and risk of pulm compllications, e.g. hypoxia or hypercapnia, increases. Procedure may take longer as well.

Characteristic for Colonoscopy	ICD-9-CM Codes	Reason for increased facility cost (according to clinical expert)
Cirrhosis	if hcc026 = 1 or if any ICD-9 diagnosis code on any claim in any setting **during all 12 months of** 2001 = 571 571.2 Alcoholic cirrhosis of liver 571.5 Cirrhosis of liver without mention of alcohol 571.6 Biliary cirrhosis	hemorrhage. This depends on pt's Child-Pugh score. Mild category A probably minimal to no increase risk. B and C likely some increase risk, including hemorrhage risk if coags off. Also, cirrhosis can affect sedation clearance and will increase procedure time and costs due to slower, more careful sedation titration and possibly longer recover with increased risk of AMS in pts with encephalopathy.
Cardiomyopathy/heart failure/pulmonary edema with hospitalization or emergency department visit within past one year	If hcc080 = 1 or if any diagnosis code on any claim in any **inpatient or hospital outpatient** setting **during all 12 months of 2001** = 428 Heart failure 398.91 Rheumatic heart failure (congestive) Rheumatic left ventricular failure 402 Hypertensive heart disease 402.01 (Malignant) With heart failure 402.11 (Benign) With heart failure 402.91 (Unspecified) With heart failure	Again, depends on how stable pt is at time of procedure. If stable enough to have outpt procedure, then agree that minimal to no incr risk. May require more careful monitoring--slows procedure and increased staff time
Malignant hypertension	if any diagnosis code on any claim in any setting **during all 12 months of 2001** = 401.0 Malignant hypertension	If BP not well controlled, may slow or stop procedure
Barbiturate, chlordiazepoxide, diazepam, glutethimide, meprobamate, or methaqualone dependence or opioid type dependence	If hcc052= 1 or if any diagnosis code on any claim in any setting **during all 12 months of 2001** = 304.1 Barbiturate and similarly acting sedative or hypnotic dependence 304.0 Opioid type dependence	May take longer because difficult to sedate
Personal history of allergy to anesthetic agent	if any diagnosis code on any claim in any setting **during all 12 months of 2001** = V14.4 Anesthetic agent	Procedure may take longer. More meds or different meds, e.g. propofol, used. Potential complications. May need anesthesia assist
Personal history of allergy to analgesic agent	if any diagnosis code on any claim in any setting **during all 12 months of 2001** = V14.6 Analgesic agent	Procedure may take longer. More meds or different meds, e.g. propofol, used. Potential complications. May need anesthesia assist
Mechanical heart valve	Note from Phase 1: ? Don't think can separate mechanical from bioprosthetic	Antibiotics. May take longer.
History of partial/complete bowel obstruction	if hcc031 = 1 or if any ICD-9 diagnosis code on any claim in any setting **before the procedure date** during 2001 = 560, 560.0, 560.1, 560.2, 560.3, 560.8, or 560.9	takes longer

Characteristic for Colonoscopy	ICD-9-CM Codes	Reason for increased facility cost (according to clinical expert)
History of colorectal cancer	if any ICD-9 diagnosis code on any claim in any setting **before the procedure date** during 2001 = 153, 153.0 – 153.9, 154, or 154.0 – 154.8	takes longer. Possibly b/c more careful surveillance needed, esp for pts with genetic predispositins or syndromes, or simply more polyps to remove.
Inflammatory bowel disease	if hcc033 = 1 or if any diagnosis code on any 2001 claim in any setting **before the procedure date** = 555, 555.0-555.9, 556, or 556.0-556.9	May take longer due to extensive bx. May need extra nursing help if biopsy run being done.
Melena	if any diagnosis code on any 2001 claim in any setting **before the procedure date** = 578.1	May take longer if subtle bleeding source is sought (as opposed to simply looking for polyps).

MRI (Brain) Patient Characteristics

Characteristic for MRI (Brain)	ICD-9-CM Codes	Reason for increased facility cost (according to clinical expert)
Age > 70 years	---	in general, elderly patients more likley to take more time, but how can one specifiy an age for this?
Age > 85 years	---	yes takes longer; if infiltrate, need to draw up more gadiolinium
Unstable angina in last 3 months	if any diagnosis code on any claim in any setting **during the 3 months preceding the procedure** = 411.1 Intermediate coronary syndrome 411.89 Other Coronary insufficiency (acute), Subendocardial ischemia	(yes if complication) take time to deal with it, disrupt smooth functioning
Myocardial infarction within past 7 days	if any diagnosis code on any claim in any setting **during the 7 days preceding the procedure** = 410 Acute myocardial infarction	(yes if complication) take time to deal with it, disrupt smooth functioning
Recent myocardial infarction (> 7 days but fewer than 30 days)	if any diagnosis code on any claim in any setting **during 8-30 days preceding the procedure** = 410 Acute myocardial infarction	(yes if complication) take time to deal with it, disrupt smooth functioning
Orthopnea	if any diagnosis code on any claim in any setting **during all 12 months of 2001** = 786.02 Orthopnea	Yes take more time
Dementia	If hcc049 = 1 or if any diagnosis code on any claim in any setting during all 12 months of 2001 = 290.0 Senile dementia, simple type 331.0 Alzheimer's disease 331.82 Dementia with Lewy bodies (includes Dementia with Parkinsonism) 331.1 Frontotemporal dementia	Yes takes longer
Anxiety	If hcc059 = 1 or if any diagnosis code on any claim in any setting during all 12 months of 2001 = 300.0 Anxiety states	Yes may take longer
History of Claustrophob ia	if any diagnosis code on any claim in any setting during all 12 months of 2001 = 300.29 Other isolated or simple phobias—acrophobia, animal phobia, claustrophobia, fear of crowds	Yes takes longer
Essential, Benign, or Drug-Related Tremor/ Abnormal head movements, Fasciculations, Spasms, or Tremor Not Otherwise Specified	if any diagnosis code on any claim in any setting during all 12 months of 2001 = 781.0 or 333.1. Please check all 2001 claims, both before and after the procedure date.	Yes if head tremor, then more difficult exam and thus, takes longer
Cerebral edema	if any diagnosis code on any claim in any setting during all 12 months of 2001 = 348.5 Cerebral edema	Yes likely to be altered mental status and would take longer

Appendix D. Patient Characteristic Results for RBC and Non-RBC Colonoscopy

Table D.1 Characteristics of RBC Colonoscopy Patients By Setting, Medicare Fee-for-Service, 2001

	OPD		ASC		Office		Fisher's exact p-value		
	Number	Rate*	Number	Rate*	Number	Rate*	OPD vs. ASC	OPD vs. Off	ASC vs. Off
All RBC colonoscopies	34337	--	12983	--	1882	--	--	--	--
Age > 70 years	23152	674.3	8753	674.2	1231	654.1	0.991	0.069	0.083
Age > 85 years	1891	55.1	602	46.4	80	42.5	**0.000**§	**0.019**§	0.480
Unstable angina in last 3 months	196	5.7	47	3.6	24	12.8	**0.004**§	**0.001**§	**0.000**§
MI (>30 days but < 6 months)	1	0.0	0	0.0	0	0.0	1.000	1.000	1.000
Dementia	1166	34.0	347	26.7	51	27.1	**0.000**§	0.115	0.939
Chronic obstructive pulmonary disease (COPD) with hospitalization or emergency department visit in past year	615	17.9	158	12.2	16	8.5	**0.000**§	**0.001**§	0.206
Asthma with hospitalization or emergency department visit in past year	0	0.0	0	0.0	0	0.0	--	--	--
Bronchietasis with acute exacerbation	8	0.2	3	0.2	0	0.0	1.000	1.000	1.000
Cirrhosis	304	8.9	102	7.9	12	6.4	0.315	0.308	0.573
Cardiomyopathy/heart failure/pulmonary edema with hospitalization or emergency department visit in past year	3952	115.1	1291	99.4	221	117.4	**0.000**§	0.767	**0.018**§
Malignant hypertension	266	7.7	65	5.0	82	43.6	**0.001**§	**0.000**§	**0.000**§
Barbiturate, chlordiazepoxide, diazepam, glutethimide, meprobamate, or methaqualone dependence or opioid type dependence	194	5.6	49	3.8	7	3.7	**0.011**§	0.339	1.000
Personal history of allergy to anesthetic agent	3	0.1	1	0.1	0	0.0	1.000	1.000	1.000
Personal history of allergy to analgesic agent	50	1.5	26	2.0	0	0.0	0.198	0.113	0.068
History of partial/complete bowel obstruction	1165	33.9	363	28.0	53	28.2	**0.001**§	0.189	0.940
History of colorectal cancer	823	24.0	178	13.7	76	40.4	**0.000**§	**0.000**§	**0.000**§
Inflammatory bowel disease	848	24.7	298	23.0	68	36.1	0.284	**0.003**§	**0.001**§
Melena	822	23.9	145	11.2	116	61.6	**0.000**§	**0.000**§	**0.000**§

§Comparisons in bold are significant at p<0.05.

*Per 1,000 procedures.

Source: RAND analysis of the 5 percent Standard Analytical Files of Medicare claims, 2001.

Table D.2 Characteristics of Non-RBC Colonoscopy Patients By Setting, Medicare Fee-for-Service, 2001

	OPD		ASC		Office		Fisher's exact p-value		
	Number	Rate*	Number	Rate*	Number	Rate*	OPD vs. ASC	OPD vs. Off	ASC vs. Off
All non-RBC colonoscopies	29035	--	10520	--	2133	--	--	--	--
Age > 70 years	19604	675.2	7091	674.0	1439	674.6	0.817	0.943	0.980
Age > 85 years	1677	57.8	529	50.3	101	47.4	**0.004**§	**0.047**§	0.623
Unstable angina in last 3 months	159	5.5	35	3.3	15	7.0	**0.007**§	0.364	**0.021**§
MI (>30 days but < 6 months)	0	0.0	0	0.0	0	0.0	1.000	1.000	1.000
Dementia	1035	35.6	311	29.6	80	37.5	**0.003**§	0.629	0.055
Chronic obstructive pulmonary disease (COPD) with hospitalization or emergency department visit in past year	407	14.0	97	9.2	17	8.0	**0.000**§	**0.020**§	0.706
Asthma with hospitalization or emergency department visit within past one year	0	0.0	0	0.0	0	0.0	--	--	--
Bronchietasis with acute exacerbation	7	0.2	2	0.2	3	1.4	1.000	**0.027**§	**0.037**§
Cirrhosis	196	6.8	55	5.2	21	9.8	0.099	0.104	**0.020**§
Cardiomyopathy/heart failure/pulmonary edema with hospitalization or emergency department visit in past year	3339	115.0	918	87.3	219	102.7	**0.000**§	0.090	**0.025**§
Malignant hypertension	216	7.4	41	3.9	102	47.8	**0.000**§	**0.000**§	**0.000**§
Barbiturate, chlordiazepoxide, diazepam, glutethimide, meprobamate, or methaqualone dependence or opioid type dependence	137	4.7	29	2.8	4	1.9	**0.008**§	0.064	0.642
Personal history of allergy to anesthetic agent	1	0.0	1	0.1	0	0.0	0.461	1.000	1.000
Personal history of allergy to analgesic agent	52	1.8	11	1.0	1	0.5	0.116	0.267	0.704
History of partial/complete bowel obstruction	1081	37.2	306	29.1	71	33.3	**0.000**§	0.373	0.295
History of colorectal cancer	764	26.3	138	13.1	78	36.6	**0.000**§	**0.007**§	**0.000**§
Inflammatory bowel disease	280	9.6	81	7.7	35	16.4	0.073	**0.005**§	**0.000**§
Melena	731	25.2	130	12.4	113	53.0	**0.000**§	**0.000**§	**0.000**§

§Comparisons in bold are significant at p<0.05.

*Per 1,000 procedures.

Source: RAND analysis of the 5 percent Standard Analytical Files of Medicare claims, 2001.

Appendix E. Patient Characteristic Results for MRI (Brain) With and Without Contrast

Table E.1 Characteristics of Patients with MRI (Brain) With Contrast By Setting, Medicare Fee-for-Service, 2001

	OPD		Office		IDTF		Fisher's exact p-value		
	Number	Rate*	Number	Rate*	Number	Rate*	OPD vs. Office	OPD vs. IDTF	Office vs. IDTF
All MRI (brain) with contrast	13199	--	7742	--	2410	--			
Age > 70 years	8587	650.6	5314	686.4	1606	666.4	**0.000**§	0.136	0.068
Age > 85 years	986	74.7	532	68.7	160	66.4	0.109	0.161	0.711
Unstable angina in last 3 months	88	6.7	62	8.0	8	3.3	0.271	0.064	**0.016**§
Myocardial infarction within past 7 days	0	0.0	1	0.1	0	0.0	0.370	0.370	1.000
Recent myocardial infarction (> 7 days but fewer than 30 days)	0	0.0	0	0.0	0	0.0	1.000	1.000	1.000
Orthopnea	20	1.5	19	2.5	1	0.4	0.137	0.235	0.062
Dementia	1080	81.8	776	100.2	162	67.2	**0.000**§	**0.014**§	**0.000**§
Anxiety	127	9.6	85	11.0	21	8.7	0.353	0.733	0.421
History of claustrophob ia	6	0.5	3	0.4	1	0.4	1.000	1.000	1.000
Essential, benign, or drug-related tremor/abnormal head movements, fasciculations, spasms, or tremor not otherwise specified	276	20.9	364	47.0	37	15.4	**0.000**§	0.082	**0.000**§
Cerebral edema	60	4.5	15	1.9	5	2.1	**0.002**§	0.087	0.798

§ Comparisons in bold are significant at $p<0.05$.

*Per 1,000 procedures.

Source: RAND analysis of the 5 percent Standard Analytical Files of Medicare claims, 2001.

Table E.2 Characteristics of MRI (Brain) Without Contrast Patients By Setting, Medicare Fee-for-Service, 2001

	OPD		Office		IDTF		Fisher's exact p-value		
	Number	Rate*	Number	Rate*	Number	Rate*	OPD vs. Office	OPD vs. IDTF	Office vs. IDTF
All MRI (brain) without contrast	8034	--	6970	--	2142	--			
Age > 70 years	5692	708.5	5079	728.7	1475	688.6	**0.006**[§]	0.074	**0.000**[§]
Age > 85 years	759	94.5	635	91.1	199	92.9	0.481	0.868	0.797
Unstable angina in last 3 months	54	6.7	68	9.8	11	5.1	**0.045**[§]	0.541	**0.045**[§]
Myocardial infarction within past 7 days	0	0.0	1	0.1	0	0.0	0.465	0.465	1.000
Recent myocardial infarction (> 7 days but fewer than 30 days)	0	0.0	1	0.1	0	0.0	0.465	0.465	1.000
Orthopnea	7	0.9	17	2.4	1	0.5	**0.023**[§]	1.000	0.093
Dementia	837	104.2	923	132.4	203	94.8	**0.000**[§]	0.213	**0.000**[§]
Anxiety	74	9.2	87	12.5	21	9.8	0.057	0.800	0.362
History of claustrophob ia	3	0.4	4	0.6	3	1.4	0.712	0.112	0.366
Essential, benign, or drug-related tremor/abnormal head movements, fasciculations, spasms, or tremor not otherwise specified	173	21.5	364	52.2	42	19.6	**0.000**[§]	0.613	**0.000**[§]
Cerebral edema	9	1.1	0	0.0	1	0.5	**0.005**[§]	0.699	0.235

[§] Comparisons in bold are significant at $p<0.05$.

*Per 1,000 procedures.

Source: RAND analysis of the 5 percent Standard Analytical Files of Medicare claims, 2001.

Table E.3 Characteristics of MRI (Brain) With Contrast Patients By OPD and IDTF/Office Combined, Medicare Fee-for-Service, 2001

	OPD		IDTF/Office		Fisher's exact
	Number	Rate*	Number	Rate*	p-value
All MRI (brain) with contrast	13199	--	10152	--	
Age > 70 years	8587	650.6	6920	681.6	**0.000**[§]
Age > 85 years	986	74.7	692	68.2	0.055
Unstable angina in last 3 months	88	6.7	70	6.9	0.872
Myocardial infarction within past 7 days	0	0.0	1	0.1	0.435
Recent myocardial infarction (> 7 days but fewer than 30 days)	0	0.0	0	0.0	0.476
Orthopnea	20	1.5	20	2.0	0.428
Dementia	1080	81.8	938	92.4	**0.004**[§]
Anxiety	127	9.6	106	10.4	0.550
History of claustrophob ia	6	0.5	4	0.4	1.000
Essential, benign, or drug-related tremor/abnormal head movements, fasciculations, spasms, or tremor not otherwise specified	276	20.9	401	39.5	**0.000**[§]
Cerebral edema	60	4.5	20	2.0	**0.001**[§]

[§] Comparisons in bold are significant at p<0.05.

*Per 1,000 procedures.

Source: RAND analysis of the 5 percent Standard Analytical Files of Medicare claims, 2001.

Table E.4 Characteristics of MRI (Brain) Without Contrast Patients By OPD and IDTF/Office Combined, Medicare Fee-for-Service, 2001

	OPD		IDTF/Office		Fisher's exact
	Number	Rate*	Number	Rate*	p-value
All MRI (brain) without contrast	8034	--	9112	--	
Age > 70 years	5692	708.5	6554	719.3	0.123
Age > 85 years	759	94.5	834	91.5	0.510
Unstable angina in last 3 months	54	6.7	79	8.7	0.163
Myocardial infarction within past 7 days	0	0.0	1	0.1	1.000
Recent myocardial infarction (> 7 days but fewer than 30 days)	0	0.0	1	0.1	1.000
Orthopnea	7	0.9	18	2.0	0.071
Dementia	837	104.2	1126	123.6	**0.000**[§]
Anxiety	74	9.2	108	11.9	0.100
History of claustrophob ia	3	0.4	7	0.8	0.353
Essential, benign, or drug-related tremor/abnormal head movements, fasciculations, spasms, or tremor not otherwise specified	173	21.5	406	44.6	**0.000**[§]
Cerebral edema	9	1.1	1	0.1	**0.008**[§]

[§] Comparisons in bold are significant at p<0.05.

*Per 1,000 procedures.

Source: RAND analysis of the 5 percent Standard Analytical Files of Medicare claims, 2001.

Appendix F. Contract Deliverable: Proposed Outcome Measures for Risk Adjustment

Introduction

In the Phase 1 study, we identified a set of outcome measures for each of three procedures that are performed in multiple ambulatory settings (cataract surgery, colonoscopy, and MRI (brain)). Each outcome measure represents an adverse event that might occur as a result of a patient having the procedure. Three expert panels, one for each procedure, were set up in the Phase 1 study to discuss and rate the outcome measures. The panels rated 27 outcome measures for cataract surgery, 20 outcome measures for colonoscopy, and 18 outcome measures for MRI (brain) on preventability and severity (Table 1).

The objective of the Phase 2 study is to determine whether variation across ambulatory settings in the rate of adverse outcomes following the three procedures is related to differences in the characteristics of the Medicare beneficiaries receiving care in the different settings. In this document, we provide the results of Task 3 of the Phase 2 study which consists of compiling a list of outcome measures for each of the three procedures to be recommended for further analysis using risk adjustment. We first describe the methods used to select the outcomes, followed by the recommendations regarding outcomes for cataract surgery, colonoscopy, and MRI (brain).

Methods

For each of the three procedures, we selected outcome measures recommended for further analysis on the basis of several factors. We first determined whether the outcome might also be an indication for (i.e., reason for having) the procedure based on input from the project physician and the three clinical consultants. Outcomes that are also indications for the procedure were eliminated from consideration. We also considered the severity and preventability ratings of the Phase 1 expert panels, and the frequency of the outcome. We attempted to identify outcomes that are severe, preventable, and frequent. We created a table for each procedure containing rows representing the outcome measures and columns representing:

- the preventability scores (Table 2)
- the severity scores (Table 2)
- the incidence of the outcome (per 1000 procedures)
- whether the outcome could be an indication for the procedure.

These data were derived from the rating sheets completed by the Phase 1 panels and the tables based on the Phase 1 claims analysis in the Phase 1 report (Wynn et al., 2004) as well as input from the Phase 2 clinical consultants. We used the information in these tables as the basis for recommending outcome measures for further analysis.

We also determined the most appropriate time frame for measuring each outcome based on information from the Phase 1 panel discussions and input from the three Phase 2 clinical consultants regarding the likelihood of the outcome being the result of the procedure within a certain time period. For the possible covariates, we included patient characteristics that might influence the outcomes of the procedure, including input from the project physician and the three Phase 2 clinical consultants regarding what patient characteristics would affect which outcomes. The suggested covariates include demographic characteristics (e.g., age, gender, race), Medicaid eligibility, and disability status as well as comorbidities (e.g., diabetes) that might affect

Table F.1 Adverse Outcomes Listed in Phase 1 Ratings Sheets for Three Procedures

Cataract Surgery		Colonoscopy		MRI (Brain)	
A	Arrhythmia	A	Abdominal pain	A	Altered mental status
B	Capsule rupture or posterior capsule tear	B	Altered mental status	B	Anaphylaxis/anaphylactoid reaction
C	New or worsening congestive heart failure	C	Arrhythmia	C	Bradycardia
D	Persistent cystoid macular edema (Diabetic vs. non-diabetic)	D	Chest pain	D	Chest pain
E	Death	E	Death	E	Death
F	Endophthalmitis	F	Dyspnea	F	Dizziness
G	Hypertension	G	Hemorrhage	G	Dyspnea
H	Hypotension	H	Hypertension	H	Headache
I	Iris prolapse	I	Hypotension	I	Hypertension
J	Myocardial infarction	J	Hypoxia	J	Hypotension
K	Retained nuclear fragment (posterior chamber vs. anterior chamber)	K	Perforation	K	Ocular injury
L	Ocular hypertension	L	Post-polypectomy syndrome	L	Paresthesia
M	Persistent iridocyclitis			M	Rash
N	Poor ocular motility, excluding cranial VII palsy	A	Abdominal distension	N	Seizure
O	Retinal break	B	Endocarditis	O	Syncope
P	Retinal detachment (complicated versus uncomplicated surgery)	C	Sepsis and other infections	P	Tachycardia
Q	Stroke	D	Small bowel obstruction	Q	Vasodilatation
R	Wound dehiscence	E	Splenic rupture	R	Vasospasm
S	Wound leak	F	Splenic trauma		
T	Aspiration pneumonia	G	Vasovagal reactions		
U	Respiratory failure from surgery				
V	Hyphema				
W	Persistent corneal edema				
X	Vitreous loss				
Y	Secondary glaucoma				
Z	Dislocated ocular lenses				
AA	Iris/pupil deformation				

Table F.2 Definition of Scale Used by Phase 1 Panels to Rate Preventability and Severity

Dimension	Definition	Scale
Preventability	Likelihood that an outcome can be avoided if the individuals or system involved in delivering care follow standard practices. (Adapted from Hofer and Haywood, 2002).	1 = Not preventable 5 = Somewhat preventable 9 = Definitely preventable
Severity	The potential effect of the outcome of the procedure on the patient's life expectancy and quality of life.	1 = Not severe 5 = Somewhat severe 9 = Very severe

the occurrence of a particular adverse outcome. The variables representing comorbidities will be derived from DxCG subscores representing specific conditions. The covariates listed on the following pages are preliminary and will be modified as necessary before and during the analysis.

Results

We attempted to identify 4 – 7 measures for each procedure as specified in the project scope of work. However, given that these are relatively safe procedures with a low rate of complications, identifying this number of meaningful outcome measures was challenging. Many of the potential outcomes were eliminated on the basis of being an indication for having the procedure performed, especially those for colonoscopy (e.g., abdominal pain) and MRI (brain) (e.g., dizziness). Of those remaining, we tried to identify outcomes that are severe, preventable, and frequent, and can reasonably be assumed to have occurred as a result of the procedure. We focused primarily on outcomes related to the organ affected by the procedure, because it is more difficult to establish that the general medical outcomes occur as a result of the procedures, especially using claims data as supporting evidence.

On the following pages and in Tables 3 through 5 (in the attached Excel file), we provide the evidence used as the basis for recommending the subset of outcomes for further analysis. We recommend analyzing four outcomes for cataract surgery outcomes, two outcomes for colonoscopy, and one outcome for MRI (brain). Given the limited selection, we have also included some measures that do not meet all the criteria used in the selection process, for purposes of discussion. In this category, we considered, but are not recommending, four measures for cataract surgery, seven measures for colonoscopy, and two measures for MRI (brain). On the following pages, we have labeled each measure we considered either as "recommended for further analysis" or "considered but not recommended for further analysis."

For each outcome, we present the reason it was selected or not selected, the severity and preventability ratings by the Phase 1 panels, and the rate of occurrence within 30 days of the procedure. Note that higher panel ratings on the severity and preventability scales indicate more severe and more preventable, respectively (Table 2). We also present the most appropriate time frame for measuring each outcome, and a set of patient characteristics for use as covariates in the risk adjustment.

Proposed Outcome Measures for Cataract Surgery

Cataract removal surgeries are among the most common surgeries performed in the United States (National Eye Institute, 2003). Most cataract removal surgeries are uncomplicated and lead to improved visual acuity and patient satisfaction. In some cases, however, postoperative complications related to the eye arise. In other cases, complications occur from the sedation or anesthesia used during the procedure, as well as from the local (injected) anesthesia (Shugarman et al., 2004).

In selecting the recommended outcome measures, we considered a list of 30 outcome measures for cataract surgery, including the initial set of 27 that were rated and discussed as part of the Phase 1 panel process, plus three outcomes that were added during or after the Phase 1 panel meeting. We recommend that four of these measures be analyzed further using risk adjustment. They are:

- Endophthalmitis (F)
- Cataract fragments in eye (CC)
- Persistent corneal edema (W)
- Iris prolapse (I)

We considered but are not recommending another four measures:

- Retained nuclear fragment (K)
- Secondary glaucoma (Y)
- Aspiration pneumonia (T)
- Respiratory failure from surgery (U)

For each of these measures, we list the reasons for recommending or not recommending it, the time frame for analysis, and factors to be used in risk adjustment in the table below. The supporting evidence for the entire set of cataract surgery outcomes is provided in Table 3 (in the attached Excel file).

Of those outcomes not considered for further analysis, three were dropped because they are indications for having cataract surgery; these are persistent cystoid macular edema, retinal break, and retinal detachment. Four additional outcome measures (capsule rupture or posterior capsule tear, new or worsening congestive failure, wound dehiscence, and wound leak) were eliminated because there are no ICD-9 codes that can be used to identify the conditions in claims data. The remaining 15 outcomes were not considered to be suitable outcomes for cataract surgery (arrhythmia, death, hypertension, hypotension, myocardial infarction, ocular hypertension, persistent iridocyclitis, poor ocular motility, stroke, hyphema, vitreous loss, dislocated ocular lenses, iris-pupil deformation, nausea and vomiting, and other complications).

Recommended for further analysis
Measure: Endophthalmitis (F)
Reason for status: Endophthalmitis is an infection of the vitreous or aqueous humor of the eye that might occur following cataract surgery. It is recommended for further analysis because it is a severe condition that can be prevented. However, it occurs infrequently, so the results would have to be interpreted with caution. It occurred within 30 days in 113 of 77,572 patients (1.5 per 1000) with cataract surgeries performed in the three sites combined (HOPD, ASC, and office). Endophthalmitis was considered to be severe (all 6 panelists rating it 8 or 9) and preventable (all 5 panelists rating it 5 or 7).
Time frame for analysis: Within 30 days

Patient characteristics for risk adjustment model:

- Age
- Gender
- Race/ethnicity
- Medicaid eligible
- Disability status
- Diabetes
- Rheumatoid arthritis
- Systemic lupus erythematosus
- AIDS
- Leukemia
- Lymphoma
- Essential, benign, or drug-related tremor
- Abnormal head movements, fasciculations, spasms or tremor not otherwise specified

Recommended for further analysis

Measure: Cataract fragments in eye (CC)

Reason for status: Cataract fragments in eye describes a medical condition in which a part of the cataract falls into the eye. It is recommended for further analysis because the Phase 1 panel thought it was important enough to add it to the list of outcomes. However, it occurs infrequently, so the results would have to be interpreted with caution. Although the Phase 1 panel did not rate this outcome, the Phase 2 clinical consultant for cataract surgery rated it a 4 on the severity scale and a 7 on the preventability scale. It occurred within 30 days in 92 of 77,572 patients (1.2 per 1000) with cataract surgeries performed in the three sites combined (HOPD, ASC, and office).

Time frame for analysis: Within 30 days

Patient characteristics for risk adjustment model:

- Age
- Gender
- Race/ethnicity
- Medicaid eligible
- Disability status
- Pseudoexfoliation of lens capsule
- History of ruptured globe
- History of vitrectomy
- Pupillary abnormalities (364.75)
- Essential, benign, or drug-related tremor
- Abnormal head movements, fasciculations, spasms or tremor not otherwise specified

Recommended for further analysis

Measure: Persistent corneal edema (W)

Reason for status: Persistent corneal edema is the prolonged swelling of the corneal tissues beyond the normal healing period for cataract surgery. It is recommended for further analysis because it is a severe condition that can be prevented. However, it occurs infrequently, so the results would have to be interpreted with caution. It occurred within 30 days in 54 of 77,572

patients (0.7 per 1000) with cataract surgeries performed in the three sites combined (HOPD, ASC, and office). Persistent corneal edema was considered to be moderately severe (all 6 panelists rating it 5 or 7) and preventable (5 of 6 panelists rating it 7 or 8).

Time frame for analysis: Within 30 days

Patient characteristics for risk adjustment model:

- Age
- Gender
- Race/ethnicity
- Medicaid eligible
- Disability status
- Diabetes
- Essential, benign, or drug-related tremor
- Abnormal head movements, fasciculations, spasms or tremor not otherwise specified

Recommended for further analysis

Measure: Iris prolapse (I)

Reason for status: Iris prolapse is a condition in which a portion of the pigmented part of the iris sags into the eye. It is considered to be a complication of cataract surgery. It is recommended for further analysis because it is a somewhat severe condition that can be prevented. However, it occurs infrequently, so the results would have to be interpreted with caution. It occurred within 30 days in 62 of 77,572 patients (0.8 per 1000) with cataract surgeries performed in the three sites combined (HOPD, ASC, and office). Iris prolapse was considered to be somewhat severe (4 of 6 panelists rating it 5 or 7) and preventable (5 of 6 panelists rating it 8).

Time frame for analysis: Within 30 days

Patient characteristics for risk adjustment model:

- Age
- Gender
- Race/ethnicity
- Medicaid eligible
- Disability status
- Pseudoexfoliation of lens capsule
- History of ruptured globe
- History of vitrectomy
- Pupillary abnormalities (364.75)
- Essential, benign, or drug-related tremor
- Abnormal head movements, fasciculations, spasms or tremor not otherwise specified

Considered but not recommended for further analysis

Measure: Retained nuclear fragment (K)

Reason for status: Although it might be a good outcome measure, retained nuclear fragment is not recommended because it is a subset of the category listed above, "cataract fragments in eye." In addition, there are no ICD-9 codes to identify retained nuclear fragment directly; it has to be identified indirectly using the procedure code for vitrectomy. It is a moderately severe condition that can be prevented. It occurred within 30 days in 473 of 77,572 patients (6.1 per 1000) with

cataract surgeries performed in the three sites combined (HOPD, ASC, and office). Retained nuclear fragment was considered to be somewhat severe (all 6 panelists rating it 5 or 6) and preventable (5 of 6 panelists rating it 6 or 8).

Time frame for analysis: Within 30 days

Patient characteristics for risk adjustment model:

- Age
- Gender
- Race/ethnicity
- Medicaid eligible
- Disability status
- Pseudoexfoliation of lens capsule
- History of ruptured globe
- History of vitrectomy
- Essential, benign, or drug-related tremor
- Abnormal head movements, fasciculations, spasms or tremor not otherwise specified

Considered but not recommended for further analysis

Measure: Secondary glaucoma (Y)

Reason for status: Secondary glaucoma is not recommended because it would be difficult to distinguish between primary and secondary glaucoma using claims data because there is not a separate ICD-9 code for secondary glaucoma. Therefore, it would be difficult to establish that the occurrence of glaucoma was a result of the procedure. It is a moderately severe condition that can be prevented. It occurred within 30 days in 154 of 77,572 patients (2.0 per 1000) with cataract surgeries performed in the three sites combined (HOPD, ASC, and office). Secondary glaucoma was considered to be somewhat severe (all 5 panelists rating it 5 or 6) and moderately preventable (all 6 panelists rating it 5, 6, or 7).

Time frame for analysis: Within 30 days

Patient characteristics for risk adjustment model:

- Age
- Gender
- Race/ethnicity
- Medicaid eligible
- Disability status
- Subluxation of lens
- Recession of chamber angle
- Pseudoexfoliation of lens capsule
- Dislocation of lens
- History of ruptured globe
- History of vitrectomy
- Diabetes
- Myopia
- Hypothyroidism
- Hypertension
- Hyperlipidemia
- Chronic renal failure

- Peripheral vascular disease
- Essential, benign, or drug-related tremor
- Abnormal head movements, fasciculations, spasms or tremor not otherwise specified

Considered but not recommended for further analysis

Measure: Aspiration pneumonia (T)

Reason for status: Aspiration pneumonia was considered because it is a severe condition that can be prevented. It is not recommended, however, because it occurs very infrequently. Aspiration pneumonia was considered to be severe (all 6 panelists rating it 7 or 8) and somewhat preventable (3 of 5 panelists rating it 7 or 8). It occurred within 30 days in 16 of 77,572 patients (0.2 per 1000) with cataract surgeries performed in the three sites combined (HOPD, ASC, and office).

Time frame for analysis: Within 7 days

Patient characteristics for risk adjustment model:

- Age
- Gender
- Race/ethnicity
- Medicaid eligible
- Disability status
- Dementia
- Stroke
- COPD (include ICD 9 codes 490 thru 496)
- Dysphagia (438.82, 787.2)
- Parkinson's disease
- Myasthenia gravis (358.0)
- Pseudobulbar palsy (335.23)
- Tracheostomy (v44.0, v55.0; 519)

Considered but not recommended for further analysis

Measure: Respiratory failure from surgery (U)

Reason for status: Respiratory failure from surgery was considered because it is a severe condition that can be prevented. It is not recommended, however, because it occurs very infrequently. Respiratory failure from surgery was considered to be severe (all 6 panelists rating it 5, 7 or 8) and somewhat preventable (3 of 5 panelists rating it 5 or 8). It occurred within 30 days in 22 of 77,572 patients (0.3 per 1000) with cataract surgeries performed in the three sites combined (HOPD, ASC, and office).

Time frame for analysis: Within 7 days

Patient characteristics for risk adjustment model:

- Age
- Gender
- Race/ethnicity
- Medicaid eligible
- Disability status
- Diabetes
- Hypertension

- Hyperlipidemia
- Chronic renal failure
- Rheumatoid arthritis
- Systemic lupus erythematosus
- AIDS
- Peripheral vascular disease
- COPD (ICD 9 codes 490 thru 496)
- Leukemia
- Lymphoma

Proposed Outcome Measures for Colonoscopy

Colonoscopy is a commonly performed procedure used to screen for colorectal cancer, but it is also used to diagnose the causes of unexplained changed in bowel habits, which may be caused by cancer or some other disease/condition. Therapeutic colonoscopies can be performed to remove polyps and to treat bleeding in the colon. Generally, the procedure is performed under some level of sedation and/or with pain medication. Most colonoscopies are uncomplicated and effectively diagnose and treat various gastrointestinal conditions. However, intra-operative and post-operative complications might arise, including some conditions related to the colon and others unrelated to the colon but associated with sedation (Shugarman et al., 2004).

In selecting the recommended outcome measures, we considered a list of 20 outcome measures for colonoscopy, including the initial set of 19 that were rated and discussed as part of the Phase 1 panel process, plus one outcome that was added after the Phase 1 panel meeting. We recommend that two of these measures be analyzed further using risk adjustment. They are:

- Perforation (K)
- Splenic rupture (E)

We considered, but are not recommending, seven other measures:

- Small bowel obstruction (DD)
- Vasovagal reaction (GG)
- Dyspnea (F)
- Arrhythmia (C)
- Chest pain (D)
- Altered mental status (B)
- Death (E)

For each of these measures, we list the reasons for recommending or not recommending it, the time frame for analysis, and factors to be used in risk adjustment in the table below. The supporting evidence for the entire set of colonoscopy outcomes is provided in Table 4 (in the attached Excel file).

Of those outcomes not considered for further analysis, five were dropped because they are indications for having a colonoscopy; these are abdominal pain, hemorrhage, abdominal distension, sepsis and other infections, and hypotension. One outcome measure (post-polypectomy syndrome) was eliminated because there are no ICD-9 codes that can be used to identify the condition in claims data. The remaining five outcomes were not considered to be suitable outcomes for colonoscopy (hypertension, hypoxia, endocarditis, splenic trauma, and other complications).

Recommended for further analysis
Measure: Perforation (K)
Reason for status: Perforation is a puncture of the intestine which occurs very infrequently during colonoscopy. Once perforation has occurred, the contents of the intestine spill into the abdominal cavity. This is problematic because the intestine is full of bacteria that should not be in the abdominal cavity, and might result in a severe infection. Perforation was selected because it is a severe condition that can usually be avoided. However, it occurs infrequently, so the results would have to be interpreted with caution. Perforation was considered to be severe (all 8 panelists rating it 6, 8 or 9) and moderately preventable (6 of 9 panelists rating it 5 or 8). It

occurred within 30 days in 73 of 90,890 patients (0.8 per 1000) with colonoscopies performed in the three sites combined (HOPD, ASC, and office).

Time frame for analysis: Within 7 or 30 days

Patient characteristics for risk adjustment model:

- Age
- Gender
- Race/ethnicity
- Medicaid eligible
- Disability status
- History of partial bowel obstruction
- History of complete bowel obstruction
- History of colorectal cancer
- Inflammatory bowel disease
- Melena

Recommended for further analysis

Measure: Splenic rupture

Reason for status: Splenic rupture is a bursting of the spleen that results in red blood cells spilling from the spleen into the abdominal cavity. The patient may lose blood volume and blood pressure may drop dramatically, and the patient may experience severe abdominal pain. Splenic rupture is recommended for further analysis because it is a severe condition that was considered to be preventable by the panel. However, it occurs very infrequently, so the results would have to be interpreted with extreme caution. Splenic rupture was rated as severe (all 7 panelists rating it 8 or 9) and preventable (6 of 9 panelists rating it 5, 7, or 8). It occurred within 30 days in 35 of 90,890 patients (0.4 per 1000) with colonoscopies performed in the three sites combined (HOPD, ASC, and office).

Time frame for analysis: Within 7 or 30 days

Patient characteristics for risk adjustment model:

- Age
- Gender
- Race/ethnicity
- Medicaid eligible
- Disability status
- Splenomegaly (789.2)
- Anomalies of spleen (759.0)
- Chronic congestive splenomegaly (289.51)
- Cirrhosis
- History of partial bowel obstruction
- History of complete bowel obstruction
- History of colorectal cancer
- Inflammatory bowel disease
- Melena

Considered but not recommended for further analysis

Measure: Small bowel obstruction (D)

Reason for status: Small bowel obstruction was considered for further analysis because it is a severe condition and occurs frequently enough to test for differences among settings. However, it is not recommended because it was not considered to be preventable by the panel. Small bowel obstruction was rated as severe (all 8 panelists rating it 6, 7, 8 or 9) but not preventable (8 of 9 panelists rating it 1, 2, or 3). It occurred within 30 days in 528 of 90,890 patients (5.8 per 1000) with colonoscopies performed in the three sites combined (HOPD, ASC, and office).

Time frame for analysis: Within 7 days

Patient characteristics for risk adjustment model:

- Age
- Gender
- Race/ethnicity
- Medicaid eligible
- Disability status
- Diabetes
- Hypertension
- Dementia
- Hyperlipidemia
- Stroke
- Rheumatoid arthritis
- Systemic lupus erythematosus
- Chronic renal failure
- AIDS
- Peripheral vascular disease
- COPD
- Leukemia
- Lymphoma
- Any prior abdominal surgery
- Colorectal cancer
- Malignant neoplasm of the small intestine (152)
- Crohn's Disease
- Volvulus
- Intussusception
- Cholelithiasis (574)
- History of radiation therapy to abdomen

Considered but not recommended for further analysis

Measure: Vasovagal reactions (G)

Reason for status: Vasovagal reaction was considered because it is a moderately severe condition that occurs somewhat frequently. It is not recommended because it is probably not preventable. Vasovagal reaction was considered to be somewhat severe (5 of 8 panelists rating it 5 or higher) and somewhat preventable (4 of 9 panelists rating it 5 or 7). It occurred within 30 days in 232 of 90,890 patients (2.6 per 1000) with colonoscopies performed in the three sites combined (HOPD, ASC, and office).

Time frame for analysis: Within 7 days

Patient characteristics for risk adjustment model:

- Age
- Gender
- Race/ethnicity
- Medicaid eligible
- Disability status
- History of partial bowel obstruction
- History of complete bowel obstruction
- History of colorectal cancer
- Inflammatory bowel disease
- Melena
- Diabetes
- Hypertension
- Dementia
- Hyperlipidemia
- Stroke
- Rheumatoid arthritis
- Systemic lupus erythematosus
- Chronic renal failure
- AIDS
- Peripheral vascular disease
- COPD
- Leukemia
- Lymphoma

Considered but not recommended for further analysis

Measure: Dyspnea (F)

Reason for status: Dyspnea was considered because it is somewhat severe and might be moderately preventable and occurs frequently. It is not recommended because it might be related to underlying comorbidity that would be difficult to control for adequately. Dyspnea was considered to be somewhat severe (6 of 8 panelists rating it 4, 5, or 7), and moderately preventable (6 of 9 panelists rating it 6, 7, or 9). It occurred within 30 days in 916 of 90,890 patients (10.1 per 1000) with colonoscopies performed in the three sites combined (HOPD, ASC, and office).

Time frame for analysis: Within 7 days

Patient characteristics for risk adjustment model:

- Age
- Gender
- Race/ethnicity
- Medicaid eligible
- Disability status
- Personal history of allergy to anesthetic agent
- Personal history of allergy to narcotic agent
- Personal history of allergy to analgesic agent
- History of shock due to anesthesia in which correct substance was properly

administered

- Diabetes
- Hypertension
- Dementia
- Hyperlipidemia
- Stroke
- Rheumatoid arthritis
- Systemic lupus erythematosus
- Chronic renal failure
- AIDS
- Peripheral vascular disease
- COPD (490 through 496)
- Obstructive sleep apnea (327.23)
- Leukemia
- Lymphoma

Considered but not recommended for further analysis

Measure: Arrhythmia (C)

Reason for status: Arrhythmia was considered because it might occur as a result of a lengthy and difficult colonoscopy that induces a temporary drop in blood pressure. It was rated as somewhat severe and occurs frequently. However, it is not recommended because the panel did not consider it to be preventable and because it might be related to underlying comorbidity that would be difficult to control for adequately. Arrhythmia was considered to be somewhat severe (4 of 8 panelists rating it 4, 5, or 6), but not preventable (7 of 9 panelists rating it 1, 2, or 3) by the panel. It occurred within 30 days in 253 of 90,890 patients (2.8 per 1000) with colonoscopies performed in the three sites combined (HOPD, ASC, and office).

Time frame for analysis: Within 7 days

Patient characteristics for risk adjustment model:

- Age
- Gender
- Race/ethnicity
- Medicaid eligible
- Disability status
- Unstable angina and all other ischemic heart disease
- Heart failure/cardiomyopathy
- Myocardial infarction within 6 months
- Mobitz Type 2 atrioventricular block
- Anomalous atrioventricular excitation including accelerated, accessory ventricular pre-excitation, Wolff-Parkinson-White syndrome
- Paroxysmal Supraventricular Tachycardia
- Paroxysmal Ventricular Tachycardia
- Patient with Automatic Implanted Cardioverter Defibrillator (AICD)
- Atrial fibrillation
- Atrial flutter in past 6 months

- Persistent severe sinus bradycardia or sick sinus tachycardia-bradycardia syndrome
- Diabetes
- Hypertension
- Dementia
- Hyperlipidemia
- Stroke
- Rheumatoid arthritis
- Systemic lupus erythematosus
- Chronic renal failure
- AIDS
- Peripheral vascular disease
- COPD
- Leukemia
- Lymphoma

Considered but not recommended for further analysis

Measure: Chest pain (D)

Reason for status: Chest pain was considered for further analysis because it might occur as a result of a lengthy and difficult colonoscopy that induces a temporary drop in blood pressure. It was rated as a severe condition and occurs frequently. However, it is not recommended because the panel did not consider it to be preventable and because it might be related to underlying comorbidity that would be difficult to control for adequately. Chest pain was considered to be moderately severe (5 of 7 panelists rating it 5, 6, or 8), and somewhat preventable (5 of 9 panelists rating it 4, 5, or 6). It occurred within 30 days in 1346 of 90,890 patients (14.8 per 1000) with colonoscopies performed in the three sites combined (HOPD, ASC, and office).

Time frame for analysis: Within 7 days

Patient characteristics for risk adjustment model:

- Age
- Gender
- Race/ethnicity
- Medicaid eligible
- Disability status
- Diabetes
- Ischemic heart disease
- Heart failure/cardiomyopathy
- Stroke (433, 434, 435)
- Hypertension
- Dementia
- Hyperlipidemia
- Rheumatoid arthritis
- Fibromyalgia
- Sickle cell disease_
- Systemic lupus erythematosus
- Chronic renal failure

- AIDS
- Peripheral vascular disease
- COPD (490 through 496)
- GERD (530.81, 530.11)
- Leukemia
- Lymphoma
- Trauma to chest wall or prior chest wall pain (922, 959.11)
- Herpes zoster/postherpetic neuralgia
- Thoracic or abdominal aortic aneurysm
- Aortic stenosis
- Pericarditis
- Sarcoidosis
- Pulmonary blebs
- Pleurisy (511)
- Depression
- Anxiety

Considered but not recommended for further analysis

Measure: Altered mental status (B)

Reason for status: Altered mental status was considered because it might occur as a side effect of the sedative used during a colonoscopy. It was rated as somewhat severe and probably could be avoided. It is not recommended because it occurs infrequently and because it might be related to underlying comorbidity that would be difficult to control for adequately. Altered mental status was considered to be somewhat severe (4 of 8 panelists rating it 3, 4, or 5), and moderately preventable (7 of 9 panelists rating it 5, 6, 8, or 9). However, this outcome occurred infrequently within 30 days with only 34 cases among 90,890 patients (0.4 per 1000) with colonoscopies performed in the three sites combined (HOPD, ASC, and office).

Time frame for analysis: Within 7 days

Patient characteristics for risk adjustment model:

- Age
- Gender
- Race/ethnicity
- Medicaid eligible
- Disability status
- Cirrhosis
- Barbiturate, chlordiazepoxide, diazepam, glutethimide, meprobamate, or methaqualone dependence
- Opioid type dependence
- Diabetes
- Hypertension
- Dementia
- Hyperlipidemia
- Stroke
- Rheumatoid arthritis

- Systemic lupus erythematosus
- Chronic renal failure
- AIDS
- Peripheral vascular disease
- COPD
- Leukemia
- Lymphoma

Considered but not recommended for further analysis

Measure: Death (E)

Reason for status: Death was considered on the basis of the extreme severity of the outcome, but is not recommended because of its low frequency and an inability to control adequately for all possible comorbidities. It occurred infrequently with only 1 death within 30 days among 90,890 patients with colonoscopies performed in the three sites combined (HOPD, ASC, and office).

Time frame for analysis: Within 7 days

Patient characteristics for risk adjustment model:

- Age
- Gender
- Race/ethnicity
- Medicaid eligible
- Disability status
- Diabetes
- Hypertension
- Dementia
- Hyperlipidemia
- Stroke
- Rheumatoid arthritis
- Systemic lupus erythematosus
- Chronic renal failure
- AIDS
- Peripheral vascular disease
- COPD
- Leukemia
- Lymphoma

Proposed Outcome Measures for MRI (Brain)

Magnetic resonance imaging of the head, neck and brain (MRI (brain)) is generally considered to be a non-invasive procedure used for diagnostic purposes. Cranial and spinal MRI may be performed with or without contrast agents. Contrast agents are used to help providers to detect and characterize lesions. In general, performing MRI (brain) is associated with few adverse outcomes. Certain subgroups of patients are at higher risk of complications, including those with certain types of cardiac pacemakers, metallic vascular aneurysm clips, ferromagnetic devices, and metallic fragments in the orbit, as well as those with claustrophobia (Shugarman et al., 2004). Because of safety concerns, MRI (brain) is contraindicated for some patients with metallic foreign bodies or implants. In general, however, patients without contraindications undergo non-contrast MRI (brain) without experiencing adverse events. Patients undergoing contrast-enhanced MRI (brain) also have few adverse reactions.

In selecting the recommended outcome measures for MRI (brain), we considered a list of 19 outcome measures, including the initial set of 18 that were rated and discussed as part of the Phase 1 panel process, plus one outcome that was added after the Phase 1 panel meeting. We recommend that only one of these measures be analyzed further using risk adjustment. It is:

- anaphylaxis/anaphylactoid reaction (B)

We considered, but are not recommending, two other measures:

- Chest pain (D)
- Death (E)

For each of these measures, we list the reasons for recommending or not recommending it, the time frame for analysis, and factors to be used in risk adjustment in the table below. The supporting evidence for the entire set of MRI (brain) outcomes is provided in Table 5 (in the attached Excel file).

Of those outcomes not considered for further analysis, eight outcomes were dropped because they are indications for having an MRI (brain); these are altered mental status, dizziness, headache, ocular injury, paresthesia, seizure, syncope, and vasospasm. One additional outcome measure, vasodilatation, was eliminated because there are no ICD-9 codes that can be used to identify the condition in claims data. The remaining seven were not considered to be suitable outcomes for MRI (brain) (bradycardia, dyspnea, hypertension, hypotension, rash, tachycardia, and other complications).

Recommended for further analysis
Measure: Anaphylaxis/anaphylactoid reaction (B)
Reason for status: Anaphylaxis/anaphylactoid reaction is a severe, life-threatening allergic reaction involving the entire body. It might result in difficulty breathing and, in rare cases, death. It would occur as a result of an allergic reaction of the patient to the contrast media used in some MRIs. It is included despite the fact that it occurs very infrequently and might not be preventable, because there are no other reasonable outcome measures for MRI (brain). This outcome was considered to be very severe (all 7 panelists rating it 7, 8, or 9). However, it occurred infrequently with only 11 cases within 30 days among 40,497 patients (0.3 per 1000) with MRI (brain) procedures performed in the three sites combined (HOPD, office, and IDTF). In addition, anaphylaxis was not considered to be preventable by the Phase 1 MRI panel, with only 2 of 7 panelists rating it 4 or higher.
Time frame for analysis: Within 7 days

Patient characteristics for risk adjustment model:

- Age
- Gender
- Race/ethnicity
- Medicaid eligible
- Disability status
- Personal allergy to radiographic dye
- History of anaphylactic shock
- Personal history of allergy to anesthetic agent
- History of shock due to anesthesia in which correct substance was properly administered

Considered but not recommended for further analysis

Measure: Chest pain (D)

Reason for status: Chest pain was considered for further analysis because it might occur as a result of stress associated with the MRI procedure that might induce a temporary drop in blood pressure. It can indicate a severe underlying condition and occurs frequently. However, it is not recommended because the panel did not consider it to be preventable and because it might be related to underlying comorbidity that would be difficult to control for adequately. This outcome was considered to be somewhat severe (3 of 7 panelists rating it 4, 5, or 7). It occurred within 30 days in 1,133 of 40,497 patients (28.0 per 1000) with MRI (brain) procedures performed in the three sites combined (HOPD, office, and IDTF). However, chest pain was not considered to be preventable by any of the six Phase 1 MRI panelists, with none of them rating it higher than 2.

Time frame for analysis: Within 7 days

Patient characteristics for risk adjustment model:

- Age
- Gender
- Race/ethnicity
- Medicaid eligible
- Disability status
- Diabetes
- Ischemic heart disease
- Heart failure/cardiomyopathy
- Stroke (433, 434, 435)
- Hypertension
- Dementia
- Hyperlipidemia
- Rheumatoid arthritis
- Fibromyalgia
- Sickle cell disease
- Systemic lupus erythematosus
- Chronic renal failure
- AIDS
- Peripheral vascular disease

- COPD (490 through 496)
- GERD (530.81, 530.11)
- Leukemia
- Lymphoma
- Trauma to chest wall or prior chest wall pain (922, 959.11)
- Herpes zoster/postherpetic neuralgia
- Thoracic or abdominal aortic aneurysm
- Aortic stenosis
- Pericarditis
- Sarcoidosis
- Pulmonary blebs
- Pleurisy (511)
- Depression
- Anxiety

Considered but not recommended for further analysis

Measure: Death (E)

Reason for status: Death was considered because of the extreme severity of the outcome, but not recommended mainly because of its low frequency and an inability to control adequately for all possible comorbidities. Only 2 deaths occurred within 30 days among 40,497 patients with MRI (brain) procedures performed in the three sites combined (HOPD, office, and IDTF). In addition, death was considered to be only somewhat preventable by the Phase 1 MRI panelists, with only 4 of 6 panelists rating it 5, 6, or 7.

Time frame for analysis: Within 7 days

Patient characteristics for risk adjustment model:

- Age
- Gender
- Race/ethnicity
- Medicaid eligible
- Disability status
- AIDS
- Myocardial infarction
- Heart failure
- Peripheral vascular disease
- Cirrhosis
- Chronic kidney failure
- Diabetes
- Hypertension
- Hyperlipidemia
- Arrhythmia
- Leukemia
- Lymphoma

Table F.3 Cataract Surgery Summary Based on Panel Ratings and Claims Analysis

		Preventability* (shaded are those with at least 3 ratings >6)										**Severity**** (shaded are those with at least 3 ratings >6)										**N**	**Rate/ 1,000**	**Indi-cation**
	Cataract Surgery Outcomes	**# Resp**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**# Resp**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	(shaded = >1 per 1000)		
A	Arrhythmia	6	0	1	3	1	0	0	1	0	0	6	0	0	1	1	4	0	0	0	0	150	1.9	
B	Capsule rupture or posterior capsule tear	6	0	0	1	0	2	1	2	0	0	6	0	0	1	3	1	0	1	0	0	No codes	No codes	
C	New or Worsening Congestive heart failure	6	0	1	1	0	0	2	2	0	0	6	0	0	0	0	1	0	3	2	0	No codes	No codes	
D	Persistent cystoid macular edema	5	0	0	0	0	3	0	2	0	0	5	0	0	0	0	2	2	0	1	0	18	0.2	Yes
E	Death	6	0	0	0	1	2	1	1	1	0	6	0	0	0	0	0	0	0	0	6	0	0.0	
F	Endophthalmitis	5	0	0	0	0	2	0	3	0	0	6	0	0	0	0	0	0	0	3	3	113	1.5	
G	Hypertension	6	0	0	0	0	1	4	0	1	0	6	0	0	2	2	0	1	0	1	0	3	0.0	
H	Hypotension	6	0	0	0	1	3	0	1	1	0	6	0	0	0	1	4	1	0	0	0	59	0.8	
I	Iris prolapse	6	0	0	0	0	0	1	0	5	0	6	0	0	0	2	2	0	2	0	0	62	0.8	
J	Myocardial infarction	6	0	0	2	2	0	1	1	0	0	6	0	0	0	0	0	0	1	1	4	229	3.0	
K	Retained nuclear fragment (posterior chamber vs. anterior chamber)	6	0	0	0	1	0	1	0	4	0	6	0	0	0	0	3	3	0	0	0	473	6.1	
L	Ocular hypertension	6	0	0	0	0	1	4	0	1	0	6	0	0	1	3	1	1	0	0	0	10	0.1	
M	Persistent iridocyclitis	6	0	0	0	0	2	2	2	0	0	6	0	0	0	0	2	3	1	0	0	41	0.5	
N	Poor ocular motility, excluding cranial VII palsy	6	0	0	0	0	1	3	1	1	0	5	0	0	0	1	3	1	0	0	0	0	0.0	
O	Retinal break	6	0	1	1	1	1	2	0	0	0	7	0	0	1	0	0	2	3	1	0	7	0.1	Yes
P	Retinal detachment (comp vs uncomp surgery)	6	0	0	2	1	1	2	0	0	0	7	0	0	0	0	0	0	2	5	0	58	0.7	Yes
Q	Stroke	6	0	1	2	0	1	1	1	0	0	7	0	0	0	0	0	0	0	5	2	484	6.2	
R	Wound dehiscence	7	0	0	1	0	0	3	2	1	0	7	0	0	0	0	0	1	4	2	0	No codes	No codes	
S	Wound leak	7	0	0	0	0	0	1	1	5	0	6	0	0	0	0	1	2	3	0	0	No codes	No codes	
T	Aspiration pneumonia	5	0	2	0	0	0	0	2	1	0	6	0	0	0	0	0	0	4	2	0	16	0.2	
U	Respiratory Failure From Surgery	5	0	1	1	0	2	0	0	1	0	6	0	0	0	0	1	0	1	4	0	22	0.3	
V	Hyphema	6	0	0	0	0	0	3	2	1	0	6	0	0	0	2	2	2	0	0	0	20	0.3	
W	Persistent Corneal Edema	6	0	0	0	0	1	0	4	1	0	6	0	0	0	0	1	0	5	0	0	54	0.7	
X	Vitreous Loss	6	0	0	1	0	0	2	3	0	0	6	0	0	0	1	2	1	2	0	0	54	0.7	
Y	Secondary Glaucoma	6	0	0	0	0	3	1	2	0	0	5	0	0	0	0	2	3	0	0	0	154	2.0	
Z	Dislocated Ocular Lenses	6	0	0	0	0	1	0	2	3	0	6	0	0	0	0	3	1	2	0	0	108	1.4	
AA	Iris/pupil deformation	6	0	0	0	0	1	0	3	2	0	6	0	0	1	1	3	1	0	0	0	0	0.0	
BB	Nausea and vomiting																					200	2.6	
CC	Cataract fragments in eye																					92	1.2	

*The preventability scale is defined as follows: 1=Not preventable; 9=Definitely preventable.

**The severity scale is defined as follows: 1=Not severe, 5=Somewhat severe, 9=Very severe.

Table F.4 Colonoscopy Summary Based on Panel Ratings and Claims Analysis

		Preventability* (shaded rows are those with at least 4 ratings >6)										**Severity**** (shaded rows are those with at least 4 ratings >6)										**N**	**Rate per 1,000**	**Indication**
	Colonoscopy Outcomes	**# Resp**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**# Resp**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	(shaded = incidence of >2 per 1000)		
A	Abdominal pain	9	0	0	0	0	6	3	0	0	0	7	0	5	2	0	0	0	0	0	0	3678	40.5	Yes
B	Altered mental status	9	0	0	1	1	2	2	0	2	1	8	1	3	2	1	1	0	0	0	0	34	0.4	
C	Arrhythmia	9	2	3	2	1	1	0	0	0	0	8	0	2	2	1	2	1	0	0	0	253	2.8	
D	Chest pain	9	1	2	1	1	3	1	0	0	0	7	0	0	2	0	1	3	0	1	0	1346	14.8	
E	Death	9	0	1	0	1	0	0	1	3	3	8	0	0	0	0	0	0	0	0	8	1	0.0	
F	Dyspnea	9	0	2	1	0	0	1	4	0	1	8	0	0	2	3	1	0	2	0	0	916	10.1	
G	Hemorrhage	9	0	2	0	0	3	0	4	0	0	8	0	0	0	0	3	1	3	1	0	1873	20.6	Yes
H	Hypertension	9	0	1	0	1	2	3	2	0	0	8	0	2	3	1	0	0	1	1	0	2	0.0	
I	Hypotension	9	0	2	2	1	2	0	2	0	0	8	0	0	1	1	1	1	2	2	0	106	1.2	Yes
J	Hypoxia	9	0	1	3	0	1	1	0	3	0	8	0	0	0	0	1	0	4	2	1	4	0.0	
K	Perforation	9	0	3	0	0	2	0	0	4	0	8	0	0	0	0	0	1	0	2	5	73	0.8	
L	Post-polypectomy syndrome	9	0	3	0	0	3	2	0	1	0	8	0	0	0	0	1	2	2	3	0	No codes	No codes	
A	Abdominal distension	9	0	0	1	0	4	3	1	0	0	8	0	0	2	4	1	0	0	1	0	151	1.7	Yes
B	Endocarditis	9	0	2	0	0	1	2	3	0	1	8	0	0	0	0	0	0	0	4	3	10	0.1	
C	Sepsis and other infections	9	0	2	0	0	0	2	4	1	0	7	0	0	0	0	0	1	2	4	0	154	1.7	Yes
D	Small bowel obstruction	9	1	5	2	0	1	0	0	0	0	8	0	0	0	0	0	3	2	2	1	528	5.8	
E	Splenic rupture	9	0	3	0	0	2	0	1	3	0	7	0	0	0	0	0	0	0	2	5	35	0.4	
F	Splenic trauma	9	0	3	0	0	2	0	1	3	0	7	0	0	0	0	0	0	0	4	3	0	0.0	
G	Vasovagal reactions	9	1	2	1	1	3	0	1	0	0	8	0	0	0	3	2	1	0	1	1	232	2.6	
	Other complications***																					116	1.3	

*The preventability scale is defined as follows: 1=Not preventable, 5=Somewhat preventable, 9=Definitely preventable.

**The severity scale is defined as follows: 1=Not severe, 5=Somewhat severe, 9=Very severe.

***Other complications are diagnosis codes 998.89 (Other specified complications of procedures, not elsewhere classified), and 669.4 (Postoperative complication NOS).

Table F.5 MRI (Brain) Summary Based on Panel Ratings and Claims Analysis

		Preventability* (shaded rows are those with at least 1 rating >4)										**Severity**** (shaded rows are those with at least 1 rating >6)										**N**	**Rate per 1,000**	**Indication**
	MRI (Brain) Outcomes	**#Resp**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**#Resp**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	(shaded = incidence of > 10 per 1000)		
A	Altered mental status	7	3	2	2	0	0	0	0	0	0	7	2	3	1	0	0	1	0	0	0	65	1.6	
B	Anaphylaxis/anaphylactoid reaction	7	3	1	1	1	1	0	0	0	0	7	0	0	0	0	0	0	1	4	2	11	0.3	
C	Bradycardia	7	5	0	2	0	0	0	0	0	0	7	3	2	2	0	0	0	0	0	0	277	6.8	
D	Chest pain	7	5	2	0	0	0	0	0	0	0	7	2	0	2	1	1	0	1	0	0	1133	28.0	
E	Death	6	2	0	0	0	1	2	1	0	0	6	0	0	0	0	0	0	0	0	6	2	0.0	
F	Dizziness	5	3	0	2	0	0	0	0	0	0	6	2	3	1	0	0	0	0	0	0	2151	53.1	Yes
G	Dyspnea	6	1	0	4	0	1	0	0	0	0	6	0	2	0	1	2	0	1	0	0	799	19.7	
H	Headache	6	5	1	0	0	0	0	0	0	0	4	0	4	0	0	0	0	0	0	0	1512	37.3	Yes
I	Hypertension	6	2	2	2	0	0	0	0	0	0	6	1	1	2	1	1	0	0	0	0	4	0.1	
J	Hypotension	6	2	2	1	0	1	0	0	0	0	6	1	0	1	1	1	2	0	0	0	152	3.8	
K	Ocular injury	6	0	0	0	0	0	0	2	2	2	6	0	0	1	0	0	0	1	3	1	No codes	No codes	Yes
L	Paresthesia	7	4	1	2	0	0	0	0	0	0	7	4	2	1	0	0	0	0	0	0	521	12.9	Yes
M	Rash	7	2	1	2	1	1	0	0	0	0	7	2	2	3	0	0	0	0	0	0	58	1.4	
N	Seizure	6	5	1	0	0	0	0	0	0	0	7	0	0	1	1	2	0	1	1	1	904	22.3	Yes
O	Syncope	7	5	0	0	0	2	0	0	0	0	7	1	3	0	1	1	0	0	0	1	877	21.7	Yes
P	Tachycardia	7	3	1	2	0	1	0	0	0	0	7	2	0	2	1	2	0	0	0	0	53	1.3	
Q	Vasodilatation	7	6	0	0	0	1	0	0	0	0	7	2	1	3	0	1	0	0	0	0	No codes	No codes	
R	Vasospasm	7	5	0	1	0	1	0	0	0	0	7	1	1	3	0	2	0	0	0	0	No codes	No codes	Yes
	Other complications***																					18	0.4	

*The preventability scale is defined as follows: 1=Not preventable, 5=Somewhat preventable, 9=Definitely preventable.

**The severity scale is defined as follows: 1=Not severe, 5=Somewhat severe, 9=Very severe.

***Other complications are diagnosis codes 998.89 (Other specified complications of procedures, not elsewhere classified), and 998.9 (Unspecified complication of procedures).

Table F.6 Recommended Measures with Panel Ratings and Frequency

		Preventability*										Severity**										Frequency***		Indication
	Outcome	**#Resp**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**#Resp**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**N**	**Rate per 1,000**	
	Cataract surgery	(shaded are those with at least 3 ratings >6)										(shaded are those with at least 3 ratings >6)										(shaded=incidence of > 1 per 1000)		
F	Endophthalmitis	5	0	0	0	0	2	0	3	0	0	6	0	0	0	0	0	0	0	3	3	113	1.5	No
CC	Cataract fragments in eye																					92	1.2	No
W	Persistent corneal edema	6	0	0	0	0	1	0	4	1	0	6	0	0	0	0	1	0	5	0	0	54	0.7	No
I	Iris prolapse	6	0	0	0	0	0	1	0	5	0	6	0	0	0	2	2	0	2	0	0	62	0.8	No
	Colonoscopy	(shaded rows are those with at least 4 ratings >6)										(shaded rows are those with at least 4 ratings >6)										(shaded = incidence of >2 per 1000)		
K	Perforation	9	0	3	0	0	2	0	0	4	0	8	0	0	0	0	0	1	0	2	5	73	0.8	No
E	Splenic rupture	9	0	3	0	0	2	0	1	3	0	7	0	0	0	0	0	0	0	2	5	35	0.4	No
	MRI (Brain)	(shaded rows are those with at least 1 rating >4)										(shaded rows are those with at least 1 rating >6)										(shaded = incidence of > 10 per 1000)		
B	Anaphylaxis/anaphylactoid reaction	7	3	1	1	1	1	0	0	0	0	7	0	0	0	0	0	0	1	4	2	11	0.3	No

*The preventability scale is defined as follows: 1=Not preventable, 5=Somewhat preventable, 9=Definitely preventable.

**The severity scale is defined as follows: 1=Not severe, 5=Somewhat severe, 9=Very severe.

***Within 30 days of the procedure.

Appendix G. Cataract Surgery: Covariates and Parameter Estimates for Logistic Regression Models

Table G.1 Cataract Surgery Covariates Used in Logistic Regression Models By Setting, Medicare Fee-for-Service, 2001

	OPD		ASC		All Sites	
	Number	**Percent**	**Number**	**Percent**	**Number**	**Percent**
All cataract surgeries	36623	100.0	40671	100.0	77294	100.0
Under 65 years	1256	3.4	1159	2.9	2415	3.1
65-74 years	13482	36.8	15988	39.3	29470	38.1
75-84 years	17655	48.2	19488	47.9	37143	48.1
85 years and over	4229	11.5	4030	9.9	8259	10.7
Female	23784	64.9	25461	62.6	49245	63.7
White	32698	89.3	37228	91.5	69926	90.5
African-American	2534	6.9	1954	4.8	4488	5.8
Other race	1390	3.8	1483	3.6	2873	3.7
Medicaid eligible	4966	13.6	4321	10.6	9287	12.0
Originally disabled	3701	10.1	3641	9.0	7342	9.5
Diabetes mellitus	10463	28.6	10421	25.6	20884	27.0
Rheumatoid arthritis/ Systemic lupus erythematosus	2132	5.8	2183	5.4	4315	5.6
Metastatic cancer/Leukemia/ Lymphoma	653	1.8	691	1.7	1344	1.7
History of vitrectomy	140	0.4	176	0.4	316	0.4
Essential, benign, or drug-related tremor/Abnormal head movements, fasciculations, spasms or tremor not otherwise specified	208	0.6	156	0.4	364	0.5

Source: RAND analysis of the 5 percent Standard Analytical Files of Medicare claims, 2001.

Appendix H. Perforation: Covariates and Parameter Estimates for Logistic Regression Models

Table H.1 Perforation Covariates Used in Logistic Regression Models By Ambulatory Setting, Medicare Fee-for-Service, 2001

	OPD		ASC		Office		All Sites	
	Number	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**
All colonoscopies	63372	100.0	23503	100.0	4015	100.0	90890	100.0
Under 65 years	5567	8.8	1591	6.8	323	8.0	7481	8.2
65-74 years	32061	50.6	12571	53.5	2176	54.2	46808	51.5
75-84 years	22165	35.0	8208	34.9	1335	33.3	31708	34.9
85 years and over	3568	5.6	1131	4.8	181	4.5	4880	5.4
Female	35703	56.3	13260	56.4	2206	54.9	51169	56.3
White	56980	89.9	21313	90.7	3433	85.5	81726	89.9
African-American	4480	7.1	1453	6.2	301	7.5	6234	6.9
Other race	1901	3.0	735	3.1	281	7.0	2917	3.2
Medicaid eligible	7222	11.4	1965	8.4	333	8.3	9520	10.5
Originally disabled	9540	15.1	2782	11.8	574	14.3	12896	14.2
History of partial or complete bowel obstruction	2246	3.5	669	2.8	124	3.1	3039	3.3
History of colorectal cancer	1587	2.5	316	1.3	154	3.8	2057	2.3
Inflammatory bowel disease	1128	1.8	379	1.6	103	2.6	1610	1.8
Melena	1553	2.5	275	1.2	229	5.7	2057	2.3

Source: RAND analysis of the 5 percent Standard Analytical Files of Medicare claims, 2001.

Table H.2 Parameters from Logistic Regression for Perforation within 30 Days of RBC Colonoscopies, Medicare Fee-for-Service, 2001

Variable	Parameter Estimate	Standard Error	p Value
Intercept	**-7.505**	**0.312**	**<.0001**[§]
age_under_65	-0.474	0.817	0.5618
age_75_84	0.327	0.308	0.2872
age_85p	-0.208	0.742	0.7797
female	0.053	0.296	0.8586
race_afam	-0.182	0.615	0.7666
race_other	-0.179	0.758	0.8136
disabled	-0.140	0.603	0.8166
medicaid	**1.102**	**0.411**	**0.0074**[§]
bowel_obstruct	0.819	0.534	0.1253
colorectal_cancer	1.049	0.609	0.0852
inflam_bowel_disease	0.556	0.727	0.4443
melena	0.757	0.727	0.2977
inasc	**0.715**	**0.296**	**0.0156**[§]
inoff	-12.452	403.600	0.9754

[§] Parameters in bold are significant at p<0.05.

Table H.3 Parameters from Logistic Regression for Perforation within 30 Days of Non-RBC Colonoscopies, Medicare Fee-for-Service, 2001

Variable*	Parameter Estimate	Standard Error	p Value
Intercept	**-7.560**	**0.358**	**<.0001**[§]
age_under_65	-1.233	0.848	0.1460
age_75_84	0.012	0.352	0.9723
age_85p	0.794	0.507	0.1172
female	-0.039	0.324	0.9045
race_afam	0.211	0.545	0.6988
disabled	0.649	0.499	0.1933
medicaid	0.350	0.483	0.4693
bowel_obstruct	**1.449**	**0.456**	**0.0015**[§]
colorectal_cancer	0.495	0.743	0.5050
inflam_bowel_disease	0.846	1.020	0.4068
melena	0.745	0.733	0.3096
inasc	**0.894**	**0.329**	**0.0066**[§]
inoff	0.663	0.621	0.2853

*A variable representing "other race" was dropped from the model based on initial results indicating the coefficient was insignificant and unstable because of small numbers.

[§] Parameters in bold are significant at p<0.05.

Appendix I. Anaphylaxis: Covariates and Parameter Estimates for Logistic Regression Models for Comparison of Three Settings

Table I.1 Anaphylaxis Covariates for Three Ambulatory Settings Used in Logistic Regression Models, Medicare Fee-for-Service, 2001

	OPD		Office		IDTF		All Sites	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent
All MRI (brain)	21233	100.0	14712	100.0	4552	100.0	40497	100.0
Under 65 years	3181	15.0	1697	11.5	641	14.1	5519	13.6
65-74 years	8545	40.2	6027	41.0	1834	40.3	16406	40.5
75-84 years	7760	36.6	5821	39.6	1718	37.7	15299	37.8
85 years and over	1745	8.2	1167	7.9	359	7.9	3271	8.1
Female	12891	60.7	9043	61.5	2875	63.2	24809	61.3
White	19009	89.5	13304	90.4	4116	90.4	36429	90.0
African-American	1510	7.1	826	5.6	211	4.6	2547	6.3
Other race	712	3.4	582	4.0	225	4.9	1519	3.8
Medicaid eligible	3450	16.2	1770	12.0	795	17.5	6015	14.9
Originally disabled	4599	21.7	2582	17.6	951	20.9	8132	20.1
History of anaphylactic shock	131	0.6	239	1.6	20	0.4	390	1.0

Source: RAND analysis of the 5 percent Standard Analytical Files of Medicare claims, 2001.

Table I.2 Parameters from Logistic Regression for Anaphylaxis within 7 Days of MRIs (Brain) with Contrast for Three Settings, Medicare Fee-for-Service, 2001

Variable*	Parameter Estimate	Standard Error	p Value
Intercept	-26.539	198.000	0.8934
age_under_65	-5.784	185.900	0.9752
age_75p	-10.338	148.500	0.9445
female	8.965	146.600	0.9512
race_afam	-9.863	297.700	0.9736
disabled	-9.473	168.300	0.9551
medicaid	12.194	133.100	0.9270
inidtf	-9.978	272.500	0.9708
inoff	-9.553	160.200	0.9525

*Four variables representing age over 85 years, "other race," personal allergy to radiographic dye, and history of anaphylactic shock were dropped from the model based on initial results indicating the coefficients were insignificant and unstable because of small numbers.

Table I.3 Parameters from Logistic Regression for Anaphylaxis within 7 Days of MRIs (Brain) without Contrast for Three Settings, Medicare Fee-for-Service, 2001

Variable*	Parameter Estimate	Standard Error	p Value
Intercept	-36.375	224.600	0.8713
age_under_65	-1.473	1.428	0.3024
age_75_84	-9.245	186.900	0.9606
age_85p	-9.266	386.900	0.9809
female	-0.837	1.423	0.5565
disabled	10.598	136.000	0.9379
medicaid	11.198	133.100	0.9330
history_anaph_shock	-9.758	890.200	0.9913
inidtf	10.767	119.300	0.9281
inoff	10.145	119.300	0.9322

*Three variables representing African-American, "other race," and personal allergy to radiographic dye were dropped based on initial results indicating the coefficients were insignificant and unstable because of small numbers.

Table I.4 Parameters from Logistic Regression for Anaphylaxis within 30 Days of All MRIs (Brain) for Three Settings, Medicare Fee-for-Service, 2001

Variable*	Parameter Estimate	Standard Error	p Value
Intercept	**-8.791**	**0.771**	**<.0001**[§]
age_under_65	-0.709	0.939	0.4501
age_75_84	-0.712	0.849	0.4017
age_85p	0.169	1.113	0.8795
female	0.460	0.684	0.5008
race_afam	-0.090	1.078	0.9338
disabled	1.132	0.859	0.1875
medicaid	0.766	0.729	0.2936
history_anaph_shock	**2.401**	**1.066**	**0.0244**[§]
inidtf	0.451	0.819	0.5818
inoff	-0.314	0.715	0.6602

*Two variables representing "other race" and personal allergy to radiographic dye were dropped from the model based on initial results indicating the coefficients were insignificant and unstable because of small numbers.

[§] Parameters in bold are significant at $p<0.05$.

Table I.5 Parameters from Logistic Regression for Anaphylaxis within 30 Days of MRIs (Brain) with Contrast for Three Settings, Medicare Fee-for-Service, 2001

Variable*	Parameter Estimate	Standard Error	p Value
Intercept	**-8.102**	**0.859**	**<.0001**[§]
age_under_65	-0.525	1.245	0.6736
age_75p	-1.348	1.129	0.2324
female	0.499	0.843	0.5534
race_afam	0.539	1.115	0.6290
disabled	0.745	1.139	0.5130
medicaid	0.310	0.960	0.7467
inidtf	0.129	1.098	0.9064
inoff	-1.012	1.097	0.3562

*Four variables representing age over 85 years, "other race," personal allergy to radiographic dye, and history of anaphylactic shock were dropped from the model based on initial results indicating the coefficients were insignificant and unstable because of small numbers.

[§] Parameters in bold are significant at p<0.05.

Table I.6 Parameters from Logistic Regression for Anaphylaxis within 30 Days of MRIs (Brain) without Contrast for Three Settings, Medicare Fee-for-Service, 2001

Variable*	Parameter Estimate	Standard Error	p Value
Intercept	**-10.845**	**1.748**	**<.0001**[§]
age_under_65	-0.849	1.600	0.5958
age_75_84	0.216	1.446	0.8814
age_85p	1.807	1.477	0.2210
female	0.453	1.175	0.6998
disabled	1.762	1.354	0.1933
medicaid	1.517	1.180	0.1986
history_anaph_shock	**3.702**	**1.235**	**0.0027**[§]
inidtf	1.288	1.422	0.3651
inoff	0.777	1.254	0.5357

*Three variables representing African-American, "other race," and personal allergy to radiographic dye were dropped from the model based on initial results indicating the coefficients were insignificant and unstable because of small numbers.

[§] Parameters in bold are significant at p<0.05.

Table I.7 Parameters from Logistic Regression for Anaphylaxis within 7 Days of All MRIs (Brain) for Two Settings, Medicare Fee-for-Service, 2001

Variable*	Parameter Estimate	Standard Error	p Value
Intercept	-19.276	151.2	0.8985
age_under_65	-1.717	1.4	0.2245
age_75p	-10.792	196.4	0.9562
age_85p	-10.854	422.4	0.9795
female	-0.201	1.2	0.8704
race_afam	-10.928	319.8	0.9727
disabled	0.903	1.4	0.5227
medicaid	12.937	151.2	0.9318
history_anaph_shock	-9.794	996.3	0.9922
inopd	-0.935	1.2	0.4460

*Two variables representing "other race" and personal allergy to radiographic dye were dropped from the model based on initial results indicating the coefficients were insignificant and unstable because of small numbers.

Table I.8 Parameters from Logistic Regression for Anaphylaxis within 7 Days of MRIs (Brain) with Contrast for Two Settings, Medicare Fee-for-Service, 2001

Variable*	Parameter Estimate	Standard Error	p Value
Intercept	-35.866	227.6	0.8748
age_under_65	-5.742	181.9	0.9748
age_75p	-10.273	143.7	0.9430
female	8.854	138.7	0.9491
race_afam	-9.887	301.3	0.9738
disabled	-9.431	164.7	0.9543
medicaid	12.073	125.3	0.9232
inopd	9.560	130.0	0.9414

*Four variables representing age over 85 years, "other race," personal allergy to radiographic dye, and history of anaphylactic shock were dropped from the model based on initial results indicating the coefficients were insignificant and unstable because of small numbers.

Table I.9 Parameters from Logistic Regression for Anaphylaxis within 7 Days of MRIs (Brain) without Contrast for Two Settings, Medicare Fee-for-Service, 2001

Variable*	Parameter Estimate	Standard Error	p Value
Intercept	-24.487	128.3	0.8486
age_under_65	-1.424	1.4	0.3165
age_75_84	-8.480	123.0	0.9450
age_85p	-8.162	253.9	0.9744
female	-0.825	1.4	0.5618
disabled	9.826	91.9	0.9148
medicaid	10.460	89.6	0.9070
history_anaph_shock	-8.848	552.9	0.9872
inopd	-9.591	79.1	0.9035

*Three variables representing African-American, "other race," and personal allergy to radiographic dye were dropped based on initial results indicating the coefficients were insignificant and unstable because of small numbers.

Table I.10 Parameters from Logistic Regression for Anaphylaxis within 30 Days of All MRIs (Brain) for Two Settings, Medicare Fee-for-Service, 2001

Variable*	Parameter Estimate	Standard Error	p Value
Intercept	**-8.864**	**0.788**	**<.0001**[§]
age_under_65	-0.703	0.939	0.4540
age_75_84	-0.715	0.848	0.3993
age_85p	0.168	1.113	0.8797
female	0.461	0.684	0.5007
race_afam	-0.119	1.077	0.9119
disabled	1.135	0.859	0.1865
medicaid	0.801	0.729	0.2721
history_anaph_shock	**2.307**	**1.060**	**0.0294**[§]
inopd	0.067	0.610	0.9126

*Two variables representing "other race" and personal allergy to radiographic dye were dropped from the model based on initial results indicating the coefficients were insignificant and unstable because of small numbers.

[§] Parameters in bold are significant at $p<0.05$.

Table I.11 Parameters from Logistic Regression for Anaphylaxis within 30 Days of MRIs (Brain) with Contrast for Two Settings, Medicare Fee-for-Service, 2001

Variable*	Parameter Estimate	Standard Error	p Value
Intercept	**-8.7042**	**1.011**	**<.0001**[§]
age_under_65	-0.5245	1.245	0.6734
age_75p	-1.3459	1.129	0.2330
female	0.5001	0.842	0.5527
race_afam	0.5231	1.116	0.6391
disabled	0.7478	1.140	0.5117
medicaid	0.3302	0.962	0.7314
inopd	0.5962	0.839	0.4773

*Four variables representing age over 85 years, "other race," personal allergy to radiographic dye, and history of anaphylactic shock were dropped from the model based on initial results indicating the coefficients were insignificant and unstable because of small numbers.

[§] Parameters in bold are significant at p<0.05.

Table I.12 Parameters from Logistic Regression for Anaphylaxis within 30 Days of MRIs (Brain) without Contrast for Two Settings, Medicare Fee-for-Service, 2001

Variable*	Parameter Estimate	Standard Error	p Value
Intercept	**-9.920**	**1.532**	**<.0001**[§]
age_under_65	-0.830	1.595	0.6030
age_75_84	0.215	1.445	0.8819
age_85p	1.822	1.482	0.2189
female	0.438	1.172	0.7084
disabled	1.777	1.355	0.1897
medicaid	1.557	1.172	0.1838
history_anaph_shock	**3.606**	**1.204**	**0.0027**[§]
inopd	-0.936	1.168	0.4230

*Three variables representing African-American, "other race," and personal allergy to radiographic dye were dropped from the model based on initial results indicating the coefficients were insignificant and unstable because of small numbers.

[§] Parameters in bold are significant at p<0.05.

Appendix J. Specifications for Computer Runs to Analyze Outcome Measures

Please use SAS PROC LOGISTIC for the runs, specifying the DESCENDING option in your PROC statement (i.e., PROC LOGISTIC DATA=_____ DESCENDING;).

The dependent and independent variables, including patient characteristics and setting dummies, samples, and exclusions are specified below.

Cataract Surgery Outcomes

For each of the four cataract surgery outcomes, you'll run two logistic regression models:

Model 1: covariates are patient characteristics/comorbidities only

Model 2: covariates are patient characteristics/comorbidities **and** setting dummy

For the cataract surgery outcomes, you'll run a total of 8 models (4 outcomes, 2 models).

Measure: Endophthalmitis (F)

Set outcome indicator equal to 1 if these ICD codes are found on any record for any setting:

360.00 Purulent endophthalmitis, unspecified

360.01 Acute endophthalmitis

For each cataract surgery patient, search all records in all files (OPD, physician/supplier, inpatient), excluding the index procedure file. Search all fields on records included in the search.

Time frame for outcome: Search for outcome within 30 days of procedure date

Patient characteristics for Models 1 and 2 (a variable in bold and parens below is the reference category, that should not be included in the model)**:**

Create dummy variables (0,1) for each of the following:

- Under 65 years at time of procedure
- **(65-74)**
- 75-84
- 85+
- **(Male)**
- Female
- **(White)**
- Afr-Amer
- Other race
- (Medicaid eligible) (if buy-in code for any month in 2001 equals "C", then =1)
- **(not Medicaid eligible)**
- Originally disabled (if OREC = 1 or 3)
- **(not originally disabled)**
- Diabetes (if acc004 or hcc015 or hcc016 or hcc017 or hcc018 or hcc019 or hcc020 or hcc119 or hcc120=1 or if any ICD-9 diagnosis code on any claim in any setting during all 12 months of 2001 = 250 or 250.0x – 250.9x)
- Rheumatoid arthritis/ Systemic lupus erythematosus (if hcc038=1 or if any ICD-9 diagnosis code on any claim in any setting during all 12 months of 2001 = 714, 714.0 – 714.3x, 695.4, or 710.0)
- Metastatic cancer/Leukemia/Lymphoma (if hcc007=1 or if any ICD-9 diagnosis code on any claim in any setting during all 12 months of 2001 = 201, 201.xx, 202, 202.xx, 204, 204.xx, 205, 205.xx, 206, 206.xx, 207, 207.xx, 208, 208.xx

Dummy variables for setting:

Model 1: none included

Model 2: ASC

Sample: all cataract surgeries performed in the OPD or in an ASC

Exclusions:

- beneficiaries not enrolled in Part A and Part B
- any procedures performed in an office setting
- any other exclusion used in Phase 1 for the cataract surgery outcome table.

Missing values: exclude records with a missing for any covariate in the model

NOTE: please set the outcome indicator to zero for selected cases with 2 or 3 procedures per my 1/4/06 e-mail.

Measure: Cataract fragments in eye (CC)
Set outcome indicator equal to 1 if this ICD-9 code is found on any record for any setting:

998.82 Cataract fragments in eye following cataract surgery

For each cataract surgery patient, search all records in all files (OPD, physician/supplier, inpatient), excluding the index procedure file. Search all fields on records included in the search.

Time frame for analysis: Search for outcome within 30 days of procedure date

Patient characteristics for risk adjustment model:

- Under 65 years at time of procedure
- **(65-74)**
- 75-84
- 85+
- **(Male)**
- Female
- **(White)**
- Afr-Amer
- Other race
- (Medicaid eligible) (if buy-in code for any month in 2001 equals "C", then =1)
- **(not Medicaid eligible)**
- Originally disabled (if OREC = 1 or 3)
- **(not originally disabled)**
- History of vitrectomy (if any HCPCS/CPT code on any claim in any setting **before the procedure date** during 2001 = 67005, 67036, **67108 (NOTE: code added since Phase 1),** 67010, 67040, 67038, 67039
- Essential, benign, or drug-related tremor/Abnormal head movements, fasciculations, spasms or tremor not otherwise specified (if any diagnosis code on any claim in any setting **during all 12 months of 2001** = 781.0 or 333.1. Please check all 2001 claims, both before and after the procedure date.)

Dummy variables for setting:

Model 1: none included
Model 2: ASC

Sample: all cataract surgeries performed in the OPD or in an ASC

Exclusions:

- beneficiaries not enrolled in Part A and Part B
- any procedures performed in an office setting
- any other exclusion used in Phase 1 for the cataract surgery outcome table.

Missing values: exclude records with a missing for any covariate in the model

NOTE: please set the outcome indicator to zero for selected cases with 2 or 3 procedures per my 1/4/06 e-mail.

Measure: Persistent corneal edema (W)
Set outcome indicator equal to 1 if this ICD code is found on any record for any setting:

371.22 Secondary corneal edema

For each cataract surgery patient, search all records in all files (OPD, physician/supplier, inpatient), excluding the index procedure file. Search all fields on records included in the search.
In addition, set outcome indicator equal to 1 if any of these HCPCS/CPT procedure codes are found on any record for any outpatient setting:

65710: Keratoplasty (corneal transplant); lamellar.
65730: Keratoplasty (corneal transplant); penetrating (except in aphakia).
65750: Keratoplasty (corneal transplant); penetrating (in aphakia).
65755: Keratoplasty (corneal transplant); penetrating (in pseudophakia).

Search all fields on records included in the search.
In addition, set outcome indicator equal to 1 if any of these ICD-9-CM procedure codes are found on any record for the inpatient setting:

11.60, 11.61, 11.62, 11.63, 11.64, 11.69: Keratoplasty (corneal transplant), all types.

Search all fields on records included in the search.
For each cataract surgery patient, search all records in all files (OPD, physician/supplier, inpatient), excluding the index procedure file. Search all fields on records included in the search.

Time frame for analysis: Search for outcome within 30 days of procedure date

Patient characteristics for risk adjustment model:

- Under 65 years at time of procedure
- **(65-74)**
- 75-84
- 85+
- **(Male)**
- Female
- **(White)**
- Afr-Amer
- Other race
- (Medicaid eligible) (if buy-in code for any month in 2001 equals "C", then =1)
- **(not Medicaid eligible)**
- Originally disabled (if OREC = 1 or 3)
- **(not originally disabled)**
- Diabetes (if acc004 or hcc015 or hcc016 or hcc017 or hcc018 or hcc019 or hcc020 or hcc119 or hcc120=1 or if any ICD-9 diagnosis code on any claim in any setting during all 12 months of 2001 = 250 or 250.0 – 250.9)

Dummy variables for setting:

Model 1: none included
Model 2: ASC

Sample: all cataract surgeries performed in the OPD or in an ASC
Exclusions:

- beneficiaries not enrolled in Part A and Part B
- any procedures performed in an office setting

- any other exclusion used in Phase 1 for the cataract surgery outcome table.

Missing values: exclude records with a missing for any covariate in the model

Measure: Iris prolapse (I)
Set outcome indicator equal to 1 if this ICD code is found on any record for any setting:

364.75 Pupillary abnormalities.

For each cataract surgery patient, search all records in all files (OPD, physician/supplier, inpatient), excluding the index procedure file. Search all fields on records included in the search.

Time frame for analysis: Search for outcome within 30 days of procedure date

Patient characteristics for risk adjustment model:

- Under 65 years at time of procedure
- **(65-74)**
- 75-84
- 85+
- **(Male)**
- Female
- **(White)**
- Afr-Amer
- Other race
- (Medicaid eligible) (if buy-in code for any month in 2001 equals "C", then =1)
- **(not Medicaid eligible)**
- Originally disabled (if OREC = 1 or 3)
- **(not originally disabled)**

Dummy variables for setting:

Model 1: none included
Model 2: ASC

Sample: all cataract surgeries performed in the OPD or in an ASC

Exclusions:

- beneficiaries not enrolled in Part A and Part B
- any procedures performed in an office setting
- any other exclusion used in Phase 1 for the cataract surgery outcome table.

Missing values: exclude records with a missing for any covariate in the model

NOTE: please set the outcome indicator to zero for selected cases with 2 or 3 procedures per my 1/4/06 e-mail.

Colonoscopy Outcome
For perforation, you'll run the following three models on three different samples:

Model 1: covariates include patient characteristics only
Model 2: covariates include pt chars plus two setting dummies (ASC, OFFICE)
Model 3: covariates include pt chars plus two other setting dummies (OPD, ASC)

Sample 1: all colonoscopies
Sample 2: all RBC colonoscopies (RBC=lesion removal, biopsy, or control of bleeding)[36]
Sample 3: all non-RBC colonoscopies[37]

You'll run a total of 9 models (1 outcome, 3 models, 3 samples) for the colonoscopy outcomes.

[36] The HCPCS/CPT codes for RBC colonoscopy are 44389, 44391, 44392, 44393, 44394, 45379, 45380, 45382, 45383, 45384, 45385, and 45387.

[37] The HCPCS/CPT codes for "non-RBC" colonoscopy are 44388, 45378, and G0105.

Measure: Perforation (K)

Set outcome indicator equal to 1 if these ICD codes are found on any record for any setting:

998.2 Accidental puncture or laceration during a procedure Accidental perforation by catheter or other instrument during a procedure on: blood vessel nerve organ -

E870.4 Accidental cut, puncture, perforation, or hemorrhage during medical care, Endoscopic examination

569.83 Perforation of intestine

For each colonoscopy patient, search all records in all files (OPD, physician/supplier, inpatient), excluding the index procedure file. Search all fields on records included in the search.

Time frame for analysis: Search for outcome within 30 days of procedure date

Patient characteristics for risk adjustment model:

- Under 65 years at time of procedure
- **(65-74)**
- 75-84
- 85+
- **(Male)**
- Female
- **(White)**
- Afr-Amer
- Other race Include this variable only in the ALL Colonoscopy and RBC models; drop it from the non-RBC models.
- Medicaid eligible (if buy-in code for any month in 2001 equals "C", then =1)
- **(not Medicaid eligible)**
- Originally disabled (if OREC = 1 or 3)
- **(not originally disabled)**
- History of partial or complete bowel obstruction (if hcc031 = 1 or any ICD-9 diagnosis code on any claim in any setting **before the procedure date** during 2001 = 560, 560.0, 560.1, 560.2, 560.3x, 560.8x, or 560.9).
- History of colorectal cancer (if any ICD-9 diagnosis code on any claim in any setting **before the procedure date** during 2001 = 153, 153.0 – 153.9, 154, or 154.0 – 154.8)
- Inflammatory bowel disease (if hcc033 = 1 or if any diagnosis code on any 2001 claim in any setting **before the procedure date** = 555, 555.0-555.9, 556, or 556.0-556.9)
- Melena (if any diagnosis code on any 2001 claim in any setting **before the procedure date** = 578.1)

Dummy variables for setting:

Model 1: none

Model 2: ASC, OFFICE

Model 3: OPD, ASC

Analytic Sample

Sample 1: All procedures

Sample 2: RBC procedures

Sample 3: Non-RBC procedures

Exclusions:

- beneficiaries not enrolled in Part A and Part B
- any other exclusion used in Phase 1 for the colonoscopy outcome table.

Missing values: exclude records with a missing for any covariate in the model

MRI Outcome

For the MRI outcome, anaphylaxis, you'll run the following four models on three different samples:

Model 1: covariates include patient characteristics only
Model 2: covariates include pt chars plus two setting dummies (IDTF, OFFICE)
Model 3: covariates include pt chars plus two other setting dummies (OPD, IDTF)
Model 4: covariates include pt chars plus one setting dummy (OPD)

Sample 1: all MRIs
Sample 2: all MRIs with contrast[38]
Sample 3: all MRIs without contrast[39]

You'll run a total of 12 models (1 outcome, 4 models, 3 samples) for the MRI (brain) outcome.

[38] The HCPCS codes for MRI with contrast are 70541, 70542, 70543, 70545, 70546, 70548, 70549, 70552, and 70553.

[39] The HCPCS codes for MRI without contrast are 70544, 70547, and 70551.

Measure: Anaphylaxis/anaphylactoid reaction (B)

Set outcome indicator equal to 1 if these ICD codes are found on any record for any setting:

995.0 Other anaphylactic shock Allergic shock NOS or due to adverse effect of correct medicinal substance properly administered Anaphylactic reaction NOS or due to adverse effect of correct medicinal substance properly administered Anaphylaxis NOS or due to adverse effect of correct medicinal substance properly administered –

977.8 Poisoning by Other specified drugs and medicinal substances Contrast media used for diagnostic x-ray procedures Diagnostic agents and kits

E947.8 Adverse effect from other drugs and medicinal substances Contrast media used for diagnostic x-ray procedures Diagnostic agents and kits

For each MRI (brain) patient, search all records in all files (OPD, physician/supplier, inpatient), excluding the index procedure file. Search all fields on records included in the search.

Time frame for analysis: Run two sets of models. First, search for outcome within 7 days of procedure. Then, search for the outcome within 30 days of procedure.

Patient characteristics for risk adjustment model:

- Under 65 years at time of procedure
- **(65-74)**
- 75-84
- 85+ Include this variable only in the ALL MRI and "without contrast models"; re-define the variable as age>75 for the "with contrast" models.
- **(Male)**
- Female
- **(White)**
- Afr-Amer Include this variable only in the ALL MRI and "with contrast models"; drop from the "without contrast" models.
- Medicaid eligible (if buy-in code for any month in 2001 equals "C", then =1)
- **(not Medicaid eligible)**
- Originally disabled (if OREC = 1 or 3)
- **(not originally disabled)**
- History of anaphylactic shock (if any ICD-9 diagnosis code on any claim in any setting **before the procedure date** during 2001 = 995.0, 995.6x, or 995.2). Include this variable only in the ALL MRI and "without contrast" models; drop from the "with contrast" models.

Dummy variables for setting:

Model 1: none
Model 2: IDTF, OFFICE
Model 3: OPD, IDTF
Model 4: OPD

Analytic Sample

Sample 1: All procedures
Sample 2: Procedures with contrast
Sample 3: Procedures without contrast

Exclusions:

- beneficiaries not enrolled in Part A and Part B
- any other exclusion used in Phase 1 for the MRI outcome table.

Missing values: exclude records with a missing for any covariate in the model

Mean Predicted Values for Report

As I've mentioned to you, one set of tables in the results section of the report will contain mean predicted values for each outcome. This approach entails using the model parameters to calculate a predicted value for each case and then calculating a mean predicted value by site for each outcome. Because we want means by site, you will use only some of the models with site dummy variables to generate the predicted values.

- For cataract surgery, there are a total of 4 models that need to be run to generate the predicted values (4 outcomes, 1 site model).
- For colonoscopy, there are 3 models that need to be run to generate the predicted values (1 outcome, 1 site model, 3 samples).
- For MRI (brain), there are 12 models that need to be run to generate the predicted values (1 outcome, 2 site models, 3 samples, 2 time periods).

For each of these models, please generate a set of site-specific predicted values for every case in the sample for that model, using the parameters (intercept and regression coefficients) from the logistic regression model. These can be generated as part of the program that runs the model.

For each cataract surgery model, you will generate two predicted values for every case, one for ASC and one for OPD. To generate the predicted values, use this SAS code shown below.

```
proc logistic data=dsname descending outest=beta;
  model y = inasc var1 var2 ... vark;
  output out=tmp xbeta=xbeta;
run;
data tmp;
  set tmp;
  if _n_ = 1 then set beta (keep=inasc rename=(inasc=_binasc));
  xbeta0 = xbeta – (X * _binasc);
  xbeta1 = xbeta0 + _bx;
  p0 = 1/(1+exp(-xbeta0));
  p1 = 1/(1+exp(-xbeta1));
run;
proc means data=tmp;
  var p0 p1;
run;
```

For each of the three perforation models (all, RBC, and non-RBC), you will generate three predicted values for every case, one for ASC, OPD, and office.

For each of the three anaphylaxis models (all, with contrast, and without contrast), you will generate three predicted values for every case, one for IDTF, OPD, and office.

For each of the three anaphylaxis models (all, with contrast, and without contrast), there will be a second set of predicted values for the OPD vs. IDTF/office comparison. For these, you will generate two predicted values for every case, one for OPD, and one for IDTF/office.

Tables for Report

The attached Excel file contains templates for a total of 13 tables:

- 3 descriptive tables (based on frequency tables for variables that are in the models)
- 4 tables of predicted rates (based on specs given above for mean predicted values). You don't need to fill in the chi-square p values.
- 6 tables of model parameters (intercept, and, for each variable, coefficients, standard errors, and p-values directly from the output)

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