



Evaluation of the Second Phase of the Oncology Demonstration
Contract No. HHSM-500-2006-000091/Task Order #2

Evaluation Report – FINAL

May 21, 2009

Prepared for:

Pauline Karikari-Martin, MPH, MSN, RN, Co-Project Officer
Centers for Medicare & Medicaid Services (CMS)

Steve Clauser, PhD, Co-Project Officer
National Cancer Institute (NCI)

Prepared by:

L&M Policy Research, LLC
Attn: Myra A. Tanamor
P.O. Box 42026
Washington, DC 20015
mtanamor@Lmpolicyresearch.com
(202) 230-9029

The Centers for Medicare & Medicaid Services' Office of Research, Development, and Information (ORDI) strives to make information available to all. Nevertheless, portions of our files including charts, tables, and graphics may be difficult to read using assistive technology.

Persons with disabilities experiencing problems accessing portions of any file should contact ORDI through e-mail at ORDI_508_Compliance@cms.hhs.gov.



ACKNOWLEDGEMENTS

This evaluation was conducted for the Centers for Medicare & Medicaid Services (CMS) by L&M Policy Research, LLC and its subcontractor partners, Lewin Group, NORC at the University of Chicago, Social & Scientific Systems, and American Institutes for Research. Authors of this report include Project Director Myra A. Tanamor, MPP; Julia Doherty, MHSA of L&M; John Feigert, MD, L&M clinical consultant; Audrey El-Gamil; Jeannine Dollard of Lewin Group; Angie Jaszczak; Katie Lundeen; Eric Wargo of NORC; Marc Berk, PhD; Jack Feldman, PhD of Social & Scientific Systems

The research team would like to thank all the physician practices that participated in the case study interviews as well as the numerous telephone interviews we conducted. In addition, hearty thanks to the members of our advisory panel who spent many evenings with us to develop and assess the results of the validation analysis. The members of the advisory panel included: Peter Bach, MD, MAPP, Gary I. Cohen, MD, Debra Hughes, RN, Richard Ingram, MD, Richard Krumdieck, MD, Robert Warner, MD, Michael Kuettel, MD, and Donald Wender, PhD, MD. Special thanks to our advisory panel chair, John Feigert, MD. We also appreciate all the comments that reviewers provided on earlier drafts of this report. Finally, we would like to thank our project officers for their tireless efforts, Pauline Karikari-Martin, MPH, MSN, RN of CMS and Steve Clauser, PhD of the National Cancer Institute (NCI), as well as their colleagues at CMS and NCI who have shared valued insight and commentary to the draft report.



TABLE OF CONTENTS

ACKNOWLEDGEMENTS I

A. EXECUTIVE SUMMARY 1

A.1. BACKGROUND OF THE STUDY 1

A.2. PURPOSE OF THIS REPORT 1

A.3. OVERVIEW OF THE 2006 MEDICARE ONCOLOGY DEMONSTRATION 1

A.4. OVERVIEW STUDY DESIGN..... 3

A.5. KEY FINDINGS FROM CASE STUDIES 4

A.5.1. Characteristics of Case Study Participants 4

A.5.2. Participation in the Demonstration 5

A.5.3. Information Sources for the Demonstration 5

A.5.4. Initial Implementation..... 5

A.5.5. Interpretation of G-Code Descriptions 6

A.5.6. Recommendations from Participants 6

A.5.7. Implications and Recommendations for Future Demonstrations 6

A.6. KEY FINDINGS FROM PHYSICIAN SURVEY 7

A.6.1. Characteristics of Survey Participants 7

A.6.2. Participation in the Demonstration 7

A.6.3. Information Sources for the Oncology Demonstration 8

A.6.4. Implementation and Coding Issues 8

A.6.5. Impact of the Demonstration 8

A.6.6. Summary and Implications 9

A.7. KEY FINDINGS FROM CLAIMS ANALYSIS 10

A.8. KEY FINDINGS FROM VALIDATION STUDY 11

A.8.1. Validity Checks of the Demonstration Data 11

A.8.2. Development of and Results from Clinical Algorithms 12

A.9. IMPLICATIONS AND RECOMMENDATIONS FOR FUTURE DEMONSTRATIONS 14

A.9.1. Implications for Future Demonstration Projects 14

B. INTRODUCTION..... 15

B.1. 2006 MEDICARE ONCOLOGY DEMONSTRATION PROGRAM 15

B.2. EVALUATION ACTIVITIES 17

C. CASE STUDIES..... 19

C.1. PURPOSE OF CASE STUDIES 19

C.2. METHODOLOGY 19

C.2.1. Site Visit Methodology 20





| | | |
|--|--|-----------|
| C.2.2. | <i>Characteristics of Site Visit Participants</i> | 20 |
| C.2.3. | <i>Interviews with Non-Participating Physicians</i> | 21 |
| C.3. | FINDINGS..... | 22 |
| C.3.1. | <i>Reasons for Participating in the Oncology Demonstration</i> | 22 |
| C.3.2. | <i>Reasons for Not Participating in the Demonstration</i> | 23 |
| C.3.3. | <i>Sources of Information for Participating in Oncology Demonstration</i> | 24 |
| C.3.4. | <i>Perceptions of the Demonstration's Purpose and Value of Data Collected</i> | 25 |
| C.3.5. | <i>Implementation Process and Challenges</i> | 25 |
| C.3.6. | <i>Clinical Practice Guidelines</i> | 31 |
| C.4. | IMPACT OF DEMONSTRATION..... | 33 |
| C.5. | INTERVIEWEE RECOMMENDATIONS AND IMPROVEMENTS TO THE DEMONSTRATION..... | 33 |
| C.6. | FUTURE DEMONSTRATIONS AND HEALTH CARE REFORM..... | 34 |
| C.7. | RESEARCH LIMITATIONS..... | 35 |
| CHAPTER D. PHYSICIAN SURVEY | | 37 |
| D.1. | PURPOSE OF PHYSICIAN SURVEY..... | 37 |
| D.2. | QUESTIONNAIRE DEVELOPMENT AND QUESTIONNAIRE TESTING..... | 37 |
| D.3. | OMB AND IRB APPROVAL..... | 37 |
| D.4. | DATA COLLECTION METHODOLOGY..... | 38 |
| D.4.1. | <i>Sample</i> | 39 |
| D.4.2. | <i>Initial Sample Locating</i> | 39 |
| D.4.3. | <i>Questionnaire Mailing</i> | 40 |
| D.4.4. | <i>Overview of Prompting</i> | 40 |
| D.4.5. | <i>Incentive Payments</i> | 42 |
| D.5. | FINAL DISPOSITIONS, RESPONSE RATES AND STUDY LIMITATIONS..... | 42 |
| D.6. | SURVEY NON-RESPONSE BIAS..... | 44 |
| D.7. | SURVEY DATA ANALYSIS..... | 47 |
| D.8. | PHYSICIAN SURVEY FINDINGS..... | 48 |
| D.8.1. | <i>Characteristics of Physicians and Their Practices</i> | 48 |
| D.8.2. | <i>2006 Medicare Oncology Demonstration Background</i> | 53 |
| D.8.3. | <i>Implementation of 2006 Medicare Oncology Demonstration Program</i> | 56 |
| D.8.4. | <i>Physician Perceptions of Clinical Guidelines and the 2006 Demonstration</i> | 62 |
| D.8.5. | <i>2006 Oncology Demonstration Program</i> | 63 |
| D.8.6. | <i>Impact of 2006 Medicare Oncology Demonstration Program</i> | 64 |
| D.8.7. | <i>Overall Impressions</i> | 66 |
| D.8.8. | <i>Additional Comments</i> | 67 |





| | |
|--|-----------|
| CHAPTER E. CLAIMS ANALYSIS | 69 |
| E.1. PURPOSE OF CLAIMS ANALYSIS | 69 |
| E.2. METHODOLOGY..... | 69 |
| E.3. CLAIMS ANALYSIS RESULTS | 71 |
| <i>E.3.1. Physician participation in the demonstration</i> | 71 |
| <i>E.3.2. Medicare beneficiaries impacted by the demonstration</i> | 74 |
| <i>E.3.3. Demonstration claims volume and participation rate</i> | 75 |
| <i>E.3.4. Aggregate Demonstration Claims Expenditures</i> | 77 |
| <i>E.3.5. G-Code Use for Primary Focus of Visit</i> | 78 |
| <i>E.3.6. G-Code Use for Guidance Adherence</i> | 80 |
| <i>E.3.7. G-Code Use for Disease State</i> | 80 |
| CHAPTER F. VALIDATION STUDY | 82 |
| F.1. PURPOSE OF VALIDATION STUDY..... | 82 |
| F.2. METHODOLOGY..... | 82 |
| <i>F.2.1. Technical Advisory Panel</i> | 82 |
| <i>F.2.2. Developing Validity Questions and Clinical Algorithms</i> | 82 |
| <i>F.2.3. Programming of Clinical Algorithms</i> | 83 |
| F.3. INTERNAL VALIDITY OF ONCOLOGY DEMONSTRATION DATA | 83 |
| <i>F.3.1. Do cancer ICD-9 codes correctly correspond to disease state G-codes submitted for each patient?</i> .84 | |
| <i>F.3.2. Do patients have the appropriate disease state for breast cancer? Do patients have the appropriate disease status for esophageal cancer?</i> | 85 |
| <i>F.3.3. What percent of patients within each cancer type are participating in clinical trials?</i> | 89 |
| F.4. CLINICAL ALGORITHMS AND RESULTS..... | 90 |
| <i>F.4.1. Breast Cancer: Radiation Therapy</i> | 91 |
| <i>F.4.2. Breast Cancer: Surveillance</i> | 92 |
| <i>F.4.3. Colon Cancer: Adjuvant Therapy</i> | 93 |
| <i>F.4.4. Discussion of Results from Clinical Algorithms</i> | 94 |
| F.5. SUMMARY AND RECOMMENDATIONS | 96 |
| F.5. RESEARCH LIMITATIONS | 97 |





TABLE OF TABLES

| | |
|--|----|
| TABLE 1. ELIGIBLE CANCER DIAGNOSES FOR 2006 MEDICARE ONCOLOGY DEMONSTRATION PROGRAM..... | 2 |
| TABLE 2. CHARACTERISTICS OF ONCOLOGY PHYSICIAN PRACTICES PARTICIPATING IN FIELD VISITS..... | 4 |
| TABLE 3. INTERNAL VALIDITY CHECKS | 11 |
| TABLE 4. CLINICAL ALGORITHMS..... | 12 |
| TABLE 5. COMPARISON OF 2006 ONCOLOGY DEMONSTRATION FINDINGS TO PUBLISHED LITERATURE..... | 13 |
| TABLE 6. ELIGIBLE CANCER DIAGNOSES FOR 2006 MEDICARE ONCOLOGY DEMONSTRATION PROGRAM..... | 16 |
| TABLE 7. CHARACTERISTICS OF PHYSICIAN PRACTICES PARTICIPATING IN FIELD VISITS | 22 |
| TABLE 8. REASONS FOR PARTICIPATING IN THE 2006 DEMONSTRATION | 23 |
| TABLE 9. EXAMPLES OF STEPS OF TYPICAL G-CODE PROCESS | 27 |
| TABLE 10. DESCRIPTION OF G9071 FROM CASE STUDY PHYSICIAN PRACTICES VS. CMS INSTRUCTIONS..... | 28 |
| TABLE 11. FINAL DISPOSITIONS OF ALL SAMPLE CASES (N=1,219)..... | 43 |
| TABLE 12. RESPONSE RATES BY KEY MILESTONES DURING DATA COLLECTION BY BATCH | 44 |
| TABLE 13. NUMBER OF PHYSICIANS REPORTING TYPE OF CANCER IN THE TOP FIVE TREATED | 53 |
| TABLE 14. HOW DID YOU HEAR ABOUT THE 2006 DEMONSTRATION?..... | 54 |
| TABLE 15. IMPORTANCE OF THE FOLLOWING REASONS IN YOUR PARTICIPATION IN THE DEMONSTRATION | 55 |
| TABLE 16. IF YOU DID NOT SUBMIT G-CODES FOR ALL THESE QUALIFYING PATIENTS, WHY NOT? (MULTIPLE RESPONSES ALLOWED) | 57 |
| TABLE 17. DIFFICULTY WITH ONCOLOGY DEMONSTRATION PROGRAM ACTIVITIES? | 58 |
| TABLE 18. CHANGES AS A RESULT OF PARTICIPATION IN THE 2006 DEMONSTRATION..... | 61 |
| TABLE 19. PHYSICIAN PERCEPTION OF CLINICAL GUIDELINES | 62 |
| TABLE 20. PHYSICIAN PERCEPTIONS OF THE 2006 DEMONSTRATION..... | 63 |
| TABLE 21. COMPARED TO 2006, HOW FREQUENTLY DO YOU ENGAGE IN THE FOLLOWING ACTIVITIES NOW?..... | 66 |
| TABLE 22. OVERALL, WHAT IS YOUR GENERAL IMPRESSION OF THE 2005 AND 2006 DEMONSTRATION? | 67 |
| TABLE 23. 2006 DATA USE FOR ONCOLOGY DEMONSTRATION CLAIMS ANALYSIS | 69 |
| TABLE 24. BENEFICIARY COUNTS FROM CCW AND ONCOLOGY DEMONSTRATION DATA | 70 |
| TABLE 25. CALCULATIONS FOR DETERMINING "PARTICIPATION RATES" FOR 2006 ONCOLOGY DEMONSTRATION..... | 71 |
| TABLE 26. OVERALL PHYSICIAN PARTICIPATION RATE BY SPECIALTY..... | 72 |
| TABLE 27. PHYSICIAN PARTICIPATION RATE BY TYPE OF CANCER | 73 |
| TABLE 28. PHYSICIAN PARTICIPATION BY PRACTICE SETTING | 74 |
| TABLE 29. BENEFICIARY COUNT BY CANCER TYPE FROM DEMONSTRATION DATA | 75 |
| TABLE 30. DEMONSTRATION CLAIMS BY CANCER TYPE | 76 |
| TABLE 31. AVERAGE NUMBER OF DEMONSTRATION CLAIMS PER PARTICIPATING PHYSICIAN BY CANCER TYPE | 77 |
| TABLE 32. AGGREGATE DEMONSTRATION CLAIMS EXPENDITURES BY CANCER TYPE..... | 78 |
| TABLE 33. G-CODE USE FOR PRIMARY FOCUS OF VISIT | 79 |
| TABLE 34. G-CODE USE FOR SELF-REPORTED GUIDELINE ADHERENCE | 80 |





| | |
|--|----|
| TABLE 35. COMPARISON OF FREQUENCIES BETWEEN DEMONSTRATION AND SEER-MEDICARE BY CANCER..... | 81 |
| TABLE 36. INTERNAL VALIDITY CHECKS | 84 |
| TABLE 37. ALIGNMENT OF CANCER-SPECIFIC ICD-9 CODES WITH DISEASE STATUS G-CODES BY CANCER TYPE | 85 |
| TABLE 38. DISTRIBUTION OF DEMONSTRATION CLAIMS WITH INCORRECT DISEASE STATUS FOR BREAST CANCER | 87 |
| TABLE 39. DISTRIBUTION OF DEMONSTRATION CLAIMS WITH INCORRECT CHARACTERIZATION OF ER+/- | 87 |
| TABLE 40. DISTRIBUTION OF DOWN-CODED CLAIMS ACROSS G-CODES FOR ESOPHAGEAL CANCER..... | 88 |
| TABLE 41. DEMONSTRATION PATIENTS PARTICIPATING IN CLINICAL TRIALS..... | 89 |
| TABLE 42. COMPARISON OF 2006 ONCOLOGY DEMONSTRATION FINDING TO PUBLISHED LITERATURE | 94 |





TABLE OF FIGURES

| | |
|---|----|
| FIGURE 1. COMPLETION RATES BY VOLUME OF G-CODE CLAIMS..... | 46 |
| FIGURE 2. PERCENT DISTRIBUTION OF RESPONDENTS AND NON-RESPONDENTS BY CLAIMS VOLUME..... | 46 |
| FIGURE 3. PERCENT RESPONSE RATE BY STATE..... | 47 |
| FIGURE 4. PERCENT OF PHYSICIANS BY PRACTICE TYPE..... | 49 |
| FIGURE 5. DOES YOUR PRACTICE CURRENTLY USE AN ELECTRONIC MEDICAL RECORD SYSTEM?..... | 50 |
| FIGURE 6. PERCENT OF PATIENTS THAT ARE MEDICARE BENEFICIARIES..... | 51 |
| FIGURE 7. PERCENT OF PATIENTS THAT ARE CANCER PATIENTS..... | 52 |
| FIGURE 8. TO WHAT EXTENT DID CMS ANSWER YOUR QUESTIONS REGARDING THE 2006 DEMONSTRATION?..... | 54 |
| FIGURE 9. IMPORTANCE OF ADDITIONAL REVENUE BY PERCENT OF PATIENTS WITH MEDICARE..... | 55 |
| FIGURE 10. HOW OFTEN DID YOU SUBMIT A G-CODE WHEN A PATIENT HAD A QUALIFYING VISIT?..... | 56 |
| FIGURE 11. HOW OFTEN PHYSICIAN LOOKED-UP CLINICAL GUIDELINES TO CHECK G-CODE FOR PATIENT?..... | 57 |
| FIGURE 12. FOR YOU, HOW MUCH EXTRA WORK DID IT TAKE TO PARTICIPATE IN THE 2006 DEMONSTRATION?..... | 59 |
| FIGURE 13. FOR YOUR NON-PHYSICIAN PERSONNEL, HOW MUCH EXTRA WORK DID IT TAKE TO PARTICIPATE IN THE 2006 DEMONSTRATION?..... | 59 |
| FIGURE 14. NUMBER OF NON-PHYSICIAN PERSONNEL TAKING ON NEW RESPONSIBILITIES AS RESULT OF DEMONSTRATION..... | 60 |
| FIGURE 15. HOW WAS DEMONSTRATION COINSURANCE EXPLAINED TO PATIENTS?..... | 61 |
| FIGURE 16. TO WHAT DEGREE DID THE 2006 DEMONSTRATION IMPROVE OR WORSEN THE FOLLOWING AT YOUR PRACTICE?..... | 64 |
| FIGURE 17. TO WHAT DEGREE DID THE 2006 DEMONSTRATION IMPROVE OR WORSEN FINANCES BY PERCENTAGE OF PATIENTS WHO HAVE MEDICARE?..... | 65 |

APPENDICES

| |
|--|
| APPENDIX A: G-CODE DESCRIPTIONS |
| APPENDIX B: CASE STUDY PROTOCOLS |
| APPENDIX C: PHYSICIAN SURVEY FREQUENCIES |
| APPENDIX D: G-CODE USE BY TYPE OF CANCER |
| APPENDIX E: CLINICAL ALGORITHMS |
| APPENDIX F: VALIDATION RESEARCH QUESTIONS - SUPPORTING DOCUMENTATION |





A. EXECUTIVE SUMMARY

A.1. Background of the Study

The Centers for Medicare & Medicaid Services (CMS) is committed to encouraging quality in cancer treatment and cancer care. To that end, the Agency sponsored two separate demonstration programs in 2005 and 2006 to foster quality care and promote evidence-based best practices for Medicare beneficiaries. The 2005 Chemotherapy Demonstration Program, *Demonstration of Improved Quality of Care for Cancer Patients Undergoing Chemotherapy*, focused on measuring patient outcomes in three common chemotherapy-related symptoms: pain, nausea or vomiting, and fatigue.

The 2006 Medicare Oncology Demonstration Program (or oncology demonstration), *Improved Quality of Care for Cancer Patients Through More Effective Payments And Evidence-Based Care*, furthered CMS' goal by capturing information relevant to the nature of care provided to cancer patients, including their treatment and staging, the range of services they received from their providers, and whether the care provided by participating oncologists represented evidence-based best practices.

The oncology demonstration was announced in November 2005, with an implementation date of January 1, 2006. The short timeframe between the announcement of the demonstration and its implementation resulted in a small window of time to plan for and implement the year long demonstration.

L&M Policy Research (L&M) was awarded the contract to conduct an evaluation of the 2006 Medicare Oncology Demonstration Program in August 2006. The evaluation contract began in August 2006, and lasted 32 months.

A.2. Purpose of this Report

This report addresses how physicians adapted their practice to the oncology demonstration. It also provides an understanding of the impact of using evidence-based clinical guidelines to deliver care and presents lessons learned for future demonstrations involving specialist physicians. The findings are based on primary and secondary data from participating oncologists and hematologists and information collected from Medicare claims. Conclusions and recommendations based on the findings from the evaluation are also presented in this report.

A.3. Overview of the 2006 Medicare Oncology Demonstration

The 2006 Medicare Oncology Demonstration Program sought to improve the quality of cancer services and care by fostering the use of evidence-based practice guidelines and to support care that has been shown to lead to better health care outcomes. This demonstration began on January 1, 2006 and ended on December 31, 2006.





The demonstration was limited to the following physician specialties:

- Hematology (specialty code: 82);
- Hematology/Oncology (specialty code: 83);
- Medical Oncology (specialty code: 90); and,
- Gynecological Oncology (specialty code: 98).

Office-based physicians enrolled in this demonstration by billing the correct combination of G-codes (described below) along with the Evaluation & Management (E/M) service of level 2, 3, 4, or 5 for an established patient. The demonstration was limited to patients with one of 13 major cancer diagnoses, as illustrated in Table 1.

Table 1. Eligible Cancer Diagnoses for 2006 Medicare Oncology Demonstration Program

| | |
|------------------------------|---------------------------------------|
| Breast cancer | Non-Hodgkin’s lymphoma |
| Chronic myelogenous leukemia | Non-small cell/small cell lung cancer |
| Colon cancer | Ovarian cancer |
| Esophageal cancer | Pancreatic cancer |
| Gastric cancer | Prostate cancer |
| Head and neck cancer | Rectal cancer |
| Multiple myeloma | |

Eighty-one demonstration-specific G-codes were developed. A full description of the G-codes is located in Appendix A. Physicians reporting at least one G-code for each of the three categories were eligible for an additional payment of \$23.

- **Primary reasons for the evaluation and management (E/M) visit (G9050 to G9055).** The physician identified the primary focus of the office visit, including supervision of therapy and attendant toxicity management, palliation and pain control, or surveillance for disease recurrence.
- **Whether current management follows the clinical guidelines (G9056 to G9062).** The physician self-reported whether the patient’s management adhered to clinical guidelines developed by the National Comprehensive Cancer Network (NCCN) or the American Society for Clinical Oncology (ASCO) for the management of patients with that type and extent of cancer. Physicians may have indicated that the clinical guidelines were followed, or were not followed, whether there were alternative treatments due to patient preference, or when the physician did not agree with the guidelines.
- **Current disease state (G9063 to G9130).** The physician reported the status of the patient’s cancer, for example, characterizing the extent of spread of the cancer as best understood clinically at the time.

Physician participation was voluntary. While information was collected on certain aspects of the beneficiaries’ care, participating physicians were not required to obtain permission from



beneficiaries to participate in the oncology demonstration. The demonstration applied only to Medicare beneficiaries in fee-for-service (FFS) or Original Medicare; it did not include Medicare Advantage (MA) enrollees. However, the Part B beneficiary deductible and coinsurance (of \$4.60) also applied to the demonstration service.

A.4. Overview Study Design

The goals of the evaluation were to determine how oncologists and hematologists adapted their practice in response to the CMS payment incentive, to understand the impact of using evidence-based clinical guidelines to deliver care and to uncover lessons learned for future demonstrations involving specialist physicians.

The key objectives of the study included:

- Identifying reasons for physician participation and non-participation in the demonstration;
- Describing the operational and process issues impacted by participation in the demonstration;
- Documenting the prevalence of G-code use and adherence to clinical guidelines;
- Documenting the financial effect of the demonstration on physicians and the Medicare program.

This evaluation study was designed to identify factors that influenced physician participation in the oncology demonstration, as well as the effect of the demonstration on both physician practices and the Medicare program. The research team used qualitative and quantitative analyses, using both primary and secondary data. Primary data collection included:

- A national survey of physicians who participated in the oncology demonstration;
- Field visits to participating physician practices;
- Telephone discussions with non-participating physician practices.

Secondary data sources, primarily the oncology demonstration claims, were used to: 1) describe the extent of physician participation in the demonstration; 2) explore the impact of the demonstration on beneficiaries; 3) document the financial effect of the demonstration on physicians and the Medicare program; and 4) assess the extent to which reported compliance with clinical guidelines were consistent with oncology demonstration and other claims submissions.

The following sections describe the findings from each aspect of the study and then summarize the key implications and recommendations for future demonstrations.

A.5. Key Findings from Case Studies

Case studies were an important tool for collecting first-hand information from practices regarding their understanding of the demonstration. Information from these case studies captured a more detailed and nuanced picture of the demonstration implementation process and its impact at the physician practice level. Appendix B includes the protocols used to guide the discussions.

A.5.1. Characteristics of Case Study Participants

General characteristics of each oncology practice participating in the field visits are summarized in Table 2. Staff at the individual sites self-reported these characteristics including their own assessment of the level of management sophistication in their practice as either “basic”, “intermediate”, or “advanced”.

Table 2. Characteristics of oncology physician practices participating in field visits

| Region/ Site | # of Practice Sites | # of Physicians | % Medicare Patients | # of Patients Seen per Day | Practice Management Level | Electronic Medical Records |
|------------------|---------------------------|--------------------|---------------------------|----------------------------------|---------------------------------|----------------------------------|
| Midwest 1 | 2 | 6 | 80% FFS | 10-30 | Intermediate | Not in the foreseeable future |
| Midwest 2 | 9 | 4 | 59% FFS 10% MA | 22-32 | Intermediate | Not in the foreseeable future |
| Midwest 3 | 18 | 5 | 60-65% Total | 25-40 | Intermediate to Advanced | Within the next two years |
| East 4 | 1 | 4 | 30% FFS 30% MA | 20 (varies) | Advanced | Not in the foreseeable future |
| East 5 | 1 | 4 | 62% FFS 5% MA | 20 (varies) | Intermediate to Advanced | Not in the next five years |
| East 6 | 1 | 6 | 40% FFS 5% MA | 15 | Intermediate | No |
| West 7 | 1 | 4 | 40% FFS | n/a | Intermediate | No |
| West 8 | 1 | 5 | 40% Total | 20 | Advanced | No |
| West 9 | 1 | 6 | 20% FFS 10% MA | 20 | Advanced | Yes |

FFS: Fee-for-service; MA: Medicare Advantage



A.5.2. *Participation in the Demonstration*

The case studies provided insight regarding physician practices' rationale for choosing to participate or *not* participate in the oncology demonstration.

- Office managers and practice administrators were the key drivers in the decision to participate in the oncology demonstration. They gathered information on the demonstration, weighed the advantages and disadvantages of participation, and then presented their recommendations to the physicians.
- Of those choosing to participate, a majority of physicians cited the additional payment of \$23 per encounter as an important source of revenue given the reimbursement cuts experienced by their oncology practices.
- Of those choosing not to participate, many physicians reported that the additional payment offered would not have adequately compensated them for the effort required. These physicians tended to have smaller or solo practices. Given their size, they could not dedicate time or resources to the demonstration.

A.5.3. *Information Sources for the Demonstration*

Physician practices used a variety of information sources to learn more about the demonstration, including CMS.

- Many relied on other sources for information, including national specialty and state medical societies and practice administration associations. These association groups also developed tools and “cheat sheets” that summarized the G-code descriptions for use by physician practices.
- Many practices, however, developed their own tools, “cheat sheets” and training materials for the demonstration since few tools were available in advance of the demonstration's implementation.
- The level of detail, focus and precision in these tools varied from practice to practice. The lack of uniformity in the tools coupled with physicians' unfamiliarity with the detailed G-code descriptions resulted in unintentional miscoding within demonstration coding categories.

A.5.4. *Initial Implementation*

The initial implementation of the oncology demonstration posed challenges to physician practices, especially given the timeframe for implementation.

- All of the practice managers indicated that the implementation process was more intense on the front end. Most indicated that it became more routine and relatively easy to implement after the first several months of the demonstration.

-
- 
- In implementing the demonstration, practice managers were focused on making it “as easy on the docs as possible”.
 - A few pointed to the extra challenges presented by the late notice from CMS announcing the oncology demonstration. Practice administrative staff made operational and systems changes over the holidays and close to the demonstration’s implementation date.

A.5.5. Interpretation of G-Code Descriptions

During our interviews, physicians gave differing interpretations of adherence to clinical guidelines.

- A number stated that it would be easy to indicate guideline adherence for one portion of the guideline while practicing outside of the guideline for another aspect of the patient’s cancer care.
- Many physicians expressed skepticism that the demonstration data would be useful in determining compliance with clinical guidelines. They cited the potential for inaccurate and inconsistent coding of the data.

A.5.6. Recommendations from Participants

Physicians made various recommendations for improving the oncology demonstration.

- Some focused on the potential for providing physicians with feedback on how their practice compared to national and regional averages.
- A number suggested focusing future demonstrations and research on the areas of palliative care and increasing the use of evidenced-based medicine in chemotherapy treatments.
- Almost all participants emphasized the need to improve reimbursement for support services (such as care coordination, patient-support services) provided by oncology practices.

A.5.7. Implications and Recommendations for Future Demonstrations

A key finding from the case studies was the important role the practice administrative staff played in deciding whether or not to participate in the demonstration and subsequently how to implement it. Administrative staff relied on their professional and management associations for coding tools to facilitate implementing the demonstration. However, in response to the aggressive implementation timeline, some practices developed their own coding tools, which may not have captured the nuances of the detailed coding descriptions provided by CMS.

These issues raised during the case studies can be addressed by the following suggestions, which should be considered when implementing similar demonstrations in the future:

- Ensure that physician practices have a longer implementation timeline;



-
- 
- Provide an opportunity for clinicians and practice administrative staff to comment on the demonstration design to allow for refinements prior to implementation;
 - Develop uniform data collection tools to reduce the burden on administrative staff. The data collection tools developed by CMS or its designee, must be used by demonstration physicians to ensure quality and consistency of the data;
 - Pilot test the demonstration with physician practices, paying close attention to the understanding and use of the G-codes; and
 - Conduct training session with physicians (and administrative staff) to stress the importance of understanding the purpose of the demonstration, to review the coding requirements, and to emphasize the importance of collecting data in a consistent manner.

A.6. Key Findings from Physician Survey

The physician survey was conducted to gain an understanding of how oncologists and hematologists adapted their practice in response to the oncology demonstration, understand the impact of clinical guidelines on the delivery of care, and uncover lessons learned for future demonstrations. The survey was fielded between April and October 2008. A total of 526 physicians completed the questionnaire, for a response rate of 54 percent.¹ A copy of the survey with reported frequencies is located in Appendix C.

A.6.1. Characteristics of Survey Participants

- Participation in the demonstration was highly correlated with volume of Medicare claims, with 60 percent of the low claims volume physicians participating, compared to almost 96 percent of the high claim volume physicians.²
- The majority of the physicians (65 percent) worked in a group practice with a single specialty and/or worked in a physician-owned practice. Forty percent of survey participants reported greater than 50 percent of their patients were Medicare beneficiaries.
- About half of the physicians responded that greater than 75 percent of their patients were cancer patients. Overall, most physicians responding to the survey placed breast cancer in the top five cancers treated, followed by colon cancer, non-small cell/small cell lung cancer, non-Hodgkin's lymphoma and prostate cancer.

A.6.2. Participation in the Demonstration

- When asked about the reasons for participating in the oncology demonstration, over 90 percent of the physicians indicated that obtaining additional revenue for the practice,

¹ This rate was calculated based on the AAPOR RR4 (American Association for Public Opinion Research, Response Rate 4).

² Claims volume refers to total the number of *total* Medicare oncology claims submitted by the physician for the demonstration year, not just those claims submitted that included the demonstration G-codes.

following clinical guidelines, and assisting in the effort to improve quality of care, were reported as either “important” or “very important”.

- Of those responding to the survey, 83 percent had also participated in the 2005 chemotherapy demonstration.

A.6.3. Information Sources for the Oncology Demonstration

- Physicians heard about the demonstration through a variety of ways. Fifty-two percent heard about the demonstration through their own office manager or staff. Forty-five percent reported hearing about it through CMS and 33 percent through a medical association or professional society. High claim volume physicians were more likely to have heard about the demonstration through medical or professional associations.

A.6.4. Implementation and Coding Issues

- Sixty-four percent of physicians found the initial implementation “very difficult” or “difficult”.
- Coding, billing and data reporting and documentation were also found to be “very difficult” or “difficult” by over 40 percent of the participants.
- By contrast, physicians reported the following demonstration tasks as “not difficult”: determining the current disease state (91 percent); determining the primary focus of an E/M visit (78 percent); and reporting adherence to practice guidelines (64 percent).
- Eighty-four percent found that their non-physician personnel had to take on “a lot” or “some” extra work in order to participate in the demonstration. More than half reported the work involved between one and three non-physician personnel. Changes made as a result of participation included training staff and implementing new policies and procedures.
- In terms of G-code submissions, high claim volume physicians were more likely to submit G-codes when a patient had a qualifying visit than low claim volume physicians. Seventy percent of high claim volume physicians indicated they “always” submitted a G-code.
- The most frequent reason given for not submitting a G-code was a “clerical error, forms not attached” (53 percent). Other reasons for G-codes not being submitted were “documenting and reporting were time consuming” (39 percent) and “overlap in G-code descriptions made selection difficult” (28 percent).

A.6.5. Impact of the Demonstration

- Few agreed that the demonstration had improved care, although 34 percent “agreed” or “strongly agreed” with the following statement: “This demonstration promotes and improves the overall quality of care for cancer patients”. An equal percentage of physicians agreed as disagreed with the statement “The demonstration was worth the effort”.

-
- 
- More physicians disagreed (40 percent) than agreed (30 percent) with the statement “Relative to the amount of work required to document patient care and report G-codes, the compensation is appropriate.”
 - The responses differed, however, when asked whether they thought the demonstration “improved” or “worsened” aspects of their practice including patient health outcomes and process of clinical care. More than 75 percent of physicians reported the demonstration had not changed patient health outcomes, patient satisfaction or overall patient care. Seventy-three percent reported that the process of clinical care had not changed. The most change was reported in the area of finances. Forty-two percent said their finances had “improved” or “greatly improved”.
 - Overall, physicians were more likely to agree than disagree about the importance of using clinical guidelines and the majority did not find them difficult to use.
 - The majority of physicians reported that they looked up and/or followed clinical guidelines and identified the stage of the cancer with the same frequency as before the oncology demonstration. High claims volume physicians, however, reported both that they were more likely to look up clinical guidelines and use them in determining a disease state than they had before the demonstration.
 - Overall, the physicians’ rating of the 2005 chemotherapy demonstration was very similar to the 2006 oncology demonstration, with the majority of respondents rating the 2006 demonstration as “good” or “fair” (82 percent).

A.6.6. Summary and Implications

The survey results, combined with results from the cases studies and claims analysis, pointed to some interesting findings:

- Physician practices participated in the demonstration for financial reasons, with 90 percent of survey participants citing finances as their primary reason for participating. This is underscored by the survey finding that 96 percent of high claims volume claims physicians participated in the demonstration.
- Interviews with practice administrative staff for the case studies highlighted their role in implementing the demonstration and establishing procedures that were easy for physicians to follow. The survey found that 30 percent of physicians reported that non-physician staff had to take on “a lot” of extra work to participate in the demonstration compared to 11 percent of physicians who said that the demonstration required “a lot” of extra work on their part.
- Physicians reported that determining disease status was “not difficult”. Furthermore, from the validation analysis we found that participating physicians in general reported disease status codes accurately.
- During the interviews, physicians raised concerns regarding the potential for wide variations in interpreting the phrase “adherence to guidelines”. They indicated that these differing but legitimate interpretations of the phrase would make any analysis of

guideline adherence codes difficult. Survey findings indicated that of the three broad categories (e.g., primary reason for visit, adherence to guidelines and current disease state) in which codes were reported, about one-third of the physicians reported determining adherence to guidelines as “difficult”.

- Physicians indicated that they did not believe that the demonstration impacted their clinical practice or improve patient health outcomes. More than 75 percent of physicians reported the demonstration had not changed patient health outcomes, patient satisfaction or overall patient care. Seventy-three percent of the physicians reported that the process of clinical care had not changed. Furthermore, about one-third of the physicians agreed (either agreed or strongly agreed) that the demonstration promotes and improves quality of care for cancer patients.

A.7. Key Findings from Claims Analysis

The research team analyzed the Medicare claims for the demonstration period to assess 1) the level of physician and beneficiary participation; and 2) the financial effect of the demonstration on participating physicians and the Medicare program.

- Total Medicare expenditures for the 13 cancers included in the oncology demonstration were \$4.7 billion in 2006. Only a small percentage (1.4 percent) of these expenditures were for the oncology demonstration, amounting to \$66 million including beneficiary liabilities. In aggregate, beneficiary liability for the demonstration totaled approximately \$13 million.
- Approximately 5,600 physicians participated in the 2006 oncology demonstration, which meant that about two-thirds of eligible physicians took part. The average amount allowed per participating physician for the demonstration was about \$9,500.
- The 2006 oncology demonstration had a lower participation rate than the 2005 chemotherapy demonstration, which had over a 90 percent of eligible physicians participating.³
- Participating physicians reported on the full range of cancers eligible for the demonstration, with the most frequent G-codes being submitted for multiple myeloma and the least frequent being for head and neck cancer (80 percent and 59 percent, respectively).

Participating physicians enrolled in the oncology demonstration by billing the correct combination of G-codes (at least one G-code from each of the three categories) along with the Evaluation & Management (E/M) service of level 2, 3, 4, or 5 for an established patient with one of 13 major cancer diagnoses.

- Demonstration data indicated that 88 percent of the E/M visits were either Levels 3 or 4.

³ Department of Health and Human Services. Office of the Inspector General. Cost and Performance of Medicare’s 2005 Chemotherapy Demonstration Project (August 2006, OEI-09-05-00171).

- For the primary focus of the office visit category, about two-thirds of the demonstration claims were reported as visits for treatment decision-making after the disease was staged or re-staged. One-quarter of the claims were submitted for visits involving surveillance for disease recurrence. Six percent of the demonstration claims were directed toward palliation. Four percent of demonstration claims were for visits that included a work-up, evaluation or staging at the time of cancer diagnosis or recurrence.
- For the guideline adherence category, about nine of 10 demonstration claims for visits to participating oncologists indicated that their management adhered to NCCN or ASCO guidelines. In instances where physicians reported that they did not adhere to clinical guidelines, three percent indicated their management differed from guidelines for reasons associated with a patient’s comorbid illness.
- For the disease state category, the oncology demonstration data had more beneficiaries for whom participating physicians reported later stages of cancer when compared to SEER-Medicare. SEER provides cancer staging at the time of diagnosis while the demonstration data focused on the extent of the disease at the time of treatment. Since the participating physicians would tend to consult with beneficiaries later in the disease progression, it is consistent that the demonstration data include beneficiaries in more advanced stages of cancer.

A.8. Key Findings from Validation Study

The validation study provided an opportunity to test the usefulness of the oncology demonstration codes that for the first time include clinical information on disease states collected through Medicare billing system. Moreover, it allowed an opportunity to assess the ability of participating physicians to accurately report information such as primary focus of visit, adherence to clinical guidelines and current disease state of their patients. Finally, it provided an opportunity to identify lessons learned with demonstration coding in order to inform future quality improvement and reporting efforts.

A.8.1. Validity Checks of the Demonstration Data

Validity tests were used as a baseline to make sure that the demonstration codes were reasonable proxies for patient status and treatment protocols. Table 3 shows the internal validity checks that were performed prior to answering any research questions using demonstration codes:

Table 3. Internal validity checks

| |
|--|
| <p>Do cancer ICD-9 codes correctly correspond to disease state G-codes submitted for each patient?</p> <p>Do patients have the appropriate disease status for breast cancer?</p> <p>Do patients have the appropriate disease status for esophageal cancer?</p> <p>What percent of patients within each cancer diagnosis participated in clinical trials?</p> |
|--|



- Demonstration claims that had at least the three required G-codes (one from each category), including the cancer disease state codes, were analyzed to determine if the claims also contained the appropriate ICD-9 diagnoses codes. Across all demonstration eligible cancers, 97 percent of demonstration claims that contained a disease state G-code also contained the appropriate cancer diagnosis ICD-9 code.
- The number of claims that were incorrectly billed determined the patient’s initial disease status G-code. For all eligible breast cancer patients, only four percent of the claims were erroneously billed. For esophageal cancer, about 17 percent of the esophageal cancer claims were down-coded based on the initial disease status G-code.
- Another validity check explored the percentage of oncology patients participating in clinical trials. We found that about 1.7 percent of beneficiaries participated in clinical trials. This percentage is consistent with clinical trial participation rates for the elderly in the population at large, which tends to be between one and three percent.⁴

A.8.2. Development of and Results from Clinical Algorithms

In developing the clinical algorithms, the research team focused on cancers with the highest prevalence. We initially developed eight research questions to consider aspects of cancer care delivered across the continuum, from initial treatment and work-ups, monitoring, and surveillance of patients.

We present three of the clinical algorithms the research team could benchmark against peer-reviewed literature that used SEER-Medicare data, which are the most comparable data source (Table 4). The other algorithms developed did not have such benchmarks and thus the validity of the findings are difficult to assess.

Table 4. Clinical algorithms

| |
|--|
| Are breast cancer patients who have had breast-conserving surgery (BCS) in receiving radiation treatment? |
| Are physicians appropriately using mammography and magnetic resonance imaging to monitor breast cancer patients after BCS? |
| Is adjuvant chemotherapy being appropriately offered to colon cancer patients? |

- The findings from the validation study suggest that the demonstration data, when linked to the Medicare administrative data, may not accurately reflect the expected patterns of cancer care.
- Table 5 summarizes the findings from the demonstration data compared to peer-reviewed literature. In presenting the oncology demonstration findings, we compare them against studies that use SEER data that has been linked to Medicare administrative data. The

⁴ <http://www.cancertrialshelp.org/>



reported rates from the oncology demonstration data are divergent from the published literature.

Table 5. Comparison of 2006 Oncology Demonstration findings to published literature

| Clinical Algorithm | Results from 2006 Oncology Demonstration Claims | Range from Published Literature |
|---|---|--|
| % of breast cancer patients that received radiation treatment after BCS | 34% | Riley 1999 64% ⁵ Riley 2008 70% ⁶ |
| % of breast cancer patients that have received mammogram or MRI after breast-conserving surgery | 55% | Keating 2006 78% ^{7**} |
| % of colon cancer patients that received adjuvant chemotherapy | 27% | Etzioni 46% to 62% ^{8**} |

*Keating et al uses SEER-Medicare data but does not specifically provide a figure for BSC only.

**Primary source was a meta-analysis and we present the most recent data available with SEER-Medicare as the data source.

- There is a key difference between the oncology demonstration claims data and the SEER-Medicare data. While SEER-Medicare collects information on physician specialty from the administrative data, the peer-reviewed literature that we cite does not provide findings of cancer staging and disease status as reported by physician specialties. The demonstration data, instead, is based on the voluntary reporting of only four specialties. As such, the findings reflect only the participating physicians' reports during the demonstration of patients having cancer at any time during the demonstration time period.
- Since the discrepancies cannot be fully explained by constraining the data to participating physicians reporting demonstration codes, further investigation is recommended to fully understand the extent to which the demonstration data is showing an undercount. Further study and a greater understanding of the impact of the linkage between demonstration codes and claims information necessary prior to making any assumptions about expected patterns of care.

⁵ Riley GF, et al., 1999 "Stage at Diagnosis and Treatment Patterns Among Older Women With Breast Cancer: An HMO and Fee-for-Service Comparison" JAMA, 281, 8, 720-726.

⁶ Riley GF, et al., 2008 "Comparison of Diagnosis and Treatment in Medicare Fee-for-Service and Managed Care Plans," Medical Care 46, 10, 1108-1115.

⁷ Keating NL, et al., 2006 "Factors Related to Underuse of Surveillance Mammography Among Breast Cancer Survivors," Journal of Clinical Oncology 24, 1, 85-94.

⁸ Etzioni DA, et al., 2008 "Rates and Predictors of Chemotherapy Use for Stage III Colon Cancer: A Systematic Review," Cancer 113, 12, 3279-89.



-
- 
- It must be noted that this analysis focused on the oncology demonstration data and the unexpected results are not a reflection of the usefulness of Medicare administrative data to evaluate patterns of cancer care.

A.9. Implications and Recommendations for Future Demonstrations

This section reviews the lessons learned and resulting recommendations for future demonstrations. It also presents key considerations to be taken into account in future demonstration and research studies involving the collection of clinical information linked to Medicare claims data.

A.9.1. Implications for Future Demonstration Projects

Findings from the case studies and physician survey indicate that key administrative personnel are integral in the decision to participate in demonstrations involving oncology busy practices. Practice managers or administrators organized and briefed the employees, including the physicians, on how to implement the oncology demonstration. Physicians themselves depend on their staff to interpret CMS rulings and instructions, including those provided for demonstrations in which physicians play a primary role. These findings have several important implications outlined below for future demonstration projects:

- Communication materials and practice tools to implement demonstrations involving office-based physicians should address issues and concerns likely to be raised by administrative staff. Such materials need to take into account that the physicians rely on their administrative staff to summarize program requirements and develop the tools used to implement demonstrations.
- Taking the time in advance to refine G-code descriptors and accompanying instructions as well as practice tools through pre-testing with physicians, administrative staff and key professional associations well before the demonstration implementation date could significantly add value to resulting analyses.
- The appropriate level of remuneration for the tasks required of a given physician practice in any demonstration requires careful consideration.

In addition, while the oncology demonstration's coinsurance was nominal and oftentimes went unnoticed, a number of office staff expressed concern that beneficiaries would pay the coinsurance for a demonstration in which they knew very little, if anything. This was a greater issue for beneficiaries for the chemotherapy demonstration where the coinsurance amount was larger.

- CMS may want to take into account the potential impact on the beneficiaries and their role in future demonstrations, especially when the physicians, rather than the beneficiaries themselves, are choosing whether or not to participate.



B. INTRODUCTION

B.1. 2006 Medicare Oncology Demonstration Program

The Centers for Medicare & Medicaid Services (CMS) is committed to encouraging quality care in cancer treatment and cancer care. To this end, the Agency sponsored two separate demonstration programs in 2005 and 2006 to foster quality care and promote evidence-based best practices for Medicare beneficiaries with cancer. The 2005 Chemotherapy Demonstration Program, *Demonstration of Improved Quality of Care for Cancer Patients Undergoing Chemotherapy*, focused on measuring patient outcomes in three common chemotherapy-related symptoms: pain, nausea or vomiting, and fatigue. Physician practices that reported information on these symptoms qualified for an additional payment of \$130 per encounter for chemotherapy administration. Practitioners enrolled in this demonstration by reporting data on all three factors through the use of specifically developed G-codes (temporary national codes for items or services requiring uniform national coding).⁹

CMS and Medicare beneficiaries spent approximately \$275 million on the chemotherapy demonstration.¹⁰ The demonstration was criticized for its underlying purpose, the amount of the additional payment, and the value of the demonstration data collected. Critics charged that the payment amount was excessive given the amount of work involved. In addition, this payment was being used to offset reimbursement cuts. The Medicare Payment Advisory Commission recommended: “The Secretary should use his demonstration authority to test innovations in the delivery and quality of health care. Demonstrations should not be used as a mechanism to increase payments”.¹¹ Furthermore, the Office of the Inspector General concluded that the chemotherapy demonstration had an inconsistent data collection methodology, which resulted in incomplete and unreliable demonstration data on the quality of cancer care.¹²

For the following year, CMS implemented a less costly demonstration, estimated to incur \$150 million in charges for oncology services.¹³ The 2006 Medicare Oncology Demonstration Program, *Improved Quality of Care for Cancer Patients Through More Effective Payments and Evidence-Based Care*, furthered CMS’ goal by capturing information relevant to the quality of care provided to cancer patients, including their disease state and treatment, the range of services they received from their physicians, and whether the care provided represented evidence-based best practices. Participation was voluntary, and physicians reporting the information at least one G-code for each of the three categories qualified for an additional payment of \$23.

⁹ Department of Health and Human Services. Office of the Inspector General. Cost and Performance of Medicare’s 2005 Chemotherapy Demonstration Project (August 2006, OEI-09-05-00171).

¹⁰ Department of Health and Human Services. Office of the Inspector General. Cost and Performance of Medicare’s 2005 Chemotherapy Demonstration Project (August 2006, OEI-09-05-00171).

¹¹ Medicare Payment Advisory Commission. Report to the Congress on Effects of Medicare Payment Changes on Oncology Services (January 2006).

¹² Department of Health and Human Services. Office of the Inspector General. Cost and Performance of Medicare’s 2005 Chemotherapy Demonstration Project (August 2006, OEI-09-05-00171).

¹³ CMS Announces 2006 Medicare Oncology Demonstration Project. *J Oncol Pract* 2006 2:25.



The oncology demonstration was announced in November 2005, with an implementation date of January 1, 2006. The short timeframe between the announcement of the demonstration and its implementation resulted in limited time for physician offices to plan for and implement the one-year demonstration.

Instead of chemotherapy administration services, the oncology demonstration focused on physician evaluation and management (E/M) visits for established patients with certain cancers. E/M visits are frequent and essential to maintaining quality cancer care.

The demonstration was limited to the following physician specialties:

- Hematology (specialty code: 82);
- Hematology/Oncology (specialty code: 83);
- Medical Oncology (specialty code: 90); and,
- Gynecological Oncology (specialty code: 98).

Office-based hematologists and oncologists voluntarily enrolled in this demonstration by billing the correct combination of G-codes. At least one G-code from each of the three categories along with the E/M service of levels 2, 3, 4, or 5 for an established cancer patient was required for the additional payment.¹⁴ The demonstration encompassed 13 major cancer diagnoses (Table 6).

Similar to the chemotherapy demonstration, the 2006 oncology demonstration focused on clinician participation in the program, although the participation was primarily by physicians rather than nursing staff. While information was collected on certain aspects of the beneficiaries' care, participating physicians were not required to obtain permission from beneficiaries to participate in the oncology demonstration.

Table 6. Eligible cancer diagnoses for 2006 Medicare Oncology Demonstration Program

| | |
|------------------------------|---------------------------------------|
| Breast cancer | Non-Hodgkin's lymphoma |
| Chronic myelogenous leukemia | Non-small cell/small cell lung cancer |
| Colon cancer | Ovarian cancer |
| Esophageal cancer | Pancreatic cancer |
| Gastric cancer | Prostate cancer |
| Head and neck cancer | Rectal cancer |
| Multiple myeloma | |

Eighty-one demonstration-specific G-codes were developed and divided into three categories:

- **Primary reasons for the evaluation and management (E&M) visit** (G9050 to G9055). The physician identified the primary focus of the office visit, including supervision of therapy and attendant toxicity management, palliation and pain control, or surveillance for disease recurrence.

¹⁴ 70 Federal Register 70272-3 (2005).



-
- 
- **Whether current management follows the clinical guidelines** (G9056 to G9062). The participating physician self-reported whether the patient's management adhered to clinical guidelines developed by the National Comprehensive Cancer Network (NCCN) or the American Society for Clinical Oncology (ASCO) for the management of patients with that type and extent of cancer. Physicians may have indicated that the clinical guidelines were followed, or were not followed, when there were alternative treatments due to patient preference, or where the physician did not agree with the clinical guidelines.
 - **Current disease state** (G9063 to G9130). The physician reported the status of the patient's cancer, for example, characterizing the extent of spread of the cancer as best understood clinically at that time.

The demonstration applied only to Medicare beneficiaries in fee-for-service (FFS) Medicare; it did not include Medicare Advantage (MA) enrollees. The Part B beneficiary deductible and coinsurance (of \$4.60) also applied to the demonstration service. The oncology demonstration began on January 1, 2006 and ended on December 31, 2006.¹⁵

B.2. Evaluation Activities

L&M Policy Research (L&M) along with its subcontractors, American Institutes for Research, The Lewin Group, NORC at the University of Chicago, and Social & Scientific Systems, were awarded a contract to conduct an evaluation of the 2006 Medicare Oncology Demonstration Program in August 2006. The evaluation activities were jointly managed by the Centers for Medicare & Medicaid Services (CMS) and the National Cancer Institute (NCI).

The goals of the evaluation were: 1) to determine how oncologists and hematologists adapted their practice in response to the CMS payment incentive; 2) to understand the impact of using evidence-based guidelines to deliver care; and 3) to uncover lessons learned for future demonstration projects involving specialist physicians.

The key study objectives included:

- Objective 1: Identify reasons for physician participation and non-participation.
- Objective 2: Describe the operational and process issues impacted by participation in the oncology demonstration.
- Objective 3: Document the prevalence of G-code use and adherence to clinical guidelines.
- Objective 4: Document the financial effect of the demonstration physicians, beneficiaries and the Medicare program.

¹⁵ Centers for Medicare & Medicaid Services. MLN Matters: 2006 Oncology Demonstration Project. MLN Matters (MM4219).



The following combination of qualitative and quantitative research methods were used throughout the evaluation:

- **Case studies** were used to gain first-hand information from participating and non-participating physicians regarding the demonstration's implementation process and the impact of the demonstration on physician practices.
- A **physician survey** of participating providers was fielded to assess experience with and attitudes towards participation in the oncology demonstration. The primary objective of the survey was to profile the participating physicians, collect physician's experience with demonstration participation and assess physician attitudes about the demonstration and more broadly about clinical guidelines.
- A **claims analysis** was conducted to provide additional perspective on the physicians participating in the demonstration by exploring the nature and degree of their participation and the financial effect of the demonstration on participating physicians and the Medicare program.
- A **validation study** was conducted to explore the value of the data collected during the demonstration. The demonstration data provided a unique opportunity to study the advantages and disadvantages of combining clinical information (e.g., staging information) with Medicare administrative data from different settings (e.g., hospital, outpatient).





C. CASE STUDIES

C.1. Purpose of Case Studies

Case studies were an important tool for collecting first-hand information from physician practices regarding their understanding of the oncology demonstration. This approach captured a more detailed picture of the demonstration's implementation process and its impact at the practice level. The discussions explored physician practices' reasons for participating in the oncology demonstration as well as identifying barriers and challenges to participation. More specifically, the case studies explored the following aspects of the oncology demonstration:

- Physicians' understanding of the demonstration;
- Factors influencing physicians' decision to participate (or not participate);
- Physician practices' experiences with the demonstration;
- Impact of evidence-based guidelines on the quality of care provided to cancer patients; and
- Barriers to and/or challenges in participating in the demonstration.

C.2. Methodology

The research team conducted field visits between October 2006 and December 2006 with nine oncology physician practices participating in the demonstration. In addition, we conducted nine telephone interviews with physician practices that did *not* participate in the demonstration.

There were several advantages to conducting field visits with participating oncology practices. The research team was able to collect richer, more nuanced information from participating practices than could be done through a written survey. Oncologists, who rarely make the time to respond to telephone calls or written surveys, responded positively to in-person discussions. They dedicated their time during office hours to reflect on their participation in the demonstration and ways to improve it.

The field visits also provided the research team the opportunity to interview the practice administrative staff. We gained perspective on the factors that influenced the decision to participate in the demonstration and the implementation of the demonstration within the practice. Finally, the research team collected tools that physician practices used in implementing the demonstration.



C.2.1. Site Visit Methodology

The research team conducted discussions with physician practice staff most involved in the oncology demonstration. The number of staff interviewed was dependent on the size, organizational structure and management of the practice, but generally included the following:

- Oncologist(s)
- Practice administrator or office manager¹⁶
- Nurses and nurse/clinical manager
- Billing specialist
- Medical records clerk

In selecting the sites for the field visit, the research team considered practice size, region, and patient population so that they were generally reflective of the underlying relevant physician community. The research team called over 225 oncology practices to recruit participants and determine where clusters of site visits could be performed within several days.

Several interviews were also conducted over the telephone with individuals in physician practices who were unable to schedule a field visit. Individuals, generally office managers, discussed their perceptions of the demonstration and the implementation issues their practices faced. This information was helpful in refining the site visit protocol and provided context to ensure the field visits were as informative as possible.

The research team conducted a total of nine site visits with participating oncology practices: three in Pennsylvania and Virginia; three in Iowa and Nebraska; and three in Colorado. At least two L&M team members participated in each site visit, with one participating in all nine to ensure continuity. The interviews lasted between two to three hours, and included at least 20 minutes with one or more oncologists in the practice.

The research team used a semi-structured protocol to guide the discussions with multiple staff at each site. The protocol was reviewed and approved by CMS and NCI. A copy of the protocol is provided in Appendix B.

C.2.2. Characteristics of Site Visit Participants

All of the physician practices interviewed were single specialty oncology practices and those in the Eastern and Western regions had only one practice location. Several of these oncology practices, while independent, were associated with a national oncology practice management group. The three practices visited in the Midwest included physicians who covered multiple sites, from two to 18. Physicians covered these sites, located in small, rural community hospitals,

¹⁶ Generally, the practice administrator or office manger was present for the field visit and provided a tour of the practice once the interviews were completed.

one day per week (or month). The research team also conducted a site visit to the regional office of an oncology practice management group, which represented over 50 oncologists in the region.

The practices ranged in size from four to six physicians. The average number of patients seen per day by oncologists at the different sites and within a practice varied from between 15 and 40. Staff size varied, from 17 to over 30 staff, depending upon the level of chemotherapy and other services offered at the site.

At least half of the sites had Pixus[®] machines in their chemotherapy areas (for automatic pharmacy dispensing), and two had pharmacy technicians on site to mix the medications rather than depending on the nursing staff. One site had an advanced imaging technology suite within the practice. That site, as well as the other site that was part of a regional and national oncology network, offered MRI services through a mobile unit on site once a week.

All practices visited considered themselves at either an intermediate or close to an advanced level of practice management. While only one of the practices visited had an operating electronic medical records (EMR) system, most envisioned moving in that direction in the next five years. One additional practice that was part of the same national oncology practice management organization anticipated adopting the same system as the one in place at its sister practice within two years.

General characteristics of each of the oncology practices participating the case studies are summarized by region in Table 7.

C.2.3. Interviews with Non-Participating Physicians

Non-participating oncology practices were identified via universal provider identification numbers (UPIN) that were matched to the 2006 demonstration claims. Through this process, physicians without demonstration G-code submissions were considered non-participating physicians. The research team initiated calls to physicians from this list and scheduled interviews with them through their administrative staff. Front-office staff often simply indicated they “*do not participate in surveys*”. Others asked that additional information regarding the study be sent via email. Many simply did not return phone calls. After sending information describing the study to several physicians by email and by telephone, nine interviews were scheduled with non-participating physicians.

These interviews were primarily conducted with an oncologist or the practice office manager in Colorado, Georgia, Illinois, Iowa, Nebraska, New York, Pennsylvania, Texas and Washington State. The practice size of those interviewed ranged from two to six physicians, and all but one of the practices interviewed had participated in the 2005 chemotherapy demonstration.

Table 7. Characteristics of physician practices participating in field visits

| Region/ Site | # of Practice Sites | # of Physicians | % Medicare Patients | # of Patients Seen per Day | Practice Management Level | Electronic Medical Records |
|-----------------|---------------------------|--------------------|---------------------------|----------------------------------|---------------------------------|----------------------------------|
| Midwest 1 | 2 | 6 | 80% FFS | 10-30 | Intermediate | Not in the foreseeable future |
| Midwest 2 | 9 | 4 | 59% FFS 10% MA | 22-32 | Intermediate | Not in the foreseeable future |
| Midwest 3 | 18 | 5 | 60-65% Total | 25-40 | Intermediate to Advanced | Within the next two years |
| East 4 | 1 | 4 | 30% FFS 30% MA | 20 (varies) | Advanced | Not in the foreseeable future |
| East 5 | 1 | 4 | 62% FFS 5% MC | 20 (varies) | Intermediate to Advanced | Not in the next five years |
| East 6 | 1 | 6 | 40% FFS 5% MA | 15 | Intermediate | No |
| West 7 | 1 | 4 | 40% FFS | n/a | Intermediate | No |
| West 8 | 1 | 5 | 40% Total | 20 | Advanced | No |
| West 9 | 1 | 6 | 20% FFS 10% MA | 20 | Advanced | Yes |

FFS: Fee-for-service; MA: Managed Advantage

C.3. Findings

C.3.1. Reasons for Participating in the Oncology Demonstration

Administrative staff were asked about their reasons for participating in the oncology demonstration (Table 8). Every physician practice indicated that financial reimbursement was a key factor in their decision to participate. All but one site indicated that the \$23, while not commensurate with the work involved in the demonstration, was a monetary incentive that could not go uncollected. Each practice, without prompting, mentioned increased financial pressure on their practices given recent changes in reimbursement. Some participants commented:

“I pushed our docs into participating. They were hesitant since it seemed like a lot of work for very little reimbursement. I pointed out how much each \$23 adds up to if you see 25 patients each per day times the four docs in our practice.”

“We sat down and figured out in terms of dollars with all cuts we have taken and anticipated beginning in January 2006, we simply needed the money.”



Table 8. Reasons for participating in the 2006 demonstration

| |
|---|
| Financial reimbursement to improve revenue stream; |
| Commitment to cooperate with government initiatives; |
| Commitment to quality of care through clinical guidelines; |
| Gaining experience in any possible pay-for-performance initiatives; |
| Fear of appearing uncooperative to CMS |

A recommendation to participate in the oncology demonstration was normally made by the administrative staff (e.g., the office manager or practice administrator) and then presented to physicians in the practice for discussion during weekly or monthly staff meetings. These managers generally had already thought through how to make implementation “*as easy on the docs as possible*” before recommending that the practice participate in the demonstration.

Other reasons for participating in the demonstration included: a commitment to cooperating with government initiatives, an interest in gaining experience with demonstrations related to pay-for-performance (P4P) initiatives and improving quality of care through the use of clinical guidelines. Finally, a few staff members expressed fear that had they chosen not to participate, Medicare would have viewed them as uncooperative and potentially less desirable participants in future demonstrations.

C.3.2. Reasons for Not Participating in the Demonstration

Inadequate compensation was the key driver in the decision not to participate in the oncology demonstration among those interviewed. Several of the physician practices conducted a financial analysis or time and motion study to determine whether or not to participate. All were aware of the smaller incentive associated with the oncology demonstration compared to the chemotherapy demonstration. The decrease in reimbursement was of particular concern since the demonstration required more of the physician’s time than the chemotherapy demonstration. Some participants commented:

“It looked like it was too technically demanding compared to what we would be paid for.”

“It looked too paper and time intensive for the return associated with it. We did participate in 2005 because it was more straightforward and also involved less of the physician’s time.”

Similar to those practices choosing to participate in the demonstration, the administrative staff and the physicians jointly made the decision not to participate. Some perceived that the physician reporting and documentation requirements would take away time from providing care to patients. Other reasons for non-participation included the perception that there was too much additional paperwork involved for physicians and administrative staff. Some practices were hesitant to have to create new “cheat sheets” for the physicians or change codes in the billing system for a temporary demonstration. One oncology practice indicated that their charge system could not



easily track the demonstration codes. Given the costs associated with manually tracking the codes, this practice reported that the reimbursement was inadequate.

Several of those interviewed indicated their decision may have been different had one or more of the following occurred:

- Increase in reimbursement for participation;
- Improved communication of the value and reasons for the demonstration;
- Provision of additional tools and materials, such as “cheat sheets” to use in their practices;
- Explanation that there would be no penalties associated with errors in demonstration coding submissions; and
- Clarification of the potential time and resources required for participation in the demonstration.

Regardless of the rationale for choosing not to participate in the demonstration, these practices did not revisit their decision at a later time during the demonstration year.

C.3.3. Sources of Information for Participating in Oncology Demonstration

Oncology practice staff used multiple sources of information to learn more about the demonstration and included:

- CMS
- National specialty societies (e.g., American Society of Clinical Oncology, Community Oncology Alliance)
- State medical societies
- Practice administration associations (e.g., Administration in Oncology/Hematology Assembly)

Physicians and office managers obtained additional information on the oncology demonstration from conferences and informal discussions with colleagues. Some mentioned that the program guidance was released too close to the implementation date, resulting in delays of tools being developed by medical societies and associations. Generally, the practices found the checklists developed by a third party to be very helpful. Those choosing to create their own checklists generally did so because they wanted to have them available to use on the first day of the demonstration’s implementation.

When asked about the informational materials from CMS, almost all practices interviewed found them helpful and indicated they had no unanswered questions. Several participants indicated that CMS should have provided such tools prior to the implementation start date.



C.3.4. Perceptions of the Demonstration's Purpose and Value of Data Collected

Physicians and administrative staff provided a wide range of perceptions about the main purpose of the oncology demonstration. Most administrative staff focused on the reimbursement aspect of the demonstration. Some believed its purpose was to offer additional reimbursement to offset payment cuts experienced by oncology practices. Both administrative and physician staff reported that collecting the information was a way of showing that the practices were providing something in return for the additional funding.

Physicians echoed their administrative staff's perception that the purpose of the demonstration was an offset to reduced oncology reimbursement. Some physicians further explained that the government was collecting data for several purposes, including studying how oncology practices worked, determining how best to implement P4P programs and exploring ways to contain oncology costs.

Several physicians also speculated that the oncology demonstration was designed to increase the use of clinical guidelines and/or potentially to identify problem providers. These physicians maintained that because the demonstration was voluntary, it was not targeting clinicians who needed the most encouragement to use clinical guidelines. They speculated that the individuals not practicing standards of care were less likely to be full-time oncologists or in the large practices where guideline adherence is standard.

When probed further about the potential value of the data collected and how it might be used, some physicians expressed skepticism regarding the demonstration's ability to improve the quality of cancer care given that the data was self-reported. Others were concerned that the sample size for the demonstration may be too small to allow for conclusive findings. More importantly, many physicians expressed concern that the program design left too much potential for inaccuracy or inconsistencies in physician reporting of demonstration data.

C.3.5. Implementation Process and Challenges

All of the sites had participated in the 2005 chemotherapy demonstration and indicated that the 2006 oncology demonstration was more challenging to implement. Physicians were responsible for the demonstration coding in the 2006 demonstration as opposed to the nursing or administrative staff (who were allowed to complete the coding for the 2005 demonstration). In addition, the oncology demonstration had a greater number of codes than the chemotherapy demonstration. There were 81 G-codes in the 2006 demonstration compared to 12 G-codes in the 2005 demonstration.

For the oncology demonstration, administrative staff created new procedures and integrated demonstration coding to the practice's existing billing and documentation system. This required time from many practice staff, from the front desk staff to the billing staff. Many expressed frustration with the change in focus between the 2005 and 2006 demonstration, which required staff resources to implement new codes and procedures for the year-long duration of the demonstration.

All of the administrative staff commented that the compensation was not commensurate with the work required. They often compared the level of reimbursement between the chemotherapy demonstration and the oncology demonstration. Many indicated a preference for redistributing demonstration funds rather than sponsoring brief demonstrations. Staff suggested applying the resources directly towards chemotherapy or support services. They viewed these services as inadequately reimbursed and were important to delivery of quality cancer care.

The Process

As mentioned above, the decision-making process to participate in the oncology demonstration was made jointly by the physicians and practice administrators. Practices that chose to participate generally decided to do so across the board, for all of the physicians in the practice and for all the eligible cancer diagnoses. Administrative staff emphasized the importance of simplifying the process for their busy physicians.

Several common tasks were identified to initially implement the demonstration. The tasks took varying degrees of time and resources on the part of practice administrative staff and included:

- Training physicians and non-physician personnel;
- Amending billing system to include new G-codes;
- Creating and/or using tools or “cheat sheets” from various sources (these were either diagnosis-specific or one sheet for all diagnoses);
- Establishing processes for identifying and documenting eligible demonstration patients;
- Implementing “check and balance” system to ensure G-codes are complete;
- Monitoring secondary insurance submissions and G-code claim denials;
- Collecting unpaid coinsurance (for practices that chose to collect them).

Each oncology practice site interviewed had developed a slightly different approach to identifying eligible patients. Some had an automated system for identifying the payer on their practice’s “superbill” (patient encounter form) prior to the demonstration.¹⁷ Other systems automatically produced the most recent diagnosis on the superbill, allowing the staff to quickly identify eligible patients by diagnosis. Those physician practices without automated systems had to identify patients by payer or diagnosis, resulting in significant operational adjustments to implement the demonstration. In addition, these practices had to train their medical records and front desk staff in procedural changes. This was further complicated by the fact while the payer

¹⁷ Superbills varied by practice but functioned as patient encounter forms. They generally included basic patient and payer information as well as a list of the top codes billed by the practice with space for unusual codes and comments. These sheets were then attached to the front of the chart and used by staff throughout the visit to document services provided and the corresponding codes. At the end of the visit, the superbill was normally detached from the record, with at least one copy going into the record and one to the billing office staff, depending on the individual office’s standard operation. Some practices chose to amend their superbill, while others used an additional form designed specifically to document G-codes associated with the demonstration.

was Medicare, not all beneficiaries were eligible for the oncology demonstration. Only fee-for-service beneficiaries were eligible for the demonstration; Medicare Advantage beneficiaries were excluded from the demonstration.

A typical process generally followed by those sites with some existing automation in place is described in Table 9. As part of this process, physicians were generally provided a document in which they would check one G-code for each of the required categories (e.g., reason for visit, staging, and guideline adherence).

Table 9. Examples of steps of typical G-code process

| Step | Activity | Responsible Staff |
|------|--|-------------------|
| 1 | Identify Medicare patient from medical record on superbill | Front desk |
| 2 | Highlight Medicare patient eligibility on superbill | Front desk |
| 3 | Add new G-code charge slip or cheat sheet (based on previous or anticipated diagnosis) with record for physician | Front desk |
| 4 | Collect coinsurance from patient (if practice chose to do so) | Front desk |
| 5 | Confirm eligibility and selects G-codes for billing | Physician |
| 6 | Review charge slip for accuracy and completeness and follows-up with physician, if needed | Billing |
| 7 | Review and manage denied claims | Billing |

At one oncology practice site, physicians were provided a reference chart that summarized the demonstration G-codes. Physicians then hand wrote the appropriate codes on the superbill. This and other management decisions at this site (which was also less automated in other ways) resulted in more time being required by both the physicians and administrative staff in demonstration implementation.

Regardless of the process followed, physicians rarely read the full instructions available from CMS. They instead relied on the summary tools provided by their administrative staff. One physician explained:

“Keep in mind even if the [G-code] descriptions were laid out in detail somewhere in the CMS paperwork, many of us never saw the original detailed descriptions and instead only saw a summary sheet that could be attached to the patient encounter form.”

Often, this summary information in the form of a “cheat sheet” or other tool did not provide a sufficient level of precision to ensure that the coding was consistent with the demonstration guidelines. Some physician practices provided their staff with abbreviated formats of the demonstration codes. Table 10 provides an example of how some practices characterized G9071, which is related to female breast cancer:

Table 10. Description of G9071 from case study physician practices vs. CMS instructions

| Description of G071 (breast cancer) | Source |
|--|-------------------------------|
| Oncology; disease status; invasive female breast cancer (does not include ductal carcinoma in situ); adenocarcinoma as predominant cell type; Stage I or Stage IIA-IIB; or T3, N1, M0; and estrogen-receptor (ER) and/or progesterone-receptor (PR) positive; with no evidence of disease progression, recurrence, or metastases | CMS guidelines ¹⁸ |
| “Stage 1-2B, ER/PR POS or T3, N1, M0, Stable” | Case study physician practice |
| “Onc Dx breast Stg 1 or Stg IIA-IIB HR no progression” | Case study physician practice |
| “Onc Dx brst Stg 1-2B no dx pr” | Case study physician practice |

Some physicians made incorrect assumptions about the coding. For example, one physician indicated using G9050 for any work up, not just those at the time of diagnosis or staging, rather than G9051 for established patients. The summary sheet provided by his or her staff did not convey this distinction. Another physician indicated using G9056 rather than G9057 to indicate guideline adherence when a patient was involved in a clinical trial. While the detailed description specified G9057 for clinical trial participation, this physician indicated that the NCCN guidelines consider participation in clinical trials to be within guidelines.

Physician Engagement

The primary focus of administrative staff with regard to the oncology demonstration was to simplify the implementation and documentation process for physicians. This was especially important, as many administrative staff noted, because the 2005 chemotherapy demonstration required little physician participation and comparably simpler coding and documentation requirements for significantly greater reimbursement.

The oncology demonstration however required physician participation in a significant way. Physicians had to confirm disease state (including diagnoses and staging), clinical guideline adherence (or not) using the demonstration coding as well as documenting this information in each patient’s medical record.¹⁹ Administrative and physician staff often expressed divergent impressions of the degree to which implementation was a challenge. Administrative staff were generally responsible for ensuring a smooth implementation. Physicians were often unaware of the implementation challenges faced by their administrative staff and the additional effort required to ensure that the correct patient records were flagged in advance and at least three G-codes were provided by the physicians for each patient visit.

¹⁸ Centers for Medicare & Medicaid Services. MLN Matters: 2006 Oncology Demonstration Project. MLN Matters (MM4219).

¹⁹ Physicians were instructed that in addition to the G-codes being submitted to CMS, they also needed to document in the patient chart to which clinical guidelines were being adhered to or the reason for non-compliance.



Initial Implementation

One reason the oncology demonstration was viewed as more challenging to implement than the chemotherapy demonstration was the number of coding choices for each patient (81 G-codes in 2006 compared to 12 G-codes in 2005). The 2005 chemotherapy demonstration was specific to the chemotherapy services and primarily handled by chemotherapy nurses who did not have to perform additional tasks or reference clinical guidelines. For some oncology practices, the identification of eligible Medicare patients by diagnosis at the front end had not previously occurred, so this required changes in procedures by the front office and medical records staff as well as that of physicians.

All sites visited found implementation more “difficult” for the first month or so, but indicated that later the process became more “routine”. During the initial implementation period, staff needed to follow new procedures, flag appropriate charts based on likely diagnosis, include G-code sheets in the charts for the physician’s notations, and follow-up with physicians when entries were confusing or missing. The new demonstration codes needed to be loaded into the system for billing soon after they were received (over the holidays). For some practices, the G-codes needed to always be listed within the top 10 lines of the electronic claim to ensure appropriate reimbursement. Physicians reported that during the first month or so it seemed that there were “too many G-codes”. They however became familiar with the codes and were able to report the information easily, taking only a few extra minutes of their time for each patient.

G-Code Descriptors

Physicians interviewed were asked to describe their experience with the demonstration G-codes. Several physicians indicated that the G-code descriptors were sometimes ambiguous. They also expressed discomfort with using G9055 for “unspecified service, not otherwise listed” because it provided limited information and value. Some physicians reported using another G-code rather than selecting the unspecified option for both the primary focus of the visit (G9055) or guideline adherence (G9062).

Several physicians indicated that it was unclear whether chronic lymphocytic leukemia (CLL) should be considered as part of non-Hodgkin’s Lymphoma or excluded from the demonstration. One physician commented:

I didn’t think of putting in CLL as non-Hodgkin’s or a lymphoma, even though it could be classified as leukemia or lymphoma...I did not initially see CLL. It would have been better to clarify that [CLL was included or not].

The research team collected “cheat sheets” that summarized the demonstration codes from individual practices and other organizations. Many of the cheat sheets did not include the cancer ICD-9 diagnosis codes that correspond to the eligible cancers. The CMS instructions include the ICD-9 diagnosis code for each cancer eligible for the demonstration. For non-Hodgkin’s lymphoma, the ICD-9 codes that are relevant are 202.00-202.08, 202.80-202.98, but the ICD-9 code for CLL is 204.1, indicating that CLL was not an eligible cancer for the demonstration.

Over time, physicians reported developing their own approach for consistently working with the G-code descriptors provided, and after the first month or so of implementation, all those interviewed commented that they had become efficient in G-code selection.

Finally, some physicians were concerned that, given their fast-paced environment, they may not have had the time to look up the clinical guidelines for each patient, and as a result may have selected an incorrect G-code. One physician explained:

“We (hematologists/oncologists) are not anywhere near fully familiar with NCCN guidelines. I never once stopped what I was doing during a patient encounter to check on exact guidelines. Rather, I used my best judgment (inexact I am sure).”

Some physicians commented that while it was easy to comply with clinical guidelines, the G9056 or “management adheres to guideline” could mean a number of things depending on the patient’s condition and needs. The demonstration code reported may also differ due to individual physician interpretation, given two similar patients presenting the same circumstances. Furthermore, physicians interpreted the demonstration code for adherence to guidelines in varying ways, from very strictly to very loosely. However, physicians reported that they were providing care according to established “standards of care”. For instance, it is possible that some patients were receiving treatment and care for which multiple aspects of a given guideline were applied. Many of the clinical guidelines are complex, with different branches provided for different aspects of the patient’s care. In these instances, a physician could indicate clinical guideline adherence for an area where he or she *was* practicing within guidelines, but not reference the additional drugs or treatment being prescribed *outside* the guidelines. Given these issues, some physicians concluded that the demonstration codes may not have enough specificity to indicate which aspect of a given clinical guideline is or is not being followed, and to what extent. Finally, some physicians reported that the ASCO and NCCN guidelines were also not always consistent, which may have skewed the demonstration findings.

Patient Coinsurance for 2006 Demonstration

During the site visits, staff indicated there were substantially fewer inquiries regarding coinsurance for the 2006 oncology demonstration as compared to the 2005 chemotherapy demonstration. This was in large part due to the smaller coinsurance required (\$26.00 in 2005 versus \$4.60 in 2006). Some practices chose not to collect this amount because they felt patients should not have to fund the demonstration. In addition, many physician practices expressed concern about the total amount that patients were paying out-of-pocket for chemotherapy drugs and other coinsurance, and viewed that this was an unnecessary and inappropriate burden for those patients. For the practices that initially balance billed patients for demonstration coinsurance, many said that they made no effort to collect that portion of a patient’s bill if the patient did not pay it after the first statement. Instead, oncology practices generally “wrote it off”.



Denial Management

Several practices indicated that soon after implementation, they found that it was important to list the G-codes early (within the first 10 lines) on the electronic claim to ensure that all of the G-codes were considered part of the same claim. One practice experienced repeated problems with denied claims because the primary focus of the visit code, and/or the staging or adherence code were not on the same “claim” as the E/M codes with which they were reported due to the system automatically splitting electronic claims at line 13. Staff reported that they did not encounter this issue with the 2005 chemotherapy demonstration.

Clinical Decision Support and Billing Systems

None of the practices visited made software changes in their billing or data entry systems aside from adding the new G-codes at the beginning of the demonstration year. Only one of the practices visited used a clinical decision support system (which was still in developmental stages) designed specifically for oncology patients. This system was connected to their EMR and offered prompts for physicians to ensure that they had completed all of the appropriate G-code information and had carefully reviewed the applicable clinical guidelines.

C.3.6. Clinical Practice Guidelines

Defining Clinical Guidelines, Guideline Adherence and Best Practices

Interviews with physicians revealed differing nomenclature used within the context of “clinical guidelines”. None of the physicians interviewed described clinical practice guidelines as defined by Field and Lohr, “systematically developed statements to assist practitioners and patient decisions about appropriate health care for specific circumstances”.²⁰ Some physicians were very specific in their definitions, particularly those who participated in clinical research or clinical trials. When probed, all of them recognized the difference between general guidelines and clinical protocol. However, the following terms were frequently used interchangeably by many of the physicians interviewed to describe clinical guidelines:

- Standard of care
- Best practices
- Evidence-based medicine
- Evidence-based guidelines
- Clinical pathways
- Clinical guidelines (e.g., www.UpToDate.com or www.adjuvantonline.com)
- Quality patient care

²⁰ Field MJ, Lohr MJ, eds. *Clinical Practice Guidelines: Directions for a New Program*. Washington, DC: National Academy Press: 1990.

Within the context of adherence to clinical guidelines, the meaning of this varied significantly among the physicians interviewed. Some physicians indicated checking “adheres to guidelines” even though they “went beyond” the clinical guidelines due to more current evidence. They explained that this was the appropriate selection since treatment that went “over and above” the guidelines would likely be adopted in the next updated clinical guidelines.

Other physicians reported checking “adherence to guidelines” (G9056) since they always practiced a “high standard of care, consistent with evidence-based medicine”. However, physicians reported that they often did *not* review the applicable ASCO or NCCN guidelines to ensure that their treatment decision was within the clinical guidelines. Some physicians said: “*The guidelines are pretty much already in our heads*”. They felt no need to look up the specific guidelines before checking whether or not they adhered to guidelines. Some physicians maintained that any oncologist providing quality care would be following the guidelines or the care would not be paid for or would be considered inappropriate.

Other physicians indicated that they only refer to the clinical guidelines for a patient with a diagnosis with which they were not as familiar. Some physicians said that their fast-paced environment limited their ability to look up the guidelines for each patient. For these physicians, they only checked the “management differs from guidelines” (G9057 to G9062) if they were consciously going outside of their normal approach to treatment due to circumstances unique to that patient. A few physicians said they would check the “guideline adherence” even if one of the applicable guidelines for that visit was not followed, since usually at least some aspect of the care was provided within a certain portion of the guideline.

When probed, a few physicians indicated that they reviewed clinical guidelines more often since the oncology demonstration. There seemed to be an apparent split in terms of the frequency with which physicians referred back to the ASCO or NCCN guidelines depending on the number of years in practice. Physicians with fewer years of experience reported being more in the habit of referring regularly to clinical guidelines.

Perceptions of ASCO and NCCN Guidelines

Most physicians acknowledged the credibility and helpfulness of ASCO and NCCN clinical guidelines for infrequent diagnoses (i.e., rectal cancer or head and neck cancer). However, the usefulness of clinical guidelines varied depending on those used. Most oncology practices interviewed referred more frequently to the NCCN guidelines rather than those from ASCO. Many physicians mentioned they found the explanatory narrative accompanying the clinical guidelines more valuable than the decision trees provided. They also noted the broad nature of the clinical guidelines, citing how divergent treatments could be provided with varied results and still be considered “within the guidelines”.

All physicians interviewed spoke of the importance of keeping abreast of recent findings and the accumulation of evidence-based medicine that resulted in the clinical guidelines, by their nature, being sometimes “out-of-date”. Others noted that numerous drugs are often included in the clinical guidelines despite significant differences in efficacy, making the guidelines less helpful.

Some of the older physicians interviewed were more skeptical of the value of clinical guidelines. They explained that clinical guidelines are “too broad and lack the needed specificity” to address the complexities of their patient treatment planning. One physician reported that when he faces a challenging case, he relies on the opinion of knowledgeable colleagues at respected cancer centers than on the clinical guidelines. Others indicated the clinical guidelines fail to address the next steps following failed treatment plans or multiple co-morbidities. A physician commented, *“It is helpful for the beginners but not helpful in difficult situations.”*

C.4. Impact of Demonstration

The physicians interviewed had varied responses on the impact of the oncology demonstration on patient care. Most believed that the oncology demonstration had little or no impact on patient care since they were already providing the best care to their patients. A few indicated that they were now more careful in reviewing clinical guidelines. In terms of the financial impact of the demonstration, many physicians did not feel that establishing the codes and systems for the demonstration were commensurate with the payment.

C.5. Interviewee Recommendations and Improvements to the Demonstration

Each of the physicians and practice managers at the conclusion of the interview were asked to provide their recommendations for improving the demonstration. In addition, they provided their suggestions on how to improve the delivery of cancer care. Specific suggestions included:

- **Make the payment for the demonstration commensurate with the costs of implementing it:** All of the administrative staff interviewed made this recommendation. They reiterated that it was more important to appropriately compensate practices for specific services being provided rather than implementing demonstrations.
- **Expand the demonstration to all cancer diagnoses:** Some suggested that this expansion would make the demonstration less confusing and provide for more comprehensive data.
- **Expand the demonstration to all specialties providing cancer care, and/or mandating participation to include “problem practices”:** Some theorized that the “problem docs” would most likely not participate in this voluntary demonstration. Thus, the demonstration did not provide incentives to those who may need to use clinical guidelines. Others indicated that some “non-oncologists” provide cancer care but are less familiar with the clinical guidelines. These providers should be included in future demonstrations since they should be familiar with clinical guidelines.
- **Limit the focus of any analyses to specific diagnoses and treatments based on prevalence and cost:** This was a suggestion repeated by most physicians when asked what they would do if they could work with the demonstration claims data. While physicians recognized some limitations in the data collected given the issues related to definitions of adherence, they reported interest in exploring the results. One also

mentioned the value of linking the information from the 2005 and 2006 demonstrations because the combination of staging information with the responses of patients to treatment would be especially powerful.

- **Provide feedback to physicians on national norms for guideline adherence by diagnosis:** Several physicians believed it would be helpful to have information regarding their performance and comparisons to their peers with regard to the demonstration. They speculated that if physicians found they were practicing outside of the norm, this information would make them look more closely at their clinical practice patterns.
- **Focus on cancer metastasis rather than early stage for the validation study:** Several physicians believed that given the demonstration data, it would be especially important to limit the area of focus of the validation study. They recommended focusing on aspects of the clinical guidelines that involved treatment of metastases rather than those in the early stages, since these are often more complex and expensive.

C.6. Future Demonstrations and Health Care Reform

In terms of future demonstrations related to cancer, and finding other ways of improving cancer care, several other suggestions were made repeatedly:

- **Focus more on the areas that are likely to result in improved efficiencies (e.g., eliminate duplicative testing) and quality of life (e.g., palliative and hospice care):** Several physicians suggested that a more efficient way of identifying problem areas in cancer treatment were needed, such as examining areas where there are excessive testing and diagnostic work-ups, such as diagnostic imaging.
- **Focus more on the area of palliative care to prevent the delivery of unnecessary and ineffective care through education:** Both administrators and physicians suggested that additional effort is needed to assure quality care to patients receiving palliative care. They suggested that palliative care could be managed more effectively and provide patients with better quality of life if additional attention was given to the time when aggressive treatments are no longer likely to be successful (for example, finding ways to help both practitioners and families confront issues related to end of life care or encouraging earlier referrals to hospice care).
- **Explore patient non-compliance with recommended treatment regimens:** Several suggested further research to determine the reasons why patient do not follow the recommended treatment. They speculated patient non-compliance was another reason why physicians may report that they did not adhere to guidelines.
- **Improve reimbursement for support services to encourage best practices:** Almost all those interviewed mentioned the importance of cancer support services. These support services are not currently recognized in the payment system because they are not directly clinical in nature, but are vital to the successful treatment of a patient by helping maintain

quality of life during and after treatment. Many suggested changing the payment system so that it encourages providers to focus on patient quality of life throughout the progression of the disease.

C.7. Research Limitations

Qualitative research aims to provide in-depth narrative results. It allows researchers to ask open-ended questions, as well as appropriate follow-up questions, to gain a more comprehensive picture of participants' understanding, attitudes, and experiences. However, because these discussions are conducted with a limited number of participants, the team cannot know whether these results are representative of all individuals within a segment. In-depth discussions with participating physician practices, on the other hand, provided a complete description of a few participants' experience, including the specific problems encountered, their impact, and the steps taken to address them. In selecting the oncology practices to be visited, the research team made every effort to include practices that are generally reflective of the underlying physician community.

The following outlines some limitations of the case study research:

- **Timing of evaluation contract award:** Due to the timing of the contract award for the evaluation of the demonstration, the site visits were conducted at least nine months following the implementation of the oncology demonstration. Thus, recollections of the challenges during implementation were limited by participants' ability to recall the specific issues that arose the previous December 2005 and early January 2006. By the time the site visits were conducted, most implementation challenges had long since been worked through.
- **Potential under-representation of solo practitioners and those in multi-specialty practices:** A number of solo practitioners in rural areas chose not to participate in the case study interviews due to their own limitations in terms of administrative staff and resources. We were nonetheless able to interview physicians who regularly provided care in multiple rural settings several days a week. In addition, none of the sites visited for this evaluation were part of multi-specialty groups.
- **Voluntary participation:** As with all voluntary research participation, it is possible that the individuals who chose to participate were more interested in or familiar with the subject area, and/or had stronger opinions (either positive or negative) about the discussion topics than those who declined to participate. Specifically, the participating oncology practices reflected:
 - a special interest in the demonstration and the future direction of Medicare cancer policy;
 - a desire to learn more about the government's focus on clinical guidelines and potential P4P programs;
 - staff who were responsive and efficient in terms of practice management;

-
- 
- both administrative and physician staff involved in professional associations (oncology management, oncology medical societies);
 - a greater frequency of participation in clinical trials than other oncology practices.



CHAPTER D. PHYSICIAN SURVEY

D.1. Purpose of Physician Survey

The purpose of the physician survey was to determine how oncologists and hematologists adapted their practice in response to the oncology demonstration, to understand the impact of using clinical guidelines to deliver care, and to uncover lessons learned for future demonstrations involving specialists. The primary objectives of the physician survey were to:

- Profile demonstration physicians
- Collect the process experiences associated with participation
- Assess physician attitudes about the demonstration
- Assess physician attitudes about evidence-based clinical guidelines

D.2. Questionnaire Development and Questionnaire Testing

The research team developed a draft survey instrument based on the goals of the evaluation. Prior to the data collection, the questionnaire was tested with five physicians who participated in the 2006 Medicare Oncology Demonstration Program. The goals of the questionnaire testing were to assess comprehension, recall, response process, and identify problems. Questionnaire testing was conducted in November 2006.

During scheduled one-on-one telephone calls, the physicians completed the questionnaire and then were led through a respondent debriefing. In addition to verbal feedback provided during the debriefing, the completed physician questionnaires were reviewed. Overall, the participants thought the questionnaire was easy to complete and did not need help from their office staff to answer the questions. On average, the survey took nine minutes to complete. Minor revisions were made to the questionnaire, such as modifying language and simplifying skip patterns to make the questionnaire easier for respondents to follow.

In addition, questionnaire drafts were shared with CMS and NCI throughout the development process and feedback was incorporated along the way.

D.3. OMB and IRB Approval

Once the data collection protocol and questionnaire were finalized, the OMB clearance package was developed. The package was submitted to OMB and approved (control number 0938-1031) on December 28, 2007. In addition, the research team submitted the data collection protocol and respondent materials to the NORC Institutional Review Board (IRB) and the physician survey was approved.



D.4. Data Collection Methodology

Data collection procedures for the physician survey followed the standards of the well-established and proven Total Design Method (TDM)²¹. The basic components of the TDM are to:

- Minimize respondent burden through the design of high-quality instruments that are attractive and easy to complete;
- Use persuasive communications which provide information about the study; and
- Conduct a series of follow-up techniques that vary by mode, such as reminder mailings and telephone calls.

In addition, the methodology included a pre-paid incentive of \$25 for study participation. The incentive was included in the initial questionnaire mailing to the physicians. Payment for completing an interview or survey is standard practice when seeking participation of professionals such as physicians. Experiments to study the effect of incentives have conclusively shown that incentives are effective on both the general population²² as well as on physician surveys^{23,24}. The incentive payment was used as a method to draw physicians' attention to the study and gain their cooperation in completing the survey. Incentives were *not* intended to be a payment for their time.

In summary, data collection for the physician survey included:

- Mailing a pre-notification letter alerting physicians to an upcoming survey.
- Sending an initial mailing of the questionnaire that included a cover letter, a support letter from NCI, a copy of the questionnaire, and a pre-paid incentive of \$25 to the physicians. In addition, a postage-paid envelope addressed to NORC was included, providing the physicians with an easy and no-cost way of returning the completed questionnaire.
- Sending a reminder mailing that included a cover letter, an additional copy of the questionnaire and a postage-paid envelope. In addition, the cover letter reiterated the past inclusion of a prepaid \$25 incentive check to physicians whose questionnaires were not received after the initial mailing.
- Prompting physicians by telephone if a completed survey was not received as a result of the two previous mailings.
- Sending a final tailored written prompt by FedEx to physicians who had not responded to previous attempts.

²¹ Dillman, Don A. 1978. *Mail and Telephone Surveys: The Total Design Method*. New York: Wiley.

²² Berk M, Mathiowetz N, Ward P, and White L. 1987. "The Effect of Prepaid and Promised Incentives: Results of a Controlled Experiment," *Journal of Official Statistics* 3.

²³ Berk M, Edwards W, and Gay N. 1993. "The Use of a Prepaid Incentive to Convert Nonresponders on a Survey of Physicians," *Evaluation and the Health Professions* 16, 2.

²⁴ Berry SH and Kanouse DE. 1987. "Physician Response to a Mailed Survey: An Experiment of Timing and Payment," *Public Opinion Quarterly*, 51, 102-116.



D.4.1. Sample

The sample file included the physician's Unique Physician Identification Number (UPIN), claims volume indicator, specialty code, and credentials (MD or DO). For contacting purposes, it also contained the physician's first and last name and address information from CMS for 2006 and 2007. In addition, Verispan was contracted to provide updated address information. The updated addresses, originally from the AMA Physician Professional Data File (AMA-PPD), served as the "Primary Address" for the data collection. The 2007 and 2006 addresses provided by CMS served as secondary and tertiary addresses as needed. No phone numbers were included in the initial sample file. Instead, telephone numbers were obtained from Verispan later in the data collection period before the telephone prompting began.

The initial sample file used by the research team contained 1,500 cases divided into 100 replicates of 15. Each replicate contained equal distributions of high, medium, and low claims volume physicians. This variable did not factor in the number of claims submitted by a physician that included demonstration codes, rather the number of total oncology claims for each physician in 2006. In order to track the number of cases in the sample that were needed to achieve production and response rate goals, the sample was split into two batches. Both batches were released and a total of 1,219 eligible physicians were contacted regarding the survey.²⁵ The resulting distribution of eligible physicians by volume included in the sample was as follows:

- Low Volume (< 294 claims): 300 physicians
- Medium Volume (295 to 1806 claims): 440 physicians
- High Volume (>1807 claims): 479 physicians

D.4.2. Initial Sample Locating

Before the mailing, the sample file of 1,500 physicians was sent to Verispan to identify mailing addresses. Of the 1,500 sampled physicians, Verispan provided addresses for 1,338 physicians (89 percent). Locating efforts were conducted to find addresses for the remaining cases. For the 162 cases with no addresses, the research team reviewed address files provided by CMS from 2006 and 2007. For the 50 cases where the address was an exact match, the CMS address became the primary address. For the remaining 112 cases that did not have an exact address match, locating was performed to identify an address.

Address and telephone number locating efforts produced contact information for 97 percent of cases. However, even with repeated attempts to locate physicians by both mail and telephone, a total of 40 physicians were coded as "unlocatable" at the end of data collection.

²⁵ Of the original sample of 1,500 physicians, 281 physicians were included that did not participate in the demonstration, and thus excluded from the denominator.



D.4.3. Questionnaire Mailing

The first step in the process was to mail to each physician a pre-notification letter, which explained the evaluation, emphasized why participation is important, and notified the physicians that a survey would be arriving soon. The letter was printed on CMS letterhead and signed by CMS to lend legitimacy to the evaluation. Also included in the mailing was an endorsement letter from NCI. Before sending the pre-notification letters, the research team conducted address cleaning using Smartmailer, a software package that reviews address files for accuracy and completeness, standardizes the address format, updates missing address fields when possible and flags any addresses which are in some way questionable or undeliverable by U.S. Postal Service standards.

Approximately 1 to 2 weeks later, the research team mailed the questionnaire. Integrated into each questionnaire mailing was a cover letter from CMS that was similar in nature to the pre-notification letter, and a \$25 incentive check. The \$25 incentive served as a token of appreciation for the physician's contribution to the evaluation. In addition, a return-addressed, postage-paid envelope was included, providing an easy and no-cost way for the physicians to return the completed questionnaire.

The first page of the questionnaire asked the physician to confirm their eligibility for participation in the survey. The target population for the survey was office-based physicians who specialize in medical oncology, hematology, hematology/oncology, or gynecological oncology. In addition, all physicians must have participated in the 2006 Medicare Oncology Demonstration Program. Physicians who did not meet all eligibility requirements were instructed to stop and return the survey. The supporting materials provided in the mailings described the oncology demonstration to remind physicians about the details of the demonstration.

A second mailing followed the first questionnaire mailing for physicians whose questionnaires had not been received. The second mailing included another copy of the questionnaire, another pre-addressed, postage-paid envelope, and a reminder letter. The reminder letter was similar to the pre-notification letter and cover letter while acknowledging this was our second attempt to contact them regarding the evaluation.

D.4.4. Overview of Prompting

Physicians who did not return a completed questionnaire in response to the mailings received telephone calls from professional interviewers to prompt the physicians to complete the self-administered questionnaire and return it. While we expected that most physicians would prefer to complete their questionnaire and return it in the postage-paid envelope, alternate options, such as returning the completed questionnaire via toll-free fax or email, or completing the questionnaire over the phone with the interviewer were provided. Telephone prompting began on June 26, 2008 for Batch 1 and July 17, 2008 for Batch 2. Telephone prompting ended for both batches on September 19, 2008 and completed questionnaires were accepted until October 17, 2008. We staffed the physician survey with experienced field and telephone interviewers. Seven interviewers were trained and certified to work on the project before beginning prompting. As

data collection progressed, the staffing was streamlined so that only the most successful interviewers remained at the end of data collection.

Prompting Calls and Strategies

Telephone prompting was typically conducted Monday through Friday from 8:00 am to 6:00 pm Central Time. Time zones and requested call back times were taken into consideration when calling physician offices. Cases were generally worked at least once every seven days during prompting. Often there were multiple call attempts in a week for a single case, other times the case needed some time between calls before the next contact.

We employed multiple prompting strategies to increase survey response. Some of the prompting strategies included:

- Faxing the questionnaire to physician offices;
- Requesting physicians to call the 800 line so that interviewers could speak with the physician and explain the demonstration;
- Using the word “evaluation” instead of survey, study, or research;
- Developing specific conversion strategies emphasizing that the doctor participated in the demonstration and the evaluation was an important and final step in the demonstration. This served as an effective counter to “I don’t do surveys”;
- FedEx’ing requests for re-mails;
- Calling pending cases that cashed the incentive check;
- Calling early in the morning before the office was open to patients to try to reach the doctor;
- Conducting additional in-depth locating on our “unlocatables”;
- Conducting literature searches on contact and cooperation strategies for physician surveys to uncover additional strategies; and
- Holding two “gaining cooperation and strategy” sessions for interviewers to refresh the skills learned at training and to share successful ideas for prompting with their colleagues.

Seven hundred eighty-nine physicians (65 percent) received prompting calls. Physicians did not receive prompting calls if they returned a completed questionnaire prior to prompting (309 physicians), if they returned an ineligible questionnaire prior to prompting (81 physicians), or if they had persistent telephone number locating issues (40 physicians). Physicians that received prompting calls received an average of eight calls during the prompting period with a range of 1 to 19 calls. On average, it took 3.9 calls to identify a physician as out of scope (the lowest mean number of calls), compared to 6.1 calls to receive a completed questionnaire, and 9.4 calls to the non-interviewed respondents.



Final Written Prompt

At the end of the data collection period, a final tailored written prompt was mailed to a subset of physicians whose questionnaires had not been received. Out of 600 pending cases, a final mailing was sent via FedEx to 396 pending cases. The final mailing included a tailored letter that specifically addressed the physician's reason for not completing the survey, the original endorsement letter from NCI, another copy of the questionnaire, and an addressed, postage-paid FedEx return mailer. In addition, hand-written notes were added to the letter for some of the most promising cases. The cases were divided into one of seven mailing groups based on prior telephone prompting attempts:

- Gatekeeper refusal (n=13)
- Gatekeeper requested fax or re-mail of questionnaire (n=197)
- Doctor doesn't do surveys (n=18)
- Doctor is too busy (n=57)
- Doctor had been on vacation or out of the office (n=41)
- Cashed incentive, but completed questionnaire not received yet (n=24)
- Miscellaneous (n=46)

The written prompt was mailed on August 29, 2008. This date was selected so the packages would arrive on the Tuesday after Labor Day, which typically indicates the end of the summer vacation season. As a result of the final written prompt, 81 completed questionnaires (20 percent of the cases receiving the written prompt and 15 percent of all completed cases) were received in the final seven weeks of data collection.

D.4.5. Incentive Payments

During data collection, the team received requests to resend the \$25 incentive check when the physician stated he or she never received or had misplaced the incentive. Alternately, there were a handful of physicians who returned the check with their completed questionnaire and several physicians that did not cash their check. Overall, there were 28 more cashed checks than completed surveys.

D.5. Final Dispositions, Response Rates and Study Limitations

The final dispositions for all 1,219 cases in the survey sample are shown in Table 11. The majority of completed questionnaires were returned by mail, followed by questionnaires that were returned by fax.

Table 11. Final dispositions of all sample cases (n=1,219)

| Final Disposition Description | Number of Physicians |
|---|-----------------------------|
| Completed Questionnaires | |
| Completed questionnaire by mail | 449 |
| Completed questionnaire by phone | 4 |
| Completed questionnaire by email | 0 |
| Completed questionnaire by fax | 73 |
| Total Completes | 526 |
| Non-Interviewed Respondents (NIR) | |
| Prompted by phone/questionnaire never returned | 431 |
| Completed questionnaire returned after Field Period | 4 |
| Refusal | 25 |
| Hostile refusal | 26 |
| Locating/correct phone number not found | 40 |
| Total NIR | 526 |
| Out of Scope (OOS) | |
| Ineligible, did not participate in demonstration | 128 |
| Ineligible, specialty | 1 |
| Ineligible, not office-based | 2 |
| Deceased | 3 |
| Retired | 33 |
| Total OOS | 167 |

In addition, response rates were tracked throughout data collection. Table 12 presents approximate response rates (American Association of Public Opinion Research, AAPOR RR4) for each batch at important milestones in data collection. After the mailing of the initial questionnaire, both batches had similar response rates. At the time of the second questionnaire mailing, Batch 1 had a slightly higher response rate than Batch 2. However, prompting for Batch 2 cases began one week after the second questionnaire was mailed, whereas prompting for Batch 1 began four weeks after the second questionnaire was mailed. Table 12 shows that before prompting began approximately half of the survey's final response rate was achieved as a result of the first two mailings.

The higher response rate for Batch 2 cases during prompting and at the end data collection could be a result of factors such as a higher percentage of out of scope cases in Batch 2 compared to Batch 1 (23 percent compared to 18 percent) or a shorter prompting period for Batch 2 resulting in less time for offices to receive repeated calls (Batch 1 cases were prompted three weeks longer than Batch 2 cases). Table 12 also shows an 11 percent increase in the overall response rate due to the final tailored written prompt.

Table 12. Response rates by key milestones during data collection by batch

| Batch | Response Rate after initial mailing (before reminder mailing) | Response Rate after reminder mailing (before prompting) | Response Rate before tailored written prompt | Final Response Rate |
|-----------------|--|--|---|----------------------------|
| Batch 1 (n=883) | 23% | 30% | 42% | 51% |
| Batch 2 (n=336) | 25% | 27% | 47% | 61% |
| Total (n=1,219) | n/a | n/a | 43% | 54% |

Note: The total response rates after the initial and second mailing are shown as N/A because the different mailings for the two batches occurred at different points in time.

Completed questionnaires by week were also tracked. After each initiative to contact or prompt physicians, the number of completed questionnaires spiked in the following weeks. Different contacting efforts were scheduled to maximize response rates after responses to previous initiatives diminished.

In summary, 526 physicians participated in the survey, yielding a 54 percent response rate.²⁶ This response rate is relatively high given that the participants were providing input into their experience in the oncology demonstration as late as October 2008. The survey was fielded more than one and a half years after the end of the oncology demonstration (December 2006).

As mentioned above, the survey was approved by OMB in time to begin fielding in January 2008. While this delay in fielding the survey did not result in a low response rate, it likely had an impact on the respondents' ability to accurately recall their experiences and impressions of participation in the 2006 demonstration. Other limitations of the survey include the possibility of self-reported bias, the natural tendency of respondents to provide positive responses and the possibility that those responding might be physicians in practices that are more efficient, with more resources, and more readily able to respond to issues not directly related to patient care. In addition, with this method of obtaining input, it is inevitable that physicians' recollection of their behavior (such as how often they refer to or use clinical guidelines) is different from their actual behavior. Finally, the research team considered the potential for non-response bias. Every possible action was taken to minimize the effect of such a bias on the survey results.

D.6. Survey Non-Response Bias

As noted earlier, the final response rate for the survey was 54 percent. About half of the respondents completed the survey after the initial mailing, while others required follow up attempts including additional mailings and telephone prompts.

²⁶ This 54 percent AAPOR RR4 response rate is defined as the number of complete and partial interviews divided by the number of interviews (complete plus partial) plus the number of non-interviews, plus noncontacts, plus others, plus an estimate of the proportion of cases of unknown eligibility that would have likely been eligible for the study.



While there is a clear consensus among survey methodologists that high response rates are desirable, there is also substantial evidence that physician surveys are more resilient to non-response biases than surveys of the general population. Several evaluations of physician surveys have concluded that the addition of respondents in later portions of the field period has little effect on survey estimates (Berk, 1985; Guadagnoli & Cunningham, 1989; Sobal & Ferentz, 1989; and Schoenman et al, 2003).

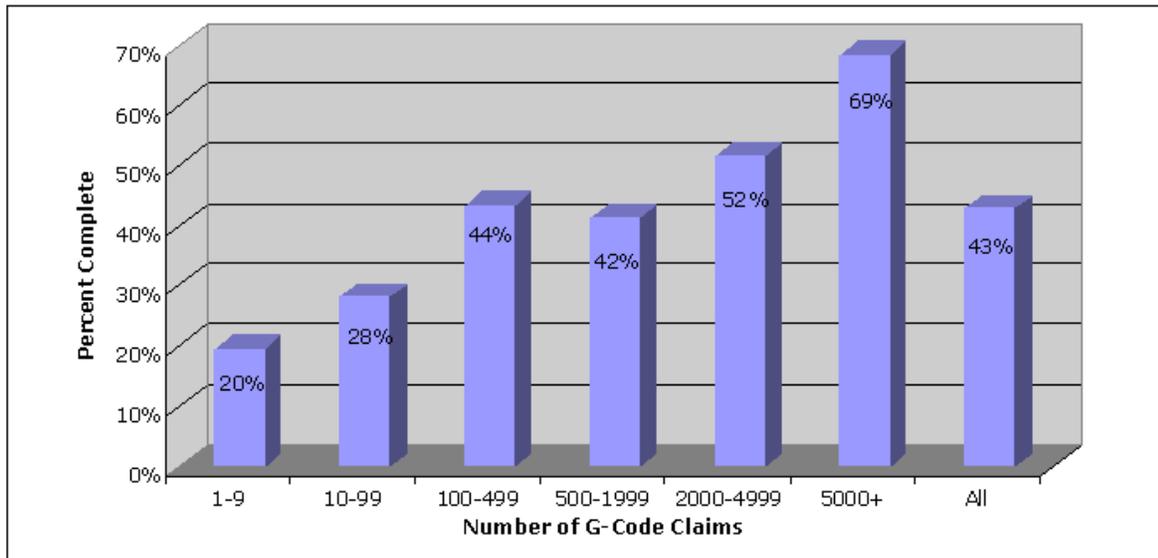
The original sample selected for the survey consisted of 1,500 oncologists, with 500 cases each assigned to low, medium, and high volume physicians. As expected, demonstration participation was highly correlated with volume of Medicare claims, with a participation rate of 60 percent for low claim volume physicians, 88 percent for medium claim volume physicians, and almost 96 percent for high claim volume physicians.

As shown in Figure 1, survey completion rates were also correlated with the number of G-code claims. Completion rates were very low for respondents with fewer than 100 G-code claims. Approximately 20 percent of respondents with fewer than 10 G-code claims completed the survey and approximately 28 percent of respondents with 10 to 99 G-code claims completed the survey. While completion rates for these groups were relatively low, fewer than 200 cases fell into this category, reducing the likelihood of bias in the overall estimates. Completion rates were between 40 and 45 percent for those with 100 to 2,000 claims. The highest completion rates were found among those with a large number of G-code claims. Approximately 52 percent of respondents with 2,000 to 4,999 claims completed the survey, while the completion rate was almost 69 percent for those with 5,000 or more claims.

It should be noted that there is a difference between the completion rates shown here and the response rates shown earlier. The response rates are higher because they are adjusted based on rates of eligibility; specifically, some non-responders are assumed to be ineligible and excluded from the denominator in the calculation. While this adjustment is commonly used, it does not identify the specific cases that are ineligible, rather serves as an estimate. The non-response analysis is therefore based on all cases that could not be completed including some cases that would be considered ineligible.



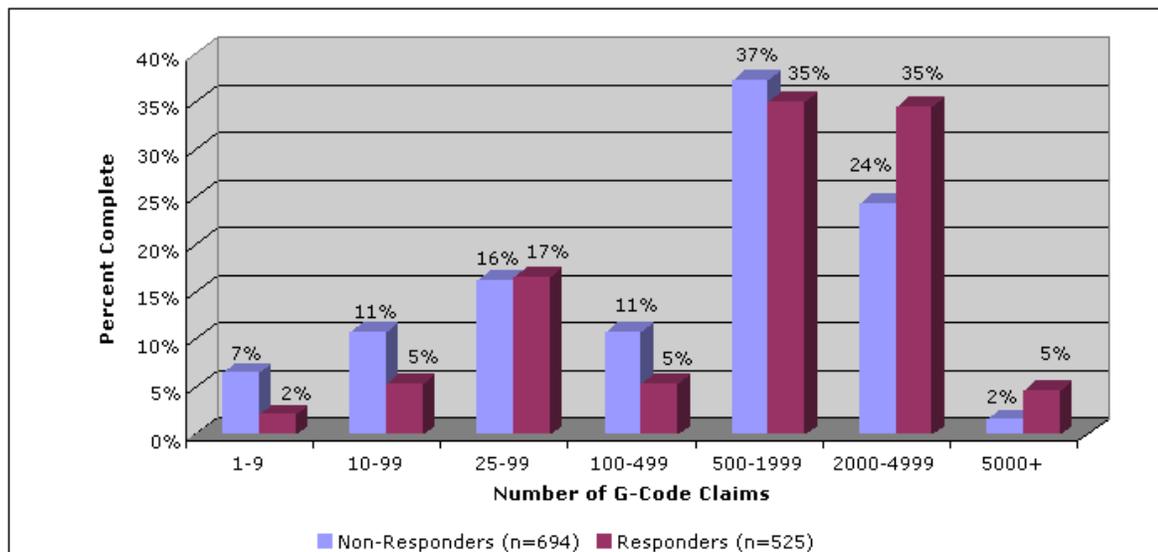
Figure 1. Completion rates by volume of G-code claims



Source: 2006 Medicare Oncology Demonstration Program: Physician Survey. Survey completed by physicians April-October 2008.

Figure 2 shows the distribution of the non-respondent and respondent population, by claims volume. About 10 percent of non-respondents had fewer than 25 claims compared to only 4 percent of respondents. Conversely, about 26 percent of non-respondents had 2,000 or more claims compared to about 39 percent of respondents. While it seems preferable to have similar non-response rates across different categories of claims volume, there may be advantages to having a disproportionate number of high-volume physicians respond to the survey, as these are the persons for whom the demonstration is most salient. These physicians are also likely to represent those who have both greater interest and knowledge of the demonstration.

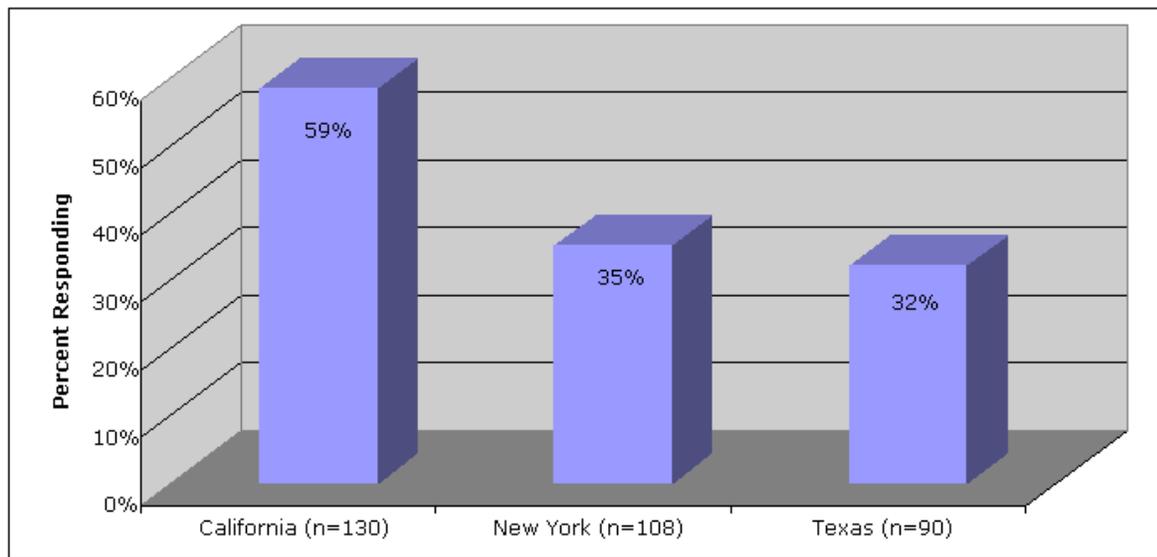
Figure 2. Percent Distribution of Respondents and Non-Respondents by Claims Volume



Source: 2006 Medicare Oncology Demonstration Program: Physician Survey. Survey completed by physicians April-October 2008.

Large differences in completion rates between Census Divisions were observed. The Pacific division had a much higher survey participation rates than the Middle Atlantic and West South Central divisions. Within the divisions, California had a higher survey completion rate (59 percent) than either New York (35 percent) or Texas (32 percent). See Figure 3. Some of this variation may be explained by the fact that California oncologists, on average, file more G-code claims than oncologists in New York. In addition, there tend to be more large group practices in California than in other states, which may indicate that those physicians had more support and time for completing the surveys. Beyond differences in volume, it is not clear why California physicians were more willing than others to participate.

Figure 3. Percent response rate by state



Source: 2006 Medicare Oncology Demonstration Program: Physician Survey. Survey completed by physicians April-October 2008.

D.7. Survey Data Analysis

The data analysis focused on descriptive statistics to characterize physicians' assessment of the oncology demonstration, including their experiences implementing the demonstration in their practice, and their perceptions of the demonstration. Frequencies of categorical variables and distributions of continuous variables were examined for all physicians and for those with high, medium and low claims volume as described above. A Pearson chi-squared test was conducted to test for differences in the distributions of categorical variables among the three groups. For numerical responses (e.g., age, number of years in practice), a Kruskal-Wallis equality-of-populations rank test was conducted. Where there were no significant differences between the groups, totals were reported. Where significant differences were found, responses by claims volume were reported. A copy of the physician survey with reported frequencies is located in Appendix C.

In some cases, new variables were derived by collapsing items. For Question 11, responses "Very Difficult" and "Difficult" were collapsed into one group. For Questions 20 and 21, responses "Strongly Agree" and "Agree" were collapsed into one category, and responses

“Disagree” and “Strongly Disagree” were collapsed into one category. For Question 22, responses “Greatly Improved,” and “Somewhat Improved,” were collapsed into one category, while “Somewhat Worsened” and “Greatly Worsened” were collapsed into another category. Finally, for some analyses, Question 28 – “What percentage of the physician’s patients were on Medicare?” – was collapsed into two categories: 0-50 percent and 50 percent or greater. Further, Question 29 – “What percentage of the physician’s patients were cancer patients?” – was collapsed into two categories: 0 to 75 percent and 75 percent or greater.

In addition to the descriptive analyses, a limited number of bivariate analyses were conducted to compare physicians’ perceptions by the proportion of their patients who have Medicare, and by the proportion of their patients who were cancer patients. Only significant results of these analyses are included in this report.

Some of the survey questions were open-ended and allowed physicians to fill in responses. For these answers, the team created codes to characterize the responses, and then two reviewers independently categorized the responses. Where there were discrepancies in categorizing responses, the reviewers discussed the responses and consensus was reached. The results of this approach are reported for Question 38 of the survey, which instructed the physician to “Please tell us anything else you would like to add about the 2006 demonstration.”

D.8. Physician Survey Findings

D.8.1. Characteristics of Physicians and Their Practices

Claims Volume

As the sample selection criteria included information about the total number of oncology claims submitted by the physician, the team categorized responses by oncology claims volume. Overall, 526 physicians completed the survey.²⁷ Of those physicians who returned a survey, 45 percent were high claims volume physicians, 37 percent were medium claims volume, and 18 percent had a low claims volume.

Participation in 2005 and 2006 Demonstration

All of the physicians surveyed participated in the 2006 oncology demonstration and 83 percent of these physicians also participated in the 2005 chemotherapy demonstration. High claims volume physicians were more likely to have participated in the chemotherapy demonstration (94 percent). Eighty-two percent of physicians with medium claims volume and 58 percent with low claims volume participated in the 2005 demonstration (differences in the distribution between high, medium and low claims volume physicians were significant, $p < .01$).

²⁷ One respondent removed the cover page of the questionnaire before mailing it in. As the cover page contained the physician identification, this respondent could not be classified by high, medium or low claims volume. This individual was included in analyses where responses were not broken down by claims volume, and removed from analyses where responses were broken down by claims volume.

Physician Specialty

Specialties that were eligible in the oncology demonstration included Hematology, Medical Oncology, Hematology/Oncology, and Gynecological Oncology. Over 75 percent of the physicians self-reported that their specialty was Hematology/Oncology, less than 2 percent reported their specialty was Hematology, 16 percent reported their specialty was Medical Oncology, and about five percent reported their specialty was Gynecological Oncology.

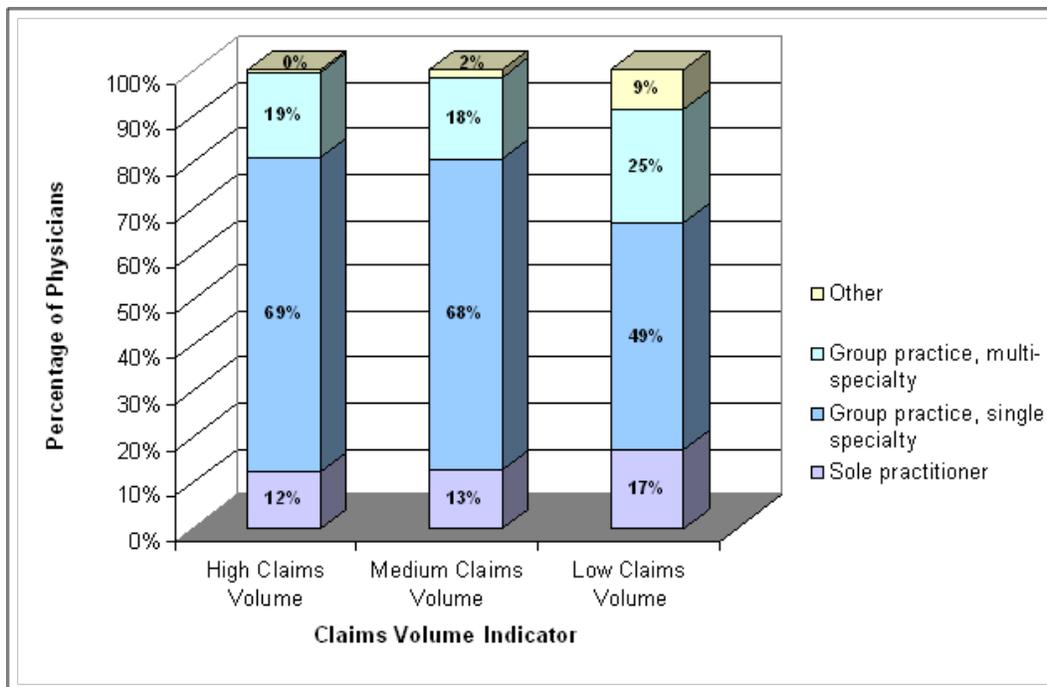
However, low claims volume physicians were more likely to report their specialty was Gynecological Oncology, with 20 percent of them reporting this specialty (differences in the distribution between high, medium and low claims volume physicians were significant, $p < .01$).

Practice Characteristics

Most of the physicians responding to the survey worked in a group practice with a single specialty (65 percent). The remainder worked as sole practitioners (13 percent), in a multi-specialty group practice (19 percent) or some other type of practice (2 percent).

Low claims volume physicians were more likely to work in a group practice with a single specialty (49 percent), and less likely to work as a sole practitioner (17 percent), or in a group practice with multiple specialties (25 percent), see Figure 4 below (differences in the distribution between high, medium and low claims volume physicians were significant, $p < .01$).

Figure 4. Percent of physicians by practice type



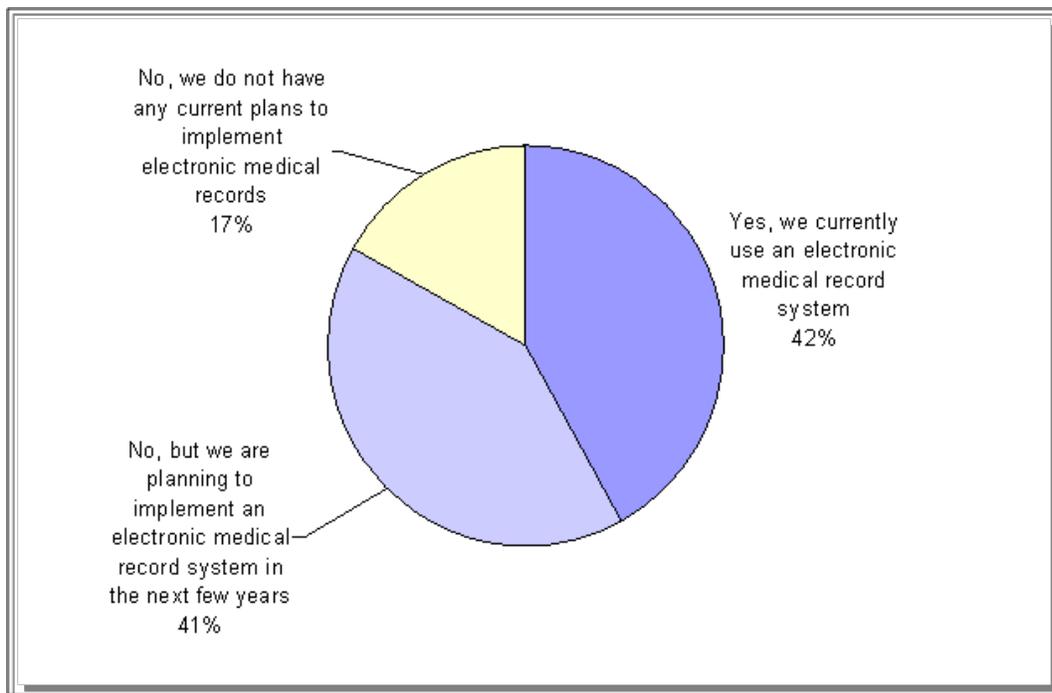
Source: 2006 Medicare Oncology Demonstration Program: Physician Survey. Survey completed by physicians April-October 2008.

Most physicians participating in the demonstration worked in physician-owned practices (80 percent). The remainder worked in academic medical centers (9 percent), hospitals (5 percent), or health care corporations (4 percent). The demonstration included only physicians in an office-based setting, and as such fewer academic-oriented physicians participated.

The distribution, however, varied by claims volume (differences in the distribution between high, medium and low claims volume physicians were significant, $p < .01$). Physicians with high claims volume were more likely to work in an ownership structure of one or more physicians or physician-owned practices (95 percent). However, physicians with low claims volume were more likely to work in academic medical settings (40 percent).

More than half of the physicians (54 percent) indicated that compared to other practices, the technological aspects of their practice were “above average.” About 37 percent reported their practice was “average”. Corresponding to these assessments, 42 percent of physicians reported that their practice currently uses an electronic medical record system (EMR) as shown in Figure 5 below.

Figure 5. Does your practice currently use an electronic medical record system?



Source: 2006 Medicare Oncology Demonstration Program: Physician Survey. Survey completed by physicians April-October 2008.

Gender, Age and Experience

Survey respondents were predominantly male (84 percent). For large claims volume physicians, 93 percent were male, while medium and low claims volume physicians were more likely to be female (differences in the distribution between high, medium and low claims volume physicians were significant, $p < .01$).

Of those responding, the median physician age was 55. The distribution of age differed by claim volume, in that physicians who submitted a higher volume of claims tended to be older. For high claims volume physicians the median physician age was 59, for medium claims volume physicians the median age was 51, and for low claims volume physicians the median age was 47. These differences were significant ($p < .01$).

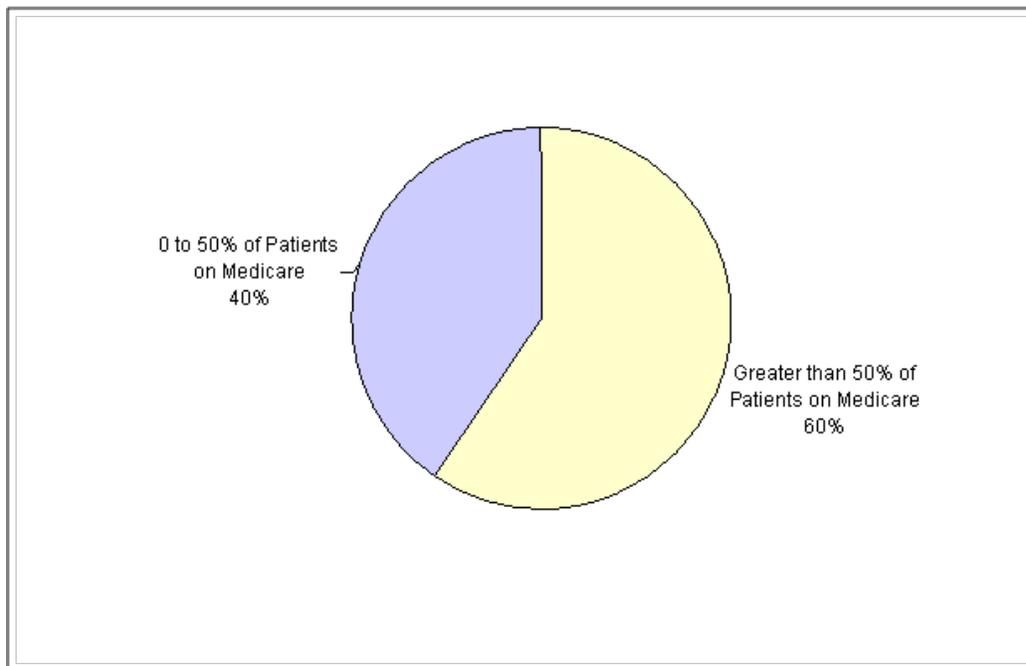
Similarly, physicians with high claims volume were likely to have been practicing in their specialty longer than those with medium or low claims volume (median number of years physicians reported practicing in their specialty was 27, 18 and 12 years, respectively and distributions were significantly different, $p < .01$). Overall, the median number of years physicians had been practicing in their specialty was 23 years.

Finally, 95 percent of survey participants reported that they were board certified.

Patient Mix

Approximately 40 percent of survey participants reported that greater than 50 percent of their patients were Medicare beneficiaries (Figure 6). Differences in the distribution between high, medium and low claims volume physicians were significant ($p < .01$). High claims volume physicians were significantly more likely to report that more than 50 percent of their patients were Medicare beneficiaries (49 percent), while for medium claims volume physicians it was 39 percent and for low claims volume physicians it was 20 percent.

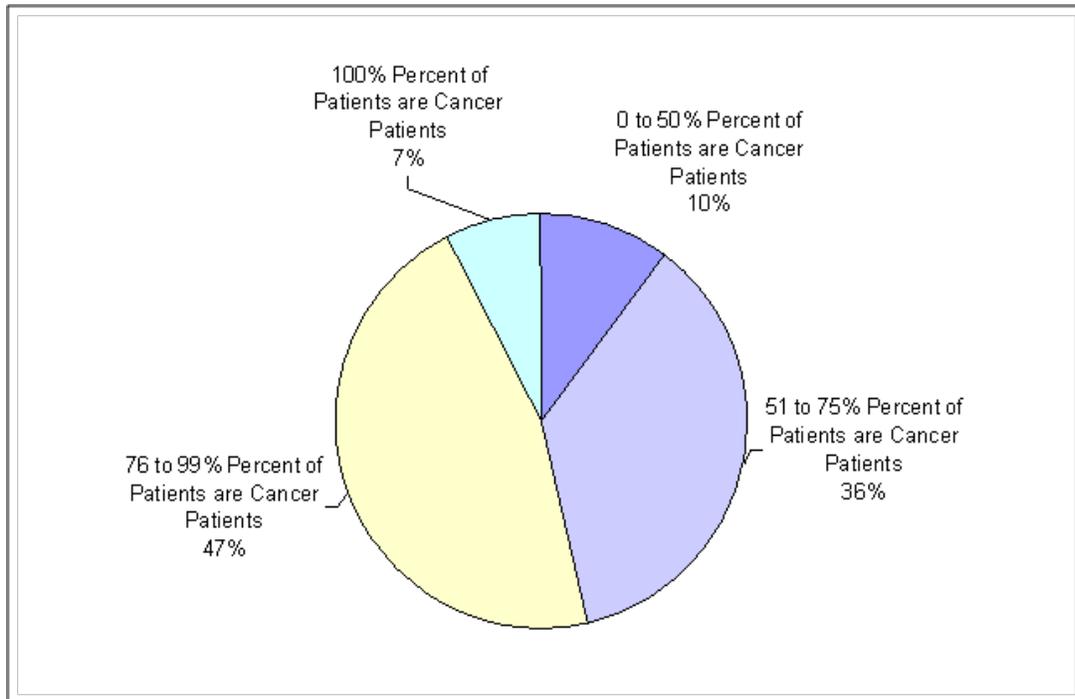
Figure 6. Percent of patients that are Medicare beneficiaries



Source: 2006 Medicare Oncology Demonstration Program: Physician Survey. Survey completed by physicians April- October 2008.

Approximately half of the physicians reported that greater than 75 percent of their patients were cancer patients, as shown in Figure 7 below. In a typical week, physicians reported seeing an average of 60 cancer patients. For high claims volume physicians, the median number of cancer patients seen in a week was 80, for medium claims volume physicians it was 60 and for low claims volume physicians it was 40. Differences in the distribution between high, medium and low claims volume physicians were significant ($p < .05$).

Figure 7. Percent of patients that are cancer patients



Source: 2006 Medicare Oncology Demonstration Program: Physician Survey. Survey completed by physicians April-October 2008.

Respondents were asked to rank the top five cancers they treated (from one to five, with one being the highest). Overall, the greatest number of physicians reported that breast cancer was in the top five cancers they treated, followed by colon cancer, non-small cell/small cell lung cancer, non-Hodgkin’s lymphoma and prostate cancer (see Table 13).

Table 13. Number of physicians reporting type of cancer in the top five treated

| Cancer Type | High Claims Volume (n=233) | Medium Claims Volume (n=189) | Low Claims Volume (n=88) | Total (n=511) |
|---------------------------------------|----------------------------|------------------------------|--------------------------|---------------|
| Breast Cancer | 96% | 87% | 56% | 86% |
| Colon Cancer | 98% | 85% | 55% | 86% |
| Non-Small Cell/Small Cell Lung Cancer | 93% | 83% | 47% | 81% |
| Non-Hodgkin’s Lymphoma | 77% | 69% | 45% | 68% |
| Prostate Cancer | 45% | 37% | 19% | 38% |
| Multiple Myeloma | 27% | 34% | 34% | 31% |
| Other Cancers | 12% | 22% | 39% | 20% |
| Ovarian Cancer | 11% | 19% | 24% | 16% |
| Rectal Cancer | 15% | 17% | 7% | 14% |
| Head and Neck Cancer | 15% | 13% | 14% | 14% |
| Pancreatic Cancer | 11% | 15% | 15% | 13% |
| Chronic Myelogenous Leukemia | 4% | 8% | 16% | 8% |
| Cervical Cancer | 2% | 6% | 22% | 7% |
| Esophageal Cancer | 4% | 6% | 6% | 5% |
| Gastric Cancer | 2% | 4% | 5% | 3% |
| Other Cancers | 12% | 22% | 39% | 20% |

Source: 2006 Medicare Oncology Demonstration Program: Physician Survey. Survey completed by physicians April-October 2008.

Note: Percentages reflect the proportion of physicians who marked the cancer as one of the top five cancers they treated. Percentages do not sum to 100, i.e., 86% of physicians selected breast cancer as one of the top five cancers they treat, and 86% selected colon cancer as one of the top five cancers they treat. **Bold** indicates differences in the distribution between high, medium and low claims volume physicians were significant (p<.01).

D.8.2. 2006 Medicare Oncology Demonstration Background

Physicians heard about the oncology demonstration in a variety of ways. The survey asked physicians to check all of the ways they heard about the demonstration (Table 14). Overall, 52 percent of physicians marked that they had heard about the demonstration through their Office Manager/Staff. Forty-five percent heard about the demonstration through CMS, with high claims volume physicians significantly more likely to be informed of the demonstration through this channel (p<.01). Overall, about one-third of physicians heard about the demonstration through their medical association or professional society, with high claims volume physicians significantly more likely to report that they heard about the demonstration through this channel (p<.01).

Table 14. How did you hear about the 2006 demonstration?

| | High Claims Volume (n=237) | Medium Claims Volume (n=192) | Low Claims Volume (n=100) | Total (n=523) |
|--|---|---|--|--------------------------|
| CMS | 52% | 46% | 21% | 45% |
| Medical Association/Professional Society | 39% | 30% | 18% | 32% |
| NCCN | 7% | 5% | 4% | 6% |
| Colleague | 6% | 10% | 10% | 9% |
| Office Manager/Staff | 50% | 50% | 58% | 52% |
| Other | 4% | 5% | 2% | 4% |

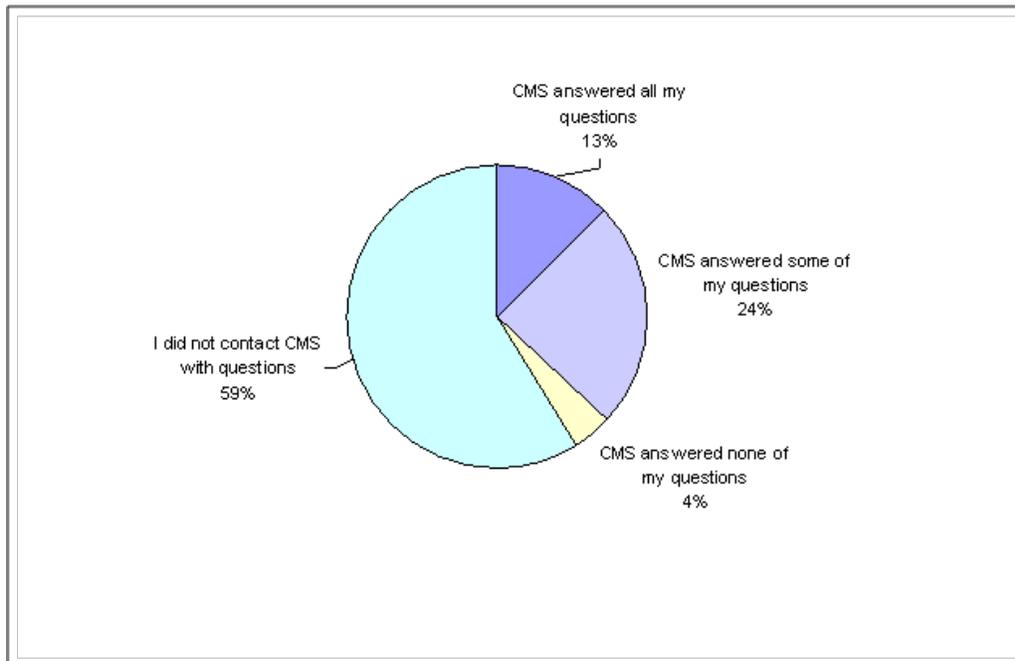
Source: 2006 Medicare Oncology Demonstration Program: Physician Survey. Survey completed by physicians April-October 2008.

Note: Percentages reflect the proportion of physicians who marked the category as a way they heard about the demonstration. Percentages do not sum to 100. **Bold** indicates differences in the distribution between high, medium and low claims volume physicians were significant ($p < .01$).

When asked to rate their understanding of the goals of the demonstration, 72 percent of physicians rated their understanding as “Excellent”, “Very Good” or “Good”. Twenty-three percent of physicians rated their understanding of the demonstration as “Fair” or “Poor”.

In terms of receiving assistance from CMS to understand the demonstration, 59 percent of physicians responded that they had not contacted CMS with questions. For physicians with low claims volume, 74 percent had not contacted CMS with questions. Differences in the distribution between high, medium and low claims volume physicians were significant ($p < .05$). Among those that contacted CMS with questions, over 90 percent responded that CMS answered all or some of their questions as shown in Figure 8.

Figure 8. To what extent did CMS answer your questions regarding the 2006 demonstration?



Source: 2006 Medicare Oncology Demonstration Program: Physician Survey. Survey completed by physicians April-October 2008.

Physicians were asked to rate various reasons for choosing to participate in the demonstration, as shown in Table 15. Few respondents reported that the reasons listed were **not important**, with the exception of, “Believe in cooperating with government initiatives,” (25 percent found this not important). Only 9 percent responded that “additional revenue for my practice” was **not important**. Less than 4 percent responded that “believe it is important to follow clinical guidelines,” was **not important**. Differences in ratings were not significantly different except for the reason “additional revenue for my practice.” For this reason, high claims volume physicians were more likely to rate it as “Very important (53 percent),” than low claims volume (40 percent) or medium claims volume physicians (42 percent, $p < .01$).

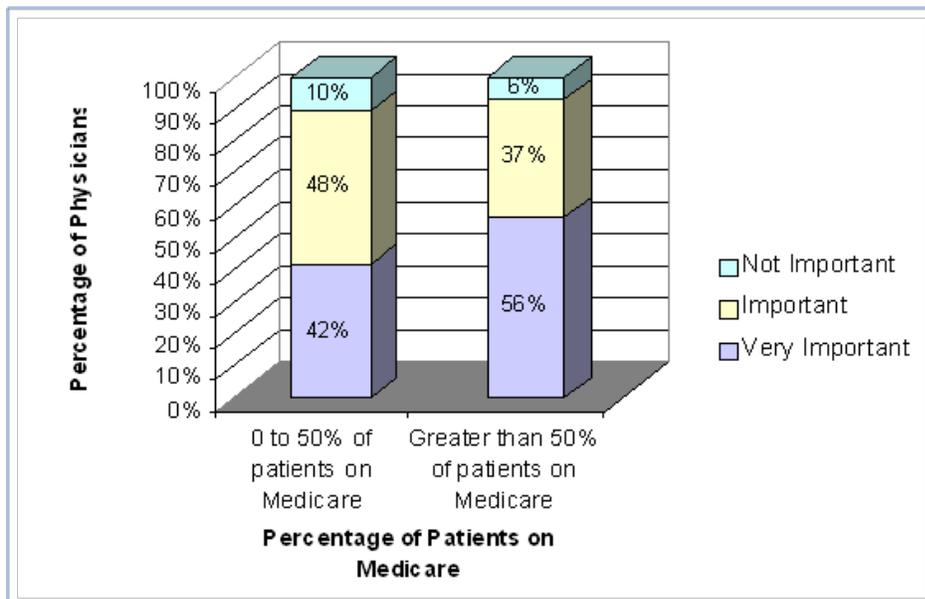
Table 15. Importance of the following reasons in your participation in the demonstration

| Reasons for participating | Very Important | Important | Not Important |
|--|----------------|-----------|---------------|
| Additional revenue for my practice (n=519) | 47% | 44% | 9% |
| Believe it is important to follow clinical guidelines (n=516) | 44% | 52% | 4% |
| To assist in efforts for improving the quality of care (n=518) | 52% | 41% | 7% |
| Believe in cooperating with government initiatives (n=512) | 24% | 51% | 25% |

Source: 2006 Medicare Oncology Demonstration Program: Physician Survey. Survey completed by physicians April-October 2008.

When looking at the percentage of physicians’ Medicare patients, physicians who reported more than 50 percent of their patients had Medicare were more likely to respond that additional revenue for the practice was “Important” or “Very important” than those physicians with less than 50 percent of their patients with Medicare ($p < .01$) as shown in Figure 9 below.

Figure 9. Importance of additional revenue by percent of patients with Medicare



Source: 2006 Medicare Oncology Demonstration Program: Physician Survey. Survey completed by physicians April-October 2008.

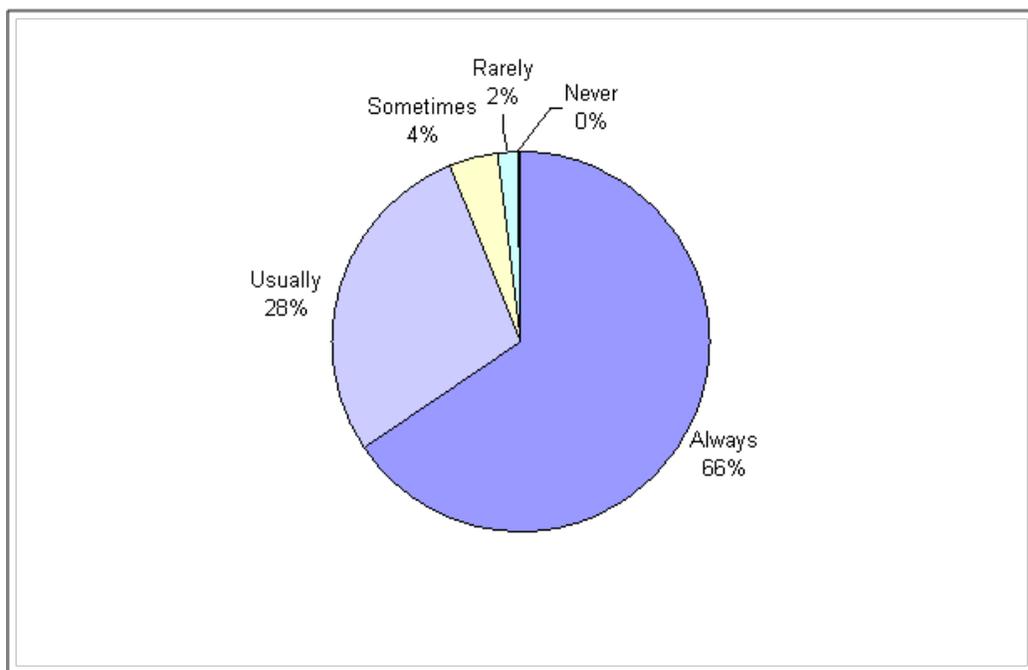
D.8.3. Implementation of 2006 Medicare Oncology Demonstration Program

The survey also focused on the physicians' experiences with the oncology demonstration, including their use of G-codes and their perception of the burden of the demonstration. In addition, the survey asked respondents to indicate if and how they had made changes to accommodate the demonstration in their practice.

Use and Burden of G-codes

When asked how often a G-code was submitted when a patient had a qualifying visit, two-thirds of physicians responded that they "Always" submitted a G-code and 28 percent said they "Usually" submitted a G-code (see Figure 10). High claims volume physicians were significantly more likely to indicate that they "Always" submitted a G-code (70 percent) than low claims volume physicians (50 percent). Differences in the distribution between high, medium and low claims volume physicians were significant ($p < .05$).

Figure 10. How often did you submit a G-code when a patient had a qualifying visit?



Source: 2006 Medicare Oncology Demonstration Program: Physician Survey. Survey completed by physicians April-October 2008.

If physicians did not indicate that they always used a G-code for a qualifying visit, they were asked to report the reason why they had not submitted a G-code. Multiple responses were recorded. Of those not using a G-code, over 50 percent checked the reason, "Clerical error, forms not attached." Close to 40 percent marked "Documenting and reporting is time consuming." Almost 30 percent cited the reason, "Overlap in G-code descriptions made selection difficult," as shown in Table 16. About 25 percent reported the coding and billing aspects of the demonstration were time consuming.

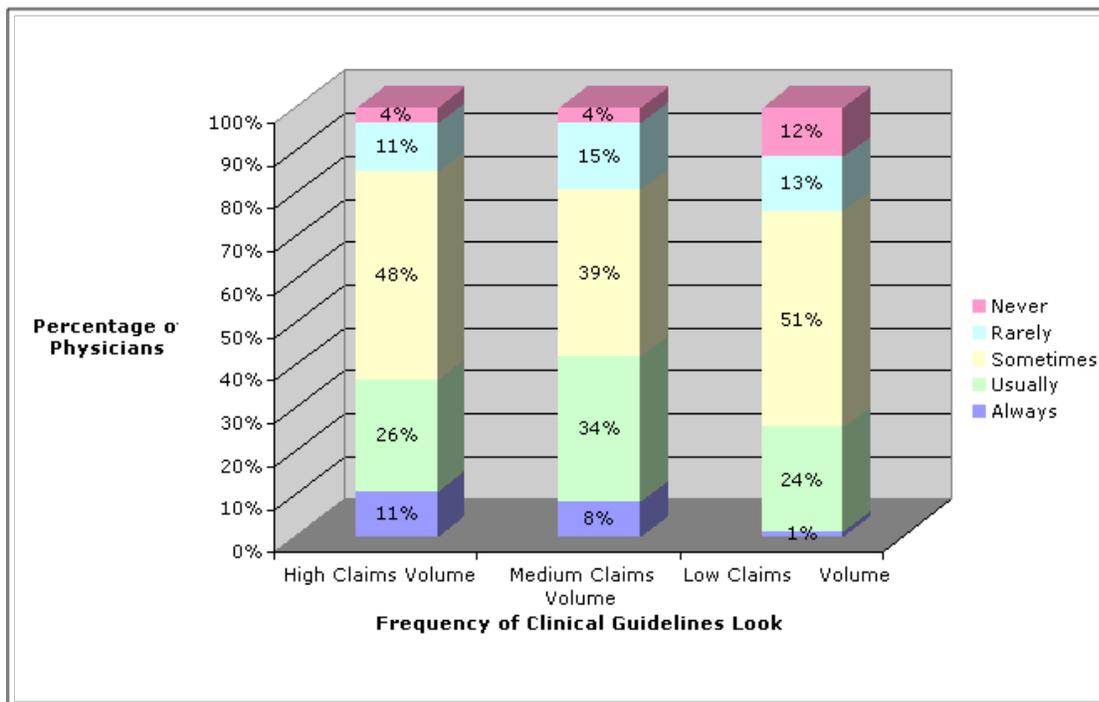
Table 16. If you did not submit G-codes for all these qualifying patients, why not? (multiple responses allowed)

| Reason for G-codes not submitted | Percentage (n=170) |
|---|--------------------|
| Clerical error, forms not attached | 53% |
| Documenting and reporting is time consuming | 39% |
| Overlap in G-code descriptions made selection difficult | 28% |
| Coding and billing is time consuming | 26% |
| I did not want to bill my patients additional coinsurance amounts | 12% |
| I am less familiar with ASCO/NCCN guidelines for certain eligible diagnoses | 4% |
| Other | 8% |

Source: 2006 Medicare Oncology Demonstration Program: Physician Survey. Survey completed by physicians April-October 2008.

The survey also asked physicians to indicate how often they needed to look-up clinical guidelines to determine if they could check the “Adhere to Guidelines” G-code for a patient. Eight percent of physicians indicated they “Always” looked up clinical guidelines and 28 percent said they “Usually” looked up clinical guidelines. Slightly less than half of the physicians (45 percent) said they “Sometimes” looked up clinical guidelines as shown in Figure 11. Only four percent of high claims volume physicians said they “Never” looked up guidelines, while 12 percent of low claims volume physicians indicated such. Low claims volume physicians were also less likely to have marked “Always”, with only 1 percent indicating such. Differences in the distribution between high, medium and low claims volume physicians were significant ($p < .01$).

Figure 11. How often physician looked-up clinical guidelines to check G-code for patient?



Source: 2006 Medicare Oncology Demonstration Program: Physician Survey. Survey completed by physicians April- October 2008.

For two-thirds of the responding physicians (67 percent), looking up guidelines to determine if they could check the “Adhere to Guidelines” G-code took between one and five minutes. For a little less than one quarter, this took between six and 10 minutes. Eleven percent indicated that it took less than one minute, and less than five percent indicated it took more than 10 minutes.

Rating Difficulty of Activities of the Demonstration

Physicians were asked to rate how difficult they found activities related to the demonstration. More than half responded that the initial implementation of the program was “Difficult” or “Very Difficult” (64 percent). Almost half (47 percent) found coding and billing “Difficult” or “Very Difficult.” Data reporting and documentation was “Difficult” or “Very Difficult” for 44 percent of respondents. Of the activities listed, the least difficult for the physicians surveyed was determining the current disease state. Only nine percent found this activity “Difficult” or “Very Difficult” as shown Table 17 below.

Table 17. Difficulty with oncology demonstration program activities?

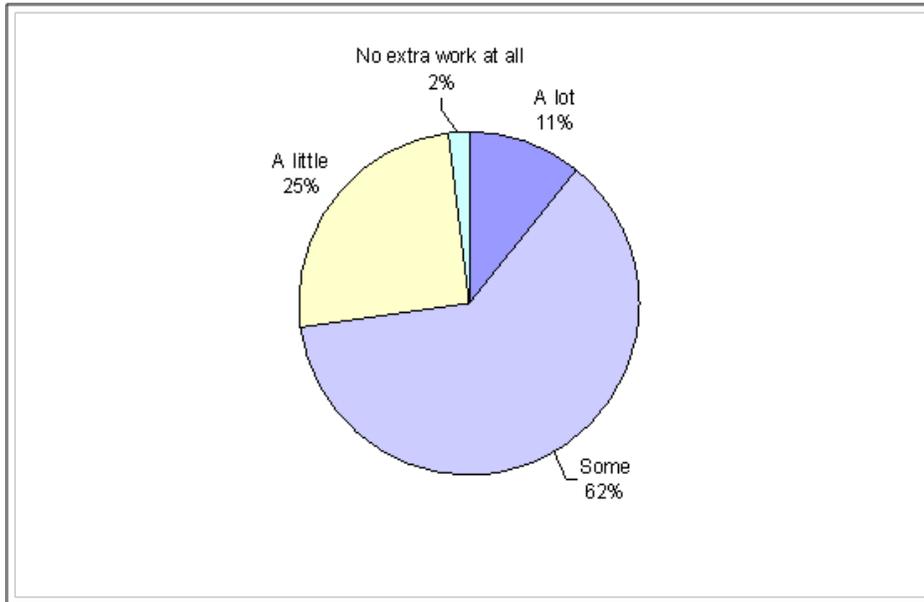
| Activity | Very difficult or difficult | Not difficult |
|--|------------------------------------|----------------------|
| Initial Implementation | 64% | 36% |
| Coding and Billing | 47% | 53% |
| Data Reporting & Documentation | 44% | 56% |
| Reporting Adherence to Practice Guidelines | 36% | 64% |
| Determining the Primary Focus of E&M | 22% | 78% |
| Determining the Current Disease State | 9% | 91% |

Source: 2006 Medicare Oncology Demonstration Program: Physician Survey. Survey completed by physicians April-October 2008.

Burden of the Demonstration

The survey also asked about the overall burden of the demonstration. Specifically, the survey asked physicians to indicate how much extra work resulted from the demonstration for the physician and for other personnel. Most physicians (62 percent) responded “Some” to the question “For you, how much extra work did it take to participate in the 2006?” Eleven percent responded “A lot”, 25 percent responded “A little,” and only 2 percent responded “None” as seen in Figure 12.

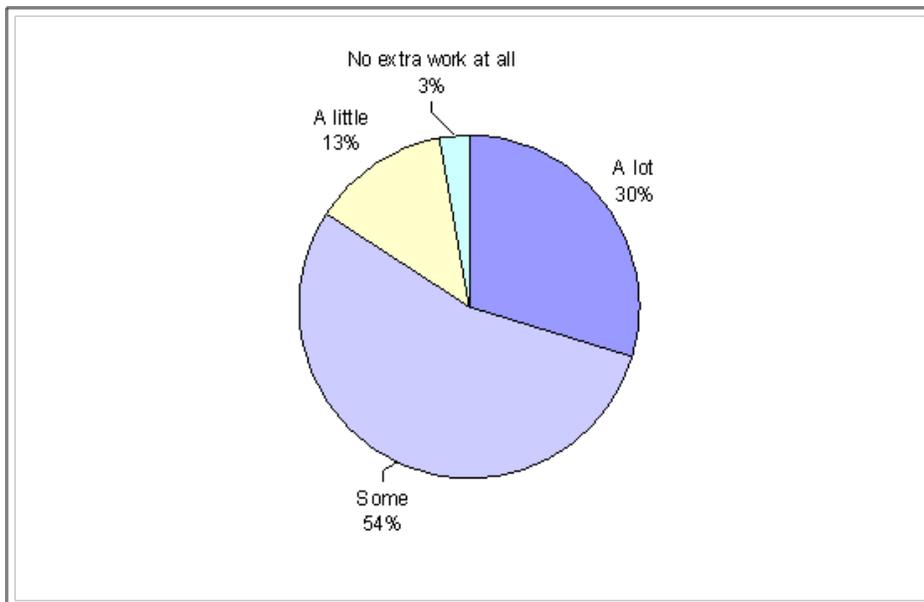
Figure 12. For you, how much extra work did it take to participate in the 2006 demonstration?



Source: 2006 Medicare Oncology Demonstration Program: Physician Survey. Survey completed by physicians April-October 2008.

In general, physicians indicated that the demonstration resulted in more work for their non-physician personnel than for themselves. Thirty percent responded that it resulted in “A lot” of extra work for their non-physician personnel. Fifty-four percent of physicians reported that it resulted in “Some” extra work for their non-physician personnel, 13 percent responded “A little” and 3 percent responded “None” as shown in Figure 13.

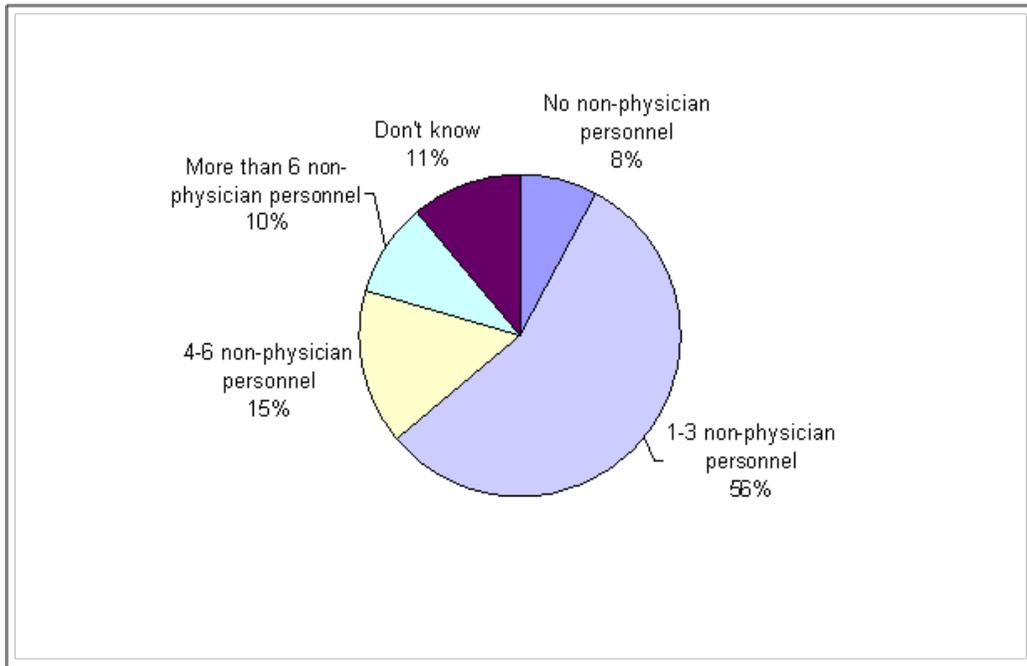
Figure 13. For your non-physician personnel, how much extra work did it take to participate in the 2006 demonstration?



Source: 2006 Medicare Oncology Demonstration Program: Physician Survey. Survey completed by physicians April-October 2008.

Further characterizing the amount of new work non-physician personnel had to take on, the survey asked how many non-physician personnel in the office took on new responsibilities as a result of the demonstration. Fifty-six percent of physicians responded that one to three non-physician personnel took on new responsibilities as a result of the demonstration and 25 percent responded that more than four non-physician personnel took on new responsibilities (Figure 14).

Figure 14. Number of non-physician personnel taking on new responsibilities as result of demonstration



Source: 2006 Medicare Oncology Demonstration Program: Physician Survey. Survey completed by physicians April-October 2008.

Changes Made to Practice in Response to Demonstration

In order to accommodate the demonstration, physicians noted a number of ways that they made changes to their practice. Sixty-three percent of physicians noted that they had trained staff. Twenty-five percent had either modified software for billing, or had bought software to help administer the demonstration. Nearly one quarter (22 percent) had downloaded resources and tools from an association or other group and six percent indicated that they had hired new staff. Twenty-two percent indicated that no changes were made as shown in Table 18.

Table 18. Changes as a result of participation in the 2006 demonstration

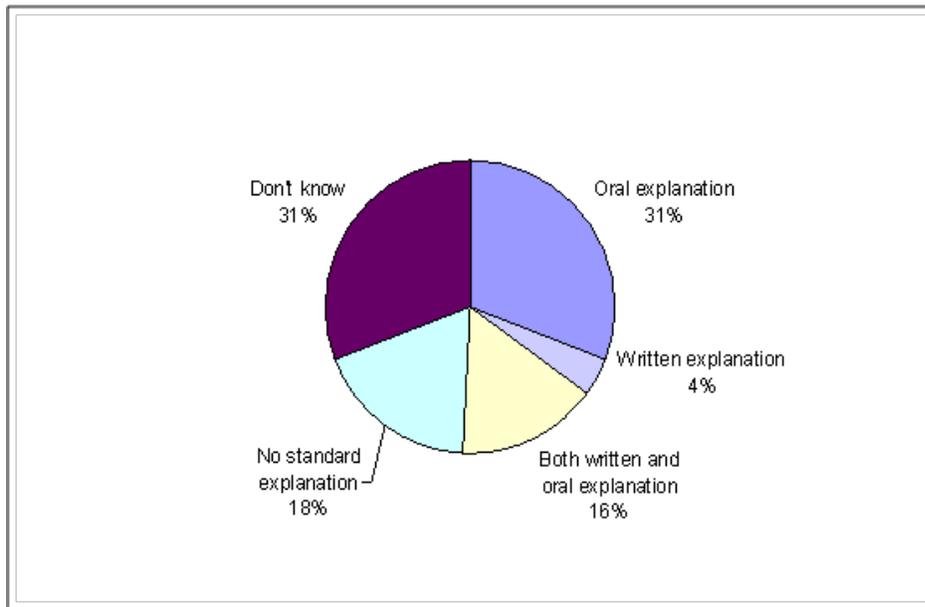
| Reasons for participating in demonstration | % of All Physicians | % of High Claims Volume Physicians | % of Medium Claims Volume Physicians | % of Low Claims Volume Physicians |
|---|---------------------|------------------------------------|--------------------------------------|-----------------------------------|
| Train staff | 63% | 70% | 62% | 50% |
| Implement new policies/procedures | 34% | 38% | 32% | 29% |
| Download resources and tools from an association or other group | 22% | 28% | 20% | 13% |
| Modify software for billing | 22% | 24% | 21% | 20% |
| No changes were made | 22% | 19% | 20% | 32% |
| Hire new staff | 6% | 8% | 5% | 2% |
| Other | 4% | 4% | 3% | 4% |

Source: 2006 Medicare Oncology Demonstration Program: Physician Survey. Survey completed by physicians April-October 2008.
 Note: Bold indicates differences in the distribution between high, medium and low claims volume physicians were significant (p < .05).

Demonstration Coinsurance

The survey asked about the coinsurance amount collected by physician practices from beneficiaries. When asked how the coinsurance was explained to patients, 31 percent responded that it was explained verbally, four percent said they provided a written explanation, and 16 percent responded that they provided both an oral and written explanation. Eighteen percent indicated that there had been no standard as shown in Figure 15 below.

Figure 15. How was demonstration coinsurance explained to patients?



Source: 2006 Medicare Oncology Demonstration Program: Physician Survey. Survey completed by physicians April-October 2008.

Many physicians did not know what percentage of their patients had commented on the demonstration coinsurance amount (28 percent). Slightly more (30 percent) reported that none of their patients had commented on the demonstration coinsurance amount. Less than 10 percent of physicians (9 percent) reported that more than 25 percent of their patients had commented on the coinsurance amount. Focusing only at the physicians who *did* know what percentage of their patients had commented on the coinsurance amounts, low claims volume physicians were more likely to indicate that none of their patients had commented on the coinsurance amount (62 percent) than were medium or high claims volume physicians (42 percent and 35 percent, respectively). These differences between low, medium and high claims volume physicians were significant ($p < .05$).

D.8.4. Physician Perceptions of Clinical Guidelines and the 2006 Demonstration

Clinical Guidelines

Physicians were asked to indicate how much they agreed or disagreed with the statements regarding clinical practice guidelines (Table 19).

Table 19. Physician perception of clinical guidelines

| | % Strongly Agree | % Agree | % Neutral | % Disagree | % Strongly Disagree |
|--|---------------------------------|--------------------|----------------------|-----------------------|------------------------------------|
| Clinical guidelines are one of the most important tools that help me provide quality oncology care | 24% | 49% | 18% | 8% | 1% |
| Clinical guidelines are easy to use | 10% | 48% | 28% | 13% | 1% |
| Using clinical guidelines is like practicing cookbook medicine | 8% | 28% | 29% | 29% | 6% |
| Clinical guidelines are too rigid to apply to individual patients. | 7% | 25% | 28% | 34% | 6% |
| Clinical guidelines limit my ability to apply clinical judgment. | 6% | 24% | 21% | 39% | 11% |

Source: 2006 Medicare Oncology Demonstration Program: Physician Survey. Survey completed by physicians April-October 2008.

Bold indicates differences in the distribution between high, medium and low claims volume physicians were significant ($p < .05$).

Overall, they were more likely to agree than disagree with the importance of using clinical guidelines, and the majority did not find them difficult to use. The majority of physicians (73 percent) responded “Agree” or “Strongly Agree” to the statement: “Clinical guidelines are one of the most important tools that help me provide quality oncology care”.

With regard to the statement, “Clinical guidelines are easy to use,” 58 percent of physicians surveyed responded “Agree” or “Strongly Agree”, while 15 percent responded “Disagree” or “Strongly Disagree”.

Fewer physicians agreed with the statement “Using clinical guidelines is like practicing cookbook medicine,” or “Clinical guidelines are too rigid to apply to individual patients.” Overall, approximately one-third responded “Agree” or “Strongly Agree” with these statements (36 percent and 32 percent, respectively).

Physicians were also more likely to “Disagree” or “Strongly Disagree” (50 percent) than “Agree” or “Strongly Agree” (30 percent) to the statement “Clinical guidelines limit my ability to apply clinical judgment.” However, high claims volume physicians were less likely to “Disagree” or “Strongly Disagree” with the statement than low or medium claims volume physicians (42 percent vs. 58 percent and 53 percent respectively). Differences between low, medium and high claims volume physicians were significant ($p < .05$).

D.8.5. 2006 Oncology Demonstration Program

The survey sought physician feedback on the 2006 oncology demonstration (Table 20):

Table 20. Physician perceptions of the 2006 demonstration

| | % Strongly Agree | % Agree | % Neutral | % Disagree | % Strongly Disagree |
|--|------------------------|------------|--------------|---------------|---------------------------|
| This demonstration has improved the way I provide care to my Medicare patients. | 3% | 16% | 35% | 32% | 14% |
| This demonstration has improved the way I provide care to my non-Medicare patients. | 2% | 15% | 36% | 33% | 14% |
| This demonstration promotes and improves the overall quality of care for cancer patients. | 8% | 28% | 29% | 29% | 6% |
| Relative to the amount of work required to document patient care and report G-codes, the compensation is appropriate | 2% | 28% | 30% | 28% | 12% |
| The demonstration has been worth the effort. | 3% | 27% | 40% | 19% | 11% |

Source: 2006 Medicare Oncology Demonstration Program: Physician Survey. Survey completed by physicians April-October 2008.

- A small percent of physicians agreed that the demonstration had improved care for Medicare or non-Medicare patients. Responding to the statement, “The demonstration has improved the way I provide care to my Medicare patients,” 18 percent of physicians indicated “Agree” or “Strongly Agree”. Similarly, 17 percent of physicians marked “Agree” or “Strongly Agree” to the statement “The demonstration has improved the way I provide care to my non-Medicare patients.”
- A greater percent of physicians responded positively to the statement “This demonstration promotes and improves the overall quality of care for cancer patients,” with 34 percent selecting “Agree” or “Strongly Agree.”

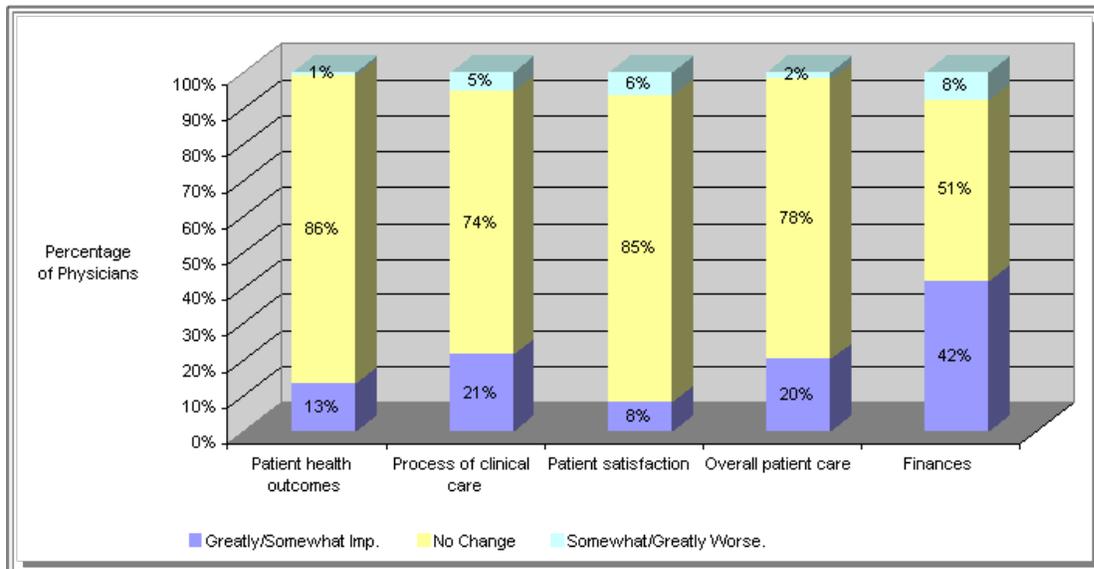
- More physicians disagreed than agreed with the statement “Relative to the amount of work required to document patient care and report G-codes, the compensation is appropriate.” Forty percent marked “Disagree” or “Strongly Disagree”, while 30 percent marked “Agree” or “Strongly Agree” to the statement.
- An equal number of physicians agreed and disagreed with the statement, “The demonstration has been worth the effort.” Thirty percent marked “Agree” or “Strongly Agree” and 30 percent marked “Disagree” or “Strongly Disagree.” Forty percent marked “Neutral”.

D.8.6. Impact of 2006 Medicare Oncology Demonstration Program

Impact during the Demonstration

The survey sought feedback from physicians to determine whether they thought the demonstration improved or worsened aspects of their practice including patient health outcomes, process of clinical care, patient satisfaction, overall patient care and finances (Figure 16). More than 75 percent of physicians reported that the demonstration had not changed patient health outcomes, patient satisfaction, or overall patient care (86 percent, 85 percent and 78 percent, respectively). Seventy-four percent reported that the process of clinical care had not changed. Of physicians who reported change, most said the change was an improvement (“Greatly Improved” or “Somewhat Improved”). The most change was reported in the area of finances. Forty-two percent said their finances had improved or greatly improved. However, in this area, there were significant differences ($p < .05$) among physicians with different claims volume. Sixty-two percent of low claims volume physicians reported no change, compared to 46 percent of high claims volume physicians.

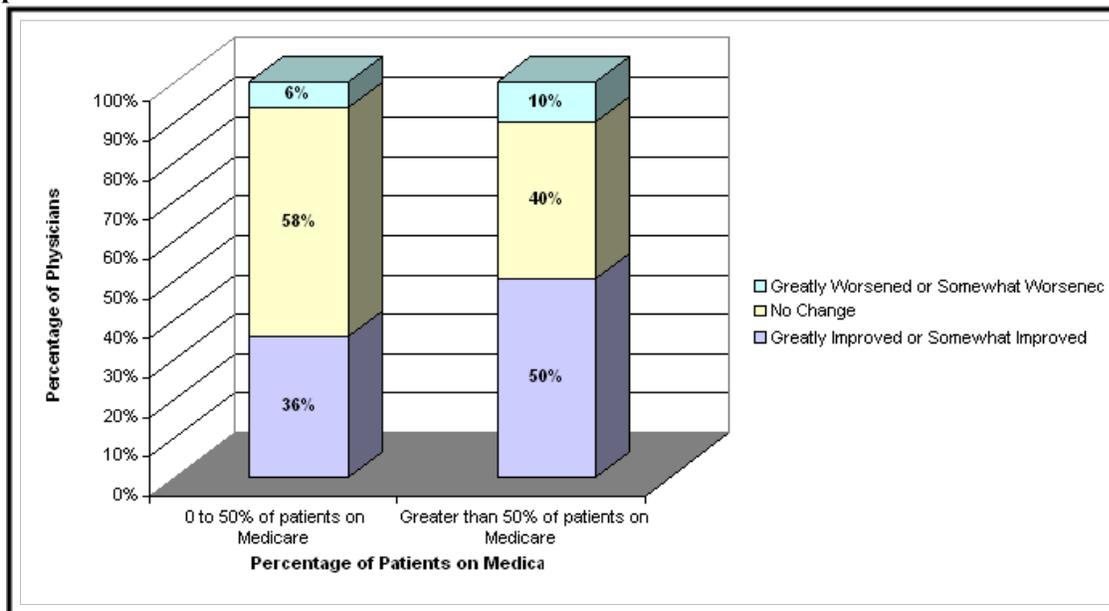
Figure 16. To what degree did the 2006 demonstration improve or worsen the following at your practice?



Source: 2006 Medicare Oncology Demonstration Program: Physician Survey. Survey completed by physicians April through October of 2008.

When the issue of finances was analyzed in terms of the percentage of physicians' patients who have Medicare, physicians with a higher percentage of Medicare patients were more likely to report positive ("Greatly Improved" or "Somewhat Improved") financial results due to the oncology demonstration. For physicians who reported that greater than 50 percent of their patients have Medicare, 51 percent reported that the demonstration had "Greatly Improved" or "Somewhat Improved" finances at their practice. For physicians who reported that 50 percent or less of their patients have Medicare, 36 percent indicated that the demonstration "Greatly Improved" or "Somewhat Improved" finances at their practice. These results are shown in Figure 17.

Figure 17. To what degree did the 2006 demonstration improve or worsen finances by percentage of patients who have Medicare?



Source: 2006 Medicare Oncology Demonstration Program: Physician Survey. Survey completed by physicians April-October 2008.

Impact after the Demonstration

The survey also asked physicians to compare their activities post-demonstration (when the survey was fielded in 2008) to their activities pre-demonstration (in 2006) with respect to the care they provided to their cancer patients. The majority of physicians reported that they did the following activities with the same frequency when surveyed as they did in 2006:

- Look up clinical guidelines (66 percent indicated same frequency now as in 2006)
- Follow clinical guidelines (74 percent indicated same frequency now as in 2006)
- Use clinical guidelines to determine the current disease state of my patient (77 percent indicated same frequency now as in 2006)
- Identify the stage of the cancer (82 percent indicated same frequency now as in 2006)

Of those who reported their activities had changed from 2006, more physicians reported performing the activity with more frequency now than in 2006, with the exception of using the coding procedure developed for the demonstration as seen in Table 21.

Table 21. Compared to 2006, how frequently do you engage in the following activities now?

| | Less often now than in 2006 | Same frequency now as in 2006 | More often now than 2006 |
|--|-----------------------------|-------------------------------|--------------------------|
| Look up clinical guidelines (n=523) | 6% | 66% | 28% |
| Follow clinical guidelines (n=523) | 2% | 74% | 24% |
| Use clinical guidelines to determine the current disease state of patients (n=523) | 3% | 77% | 20% |
| Identify the stage of the cancer (n=523) | 1% | 82% | 17% |
| Use coding procedures developed for the demonstration (n=508) | 22% | 63% | 15% |

Source: 2006 Medicare Oncology Demonstration Program: Physician Survey. Survey completed by physicians April-October 2008.

There were significantly different ($p < .05$) impacts of the demonstration, however, by claims volume. High claims volume physicians were more likely to look up clinical guidelines now than in 2006 compared to low or medium claims volume physicians (34 percent vs. 26 percent and 18 percent, respectively).

High claims volume physicians were also using clinical guidelines to determine the disease state of their patients more than in 2006 (26 percent) compared to the medium claims volume physicians (17 percent) or low claims volume physicians (12 percent).

Finally, a greater percentage of high claims volume physicians were now identifying the stage of the cancer more than in 2006 than low or medium claims volume physicians (23 percent, 12 percent and 12 percent, respectively). For these activities, the demonstration had a larger self-reported impact on those physicians who submitted a higher volume of demonstration claims.

D.8.7. Overall Impressions

Physicians were asked to give their overall impression of both the 2005 and 2006 demonstrations. For the 2006 demonstration, most physicians rated the demonstration as “Good” (40 percent) or “Fair” (42 percent) as seen in Table 22 below.

After removing those physicians that did not participate in the 2005 chemotherapy demonstration, the ratings for the chemotherapy demonstration were very similar to the 2006 oncology demonstration, with the majority of respondents rating the demonstration “Good” (38 percent) or Fair (44 percent).

Table 22. Overall, what is your general impression of the 2005 and 2006 demonstration?

| | 2005 Chemotherapy Demonstration | 2006 Oncology Demonstration |
|-----------|--|--|
| Excellent | 6% | 6% |
| Good | 38% | 40% |
| Fair | 44% | 42% |
| Poor | 12% | 12% |

Source: 2006 Medicare Oncology Demonstration Program: Physician Survey. Survey completed by physicians April-October 2008.

D.8.8. Additional Comments

The survey provided the respondents (in an open-ended section) the opportunity to add any further comments or thoughts regarding the 2006 demonstration. In summary:

- Seventeen physicians thought the demonstration needed improvement. Most of these physicians reported the goals of the demonstration were unclear or confusing. Several commented that there should be attempts to preserve physician creativity. One physician mentioned that there were too many clerical errors, another that all data should be accrued online, and another that more health questions should be asked.
- Thirteen physicians made comments that the demonstration was a weak attempt to make up for inadequate payments provided by Medicare. Some stated that cancer care is suffering because of limited reimbursements for care that is costly and complex. They suggested that the system of payments must be fixed in order to improve patient care.
- Fifteen physicians commented that the demonstration was an inefficient use of time and money. Some stated that these resources should be applied directly to providing better treatment for cancer patients.
- Similarly, three physicians commented that there was too much paperwork involved and that it drastically took time away with patients.
- Approximately 10 physicians reported the demonstration was too costly given the amount of reimbursement.
- Five physicians indicated that the G-codes or guidelines were confusing or incomplete, stating that they were lacking sufficient choices to cover important diagnoses or that the clinical guidelines were too broad.
- Ten physicians commented that they would like to be given feedback about their performance with regard to the demonstration. They would feel better about the time and effort they spent if they were provided this information.
- Four physicians disagreed with the goals of the demonstration. One physician stated that the clinical guidelines dictated by the government are useless in a specialty that has developed guidelines superior to other areas of medicine.



- Four physicians commented that the initiative was important to promote compliance with guidelines. A few also mentioned that it was a good initiative and that such efforts should continue.
- Other positive feedback mentioned by physicians included that the demonstration showed that the government is capable of doing large scale research, the compensation in 2006 was sufficient, that they preferred to receive payment as claims were submitted rather than a lump sum, and that the demonstration was fairly simple.



◆◆◆

CHAPTER E. CLAIMS ANALYSIS

E.1. Purpose of Claims Analysis

The claims analysis provides a description of the information collected through the oncology demonstration codes. The purpose of the claims analysis was to assess the following:

- Level of physician participation in the demonstration and their utilization of demonstration codes;
- Level of beneficiary participation in the demonstration (beneficiaries under the care of participating physicians with an eligible cancer diagnosis), and,
- Financial effect of the demonstration on participating physicians and the Medicare program.

E.2. Methodology

In creating the analytic file used to conduct the claims analysis and subsequently the validation study, the research team obtained an extract of the Standard Analytics Files for the oncology demonstration period and the year prior. The claims files requested from CMS are provided in Table 23. A step-wise process was used to generate the data extract. First, beneficiaries were identified in the Physician Supplier or Carrier claims for 2005 and 2006 that either had an ICD-9 diagnosis of the eligible demonstration cancers or the demonstration G-codes *and* included the office visit code (either for a new office visit or for an established office visit). For the beneficiaries identified in the first step, all claims were pulled from the following files: inpatient, outpatient, home health, hospice, carrier, durable medical equipment, skilled nursing facility, and denominator. Thus, the data extract captured any beneficiary that had an eligible cancer diagnosis in an office visit setting for 2005 and 2006, and any other claim that the patient had in any setting (such as outpatient or home health).

Table 23. 2006 data use for oncology demonstration claims analysis

| |
|--|
| Inpatient SAF |
| Outpatient SAF |
| Hospice SAF |
| Home Health SAF |
| Physician Supplier SAF |
| Durable Medical Equipment |
| Skilled Nursing Facility |
| Denominator |
| Medicare Physician Identification and Eligibility Registry (MPIER) |
| Unique Physician Identification Number (UPIN) Directory |

To confirm that the accuracy of the data extract requested from CMS, we compared Medicare beneficiary counts found in the data extract of the 100% Carrier SAF with beneficiary counts reported by the Chronic Care Warehouse (CCW). The CCW is a research database that contains fee-for-service institutional and non-institutional claims, enrollment/eligibility, and assessment data from January 1, 1999 forward.

The CCW has data on 21 chronic care conditions, four of which are also eligible conditions under the oncology demonstration. These four cancer diagnoses with available data from the both CCW and oncology data extract include: breast, colorectal, lung and prostate cancer. Because the CCW data encompasses all physicians and specialists treating beneficiaries with cancer, we provide data from the oncology data extract in a similar manner. Table 24 shows the number of Medicare beneficiaries diagnosed with breast, colorectal, lung or prostate cancer from the CCW and the oncology demonstration extract. Note that we provide estimates of the beneficiary counts from the CCW since the CCW data is based on a 5% sample of Medicare beneficiaries.

Table 24. Beneficiary counts from CCW and oncology data extract

| | Beneficiary Count (2006 CCW data)* | Beneficiary Count (100% Carrier SAF) |
|------------|---|---|
| Colorectal | 327,420 | 373,773 |
| Lung | 324,600 | 267,870 |
| Breast | 635,480 | 639,531 |
| Prostate | 961,880 | 927,202 |

*Data derived from CMS CCW, Table B.2 Medicare Beneficiary Counts for Chronic Conditions for 2000-2006.

The oncology demonstration data extract tracks to the CCW data. We do not expect complete concordance, as the CCW inclusion criteria, contains a slightly different set of ICD-9 codes and requires a different setting requirement than was specified for this project. Discrepancies in the beneficiary counts may be explained by the ICD-9 codes used to identify the cancers. In addition, the CCW data specifies the number and type of claims to be included as an eligible cancer diagnosis. For each of the cancers, a beneficiary would be counted if there were at least one inpatient *or* two hospital outpatient or carrier claims. The research team did not include these criteria in the extract. Given the relative similarity of the beneficiary counts, which may be explained by the slightly different population definitions, we are confident that there were no significant problems with the data extract in terms of capturing the appropriate set of beneficiaries.

For the purposes of our analyses, we defined physician participation in the oncology demonstration to mean those eligible physicians who billed for an E/M code of level 2 through 5 with at least three corresponding G-codes for an individual visit, including at least one from each of the three required categories. Thus, physicians who submitted claims with the G-codes, but for whom claims would have been denied since they did not include at least one G-code from each of the three required categories, were not considered as participating physicians in our analyses.

The research team linked the physician claims for the identified cancer patients with relevant hospital inpatient and outpatient, hospice, or home health files to create a complete patient-level file. We used the provider number from the claims field in question to create “physician practices” for each UPIN.²⁸

The following table outlines how the participation rates were calculated. We measured participation rates by claims, providers and beneficiaries (Table 25). This allowed us to determine the proportion of eligible claims that contained all three G-codes (participation by claims), the proportion of physicians who submitted at least one claim for an eligible cancer and submitted at least one claim with all three G-codes (participation by physician), and the proportion of beneficiaries with an eligible claim who received care with an accompanying claim with all three G-codes (participation by beneficiary). While the “participation by beneficiary” indicates whether a beneficiary had at least one eligible claim submitted on their behalf by a participating physician, the beneficiaries themselves did not actually choose to participate in the oncology demonstration.²⁹

Table 25. Calculations for determining "participation rates" for 2006 oncology demonstration

| <i>Variable</i> | <i>“Participants” (Numerator)</i> | <i>Total Eligible (Denominator)</i> |
|--------------------|---|--|
| Claims | Number of claims for any of the 13 cancer types that were billed by any of the four eligible specialists and contained all three G-codes, one from each category. | Total number of claims billed by any of the four eligible specialists for any of the 13 eligible cancers. |
| Provider | Number of physicians (identified by UPIN) with at least one cancer claim containing all three G-codes, one from each category. | Total number of physicians within the four eligible specialties who have at least one claim containing any one of the 13 eligible cancers. |
| Beneficiary | Number of beneficiaries with at least one cancer claim containing all three G-codes, one from each category. | Total number of beneficiaries with at least one claim treated by any of the four eligible specialties for any of the 13 eligible cancers. |

E.3. Claims Analysis Results

E.3.1. Physician participation in the demonstration

Over 8,300 physicians were eligible to participate in the oncology demonstration. These eligible physicians included those in the four specialties (hematology, hematology/oncology, medical oncology and gynecological oncology) who treated beneficiaries during the demonstration period for at least one of the 13 eligible cancers. Approximately 5,600 physicians participated in the oncology demonstration, which meant that about two-thirds of eligible physicians took part.

²⁸ Baldwin L, Adamache W, Klabunde C. et al. (2002) Linking Physician Characteristics and Medicare Claims Data: Issues in Data Availability, Quality and Measurement. *Medical Care* 40(8) Supplement: 82-95.

²⁹ A number of administrative staff interviewed during the case studies reported that many beneficiaries were unaware of the demonstration.

The oncology demonstration had a lower participation rate than the chemotherapy demonstration, which had over a 90 percent of eligible physicians participating.³⁰

Table 26 illustrates the rate of participation in the demonstration by specialty type. Medical oncologists, as identified in the UPIN directory, were more likely to participate in the demonstration (73 percent participation rate). Gynecological oncologists were the least likely to participate in the demonstration (28 percent participation rate). A possible explanation for the lower participation rate of gynecological oncologists may be attributed to the later entrance of this specialty to the demonstration. In addition, gynecological oncologists are generally OBGYNs with a subspecialty in gynecological oncology. Thus, they generally have a larger number of non-cancer claims than other participating physicians.

When making comparisons among these specialties, it is important to note that oncologists use the terms hematology/oncology, medical oncology and hematology interchangeably even though they may not be necessarily board certified in each specialty. Thus, the breakdown provided, outside of the gynecological oncologists, is likely to be somewhat arbitrary.

Table 26. Overall physician participation rate by specialty

| | All Specialties (n=8385) | Hematology (n=533) | Medical Oncology (n=5623) | Hematology/ Oncology (n=1628) | Gynecological Oncology (n=601) |
|---------------------------------|--------------------------------|-----------------------|---------------------------------|-------------------------------------|--------------------------------------|
| Participating Physicians | 67% | 54% | 73% | 65% | 28% |
| Non-Participating Physicians | 33% | 46% | 27% | 35% | 72% |

Source: Claims analysis of 2006 Medicare Oncology Demonstration Claims.

Participating physicians treated the full range of cancers eligible for the demonstration. The proportion of physicians submitting demonstration claims for a specific type of cancer ranged from 59 percent to 80 percent. However, participating physicians were less likely to submit demonstration claims for head and neck cancer and more likely to submit for chronic myelogenous leukemia and multiple myeloma, as shown in Table 27.

³⁰ Department of Health and Human Services. Office of the Inspector General. Cost and Performance of Medicare's 2005 Chemotherapy Demonstration Project (August 2006, OEI-09-05-00171).

Table 27. Physician participation rate by type of cancer

| | Total # of Physicians | Total # of Participating Physicians | % of participating physicians³¹ |
|------------------------------------|------------------------------|--|---|
| Total | 8,385 | 5,603 | 67% |
| Multiple Myeloma | 5,780 | 4,613 | 80% |
| Chronic Myelogenous Leukemia | 3,382 | 2,684 | 79% |
| Colon | 6,534 | 4,810 | 74% |
| Small Cell and Non-Small Cell Lung | 6,782 | 4,976 | 73% |
| Rectal | 6,155 | 4,471 | 73% |
| Non-Hodgkin's Lymphoma | 6,803 | 4,927 | 72% |
| Prostate | 6,540 | 4,725 | 72% |
| Breast | 7,254 | 5,118 | 71% |
| Ovarian | 6,099 | 4,189 | 69% |
| Pancreatic | 5,619 | 3,811 | 68% |
| Esophageal | 5,158 | 3,481 | 67% |
| Gastric | 5,036 | 3,116 | 62% |
| Head and Neck | 4,963 | 2,923 | 59% |
| Unknown Cancer Diagnosis | 7,872 | 3,962 | 50% |

Source: Claims analysis of 2006 Medicare Oncology Demonstration Claims.

Note: Unknown cancer diagnosis indicates the expenditures for claims that had no ICD-9 cancer diagnosis reported. The claim was considered participating if all three G-codes are billed, although no cancer diagnosis was reported.

Physicians participating in the demonstration tended to be slightly younger than non-participating physicians, with the average age of participating physicians at 50 years old versus 51 years old for eligible non-participating physicians.

³¹ Physician participation rate by cancer diagnosis was calculated by dividing the number of physicians with at least one cancer claim for specified cancer containing all three G-codes by the total number of physician within four eligible specialties who had at least one claim for the 13 eligible cancer diagnoses.

About three-quarters of the participating physicians were in group practice settings compared to 61 percent of the eligible non-participating physicians (see Table 28).

Table 28. Physician participation by practice setting

| | All Specialties (n=8385) | Participating Physicians (n=5603) | Non- Participating Physicians (n=2782) |
|----------------|---|--|---|
| Solo practice | 23% | 21% | 28% |
| Group practice | 71% | 75% | 61% |
| Unknown | 6% | 4% | 10% |

Source: Claims analysis of 2006 Medicare Oncology Demonstration Claims.

The physician participation rate varied widely by state, ranging from 36 percent (New Hampshire) to 89 percent (South Carolina). The following states had participation rates above 80 percent: Wyoming (80 percent), Iowa (81 percent), Oklahoma (81 percent), Virginia (81 percent), Colorado (83 percent), Montana (83 percent), Tennessee (85 percent), Utah (86 percent), and South Carolina (89 percent).

Physicians participating in the demonstration submitted an average of 514 eligible oncology claims. By speciality, medical oncologists (531 claims) and hematologists/oncologists (529 claims) tended to submit demonstration claims similar to the average (514 claims), while hematologists submitted an average of 474 claims. Not only did significantly fewer gynecological oncologists participate, but they submitted fewer claims on average than any of the other specialties.

E.3.2. Medicare beneficiaries impacted by the demonstration

About 2.6 million Medicare beneficiaries were identified from the demonstration data as being diagnosed with at least one of the 13 eligible cancers. Over half of the beneficiaries (or 1.3 million) were identified as eligible to be counted as part of the oncology demonstration. That is, these beneficiaries had an eligible cancer diagnosis and were seen by an eligible physician in an office setting. Over 732,000 beneficiaries (56 percent) of those eligible were impacted by the oncology demonstration, as their physician(s) submitted qualifying demonstration codes. See Table 29.

Seventy-four percent of beneficiaries who were counted as part of the demonstration had been diagnosed with breast cancer (38 percent); lung cancer (14 percent); Non-Hogkin's Lymphoma (11 percent); and, colon cancer (11 percent). These figures generally track to the most common cancers in the United States: lung cancer, breast cancer, colon and rectal cancer, and prostate cancer.³²

³² National Cancer Institute. Common cancer types, <http://www.cancer.gov/cancertopics/commoncancers>, accessed 4/15/09.

Table 29. Beneficiary count by cancer type from demonstration data

| | Total # of Beneficiaries with Diagnosed with Eligible Cancer | Total Eligible Beneficiary Count | “Participating” Beneficiary Count | “Participating” Beneficiaries as % of Total Eligible |
|------------------------------------|---|---|--|---|
| Total | 2,647,645 | 1,304,585 | 732,420 | 56% |
| Breast | 639,531 | 411,759 | 280,418 | 38% |
| Small Cell and Non-Small Cell Lung | 267,870 | 149,400 | 102,139 | 14% |
| Non-Hodgkin's Lymphoma | 167,303 | 120,455 | 83,025 | 11% |
| Colon | 236,828 | 114,588 | 78,772 | 11% |
| Prostate Cancer | 927,202 | 75,761 | 45,829 | 6% |
| Rectal | 136,945 | 48,352 | 31,192 | 4% |
| Ovarian Cancer | 50,823 | 31,795 | 19,225 | 3% |
| Multiple Myeloma | 34,824 | 29,124 | 26,847 | 4% |
| Pancreatic | 34,462 | 17,692 | 10,675 | 1% |
| Head and Neck | 86,560 | 15,813 | 7,993 | 1% |
| Esophageal | 27,805 | 13,079 | 8,435 | 1% |
| Gastric | 30,373 | 11,937 | 6,480 | 1% |
| Chronic Myelogenous Leukemia | 7,119 | 5,609 | 5,020 | 1% |
| Cancer Diagnosis Unknown | n/a | 259,221 | 26,370 | 4% |

Source: Claims analysis of 2006 Medicare Oncology Demonstration Claims.

Note: Unknown cancer diagnosis indicates the expenditures for claims that had no ICD-9 cancer diagnosis reported. The claim was considered participating if all three G-codes are billed, although no cancer diagnosis was reported.

E.3.3. Demonstration claims volume and participation rate

Of the over 12 million eligible cancer claims³³ submitted in 2006, 23 percent of the claims (or 2.9 million claims) were considered participating demonstration claims (contained all three G-codes). By cancer diagnosis, demonstration claims participation rates mirrored the beneficiary counts, with breast, lung, non-Hodgkin’s Lymphoma, and colon cancers accounting for 71 percent of the demonstration claims (see Table 30).

³³ Eligible cancer claims are the total number of claims billed by participating physicians for any of the 13 cancers.

Table 30. Demonstration claims by cancer type

| | Total Oncology Claims | Participating Oncology Claims | % of Total Oncology Claims |
|------------------------------------|--------------------------------------|--|---|
| Total | 12,813,630 | 2,878,600 | 23% |
| Breast | 2,780,619 | 828,718 | 29% |
| Small Cell and Non-Small Cell Lung | 2,233,733 | 529,505 | 18% |
| Non-Hodgkin's Lymphoma | 1,345,853 | 335,072 | 12% |
| Colon | 1,432,335 | 332,282 | 12% |
| Prostate Cancer | 834,709 | 210,036 | 7% |
| Multiple Myeloma | 608,995 | 172,922 | 6% |
| Rectal | 569,563 | 127,928 | 4% |
| Ovarian Cancer | 512,367 | 105,292 | 4% |
| Pancreatic | 280,383 | 60,953 | 2% |
| Esophageal | 177,971 | 39,681 | 1% |
| Head and Neck | 165,047 | 31,366 | 1% |
| Gastric | 133,970 | 27,867 | 1% |
| Chronic Myelogenous Leukemia | 63,545 | 21,533 | 1% |
| Cancer Diagnosis Unknown | 1,674,540 | 55,445 | 2% |

Source: Claims analysis of 2006 Medicare Oncology Demonstration Claims.

Note: Unknown cancer diagnosis indicates the expenditures for claims that had no ICD-9 cancer diagnosis reported. The claim was considered participating if all three G-codes are billed, although no cancer diagnosis was reported.

By cancer diagnosis, the average number of claims per participating physician varied, as shown in Table 31. An average of 162 demonstration claims were submitted for breast cancer by participating physicians followed by an average of 106 demonstration claims for lung cancer. On average, only eight demonstration claims were submitted for chronic myelogenous leukemia and nine demonstration claims for gastric cancer by any given participating physician.



Table 31. Average number of demonstration claims per participating physician by cancer type

| | Average Number of Demonstration Claims per Physician |
|------------------------------------|--|
| Breast | 162 |
| Small Cell and Non-Small Cell Lung | 106 |
| Colon | 69 |
| Non-Hodgkin’s Lymphoma | 68 |
| Prostate | 45 |
| Multiple Myeloma | 38 |
| Rectal | 29 |
| Ovarian | 25 |
| Pancreatic | 16 |
| Esophageal | 11 |
| Head and Neck | 11 |
| Gastric | 9 |
| Chronic Myelogenous Leukemia | 8 |
| Unknown Cancer Diagnosis | 14 |

Source: Claims analysis of 2006 Medicare Oncology Demonstration Claims.

Note: Unknown cancer diagnosis indicates the expenditures for claims that had no ICD-9cancer diagnosis reported. The claim was considered participating if all three G-codes are billed, although no cancer diagnosis was reported.

E.3.4. Aggregate Demonstration Claims Expenditures

Total Medicare expenditure for the 13 cancers included in the oncology demonstration submitted by the eligible physicians was \$4.7 billion in 2006. Only a small percentage (1.4 percent) of these expenditures were for the oncology demonstration, amounting to \$53 million. This expenditure is well below the \$150 million originally budgeted for the demonstration.³⁴

Beneficiaries were responsible for a 20 percent coinsurance (or \$4.60) payment for each demonstration claim. In aggregate, beneficiary liability for the demonstration could have totaled up to \$13.2 million. As mentioned earlier, we found from the case study interviews that some physician practices chose not collect the demonstration coinsurance amount from their patients.

Table 32 illustrates the distribution of cancer diagnosis by type of cancer. Four cancer diagnoses accounted for 71 percent of the demonstration expenditures: breast cancer (\$15.2 million); lung cancer (\$9.7 million); Non-Hodgkin’s Lymphoma (\$6.2 million); and, colon cancer (\$6.1 million).

³⁴ CMS Announces 2006 Medicare Oncology Demonstration Project, *J Oncol Pract* 2006 2:25.



Table 32. Aggregate demonstration claims expenditures by cancer type

| | \$ expenditures (in millions) | % of demonstration expenditures |
|---|--|--|
| Breast Cancer | \$15.2 | 29% |
| Small Cell and Non-Small Cell Lung Cancer | \$9.7 | 18% |
| Non-Hodgkin's Lymphoma | \$6.2 | 12% |
| Colon Cancer | \$6.1 | 12% |
| Prostate Cancer | \$3.9 | 7% |
| Multiple Myeloma | \$3.2 | 6% |
| Rectal Cancer | \$2.4 | 4% |
| Ovarian Cancer | \$1.9 | 4% |
| Pancreatic Cancer | \$1.1 | 2% |
| Esophageal Cancer | \$0.7 | 1% |
| Head and Neck Cancer | \$0.6 | 1% |
| Gastric Cancer | \$0.5 | 1% |
| Chronic Myelogenous Leukemia | \$0.4 | 1% |
| Unknown Cancer Diagnosis | \$1.0 | 2% |

Source: Claims analysis of 2006 Medicare Oncology Demonstration Claims.

Note: Unknown cancer diagnosis indicates the expenditures for claims that had no ICD-9 cancer diagnosis reported. The claim is considered participating if all three G-codes are billed, although no cancer diagnosis was reported.

The average amount allowed per participating physician for the oncology demonstration was approximately \$9,458. By speciality, medical oncologists and hematologists/oncologists received an average additional payment of \$9,770 and \$9,734 respectively for participating in the demonstration. Hematologists received an average of \$8,722 for their participation in the demonstration. Fewer gynecological oncologists submitted participating oncology claims, resulting in significantly lower payments. The average amount allowed for a gynecological oncologist was \$1,509.

E.3.5. G-Code Use for Primary Focus of Visit

To facilitate the collection of oncology demonstration information, CMS established 81 codes in three categories: 1) primary reasons for the E/M visit; 2) whether current management follows the clinical guidelines; 3) current disease state. Participating physicians were able to participate in the oncology demonstration if they provided an E/M level of service 2, 3, 4, or 5 for an established patient. As the level of service increases, the amount of history, the extent of examination and complexity of medical decision-making also increases. From the demonstration data, about 88 percent of the E/M visits were either Levels 3 or 4. Five percent were categorized as Level 2 and 7 percent as Level 5.

For the primary focus of the office visit category, about two-thirds of the the demonstration claims were for treatment decision-making after the disease has been staged or re-staged, treatment options were discussed and active cancer directed therapy was supervised (G9051). One-quarter of the claims were submitted for surveillance for disease recurrence (G9052). Four percent of claims were for work-up, evaluation or staging at the time of cancer diagnosis or recurrence (G9050). Physicians did not often report palliative care as the primary reason for the office visit. Only six percent reported the focus of visit to be directed to palliation (G9053, G9054). Anecdotally, in interviews with physicians and staff, they expressed that palliative care should be a more prominent component in the care continuum. See Table 33.

Table 33. G-code use for primary focus of visit

| | Description | Percent of G-Code Use (n=2,943,419) |
|--------------|--|--|
| G9050 | ONCOLOGY; PRIMARY FOCUS OF VISIT; WORK-UP, EVALUATION, OR STAGING AT THE TIME OF CANCER DIAGNOSIS OR RECURRENCE (FOR USE IN A MEDICARE-APPROVED DEMONSTRATION PROJECT) | 4% |
| G9051 | ONCOLOGY; PRIMARY FOCUS OF VISIT; TREATMENT DECISION-MAKING AFTER DISEASE IS STAGED OR RESTAGED, DISCUSSION OF TREATMENT OPTIONS, SUPERVISING/COORDINATING ACTIVE CANCER DIRECTED THERAPY OR MANAGING CONSEQUENCES OF CANCER DIRECTED THERAPY | 63% |
| G9052 | ONCOLOGY; PRIMARY FOCUS OF VISIT; SURVEILLANCE FOR DISEASE RECURRENCE FOR PATIENT WHO HAS COMPLETED DEFINITIVE CANCER-DIRECTED THERAPY AND CURRENTLY LACKS EVIDENCE OF RECURRENT DISEASE; CANCER DIRECTED THERAPY MIGHT BE CONSIDERED IN THE FUTURE | 25% |
| G9053 | ONCOLOGY; PRIMARY FOCUS OF VISIT; EXPECTANT MANAGEMENT OF PATIENT WITH EVIDENCE OF CANCER FOR WHOM NO CANCER DIRECTED THERAPY IS BEING ADMINISTERED OR ARRANGED AT PRESENT; CANCER DIRECTED THERAPY MIGHT BE CONSIDERED IN THE FUTURE | 5% |
| G9054 | ONCOLOGY; PRIMARY FOCUS OF VISIT; SUPERVISING, COORDINATING OR MANAGING CARE OF PATIENT WITH TERMINAL CANCER OR FOR WHOM OTHER MEDICAL ILLNESS PREVENTS FURTHER CANCER TREATMENT; INCLUDES SYMPTOM MANAGEMENT, END-OF-LIFE CARE PLANNING, MANAGEMENT OF PALLIATIVE THERAPIES | 1% |
| G9055 | ONCOLOGY; PRIMARY FOCUS OF VISIT; OTHER, UNSPECIFIED SERVICE NOT OTHERWISE LISTED | 1% |

Source: Claims analysis of 2006 Medicare Oncology Demonstration Claims.

E.3.6. G-Code Use for Guidance Adherence

For physician self-reporting of guideline adherence, about nine of 10 demonstration claims indicated that management adheres to guidelines (G9056). In instances where physicians reported that their care did not adhere to clinical guidelines, three percent indicated that management differs from guidelines for reasons associated with a patient’s comorbid illness (G9060). Two percent indicated participation in clinical trials (G9057) and two percent indicated that patient opted for alternative treatment (G9059). See Table 34.

Table 34. G-code use for self-reported guideline adherence

| | Description | Percent of G-Code Use (n=2,942,333) |
|--------------|--|-------------------------------------|
| G9056 | ONCOLOGY; PRACTICE GUIDELINES; MANAGEMENT ADHERES TO GUIDELINES | 89% |
| G9057 | ONCOLOGY; PRACTICE GUIDELINES; MANAGEMENT DIFFERS FROM GUIDELINES AS A RESULT OF PATIENT ENROLLMENT IN AN INSTITUTIONAL REVIEW BOARD APPROVED CLINICAL TRIAL | 2% |
| G9058 | ONCOLOGY; PRACTICE GUIDELINES; MANAGEMENT DIFFERS FROM GUIDELINES BECAUSE THE TREATING PHYSICIAN DISAGREES WITH GUIDELINE RECOMMENDATIONS | 1% |
| G9059 | ONCOLOGY; PRACTICE GUIDELINES; MANAGEMENT DIFFERS FROM GUIDELINES BECAUSE THE PATIENT, AFTER BEING OFFERED TREATMENT CONSISTENT WITH GUIDELINES, HAS OPTED FOR ALTERNATIVE TREATMENT OR MANAGEMENT, INCLUDING NO TREATMENT | 2% |
| G9060 | ONCOLOGY; PRACTICE GUIDELINES; MANAGEMENT DIFFERS FROM GUIDELINES FOR REASON(S) ASSOCIATED WITH PATIENT COMORBID ILLNESS OR PERFORMANCE STATUS NOT FACTORED INTO GUIDELINES | 3% |
| G9061 | ONCOLOGY; PRACTICE GUIDELINES; PATIENT’S CONDITION NOT ADDRESSED BY AVAILABLE GUIDELINES | 2% |
| G9062 | ONCOLOGY; PRACTICE GUIDELINES; MANAGEMENT DIFFERS FROM GUIDELINES FOR OTHER REASON(S) NOT LISTED | 1% |

Source: Claims analysis of 2006 Medicare Oncology Demonstration Claims.

E.3.7. G-Code Use for Disease State

For each eligible cancer, the research team developed specific demonstration codes to describe the disease state, including diagnosis, morphology and stage of the cancer. Appendix D provides a complete listing of the G-code frequencies for disease status for each eligible cancer. In the following tables, we present a comparison between the oncology demonstration reported disease states and those of the staging data from SEER-Medicare, where available (see Table 35). Generally, the oncology demonstration data had more beneficiaries for whom participating physicians reported later stages of cancer when compared to SEER-Medicare. SEER provides cancer staging at the time of diagnosis while the demonstration data focused on the extent of the disease at the time of treatment. Since the participating physicians would tend to consult with

beneficiaries later in the disease progression, it is consistent that the demonstration data include beneficiaries in more advanced stages of cancer.

Table 35. Comparison of frequencies between Demonstration and SEER-Medicare by cancer

| | Lung Cancer SEER-Medicare ³⁵ | Lung Cancer Oncology Data | Breast Cancer SEER-Medicare | Breast Cancer Oncology Data | Prostate Cancer SEER-Medicare | Prostate cancer Oncology Data |
|--------------------------------|---|---------------------------|-----------------------------|-----------------------------|-------------------------------|-------------------------------|
| % In situ | 0% | n/a | 12% | n/a | 0% | n/a |
| % Localized or Regional | 77% | 30% | 84% | 66% | 93% | 56% |
| % Distant | 17% | 64% | 3% | 30% | 4% | 39% |
| % Unknown | 6% | 6% | 1% | 4% | 3% | 6% |

| | Colorectal Cancer SEER-Medicare | Colorectal Cancer Oncology Data | Esophageal Cancer SEER-Medicare | Esophageal Cancer Oncology Data | Gastric Cancer SEER-Medicare | Gastric Cancer Oncology Data |
|--------------------------------|---------------------------------|---------------------------------|---------------------------------|---------------------------------|------------------------------|------------------------------|
| % In situ | 6% | n/a | 3% | n/a | 2% | n/a |
| % Localized or Regional | 84% | 49% | 72% | 49% | 79% | 49% |
| % Distant | 7% | 48% | 13% | 43% | 11% | 43% |
| % Unknown | 3% | 3% | 12% | 8% | 8% | 8% |

| | Pancreatic Cancer SEER-Medicare | Pancreatic Cancer Oncology Data | Head and Neck Cancer SEER-Medicare | Head and Neck Cancer Oncology Data | Ovarian Cancer SEER-Medicare | Ovarian Cancer Oncology Data |
|--------------------------------|---------------------------------|---------------------------------|------------------------------------|------------------------------------|------------------------------|------------------------------|
| % In situ | 1% | n/a | 7% | n/a | 0% | n/a |
| % Localized or Regional | 62% | 19% | 86% | 59% | 20% | 9% |
| % Distant | 26% | 74% | 4% | 34% | 75% | 67% |
| % Unknown | 11% | 8% | 3% | 7% | 5% | 4% |

Source: Claims analysis of 2006 Medicare Oncology Demonstration Claims.

Yabroff, RK. Cost of care for elderly cancer patients in the U.S. *J Natl Canc Inst* 100(9) May 7, 2008, 630-641.

³⁵ Lung cancer represents a combination of both non-small cell and small cell lung cancer (162.2-162.9)



CHAPTER F. VALIDATION STUDY

F.1. Purpose of Validation Study

The validation study tests the usefulness of the oncology demonstration codes that for the first time include clinical information on disease states collected through Medicare billing system. Moreover, it allows an opportunity to assess the ability of participating physicians to accurately report information such as primary focus of visit, adherence to clinical guidelines and current disease state of their patients. Finally, it provides an opportunity to identify lessons learned with demonstration coding in order to inform future quality improvement and reporting efforts.

F.2. Methodology

F.2.1. Technical Advisory Panel

The research team brought together a technical advisory panel (advisory panel) to assist in identifying appropriate research questions to be examined in the validation analysis. The nine-member advisory panel was comprised of practicing hematologists and oncologists (including a radiation oncologist) from different parts of the country as well as a nurse experienced in coding. The advisory panel assisted the research team:

- Identify the most appropriate cancers and stages to model;
- Identify which aspect of the practice guidelines, given the nuances within them, might be most conducive to a claims analysis;
- Develop clinical assumptions (such as timing and frequency of procedures) to be used in extracting claims data to make the data as consistent as possible with the focused area of guideline adherence;
- Review of mapping ICD-9 diagnosis and procedure codes and HCPCS/CPT codes to the research questions and understand the limitations of claims data; and
- Review findings of the analysis to provide the clinical context for such results.

F.2.2. Developing Validity Questions and Clinical Algorithms

Prior to developing clinical algorithms, the research team developed a series of internal validity checks to determine the potential “cleanliness” or accuracy of the demonstration data. Clinical algorithms were then developed, based on NCCN and/or ASCO guidelines, and reviewed for clinical appropriateness. The research team, in collaboration with the TAP and CMS and NCI staff, used an iterative process to refine the clinical algorithms.

The clinical algorithms were consistent with current clinical guidelines and allowed the research team to examine the range of cancer services, including work-up and evaluation staging, treatment, and surveillance. The team streamlined the clinical algorithms to focus solely on services that were more likely to allow for estimating practice guideline adherence for the

specific research question. For example, when analyzing whether or not patients were appropriately given certain chemotherapy regimens, the algorithm checked for a claim for the chemotherapy agents but did *not* require that the physician bill the appropriate chemotherapy administration code or subsequent Evaluation & Management code (E/M). While including these codes would confirm whether physicians were billing their services correctly, it was not relevant to the clinical care being delivered, and would have further reduced the total number of claims or sample size in consideration.

The advisory panel, in consultation with CMS and NCI, selected the research questions to be studied based on both the prevalence of certain cancers and the ease of modeling their specific treatment protocol using claims data. We focused on cancers with the highest prevalence. In addition, the clinical algorithms considered aspects of cancer care delivered across the care continuum, from initial treatment and work-up to monitoring and surveillance of patients. Following the identification of these questions, the research team developed eight corresponding clinical algorithms, representing four cancer types, to use in the analysis. Cancers covered in the initial questions presented in this report include breast, colon, small cell lung cancer and non-Hodgkin's lymphoma. Breast, lung and colon cancer are considered three of the most costly and prevalent cancers.³⁶ Appendix E provides a description of the eight clinical algorithms developed by the research team.

F.2.3. Programming of Clinical Algorithms

Once the clinical algorithms were finalized, they were programmed into SAS, a statistical software package. Using an extract of the 100% Standard Analytic File (SAF) datasets, patient episodes were created by linking all the claims from all sites of service by encrypted unique patient identifiers. Procedures and services were identified using the HCPCS/CPT codes for outpatient and carrier services, as well as ICD-9 procedure codes for inpatient services. Since CPT codes are not required for all inpatient hospital claims to be processed, the research team identified the corresponding ICD-9-CM. Based on the HCPCS/CPT codes that were vetted by research team, Ingenix provided a crosswalk from CPT codes to ICD-9 procedure code, using Ingenix's EncoderPro Expert® program.

F.3. Internal Validity of Oncology Demonstration Data

The research team conducted basic internal validity checks to test whether the demonstration codes as self-reported by participating oncologists were consistent with what has been reported elsewhere in peer-reviewed literature in terms of clinical trial participation. The team also checked to see if there was any correspondence between the demonstration codes and diagnosis codes in the claims data. These tests were used as a baseline to ensure that the demonstration codes were reasonable proxies for patient status and treatment protocols. Table 36 shows the internal validity checks performed on the demonstration data:

³⁶ National Cancer Institute, Cancer Trends Progress Report – 2005 Update. ACS, Estimated New Cancer Cases and Deaths by Sec for All Sites, US, 2007.



Table 36. Internal validity checks

| |
|---|
| Do cancer ICD-9 codes correctly correspond to disease state G-codes submitted for each patient? |
| Do patients have the appropriate disease status for breast cancer? |
| Do patients have the appropriate disease status for esophageal cancer? |
| What percent of patients within each cancer diagnosis participated in clinical trials? |

F.3.1. Do cancer ICD-9 codes correctly correspond to disease state G-codes submitted for each patient?

As stated earlier, the oncology demonstration collected cancer disease states, to include diagnosis, morphology and staging, data, which had not been collected previously. It was important to determine the strength of the alignment between the administrative billing codes, which include ICD-9 codes, and the demonstration disease state codes prior to seeking answers to any more complex questions with the demonstration data. Since the demonstration data focused on invasive cancers, the demonstration disease state codes should highly correlate to the appropriate ICD-9 codes with only malignant indications.

Demonstration claims that had at least the three required G-codes, including the cancer disease state codes, were analyzed to determine if the claims also contained the appropriate ICD-9 diagnoses codes. Across all demonstration eligible cancers, 97 percent of demonstration claims that contained a disease state G-code also contained the appropriate cancer diagnosis ICD-9 code. See Table 37.

Of those claims that did not correctly align the disease state G-codes to the correct ICD-9 diagnosis codes, less than one percent contained diagnosis codes with a benign indication within the disease state G-codes for lung, breast, prostate and colon cancer. The remaining cancers contained no claims with a diagnosis code with a benign indication and disease state G-codes.

There were two categories for which the expected correlation was not as strong. First, claims with rectal cancer disease state G-codes only corresponded to the ICD-9 diagnosis codes in 66 percent of demonstration claims. This is likely due to the course of treatment for rectal cancer. When being treated for rectal cancer, patients' undergo pre-operative chemotherapy prior to identifying the appropriate staging of the cancer. Thus, it is possible that many such claims would not include the appropriate ICD-9 diagnosis code for at least the initial visit to an oncologist. Secondly, for Chronic Myelogenous Leukemia (CML), the correlation rate was 87 percent. This may be attributed to the difficulty sometimes encountered in properly identifying CML and the potential for CML to be confused with leukocytosis, or an elevated white cell count.



Table 37. Alignment of cancer-specific ICD-9 codes with disease status G-codes by cancer type

| Cancer | Number of Claims with Disease Status G-Codes | % of Claims Where Disease Status G-Code Corresponds with ICD-9 |
|------------------------------------|--|--|
| Breast | 822,291 | 99% |
| Small Cell and Non-Small Cell Lung | 534,237 | 99% |
| Prostate | 203,468 | 99% |
| Ovarian | 103,615 | 99% |
| Pancreatic | 61,294 | 99% |
| Colon | 338,028 | 97% |
| Multiple Myeloma | 169,660 | 97% |
| Esophageal | 40,272 | 97% |
| Head and Neck | 31,642 | 97% |
| Non-Hodgkin's Lymphoma | 324,943 | 96% |
| Gastric | 27,797 | 92% |
| Chronic Myelogenous Leukemia | 20,496 | 87% |
| Rectal | 127,093 | 66% |
| Multiple Cancers | 65,146 | 97% |

Source: Analysis of 2006 Medicare Oncology Demonstration Claims.

F.3.2. Do patients have the appropriate disease state for breast cancer? Do patients have the appropriate disease status for esophageal cancer?

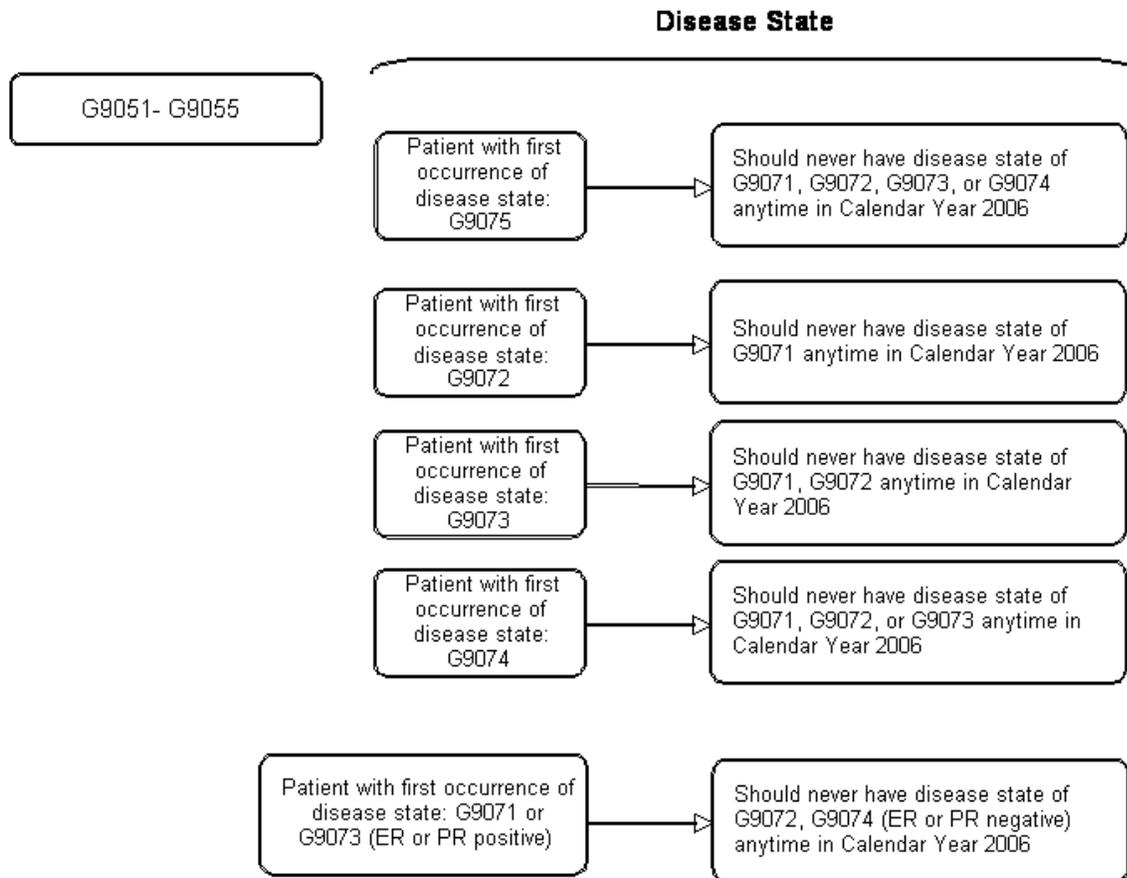
The research team explored participating physicians' ability to appropriately report disease states for breast cancer and esophageal cancer. This was done in order to test the usefulness of the demonstration data. In order to examine participating physicians' accuracy in reporting breast cancer disease states for visits that occurred during the demonstration, the research team developed a method of checking the frequency with which cancer diagnoses were down-coded. It is generally understood that during a cancer patient's course of treatment, the cancer disease status, to include staging, usually does not decrease or get down-coded (i.e., stage IIIA breast cancer should never in the future be staged as stage IIA).³⁷ Furthermore, cancers characterized as ER (estrogen receptor) positive or negative should also not change. Such changes usually reflect an inappropriate initial disease status.

To determine whether breast cancer was generally being recorded with the appropriate disease status G-codes, the research team followed all eligible breast cancer patients through the disease progression based on their initial disease status G-code. For example, if a patient had an initial disease status code G9073 on March 1, 2006, this patient should not have a lesser status reported

³⁷ The team's technical advisory panel (comprised of oncologists) indicated that from their experience, the disease status, for breast cancer does not generally decrease.

(G9072 or G9071) after that date in their claims. Figure 18 outlines the scenarios that should not occur across a breast cancer patient's treatment.

Figure 18. Inappropriate use of disease state G-Codes for breast cancer patients



With all breast cancer claims linked by patient, the research team determined the number of claims that were incorrectly billed, based on the patient's initial disease status G-code. For all eligible breast cancer patients, only 3.6 percent of the claims were erroneously billed (28,687 claims of 787,256 claims with disease status G-codes G9072 to G9075). The largest proportion of the errors occurred when patients had an initial status code of G9072, but later had a disease state of G9071. See Table 38.

Table 38. Distribution of demonstration claims with incorrect disease status for breast cancer

| Initial Disease Status Code | n | % of Claims Containing Incorrect Status Based on First Occurrence | % Claims with incorrect code: G9071 | % Claims with incorrect code: G9072 | % Claims with incorrect code: G9073 | % Claims with incorrect code: G9074 | % Claims with incorrect code: G9075 |
|-----------------------------|---------------|---|-------------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|
| G9074 | 11,215 | 1.4% | 1.4% | - | - | - | - |
| G9073 | 5,417 | 0.7% | 0.5% | 0.2% | - | - | - |
| G9074 | 3,542 | 0.4% | 0.1% | 0.1% | 0.2% | - | - |
| G9075 | 8,513 | 1.1% | 0.4% | 0.1% | 0.2% | 0.3% | - |
| Total | 28,687 | 3.6% | 2.4% | 0.5% | 0.5% | 0.3% | - |

Source: Analysis of 2006 Medicare Oncology Demonstration Claims.

An additional 1.8 percent of claims contained status G-codes that started as ER positive and were later billed as ER negative, or vice versa. Most of these errors (1.3 percent of the total 1.8 percent) started as ER positive but were later reported as ER negative, as shown in Table 39.

Table 39. Distribution of demonstration claims with incorrect characterization of ER+/-

| Initial Disease Status Code | n | % of Claims Containing Incorrect Disease Status Based on First Occurrence | % Claims with incorrect code: G9071 | % Claims with incorrect code: G9072 | % Claims with incorrect code: G9073 | % Claims with incorrect code: G9074 | % Claims with incorrect code: G9075 |
|-----------------------------|---------------|---|-------------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|
| G9071 | 10,551 | 1.3% | - | 1.3% | - | 0.1% | - |
| G9073 | 3,253 | 0.4% | - | 0.2% | - | 0.2% | - |
| Total | 13,804 | 1.8% | - | 1.5% | - | 0.3% | - |

Source: Analysis of 2006 Medicare Oncology Demonstration Claims.

We conducted a similar analysis for esophageal cancer. Esophageal cancer patients should generally not have disease status codes that decrease over the cancer treatment period. While this down-coding is generally inappropriate, it is more understandable for certain cancers. Both esophageal and rectal cancers are more likely to result in down-coding than others.³⁸ Figure 19 outlines scenarios that generally should not occur across the treatment course for a patient with esophageal cancer.

³⁸ Assumptions regarding disease status may change due to information not available at the time of the initial diagnosis or visit to an oncologist, such as results following pre-operative chemotherapy, or prior to the pathology review being conducted during a surgery for a difficult to diagnose patient.

Figure 19. Inappropriate use of disease state G-Codes for esophageal cancer patients

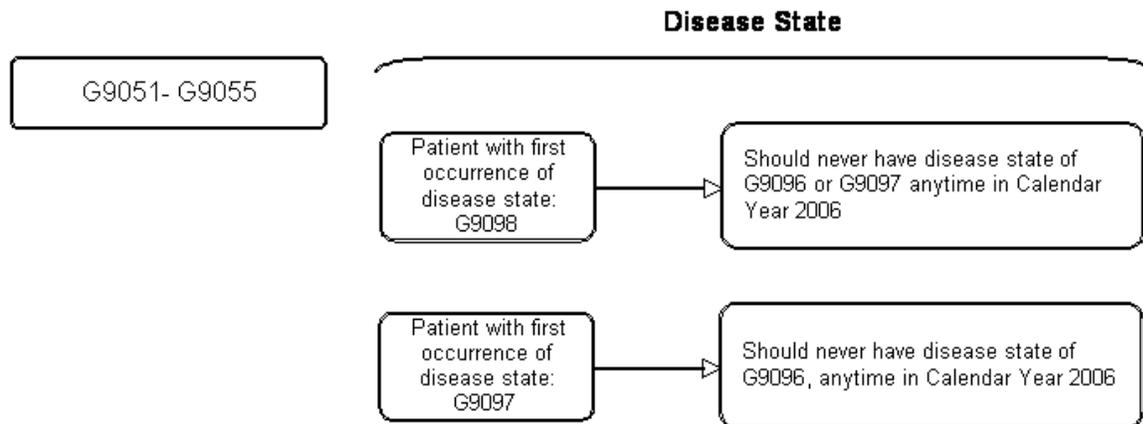


Table 40 shows that 17 percent of the esophageal cancer claims were down-coded based on the initial disease status G-code (1,411 claims out of 8,215 claims with status G-codes G9097 to G9098). The most common down-coding occurred when the initial disease status G-code was G9097 but later reported as G9096, representing eight percent of the total 17 percent. These errors could be a result of the particular challenges presented in determining an appropriate disease status for esophageal cancer. Treatment for this cancer is primarily done soon after diagnosis, prior to any surgery and a full pathology report. After surgery and a full pathological review, it is sometime necessary to re-examine the disease state, resulting in down-coding.

Table 40. Distribution of down-coded claims across G-codes for esophageal cancer

| Initial Disease Status Code | % of Demonstration Claims Containing Incorrect Disease Status Based on First Occurrence | % Claims with incorrect code: G9096 | % Claims with incorrect code: G9097 | % Claims with incorrect code G9098 |
|-----------------------------|---|-------------------------------------|-------------------------------------|------------------------------------|
| G9097 | 8% (n=642) | 8% | - | - |
| G9098 | 9% (n=769) | 4% | 5% | - |
| Total | 17% (1,411) | 12% | 5% | - |

Source: Analysis of 2006 Medicare Oncology Demonstration Claims.

Findings from the physician survey showed that most participating physicians reported that they did not find any difficulty in determining the current disease status of their patients. The findings from this analysis underscore that not only did participating physicians report ease in determining disease status but that they also generally reported them accurately.

F.3.3. What percent of patients within each cancer type are participating in clinical trials?

Another test of the demonstration codes was specific to the category of *management adheres to guidelines*. There were seven demonstration codes related to clinical guideline adherence. Participation in clinical trials was an option that participating physicians could use to report as a reason for not adhering to clinical guidelines. Participating physicians reported adhering to clinical guidelines almost 90 percent of the time. Overall, participating physicians reported that they did not adhere to clinical guidelines about two percent of the time because of patient enrollment in approved clinical trials. The reported participation in clinical trials varied by cancer type, with the highest trial participation rate reported for pancreatic cancer (nearly three percent), and the lowest being for non-Hodgkin’s Lymphoma (one percent), as shown in Table 41.

Table 41. Demonstration patients participating in clinical trials

| Cancer | # of patients with any Management Adheres to Guidelines Reported | # of patients reporting participation in clinical trials | % of total |
|------------------------------------|--|--|-------------|
| Small cell and non-small cell lung | 530,916 | 9,624 | 1.8% |
| Breast | 816,923 | 12,152 | 1.5% |
| Prostate | 202,124 | 4,497 | 2.2% |
| Colon | 335,016 | 6,797 | 2.0% |
| Rectal | 126,244 | 1,681 | 1.3% |
| Esophageal | 39,982 | 448 | 1.1% |
| Gastric | 27,520 | 354 | 1.3% |
| Pancreatic | 60,538 | 1,783 | 2.9% |
| Head and neck | 31,503 | 422 | 1.3% |
| Ovarian | 102,976 | 1,796 | 1.7% |
| Non-Hodgkin’s Lymphoma | 322,621 | 3,082 | 1.0% |
| Multiple Myeloma | 168,539 | 4,010 | 2.4% |
| Multiple Cancers | 64,872 | 683 | 1.1% |
| Total Cancers | 2,850,159 | 47,840 | 1.7% |

Source: Analysis of 2006 Medicare Oncology Demonstration Claims.

The Coalition of Cancer Cooperative Groups evaluated accrual to NCI publicly-funded treatment trials from January 2003 through June 2005. In this study, three to five percent of the over 10

million adults with cancer in the United States participate in cancer clinical trials.³⁹ While this rate is higher than that of demonstration participants as reported by participating oncologists, it is not inconsistent with figures associated with the participation of the elderly, minorities and those living in rural areas, who are generally under-represented in clinical trials.

In a study conducted of trial participation in breast, colorectal, lung and prostate trials from 2000 to 2002, a strong relationship between age and enrollment was apparent.⁴⁰ Clinical trial participants between 30 and 64 years of age represented three percent of those in that age group with cancer, in comparison to 1.3 percent of the 65 to 74-year old patients and less than half a percent of patient 75 years of age and older. Thus, when comparing clinical trial participation rates of the elderly and those in the oncology demonstration, patients whose physicians participated in the demonstration seem to participate in clinical trials at a greater rate than the general elderly population.

This higher participation rate may in part be explained by the potential selection bias of physicians choosing to participate in the demonstration. Physicians choosing to participate in the demonstration may have been more likely to be interested in research. In addition, participating physicians tended more often to come from group practices. Solo practitioners and those with limited resources are less likely to participate both in clinical trials and in demonstrations. Regardless of the participation rates for participating and non-participating physicians, these results demonstrate that the participating physicians appeared to accurately report their patients' clinical trial participation through the use of newly introduced demonstration codes.

F.4. Clinical Algorithms and Results

As mentioned earlier, the research team developed eight clinical algorithms to test the usefulness of the demonstration data. In this section, we present three of the clinical algorithms the research team could benchmark against peer-reviewed literature that used SEER-Medicare data, the most comparable data source. The other algorithms developed did not have such benchmarks and thus the validity of the findings would be difficult to assess. The three clinical algorithms presented in this section include:

- Are breast cancer patients who have had breast-conserving surgery receiving radiation treatment?
- Are physicians appropriately using mammography and magnetic resonance imaging to monitor breast cancer patients after BCS?
- Is adjuvant chemotherapy being appropriately offered to colon cancer patients?

³⁹ Report to Global Access Project, 2006. "Baseline Study of Patient Accrual Onto Publicly Sponsored US Cancer Clinical Trials," Coalition of Cancer Cooperative Groups.

⁴⁰ Murthy VH, Krumholz HM, Gross CP. 2004. "Participation in cancer clinical trials: race-, sex-, and age-based disparities," JAMA, 291:2720-2726

For details on the primary sources for codes selected for each algorithm and a description of each code, refer to the Tables provided for each research question in the Appendix F.

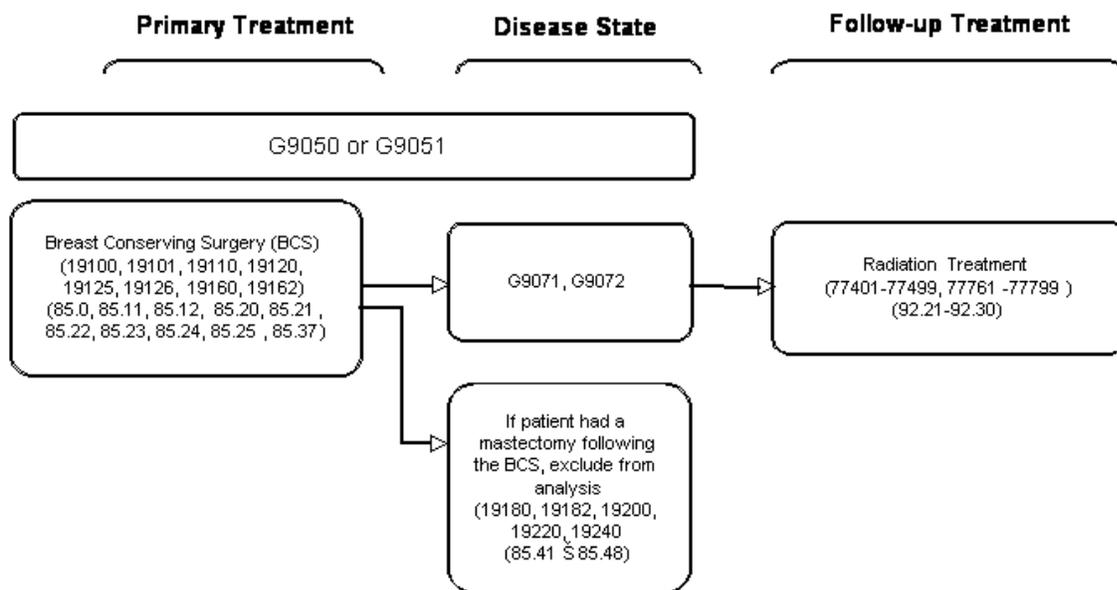
F.4.1. Breast Cancer: Radiation Therapy

Question 1: Are breast cancer patients who have had breast-conserving surgery receiving radiation treatment?

Clinical practice guidelines recommend radiation therapy when BCS is provided as primary treatment for breast cancer, in order to minimize local disease recurrence.⁴¹ Generally, radiation treatment is also recommended within a few months of BCS for non-chemotherapy treated patients or a few months later for chemotherapy-treated patients.⁴²

To be eligible for this analysis, BCS must have been performed after November 15, 2005. Both new and existing patients (G9050 and G9051) were included in the analysis. This timing allowed for participating physicians to diagnose and stage breast cancer through the demonstration codes during the demonstration period. We allowed a window for participating physicians of five months (from January 1, 2006 to June 1, 2006) to submit the disease status code in the administrative claims. Radiation treatment would occur after the submission of the demonstration codes (G9059, G9051, G9071, G9072). This algorithm maximized the demonstration time period to allow for radiation therapy to occur after BCS. Beneficiaries who had a mastectomy following the BCS were excluded from this analysis, as these patients would not require radiation therapy. See Figure 20.

Figure 20. Are breast cancer patients who have had BCS receiving radiation treatment?



⁴¹ Smith BD, Gross CP, Smith, GL, Galusha DH, Bekelman JE, Haffty BG. 2006. "Effectiveness of Radiation Therapy for Older Women With Early Breast Cancer," J Natl Cancer Inst, 98, 10, 681-90.

⁴² NCCN Practice Guidelines in Oncology – v.2.2006.

Results

From the demonstration claims, our analysis identified 8,765 breast cancer claims with the demonstration codes of G9050, G9051, G9071 and G9072. Using these claims, we then identified 3,792 beneficiaries as undergoing BCS (after November 15, 2005). One-third of the beneficiaries who received BCS (or 1,279 patients) then received radiation therapy after the initial reporting of disease status by a participating physician. In other words, the demonstration claims indicated that 34 percent of beneficiaries seen by a participating oncologist during the demonstration who received BCS subsequently received radiation therapy to minimize breast cancer recurrence.

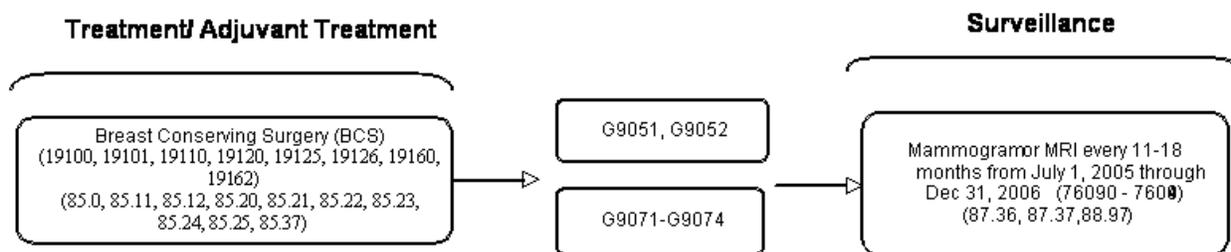
F.4.2. Breast Cancer: Surveillance

Question 2: Are physicians appropriately using mammography and magnetic resonance imaging to monitor breast cancer patients after BCS?

Early recognition and treatment of disease recurrence is a key goal of surveillance after primary treatment for breast cancer. Family history, regular physicals and regular mammography are still the most useful tools for following breast cancer patients. Clinical guidelines recommend that women who have had BCS should receive their first post-treatment mammogram (or MRIs, when preferable) no earlier than six months after radiation therapy, but typically within 12 months following the BCS.⁴³

A subset of patients was created that included new and existing patients (G9050 and G9051) for whom participating physicians reported disease status codes of G9071 to G9074. Eligible patients were then required to have BCS during the first half of 2005, from January 1, 2005 to June 30, 2005. This allowed post-treatment mammograms or MRIs to occur from July 1, 2005 to December 31, 2006. The timing would allow for post-treatment mammograms or MRIs to occur at the earliest six months after breast-conserving surgery and at the latest 18 months after BCS, as illustrates in Figure 21.

Figure 21. Are physicians appropriately using mammography and magnetic resonance imaging to monitor breast cancer patients after treatment?



⁴³ NCCN Practice Guidelines in Oncology – v.2.2006.

Results

From the demonstration claims, our analysis identified 493,907 breast cancer claims with the demonstration codes of G9050, G9051, G9071, G9072, G9073, and G9074. The 493,900 claims correspond to 225,589 unique individuals with breast cancer. From January 1 to June 30, 2005, 4,505 patients were identified as undergoing BCS. During the demonstration period, these patients had the appropriate demonstration codes. About 55 percent of breast cancer patients (or 2,464 patients), seen by a participating physician, received a mammogram or breast MRI for surveillance purposes about one year after BCS.

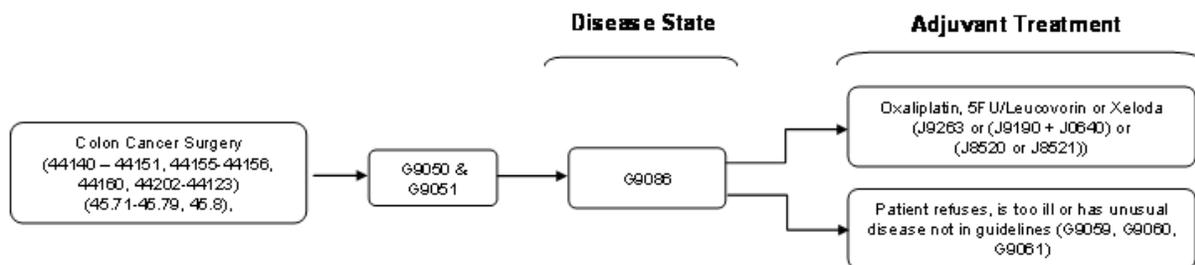
F.4.3. Colon Cancer: Adjuvant Therapy

Question 3: Is adjuvant chemotherapy being appropriately offered to colon cancer patients?

New therapies for colorectal cancer have emerged during the past decade, and have helped to prolong survival. These new therapies have provided clinicians with the ability to tailor patient treatment plans while minimizing toxicity. The guidelines for treating colon cancer list the following as first-line treatments: FOLFOX (oxaliplatin, leucovorin and 5-fluorouracil); FOLFIRI (leucovorin, 5-fluorouracil and irinotecan); 5-fluorouracil/leucovorin; IFL (irinotecan plus 5-fluorouracil and leucovorin); and CAPOX (cetuximab with oxaliplatin and capecitabine) in combination with bevacizumab (avastin). Avastin, a new chemotherapy agent, has dramatically improved outcomes for this illness and current guidelines recommend it be offered to all patients in this category.⁴⁴ First line chemotherapy is used for patients that are able to tolerate this intensive therapy.

Both new and existing colon cancer patients (G9050 and G9051) are included in this analysis with a disease status of G9086 as reported by a participating physician. To be eligible for this analysis, colon cancer surgery, not including any portion of the rectum, must be performed between November 15, 2005 and October 1, 2006. The disease status code must also be billed between January 1, 2006 and June 30, 2006. The adjuvant chemotherapy treatment must occur and be billed after the disease state code. This algorithm maximized the window to allow for adjuvant treatment after colon cancer surgery during the demonstration time period. In addition, patients who refused adjuvant chemotherapy treatment were excluded from the analysis. See Figure 22.

Figure 22. Is adjuvant chemotherapy being appropriately offered to colon cancer patients?



⁴⁴ NCCN Practice Guidelines in Oncology – v.2.2006.

Results

From the demonstration claim, our analysis identified 7,718 colon cancer claims with the demonstration codes of G9050, G9051, and G9086. Using these claims, we identified 2,093 patients who had undergone colon cancer surgery between November 15, 2005 and October 1, 2006. Twenty-seven percent of patients (or 558 patients) who had colon surgery subsequently received adjuvant treatment.

F.4.4. Discussion of Results from Clinical Algorithms

The findings from the validation study suggest that the demonstration data, when linked to the Medicare administrative data, may not accurately reflect the expected patterns of cancer care. The table below summarizes the findings from the demonstration data compared to peer-reviewed literature. In presenting the oncology demonstration findings, we compare them against studies that use SEER-Medicare, as this database would be the most directly comparable. The reported rates from the oncology demonstration data are divergent from the published literature. See Table 42.

Table 42. Comparison of 2006 Oncology Demonstration finding to published literature

| Clinical Algorithm | Results from 2006 Oncology Demonstration Claims | Range from Published Literature |
|--|---|--|
| % of breast cancer patients that have received radiation treatment after BCS | 34% | Riley 1999 64% ⁴⁵ Riley 2008 70% ⁴⁶ |
| % of breast cancer patients that have received mammogram or MRI after BCS | 55% | Keating 2006 78% ^{47**} |
| % of colon cancer patients receiving adjuvant chemotherapy | 27% | Etzioni 46% to 62% ^{48**} |

*Keating et al uses SEER-Medicare data but does not specifically provide a figure for BSC only.

**Primary source was a meta-analysis and we present the most recent data available with SEER-Medicare as the data source.

There is a key difference between the oncology demonstration claims data and the SEER-Medicare data. The SEER program uniformly collects data, including patient's tumor characteristics, demographic characteristics, and date of diagnosis, from population-based cancer registries. SEER data has been linked to Medicare administrative data. While SEER-Medicare collects information on physician specialty from the administrative data, the peer-reviewed

⁴⁵ Riley GF, et al., 1999 "Stage at Diagnosis and Treatment Patterns Among Older Women With Breast Cancer: An HMO and Fee-for-Service Comparison" JAMA, 281, 8, 720-726.

⁴⁶ Riley GF, et al., 2008 "Comparison of Diagnosis and Treatment in Medicare Fee-for-Service and Managed Care Plans," Medical Care 46, 10, 1108-1115.

⁴⁷ Keating NL, et al., 2006 "Factors Related to Underuse of Surveillance Mammography Among Breast Cancer Survivors," Journal of Clinical Oncology 24, 1, 85-94.

⁴⁸ Etzioni DA, et al., 2008 "Rates and Predictors of Chemotherapy Use for Stage III Colon Cancer: A Systematic Review," Cancer 113, 12, 3279-89.



literature that we cite does not provide findings of cancer staging and disease status as reported by physician specialties. The demonstration data, instead, is based on the voluntary reporting of the four eligible specialties (medical oncologists, hematologists, hematologists/oncologists, and gynecological oncologists). As such, the findings reflect only the participating physicians' reports during the demonstration of patients having cancer at any time during the demonstration time period. In addition, the SEER data has cancer staging only four months after diagnosis, rather than at any time during a patient's disease progression.

For the first algorithm on the percent of patients who received radiation therapy following BCS and the second algorithm on the percent of patients who received a mammogram after BCS, a potential undercount may occur as a result of only having data self-reported by participating physicians. Not all patients receiving BCS during the study period are included in the analysis, rather only those participating physicians whose patients had BCS. Similarly, not all patients who had colon surgery are included in the analysis, but only those participating oncologists whose patients had colon surgery.

The third algorithm concerning the prevalence of adjuvant therapy for colon cancer also had similar issues as those described above. In addition, the published literature generally included rectal surgeries, which were not included in our analysis since the adjuvant therapy in the study question was designed only for colon cancer patients with stage III colon cancer. Finally, one of the approved chemotherapy agents (xeloda) is an oral cancer drug that was inexplicably not found in the demonstration data.

Finally, we reported in Table 29 that 2.6 million beneficiaries had been diagnosed with at least one of the 13 eligible cancers. About 28 percent of those beneficiaries with an eligible cancer diagnosis (or 732,420 beneficiaries) were considered to have participated in the oncology demonstration. That is, these beneficiaries had an eligible cancer diagnosis and were seen by an eligible physician. For the two cancer diagnoses that were the focus of the algorithms, 44 percent of breast cancer patients and 33 percent of colon cancer patients participated in the oncology demonstration. These low participation rates likely impacted the compliance rates derived from the demonstration data.

Since the discrepancies however cannot be fully explained by constraining the data to participating physicians reporting demonstration codes, further investigation is recommended to fully understand the extent to which the demonstration data is showing an undercount. Further study and a greater understanding of the impact of the linkage between demonstration codes and claims information are necessary in order to make any assumptions about expected patterns of care.

It must be noted that this analysis focused solely on the oncology demonstration data. Therefore, the unexpected results are not a reflection of the usefulness of Medicare administrative data to evaluate patterns of cancer care.





F.5. Summary and Recommendations

A number of potential suggestions in terms of further study are provided below.

- When possible, run analyses to compare these findings to those of the Medicare population as a whole (not only demonstration physicians or demonstration claims) to determine whether similar issues related to concerns about low compliance rates occur in the larger population.
- Re-run the clinical algorithm with a physician-specific analysis to examine at the frequency of “adherence” by each physician and determine variations among participating physicians.
- Identify a method of excluding or identifying patients who had recurring cancer or had certain co-morbidities during any period during the study, and potentially develop a separate stratum for such patients.
- Consider revising the time periods for anchoring the distance between diagnosis and treatment, or work-up and staging codes depending on the research question. With radiation therapy for BCS, for example, one could further limit the sample by only including claims for which the disease state codes were billed between January and March, to allow for patients to have received radiation therapy treatment within nine months rather than six months of diagnosis, consistent with the study conducted by Smith et al. in 2006. The sample size would be far more limited, but the findings would be more generalizable.
- Enhance specificity by including diagnosis codes only if they appeared either more than once over a period of time (one month, for instance) or also in Part A claims. Those without prior claims could then be treated as a separate stratum in a separate analysis.
- Limit the sample patients to those that were alive and enrolled in Medicare fee-for-service for the entire period for which any treatment regimen is being considered. If this is not possible, then at least attempt to determine how frequently the treatments or other codes in question might be billed through a secondary payer.
- Refine the demonstration codes, training materials and practice tools to improve the overall accuracy of coding efforts by participating physicians, thereby limiting variation in interpretation of summary code descriptors and varying definitions of guideline adherence. If such codes are to be determined by physicians in their fast-paced practices, it is critical that the coding methodology is easy to understand and use thereby preventing miscoding. Revisions might be made not only to the G-code descriptions identified as problematic, but also to the number of G-codes being used in order to get more comprehensive clinical information for the questions to be asked allowing future studies to more directly link such codes (and corresponding treatments) to the appropriate administrative data.

In summary, given the divergence in results from other studies, it is critical that these study results not be used to reach conclusions about the quality of cancer care being delivered to beneficiaries. Instead, the focus of future studies needs to be on gaining further understanding of the challenges and limitations presented when combining clinical data with claims data and how to address them in order to develop a more effective way to look at quality measurements in such data sets.

F.5. Research Limitations

The following describes some data limitations encountered in conducting the validation analysis. A number of these limitations are inherent in the nature of the data made available for analysis.

- **Possible selection bias among demonstration physicians:** Participation in the demonstration was voluntary. As with all voluntary participation, it is possible that the individuals participating were more interested or more likely to be active in the broader oncology community.
- **Newly diagnosed patients not recognized as intended:** The demonstration code G9050 was designed to signal the beginning of an episode of care and a new cancer patient. However, from interviews with participating physicians and after reviewing the data set, we found that this code was not always used as intended. Some physicians reported using this demonstration code for patients who had been diagnosed with cancer, or patients who are currently receiving cancer treatments but seeing a new provider for the first time. Thus, this demonstration code limited the research team's ability to properly identify new cancer patients.⁴⁹
- **Variation in interpretation of G-code descriptions by physicians:** Some of the participating physicians expressed skepticism regarding the consistent use of G-codes. In addition to the problems in interpreting G9050, the most apparent inconsistency was in the area of adherence to guidelines. These differing interpretations of guideline adherence limited the usefulness of these codes.
- **Inability to link chemotherapy administration to specific and complex chemotherapy regimens:** Given the limitations in using CPT codes and connected dates of service, it was difficult to reconstruct the logical series of chemotherapy administrations and regimens in a manner that would allow for a comprehensive look at the administration and drug codes that define a specific treatment or series of treatments. An added limitation was that oral chemotherapy regimens or medications provided through secondary insurance coverage were not included in the claims data.

⁴⁹ For analyses where it was important to distinguish newly diagnosed patients, the research team went back adjusted claims data to ameliorate this situation. When previous claims were found indicating a given patient was in fact not a newly diagnosed patient, that patients' full records were moved from the G9050 category to the established patient grouping.

-
- ◆◆◆
- **Medicare Advantage claims and those for which there was an incomplete or dually eligible enrollment:** This analysis is limited to claims submitted for Medicare fee-for-service beneficiaries or those on fee-for-service for any portion of the study period. If a patient changed from fee-for-service to Medicare Advantage during any part of that time, the complete data on their treatment would not be reflected, possibly resulting in an erroneous “non-compliance” or lower proxy adherence rates.
 - **Estimated timeframes for completion of treatment and patients obtaining diagnoses and workups:** When trying to estimate appropriate timeframes for analysis, the research team was limited by needing to assess care that is delivered sequentially over longer periods of time than are covered by the demonstration. As a result, some timeframes established between diagnoses and treatment were established as if patient compliance and specialty availability would not result in patients receiving care a month or two later than recommended. Broader anchoring of the timeframes over a longer time period in the algorithms would require further study to include running the clinical algorithms on a larger data set and/or examining results after inputting different but also viable timelines.
 - **Cancer diagnosis and treatment is an iterative process:** Cancer is often a complex disease where information changes during the course of diagnosis and treatment. Some of these changes will not be captured when examining clinical and claims data. It is possible that a physician may have followed an appropriate course of treatment that was simply not captured within the normal expected timeframe or the data set available for analysis.
 - **Reliance on administrative data for clinical information:** While the oncology demonstration offered new information about cancer disease states, these codes could not be directly linked in the claims data to specific procedure codes performed by another physician specialist or the same physician on a different day. In addition, CPT codes were created for billing purposes without regard to clinical considerations, with certain codes being quite generic in the sense that they could be used to bill for services for many different diagnoses. While those generic codes provide information on procedures performed for the patient, they do not indicate any results of testing or treatment. Thus, to properly use procedure codes with demonstration codes to determine quality of care, clinical information and a validation of codes against medical charts may be appropriate.

As with many other efforts to examine clinical practice patterns with claims data, the research team encountered a number of challenges inherent in the data set. Given the multitude of potential causes for the results than might be expected, further study is required to determine the extent to which this might merely be attributable to the study limitations listed above rather than physician behavior. At this point, attempts to make inferences about physician performance regarding cancer treatment patterns using the demonstration data would be premature.