VOLUME 3: Research and Clinical Supporting Documentation

OASIS and Outcome-Based Quality Improvement in Home Health Care

February 2002

VOLUME 3

RESEARCH AND CLINICAL SUPPORTING DOCUMENTATION

in the report series entitled

OASIS and Outcome-Based Quality Improvement in Home Health Care: Research and Demonstration Findings, Policy Implications, and Considerations for Future Change

for three interrelated studies:

The National Medicare Quality Assurance and Improvement Demonstration
The New York State Outcome-Based Quality Improvement Demonstration
A Project to Assist Home Care Providers to Effectively Use Patient Outcomes

by

Kathryn S. Crisler, MS, RN
David F. Hittle, PhD
Karin S. Conway, MBA, RN
Lecia R. West, MA
Peter W. Shaughnessy, PhD
Angela A. Richard, MS, RN

with
Martha C. Powell, PhD.
Kendra L. Lawlor, MA
Nancy S. Donelan-McCall, PhD
James M. Beaudry, BA
Lorna L. Baillie, BS, RN
Robert E. Schlenker, PhD
Karen Engle, MA

Center for Health Services Research
University of Colorado Health Sciences Center
Denver, Colorado

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This document is part of the report series for three studies: The National Medicare Quality Assurance and Improvement Demonstration project, funded by the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, (Contract No. 500-94-0054), the CMS Project Officer for this contract is Dr. Armen Thoumaian of the Quality Measurement and Health Assessment Group; The New York State Outcome-Based Quality Improvement Demonstration project, funded by the New York Department of Health (NYDoH), (Contract No. C-015111), the NYDoH Project Officer for this contract is Dr. Nancy Barhydt; and the Assisting Home Care Providers in Effectively Monitoring and Using Patient Outcomes project, funded by the Robert Wood Johnson Foundation (RWJF), (Grant No. 031950), the Program Officer for this grant is Dr. David Colby.

SYNOPSIS AND RATIONALE FOR THE FOUR-VOLUME REPORT

The volumes in the report on

OASIS and Outcome-Based Quality Improvement in Home Health Care:
Research and Demonstration Findings, Policy Implications,
and Considerations for Future Change

are entitled

Volume 1: Policy and Program Overview
Volume 2: Research and Technical Overview
Volume 3: Research and Clinical Supporting Documentation
Volume 4: OASIS Chronicle and Recommendations

This report series documents findings and conclusions resulting from two large-scale demonstration projects to assess the value of a continuous quality improvement (CQI) methodology to measure and improve outcomes of home health care. A third project to assist nondemonstration agencies interested in the CQI methodology supported information dissemination and refinements to the approach during and after the latter stages of the demonstrations. The methodology, termed outcome-based quality improvement (OBQI), was designed primarily to benefit both Medicare and non-Medicare patients who receive home health care. OBQI relies on accurate and uniform information on the health status of patients collected at regular time intervals to measure the outcomes of care provided. Outcome measures are adjusted for factors that may differentially predispose patients to attaining or not attaining specific outcomes. The second objective of OBQI is to assist home care providers to evaluate and improve their own performance. Reports generated through OBQI allow providers to understand and use patient outcomes as performance indicators, changing care behaviors to enhance patient outcomes when appropriate.

In the interest of readability, the four-volume report proceeds from general to progressively more technical and clinical topics. This necessitates a certain amount of redundancy among the volumes, particularly the first two (portions of Volume 1 are excerpted from or closely paraphrase material in Volume 2). A summary of selected topics from Volume 1 stands apart from the four-volume set. It highlights major points and conclusions but provides only exceptionally terse discussion of the rationale for the main conclusions and recommendations. The first volume is a relatively brief document intended for a wide audience of individuals interested in (1) how to evaluate the adequacy of home health care for Medicare beneficiaries under a payment climate that has powerful incentives to underprovide services needed by patients, and (2) how to improve the quality of care in areas for which patient outcomes are poor and should be improved. An overview of the success that is attainable through OBQI to enhance patient outcomes is provided in this document.

Volume 1 is framed in the context of issues and events that led to the present-day environment for home health care. It is this environment and its likely future that the programs at the Centers for Medicare & Medicare Services (CMS)[1] must address on behalf of Medicare and Medicaid recipients. The recommendations presented in this volume are based on a 15-year research and development effort. They are focused on ways to guide the continued evolution of the Outcome and Assessment Information Set (OASIS) and, most importantly, the quality monitoring, quality improvement, payment, certification, and program integrity applications that rely on OASIS. These recommendations are intended to strike the appropriate balance between CMS's primary responsibility to beneficiaries and its secondary responsibilities to other governmental agencies, providers, payers, commercial interests, and voluntary accreditation programs.

[1] The Health Care Financing Administration (HCFA) changed its name to Centers for Medicare & Medicaid Services in June 2001. Both names (and acronyms) are used in this report depending on context and dates.

Volume 2 also is reasonably brief and highlights the research approach and technical findings from the OBQI demonstration trials. Written for a more technical audience, it summarizes the research methodology, experimental approach, and statistical findings from the demonstration. A one-page research abstract is presented that encapsulates the methods, findings, and conclusions. Cross-references to Volume 3 guide the reader to further information on several technical, clinical, statistical, and programmatic topics. Conclusions that derive from the demonstration findings and their relevance to current policy and programmatic considerations are summarized in the final section (these conclusions are discussed in more detail in the final sections of Volume 1).

The third volume consists of supporting documents covering (1) a chronology of research and policy developments that form the backdrop for the results and conclusions of the first two volumes; (2) findings from OASIS reliability studies; (3) an overview of the measurement constructs and issues germane to the research; (4) the OASIS data set with an explanatory prologue; (5) an operations manual for implementing and maintaining OBQI in a home health agency; (6) illustrative agency-level outcome, case mix, and adverse event reports; (7) a summary of the operational components of the demonstration trials; (8) methods used by home health care providers in successfully enhancing patient outcomes; and (9) a bibliography of relevant literature.

Volume 4 contains points of rationale for why certain steps are prerequisite to or inherent in collecting and processing accurate OASIS data in order to measure and improve patient outcomes. An "OASIS Chronicle" constitutes the largest portion of Volume 4. This document provides an item-by-item summary of key attributes and recommendations for every OASIS data item. The attributes provided for each item include its precise wording, the time points at which data are recorded, clarifying or explanatory information, the rationale for the item, uses for the item that pertain to both agency-specific and CMS applications, the developmental and empirical testing history for the item, information on validity and reliability, perceived and real constraints or limitations, other points of information as appropriate, the overall necessity of the item, and a recommendation for retention or change. The OASIS Chronicle and its introductory documentation are intended to form a starting point for the continued evolution and improvement of OASIS and its applications.

PREFACE

The Center for Health Services Research in the Division of Health Care Policy and Research is a multidisciplinary research organization established in 1976 at the University of Colorado Health Sciences Center. The research programs of the Center focus on health policy, clinical issues, health outcomes, quality measurement, quality evaluation and improvement, performance measurement and analysis, case mix assessment and measurement, cost and payment analysis, health care regulation, and research and quantitative methods. Substantively, the primary research undertakings of the Center have been in long-term, geriatric, gerontological, chronic, and managed care in both noninstitutional and institutional provider environments.

This four-volume report was prepared as part of three separate studies: (1) the National Medicare Quality Assurance and Improvement Demonstration, (2) the New York State Outcome-Based Quality Improvement Demonstration, and (3) the Assisting Home Care Providers in Effectively Monitoring and Using Patient Outcomes study, with project or program officers Dr. Armen Thoumaian, Dr. Nancy Barhydt, and Dr. David Colby from three respective funding organizations: the Centers for Medicare & Medicaid Services, the New York State Department of Health, and the Robert Wood Johnson Foundation. The principal investigator for these three studies is Peter W. Shaughnessy, PhD; co-principal investigators on these or other studies that have contributed to the foundation for these reports include Robert E. Schlenker, PhD; Kathryn S. Crisler, MS, RN; David F. Hittle, PhD; Martha C. Powell, PhD; Angela A. Richard, MS, RN; James M. Beaudry, BA; and Andrew M. Kramer, MD. Study and program managers include Karin S. Conway, MBA, RN; Lecia R. West, MA; Rachael E. Bennett, MA; Angela G. Brega, PhD; and Nancy S. Donelan-McCall, PhD.

The findings and conclusions documented in this four-volume report derive from several projects conducted during the past 15 years that provided the research, clinical, and analytic approaches and framework employed in the demonstration trials documented here. This entire program is indebted to over one thousand home health care clinicians and administrators who contributed to all facets of outcome measurement and quality improvement research during this period.

We are grateful to several individuals for assisting with and enabling the OBQI demonstrations and promulgation of information about OBQI. Captain Armen H. Thoumaian, PhD, USPHS, was significantly and substantively involved in the National Demonstration trial and in facilitating ongoing national OBQI applications resulting from the demonstration. The interest and support of Steven Clauser, PhD, MPA throughout the demonstration and later stages of the CMS-sponsored research was integral to maintaining the entire OBQI program. CMS staff members Elizabeth Goldstein, PhD; Tony Hausner, PhD; and Barbara Greenberg, PhD helped guide early research activities that shaped this work. Other staff who were instrumental in guiding OBQI and OASIS applications and analyses at CMS include Helene Fredeking, BA, MEd; John Thomas, BS; Mary Wheeler, MS, RN; Mary Weakland, MS, RN; Tracey Mummert, BS, MT (ASCP); Heidi Gelzer, MSPH, RN; and Mavis Connolly, RN, MSW. Nancy Barhydt, DrPH, at the New York State Department of Health, provided leadership essential to the success of the New York State Demonstration, with assistance from Keith Servis, MA, and Mary Anne Tosh, MS, RN of the New York State Department of Health. Beth Stevens, PhD; Andrea Kabcenell, MPH, RN; Alan Cohen, ScD; and David Colby, PhD from the Robert Wood Johnson Foundation and Karen Pace, MS, RN from the National Association for Home Care assisted on several studies and programs that were part of the OBQI developmental effort.

The National Advisory Committee for the demonstration programs has played a critical role in formulating the foundational research and programmatic applications of OASIS and OBQI. Its members include Nancy Barhydt, DrPH, Director, Division of Home and Community Based Care, State of New York Department of Health; Andrea Kabcenell, MPH, RN, Deputy Director, Pursuing Perfection; A. E. Benjamin, PhD, Professor, Department of Social Welfare, School of Public Policy and Social Research, University of California at Los Angeles; Joan Marren, MEd, MA, RN, Vice President for Clinical Services, Visiting Nurse Service of New York; Barbara McCann, MSW, Vice President, Interim Health Care, Inc.; Peter Boling, MD, Professor of Internal Medicine, Virginia Commonwealth University; Sharon Johnson, MS, RN, Director, Jefferson Homecare Network; Paula Reichel, BSN, RN, CEO Community Health Center; and Randall Brown, PhD, Senior Fellow, Mathematica Policy Research, Inc.

Over 80 faculty and staff at the Center for Health Services Research were involved in the several phases of this research. We particularly wish to acknowledge the efforts of Dee Smyth, Natasha Floersch, Patti DeVore, Laura McLaughlin, Karis May, and Lanee Bounds in all facets of editing, word processing, proof reading, and producing these four volumes. We deeply appreciate the efforts and contributions of all the aforementioned individuals.

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(Cont'd)

SUPPORTING DOCUMENT 1:

CHRONOLOGY OF MAJOR RESEARCH AND POLICY EVENTS INFLUENCING THE OUTCOME-BASED QUALITY IMPROVEMENT INITIATIVE

in Volume 3 of the report series entitled:

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OVERVIEW

In Section A of this document, an enumeration is provided of significant research and policy events that shaped the Outcome-Based Quality Improvement (OBQI) approach and its accompanying data set, OASIS, as they exist today. A brief description of each research activity and event is provided. Thereafter, Section B contains a listing of some of the more important home care research studies conducted by the University of Colorado Center for Health Services Research as additional background information. Most of these studies (conducted over the past two decades) have entailed developing or analyzing patient outcomes; reporting on home care outcomes, case mix, utilization, and cost; implementing or disseminating information about OBQI; and/or collecting patient-level primary data at home care agencies for various research and evaluation purposes.

CONTENTS

A. CHRONOLOGY OF MAJOR RESEARCH AND POLICY EVENTS

The undertakings and actions described in the following enumeration influenced the development of OBQI either through research and developmental steps or by significantly shaping the delivery of home care in the United States. The nonresearch activities are, of course, but a sampling of the events that influenced the provision of home care since 1980. These events were chosen because they were particularly salient events from the perspectives of utilization and quality of home care services in the United States. The research activities consist only of those that have directly contributed to the outcome-oriented foundation for OBQI either by design or as part of the interlocking research projects that led to OBQI. In most instances, these research activities spanned several different projects (or portions of projects). The research summarized here consists only of work conducted by the Center for Health Services Research. This is not meant to imply that significant and useful research has not been conducted in the home care field in numerous other areas.

Years	Events and Activities
1977-80	**Outcomes Measured and Compared for Long-Term Care Patients in Swing-Bed Hospitals and Nursing Homes:** As part of an evaluation study to assess the cost-effectiveness of rural hospital swing-bed care, an initial set of outcome measures was developed for long-term care patients. The risk-adjusted outcome measures used in this research included health status outcomes as well as utilization outcomes based on primary data collected at multiple time points for admission samples of swing-bed hospital and nursing home patients. Risk-adjusted survival analysis was employed to analyze the lengths of time between admission and the occurrence of significant events such as discharge to independent living or improvement in health status. In addition, patient-level health status data collected at multiple time points were used to measure lengths of time in improved and stabilized states.
1980	**Legislation Expanding Medicare Home Health Care:** Enabling legislation that greatly expanded the supply of Medicare-certified home health providers was enacted under the Omnibus Budget Reconciliation Act of 1980 (P.L. 96-499). This legislation clarified the eligibility criteria for home health care providers to participate in the Medicare program. As a result, the numbers and percentages of hospital-based home health agencies and proprietary agencies increased substantially during the 1980s. Between 1980 and 1990 the total number of Medicare-certified home health agencies nearly doubled, from 2924 in 1980 to 5695 agencies in 1990.
1982-87	**Research to Compare Outcomes of Home Health Care with Nursing Home Care:** In the context of a study to compare the effectiveness of home health care with nursing home care and to examine potential differences in hospital-based versus freestanding home health agencies and nursing homes, one of the earliest attempts to measure home health outcomes was undertaken. The need to develop outcome measures for home health care in this study became apparent as a result of analyzing the differences in processes of care in the two settings. The unique features of in-home care such as greater emphasis on

patient and informal caregiver education, the resulting need to increase patient and caregiver knowledge, and the challenges of motivating patients and family members to ensure compliance with treatment regimens pointed to major differences between institutional and noninstitutional long-term care. Thus, it was necessary to develop outcome measures that would be of value in examining the effectiveness of care in both settings concurrently (rather than relying exclusively on process measures of quality).

1983 **Legislation Mandating Per-Case Medicare Payment for Acute Care Hospitals Based on Diagnosis-Related Groups (DRGs):** The Social Security Amendments of March 1983 (P.L. 989-21) marked the beginning of a new and different approach to hospital reimbursement under the Prospective Payment System (PPS) for hospitals. Hospital payment under Medicare would no longer be based on the cost of each *day* of care provided. Rather, it would be based on the price that Medicare would pay for a hospital *stay*, with payment varying for different patient types (Diagnosis-Related Groups, or DRGs, were established to classify patients). Under PPS, it quickly became clear that hospital lengths of stay were decreasing as patients were being discharged earlier. Many familiar with long-term care had conjectured that as hospital lengths of stay decreased under PPS, other providers (particularly Medicare-certified home health agencies and skilled nursing facilities) would experience an increase in case mix intensity.

1985-87 **Research Showing the Impact of DRG-Based Hospital Payment on Intensifying Home Health Care Case Mix:** The hypotheses regarding greater intensity in case mix for Medicare-certified home health agencies and skilled nursing facilities was borne out by research conducted in the mid-1980s. The case mix intensity for both types of providers increased considerably after Medicare PPS had been in place for acute care hospitals for only a few years. This, in turn, heightened the importance of examining quality of care, most preferably by using patient outcomes, for these two types of Medicare providers. The primary concern focused on noninstitutional care because the challenge of providing more complex acute care in a home setting was regarded as greater than in an institutional care setting.

1989 **Clarification of Medicare Coverage of Home Health Care:** The nature of Medicare coverage in terms of eligibility of homebound patients needing intermittent care was clarified in 1989. This clarification was the result of a 1987 legal case, and subsequently led to a considerable increase in the number of certified home health agencies and the volume of home health care provided in the United States (as discussed below in the 1987-1997 description of industry growth).

1987-90 **Research Demonstrating Feasibility of Establishing a Practical Outcome Measure System for Home Care:** The feasibility and practical utility of outcome measures for home health care were examined in the context of several studies. One of these, a study to analyze home health care under

capitated versus fee-for-service payment, employed outcomes to evaluate the quality of home health care under these two payment environments. Additional research studies were conducted to extend the measures used in the first study to examine the potential viability of a systematically derived set of outcome measures spanning the most important domains of home health care. This research involved input from experts representing all disciplines involved in the home health field, with the conclusion that a pragmatic outcome measure system of value to home health care providers could be developed.

1987-97 **Exceptionally Rapid Growth and Expansion of Medicare Home Health Care Nationally:** The supply, utilization, and total cost of home health care increased dramatically as a result of the increased number of patients receiving home health care due to (1) the DRG-based PPS system for hospitals, (2) the aforementioned coverage clarification for Medicare home health care, (3) prior legislation that expanded the types of agencies eligible to provide certified home health care, and (4) a cost-based payment system. By 1997, the number of certified agencies had grown to 10,577. Total Medicare home health care visits increased from 36 million in 1987 to 256 million in 1997, and Medicare expenditures on home health care increased from $2.6 billion to $16.7 billion over the same time period. This unprecedented growth fueled concerns about both runaway expenditures and the quality of home health care. Answering the question of whether Medicare was receiving sufficient return on its large investment in home health care became paramount. It prompted serious concern about how to evaluate patient outcomes.

1990-94 **Research to Develop a System of Home Care Outcome Measures:** This program followed from the earlier research that had established the feasibility of a pragmatic approach to measure patient outcomes that would be of practical value to providers of home health care. A systematic approach to deriving, reviewing, and refining outcome measures was undertaken. The research entailed conducting literature reviews, drafting an expansive set of potential outcomes, convening clinical and research panels to review all outcomes, subsequently specifying and reviewing data items needed to measure outcomes, and empirically testing and continually refining the measures and data items on different samples of patients from home health agencies throughout the United States. The primary products of this research were twofold: (1) a system of outcome measures and an associated data set that could be used by providers of home health care to evaluate their effectiveness based on patient outcomes, and (2) a continuous quality improvement framework termed outcome-based quality improvement (OBQI), which could be integrated into the day-to-day operations of home health agencies to monitor and continually improve patient outcomes.

1993-94 **Implementation of Medicare's Home Health Initiative to Establish Improved Communication and Information Sharing with the Home Health Industry:** A program to enhance the mutual understanding of the perspectives of home health providers and those who administer the home

Years	Events and Activities

health care component of the Medicare program was implemented by HCFA. This initiative provided a forum for open discussion and communication between providers and Medicare program leaders and staff. Discussions dealt with both intermediate and longer-term issues related to payment, quality assurance, challenges of providing home health care, and needed changes in the home care delivery system. The need for an improved approach to monitoring outcomes was acknowledged at several points during this initiative, with considerable support for outcome monitoring.

1995-2001 **National and New York State OBQI Demonstration Programs Resulting in Enhanced Patient Outcomes:** Two large-scale demonstration trials were implemented to test the feasibility and efficacy of OBQI in individual home health agencies over a several year period. The national program involved certified home health agencies from 27 states. The New York State program involved both certified and noncertified (i.e., licensed) agencies. The findings from the demonstrations for certified agencies indicate that providers effectively used OBQI to significantly reduce hospitalization rates and improve health status outcomes for home health patients throughout the demonstration period. The data set required to measure and risk adjust patient outcomes, termed the Outcome and Assessment Information Set (OASIS), was integrated into comprehensive assessments for all adult, nonmaternity patients at demonstration agencies. This data set formed the empirical basis for outcome measurement, risk-adjusted outcome measures, and outcome enhancement.

1997 **Legislation Changing the Nature of Medicare Payment for Home Health Care on an Interim and a Long-Term Basis:** As a result of the Balanced Budget Act of 1997 (P.L. 105-33), Congress changed substantially the nature of Medicare payment for home health care. The goal was not only to curtail, but to reverse the rapid rise in Medicare expenditures that had occurred during the prior 10 years. This legislation first mandated an Interim Payment System (IPS) that imposed new and expanded limits on Medicare payment to home health agencies in the immediate future (i.e., during the remaining time that the cost reimbursement payment methodology would be in effect). Thereafter, the Medicare program was to implement a Prospective Payment System (PPS) that would be based on price instead of on retrospective reimbursement of agency-specific costs.

1997-2000 **Severe Curtailment of Medicare Expenditures and Negative Climate for Home Health Care:** As a result of the limits imposed by IPS, Medicare expenditures declined by approximately 50% between 1997 and 2000. This decline was accompanied by an almost one-third reduction in the number of home health agencies participating in the Medicare program. IPS brought about an understandably negative reaction throughout the home health industry, which was accompanied by a natural resistance to further change and innovation, particularly innovation that would be supported by or forthcoming from Medicare.

Years	Events and Activities
1999	**Final Regulations for Comprehensive Assessment, OASIS, and OBQI:** In keeping with the generally recognized need for an enhanced approach to quality assurance and improvement, a regulation was issued in 1999 clarifying the nature of the comprehensive assessment requirement for Medicare home health patients. The regulation is clear on the need for a comprehensive assessment of patient status at admission, discharge, and other time points. The intent to focus more strongly on patient outcomes, and to make the survey and certification process more outcome-oriented, is evident in this regulation. Providers are encouraged to use outcomes. The regulation includes a mandate for Medicare providers to include OASIS in their comprehensive assessments for patients receiving skilled care services. A concurrent regulation on data transmission indicates that OASIS is but one of several components of OBQI, which also includes outcome reports distributed to each home health agency for use in quality assessment and performance improvement programs. A catalyst for the OASIS mandate in this regulation was the need to collect uniform data on patient health status in order to case mix-adjust payment rates under the forthcoming prospective payment approach that would be implemented in 2000.
2000	**Implementation of PPS for Medicare Home Health Care:** The congressionally mandated PPS was implemented in autumn of 2000. This approach to Medicare payment for home health care permanently eliminated the previous retrospective cost-based approach, replacing it with a price-based, per-episode payment system that includes adjustments for case mix and prevailing labor market conditions or wage rates. Although PPS does not appear to provide additional dollars for providers of home health care, it seems to have received more widespread acceptance by providers than IPS. This raises the natural concern that patients may be receiving fewer services than had been the case under the prior reimbursement approach when payment was based on the number of visits as opposed to an episode of care. The ramifications of this change on patient outcomes are unknown.
2001-2002	**Implementation of a National OBQI Program:** Using OASIS data initially submitted by all certified agencies after the 1999 mandate, case mix and adverse event reports were made available electronically for all certified agencies early in 2001. Current plans call for promulgation of materials and training programs on how to implement and maintain an OBQI system at the home health agency level. The first round of outcome reports is scheduled for early 2002. These reports will include 41 outcome measures, most of which are risk adjusted, enabling individual home health agencies to compare their patient outcomes with those of other agencies throughout the country. The subsequent rounds of outcome reports that will be available in 2003 and thereafter will enable each agency not only to compare its outcomes with a national reference group, but also with its own performance during the previous time period.

B. HOME CARE PROJECTS CONDUCTED BY THE UNIVERSITY OF COLORADO CENTER FOR HEALTH SERVICES RESEARCH

Table 1 contains a listing of some of the more significant home care studies that have been conducted by the faculty and staff of the Center for Health Services Research at the University of Colorado Health Sciences Center. The studies or research programs mentioned in Section A do not correspond directly with projects listed in the below table because the research activities highlighted in Section A often combine (portions of) several individual projects listed below. (Also, the earliest research noted in Section A, on hospital swing-bed care, although important to mention from a methodologic perspective, did not involve home health care.)

TABLE 1: Selected Home Health Projects Conducted by the Center for Health Services Research at the University of Colorado Health Sciences Center.[1]

1. **National Long-Term Care Study** (1982-1987), funded by Health Care Financing Administration (HCFA), Office of Research and Demonstrations (ORD)
   a. Comparison of Long-Term Care Case Mix and Process Quality in Nursing Homes and Home Health Agencies Before and After the Implementation of Medicare's Hospital PPS
   b. Assessed Patient Status Outcomes and Utilization Outcomes for Selected Types of Nursing Home and Home Health Patients
   c. 20 Home Health Agencies, 653 Home Health Patients (Comparable Numbers of Nursing Homes and Residents)
2. **Study of Home Health Care Under Managed Care** (1987-1994), funded by HCFA, ORD
   a. Assessed Home Care Outcome, Case Mix, and Cost Differences Between HMO and Fee-for-Service Patients
   b. 38 Agencies, 1632 Patients
3. **National Quality Measure Study** (1988-1994), funded by HCFA, ORD, and the Robert Wood Johnson Foundation (RWJF)
   a. Developed and Tested Measures of Home Health Care Patient Outcomes
   b. Resulted in System of Outcome Measures and Data Required to Measure and Risk Adjust Outcomes
   c. 49 Agencies, 3427 Patients
4. **Home Care Quality Study** (1989-1994), funded by RWJF
   a. Companion to Above Study (#3), Developed Indicators and Outcome Measures of Quality for Non-Medicare Patients Covering, in Particular, More Chronic Conditions Treated by Home Health Agencies
   b. Panels of Expert Clinicians Participated in Extensively Reviewing and Revising Quality Indicators for Elderly and Nonelderly Adults
   c. Survey Sample of 50 Clinicians to Assess Relevance of Outcomes and Also Used Agency and Patient Samples in Study #3.
5. **Evaluation of Medicare's Survey and Certification Program** (1992-1994), funded by HCFA, Health Standards and Quality Bureau (HSQB)
   a. Assessed Strengths and Weaknesses, Validity, and Reliability of Survey Approach
   b. Recommended Improvements, Including a Stronger Emphasis on Patient Outcomes
6. **Home Health Quality Improvement Three-Agency Pilot** (1992-1996), funded by RWJF
   a. Phased Implementation of OBQI in Three Agencies, 2736 Patients
   b. Agencies Implemented the Two-Component OBQI Approach, as Pilot Test of Method Used in Larger Demonstrations (See #9-10).

[1] The Health Care Financing Administration (HCFA) changed its name to the Centers for Medicare & Medicaid Services (CMS) in June 2001. Both names (and acronyms) are used in this report depending on context and dates.

TABLE 1: Selected Home Health Projects Conducted by the Center for Health Services Research at the University of Colorado Health Sciences Center. (Cont'd)

7. ***Outcome-Based Quality Improvement: A Manual for Home Care Agencies on How to Use Outcomes*** (1994-1995), funded by the National Association of Home Care (NAHC)
   a. Manual Written as Part of a Collaborative Arrangement with NAHC
   b. Based on a Series of Regional and State Workshops on OBQI, Sponsored by NAHC and State Home Care Associations
   c. Resulted in User-friendly Manual on How to Use Outcomes at the Agency Level

8. **National Study of Home Care in Rural and Urban America** (1994-1999), funded by the Agency for Health Care Policy and Research (AHCPR)
   a. Assessed Outcomes, Cost, Case Mix of Home Health Care Provided to Elderly Patients in Rural vs. Urban U.S.
   b. Longitudinal Patient-Level Data, 72 Agencies, over 5000 Patients

9. **National Medicare Quality Assurance and Improvement Demonstration** (1994-2001), funded by HCFA, ORD and later by the Office of Clinical Standards and Quality (OCSQ)
   a. National Sample of 54 Home Health Agencies and 157,598 Patients
   b. Implement OBQI: Agencies Collected OASIS Data, Received Risk-Adjusted Outcome Reports, Conducted Outcome Enhancement Activities, Developed and Implemented Plans of Action. Subsequent Outcome Reports Measured Results
   c. Evaluation Found OBQI Led to Improved Outcomes

10. **New York State OBQI Demonstration Program: Phase 1** (1995-1998), funded by New York State Department of Health (NYSDoH) (Phases 2 and 3, See #16 and 20)
    a. Analogous to National OBQI Demonstration (#9) Implemented Initially in 19 Certified Home Care Agencies in New York State, 105,917 Patients Over Four Years
    b. OBQI Program Partnership between Industry and State Government
    c. Included Certified and Noncertified Agencies, Program Continued for Some Certified Agencies and for Licensed Agencies (See #20)
    d. Evaluation Found OBQI Led to Improved Outcomes

11. **A National Evaluation of Practice Pattern Variations in Home Care** (1995-2001), funded by the Office of the Assistant Secretary for Planning and Evaluation, Department of Health and Human Services (ASPE/DHHS)
    a. Identify the Actual Practice of Home Health Care in Terms of Visits, in Total and by Discipline; Length of Stay; and Decision Making in the Context of Patient, Provider, and Market-Regulatory Factors
    b. Sample of 51 Home Health Agencies, 1217 Patients in Eight States

12. **Quality Assurance and Improvement Under Prospective Payment** (1995-2001), funded by HCFA, ORD
    a. OBQI Program Built into Medicare's National Prospective Payment Demonstration
    b. Agencies Implemented OBQI as in #9 Above, Focusing on Particular Patient Conditions
    c. 87 Home Health Agencies from Five States (CA, FL, IL, MA, TX), 74,000 Patients

13. **Study of Relationship Between Outcomes and Volume of Home Care Services** (1995-2000), funded by HCFA, ORD
    a. Evaluated Outcomes as a Function of Volume of Home Health Visits
    b. 91 Agencies, 3000 Patients

14. **A Project to Develop a System of Outcome Measures for the Program for All-Inclusive Care for the Elderly (PACE)** (1996-2003), funded by HCFA, ORD, and later OCSQ
    a. Develop and Test (at Multiple PACE Sites) Outcome Measures for PACE Participants, Spans Multiple Care Settings
    b. Involves Several Clinical/Research Panels, PACE Sites, PACE Providers, and PACE Participants in the Developmental and Empirical Activities
    c. Objectives: (1) To Develop a Comprehensive Approach to Outcome-Based Continuous Quality Improvement (OBCQI) for PACE, Similar to OBQI for Home Health Care, and (2) Develop a Core Outcome and Comprehensive Assessment (COCOA) Data Set for Outcome Measurement, Risk Adjustment, and Assessment

TABLE 1: Selected Home Health Projects Conducted by the Center for Health Services Research at the University of Colorado Health Sciences Center. (Cont'd)

15. **A National Program to Assist Home Care Providers in Effectively Monitoring and Using Patient Outcomes** (1997-2003), funded by RWJF
    a. Develop and Promulgate Guidelines for Home Care Organizations, State and National Associations, Payers, and Governmental Entities on How to Collect Appropriate Data, Measure Outcomes, and Maintain an Effective Approach to OBQI
    b. Refine and Update Outcome Measures and Data Items to Enhance OBQI
    c. Provide Selected Types of Technical Assistance and Establish a National Reference Database for Benchmarking Outcomes in the Home Care Field
    d. 575 Agencies, Approximately 1,250,000 Patients
16. **New York State Quality Improvement Demonstration: Phase 2** (1998-2001), funded by NYSDoH
    a. Built on Phase 1 (#10), Added More Certified and Licensed Agencies, for a Total of 33 Certified Agencies and 24 Licensed Agencies, with 111,787 Patients
    b. OBQI Program Partnership between Industry and State Government
    c. Included Certified and Licensed Agencies, Acute and Personal Care, and Short- and Long-Term Care Patients/Clients
17. **Normative Standards for Medicare Home Health Utilization** (1998-2001), funded by HCFA (CMS), OCSQ
    a. Develop and Test a Model for Normative Standards that Combines Information on Utilization (i.e., Visits Per Episode) and Patient Outcomes, To Assist Home Health Agencies Improve Outcomes Cost-Effectively
    b. Utilize National OASIS and Claims Data for 1999 and 2000 for Model Development and Testing
18. **New York State Quality Improvement Demonstration: Phase 3** (2001-2005), funded by NYSDoH
    a. Builds on Phase 2 (#16), Will Be Implemented in Approximately 40 Home Care Agencies in New York State through 2003
    b. Focuses on (Noncertified) Licensed Agencies and Outcomes for Patients Receiving Personal Care
    c. Research Activities Directed toward Personal Care Outcome Measure Development and Testing, Resource Consumption Measure Testing, and Refined Risk Adjustment Methods
    d. OBQI Program Partnership between Industry and State Government

SUPPORTING DOCUMENT 2:

RELIABILITY AND BURDEN OF HOME HEALTH ASSESSMENT USING OASIS

in Volume 3 of the report series entitled:

OASIS and Outcome-Based Quality Improvement in Home Health Care:
Research and Demonstration Findings, Policy Implications,
and Considerations for Future Change

for the three interrelated studies:

The National Medicare Quality Assurance and Improvement Demonstration
The New York State Outcome-Based Quality Improvement Demonstration
A Project to Assist Home Care Providers to Effectively Use Patient Outcomes

February 2002

OVERVIEW

This document describes the development of OASIS, its formative research, evolution, validation, and selected features of its use by home health agencies for quality improvement and other purposes. Results of interrater reliability testing and a study of time required by clinicians to complete OASIS assessments are reported. Many of these results are incorporated into the OASIS Chronicle in Volume 4 of this report. A revised version of this document has been submitted for publication in a peer-reviewed journal.

CONTENTS

ABSTRACT

Purpose: The Outcome and Assessment Information Set (OASIS) is mandated for inclusion in comprehensive assessments for skilled care patients served by Medicare-certified home health agencies, and is used for outcome reporting and quality improvement as well as case mix adjustment of per-episode payment. The purpose of the research described here was to test OASIS items for interrater reliability and estimate the time required to complete a comprehensive assessment with and without OASIS. A summary of the OASIS development and validation process is presented, and the uses of OASIS items for payment adjustment, outcome measurement, and risk adjustment are described.

Design and Methods: Interrater reliability for OASIS data items was estimated using repeat assessments by two different clinicians within a 24-hour period for a sample of 66 home health agency patients. Percent agreement and weighted kappa measures of rater agreement were calculated for OASIS items. OASIS burden was measured by interviewing clinical care providers who completed assessments without OASIS, and an agency-matched sample of clinicians who used all of the OASIS items in the assessment.

Results: Interrater reliability is excellent (kappa >.80) for many OASIS items and at least substantial (kappa > 0.60) for most items. A minority of OASIS items has moderate or fair reliability, indicating a need for selective revision. The total reported time required to complete a comprehensive assessment including OASIS did not differ from the time required for a comparable assessment without OASIS.

Implications: The reliability of most data items is sufficiently strong for the clinical, statistical, and programmatic applications that are based on the OASIS data set. Future revisions to the data set should be considered to improve precision for selected items.

RELIABILITY AND BURDEN OF HOME HEALTH ASSESSMENT USING OASIS

A. INTRODUCTION

1. Purpose of OASIS

The Outcome and Assessment Information Set (OASIS) is a group of data items designed to be used in the context of patient assessment in the home for measuring and evaluating patient outcomes of home health care, with appropriate adjustment for patient risk factors affecting those outcomes. Outcome measurement and reporting provide the foundation for outcome-based quality improvement (OBQI), a data driven continuous quality improvement approach which has been implemented in several demonstration programs and found to be effective in measurably improving patient outcomes (as documented in Volumes 1 and 2 of this report series and elsewhere).[1-3] Other current and planned uses for OASIS data include care planning, case mix adjustment of per-episode payment under Medicare, external performance monitoring (e.g., for accreditation), and agency-specific performance reporting for consumers.

All Medicare-certified home health agencies (HHAs) are required to use the OASIS items as part of a comprehensive assessment at start of care and specific time points during an episode of care, and to encode and transmit OASIS assessment data to a central repository maintained by the Centers for Medicare & Medicaid Services (CMS, formerly the Health Care Financing Administration), as specified in the Medicare Conditions of Participation.[4-6] CMS has established a system to provide each HHA with statistical reports comparing its patients' admitting characteristics and outcomes to a national reference population and to its own patients from earlier time periods. This national reporting system included case mix and adverse event outcome reports when first implemented early in 2001. Risk-adjusted and descriptive outcome reports were introduced in late February 2002. Under the prospective payment system (PPS) that went into effect for Medicare-covered home health services on October 1, 2000, OASIS data are used to adjust per-episode payment rates to compensate for variation in patient conditions that affect service needs.[7]

The effective use of OASIS data for monitoring and improving quality of care as well as for ensuring fair and appropriate payment for home health services requires that meaningful and accurate data be collected without undue burden on patients and providers of care. This paper describes (1) the development and validation of OASIS, (2) the results of a study examining interrater reliability of OASIS items, and (3) the results of a study of time required to complete a patient assessment in the home, comparing assessments with and without OASIS. Recommendations are made for steps that can be taken to maintain and improve the data set over time.

2. OASIS Development and Validation Process

The immediate precursor to OASIS was a data collection instrument used in a research study to develop outcome measures for evaluating quality of home health care.[8]

The Patient Status Questionnaire (PSQ) used in this study relied on earlier instruments employed in home health care and nursing home research.[9-11] It was designed to measure patient characteristics for specific domains (identified by home care clinical experts as relevant to patient outcomes and quality of care), as well as risk factors affecting those outcomes. Prior to instrument development, quality indicators and patient outcome measures were reviewed by clinical panelists drawn predominantly from the home health care industry, including nurses; medical social workers; physical, occupational, and speech therapists; and physicians. Over the course of five meetings, these panelists evaluated proposed quality indicators and outcome measures for clinical validity and practical utility, and reviewed the approaches that were being developed to operationalize the measures. The panelists reached consensus on a set of indicators and measures that would be clinically meaningful and measurable, and could be completed from data collected during a routine patient assessment.[12]

Alternative methodologies for collecting patient status and outcome data, including clinical record abstraction, care provider interviews, and direct assessment, were proposed and tested over the course of this study. The conclusions ultimately drawn from this research, mirrored by findings of others,[13] were that (1) home health clinical records lacked specificity and uniformity, and (2) it was important to develop a uniform set of assessment items which could be used to record patient status at start of care and over the course of the home health episode of care. Thus, the PSQ was developed to capture those aspects of patient status that were relevant for measuring patient outcomes and risk adjusting agency-level outcome measures for use in quality assurance and quality improvement.

The items in this instrument underwent a rudimentary initial test for consistency using a concurrent assessment approach, which involved one clinician carrying out an assessment and recording data for each item while a second clinician observed and independently completed each item. This approach is less burdensome for both the patient and clinician than conducting two independent assessments, but it is methodologically less sound. On one hand, having the observer present while the first clinician conducts the assessment may artificially inflate reliability, because the behavior of the patient is held constant. On the other hand, the observer is handicapped by having to rely on the primary assessor to elicit enough information to complete each item. Although reliability estimates may be inaccurate, this approach produces at least a first approximation of interrater reliability. Items with lower reliability on this test were modified to clarify language and reduce complexity. Other steps taken to validate the outcome measures and risk factors measured using PSQ items included (1) correlation analysis of relationships among outcome measures, (2) analysis of patient- and agency-level variation in outcome measures to confirm that outcome differences among agencies can be detected, and (3) analysis of relationships between outcome measures and start of care risk factors to conduct risk-adjusted outcome comparisons among home care agencies.[14]

The research into patient outcome measurement and quality measurement in home care was the basis for the development of the initial OBQI system, which was pilot tested with three HHAs beginning in 1993. The PSQ data items continued to undergo modification in response to feedback from clinicians using them for assessment, care planning,

and care provision. At about the same time, HCFA began an effort to develop a standardized comprehensive assessment tool for home health care by convening a workgroup consisting of clinicians from the major home care disciplines, physicians, researchers, and representatives of home health industry organizations. This panel reviewed a number of alternatives and recommended that a core set of data items, rather than a comprehensive assessment tool, be adopted. After reviewing the PSQ items for face validity and applicability for home care assessment, the panel's consensus recommendation was that the core data set include the PSQ items, augmented by several additional items the panel members believed to be essential for patient assessment. This data set became the initial version of OASIS.

3. Use of OASIS for Outcome-Based Quality Improvement

The OASIS data set was first used in the National OBQI Demonstration, which involved 54 HHAs collecting OASIS data, receiving risk-adjusted outcome reports, selecting target outcomes, developing plans of action to improve outcomes, and then assessing the effects of their quality improvement efforts by monitoring changes in patient outcomes. A similar OBQI demonstration began in New York State shortly after the National Demonstration. Refinements to OASIS items continued during the demonstrations, based on formal and informal feedback from participating agencies. The initial version of OASIS, termed OASIS-A1, underwent two minor revisions (OASIS-A2 and OASIS-A3), then was revised in a comprehensive manner, resulting in OASIS-B. The process of generating risk-adjusted outcome reports was more fully developed under these demonstration projects, forming the foundation for the national outcome reporting system, which has now been implemented by CMS for all Medicare-certified home health providers.

In addition to OBQI, agencies participating in the demonstration projects used OASIS data in guiding business decisions and clinical practice. OASIS data were used to improve care planning, document justification for providing specific services (or for discontinuing services), provide feedback to physicians, and document effectiveness of care for payers and referral sources. (For examples of these and other uses HHAs have found for OASIS data, see McCann,[15] Conway and Richard,[16] and Campbell.[17])

4. Overview of OASIS Items and Their Use in Quality and Payment Applications

As indicated above, OASIS items are essential for outcome reporting as well as case mix adjustment of payment for Medicare patients. However, different items serve different purposes. Table 1 lists the OASIS items and summarizes the main purposes (quality measurement or payment) for which each OASIS item is used. (A more detailed treatment of the history and purposes of each OASIS item is included in Volume 4. Additional information on the meaning and interpretation of each item, including assessment strategies for collecting accurate data during a home visit, can be found in the *OASIS User's Manual*, published by CMS.[18]) A few OASIS items not included in the table are used only for data management purposes, such as matching assessments within the OASIS database and linking to other data sets. The first column in the table shows

TABLE 1: Importance of OASIS Items to Quality Improvement and Payment Applications.

Data Items	Quality Measurement: Outcome Measurement[a]	Quality Measurement: Risk Adjustment[b]	Payment: Case Mix Adjustment[c]
M0066: Birth date		24	
M0069: Gender		27	
M0140: Race/ethnicity		-	
M0150: Payment sources for home care		23	
M0160: Financial factors		-	
M0170: Inpatient facility discharge past 14 days		38	X
M0190: Inpatient diagnoses		40	
M0200: Medical regimen change within past 14 days		34	
M0210: Medical diagnoses		40	
M0220: Conditions prior to hospitalization/regimen change		30	
M0230/M0240: Diagnoses and severity index		40	X
M0250: Therapy (IV/Infusion/Nutrition)		17	X
M0260: Moderate to good recovery prognosis		33	
M0270: Good rehabilitation prognosis	AEO	34	
M0280: Life expectancy 6 months or less	AEO	29	
M0290: High risk factors		13	
M0300: Current residence	AEO	22	
M0310: Structural barriers		-	
M0320: Safety hazards		1	
M0330: Sanitation hazards		1	
M0340: Living situation		33	
M0350: Assisting persons other than home care agency staff	AEO	20	
M0360: Primary caregiver		4	
M0370: Frequency of primary caregiver assistance		9	
M0380: Type of primary caregiver assistance		15	
M0390: Vision		17	X
M0400: Hearing and ability to understand spoken language		4	
M0410: Speech and oral (verbal) expression of language	RAO	22	
M0420: Frequency of pain interfering with activity	RAO	7	X
M0430: Intractable pain		6	
M0440: Skin lesion or open wound	RAO, AEO	10	X
M0445: Pressure ulcer presence	AEO	13	X
M0450: Number of (observable) pressure ulcers at each stage	AEO	13	X
M0460: Stage of most problematic (observable) pressure ulcer		6	X
M0464: Status of most problematic (observable) pressure ulcer		8	
M0468: Stasis ulcer presence		6	X
M0470: Number of (observable) stasis ulcers		4	
M0474: Stasis ulcer that cannot be observed		-	
M0476: Status of most problematic (observable) stasis ulcer		6	X
M0482: Surgical wound presence	RAO	28	X
M0484: Number of (observable) surgical wounds	RAO	14	
M0486: Surgical wound that cannot be observed		-	
M0488: Status of most problematic (observable) surgical wound	RAO	6	X
M0490: Shortness of breath	RAO	8	X
M0500: Respiratory treatments		16	
M0510: Urinary tract infection	RAO, AEO	2	
M0520: Urinary incontinence or urinary catheter presence	RAO	27	X
M0530: When urinary incontinence occurs	RAO	15	X
M0540: Bowel incontinence frequency	RAO	18	X
M0550: Ostomy for bowel elimination		6	X
M0560: Cognitive functioning	RAO	16	
M0570: When confused (reported or observed)	RAO	20	
M0580: When anxious (reported or observed)	RAO	10	
M0590: Depressive feelings (reported or observed)		6	
M0600: Patient behaviors (reported or observed)		2	

TABLE 1: Importance of OASIS Items to Quality Improvement and Payment Applications. (Cont'd)

Data Items	Quality Measurement: Outcome Measurement[a]	Quality Measurement: Risk Adjustment[b]	Payment: Case Mix Adjustment[c]
M0610: Behaviors demonstrated at least once a week (reported or observed)		17	X
M0620: Frequency of behavior problems (reported or observed)	RAO	5	
M0630: Psychiatric nursing services		8	
M0640: Grooming	RAO	14	
M0650: Ability to dress upper body	RAO	19	X
M0660: Ability to dress lower body	RAO	12	X
M0670: Bathing	RAO	20	X
M0680: Toileting	RAO	25	X
M0690: Transferring	RAO	22	X
M0700: Ambulation/locomotion	RAO	27	X
M0710: Feeding or eating	RAO	18	
M0720: Planning and preparing light meals	RAO	20	
M0730: Transportation		25	
M0740: Laundry	RAO	22	
M0750: Housekeeping	RAO	22	
M0760: Shopping	RAO	27	
M0770: Ability to use telephone	RAO	27	
M0780: Management of oral medications	RAO, AEO	33	
M0790: Management of inhalant/mist medications		14	
M0800: Management of injectable medications		14	
M0810: Patient management of equipment		-	
M0820: Caregiver management of equipment		-	
M0830: Emergent care	RAO	-	
M0840: Emergent care reason	AEO	-	
M0855: Inpatient facility admission	RAO	-	
M0870: Discharge disposition	RAO, AEO	-	
M0880: Services or assistance		-	
M0890: Hospital reason		-	
M0895: Reason for hospitalization		-	
M0900: Reasons admitted to nursing home	AEO	-	
M0906: Discharge/transfer/death date		41	

[a] RAO = Currently/recently used to calculate outcome measures for risk-adjusted outcome reports for quality improvement; AEO = Currently used to calculate adverse event outcome measures for quality monitoring.

[b] Number of outcome measure risk models (out of 41) to which item currently contributes significantly as a risk factor.

[c] X = Appears in the current grouper algorithm for determining case mix adjustment for prospective payment.

whether the item currently is or recently has been used to calculate outcome measures for risk-adjusted outcome (RAO) reports or to calculate adverse event outcome (AEO) measures. The outcome measures now used in risk-adjusted outcome reports and adverse event outcome reports were selected from a larger set of measures based on their relevance for OBQI. Items that contribute to the calculation of any of these measures are essential to the functioning of the current reporting system. Outcome measures other than those that currently appear in outcome reports very likely will be relevant in the near future for reporting on specific patient subgroups or for purposes other than OBQI, such as public reporting.

The second column in Table 1 indicates the role of each OASIS item in risk adjustment for outcome reporting, by showing the number of outcome measures (out of 41) for which the item, or a measure based on the item, is used as a risk factor in logistic regression models with the outcome measures as dependent or criterion variables. Each risk factor included in the statistical risk adjustment model for a specific outcome measure must contribute in a statistically significant and clinically meaningful way to the prediction of that outcome. The number of outcome measures for which a specific item is included as a risk factor indicates the extent to which that item contributes to risk adjustment for multiple patient outcomes. However, a risk factor may not be used extensively but still may be a strong or even essential predictor for one or a few specific outcomes.

The third column indicates which items are used to assign patients to home health resource groups (HHRGs) for case mix adjustment under prospective payment. It shows only those items that are included in the current case mix "grouper" algorithm, and does not include items under consideration for future refinements to case mix adjustment. It should be noted that the grouper algorithm was changed between publication of the notice of proposed rule making for PPS and publication of the final rule, based in part on comments received from the home health industry. Some industry groups have recommended additional changes, which would require using items other than those currently included.[19]

A small subset of OASIS items in Table 1 are not currently used for outcome measurement, risk adjustment of outcomes, or case mix adjustment of payment. One of these is "Financial factors limiting the ability of the patient/family to meet basic health needs" (M0160). This item cannot contribute to current analyses of national data, because it is not submitted to CMS by home health agencies. Of the remaining items that are not currently used, some have potential applications that have not yet been developed. A few items do not contribute to current uses because, although they are theoretically relevant risk factors, they do not meet the statistical criteria for inclusion in risk adjustment models.

5. Past Research on OASIS Reliability

In addition to the initial quasi-reliability analysis described above, a second consistency analysis was undertaken as part of a research study comparing home health care provided in rural and urban settings. The data collection instrument for this study was a slightly modified version of the PSQ. To minimize burden on both home health care providers and patients, this study adopted the concurrent assessment approach described above. Data were collected on 53 patients from a total of 29 HHAs. Reliability findings were generally favorable, with 71% of items having a weighted kappa reliability value of 0.60 or higher and 40% exceeding the 0.75 reliability threshold.[20]

Madigan and Fortinsky[21] reported on an intrarater (a modified type of "test-recall") reliability analysis using OASIS-A. The methodology used in this study involved one assessment visit per patient, with the clinician completing the OASIS items during or immediately after the assessment, then completing an OASIS form again within 48 hours,

using his/her recall of the patient's condition and (non-OASIS) clinical documentation. This approach is more a test of the clinician's memory and the adequacy of agency clinical documentation than it is a test of the reliability of OASIS items. The study included 22 admission assessments and 15 discharge assessments. Several items had no variance, primarily due to the small number of cases. The same research team has since conducted a more extensive interrater reliability study employing a concurrent assessor-observer approach. Preliminary results were presented in 2001, but final analyses are still underway.[22]

A more traditional reliability study was undertaken as part of the CMS-funded project to develop a case mix adjustment methodology for home health prospective payment, conducted by Abt Associates. The reliability study (conducted by Berg) was published as an appendix[23] to an interim report for the project.[*] This study employed an independent assessment interrater reliability design, with two assessments completed independently by different agency clinicians. The protocol called for repeat assessments to be completed within 72 hours of the first assessment. The study included start of care, resumption of care, and follow-up assessments, and used the OASIS + data set, which consisted of all items in OASIS-B plus selected items from other instruments and some new items. The findings of this study are discussed later, along with its methodological strengths and limitations.

6. Past Research on Burden of OASIS Data Collection

The use of a standardized set of data items for patient assessment is a recent development for HHAs, although the practice of completing a comprehensive assessment to develop a plan of care is not new for many home care clinicians. Because OASIS items are meant to be incorporated into a standard assessment tool rather than used as an add-on data collection instrument, most of them should replace similar items that had previously been part of the assessment. The additional time required to conduct an assessment with OASIS items included should be relatively modest if the HHA's routine practice had already included comprehensive assessment. However, some providers voiced complaints that OASIS requirements impose a substantial burden. Two studies have been published which begin to shed light on this issue, although both have limitations.

A survey of 32 HHAs conducted by the General Accounting Office found that the reported amount of time needed to complete a start of care assessment including OASIS items exceeded by about 40 minutes the reported time for an assessment prior to the OASIS requirement.[24] The authors acknowledged that HHAs' responses to the survey may have been inaccurate or biased by providers' common desire to justify a higher level of compensation. Another likely source of error and potential bias in this study emerges from the fact that respondents were asked to estimate pre-OASIS assessment time retrospectively, relying on whatever documentation may (or may not) have been available. Because no such study had been conducted prior to OASIS implementation,

[*] Additional data were collected after the interim report was published. Findings are to be included in the project final report, which had not been published as of this writing.

this methodology was the only feasible way of collecting the needed information. However, the accuracy of the information collected, and the validity of comparing retrospective pre-OASIS assessment time estimates to current estimates, are inherently suspect.

In the second study, the National Association for Home Care (NAHC) asked member agencies to estimate assessment time (with OASIS) for each required assessment time point. This study was not designed to compare pre- and post-OASIS assessment time, but only to describe current assessment burden. The results of this study are likely affected by self-selection bias. Those most likely to respond are agencies in which the perceived OASIS burden is greatest. In addition, the authors erroneously summed the time estimates for each assessment time point to arrive at a total burden estimate of six hours and 45 minutes.[25] This estimate is seriously inflated, as most home health patients are assessed only two or three times during an episode of care. Estimating total assessment time per episode of care should take into account the average number of times per patient each type of assessment is conducted. This calculation would yield a much lower estimate than that presented in NAHC's published results.

B. DATA COLLECTION METHODS

The reliability and time estimate studies whose findings are presented in the next section were conducted as part of the National OBQI Demonstration. Two agencies participating in the demonstration contributed cases to the reliability study, and three additional (non-demonstration) agencies were recruited specifically for reliability data collection. Ten HHAs participating in the demonstration were selected for the assessment time estimate study.

1. OASIS Interrater Reliability

Two similar data collection efforts contributed cases to the interrater reliability analysis reported here; both occurred before the federal regulations for comprehensive assessment and reporting of OASIS data were implemented. The design called for independent assessments of home care patients by two different clinicians during separate visits to the patients' homes. In the spring of 1997, two clinicians conducted independent assessments of 41 patients from two HHAs. In the fall of 1998, 25 additional patients from three HHAs were independently assessed by two clinicians. The clinicians (RNs) who collected the data for the reliability study had previous home health care assessment experience and received training in the use of the OASIS data set from Research Center clinicians. As part of the training for each data collection effort, at least five patients, for whom two independent assessments were conducted, served as pilot cases. For the pilot cases, OASIS data were compared item by item immediately after the second assessment was completed, so that any discrepancies related to interpretation of specific OASIS items could be resolved.

Data were collected by clinicians specifically hired and trained for this project rather than HHA employees for two major reasons. First, due to tight staffing, participating home health agencies had difficulty assigning enough staff to conducting

repeat assessments in order to complete the data collection in a reasonable amount of time. Using nonagency clinicians to collect the data minimized the burden on participating agencies. Second, this approach helped to achieve a degree of uniformity in training and to minimize the effects of individual variation in assessment skills. Removing this source of variation ensured that the study reflected reliability of the OASIS assessment items, rather than variability among clinicians in training or ability. There were, however, some drawbacks. Using external assessors rather than agency staff may have hampered assessment due to a lack of connection with care provision. A clinician involved in care provision is likely to develop greater rapport (and may also have some prior familiarity) with the patient, which could make the assessment process more effective than would be the case for someone who sees the patient only once for the purpose of assessment.

Patients were selected for each of the study components by randomly sampling from recently admitted patients. Consent was obtained from the patient for two assessment visits to be conducted. In both studies, repeat assessments were conducted within 24 hours, almost always the same day. Assessments were conducted as close together as possible to minimize the likelihood that a patient's condition would change measurably from one visit to the next. (Home health care patients, particularly those requiring skilled care, such as Medicare patients, are often characterized by acute, unstable conditions that can change significantly from day to day.) The order of assessments alternated between clinicians, so that half of the patients were visited first by clinician A and half by clinician B. To ensure that assessments were truly independent, clinicians did not communicate with each other about the patients, nor did either review the other's assessments. Assessments were conducted using the start of care OASIS items, which comprise approximately 90% of the OASIS items.

There were minor protocol differences between the two data collection efforts, resulting in a reduced number of cases available for analysis for selected items. During the first data collection effort patients already on service were included, rather than restricting sampling to newly admitted patients -- in order to complete the sampling within a reasonable time frame. As a result, OASIS items related to inpatient facility discharge during the 14 days prior to home health admission could not be collected for these patients, although these items were collected on the 25 cases from the second round of reliability fieldwork. During the second data collection effort, assessment of pressure ulcers, stasis ulcers, and surgical wounds was omitted; the sample size for these items consisted only of the 41 cases from the first round of data collection.

2. OASIS Assessment Time Requirements

During the National OBQI Demonstration, a study was conducted to determine the extent to which the use of OASIS in the assessment process increased the amount of time spent on assessments. An important part of the design was to compare assessment time with all factors except OASIS held constant. Obtaining retrospective estimates of pre-OASIS assessment time was not sufficiently precise, due to (1) the unreliable nature of retrospective data collection, and (2) the confounding effects of changes in the home health care industry at the same time that OASIS was implemented in the demonstration

agencies. Ten HHAs participating in the National OBQI Demonstration were chosen for the study, based on the criterion that the agency had at least one branch or clinical team (usually several) that was not participating in the demonstration; therefore, OASIS items were not part of the assessment for those branches or teams. This matched control design allowed for a comparison of assessment times in the same agency, with and without OASIS, holding other agency-level factors constant. Comparing OASIS and non-OASIS assessments conducted at roughly the same time point rather than before and after OASIS implementation factored out the effects of any concurrent changes in policy or provider practice.

The assessment time estimate data were collected after OASIS data collection had been in place for approximately eight months. Data were collected on self-reported assessment times for start of care and discharge assessments. The agency staff providing the information did not know the purpose of the data gathering effort. At each participating agency, the protocol called for three clinicians using OASIS and three clinicians using non-OASIS assessments to be interviewed. This goal was achieved at all but two agencies, yielding a total of 31 OASIS clinician respondents and 27 non-OASIS clinician respondents. Agency administrators who identified the respondents to be interviewed were not informed of the content of the survey until after it had been completed, and, as noted above, respondents were not informed of the purpose of the survey. Respondents were asked to estimate the average time taken to complete a start of care assessment and the time taken to complete their most recent start of care assessment. They were asked to estimate separately the visit time spent in the patient's home and time spent completing documentation after leaving the patient's home. All four questions were repeated for the discharge assessment.

C. RESULTS OF RELIABILITY ANALYSIS

1. Analysis Methodology

The reliability analysis was conducted using the OASIS data exactly as entered, with three exceptions. First, items that were subject to skip patterns, where a value can be imputed from the response to the item that caused the skip, were recoded accordingly. For example, presence of pressure ulcers, stasis ulcers, and surgical wounds, and related items concerning the number, stages, and status of those types of lesions, are skipped when the clinician records that there are no open wounds or skin lesions. Rather than treat such cases as having missing data for the skipped items, each of the items is assigned a response indicating that there is no lesion of that type. Similarly, the ordinal item "When urinary incontinence occurs" (M0530) is completed only when the response to "Urinary incontinence or catheter presence" (M0520) indicates that the patient has some incontinence. For analysis purposes, the two items were combined to create a scale of urinary incontinence presence/severity.

The second type of item where recoding was appropriate was single-response items with more than two values, where the categories do not form an ordered scale. While an overall agreement measure can be calculated for these nominal items, it is more informative to know how reliably each category can be distinguished from the other

categories. Therefore, each of these items was recoded for analysis as a series of dichotomous indicators, one for each response category. The third group of items that required special treatment were those with response options including a "not applicable" category, such as patient's ability to manage injectable medications. For these items, not applicable responses were excluded from analysis, and only those cases for which both raters provided a valid scale value were included. An additional analysis (not reported here) was conducted of not applicable responses versus valid responses, which resulted in very high reliability for assignment to the not applicable category for all affected items. Because patient identifiers were used to match assessments for the same patients, discrepancies in these items had to be resolved prior to analysis. Therefore, reliability was not assessed for any of the patient identifiers except patient gender (which is also used for clinical and analytic purposes).

For each item, three measures of interrater reliability were calculated: raw percent agreement, Cohen's kappa without weighting, and weighted kappa. The unweighted or simple kappa is commonly used as a measure of rater agreement for nominal measurement. It represents the degree to which the actual proportion of cases on which raters agree (exactly) exceeds the percentage agreement that would be expected under the assumption of statistical independence (or no association between the paired values). The weighted kappa is appropriate for measures that employ an interval or ordinal scale, where the magnitude of discrepancies between raters should be taken into account. For dichotomous measures, the weighted kappa and unweighted kappa are equivalent. The Fleiss-Cohen[26] version of weighted kappa, which uses the squared difference in scale values for weighting, is used in the analysis reported here for all ordinal or interval scale measures since it imposes a greater penalty for large discrepancies between paired values. For multiple response items, reliability was assessed for each response category. In addition, a measure of overall reliability for each multiple response item was constructed by averaging reliability across response categories, including only those response categories for which a valid kappa could be calculated.

The kappa coefficient can take on values ranging from –1.00 to 1.00, with 1.00 representing perfect agreement on all cases by two raters. A commonly used rating scheme for interpreting kappa coefficients attaches the following labels to value ranges: greater than 0.80 = almost perfect agreement; greater than 0.60 but no greater than 0.80 = "substantial" agreement; greater than 0.40 but no greater than 0.60 = "moderate" agreement; greater than 0.20 but no greater than 0.40 = "fair" agreement; 0.20 or less = "slight" agreement. Landis & Koch[27] suggested this rating scheme, which has been adopted by a number of researchers. (See, for example, Hughes & Ash,[28] Madigan, Tullai-McGuiness, & Fortinsky,[22] and Morris et al.[13])

For a few OASIS items, the item variance for the sample cases was zero for one or both raters, meaning that all patients were assessed as falling into a single category on that item. The kappa coefficient is undefined under these conditions, so percent agreement is reported alone. In addition to those extreme cases, the kappa coefficient may be rather unstable and, therefore, misleading when an item has a highly skewed distribution. For example, if an item has two response categories and 95% of cases fall in one category, the "expected" percentage agreement between two raters is 91%. Therefore, in

a sample of 66 cases, if raters disagree on only two cases (3%), the kappa coefficient would be 0.65, while agreement on those two cases would raise the kappa coefficient to 1.00. Because the value of kappa under these conditions can be affected so profoundly by a very small number of aberrant cases, is could be misleading to rely on kappa as an indicator of agreement. For this reason, in addition to those cases where the item variance is zero for one or both raters, the percent agreement statistic alone is reported when more than 95% of cases for both raters fall into a single category.

Percent agreement also is reported for diagnosis codes, for a different reason. The number of different diagnoses that could be recorded (and actually appear in the data) is large relative to the number of cases. Calculating the kappa statistic under these circumstances is very cumbersome. In addition, when the number of categories is large relative to the number of cases, the number of cases where agreement would be expected by chance alone is very small, so kappa does not differ substantially from percent agreement.

2. Summary of Item Reliability

Table 2 contains results for all current OASIS items* on which reliability data were collected (with exclusions as noted above), with pooled reliability coefficients reported for multiple response items. As indicated above, the pooled reliability coefficient for a multiple response item is the mean of the coefficients for the individual response categories comprising that item. Table 3 shows results for the individual response categories of multiple response items for which pooled coefficients are reported in Table 2. This approach yields 126 separate measures from 19 OASIS multiple response items. In Table 2, OASIS items are ranked according to reliability, whereas in Table 3 measures are presented in the order in which they appear in the data set, to readily identify those specific response categories that may have higher or lower reliability than the corresponding multiple response item as a whole. In both tables (as noted above), percent agreement is substituted for kappa whenever the item variance is zero or more than 95% of cases fall in one response category. In Table 3, where each multiple response category is treated as a separate item, percent agreement is reported for 55 measures that display little or no variability. In the analysis using pooled multiple response reliability measures presented in Table 2, only five of the 95 items had insufficient variability to calculate a kappa coefficient or pooled kappa coefficient. In addition to those five items, percent agreement is reported instead of kappa for four diagnosis items appearing in Table 2.

The presentation of items in descending order of reliability (Table 2) makes it apparent where strengths and weaknesses lie in the OASIS data set. Those items with the weakest reliability (less than or equal to 0.50), are five in number, including caregiver assistance, three items related to ability to carry out instrumental activities of daily living (IADLs) 14 days prior to admission, and one behavioral status item. Thirteen additional

* One item, "Financial factors limiting the ability of the patient/family to meet basic health needs" (M0160), is included in the OASIS data set, but the data are not submitted by home health agencies to CMS. This item is excluded from the reliability analysis.

TABLE 2: OASIS Reliability with Multiple Response Items Pooled – Items Ranked by Reliability.

OASIS Item		Reliability[a]
M0069:	Gender	1.00
M0140:	Race/ethnicity	1.00[b]
M0445:	Presence of a pressure ulcer	1.00
M0470:	Number of stasis ulcers present	1.00
M0476:	Status of most problematic stasis ulcer	1.00
M0486:	Nonobservable surgical wound present	100%
M0510:	Urinary tract infection within past 14 days	1.00
M0520:	Urinary catheter presence	1.00
M0800:	Prior management of injectable medications scale	1.00
M0280:	Life expectancy 6 months or less	98%
M0630:	Psychiatric nursing services received	98%
M0474:	Nonobservable stasis ulcer present	98%
M0620:	Behavior problem frequency scale	0.96
M0488:	Status of most problematic surgical wound	0.95
M0500:	Respiratory treatments	0.95[b]
M0340:	Living situation	0.94[b]
M0790:	Current management of inhalant medications scale	0.91
M0790:	Prior management of inhalant medications scale	0.91
M0800:	Current management of injectable medications scale	0.91
M0464:	Status of most problematic pressure ulcer	0.90
M0710:	Current eating scale	0.89
M0820:	Caregiver management of equipment scale	89%[b]
M0520/530:	Urinary incontinence severity	0.88
M0700:	Current ambulation scale	0.87
M0810:	Patient management of equipment scale	0.87
M0250:	Therapy (IV/Infusion/Nutrition)	0.86[b]
M0680:	Current toileting scale	0.86
M0300:	Current residence	0.86[b]
M0440:	Presence of open wounds/lesions	0.85
M0390:	Vision impairment scale	0.85
M0482:	Presence of a surgical wound	0.84
M0484:	Number of surgical wounds present	0.84
M0450:	Number of pressure ulcers by stage	0.83[b]
M0780:	Current management of oral medications scale	0.82
M0490:	Dyspnea scale	0.82
M0230:	Primary diagnosis	80%
M0190:	Inpatient facility diagnoses	79%
M0410:	Speech/language impairment scale	0.79
M0690:	Current transferring scale	0.79
M0468:	Presence of a stasis ulcer	0.79
M0200:	Medical regimen change past 14 days	0.78
M0660:	Current dressing lower body scale	0.78
M0670:	Current bathing scale	0.77
M0270:	Good rehabilitation prognosis	0.77
M0660:	Prior dressing lower body scale	0.76
M0230:	Primary diagnosis severity	0.74
M0210:	Medical regimen change diagnoses	74%
M0770:	Current ability to use telephone scale	0.73
M0540:	Bowel incontinence scale	0.73
M0240:	Other diagnoses	72%
M0260:	Moderate to good recovery prognosis	0.72
M0780:	Prior management of oral medications scale	0.72
M0640:	Current grooming scale	0.72
M0720:	Current plan and prepare light meals scale	0.71
M0460:	Stage of most problematic pressure ulcer	0.70

TABLE 2: OASIS Reliability with Multiple Response Items Pooled – Items Ranked by Reliability. (Cont'd)

OASIS Item		Reliability[a]
M0150:	Payment sources for home care	0.70[b]
M0700:	Prior ambulation scale	0.69
M0290:	Risk factors	0.69[b]
M0400:	Hearing impairment scale	0.69
M0650:	Current dressing upper body scale	0.68
M0570:	Confusion scale	0.68
M0430:	Intractable pain	0.67
M0350:	Assisting person	0.67[b]
M0670:	Prior bathing scale	0.67
M0420:	Pain interfering with activity scale	0.66
M0550:	Ostomy related to hospitalization/regimen change	0.66
M0760:	Current shopping scale	0.65
M0360:	Primary caregiver	0.65[b]
M0680:	Prior toileting scale	0.65
M0740:	Current laundry scale	0.64
M0730:	Prior transportation scale	0.64
M0330:	Sanitation hazards	0.64[b]
M0640:	Prior grooming scale	0.63
M0730:	Current transportation scale	0.63
M0560:	Cognitive functioning scale	0.63
M0760:	Prior shopping scale	0.62
M0580:	Anxiety level scale	0.61
M0710:	Prior eating scale	0.59
M0650:	Prior dressing upper body scale	0.59
M0240:	Other diagnoses severity	0.58
M0690:	Prior transferring scale	0.57
M0320:	Safety hazards	0.56[b]
M0770:	Prior ability to use telephone scale	0.56
M0590:	Depressive feelings reported or observed	0.54[b]
M0750:	Current housekeeping scale	0.54
M0370:	Frequency of primary caregiver assistance	0.52
M0610:	Behaviors demonstrated	0.52[b]
M0170:	Inpatient facility discharge past 14 days	0.52[b]
M0220:	Conditions prior to hospitalization/regimen change	0.52[b]
M0310:	Structural barriers	0.52[b]
M0740:	Prior laundry scale	0.50
M0720:	Prior plan and prepare light meals scale	0.47
M0750:	Prior housekeeping scale	0.46
M0600:	Behaviors reported or observed	0.44[b]
M0380:	Caregiver assistance	0.40[b]

[a] Weighted kappa for ordinal/interval measures, or simple kappa for dichotomous measures, except when variance is zero for one or both raters, or more than 95% of cases fall in a single response category, when percent agreement is reported. Percent agreement is also reported for diagnoses.

[b] Multiple response item. Average kappa across all response categories.

items are found in the 0.50 to 0.60 range. These are related to behavioral and mental status factors, health status prior to admission, supportive assistance, barriers or hazards in the home, and severity of secondary diagnoses. Reliability coefficients above 0.60 are generally regarded as substantial. In all, 81% of the 95 OASIS items for which reliability is reported in Table 2 exceed the 0.60 reliability threshold, while 57% are above 0.70, and 37% exceed 0.80. Of the eight current activities of daily living (ADL) items,

TABLE 3: OASIS Multiple Response Items – Reliability by Response Category.

OASIS Item	Reliability[a]
M0140: Race/ethnicity – American Indian or Alaskan Native (0-1)	100%
M0140: Race/ethnicity – Asian (0-1)	100%
M0140: Race/ethnicity – White (0-1)	1.00
M0140: Race/ethnicity – Black or African American (0-1)	100%
M0140: Race/ethnicity – Hispanic (0-1)	1.00
M0140: Race/ethnicity – Native Hawaiian or Pacific Islander (0-1)	100%
M0150: Payment source – None, no charge (0-1)	100%
M0150: Payment source – Medicare FFS (0-1)	0.74
M0150: Payment source – Medicare HMO (0-1)	0.82
M0150: Payment source – Medicaid FFS (0-1)	0.89
M0150: Payment source – Medicaid HMO (0-1)	100%
M0150: Payment source – Worker's compensation (0-1)	100%
M0150: Payment source – Title programs (0-1)	100%
M0150: Payment source – Other government (0-1)	96%
M0150: Payment source – Private Insurance (0-1)	0.80
M0150: Payment source – Private HMO (0-1)	96%
M0150: Payment source – Self-pay (0-1)	100%
M0150: Payment source – Other (0-1)	0.25
M0170: Inpatient facility discharge – Hospital (0-1)	0.80
M0170: Inpatient facility discharge – Rehabilitation facility (0-1)	0.23
M0170: Inpatient facility discharge – Nursing home (0-1)	0.60
M0170: Inpatient facility discharge – Other (0-1)	96%
M0170: Inpatient facility discharge – None last 14 days (0-1)	0.47
M0220: Prior condition – Urinary incontinence (0-1)	0.54
M0220: Prior condition – Indwelling/suprapubic catheter (0-1)	0.28
M0220: Prior condition – Intractable pain (0-1)	0.59
M0220: Prior condition – Impaired decision-making (0-1)	0.64
M0220: Prior condition – Disruptive/inappropriate behavior (0-1)	100%
M0220: Prior condition – Memory loss needing supervision (0-1)	0.64
M0220: Prior condition – None of the above (0-1)	0.43
M0220: Prior condition – Not applicable (0-1)	0.86
M0250: Therapy – Intravenous/infusion (0-1)	0.85
M0250: Therapy – Parenteral nutrition (0-1)	100%
M0250: Therapy – Enteral nutrition (0-1)	100%
M0250: Therapy – None of above (0-1)	0.88
M0290: Risk factors – Heavy smoking (0-1)	0.86
M0290: Risk factors – Obesity (0-1)	0.47
M0290: Risk factors – Alcoholism (0-1)	0.70
M0290: Risk factors – Drug dependency (0-1)	96%
M0290: Risk factors – None of the above (0-1)	0.72
M0300: Current residence – Patient's home (0-1)	0.85
M0300: Current residence – Family member's home (0-1)	0.86
M0300: Current residence – Boarding home or rented room (0-1)	100%
M0300: Current residence – Board/care, assisted living (0-1)	0.88
M0300: Current residence – Other (0-1)	100%
M0310: Structural barriers – None (0-1)	0.63
M0310: Structural barriers – Stairs must be used (0-1)	0.70
M0310: Structural barriers – Stair use optional (0-1)	0.35
M0310: Structural barriers – Stairs from house (0-1)	0.71
M0310: Structural barriers – Narrow doorways (0-1)	0.21
M0320: Safety hazard – None (0-1)	0.53
M0320: Safety hazard – Inadequate floor/roof/window (0-1)	100%
M0320: Safety hazard – Inadequate lighting (0-1)	100%
M0320: Safety hazard – Unsafe appliance (0-1)	100%
M0320: Safety hazard – Inadequate heating (0-1)	100%
M0320: Safety hazard – Inadequate cooling (0-1)	100%
M0320: Safety hazard – Lack fire safety devices (0-1)	0.58
M0320: Safety hazard – Unsafe floor coverings (0-1)	94%
M0320: Safety hazard – Inadequate stair railings (0-1)	98%

TABLE 3: OASIS Multiple Response Items – Reliability by Response Category. (Cont'd)

OASIS Item	Reliability[a]
M0320: Safety hazard – Hazardous materials (0-1)	100%
M0320: Safety hazard – Lead-based paint (0-1)	97%
M0320: Safety hazard – Other (0-1)	97%
M0330: Sanitation hazard – None (0-1)	0.60
M0330: Sanitation hazard – No running water (0-1)	100%
M0330: Sanitation hazard – Contaminated water (0-1)	98%
M0330: Sanitation hazard – No toilet (0-1)	100%
M0330: Sanitation hazard – Outdoor toilet only (0-1)	100%
M0330: Sanitation hazard – Inadequate sewage disposal (0-1)	100%
M0330: Sanitation hazard – Inadequate food storage (0-1)	100%
M0330: Sanitation hazard – No food refrigeration (0-1)	100%
M0330: Sanitation hazard – No cooking facilities (0-1)	100%
M0330: Sanitation hazard – Insects/rodents (0-1)	98%
M0330: Sanitation hazard –No scheduled trash pickup (0-1)	100%
M0330: Sanitation hazard – Cluttered/soiled living area (0-1)	0.66
M0330: Sanitation hazard – Other (0-1)	98%
M0340: Living situation – Lives alone (0-1)	1.00
M0340: Living situation – With spouse or significant other (0-1)	0.92
M0340: Living situation – With other family member (0-1)	0.91
M0340: Living situation – With friend (0-1)	98%
M0340: Living situation – With paid help (0-1)	97%
M0340: Living situation – Other (0-1)	100%
M0350: Assisting person – Relative/friend/neighbor (0-1)	0.38
M0350: Assisting person – Person residing in home (0-1)	0.91
M0350: Assisting person – Paid help (0-1)	0.72
M0350: Assisting person – None (0-1)	96%
M0360: Primary caregiver – No one person (0-1)	0.57
M0360: Primary caregiver – Spouse or significant other (0-1)	0.91
M0360: Primary caregiver – Daughter or son (0-1)	0.69
M0360: Primary caregiver – Other family member (0-1)	0.58
M0360: Primary caregiver – Friend/neighbor etc. (0-1)	98%
M0360: Primary caregiver – Paid help (0-1)	0.50
M0380: Caregiver assistance – ADLs (0-1)	0.36
M0380: Caregiver assistance – IADLs (0-1)	0.44
M0380: Caregiver assistance – Environmental support (0-1)	0.33
M0380: Caregiver assistance – Psychosocial support (0-1)	0.36
M0380: Caregiver assistance – Facilitate medical care (0-1)	0.40
M0380: Caregiver assistance – Financial agent (0-1)	0.36
M0380: Caregiver assistance – Health care agent (0-1)	0.52
M0450: Number of stage 1 pressure ulcers (0-4)	100%
M0450: Number of stage 2 pressure ulcers (0-4)	1.00
M0450: Number of stage 3 pressure ulcers (0-4)	100%
M0450: Number of stage 4 pressure ulcers (0-4)	0.66
M0500: Treatment – Oxygen (0-1)	0.96
M0500: Treatment – Ventilator (0-1)	100%
M0500: Treatment – Continuous airway pressure (0-1)	98%
M0500: Treatment – None of above (0-1)	0.93
M0590: Depressive feelings – Depressed Mood (0-1)	0.59
M0590: Depressive feelings – Failure/self-reproach (0-1)	0.48
M0590: Depressive feelings – Hopelessness (0-1)	0.56
M0590: Depressive feelings – Preoccupation w/death (0-1)	0.53
M0590: Depressive feelings – Thoughts of suicide (0-1)	97%
M0590: Depressive feelings – None of above (0-1)	0.57
M0600: Behavior – Indecisiveness (0-1)	0.40
M0600: Behavior – Diminished interest in activities (0-1)	0.57
M0600: Behavior – Sleep disturbances (0-1)	0.59
M0600: Behavior – Change in appetite or weight (0-1)	0.18
M0600: Behavior – Agitation (0-1)	0.31
M0600: Behavior – Suicide attempt (0-1)	100%
M0600: Behavior – None of above observed/reported (0-1)	0.60

TABLE 3: OASIS Multiple Response Items – Reliability by Response Category. (Cont'd)

OASIS Item	Reliability[a]
M0610: Behavior demonstrated – Memory deficit (0-1)	0.52
M0610: Behavior demonstrated – Impaired decision-making (0-1)	97%
M0610: Behavior demonstrated – Verbal disruption (0-1)	100%
M0610: Behavior demonstrated – Physical aggression (0-1)	100%
M0610: Behavior demonstrated – Disruptive behavior (0-1)	100%
M0610: Behavior demonstrated – Delusions, etc. (0-1)	100%
M0610: Behavior demonstrated – None of above (0-1)	0.52

[a] When more than 95% of cases fall in a single response category for one or both raters, percent agreement is reported. Otherwise kappa is reported.

three have kappa coefficients above 0.80, and one is below 0.70. IADL measures tend to be less reliable than the more explicit ADL scales, and prior status items are less reliable than current status. The item "Current management of oral medications" (M0780) displays very good reliability, as do items addressing management of other medications and equipment. Many of the wound assessment items display excellent reliability, as do dyspnea and elimination status. Recovery and rehabilitation prognoses, which were found in earlier studies to be less reliable, both have coefficients exceeding 0.70.

3. Item Reliability for Multiple Response Categories

An examination of Table 3 illustrates that the range of reliability values obtained by analyzing each multiple response category separately is considerably greater than that observed when reliability estimates are pooled for multiple response categories. Several individual components of multiple response items stand out as much higher or lower than the average reliability for that item. Obesity, for example, is one of several health risks, which also include heavy smoking and alcohol abuse. The average reliability for the health risk factors is 0.69. Reliability for assessment of heavy smoking is excellent at 0.86, and alcohol abuse is assessed with good reliability of 0.70. However, the reliability of assessing obesity is only 0.47. Caregiver assistance is another item where reliability varies among different response categories. Determining whether assistance is rendered by friends and neighbors is less reliable (kappa = 0.38) than identifying assistance provided by someone living in the home or by paid help (kappa = 0.91 and 0.72). This information will be useful in future efforts to further refine OASIS items. As discussed earlier, variability in the reliability sample is very small for a number of multiple response categories, and zero for some. When there is no variability at all, percent agreement is reported as 100%, because both raters agreed on the uniform presence (or, more commonly, absence) of that characteristic in the sample.

4. Comparison of Reliability Estimates between Studies

A comparison was conducted of the results from this reliability study with those of another reliability study.[23] As noted earlier, the Berg study shares some design similarities with this study, but there are some important differences. The larger sample size (144) is an advantage in that, if estimates are unbiased, statistical power is increased and the probability that items will lack variation should lessen. However, there are

two problematic elements of the study design. First, the use of a large number of different data collectors whose expertise in clinical assessment using OASIS is unknown introduces a source of unreliability (unrelated to the psychometric characteristics of the OASIS items themselves) that is almost certain to result in lower reliability estimates than would otherwise be the case. Second, allowing up to three days between assessments increases the likelihood that real change in patient status will occur. As mentioned, this is particularly true for patients receiving Medicare-covered skilled care, whose health status can deteriorate (or improve) greatly over short periods of time because of acute rather than chronic problems. That Medicare patients can improve quickly is evidenced by short lengths of stay for many such patients. Any real change in patient condition is indistinguishable from unreliability and will, therefore, invalidly reduce reliability estimates.

In addition to the differences in data collection methodology noted above, there are minor differences between the two studies in the manner in which analyses were conducted. First, for nominal items with several categories, Berg reports only a single kappa coefficient, while multiple coefficients are reported here -- one for each category coded as a dichotomy (compared to all other categories). Second, in those cases where items were skipped due to the response to a previous item (e.g., number of stage 3 pressure ulcers is skipped when previous item indicating presence of any wounds/lesions is answered "No"), we imputed a value for the skipped item when it was logical to do so. In Berg's analysis skipped items were uniformly treated as having missing data, reducing the number of valid cases for those items. Third, in the Berg study, inpatient facility discharge prior to home health admission had more and different response options than in OASIS-B (although responses almost equivalent to the OASIS item were included).

For those items where a direct side-by-side comparison could be made, an analysis was conducted comparing reliability averages (across all items) between the two studies of both the percent agreement and kappa measures. In addition, correlation coefficients were calculated for the two sets of percent agreement measures and the two sets of kappa coefficients. Counting all single-response items, and considering all multiple response categories as separate measures, 166 measures were included in the percent agreement comparison, and 116 in the comparison of kappa coefficients. Mean percent agreement for comparable items is 90% for this sample and 92% for the Berg sample, while the corresponding means for kappa are 0.69 and 0.58, respectively. The Pearson correlation for percent agreement is 0.58, while the correlation between kappa coefficients is 0.52.

Although the percent agreement comparison indicates little or no difference in overall assessment of reliability between the two studies, the comparison of kappa coefficients seems to indicate that reliability estimates overall are lower for the Berg study. This apparent contradiction is partially accounted for by several items which showed similarly high percent agreement in both samples but lower variability in the Berg sample. As discussed previously, the value of kappa is strongly affected by a small absolute amount of rater disagreement when item variability is low. It is therefore very desirable when assessing reliability to have substantial variability within the sample. Affected items include payment source, recovery prognosis, rehabilitation prognosis, alcoholism risk factor, dyspnea, and depressive feelings.

Several items showed substantially higher reliability in this sample than in the Berg sample, as reflected by both percent agreement and the kappa coefficient. These include change in medical regimen within the last 14 days, assisting person residing in home, vision impairment, status of pressure ulcer, number and status of surgical wounds, urinary tract infection, depressed mood, and behavior problem frequency. A few items have lower reliability estimates in this sample, including rehabilitation facility discharge, obesity risk factor, and prior preparation of light meals.

Overall, the moderate correlation between reliability estimates of the two studies indicates that the reliability coefficients for the same items have a general tendency to rise and fall in unison. In other words, there is rough agreement as to which items tend to have better reliability than others and which items have lower reliability. The two studies seem to differ systematically in their estimates of the overall level of reliability for all OASIS items -- as reflected by the comparison of mean kappa values across all items described above. This result is consistent with the different methodology used in the two studies. Both the longer length of time between assessments and the use of more assessment clinicians whose training and proficiency is largely unknown would be expected to produce lower (and, we believe, less valid) reliability estimates in Berg's analysis compared to this study.

D. RESULTS OF OASIS ASSESSMENT TIME STUDY

Results of the time study analysis are summarized in Table 4. It should be noted that there is relatively close agreement between estimates of start of care assessment time reported by clinicians in this study and the GAO survey of 32 HHAs cited earlier.[24] Mean start of care assessment time reported in the GAO study was 143 minutes, very similar to the 155 to 167 minutes reported by demonstration agencies (with OASIS). However, in contrast to the GAO survey findings, no statistically significant differences in estimated assessment time emerged between the 31 clinicians using OASIS in their assessments and the 27 clinicians conducting assessments without OASIS, either for start of care or discharge assessments. The small and nonsignificant additional in-home time reported by clinicians using OASIS in their start of care assessments was offset by a similarly nonsignificant saving in documentation time, so that total time also did not differ significantly. Differences between OASIS and non-OASIS discharge assessment time were even smaller. The average time across all respondents spent conducting and documenting a start of care assessment was approximately 160 minutes for both OASIS and non-OASIS assessments. Discharge assessment time averaged slightly less than 70 minutes. These results suggest that it is possible for agencies to incorporate OASIS into a comprehensive assessment efficiently, in a way that does not substantially increase the time required to complete the assessment.

E. DISCUSSION

The utility of OASIS data for monitoring patient outcomes of care, improving quality of care, and adjusting payment rates under Medicare has been well demonstrated.[2,3,15,16,29] As the results reported here indicate, most OASIS items display acceptable reliability, and many show excellent reliability. Those items for which

TABLE 4: Comparison of Amount of Time Spent on Home Health Visits With and Without OASIS.

	Mean Amount of Time Spent (Minutes)					
	Average Visit			Most Recent Visit		
Reason for Assessment	OASIS	Non-OASIS	Sig.	OASIS	Non-OASIS	Sig.
Start of Care						
In-home time	93.9	85.6	0.26	97.6	86.1	0.22
Documentation time	61.3	75.9	0.14	69.2	75.6	0.61
Total time	155.2	161.5	0.60	166.8	161.7	0.75
Discharge						
In-home time	41.3	41.1	0.95	41.0	40.8	0.97
Documentation time	25.6	27.2	0.72	25.3	27.8	0.59
Total time	66.9	68.3	0.82	66.3	67.3	0.88

Significance levels are for a two-sample t test. N = 31 OASIS assessments, 27 non-OASIS assessments.

reliability is questionable or merely adequate should be examined to determine whether modifying wording, clarifying instructions, or improving training have promise for improving reliability substantially. Data accuracy is particularly important for items that play a key role in outcome measurement, risk adjustment, or payment adjustment.

1. Important OASIS Data Items Requiring Further Refinement

Comparing the reliability results presented in Table 2 and Table 3 with the uses of different OASIS items presented in Table 1, those items which are crucial to one of these uses, but have questionable reliability, include the following:

- M0220: Conditions prior to hospitalization or medical regimen change,
- M0290: High risk factors – obesity,
- M0370: Frequency of primary caregiver assistance,
- M0380: Type of primary caregiver assistance,
- M0590: Depressive feelings (reported or observed), and
- "Prior" activities of daily living (M0640-M0710) and instrumental activities of daily living (M0720-M0770) (i.e., 14 days prior to start of care).

Most items with questionable reliability are retrospective in nature, pertaining to the patient's condition at some point in the past. These items are included in the data set primarily to assess whether the patient has a chronic problem or one that is more recent in onset, a factor that is highly important for care planning as well as predicting outcomes of care. The results indicate that improving the reliability of these items or developing new items to assess chronic health problems should be a priority. In the case of the obesity risk factor, individual judgements may vary even among trained clinicians. Objective measurement or estimation of height and weight are both logical alternatives, but

objective measurement is somewhat burdensome and estimation may be no more reliable than the current item. It may be beneficial to revise training materials to include more specific assessment instructions for this item. Reliability for caregiver assistance items (particularly the type of assistance provided) may suffer because the clinician typically does not, in a single visit, have the opportunity to observe assistance being provided, so greater reliance on patient or caregiver interview may be required. In spite of low reliability, these items have been found to be predictive of patient outcomes. If the items can be refined to improve reliability, their utility for risk adjustment likely will improve.

As noted earlier, several OASIS items are not currently used for outcome measurement, outcome measure risk adjustment, or case mix adjustment for payment. From Table 1, they are:

- M0160: Financial factors limiting the ability of the patient/family to meet basic health needs,
- M0310: Structural barriers in the patient's environment limiting independent mobility,
- M0810: Patient management of equipment,
- M0820: Caregiver management of equipment,
- M0870: Discharge disposition,
- M0880: Services or assistance (received after discharge),
- M0890: Hospital reason (emergent, urgent, or elective), and
- M0895: Reason for hospitalization (specific causes).

In addition, a few OASIS items are not currently used for outcome measurement or case mix adjustment for payment, and their contribution to risk adjustment is minimal, as indicated by their appearance in only one or two risk adjustment models. These items are:

- M0320: Safety hazards found in the patient's current place of residence,
- M0330: Sanitation hazards found in the patient's current place of residence, and
- M0600: Patient behaviors (reported or observed).

The first item (M0160) cannot be used because the OASIS reporting regulation specified that it was not to be submitted to CMS along with other OASIS data. The three items related to the patient's living environment appear at face value to be important factors that could affect a patient's health, safety, and quality of life, but they do not generally have a significant statistical impact on patient outcomes or resource utilization. The lack of relationship between these items and patient outcomes may be partially a

result of imprecise or inconsistent measurement. Because of the poor performance of these items in a statistical sense, serious consideration should be given to reworking them for future versions of OASIS. Similarly, patient behavior (reported or observed) is important clinically, but the item does not perform well statistically. The two equipment-related items listed are of limited utility for the home health population as a whole, because most patients do not use equipment of the specified type. These items would, however, be useful for evaluating outcomes of care for the subpopulations of patients who have a need for such equipment. Several discharge status items are not currently used for outcome reporting but likely will contribute to new outcome measures as both adverse event outcome reports and risk-adjusted outcome reports continue to be redesigned and refined in the future.

2. Refinement of OASIS and Improving Data Quality

As CMS moves forward to revise and refine OASIS over time, reliability, validity, utility, and burden will be important criteria to use in evaluating individual items to determine if they should be retained, modified, or discarded. In addition to rewording or refining data items, other tools to enhance data accuracy should include education and training programs, as well as programs to monitor and evaluate the accuracy of OASIS data submitted by individual HHAs so that feedback can be provided when problems are detected. These avenues are being pursued by CMS in a variety of ways. A number of educational materials already exist related to home health assessment in general and OASIS in particular. Additional materials are under development, including a Web-based training program. Multiple data accuracy monitoring programs are in place or under development. OASIS items will undergo continuing evaluation by CMS and others. The goal should be to minimize burden, while retaining and improving OASIS as a tool for meeting the clinical information needs, first and foremost of providers and patients, and secondarily of payers and regulators.

3. Burden of OASIS Data Collection

Evaluation of the real burden of OASIS data collection should be based on empirical research rather than rhetoric. Results of the OASIS assessment time study reported here indicate no measurable difference between time required to complete an assessment with and without OASIS, employing an agency-matched design to control for between-agency variation. There may be burdens associated with encoding and transmitting OASIS data that are not captured adequately in current cost estimates. Situations occasionally arise in which the assessment requirements for payment, outcome monitoring, and other clinical purposes inadvertently create additional work for home health agencies because the assessment time points required for different purposes do not perfectly coincide. Further analysis may be required to break down the different components of agency burden associated with OASIS data collection, and to evaluate the degree to which burden can be reduced by agencies' adoption of more efficient practices. Further research also is needed to discover whether regulatory changes can be made which will reduce burden without compromising payment integrity or patient welfare, and to accurately determine legitimate costs for which providers should be compensated.

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SUPPORTING DOCUMENT 3:

CONCEPTUAL ISSUES AND MEASUREMENT CONSIDERATIONS IN ASSESSING THE QUALITY OF HOME HEALTH CARE

in Volume 3 of the report series entitled:

OASIS and Outcome-Based Quality Improvement in Home Health Care:
Research and Demonstration Findings, Policy Implications,
and Considerations for Future Change

for the three interrelated studies:

The National Medicare Quality Assurance and Improvement Demonstration
The New York State Outcome-Based Quality Improvement Demonstration
A Project to Assist Home Care Providers to Effectively Use Patient Outcomes

February 2002

OVERVIEW

The article duplicated here, Measuring and Assuring the Quality of Home Health Care, written by Center for Health Services Research staff, was originally published in the *Health Care Financing Review* in Fall 1994, Volume 16, Number 1. It discusses conceptual and applied issues and methods involved in assessing the effectiveness of home health care by measuring patient outcomes. Topics in this paper include rigorous definitions of key terms related to quality, alternative approaches to measuring outcomes, risk adjustment of outcome measures, and applications involving time-dependent data on health status.

Measuring and Assuring the Quality of Home Health Care

Peter W. Shaughnessy, Ph.D., Kathryn S. Crisler, M.S., R.N., Robert E. Schlenker, Ph.D., Angela G. Arnold, M.S., R.N., Andrew M. Kramer, M.D., Martha C. Powell, Ph.D., and David F. Hittle, Ph.D.

The growth in home health care in the United States since 1970, and the exponential increase in the provision of Medicare-covered home health services over the past 5 years, underscores the critical need to assess the effectiveness of home health care in our society. This article presents conceptual and applied topics and approaches involved in assessing effectiveness through measuring the outcomes of home health care. Definitions are provided for a number of terms that relate to quality of care, outcome measures, risk adjustment, and quality assurance (QA) in home health care. The goal is to provide an overview of a potential systemwide approach to outcome-based QA that has its basis in a partnership between the home health industry and payers or regulators.

PURPOSE

Certain terms, such as outcomes, case mix, indicators, and measures, have multiple meanings in the literature, and therefore are defined precisely in this article to frame the discussion on quality measurement and QA in home health care. Many of the concepts and issues discussed apply to health care in general, although they are anchored largely in their applicability to long-term care and especially home health care.

Primary emphasis is on patient outcomes and measuring outcomes for QA. Nonetheless, general issues related to quality of care, as well as the utility of other types of quality measures, are presented. For the most part, we concentrate on selected results from the conceptual, clinical, and empirical analyses that have constituted a research program designed to produce a system of outcome measures for use in assessing the effectiveness of home care.

The various studies that have comprised this program have afforded an opportunity to evaluate the appropriateness of most major secondary data sources and agency-obtained data for measuring outcomes, assess the feasibility of different approaches to primary data collection, obtain input from multidisciplinary clinical panels on the content and methodology of proposed methods for measuring the quality of home health care, and empirically test several different measurement approaches (Kramer et al., 1989a; Shaughnessy, Kramer, and Bauman, 1989; Kramer et al., 1989b; Crisler, Kramer, and Shaughnessy, 1990; Shaughnessy et al., 1991a; Shaughnessy et al., 1993).

CENTRALITY OF OUTCOMES

Our primary reason for providing health care is to benefit patients. In the context of analyzing issues about reimbursement, utilization, regulation, supply, integration, insurance coverage, health professions' education, cost, and even political topics, it

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is possible for us to overlook the basic fact that the *raison d'être* of health care is to influence patient outcomes. At a time when health policy and health services issues are receiving considerable attention and form the basis for extensive policy debate, the effectiveness of the many components of our health care system, taken individually and holistically, is not being measured and analyzed adequately in view of what is at stake. Does hospital care accomplish what it should on behalf of patients? Do we have adequate evidence of the outcomes of systematic approaches to managed care based on data collected on individual patients or health maintenance organization (HMO) enrollees? Is home care more effective than institutional care? In terms of what happens to patients, is primary care as effective and as logical as its proponents argue? Have the regulatory programs put in place in nursing homes over the past 2 decades enhanced the well-being of nursing home residents?

We have made inroads into answering some of these questions, but are far from definitive evidence. One reason is that we often analyze utilization patterns, provision of services, distribution or supply of providers, organizational arrangements, and cost and reimbursement issues (to name a few) on the assumption that the care provided accomplishes what we expect. This assumption has not been challenged with sufficient objectivity and intensity, although there are several studies and analyses that have addressed and are continuing to address such issues (Grover et al., 1990; Hannan et al., 1989; Hughes et al., 1988; Shaughnessy, Schlenker and Kramer, 1990; Carlisle et al., 1992; Wennberg, 1990; Tarlov et al., 1989; Braun, Rose, and Finch, 1991; Park et al., 1990; Dubois and Brook, 1988; Shaughnessy et al., 1994; Helberg, 1993; Kemper et al., 1988; Kemper, 1992; Hedrick and Inui, 1986; Hughes, 1985; Zimmer, Groth-Juncker, and McCusker, 1985). In all, when examining the value or effectiveness of care, outcomes should be considered as more than one small piece of the entire setting; they should occupy center stage because they are the fundamental reason why we provide health care.

There are several reasons outcomes have not been comprehensively analyzed in addition to the rather obvious ones of limited resources and funding for such purposes. It is difficult to precisely specify outcome measures to properly adjust for the natural progression of disease or disability in analyzing outcomes, and to reliably and comprehensively collect the requisite data to properly analyze outcomes. Yet, analysis of what we are accomplishing on behalf of patients is likely to provide highly useful information to assist us in refining and possibly even substantially altering our approach to health care in the United States. Home health care is no exception. We know little about the effectiveness of home health care, although we are aware of the strong preference patients have for home care over most other alternatives, especially institutional care. Our challenge is to specify and measure outcomes in the home care field so that we might learn more about effectiveness, facilitate decision-making on what types of patients or clients benefit most from home care, and provide a foundation for continually improving the effectiveness or outcomes of home care.

BACKGROUND

In the long-term care field, a distinction is often drawn between quality of care and quality of life (Donabedian, 1980). In a general sense, the term "quality of life" refers to the extent to which an individual is able to and does pursue a range of

functional, intellectual, emotional, and volitional behaviors that constitute and enhance the total life experience. Quality of life is perforce uniquely circumscribed for each individual by those features of one's health status and environment that are (relatively) immutable at a given point in time, such as age, birth circumstances, heredity, acquired disabilities, selected socioeconomic factors, and family composition and history. The term "quality of care" is typically used in a more specific way, connoting the adequacy or effectiveness of health care, and, at times, access to or appropriateness of health care. Without doubt, health care can and does influence quality of life. For selected types of long-term care, quality of life can be an indicator of the effectiveness of care, e.g., nursing home care and home care for the chronically ill (Patrick, 1990; Institute of Medicine, 1986).

In a temporal sense, quality of care can be conceptualized as focusing on the adequacy or effectiveness of a set of services provided within a given period of time or episode of health care. We have yet to reach a point in comprehensively evaluating health care where we truly view quality of life as a function of multiple, integrated episodes of health care (and other factors and services) over extended periods of time. We must continue to strive for such comprehensive evaluations (which may become more likely if care integration is enhanced under managed care systems and such systems collect adequate information to monitor health status outcomes). In the meantime, to take steps toward attaining this goal, it is appropriate to define, study, and assess quality of care for individual types of providers, continually expanding the purview of such efforts to include the effectiveness of care over increasing intervals of time.

In this context, this article is concerned with measuring the effectiveness of home health care. Different types of effectiveness measures, defined largely in terms of patient outcomes, are discussed. Home care is unique in several ways that make it complex to attribute outcomes to the care provided. Patient compliance or adherence to treatment regimen is critical, yet is difficult to monitor. The provider is essentially a guest of the patient. Attributes of the home environment, such as stairways, availability of transportation, language barriers, availability of communications technology, and presence of a willing and able caregiver are often essential in determining independence, improvement, or maintenance of function. To remain at home instead of in an institutional setting, most patients[1] require at least some degree of independence in terms of the cognitive, behavioral, and functional components of activities of daily living (ADLs). Although some home care patients can be severely and permanently impaired in these areas and still remain at home, they are the exception rather than the rule, because serious and enduring impairments in such areas usually result in institutional care.

Nonetheless, most of us would prefer home care not only for ourselves but also for our families and friends when confronted with a viable choice between home care and institutional long-term care. This reason alone—the desirability of home care over institutional long-term care—very likely accounts for a major portion of the growth in the home care field over the past 2 decades (Kemper, 1992; Rivlin and Weiner, 1988; McAuley and Blieszner, 1985). Is home care

[1] The terms "client" and "consumer" are often used in home care to connote the extent of choice and empowerment that should characterize individuals receiving such care. In this article, however, the term "patient" is used in most instances to be consistent with tradition.

effective, however? How do we measure effectiveness? Can we establish ways to assess and improve effectiveness over the course of time? How are continuous quality improvement (CQI) or total quality management (TQM) methods best implemented and sustained in the home care field? Third-party payers are understandably asking whether home care is more cost-effective than other types of health care, seeking to ascertain the circumstances under which home care is effective, and attempting to discern the types of agencies and even the individual agencies that are most effective. The Omnibus Budget Reconciliation Act of 1987 (Public Law 100-203) mandated that the Medicare survey and certification process shift from an emphasis on structural requirements to an evaluation of the care provided to patients and its effectiveness.

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has initiated efforts to develop outcome indicators to assess effectiveness of health care organizations (Joint Commission on Accreditation of Healthcare Organizations, 1988a). JCAHO requires "the identification of defined, measurable indicators of the quality and appropriateness of each important aspect of care, that specify activities, events, occurrences and/or outcomes" (Joint Commission on Accreditation of Healthcare Organizations, 1988b). Another accrediting body, the Community Health Accreditation Program (CHAP) of the National League for Nursing, has as a primary objective to "develop and maintain state-of-the-art consumer-oriented national standards of excellence focusing on outcomes for the full range of services and products provided by home care and community health organizations" (Community Health Accreditation Program, 1989).

A number of recent developments further demonstrate the considerable current interest in home health outcomes and the effects of care provided. Outcome scales developed for the Home Care Association of Washington include general symptom distress, functional status, caregiver strain, discharge status, taking medications as prescribed, patient satisfaction, knowledge of major health problems, and physiologic indicators (Lalonde, 1986). The Visiting Nurse Association of Omaha developed and empirically tested a QA system with a problem rating scale to measure clients' knowledge, behavior, and status outcomes for specific problems (Martin, Leak, and Aden, 1992). The Alberta Home Care Program used a client outcome tool to measure: pain management; symptom control; physiologic health status; ADL abilities; instrumental activity of daily living (IADL) abilities; sense of well-being; goal attainment; maintenance at home; knowledge of diagnosis, treatment, management, and safety; performance of prescribed treatments and management regimens; satisfaction with services; and family strain (Sorgen, 1986). Kane et al. (1991) assembled panelists to rank the importance of different types of quality indicators. Rinke (1988) developed a framework for home care agencies to use in defining and measuring home care outcomes. A system developed by Wilson (1993) focuses on measures of patient functional status (defined as encompassing health, knowledge, skill, psychosocial function, and ADLs) to generate data on patient outcomes, individually and in the aggregate. A home health care classification system for nursing diagnoses and interventions for home health care patients was developed at Georgetown University to measure, analyze, and predict resource requirements (Saba and Zuckerman, 1992). Recently concluded research was conducted by CHAP to assess outcomes and to incorporate appropriate measures into the CHAP accreditation

process. The study used three levels of outcomes: individual, intra-agency, and inter-agency outcomes (Peters, 1992).

DEFINITIONAL AND METHODOLOGICAL CONSIDERATIONS

Quality Criteria, Natural Progression, and Outcomes of Care

The challenge of measuring quality of care is as multifaceted as measuring individual health status using the dimensions of physiologic, functional, mental, social, and emotional health. A practical (single-valued) overall or global index of health status is simply not possible, or at least has not been developed to date. Necessity thus dictates that we consider the attributes of health status as multidimensional rather than unidimensional in assessing the effectiveness of health care. Quality care can be defined using any combination of three well-known criteria attributable to Donabedian (1980):

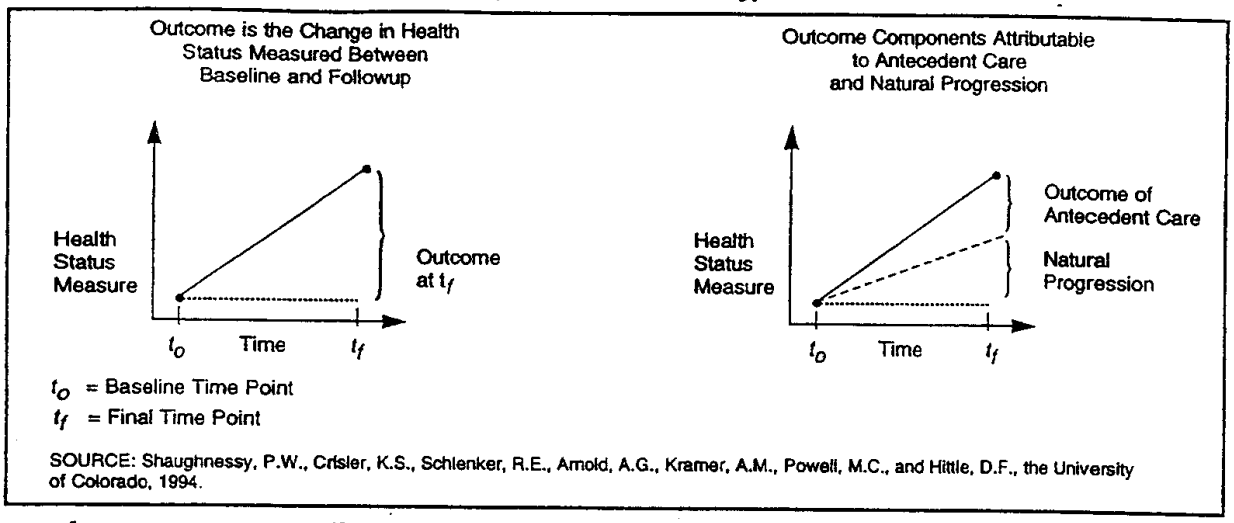
(1) *Quality of care defined in terms of outcomes.* Quality care should result in benefits to a patient that would not accrue in the absence of care.
(2) *Quality of care defined in terms of process.* Quality care should be consistent with or superior to the dictates of accepted standards that specify how care should be provided.
(3) *Quality of care defined in terms of structure.* Quality care should be consistent with or superior to the dictates of accepted standards that specify either resources that should be used or the characteristics of the environment in which care should be provided.

Although outcomes are defined more precisely in the next section, consider for the moment that the type of outcome under consideration is a change in patient health status over time (e.g., healing of a surgical wound or improvement in ability to dress the lower body after a stroke). Conceptually, it is necessary to distinguish between an outcome and an outcome of care. As shown on the left side of Figure 1, an outcome, as defined here, refers to the change in health status between a baseline time point (t_0) and a final time point (t_f). However, some or all of the change in health status (e.g., wound healing or improvement in ability to dress lower body) may have occurred independently of care provided. Some natural progression of condition would have occurred by the followup time point (e.g., for wound healing or recovery of function). The diagrams on the left and right sides of Figure 1 depict the difference between the patient outcome and the outcome of care. The outcome of care can be considered as that portion of the outcome that is attributable to care independently of natural progression of the condition.

The challenge in measuring outcomes to assess effectiveness of health care is to somehow consider both the natural progression of condition (even when condition might deteriorate) and the care provided. In this context, we must also acknowledge and compensate for the possibility that good care should minimize the likelihood of complications that might have occurred in the absence of care. (Complications are circumstances that can influence outcomes or be considered outcomes unto themselves, e.g., wound infection or a second stroke.) Sometimes care is intended to do no more than make the patient more comfortable or enhance the natural progression of patient condition (e.g., terminal care or wound healing). Figure 1 is not intended to depict all possible situations, because (a) natural progression can be neutral or even negative; (b) care can be provided only to

Figure 1

Outcomes as a Function of Antecedent Care and Natural Progression of Condition (Disease or Disability)



SOURCE: Shaughnessy, P.W., Crisler, K.S., Schlenker, R.E., Arnold, A.G., Kramer, A.M., Powell, M.C., and Hittle, D.F., the University of Colorado, 1994.

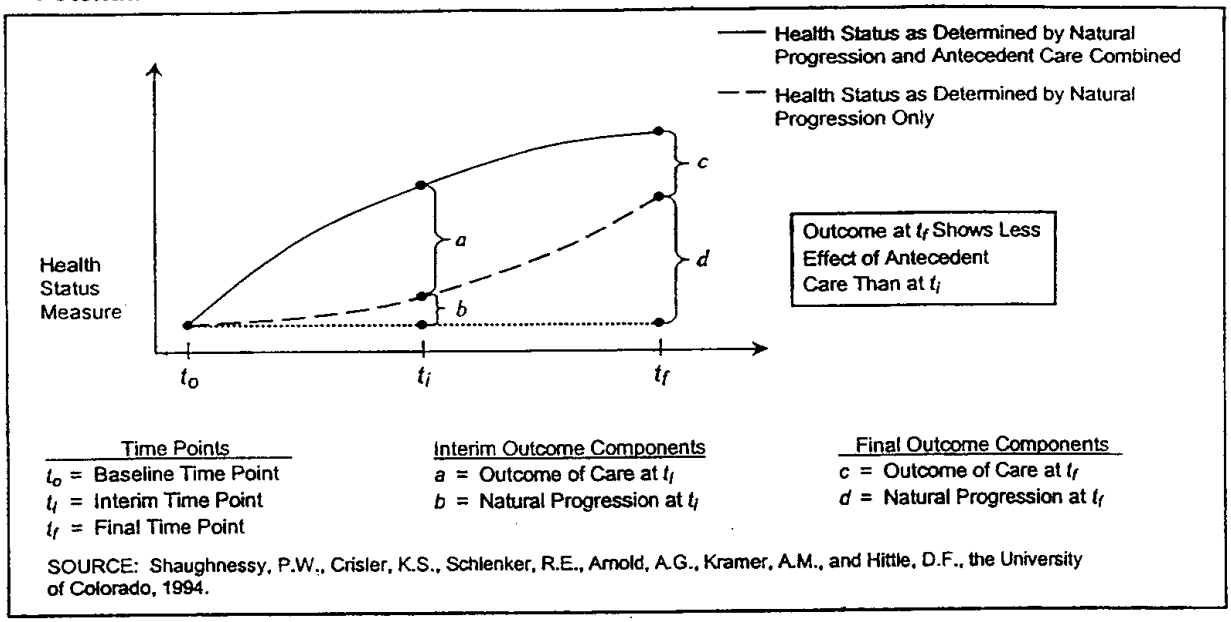
accelerate, not necessarily permanently elevate, health status to a level above that of natural progression; and (c) change in health status need not be linear or monotonic (i.e., change can occur in a nonlinear fashion and even worsen and improve over a given interval). The main point of Figure 1 is simply to demonstrate that outcomes are a function of both antecedent care and natural progression of condition.

Because the objective in outcome assessment is attributing outcomes to antecedent care, and because it is typically not possible to precisely separate the effects of natural progression from antecedent care, statistical comparisons are often useful in evaluating outcomes. Such comparisons usually entail measuring outcomes for a patient group under one set of circumstances (e.g., under the care of a given provider) and comparing such outcomes with those of another patient group, assuming that the natural progression for both groups is the same, or adjusting for potential differences in natural progression by measuring factors that predict natural progression and compensating for these factors in the analysis. Such factors are typically termed risk-factors or case-mix variables (discussed later). Comparing outcomes between the two groups theoretically compensates for potential differences in natural progression if the risk factor-adjustment process is thorough. As will be discussed, this is rarely possible to do perfectly. However, on the assumption that risk (factor) adjustment is adequate for practical purposes, the differences in risk-adjusted outcomes between the two groups can be attributed to antecedent care and are therefore regarded as differences in outcomes of care.

Time Interval Over Which Outcomes Are Measured

Duration between the baseline time point and the followup time point(s) is important to consider when assessing outcomes. Figure 2 (in which change in health status is depicted as non-linear for the sake of generality) demonstrates that change in health status at an interim time point (t_i) can be attributed to both antecedent care (effect "*a*") and natural progression (effect

Figure 2
Potential Differential Effects of Outcomes of Care Relative to Timing of Followup Observations



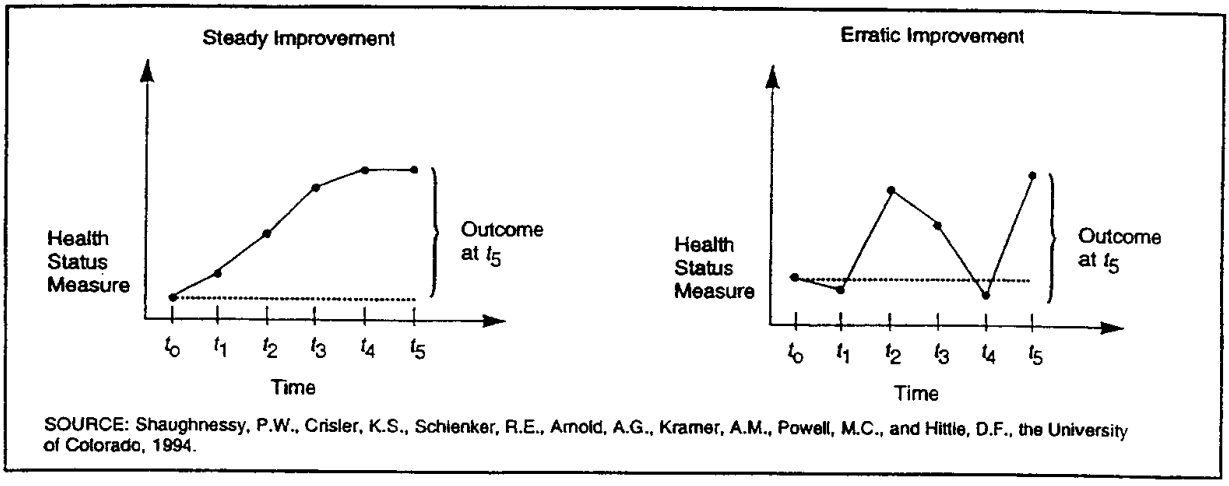
SOURCE: Shaughnessy, P.W., Crisler, K.S., Schlenker, R.E., Arnold, A.G., Kramer, A.M., and Hittle, D.F., the University of Colorado, 1994.

"*b*"). However, a substantial portion of the change in health status at the final time point (t_f), effect "*d*," would have occurred without providing the antecedent care. Thus, most of the change in health status over the interval between t_0 and t_f would have occurred independently of care provided (in this example), whereas the natural progression at t_i was considerably enhanced by care provided between t_0 and t_i. In this case, the provision of care accelerated improvement in health status, but produced a relatively small lasting effect on health status (effect "*c*") relative to that which would have occurred through natural progression. No matter what final time point is selected to measure outcomes, the dilemma of the "truly final effect" persists from a theoretical viewpoint. For example, in a recent study to examine home care provided under fee-for-service and capitated payment environments (HMOs), the final followup point was 12 weeks or discharge, whichever occurred first. A risk-adjusted difference between the two payment environments was found for several outcomes, suggesting superior outcomes for fee-for-service patients. However, it is possible that by 6 months after admission to home care, the HMO patients may have attained outcomes similar to the fee-for-service patients because of either natural progression or other types of care provided. Patients were not followed this long; hence, data were not collected to test this hypothesis because the goal was to assess the shorter run effectiveness of home health care independently of the confounding effects of other types of health care (Shaughnessy, Schlenker, and Hittle, 1994). Consequently, the time interval must be carefully selected in view of the purpose at hand, considering the possibility that as the duration of time from the initial baseline point increases, the likelihood of additional types of care increases, complicating the attribution of outcomes to a particular type of antecedent care.

The diagram in Figure 2 also demonstrates that the primary or even exclusive effect of

Figure 3

Outcomes in the Context of the Pattern of Change in Health Status



SOURCE: Shaughnessy, P.W., Crisler, K.S., Schlenker, R.E., Arnold, A.G., Kramer, A.M., Powell, M.C., and Hittle, D.F., the University of Colorado, 1994.

certain types of care can be in the form of acceleration of natural progression. However, this should not be considered a trivial type of effect, because in some instances it is highly desirable. For example, an accelerated return to a former level of functioning can substantially reduce home caregiver strain, allow an individual to return to work (or other former activities) earlier, or avoid complications that might be more probable if the recovery period is longer (e.g., risk of hospitalization is greater if a normally ambulatory individual is sufficiently impaired in mobility so that the likelihood of falling is increased).

Patterns of Change Over Time

The diagram on the left in Figure 3 demonstrates a steady improvement in health status over several time points. This pattern contrasts substantially with that on the right in Figure 3 where, although patient status improves between t_0 and t_5, two declines in health status (relative to t_0) occur at interim times.

To test for different conclusions that might be reached by examining outcomes measured using only a baseline and a single followup point relative to outcomes defined using information from several interim time points, we defined the following four types of outcome measures:

(4) *Improvement in health status.* If the patient's health status (e.g., measured using an ordinal scale for ambulation) improves between admission and the final followup point, this outcome measure takes on the value 1; otherwise it is 0. Patients who cannot improve (are not disabled relative to the health status measure under consideration, or do not have the condition or problem) are excluded from the computation of this measure.[2] Patients who died during the followup interval are also excluded.[3]

(5) *Improvement pattern in health status.* If the patient's health status improves between admission and the final followup point for the health status

[2]The challenge of taking into consideration the fact that some patients are at the optimal (minimal) level of health status when measuring improvement and some are at the minimal level of health status when measuring stabilization (non-worsening) is often termed dealing with "floor and ceiling effects." We have used a variety of methods in addressing this issue and have found case selection (i.e., excluding patients whose health status value is at the floor or ceiling) to be most useful for practical QA applications.

[3]Mortality can be used as a separate outcome measure unto itself; we typically analyze it as such. However, we have found it to be a methodologically crude measure in that it focuses on an inevitable event (which has greater possibility among the elderly), and risk adjustment is therefore extremely complex.

Table 1

Functional Outcomes at Three Months After Start of Care for 2,622 Medicare Home Health Patients Admitted From Hospital (1,905 Patients) or From Community (717 Patients)[1]

Functional Outcomes	Admitted From Hospital[2] (n = 1,905)				Admitted From Community[2] (n = 717)			
	Improvement[3]		Stabilization[3]		Improvement[3]		Stabilization[3]	
	Difference[4]	Pattern[4]	Difference	Pattern	Difference	Pattern	Difference	Pattern
Ambulation	.356	.350	.905	.875	.262	.252	.848	.796
Transferring	.505	.502	.913	.889	.343	.343	.885	.842
Toileting	.487	.470	.923	.904	.379	.369	.893	.868
Bathing	.539	.517	.883	.838	.365	.354	.786	.745
Dressing Lower Body	.523	.509	.889	.859	.306	.293	.866	.819
Grooming	.532	.515	.914	.882	.404	.386	.886	.854
Main Meal Preparation	.423	.407	.820	.773	.325	.313	.759	.695
Housekeeping	.350	.343	.814	.757	.273	.264	.704	.652

[1]The 2,622 patients were randomly sampled from Medicare admissions to 44 certified agencies in 27 States during 1991 and 1992. Patients were followed longitudinally with data collection occurring monthly until 3 months after start of care or until discharge, whichever occurred first. Data were collected prospectively using an optical scan form containing data items that had been piloted and reliability tested in earlier field trials.
[2]To be admitted from hospital, it was necessary for the patient to be discharged from an acute inpatient stay within 14 days prior to home health admission.
[3]All hospital versus community mean differences between improvement (difference and pattern) outcome measures and between stabilization (difference and pattern) outcome measures, respectively, are statistically significant ($p < .10$) using Fisher's exact test or its chi-square approximation when expected cell frequencies are ≥ 5. For example, the mean difference between the improvement pattern outcome measure in ambulation for hospital patients and the improvement pattern outcome measure in ambulation for community patients is significant at $p < .10$.
[4]The difference and pattern measures are defined in the text for improvement (definitions [4] and [5] and stabilization definitions [6] and [7]).

SOURCE: Random samples of Medicare patients, 1991-92.

measure under consideration, and does not worsen relative to health status at admission for any interim data collection points, this outcome measure takes on the value 1; otherwise it is 0. Exclusions are the same as those above.

(6) *Stabilization in health status.* If the patient's health status does not worsen between admission and the final followup point, this outcome measure takes on the value 1; otherwise it is 0. Patients who cannot worsen (are at the most severe level of the health status scale under consideration) are excluded from the computation of this measure. Patients who died during the followup interval are also excluded.

(7) *Stabilization pattern in health status.* If the patient's health status does not worsen between admission and the final followup point for the health status measure under consideration, and does not worsen relative to health status at admission at interim data collection points, this outcome measure takes on the value 1; otherwise it is 0. Exclusions are the same as above.

The improvement and stabilization measures in (4) and (6) use only the first and final time points (and sometimes are called "difference" measures here), whereas the improvement pattern and stabilization pattern measures in (5) and (7) use interim time points as well.

To assess the value of the information on patient status at interim time points, we used data from a national sample of home health agencies and patients to compare means on the improvement and stabilization difference measures with those of the improvement and stabilization pattern measures for Medicare patients admitted to home health care from a hospital versus those admitted from the community (Table 1). Because the outcome measures are dichotomous, all means can be interpreted as percents. As expected, because the pattern measures are more stringent in that a patient cannot worsen at interim time points to receive a value of "1," the means for the two pattern measures are respectively lower than the means for the improvement and stabilization difference measures. The means for the community

patients tend to be somewhat lower, conveying the greater likelihood of chronic functional impairments among patients admitted to home care from the community relative to hospital patients, who are more likely to have acute problems where functional stabilization and improvement are more probable.

However, the respective findings for the four types of measures tend to lead to consistent inferences in comparing home health patients admitted from hospitals with those admitted from the community. That is, the excess of the improvement difference mean for hospitalized patients over those for community patients tends to be about the same as the corresponding excess for the improvement pattern means, and analogously for the stabilization measures. Although this consistency between difference measures and pattern measures is not always found, it has appeared quite frequently in our research using interim time points separated by 30-day intervals. Because of this, and because of the substantially increased burden of data collection at interim time points, we would recommend data collection every 60 days for (Medicare) home health patients, because it appears the more relevant conclusions regarding outcomes can be obtained using a 60-day interval. Thus, in terms of outcome-based quality improvement (OBQI), our recommendation is to collect data every 60 days until discharge, and to collect data at discharge, whenever it occurs.

Three Types of Outcomes

Several definitions are appropriate at this stage to introduce end-result, intermediate-result, and utilization outcome measures as a taxonomy for outcome measurement that is useful for OBQI in home health care. The following first six definitions (8)-(13) provide a backdrop for defining the three types of outcome measures in (14)-(16), as well as for discussing other issues and approaches in this article.

(8) *Quality of care.* As used here, the term "quality of care" refers to a broad construct, which, in full generality, is a pervasive attribute of health care, reflecting the overall effectiveness with which health care is provided relative to its primary attributes or its objective(s) to cure, rehabilitate, assess, maintain, sustain, or palliate (patients), or to ameliorate, prevent, or retard patient problems. It is presumed that each type of (home) care has certain objectives. Quality of care refers to the extent to which these objectives are attained. When one speaks of quality of care, an implicit assumption is made that standards exist according to which the "goodness" or "badness" of care can be judged. Such standards can take the form of either expert-opinion-derived norms, or implicit or explicit statistical norms reflecting the state of care provided at a given time. By definition, "quality of care" connotes a positive attribute of care, i.e., the higher the quality, the more beneficial it is for the patient.

(9) *Quality indicator.* The term "quality indicator" also refers to a construct, i.e., an attribute of care that is conceptual or more theoretical in nature (not yet translated into a concrete attribute that is rigorously and precisely defined). A quality indicator refers to an attribute of care that can be used to gauge quality of care in a specific area. For example, the degree of improvement in patient functioning—not necessarily specifying how one should actually measure patient functioning—is a quality indicator or construct that can reflect the quality of care with respect to patient functioning. Thus, the term "quality of care" is a

broad overarching construct, whereas the term "quality indicator" refers to a more specific construct that involves a particular dimension of quality of care. As used here, the term "quality indicator" is distinct from the term "quality measure."

(10) *Quality measure.* A quality measure results from a rule that assigns numeric values to a specific quality indicator. The essential distinction between quality indicators and quality measures (in this discussion) is that quality measures take on numeric values, while quality indicators refer only to unquantified attributes of care related to quality. For example, improvement in ambulation is a quality indicator. Improvement in ambulation as quantitatively reflected by the numeric change in a five-point ordinal mobility scale between admission and 60 days after admission is a quality measure. (One reason we often distinguish between quality indicators and quality measures in our research is that, operationally, certain types of clinicians and clinical panels are effective in developing and reviewing quality indicators, whereas other types of panels are effective in developing and reviewing quality measures.) Therefore, a quality measure takes on "values" (i.e., numbers), but is clinically and conceptually rooted in a quality indicator that is an unquantified attribute of care reflecting one of many components of the overarching construct of quality of care. Depending on how they are defined, quality measures and quality indicators can reflect either good care or poor care.

(11) *Process quality measure.* A process quality measure is one that quantifies one or more dimensions of the manner in which care is actually provided or administered. For example, a process quality measure can quantify services according to a dichotomy of whether a given service is provided (0 = not provided, 1 = provided), the provider of service (different values for different types of individual service providers by discipline or professional type), the frequency of service (a numeric value indicating the number of times the service is provided per week, per month, etc.), the mix of services provided (a numeric value or set of values indicating whether prespecified health care services are provided in conjunction with one another), a composite score indicating the adequacy with which several dimensions of a service (e.g., assessment) were provided, etc. To be valid, process measures of quality must be appropriately linked to care needs of the patients under consideration and must produce intended outcomes.

(12) *Structural quality measure.* A structural quality measure is one that reflects the availability of needed care or resources, the adequacy of inputs to the service process such as staff or equipment, or the care environment associated with service provision. For example, structural quality measures can include dichotomies reflecting the availability of certain devices (e.g., walker, cane, or other types of durable medical equipment) needed for functioning or rehabilitation, a quantification of the overall staff mix available through a home health agency in view of its case mix, etc.

(13) *Outcome measure.* An outcome measure is a quantification of a (potential) effect of care on the patient. For example, a dichotomous measure indicating

whether a wound has healed between admission and 2 months after admission, a dichotomy indicating whether a patient was hospitalized due to complications of care, a quantification of whether a patient or home caregiver is satisfied with care received, a quantification of whether a home health patient or the home caregiver has become more knowledgeable about certain aspects of self-care, or a dichotomy measuring whether a surgical wound became infected, are outcome (quality) measures. For purposes of this discussion, we have subdivided outcome measures into the three-category taxonomy defined below.

(14) *End-result outcome measure.* An end-result outcome measure reflects a quantified change in patient condition that is (potentially) due to the provision of care. End-result outcomes refer to changes and non-changes in functional abilities, physiologic conditions, symptom distress, cognitive abilities, or emotional conditions that are intrinsic to the patient. For example, a quantification of change in transferring ability between admission and discharge, a quantification of change between admission and 60 days after admission in terms of dependence on intravenous medication (i.e., where the physiologic condition in this case is reflected by this dependency), and a quantification of change in symptom distress (e.g., pain present or absent) are end-result outcome measures.

(15) *Intermediate-result outcome measure.* An intermediate-result outcome measure reflects a quantified non-physiologic or non-functional outcome of care that is intrinsic to the patient, the patient's family or caregiver, or their behavior; however, the intermediate-result outcome is not the primary reason for, or the intended end result of, the care provided. For example, quantifications of the extent to which patients or caregivers are compliant with a medication regimen, a quantification of satisfaction with personal care services, or a dichotomy reflecting change in the extent of family or caregiver strain are intermediate-result outcome measures. Intermediate-result outcome measures are important in home care, where patient knowledge of self-care, compliance with treatment regimen, caregiver strain, and satisfaction can be pivotal in attaining certain end-result outcomes.

(16) *Utilization outcome measure.* Also referred to as a surrogate end-result outcome measure, a utilization outcome measure is a quantification of health services use (or non-use) that is potentially attributable to the (home) health care under consideration. Illustrations of utilization outcome measures include dichotomous indicators of admission to inpatient hospital care due to specific complications and dichotomies reflecting unscheduled physician visits for specific reasons.

As noted, the previous terms are not used consistently in the literature and it is therefore useful to define them for purposes of this discussion. The first six terms previously defined (quality of care, quality indicator, quality measure, process quality measure, structural quality measure, and outcome [quality] measure) were introduced earlier at least in heuristic terms, and are not discussed further per se.

The final three terms above that reference end-result, intermediate-result, and utilization outcome measures are important to note because they constitute a useful three-category outcome measure taxonomy for home health care. In brief,

Table 2

End-Result Outcome Measure Examples

Scale—Assume the Following Ordinal Scale for Ambulation:
Ambulation: Refers to the patient's ability to safely ambulate in a variety of settings.
0 - Is able to independently (i.e., without human assistance) walk on even and uneven surfaces without the use of a device (e.g., walker, cane) and climb stairs with or without railings.
1 - Is able to walk alone only when using a device (e.g., cane, walker) or requires human supervision/assistance to negotiate stairs/steps or uneven surfaces.
2 - Is able to walk only with the supervision/assistance of another person at all times.
3 - Chairfast, unable to ambulate even with assistance but is able to wheel self independently.
4 - Chairfast, unable to ambulate even with assistance and is unable to wheel self.
5 - Bedfast, unable to ambulate or be up in a chair.

Outcome Measure 1 (Dichotomy)
Improvement in Ambulation at 1 Month or Discharge: Defined only if the patient can improve (i.e., the patient has a value of 1 or greater at start of care [SOC] on the above scale).
1 → Patient scale value is less at followup (1 month or discharge, whichever occurred first) than scale value at SOC.
0 → Patient scale value not less at followup than at SOC.

Outcome Measure 2 (Dichotomy)
Discharged to Independent Living and Improved by 2 Months: Defined only if the patient can improve (i.e., the patient has a value of 1 or greater at SOC on the above scale).
1 → Patient was discharged to independent living within 2 months after SOC and patient scale value is less at discharge than at SOC.
0 → Patient was not discharged to independent living, or was discharged to independent living but with scale value not less at discharge than at SOC.

Outcome Measure 3 (Integer-Valued)
Degree of Change in Ambulation at 3 Months or Discharge: Defined for all patients. The numeric change in the above 6-point ordinal ambulation scale between admission and 3 months or discharge (whichever occurs first).

SOURCE: Shaughnessy, P.W., Crisler, K.S., Schlenker, R.E., Arnold, A.G., Kramer, A.M., Powell, M.C., and Hittle, D.F., the University of Colorado, 1994.

end-result outcomes refer to actual changes in patient status over time; intermediate-result outcomes refer to changes in patient/family caregiver knowledge, compliance, satisfaction, and (caregiver) strain or stress; and utilization outcomes refer to the use (or non-use) of health services (e.g., hospitalization) that are potentially attributable to the (home) health care under consideration. Utilization outcomes have been used more frequently than end-result or intermediate-result outcomes, because data are more readily available on such outcomes from secondary sources. However, as noted in the definition, utilization outcome measures are actually surrogate end-result outcome measures, because an assumption must be made that hospitalization, for example, is appropriate or inappropriate in view of patient condition. This renders it challenging to adjust utilization outcomes for risk factors that comprehensively take into consideration the natural progression of patient condition, because the multiplicity of reasons for the occurrence of emergent care, nursing home admission, or hospital admission, can be extensive.

Measurement Precision and Types

The ambulation scale provided in Table 2 provides an illustration of a health status scale that can be used to compute an outcome measure. By collecting data with such a scale at an initial time point (start of care) and a followup point, it is possible to assess whether an individual improved or worsened in ambulation ability. All levels of the ambulation scale are specifically defined. Its values are not defined simply in terms of "independent," "partially dependent," or "dependent," because such terms used alone to define a scale introduce considerable subjectivity. Outcome measure precision and reliability depend

predominantly on the precision and reliability of data item(s) used to compute the outcome measure. This scale is an ordinal scale whose levels have been reliability tested in home health care settings.

Three outcome measures, two dichotomies, and an integer-valued measure are illustrated in Table 2. Although we recommend the use of a 60-day time period, examples are provided in the table for 30 and 90 days, as well, to illustrate the varying time periods for which measures can be specified. (The data collection time periods in this article are interchangeably referred to as 1, 2, and 3 months or 30, 60, and 90 days.)

The first measure corresponds to improvement in ambulation at 30 days or discharge. It is defined in accord with definition (4) given earlier. A variant of measuring improvement is illustrated by the second measure, which combines both improvement and discharge to independent living by 60 days or discharge. This measure takes on the value 1 only if the patient has improved and has been discharged to independent living by the time point under consideration. The third measure illustrated in Table 2 is an integer-valued or polychotomous measure whose values correspond to the numeric change or difference between values on the ambulation scale at start of care and 90 days or discharge. It has the advantages that it is multivalued, its magnitude approximates the degree of change, and its sign connotes whether a positive or negative change occurred. However, because it represents a difference using an ordinal (not an interval) scale, the magnitude of its values can be misleading. The difference between a 5 and a 3 on the ambulation scale is not necessarily the same in terms of patient condition as the difference between a 3 and 1. Hence, a value of 2 for this measure obtained by a patient changing from a 5 to 3 does not necessarily reflect the same extent of improvement as a value of 2 obtained by a patient changing from a 3 to a 1. The dichotomies have the redeeming and intuitively understandable feature of yielding percentages when mean values are taken. Therefore, the average for patients who improved in ambulation actually reflects the percentage of patients improved in ambulation. Dichotomies that yield percentages as mean values are appealing in QA applications.[4] A number of researchers and providers have developed scales and measures that can be used for health status assessment and therefore outcome analysis when data are collected for such scales over time (Lohr, 1988). Doubtlessly, the precision and reliability of such scales will continue to be improved. In this regard, approaches to outcome measurement and outcome-based quality improvement should be sufficiently flexible to incorporate improved approaches to measuring health status and to adjust for the natural progression of disease and disability in assessing outcomes of care.

Risk Factors and Case Mix

Additional terms that are used somewhat differently in various settings are introduced and defined in this section for the sake of integrating several concepts. No pretense is made that the definitions provided

[4]The dichotomies simply reflect whether the patient has improved (or stabilized) and do not reflect the level of change or the starting point. We have examined this potential weakness in several ways, including analyzing transition probabilities or frequencies (as in Markov chain analysis) to ascertain whether significantly enhanced information can be obtained by using indicators of transitions from specific levels of a scale to other specific levels. For the most part, these analyses have shown that the above dichotomies are adequate for QA purposes. In part, this is because of the exclusion criteria given in definitions (4) and (6), where patients who cannot improve are excluded from improvement measures and patients who cannot worsen are excluded from stabilization measures.

here are appropriate for all health care applications, nor are they necessarily superior to other definitions of the same constructs; rather they serve the purposes of this discussion and are intended to clarify certain topics relevant to OBQI in home care.

(17) *Covariate.* As used here, the term "covariate" refers to a variable that should be taken into consideration when analyzing a given variable as a dependent variable (such as a quality, cost, or utilization measure). For example, a variable representing presence or absence of a qualified caregiver at home might be an important covariate to consider when examining measures of the quality of home health care. A covariate can refer to any type of variable that characterizes the patient's circumstances, including a characteristic of the patient environment or community, a characteristic of the provider, a patient status variable, demographic or socioeconomic characteristics of the patient, or even payer characteristics.

(18) *Patient (health) status variable.* A patient status variable denotes or reflects a quantification of patient health status. Thus, a dichotomous indicator of presence or absence of incontinence, a scale that can be used to quantify a patient's ability to feed himself or herself, an interval scale for systolic blood pressure, etc., are all patient status variables. At times variables that denote patient attributes other than health status, such as age, gender, education level, payer, etc., are referred to as patient status variables. We prefer to distinguish between these variables and patient health status variables by terming the former variables general patient characteristics.

(19) *Case mix.* Overall, patient status variables and general patient characteristic variables reflect the health service or health care needs of a patient. When aggregated across a group of patients, these variables can be termed case-mix variables and therefore refer to the case mix of the group.

(20) *Risk factor.* For our purposes, a risk factor for a particular (health-related) outcome is a patient status variable or a characteristic of the patient's environment or circumstances that can influence or mitigate the outcome. Generally speaking, risk factors can be regarded as covariates when one is analyzing any type of quality measure (i.e., not simply outcome measures).

Theoretically, then, the case mix of a group of patients refers to or translates directly into the group's service needs, independently of whether the services are actually provided. Patient status variables, including the presence, absence, or severity of problems (such as cardiac conditions, diabetes, orthopedic impairments, or pulmonary conditions), determine a patient's health care needs. These might be translated into service-specific case-mix measures such as the number or percentage of patients in need of cardiac medications, insulin, range of motion therapy, or lung auscultation, respectively. Noteworthy, however, is the fact that these measures are conceptually different from the number of patients on cardiac medications or insulin, receiving range of motion therapy, or receiving lung auscultation, because factors in the first set measure patient needs while those in the second set measure services received. The degree of concurrence between needs and services received is an indicator of the extent to which health care needs are satisfied, and therefore yields process measures of

quality. Analogously, change in patient status or health care needs over time is an indicator of patient status outcomes over that time period. Hence, the same variables that are used to measure case mix at a single point in time can be used to measure outcomes at two (or more) different points.

Two Basic Ways to Risk Adjust Outcomes

The natural progression of patient condition is a function of patient circumstances and health status. Consequently, in analyzing outcomes to discern the effects of antecedent care separately from natural progression, it is necessary to adjust (as well as possible) for those circumstances and health status attributes that determine the natural progression of the condition under consideration. Therefore, assessing outcomes typically entails adjusting for risk factors or case-mix variables. The ways to do this are twofold. First, patients (receiving care from two different agencies, say) can be grouped or stratified into categories of patients with similar conditions (e.g., patients with open wounds or lesions) so that within-strata comparisons can be made for patients with similar risk factors. Second, statistical methods such as standardization (for distributional differences in risk factors for the populations being compared) or multivariate modeling (such as logistic regression or survival analysis with covariates) can be employed, where the covariates consist of the risk factors for which one wishes to adjust.

These two methods, stratification and statistical adjustment, can be used in combination by first stratifying the patient population into meaningful groups defined in terms of the most pivotal risk factors, and then using statistical adjustment within these groups to adjust for additional risk factors if necessary. Rarely, if ever, is it possible to totally compensate for all possible risk factors, because the number and types of risk factors that can influence patient outcomes are often sufficiently extensive so as to preclude data collection from a practical point of view (e.g., the multiple dimensions of patient health and familial history, motivational and environmental circumstances that can influence outcomes, etc.). As a result, the goal is typically to minimize variation in the outcome measure(s) due to risk factors and to use the dictates of sound clinical judgment and statistical common sense in interpreting risk-adjusted findings to draw inferences about the effects of care on the outcome(s).

A Grouping Scheme for Stratification

An illustration of a grouping or stratification scheme to adjust for risk factors in analyzing outcomes of home health care is the quality indicator group (QUIG) classification scheme. In the initial stages of our work to develop a system of outcome measures for home health care, an effort was made to specify patient conditions that result in different types of health care needs, and require potentially different outcome measures to assess the effectiveness of care.

In order to distinguish between QUIG-specific quality measures and measures that are useful for multiple QUIGs, the terms focused and global measures are used:

(21) *Focused quality measure.* A focused measure pertains to a specific patient group (type) or stratum (e.g., patients with diabetes mellitus, patients with peripheral vascular disease, or terminally ill patients). Thus, focused measures always correspond to specific patient groups or strata.

(22) *Global quality measure.* A global quality measure pertains to all patients. Hospitalization, properly quantified, is a global quality measure for all home health patients under the care of a given agency. Typically, a wider array (but not necessarily a larger number) of risk factors or case-mix variables for global measures signifies poor (or exemplary) care.

Focused measures have the advantage of requiring less risk adjustment (theoretically) because certain risk factors are naturally taken into consideration by restricting the measures to specific conditions. They have the disadvantage, however, of pertaining to fewer patients and therefore lowering sample sizes, which in turn requires larger discrepancies between (statistical) standards and observed means in order to conclude that quality might be problematic or exemplary for certain patient groups. Relative to focused measures, global measures tend to overcome this problem because they are defined for larger numbers of patients. However, because global measures typically require more thorough risk adjustment, they can be more burdensome and possibly less precise.

In developing the QUIG classification approach, our intent was to group patient conditions so that: (a) outcome measures would be as homogeneous as possible for purposes of assessing within-QUIG quality, while outcome measures would be more heterogeneous across QUIGs and (b) patient conditions would be grouped according to the most clinically significant risk factors that might influence measures used to assess outcomes for all patients combined. Consequently, an effort was made to define groups using conditions that would be worthwhile for purposes of applying different (within-group or focused) quality measures and, at the same time, to specify conditions that also would be worthwhile as risk factors in adjusting (across-group or global) quality measures. Because of these operational goals, we made a continual effort to constrain the number of QUIGs, so that the taxonomy would be useful but not unwieldy for applications.

The QUIGs that emerged from the study are presented schematically in Table 3. These QUIGs are the result of several successive iterations involving development by staff, clinical panel review, monitoring other developmental efforts, pilot data collection to classify patients, and empirical revisions. QUIGs are important in the context of the overall approach taken in the research because they represent a way to adjust quality measures for case mix using clinically meaningful risk factors that have been empirically validated. The QUIGs can be used to stratify patients into (non-exclusive or overlapping) groups for purposes of examining within-condition or focused quality measures, or they can be used as case-mix variables or risk factors to be employed in adjusting global outcomes for all patients or larger groups of patients. Further specifics on conceptual and developmental approaches to the QUIG taxonomy are documented elsewhere (Shaughnessy et al., 1993; Shaughnessy et al., 1991a; Kramer et al., 1990).

As shown in Table 3, the QUIGs are divided into two broad types of conditions or care needs: acute and chronic. The nomenclature associated with these categories gave rise to a semantic dilemma. Some individuals initially viewed the terms "acute" and "chronic" as synonymous with Medicare and non-Medicare, respectively, at least from a reimbursement perspective. In fact, these terms are not used in this manner. A Medicare patient (or non-Medicare patient) usually belongs to several QUIGs, because QUIGs are condition-specific and therefore

Table 3

Quality Indicator Groups (QUIGs)

QUIG Number	Description of QUIGs and Examples
Acute Conditions	
1	Acute Orthopedic Conditions (e.g., fracture, amputation, joint replacement, degenerative joint disease)
2	Acute Neurologic Conditions (e.g., cerebrovascular accident, multiple sclerosis, head injury)
3	Open Wounds or Lesions (e.g., pressure ulcers, surgical wounds, stasis ulcers)
4	Terminal Conditions (e.g., palliative care for malignant neoplasms, advanced cardiopulmonary disease, end-stage acquired immunodeficiency syndrome [AIDS])
5	Acute Cardiac/Peripheral Vascular Conditions (e.g., congestive heart failure, angina, coronary artery disease, hypertension, myocardial infarction)
6	Acute Pulmonary Conditions (e.g., chronic obstructive pulmonary disease, pneumonia, pulmonary edema)
7	Diabetes Mellitus*
8	Acute Gastrointestinal Disorders (e.g., gastric ulcer, diverticulitis, constipation with changing treatment approaches, ostomies, liver disease)
9	Contagious/Communicable Conditions (e.g., hepatitis, tuberculosis, AIDS, Salmonella)
10	Acute Urinary Incontinence/Catheter*
11	Acute Mental/Emotional Conditions (e.g., anxiety disorder, depression, bipolar disorder)
12	Oxygen Therapy*
13	Intravenous/Infusion Therapy*
14	Enteral/Parenteral Nutrition Therapy (e.g., total parenteral nutrition, gastrostomy/jejunostomy feeding)
15	Ventilator Therapy*
16	Other Acute Conditions*
Chronic Conditions	
17	Dependence in Living Skills (e.g., meal preparation, housekeeping, laundry)
18	Dependence in Personal Care (e.g., bathing, dressing, grooming)
19	Impaired Ambulation/Mobility (e.g., ambulation, transferring, toileting)
20	Eating Disability*
21	Urinary Incontinence/Catheter Use*
22	Dependence in Medication Administration*
23	Chronic Pain*
24	Cognitive/Mental/Behavioral Problems (e.g., Alzheimer's, confusion, agitation, chronic brain syndrome)
25	Chronic QUIG Membership With Caregiver*

NOTE: For asterisked (*) items, an example is not given because the QUIG name is sufficient to define the condition(s) included.

SOURCE: Shaughnessy, P.W., Crisler, K.S., Schlenker, R.E., Arnold, A.G., Kramer, A.M., Powell, M.C., and Hittle, D.F., the University of Colorado, 1994.

not mutually exclusive. We have found that the typical adult home health patient belongs to three or four QUIGs, often belonging to acute and chronic QUIGs at the same time.

Our earliest QUIG taxonomy entailed specifying broad areas of patient needs, not conditions. From this taxonomy, we translated broad care needs into more specific conditions, yielding our first formal QUIG classification. The use of acute and chronic conditions persisted in our QUIG taxonomies thereafter. As it presently exists, the QUIG taxonomy is useful for adult patients who receive traditional home health care. In future research, we will attempt to specify patient conditions or QUIGs that correspond to preventive services, possibly to subdivide some of the acute QUIGs more precisely for high-tech or specialized care outcome assessment, to consider other patient types more directly such as pediatric populations, to refine the chronic QUIGs through further analysis and applications, and, in general, to continue to refine the QUIGs on the basis of empirical results from OBQI applications.

To illustrate the types of outcome measures used, consider the QUIG corresponding to acute cardiac/peripheral vascular conditions. This condition is often found in Medicare home health patients. Three of the outcome measures specified as important for this group are: (1) improvement in management of oral medications; (2) improvement in dyspnea; and (3) emergent

Table 4

Illustrative Quality Indicator Group (QUIG) Global and Focused Outcome Measures

Outcome Measures for All QUIGs (Global Measures)
End-Result Outcomes and Utilization Outcomes:
Functional Outcome Measures
- Improvement in Ambulation
- Stabilization in Ambulation
- Improvement in Management of Oral Medications
- Improvement in Patient/Caregiver Ability to Manage Equipment

Utilization Outcome Measures
- Acute Hospitalization

Intermediate-Result Outcomes:
Family/Caregiver Strain Outcome Measures
- Improvement in Perceived Ability to Manage Demands
- Stabilization in Perceived Ability to Manage Demands

Outcome Measures for QUIG 5: Acute Cardiac/Peripheral Vascular Conditions (Focused Measures)
End-Result Outcomes and Utilization Outcomes:
Functional Outcome Measures
- Improvement in Management of Oral Medications

Health Status Outcome Measures
- Improvement in Dyspnea
- Stabilization in Weight
- Improvement in Activity Level

Utilization Outcome Measures
- Non-Emergent MD/Outpatient Care for Cardiac Problems/Medication Side Effects
- Emergent Care in Hospital, Emergency Room, or Medical Doctor Office for Cardiac Problem

Intermediate-Result Outcomes:
Knowledge/Skill/Compliance Outcome Measures
- Improvement in Knowledge of Contraindications to Cardiac Glycoside Medication
- Stabilization in Compliance With Cardiac Glycoside Medications
- Stabilization in Compliance With Diuretics
- Improvement in Knowledge of Signs/Symptoms to Report

Outcome Measures for QUIG 1: Acute Orthopedic Conditions (Focused Measures)
End-Result Outcomes and Utilization Outcomes:
Functional Outcome Measures
- Improvement in Ambulation
- Stabilization in Transferring

Health Status Outcome Measures
- Improvement in Pain
- Stabilization in Pressure Sores

Utilization Outcome Measures
- Emergent/Urgent Care (i.e., hospitalization, emergency room/clinic/office visit) Resulting From Fall
- Acute-Care Hospitalization

Intermediate-Result Outcomes:
Family/Caregiver Strain Outcome Measures
- Improvement in Perceived Ability to Manage Demands
- Stabilization in Perceived Ability to Manage Demands

Knowledge/Skill/Compliance Outcome Measures
- Improvement in Ambulation/Walking Exercise Program

Outcome Measures for QUIG 24: Chronic Cognitive/Mental/Behavioral Problems (Focused Measures)
End-Result Outcomes and Utilization Outcomes:
Functional Outcome Measures
- Stabilization in Communication Ability
- Stabilization in Socialization Activities
- Stabilization in Use of Telephone

Health Status Outcome Measures
- Stabilization in Depression
- Stabilization in Frequency of Confusion
- Stabilization in Frequency of Behavioral Problems

Unmet Need Outcome Measures
- Improvement in Unmet Need for Supervision

Intermediate-Result Outcomes:
Knowledge/Skill/Compliance Outcome Measures
- Improvement in Knowledge of Safety
- Improvement in Knowledge of Medications
- Compliance With Medications

SOURCE: Shaughnessy, P.W., Crisler, K.S., Schlenker, R.E.; Arnold, A.G., Kramer, A.M., Powell, M.C., and Hittle, D.F., the University of Colorado, 1994.

care for cardiac problems. If, for patients in this particular QUIG, an agency performs significantly above or below average (or significantly above or below some statistical norm) for one or more of these outcomes, additional steps to reinforce or remedy the processes of care would be appropriate. If no problems were found, then it would not be necessary to remedy or change the manner in which care is provided for patients in this QUIG. Table 4 contains examples of several global and focused measures. The first category of outcome measures pertains to multiple QUIGs (i.e., all patients) and therefore consists of global measures. The next three categories consist of QUIG-specific measures and therefore illustrate focused outcome measures. Within each of the four categories, end-result and utilization outcome measures as well as intermediate-result outcome measures are illustrated. Within the category of end-result outcomes, both functional and other health status outcomes are illustrated for the focused measure sets corresponding to acute orthopedic conditions, acute cardiac/peripheral vascular conditions, and chronic cognitive/mental/behavioral problems. Precise definitions of the values taken

on by each measure in Table 4 are not given, although it should be clear from context how the various measures would be defined in view of the ambulation scale and measures given in Table 2. The measures in Table 4 are but illustrative because our current research may result in alterations to the nature and substance of such measures in order to apply them in "steady-state" OBQI.

Statistical Adjustment for Risk and Time-Period Comparisons

The various methods of statistical adjustment, including standardization and multivariate modeling, are well-known (Thomas, Holloway, and Guire, 1993). Consequently, illustrations of these procedures are not provided here. As has been the case for risk-adjusted hospital mortality and for diagnosis-related groups (DRGs), it is natural that home health care applications of OBQI using risk adjustment will evolve over the course of time (Branch and Goldberg, 1993; Smith et al., 1992; Lohr, 1988).

Another type of comparison involves assessing outcomes for patients admitted to a particular (home) health care provider during one time period and comparing the findings with outcomes for patients admitted to the same provider during another time period. For example, to implement continuous quality monitoring using 12-month time intervals, a home health agency might collect health status information on its patients, compute outcomes on the basis of change in health status measures (or compute utilization outcome measures), and compare outcomes with the preceding time period, possibly within QUIGs. Because agency case mix is reasonably stable over time (with some exceptions), especially within QUIGs, this would generally preclude the need to adjust for risk factors beyond a clinically acceptable stratification approach (such as QUIGs) in terms of patient condition. This across-time period approach to stratifying patients within QUIGs is a useful application of stratifying according to one dimension of patient care (i.e., time) combined with another dimension of patient care (i.e., patient condition) and, by so doing, minimizing or eliminating the need for statistical risk-factor adjustment in operational CQI programs at the agency level.

Outcome-Based Quality Improvement

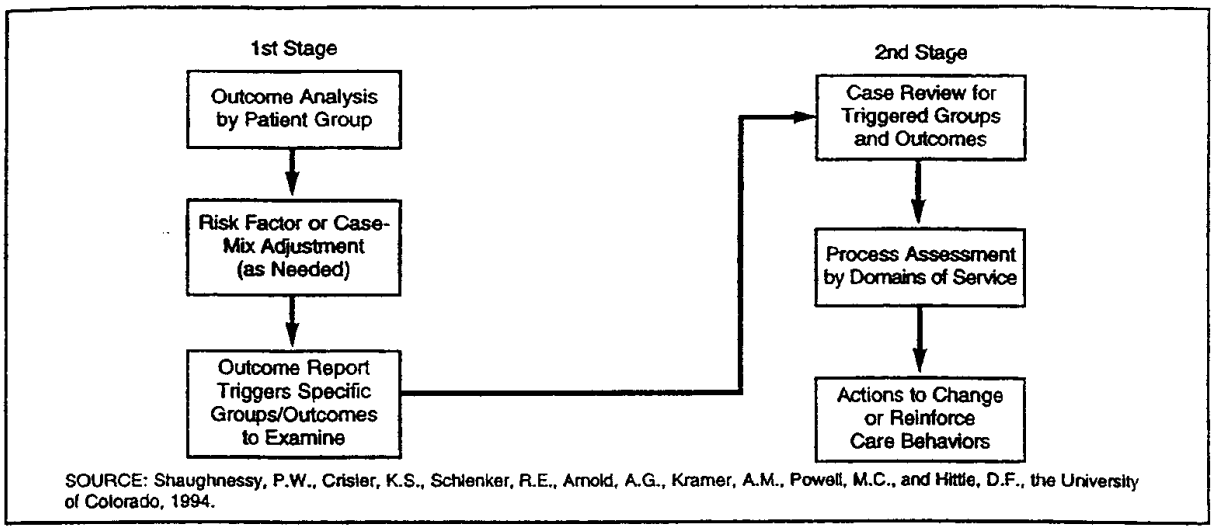
The following four terms are defined in order to facilitate the discussion of OBQI, as presented in this article:

(23) *Quality assessment.* The term "quality assessment" refers to the process of assessing and evaluating the quality of care, independently of whether the ultimate outcome of the assessment is to improve or change the quality of care. In its broadest sense, quality assessment can be conducted informally or formally, where informal approaches entail subjective impressions, certain types of cases or record review, or patient/provider opinions or reactions. More formal approaches to quality assessment can entail systematic or structured approaches to record review, patient observation, care provision, data collection, and analysis of quality measures.

(24) *Quality assurance and quality improvement.* The terms "quality assurance" and "quality improvement," as used here, refer to the process of maintaining or improving the quality of care, at times in accord with preset standards or goals. A QA or quality improvement program entails a sequence of activities targeted at maintaining and improving quality of care, often in specific areas of

Figure 4

The Quality Assessment Target: A Two-Stage Quality Improvement Screen



SOURCE: Shaughnessy, P.W., Crisler, K.S., Schlenker, R.E., Arnold, A.G., Kramer, A.M., Powell, M.C., and Hittle, D.F., the University of Colorado, 1994.

patient care. At the basis of any QA/quality improvement program or system is a means to assess quality. Quality measures are frequently used in quality assessment and QA, often in conjunction with case review by clinicians or other experts.

(25) *First-stage (quality improvement) screen.* As used here, the term "first-stage screen" refers to an approach to assessing whether potential quality of care problems exist in specific areas. The first-stage screen can be envisioned as having its basis in a set of (predominantly or exclusively outcome) measures that are used to ascertain the potential existence of quality-of-care problems. The screen does not necessarily indicate the reasons for the quality-of-care problems or prove definitively that such problems exist.

(26) *Second-stage (quality improvement) screen.* This term refers to a process of assessing the quality of home health care after conducting the first-stage screen just described. The second-stage screen might include a set of measures and related activities to more definitively indicate whether certain quality problems exist and, if so, point to their potential causes. The second-stage screen is more likely to be regarded as an operational quality improvement tool after potential quality problems (or exemplary care) have been identified using the first-stage screen. (The first-stage screen can be considered an operational QA tool, however, in that it can be used to either identify potential problems or infer that quality of care is adequate if potential problems are not found.) At the agency level, the second-stage screen could entail a variety of activities in addition to, or in lieu of, formally analyzing process quality measures, because individual case review, informal or systematic discussions with providers of care, etc., might be appropriate as agency-determined approaches to the second-stage screen.

Figure 4 provides an overview of the two-stage approach to QA introduced in definitions (25) and (26) above. In essence, the first-stage screen is an outcome screen

that entails analyzing outcomes by group (e.g., by QUIGs), and possibly further risk adjusting within QUIGs, or by using QUIGs as covariates instead of grouping and stratifying variables. If an agency's outcomes are outside of a statistically determined acceptable range, then a second-stage screen or (predominantly) process quality screen would be triggered. This screen could entail record review for those patient conditions triggered by unacceptable (or exemplary) outcomes. A less formal (and perhaps less effective) variant on the second-stage screen might entail structured or unstructured discussions with providers of care regarding reasons for the unacceptable or exemplary outcomes. In either event, the record review and/or discussions with providers of care would consist of an analysis of services provided to patients with outcomes triggered as a result of the first-stage screen. Depending on how it is structured, the second-stage screen can permit an assessment of the reasons for inferior (or superior) outcomes or an analysis of care provided to individual patients whose outcomes warrant further analysis of services provided.

Outcome measures, as well as groups or patient conditions that might be used in a first-stage screen, have been introduced in Tables 3 and 4. Service criteria that might be examined in a second-stage screen, on the assumption that QUIGs were used for group-specific outcome analyses in the first-stage screen, have undergone initial development as part of our home health research program. The QUIG-specific services are called objective review criteria (ORCs). They were initially specified by our clinical staff and then subjected to external clinical review. Data on such service criteria or ORCs can be abstracted from clinical records as part of a second-stage screen to ascertain whether the agency's service profile for the triggered outcomes reflects certain problems or exemplary types of care. Further discussion on ORCs is available elsewhere (Shaughnessy et al., forthcoming). An illustration of a (partial) set of ORCs for dependence in ambulation is given in Table 5. This table represents a form which can be used to abstract service data from clinical records.

Outcome Reporting

To implement a second-stage screen, an agency must review results from the first-stage (outcome) screen. Figure 5 provides an illustration of an outcome report for orthopedic patients that might typify an outcome profile for an individual agency. (Data and significance levels are hypothetical.) All outcome measures used in Figure 5 correspond to a baseline time point defined as start of care and a followup time point corresponding to discharge or 60 days after start of care, whichever occurred first. As they appear in Figure 5, the outcome findings are adjusted for risk factors. The outcomes include some of those specified in Table 4 for orthopedic conditions in addition to others included to demonstrate the utility of collecting a basic set of information on all patients, thereby allowing analyses of additional outcomes. The three bars for each outcome respectively depict the percentage of orthopedic patients who attained that outcome during the current (most recent) reporting period for the agency, during the (immediately) prior period for the agency, and in a national random sample of orthopedic patients from home health agencies across the country. The first numeric column (to the left of the bar chart) contains the number of cases (patients) that contributed to the outcome for each of the three groups used in the comparison. For example, 86

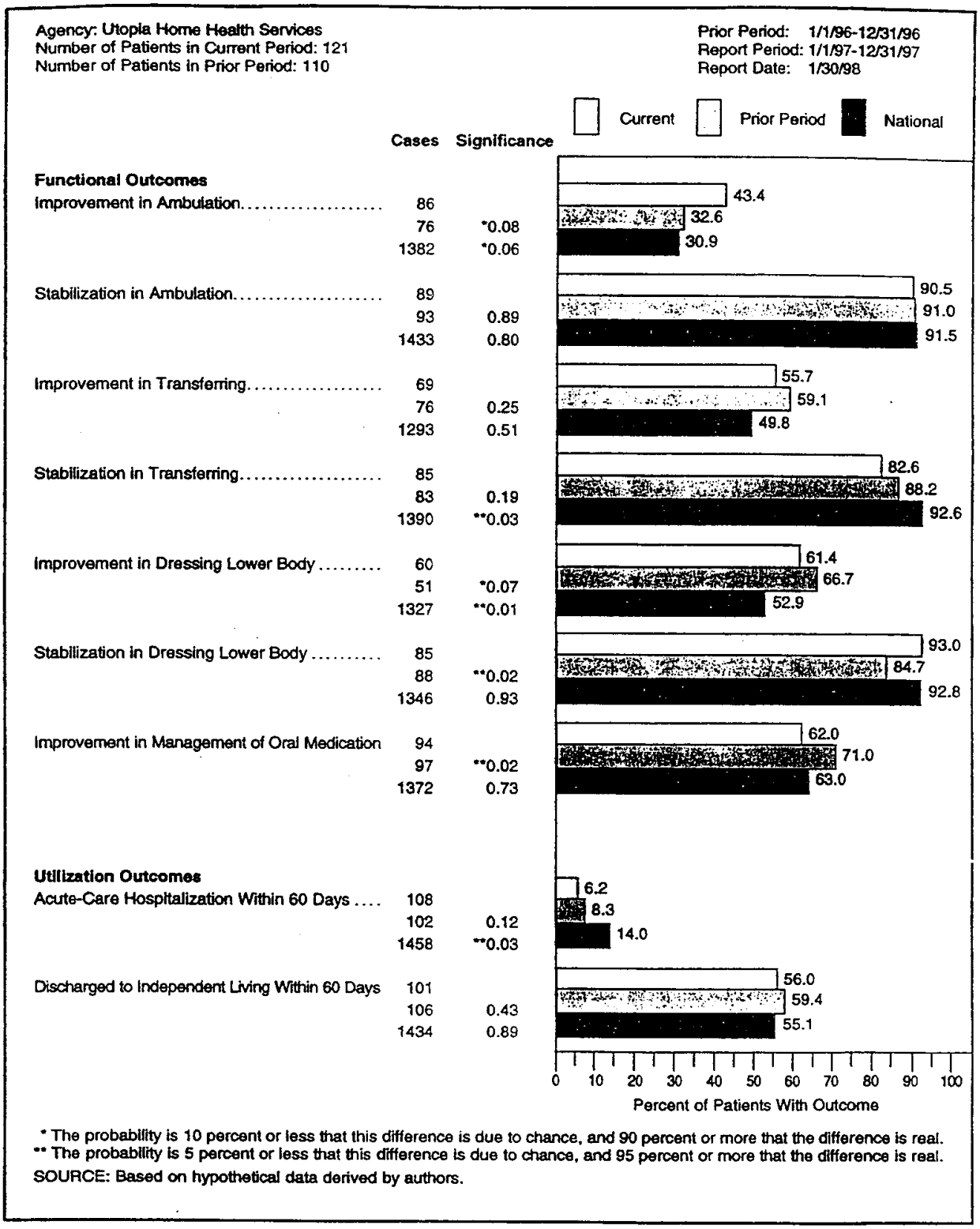
Table 5

Objective Review Criteria for Abstracting From Clinical Records to Assess Care When Ambulation Outcome Results Are Atypical

Characteristic of Patient or Environment	Assessment Services	Assessment Documented	Characteristic Present	Care Planning/Intervention Services	In Plan of Care	Intervention Documented
		Yes/No	Yes/No		Yes/No/NA	Yes/No/NA
Impaired gross motor function interfering with ambulation	**Record if the following assessments were done and if they indicate the presence of impaired gross motor function interfering with ambulation:** 1. Assess range of motion in upper extremities. 2. Assess range of motion in lower extremities. 3. Assess muscle strength in upper extremities. 4. Assess muscle strength in lower extremities. 5. Assess gait. 6. Assess balance. 7. Assess endurance. **If the presence of impaired gross motor function interfering with ambulation is indicated by any assessment activity, proceed to Care Planning/Intervention. If no impaired gross motor function interfering with ambulation is present, proceed to the next characteristic.**			1. Ensure that patient receives a physical therapy evaluation. 2. Instruct in an exercise program designed to improve ambulation. 3. Instruct in ambulation techniques adapted to patient's motor impairment. 4. Document the comparison between patient's ambulation status at start of care and at 2 weeks past start of care (or discharge if occurring earlier than 2 weeks).		
Pain interfering with activity	**Record if the following assessment was done and if it indicates the presence of pain interfering with activity:** 1. Assess for pain interfering with activity. If pain interferes with activity, Characteristic Present is "Yes." **If no pain interfering with activity is present, proceed to the next characteristic. If the presence of pain interfering with activity is indicated by any assessment activity, determine if the following detailed assessments were done:** 2. Assess location of pain. 3. Assess severity of pain using a scale (i.e., 1 to 5). 4. Assess factors which alleviate pain. 5. Assess specific activities that pain limits (e.g., transferring, ambulating). 6. Assess knowledge of non-pharmacologic measures for pain relief. **Proceed to Care Planning/Intervention.**			1. If analgesics or muscle relaxants are ordered, instruct in their use. 2. Instruct in non-pharmacologic measures (or pain relief (e.g., cold application, massage). 3. Instruct in anticipatory pain management. 4. If measures for pain relief are ineffective, consult with physician. 5. If adjustments are made in the medication regimen, instruct patient/caregiver in new regimen. 6. If adjustments are made in medication regimen, document patient's pain status with new regimen.		
Inadequate environment for ambulation	**Record if the following assessments were done and if they indicate the presence of an inadequate environment for ambulation:** 1. Assess for unsafe carpeting/rugs. 2. Assess for inadequate lighting. 3. Assess for architectural barriers to ambulating (e.g., stairs, bathroom on different level). 4. Assess for obstacles to ambulation (e.g., furniture crowding). **If the presence of an inadequate environment for ambulation is indicated by any assessment activity, proceed to Care Planning/Intervention. If an inadequate environment for ambulation is not present, proceed to the next characteristic.**			1. If unsafe carpeting/rugs are present, advise patient regarding their removal. 2. If lighting is inadequate, advise patient regarding the need for adequate lighting. 3. If architectural barriers are present, advise patient regarding the modifications needed to remove/minimize architectural barriers. 4. If obstacles to ambulation are present, advise patient regarding the need to remove obstacles to ambulation. 5. If financial assistance/counseling is needed to correct environmental problems, ensure that financial assistance/counseling is provided.		

NOTES: This table is excerpted from a form used to abstract data from clinical records. Shaded area denotes "not applicable" responses. Assessment, care planning, and information criteria correspond to a sample of the several characteristics used for dependence in ambulation. Other characteristics include altered cognitive function, activity intolerance, need for human assistance with ambulation, and need for mechanical assistance with ambulation. These ORCs relate specifically to patients with: acute orthopedic conditions (e.g., fracture, amputation, joint replacement, DJD); acute neurologic conditions (e.g., CVA, multiple sclerosis, head injury, etc.); chronic impaired ambulation/mobility (e.g., ambulation, transferring, toileting); or chronic pain.

Figure 5
Orthopedic Patients' Outcome Profile



* The probability is 10 percent or less that this difference is due to chance, and 90 percent or more that the difference is real.
** The probability is 5 percent or less that this difference is due to chance, and 95 percent or more that the difference is real.

SOURCE: Based on hypothetical data derived by authors.

orthopedic patients contributed to the computation of the measure corresponding to improvement in ambulation during the current reporting period, compared with 76 during the preceding reporting period, and 1,382 patients in the national random sample (recall that the improvement and stabilization measures have exclusions as described in definitions [4] and [6]).

The second numeric column contains statistical significance levels corresponding to the two comparisons of interest for each outcome: current period versus prior period, and current period versus national norm. Thus, the significance level associated with comparing the improvement-in-ambulation mean for the current period with the mean for the prior period (43.4 percent versus 32.6 percent) is $p = .08$. The analogous significance level associated with comparing the current period with the national norm is $p = .06$.

Using $p < .10$ as statistically significant, the results in Figure 5 would indicate that, for orthopedic patients, the agency has improved in the current reporting period relative to the preceding reporting period for the outcomes of improvement in ambulation and stabilization in dressing the lower body. Agency performance worsened, however, in terms of improvement in dressing the lower body and improvement in management of oral medications. Relative to the national sample, agency performance was superior in terms of improvement in ambulation, improvement in dressing the lower body, and acute-care hospitalization within 60 days of admission to home care, whereas agency performance was inferior in terms of stabilization in transferring. With respect to improvement in dressing the lower body, although the agency's outcome decreased significantly since the prior reporting period, its performance is still superior to the national norm.

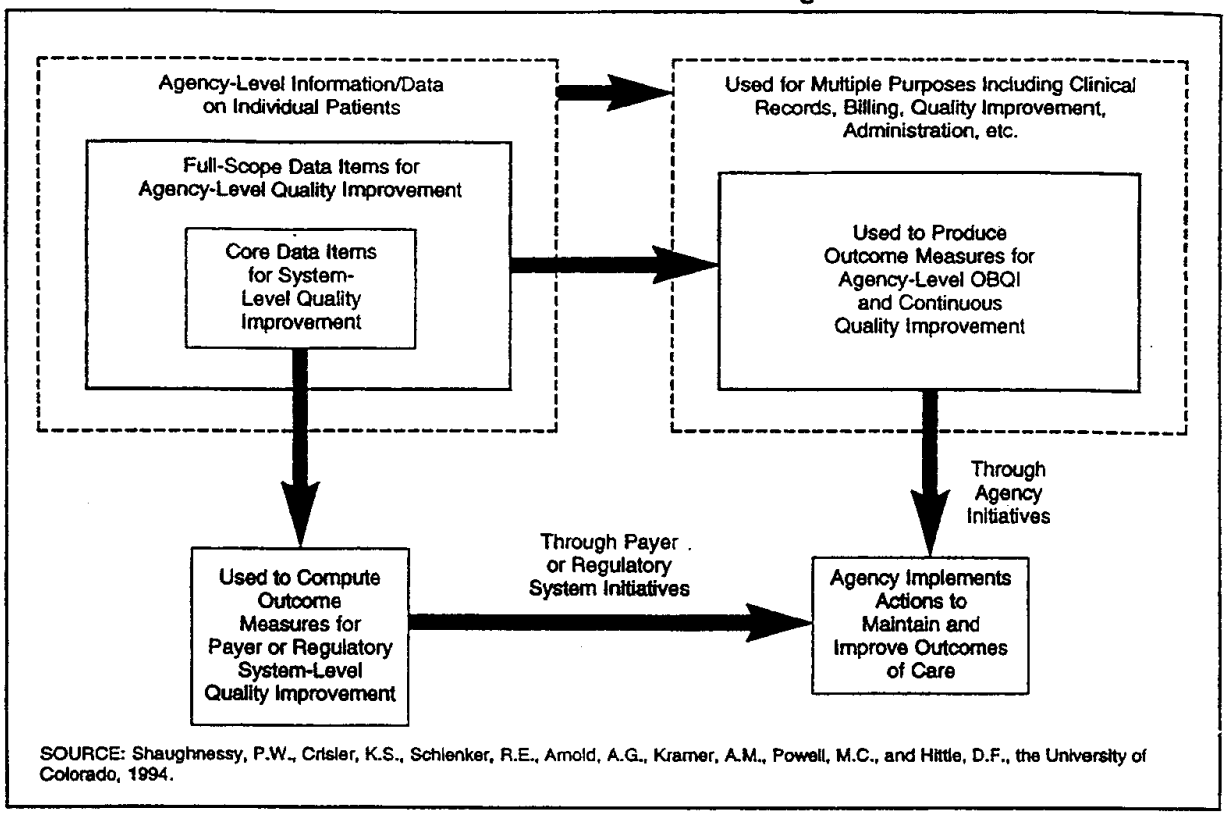
Some or all of these significant differences might warrant further investigation. It would not be our recommendation, initially, for an individual agency or for Medicare to investigate all possible differences that are statistically significant. As a starting point, it would be appropriate to ascertain reasons for the most extreme (statistically significant) differences that are meaningful both in terms of the magnitude of the differences and their clinical relevance. For example, because agency performance was inferior to the national random sample only for the outcome of stabilization in transferring, and far superior for acute hospitalizations, these two outcomes might be the focus of a second-stage screen. The QUIGs or conditions that are used for stratification should be viewed as a grouping scheme to assist in outcome assessment. It is possible to use other grouping schemes, to combine QUIGs, to subdivide them to examine outcomes for particular types of patients, and to weight selected QUIGs or even outcomes more than others. Such variations in the OBQI methods introduced here would be implemented at the discretion of individual users of the system. The type of outcome report illustrated in Figure 5 is currently being employed in a three-agency OBQI pilot project in Colorado that we have undertaken with Robert Wood Johnson Foundation funding.

Outcome-Based Quality Improvement: Starting and Evolving

The ultimate goal is to implement and maintain an OBQI system that would represent a partnership between providers (home health agencies) and payers (e.g., Medicare, Medicaid, and commercial payers). This would entail collecting data for all patients (every 60 days or until discharge, whichever occurs first) using prespecified

Figure 6

Overview of Agency-Payer Partnership for Outcome-Based Quality Improvement (OBQI) and Associated Information Sharing



SOURCE: Shaughnessy, P.W., Crisler, K.S., Schlenker, R.E., Arnold, A.G., Kramer, A.M., Powell, M.C., and Hittle, D.F., the University of Colorado, 1994.

items necessary to compute patient outcome measures. For payers, a core set of data items should be specified so that (1) a core set of outcomes can be computed and (2) risk-factor adjustment is possible using both grouping and statistical approaches. This core set of outcome measures would then be available in a report for each agency, so that agencies might compare themselves with one another and payers might be able to monitor the relative strengths and weaknesses of individual agencies. Beyond this, however, a larger set of data items (termed full-scope items) could be collected by individual agencies for purposes of implementing an outcome-based approach to CQI. The items necessary to compute a larger array of outcome measures (full-scope measures) would ideally be incorporated directly into an agency's recordkeeping approach, so that no additional burden of data collection would be imposed. Imbedded within this more expansive set of data items would be the core items required for the uniform system that would be used by both agencies and payers. This overall approach is summarized in the diagram in Figure 6.

Agency-Level Phasein

The material in this section and the next addresses phase-in issues at the agency level and the (Medicare) system level. The agency level is addressed first (in this section), because system implementation issues necessarily depend on agency-level implementation. Prior to widespread use of OBQI, it would be appropriate to phase in

such an approach on an experimental basis. Medicare is currently contemplating a reasonably large-scale demonstration program in this regard. It would also be appropriate for agencies to move forward with OBQI independently.

One way for agencies to begin is to systematically modify assessment and recordkeeping, so as to incorporate the precise health status data items and related information needed to measure outcomes over time. Such data items (primarily) would replace those currently used by an agency. Recognizing that not all agencies would be able immediately to implement such an approach, other initial steps are possible that might gradually result in attaining this objective. For example, if an agency were not to participate in the Medicare demonstration or in some form of a multiagency program to implement OBQI systematically, it might do so on its own. It could start in a focused manner, incrementally increasing the scope of its OBQI system over time. In this regard, an individual agency might begin with a specific patient condition (e.g., patients that belong to a certain QUIG or some other well-defined patient group of interest to the agency). Data would be obtained for the requisite health status items, and outcomes would be computed in the manner previously described. Even if data on the particular measures determined to be relevant by the agency are not available nationally or for other agencies, computing outcomes for the particular patient condition(s) under consideration for a baseline data collection interval of 6 months to a year would provide a foundation for CQI. Data collected for ensuing intervals could be used to compute outcomes for comparison with those for the baseline interval. Subsequently, outcomes for each ensuing interval could be compared with the preceding interval, or even some or all prior intervals combined. An approach of this nature would orient an agency to the type of information to be collected, how to collect such information, the manner in which it might be used, and the manner in which the approach might be extended to other conditions and measures. (This approach is being followed in the Robert Wood Johnson Foundation three-agency demonstration project in Colorado that was previously described.)

In selecting outcome measures, especially those to use on an experimental basis to begin OBQI, several criteria would be useful for the agency to consider. First, the data items necessary to compute the quality measures should be readily available and preferably part of a (possibly modified) ongoing data collection or recordkeeping system. Second, the data items used should be precisely defined and be as reliable as possible. Third, the initial outcomes selected might best occur with reasonable but not excessive frequency. As noted earlier, outcomes that are extremely infrequent but reflect a serious adverse circumstance for the patient can be regarded as sentinel events and investigated as they occur rather than employing prospective longitudinal data collection to detect such events.

Fourth, outcome measures that can be clearly associated with services or processes of care are desirable, because ensuing actions in the form of a second-stage or process quality screen can be implemented in a more straightforward manner. An illustration of such an outcome might be improvement in surgical wound status. If an inadequate number of patients attained this outcome (relative to a national norm or a preceding time interval for the agency under consideration), it is possibly due to inadequate assessment in the areas of wound status, knowledge of wound care protocol, environmental factors, and risk

factors for wound infection. Or inadequate outcomes may be due to failure to incorporate the following into the plan of care: requesting orders for a new wound care protocol if the wound is not healing as expected, instructing the patient or family in aseptic techniques, and assisting the patient or family to modify environmental conditions or seek other living arrangements if environmental conditions are not adequate. Inferior outcomes might also be due to inadequate provision of services such as instructing the patient or family in signs and symptoms of infection, redesigning the teaching plan if the patient did not learn, and ensuring that the patient receives wound care assistance when needed. The second-stage screen would examine the agency's performance in terms of these process indicators, possibly using ORCs to examine clinical records.

Fifth, the experimental or developmental stages of an OBQI system should not unduly burden agency staff or administrative resources, except to implement such a system (i.e., the steady-state version of such a system should not be any more burdensome than current recordkeeping and administrative activities). Data collection, data entry, and data processing should be manageable. Software or basic programming capacity should be available to compute the necessary outcomes from raw data items and generate requisite outcome findings or reports. It is even possible for the initial stages of an OBQI system to entail hand calculation if data collection and outcome measures are properly circumscribed.

Sixth, a reasonably systematic plan should be developed that incorporates the processes that would be implemented (as part of a second-stage screen) to investigate reasons for exemplary or inferior outcomes. In addition to, or in lieu of, systematic record review for patients with certain conditions whose outcomes were inadequate, staff discussions that target potential reasons for the outcome findings, or meetings analyzing care provided to patients whose outcomes are exemplary or inadequate, might be appropriate. Followup data collection to monitor changes in outcome profiles for those outcomes of most concern to the agency should be planned.

Seventh, a longer range, flexible strategic plan would ideally be developed concurrent with implementing the initial or experimental stage of OBQI. This would ensure that the experimental stage initiates the type of program that could be expanded and maintained on a steady-state basis. In this regard, forethought should be devoted to how recordkeeping might be changed (possibly gradually over the course of time) to incorporate both the data items and results of outcome analysis, how staff might be involved in and interact with data collection and analysis, which individual(s) might be responsible for coordinating various aspects of the total program, and how the OBQI program might be coordinated with or change existing or planned programs at the agency.

Eighth, agency staff should monitor Medicare and other system-level developments in OBQI. Because Medicare will very likely implement a demonstration project, the agencies that participate in such a project will contribute to shaping many of the practical aspects of OBQI within the Medicare system. In fact, it is critical that Medicare OBQI policies and practices evolve under the demonstration program and through other developmental activities and experience. It is important that individual agencies be aware of such evolution, adapting their own OBQI approaches so that when Medicare implements a systemwide program, the transition at the agency level will be as straightforward as possible.

It is not possible in an article of this length to address selected other issues such as sampling and methods for collecting data on and analyzing intermediate-result outcome measures (especially information on patient and family satisfaction). The differences between and the compatibility of statistical versus sentinel event approaches to OBQI are also consequential (e.g., OBQI can involve both statistical reports such as the one illustrated in Figure 5 and focus on single egregious events such as hospitalization due to mismanagement or inability to administer medications). Such topics should be considered, however, in designing and in implementing a systematic approach to OBQI.

Medicare System or Multiagency System Phasein

The previously mentioned guidelines pertain primarily to initiating an OBQI program within an individual agency. As discussed, it is possible to implement OBQI with a number of agencies participating simultaneously in the program, such as through a Medicare demonstration. In this instance, several Medicare-certified agencies could be recruited for the common purpose of implementing OBQI at both the agency and Medicare levels, where the initiative to do so derives from the Medicare program and the willingness of selected agencies to play a leadership role in shaping OBQI. Alternatively, several commonly owned or managed agencies might consider implementing OBQI, where the initiative would derive from the individual agencies and the corporate or management levels. Analogously, a managed care network might establish such a program within its commonly owned or even contractual home health agencies. Lastly, other payers, such as commercial insurers, might monitor outcomes for their home health patients. Any or all of these approaches can be successful, especially if they build upon the common foundation of the individual agency's potential to implement and utilize OBQI as the main vehicle for CQI.

Under its recently announced Home Health Initiative, the Medicare program will move forward with OBQI in some form. It is also clear that the success of such an effort will be greatly enhanced through a viable partnership between Medicare and the home health industry (in this case initially represented by the agencies that might participate in a demonstration program). Such a partnership would form the foundation for an agency-level OBQI system that would entail collecting requisite data on all home health patients to monitor agency-level outcomes. For those demonstration agencies that implement the full-scope approach to OBQI, a subset of these data items and outcome measures would constitute the core items and measures and would be used at the system level by Medicare for monitoring outcomes. Such a partnership would require agreement on the core set of data items and measures, willingness on the part of participating agencies to collect uniform data, Medicare's involvement to audit such data to ensure its accuracy for Medicare system purposes, and agreement on how to process the data and produce outcome reports. The data base that would be developed nationally by Medicare and eventually other payers would be used to establish national trends and patterns of patient outcomes for comparative purposes. Equally important, the data base would be valuable for agency-level OBQI and as a data set for risk adjustment of outcome measures.

Assuming that this type of multiagency system (for OBQI) is implemented, it will be necessary to finalize the core measures and

data items, as well as the full-scope measures and data items. It is our intent to specify such data items and measures for review and revision, as a result of our ongoing outcome measure research. This would permit a Medicare OBQI system to be implemented on a demonstration basis. Data collection and processing procedures should be planned, both for the demonstration program and for eventual national implementation. Initial planning and specification of the nature of the steady-state OBQI system that would exist at the national level would contribute to shaping the nature of the demonstration program. Key features of a strategic plan would include the need to integrate data collection for administrative, billing, and OBQI purposes; the nature of outcome reports and the importance of refining and revising risk adjustment over the course of time; criteria to apply in finalizing outcome measures to be employed; and incorporating an evolutionary component into the steady-state system.

SUMMARY AND FINAL COMMENTS

The overview of OBQI discussed in this article, including an industry-payer partnership, describes a paradigm that is necessarily evolutionary in nature. At present, it would be inappropriate to fixate on a final methodology to the exclusion of refinements and other approaches. For example, risk-adjustment methods must evolve, QUIGs should evolve and be revised as a grouping method, decisions on time points for data collection will likely be modified as experience is gained, outcome measures and associated data items must be continually refined and improved, and, in fact, the nature of home care will change. Presently, home health agencies collect and generate a considerable quantity of information for purposes of providing and monitoring patient care, billing, financial reporting, quality improvement administration, and management. Some of the information requirements are imposed internally by the agency itself or by the management system under which it operates. Others are imposed externally by the payers and regulators.

In view of the radical changes taking place in home health care at the present time, including its unprecedented growth, a unique window of opportunity will exist during the next few years. Home health care is clearly in transition. Patient care and financial and administrative practices and policies are likely to change considerably. So, too, will the information needs that underpin these practices and policies. As a result, and as appears to be taking place under the Home Health Initiative, a comprehensive analysis should be undertaken that targets integrating internal and external information needs. For example, the Medicare plan of treatment forms (i.e., the HCFA 485 forms), Medicare billing requirements, information needed for quality assurance by the survey and certification program, peer review organization requirements, information needed by fiscal intermediaries to conduct claims review, analogous Medicaid requirements, possibly requirements of HMOs which contract for home health care, and corresponding requirements of commercial payers can and should be integrated over time so that common data items are specified for both internal and external OBQI, for administration and billing, and for other management and financial purposes.

In the context of the transitional period now under way, it is possible to reduce (or at least not increase) the information collection burden on providers of care and at the same time increase the effectiveness of home health care by focusing on OBQI and CQI. In the process, we will be able to

determine more clearly what we are collectively purchasing for our investment in home health care nationally. Beyond this, and equally important, individual agencies can take the initiative to move forward with OBQI, using patient outcomes to profile and document their accomplishments.

The overall objective of this article is to suggest a framework or vehicle that might collectively carry us forward through a partnership among industry, payers, regulators, and consumers, so that the playing field is level, information exchange occurs with integrity and precision, and change is implemented that will benefit patients receiving home health care. This advance must target improved integration of information exchange and care provided across different settings, but, most importantly, we must move toward efficiently attained improvement in effectiveness of care. The heart of this process should be clearly specified, precisely collected, and objectively analyzed information on patient outcomes.

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Reprint Requests: Peter W. Shaughnessy, Ph.D., Center for Health Services Research, 1355 S. Colorado Boulevard, No. 706, Denver, Colorado 80222.

SUPPORTING DOCUMENT 4:

OASIS AND INSTRUCTIONS FOR USE

in Volume 3 of the report series entitled:

OASIS and Outcome-Based Quality Improvement in Home Health Care:
Research and Demonstration Findings, Policy Implications,
and Considerations for Future Change

for the three interrelated studies:

The National Medicare Quality Assurance and Improvement Demonstration
The New York State Outcome-Based Quality Improvement Demonstration
A Project to Assist Home Care Providers to Effectively Use Patient Outcomes

February 2002

OVERVIEW

An explanatory prologue for, general introductions for use of, and the latest version of the Outcome and Assessment Information Set (OASIS) for home care are presented in this supporting document. The explanatory prologue, originally published in a special supplement to the National Association for Home Care (NAHC) Report, No. 625, August 11, 1995, and subsequently revised for inclusion in an appendix to the *OASIS Implementation Manual* published by CMS, provides historical information on the purpose of OASIS, its development, and the use of OASIS in the context of outcome-based quality improvement. The prologue was last updated by Center staff in July 1999.

CONTENTS

Section A

Explanatory Prologue

Entitled

"Medicare's OASIS: Standardized Outcome and Assessment Information Set for Home Health Care -- July 1999"

MEDICARE'S OASIS: STANDARDIZED OUTCOME AND ASSESSMENT INFORMATION SET FOR HOME HEALTH CARE – July 1999

Peter W. Shaughnessy, Ph.D.
Kathryn S. Crisler, M.S., R.N.
Robert E. Schlenker, Ph.D.
David F. Hittle, Ph.D.
University of Colorado

The Outcome and Assessment Information Set (OASIS) that HCFA is requiring for purposes of outcome-based quality improvement under Medicare (as part of the new Conditions of Participation) has undergone several years of development and refinement. In addition to reviewing the purpose and evolution of the OASIS to date, this prologue provides information on selected operational issues.

Purpose, History, and Improvements

The data items that constitute the OASIS were developed largely for purposes of measuring patient outcomes in home health care. Nearly all of the items also are useful for assessing the care needs of patients, but no pretense is made that the OASIS constitutes a comprehensive assessment instrument. Since the vast majority of OASIS items are similar to those currently used by most home health agencies at start of care (often in less precise form), it is intended that home care agencies and others replace their current versions of these items with the actual OASIS items. Experience in various demonstration programs has shown that this enables home care providers to conduct more precise assessments of patient conditions for these items.

The OASIS has its genesis in 12 years of research, development, and demonstration programs to design and test outcome measures for home care (funded by HCFA and The Robert Wood Johnson Foundation). One of the important products from this program was a 73-item data set required to measure outcomes, first published in a 1994 report written by the Center for Health Services and Policy Research (the Research Center) at the University of Colorado. This was expanded to a 79-item data set as a result of recommendations from a HCFA-convened task force of home care experts who reviewed the data set from the perspective of items judged essential for assessment. The Research Center revised and rearranged the 79 items into a data set format termed OASIS-A in 1995.

The OASIS-A items that had been developed and tested in the national research program (along with those added by the expert panel) were then used operationally in two demonstration programs (summarized below) beginning in late 1995 and 1996. This experience suggested selected refinements, resulting in OASIS-B, which contained 79 items. Although a few items were dropped, a few were added, and wording changes were made to clarify items, the substance of OASIS-B was virtually the same as OASIS-A. The current (1998) release of OASIS, termed OASIS-B1, includes modifications to the patient identifiers (termed clinical record items) and one demographic item. These modifications are intended to assist HCFA in tracking and managing data. As the Medicare program moves forward with OASIS, it is clear such identifiers (also used for billing, care planning, etc., under Medicare) would naturally accompany the core OASIS items and be of value for agency-specific applications of OASIS.

Thus, OASIS-B was largely the result of applying and testing OASIS-A, beginning in 1996 in (1) the national demonstration of outcome-based quality improvement (OBQI) that HCFA is sponsoring and the University of Colorado Research Center is administering, and (2) an analogous OBQI demonstration in New York State that the Department of Health is sponsoring and the University of Colorado Research Center is administering. The experience of the 50 national demonstration agencies and the 22 New York State demonstration agencies in using the OASIS for purposes of collecting outcome data, as well as selected experiences of other agencies throughout the country which have elected to use the OASIS data set, were taken into consideration in the modest set of revisions that initially resulted in OASIS-B.

Further experience in the demonstrations and in HCFA's needs for data management and administration subsequently were taken into consideration in refining OASIS-B to produce OASIS-B1. Reliability testing, programmatic applications, and provider suggestions to improve OASIS will continue with a view toward improving the data set. Nonetheless, OASIS is now regarded as a stable data set that can be used in the context of patient assessment and outcome monitoring. At the same time as home care practices, patient conditions, and policies change, it will be necessary to occasionally update and refine the data set. As other revisions are released, the suffixes "C," "D," etc. will be used.

One of the primary reasons OASIS has been deemed stable and useful for the home care field is its multiplicity of successful applications in the demonstration programs. Nearly all demonstration agencies have been extremely successful in effectively and precisely implementing and maintaining OASIS data collection. This in turn has resulted in accurate and useful outcome reports, case mix reports, and adverse event reports. Using the findings from the outcome reports and developing methods to evaluate the care that influences specific outcomes, a majority of agencies in the national demonstration changed care behaviors to produce improved outcomes in the areas they targeted for improvement.

It is our intent at the Research Center to provide the home care industry with regular updates on OBQI demonstrations, operational issues related to OBQI that are important to both individual agencies and Medicare, strengths and weaknesses associated with using the OASIS for various purposes, and other issues pertinent to smoothly and effectively implementing the OASIS data set in order to measure outcomes. We have used and will continue to use several different forums for these communications (including the HCFA website, since much of our home care research is sponsored by HCFA). Information related to operational features of the OASIS is summarized in subsequent paragraphs.

Operational Issues

With respect to understanding and using OASIS data items, several points are important to take into consideration. Since the OASIS is used for measuring outcomes defined as change in health status between two or more time points, most data items are obtained at start of care and follow-up time points (i.e., every two calendar months and discharge). Selected items are unique to either start of care or follow-up times. These are indicated as such on the OASIS. All OASIS items are intended to be completed through routine patient assessment approaches and collection of patient subjective and objective data. The items should not be used in the form of a patient interview for collecting data.

A number of software developers currently have software available or are developing software that incorporates the OASIS into their electronic clinical record systems.[1] In addition, stand-alone OASIS-specific software, not part of a more comprehensive electronic clinical record system, has been developed for agencies that do not have or are not presently interested in a more comprehensive electronic clinical record system. This stand-alone software enables an agency to computerize or enter OASIS data that have been recorded by clinicians using forms that integrate the OASIS items into the agency's assessment instrument. HAVEN, which is distributed by HCFA at no charge, is an example of this type of software product. Regardless of whether an agency uses a comprehensive electronic clinical record system (possibly with laptops) or stand-alone software to specifically computerize OASIS items, it is important that the exact wording of OASIS items be directly incorporated into the clinical record. Agencies should be certain that their software (1) can be efficiently updated with occasional changes that might occur in OASIS, and (2) provides the capability to extract OASIS items for purposes of transmission to HCFA for outcome comparisons and benchmarking, as well as other agency internal applications that will naturally be of interest once OASIS data are computerized.

Care providers should not have the option to carry the same OASIS data from start of care to follow up in describing or assessing patient health status (this often results in inaccurate follow-up data because providers are tempted to minimize their time by carrying forward the data from the initial time point instead of properly reassessing and recording the information at follow up). This carry-forward approach should not be used in either paper or electronic documentation approaches. That is, assessment forms should not be designed with OASIS data from a prior time period on the same page as data for the current time period, and electronic clinical record software should not be designed so that OASIS data from a prior time period can simply be inserted into the current time period.

Completeness and accuracy of OASIS data are imperative. Not only are these attributes mandatory under HCFA requirements and surveillance policies, but most importantly, complete and accurate OASIS data are essential for individual home health agencies. With precise and comprehensive data, agencies will be able to systematically track case mix changes over time, compare agency-level case mix with a national reference sample, and most importantly, monitor patient outcomes from year to year and relative to national reference outcomes.

This means that agency CEOs, administrators, clinical managers, clinical staff, and fiscal staff should be aware of OASIS' purposes and, most critically, take all possible steps to ensure the accuracy and completeness of OASIS for every patient on whom such data are collected. If this is done, then the agency can derive full benefit from the multiplicity of uses of OASIS.

We wish to repeat that the OASIS was not developed as a comprehensive assessment instrument. It was developed primarily for purposes of measuring outcomes for adult home care patients. Agencies will find it necessary to supplement the OASIS in order to

[1] The OASIS data items have been copyrighted by the Center for Health Policy Research (now termed the Center for Health Services and Policy Research) and are in the public domain. They cannot be further copyrighted for exclusive use by a particular agent or organization.

comprehensively assess health status and care needs of patients (for example, the OASIS does not include vital signs nor was it developed with pediatric patients in mind).

It is also important to note that the purpose of measuring patient outcomes through the OASIS is to assist home care agencies with quality improvement activities. In 1995, we authored a book published by the National Association for Home Care, *Outcome-Based Quality Improvement, A Manual for Home Care Agencies on How to Use Outcomes.*[2] This publication provides guidance to agencies on measuring and reporting outcomes and on using them to improve quality.

[2] For additional information on *Outcome-Based Quality Improvement*, call or write the National Association for Home Care, 228 Seventh St., SE, Washington, DC 20003, (202) 547-7424, fax: (202) 547-3540.

Section B

General OASIS Instructions

GENERAL OASIS INSTRUCTIONS

1. OASIS items can be completed by any clinician who performs the comprehensive assessment. The Conditions of Participation and agency policy should determine who is responsible for completing the comprehensive assessment (and OASIS items) if individuals from more than one discipline (e.g., PT and OT) are seeing the patient concurrently.

2. All items refer to the patient's usual status or condition at the time period or visit under consideration -- unless otherwise indicated. Though patient status can vary from day to day and during a given day, the response should be selected that describes the patient's status most of the time during the specific day under consideration.

3. Some items inquire about events occurring within the past 14 days or at a specified point (e.g., discharge from an inpatient facility, ADL status at 14 days prior to start of care, etc.). In these situations, the specific time interval included in the item should be followed exactly.

4. OASIS items that are scales (e.g., shortness of breath, transferring, etc.) are arranged in order from least impaired to most impaired. For example, higher values (further down the list of options) on the transferring scale refer to greater dependence in transferring. This is true whether the scale describes a functional, physiologic, or emotional health status attribute.

5. Collection of data through direct observation is preferred to that obtained through interview, but some items (e.g., frequency of primary caregiver assistance) are most often obtained through interview. When interview data are collected, the patient should be the primary source (or a caregiver residing in the home). An out-of-home caregiver can be an alternate source of information if neither of the others are available, but should be considered only in unusual circumstances. In many instances, a combined observation-interview approach is necessary. For example, by speaking with the patient or informal caregiver while conducting the assessment, the provider can determine whether the observed ability to ambulate is typical or atypical at that time. Such combined approaches of observation and interview occur frequently during most well-conducted assessments, but warrant mention here in order to clarify the meaning of OASIS items.

6. The OASIS items may be completed in any order. Because the data collection is integrated into the clinician's usual assessment process, the clinician actually performing the patient assessment is responsible for determining the precise order in which the items are completed.

7. Unless a skip pattern is indicated (and followed), every OASIS item for the specific time point should be completed.

8. Unless the item is noted as “Mark all that apply,” only one answer should be marked.

9. Minimize the selection of “Not Applicable” and “Unknown” answer options.

10. Each agency is responsible for monitoring the accuracy of the assessment data and the adequacy of the assessment process.

Section C

The Outcome and Assessment Information Set (OASIS) for Home Care

This data set should not be reviewed or used without first reading the accompanying narrative prologue that explains the purpose of the OASIS and its past and planned evolution.

Items to be Used at Specific Time Points

Start or Resumption of Care ---------- M0010-M0825

Start of care—further visits planned
Start of care—no further visits planned
Resumption of care (after inpatient stay)

Follow-Up ---------- M0010-M0100, M0150, M0175, M0200-M0250, M0280-M0390, M0410-M0840

Recertification (follow-up) assessment
Other follow-up assessment

Transfer to an Inpatient Facility ---------- M0010-M0100, M0150, M0830-M0855, M0890-M0906

Transferred to an inpatient facility—patient not discharged from an agency
Transferred to an inpatient facility—patient discharged from agency

Discharge from Agency — Not to an Inpatient Facility

Death at home ---------- M0010-M0100, M0150, M0906
Discharge from agency ---------- M0010-M0100, M0150, M0200-M0220, M0250, M0280-M0380, M0410-M0820, M0830-M0880, M0903-M0906
Discharge from agency—no visits completed after start/resumption of care assessment ---------- M0010-M0100, M0150, M0906

Note: For items M0640-M0800, please note special instructions at the beginning of the section.

CLINICAL RECORD ITEMS

(M0010) Agency Medicare Provider Number: __ __ __ __ __ __

(M0012) Agency Medicaid Provider Number: __ __ __ __ __ __ __ __ __ __ __ __ __ __ __

Branch Identification (Optional, for Agency Use)

(M0014) Branch State: __ __

(M0016) Branch ID Number: __ __ __ __ __ __ __ __ __ __
(Agency-assigned)

(M0020) Patient ID Number: __

(M0030) Start of Care Date: __ __ /__ __ /__ __ __ __
month day year

(M0032) Resumption of Care Date: __ __ /__ __ /__ __ __ __ ☐ **NA – Not Applicable**
month day year

(M0040) Patient Name:

__ __ __ __ __ __ __ __ __ __ __ __ __   __   __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __   __ __ __
(First) (MI) (Last) (Suffix)

(M0050) Patient State of Residence: __ __

(M0060) Patient Zip Code: __ __ __ __ __ __ __ __ __

(M0063) Medicare Number: __ __ __ __ __ __ __ __ __ __ __ __ ☐ **NA – No Medicare**
(including suffix)

(M0064) Social Security Number: __ __ __ - __ __ - __ __ __ __ ☐ **UK – Unknown or Not Available**

(M0065) Medicaid Number: __ __ __ __ __ __ __ __ __ __ __ __ __ __ ☐ **NA – No Medicaid**

(M0066) Birth Date: __ __ /__ __ /__ __ __ __
month day year

(M0069) Gender:

☐ 1 - Male
☐ 2 - Female

(M0072) Primary Referring Physician ID:

__ __ __ __ __ __ __ __ __ __ ☐ **UK – Unknown or Not Available**

(M0080) Discipline of Person Completing Assessment:

☐ 1-RN ☐ 2-PT ☐ 3-SLP/ST ☐ 4-OT

(M0090) Date Assessment Completed: __ __ /__ __ /__ __ __ __
month day year

(M0100) This Assessment is Currently Being Completed for the Following Reason:

<u>Start/Resumption of Care</u>
☐ 1 – Start of care—further visits planned
☐ 2 – Start of care—no further visits planned
☐ 3 – Resumption of care (after inpatient stay)

<u>Follow-Up</u>
☐ 4 – Recertification (follow-up) reassessment **[Go to *M0150*]**
☐ 5 – Other follow-up **[Go to *M0150*]**

<u>Transfer to an Inpatient Facility</u>
☐ 6 – Transferred to an inpatient facility—patient not discharged from agency **[Go to *M0150*]**
☐ 7 – Transferred to an inpatient facility—patient discharged from agency **[Go to *M0150*]**

<u>Discharge from Agency — Not to an Inpatient Facility</u>
☐ 8 – Death at home **[Go to *M0150*]**
☐ 9 – Discharge from agency **[Go to *M0150*]**
☐ 10 – Discharge from agency—no visits completed after start/resumption of care assessment **[Go to *M0150*]**

DEMOGRAPHICS AND PATIENT HISTORY

(M0140) Race/Ethnicity (as identified by patient): **(Mark all that apply.)**

- ☐ 1 - American Indian or Alaska Native
- ☐ 2 - Asian
- ☐ 3 - Black or African-American
- ☐ 4 - Hispanic or Latino
- ☐ 5 - Native Hawaiian or Pacific Islander
- ☐ 6 - White
- ☐ UK - Unknown

(M0150) Current Payment Sources for Home Care: (Mark all that apply.)

- ☐ 0 - None; no charge for current services
- ☐ 1 - Medicare (traditional fee-for-service)
- ☐ 2 - Medicare (HMO/managed care)
- ☐ 3 - Medicaid (traditional fee-for-service)
- ☐ 4 - Medicaid (HMO/managed care)
- ☐ 5 - Workers' compensation
- ☐ 6 - Title programs (e.g., Title III, V, or XX)
- ☐ 7 - Other government (e.g., CHAMPUS, VA, etc.)
- ☐ 8 - Private insurance
- ☐ 9 - Private HMO/managed care
- ☐ 10 - Self-pay
- ☐ 11 - Other (specify) _____
- ☐ UK - Unknown

(M0160) Financial Factors limiting the ability of the patient/family to meet basic health needs: **(Mark all that apply.)**

- ☐ 0 - None
- ☐ 1 - Unable to afford medicine or medical supplies
- ☐ 2 - Unable to afford medical expenses that are not covered by insurance/Medicare (e.g., copayments)
- ☐ 3 - Unable to afford rent/utility bills
- ☐ 4 - Unable to afford food
- ☐ 5 - Other (specify) _____

(M0175) From which of the following **Inpatient Facilities** was the patient discharged during the past 14 days? **(Mark all that apply.)**

- ☐ 1 - Hospital
- ☐ 2 - Rehabilitation facility
- ☐ 3 - Skilled nursing facility
- ☐ 4 - Other nursing home
- ☐ 5 - Other (specify) _____
- ☐ NA - Patient was not discharged from an inpatient facility **[If NA, go to *M0200*]**

(M0180) Inpatient Discharge Date (most recent):

__ __ / __ __ / __ __ __ __
month day year

- ☐ UK - Unknown

(M0190) **Inpatient Diagnoses** and ICD code categories (three digits required; five digits optional) for only those conditions treated during an inpatient facility stay within the last 14 days (no surgical or V-codes):

	Inpatient Facility Diagnosis	ICD
a.	_____	(__ __ __ . __ __)
b.	_____	(__ __ __ . __ __)

(M0200) **Medical or Treatment Regimen Change Within Past 14 Days:** Has this patient experienced a change in medical or treatment regimen (e.g., medication, treatment, or service change due to new or additional diagnosis, etc.) within the last 14 days?

☐ 0 - No **[If No, go to *M0220*]**
☐ 1 - Yes

(M0210) List the patient's **Medical Diagnoses** and ICD code categories (three digits required; five digits optional) for those conditions requiring changed medical or treatment regimen (no surgical or V-codes):

	Changed Medical Regimen Diagnosis	ICD
a.	_____	(__ __ __ . __ __)
b.	_____	(__ __ __ . __ __)
c.	_____	(__ __ __ . __ __)
d.	_____	(__ __ __ . __ __)

(M0220) **Conditions Prior to Medical or Treatment Regimen Change or Inpatient Stay Within Past 14 Days**: If this patient experienced an inpatient facility discharge or change in medical or treatment regimen within the past 14 days, indicate any conditions which existed prior to the inpatient stay or change in medical or treatment regimen. **(Mark all that apply.)**

☐ 1 - Urinary incontinence
☐ 2 - Indwelling/suprapubic catheter
☐ 3 - Intractable pain
☐ 4 - Impaired decision-making
☐ 5 - Disruptive or socially inappropriate behavior
☐ 6 - Memory loss to the extent that supervision required
☐ 7 - None of the above
☐ NA - No inpatient facility discharge and no change in medical or treatment regimen in past 14 days
☐ UK - Unknown

(M0230/M0240) Diagnoses and Severity Index: List each medical diagnosis or problem for which the patient is receiving home care and ICD code category (three digits required; five digits optional – no surgical or V-codes) and rate them using the following severity index. (Choose one value that represents the most severe rating appropriate for each diagnosis.)

0 - Asymptomatic, no treatment needed at this time
1 - Symptoms well controlled with current therapy
2 - Symptoms controlled with difficulty, affecting daily functioning; patient needs ongoing monitoring
3 - Symptoms poorly controlled, patient needs frequent adjustment in treatment and dose monitoring
4 - Symptoms poorly controlled, history of rehospitalizations

	(M0230) Primary Diagnosis	ICD	Severity Rating
a.	_____	(__ __ __ . __ __)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4
	(M0240) Other Diagnoses	ICD	Severity Rating
b.	_____	(__ __ __ . __ __)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4
c.	_____	(__ __ __ . __ __)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4
d.	_____	(__ __ __ . __ __)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4
e.	_____	(__ __ __ . __ __)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4
f.	_____	(__ __ __ . __ __)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4

(M0250) Therapies the patient receives at home: **(Mark all that apply.)**

☐ 1 - Intravenous or infusion therapy (excludes TPN)
☐ 2 - Parenteral nutrition (TPN or lipids)
☐ 3 - Enteral nutrition (nasogastric, gastrostomy, jejunostomy, or any other artificial entry into the alimentary canal)
☐ 4 - None of the above

(M0260) Overall Prognosis: BEST description of patient's overall prognosis for recovery from this episode of illness.

☐ 0 - Poor: little or no recovery is expected and/or further decline is imminent
☐ 1 - Good/Fair: partial to full recovery is expected
☐ UK - Unknown

(M0270) Rehabilitative Prognosis: BEST description of patient's prognosis for functional status.

☐ 0 - Guarded: minimal improvement in functional status is expected; decline is possible
☐ 1 - Good: marked improvement in functional status is expected
☐ UK - Unknown

(M0280) Life Expectancy: (Physician documentation is not required.)

☐ 0 - Life expectancy is greater than 6 months
☐ 1 - Life expectancy is 6 months or fewer

(M0290) High Risk Factors characterizing this patient: **(Mark all that apply.)**

☐ 1 - Heavy smoking
☐ 2 - Obesity
☐ 3 - Alcohol dependency
☐ 4 - Drug dependency
☐ 5 - None of the above
☐ UK - Unknown

LIVING ARRANGEMENTS

(M0300) Current Residence:

- ☐ 1 - Patient's owned or rented residence (house, apartment, or mobile home owned or rented by patient/couple/significant other)
- ☐ 2 - Family member's residence
- ☐ 3 - Boarding home or rented room
- ☐ 4 - Board and care or assisted living facility
- ☐ 5 - Other (specify) _____

(M0310) Structural Barriers in the patient's environment limiting independent mobility: **(Mark all that apply.)**

- ☐ 0 - None
- ☐ 1 - Stairs inside home which must be used by the patient (e.g., to get to toileting, sleeping, eating areas)
- ☐ 2 - Stairs inside home which are used optionally (e.g., to get to laundry facilities)
- ☐ 3 - Stairs leading from inside house to outside
- ☐ 4 - Narrow or obstructed doorways

(M0320) Safety Hazards found in the patient's current place of residence: **(Mark all that apply.)**

- ☐ 0 - None
- ☐ 1 - Inadequate floor, roof, or windows
- ☐ 2 - Inadequate lighting
- ☐ 3 - Unsafe gas/electric appliance
- ☐ 4 - Inadequate heating
- ☐ 5 - Inadequate cooling
- ☐ 6 - Lack of fire safety devices
- ☐ 7 - Unsafe floor coverings
- ☐ 8 - Inadequate stair railings
- ☐ 9 - Improperly stored hazardous materials
- ☐ 10 - Lead-based paint
- ☐ 11 - Other (specify) _____

(M0330) Sanitation Hazards found in the patient's current place of residence: **(Mark all that apply.)**

- ☐ 0 - None
- ☐ 1 - No running water
- ☐ 2 - Contaminated water
- ☐ 3 - No toileting facilities
- ☐ 4 - Outdoor toileting facilities only
- ☐ 5 - Inadequate sewage disposal
- ☐ 6 - Inadequate/improper food storage
- ☐ 7 - No food refrigeration
- ☐ 8 - No cooking facilities
- ☐ 9 - Insects/rodents present
- ☐ 10 - No scheduled trash pickup
- ☐ 11 - Cluttered/soiled living area
- ☐ 12 - Other (specify) _____

(M0340) Patient Lives With: (Mark all that apply.)

- ☐ 1 - Lives alone
- ☐ 2 - With spouse or significant other
- ☐ 3 - With other family member
- ☐ 4 - With a friend
- ☐ 5 - With paid help (other than home care agency staff)
- ☐ 6 - With other than above

SUPPORTIVE ASSISTANCE

(M0350) Assisting Person(s) Other than Home Care Agency Staff: (Mark all that apply.)

- ☐ 1 - Relatives, friends, or neighbors living outside the home
- ☐ 2 - Person residing in the home (EXCLUDING paid help)
- ☐ 3 - Paid help
- ☐ 4 - None of the above **[If None of the above, go to *M0390*]**
- ☐ UK - Unknown **[If Unknown, go to *M0390*]**

(M0360) Primary Caregiver taking lead responsibility for providing or managing the patient's care, providing the most frequent assistance, etc. (other than home care agency staff):

- ☐ 0 - No one person **[If No one person, go to *M0390*]**
- ☐ 1 - Spouse or significant other
- ☐ 2 - Daughter or son
- ☐ 3 - Other family member
- ☐ 4 - Friend or neighbor or community or church member
- ☐ 5 - Paid help
- ☐ UK - Unknown **[If Unknown, go to *M0390*]**

(M0370) How Often does the patient receive assistance from the primary caregiver?

- ☐ 1 - Several times during day and night
- ☐ 2 - Several times during day
- ☐ 3 - Once daily
- ☐ 4 - Three or more times per week
- ☐ 5 - One to two times per week
- ☐ 6 - Less often than weekly
- ☐ UK - Unknown

(M0380) Type of Primary Caregiver Assistance: (Mark all that apply.)

- ☐ 1 - ADL assistance (e.g., bathing, dressing, toileting, bowel/bladder, eating/feeding)
- ☐ 2 - IADL assistance (e.g., meds, meals, housekeeping, laundry, telephone, shopping, finances)
- ☐ 3 - Environmental support (housing, home maintenance)
- ☐ 4 - Psychosocial support (socialization, companionship, recreation)
- ☐ 5 - Advocates or facilitates patient's participation in appropriate medical care
- ☐ 6 - Financial agent, power of attorney, or conservator of finance
- ☐ 7 - Health care agent, conservator of person, or medical power of attorney
- ☐ UK - Unknown

SENSORY STATUS

(M0390) Vision with corrective lenses if the patient usually wears them:

- ☐ 0 - Normal vision: sees adequately in most situations; can see medication labels, newsprint.
- ☐ 1 - Partially impaired: cannot see medication labels or newsprint, but can see obstacles in path, and the surrounding layout; can count fingers at arm's length.
- ☐ 2 - Severely impaired: cannot locate objects without hearing or touching them or patient nonresponsive.

(M0400) Hearing and Ability to Understand Spoken Language in patient's own language (with hearing aids if the patient usually uses them):

- ☐ 0 - No observable impairment. Able to hear and understand complex or detailed instructions and extended or abstract conversation.
- ☐ 1 - With minimal difficulty, able to hear and understand most multi-step instructions and ordinary conversation. May need occasional repetition, extra time, or louder voice.
- ☐ 2 - Has moderate difficulty hearing and understanding simple, one-step instructions and brief conversation; needs frequent prompting or assistance.
- ☐ 3 - Has severe difficulty hearing and understanding simple greetings and short comments. Requires multiple repetitions, restatements, demonstrations, additional time.
- ☐ 4 - Unable to hear and understand familiar words or common expressions consistently, or patient nonresponsive.

(M0410) Speech and Oral (Verbal) Expression of Language (in patient's own language):

- ☐ 0 - Expresses complex ideas, feelings, and needs clearly, completely, and easily in all situations with no observable impairment.
- ☐ 1 - Minimal difficulty in expressing ideas and needs (may take extra time; makes occasional errors in word choice, grammar or speech intelligibility; needs minimal prompting or assistance).
- ☐ 2 - Expresses simple ideas or needs with moderate difficulty (needs prompting or assistance, errors in word choice, organization or speech intelligibility). Speaks in phrases or short sentences.
- ☐ 3 - Has severe difficulty expressing basic ideas or needs and requires maximal assistance or guessing by listener. Speech limited to single words or short phrases.
- ☐ 4 - Unable to express basic needs even with maximal prompting or assistance but is not comatose or unresponsive (e.g., speech is nonsensical or unintelligible).
- ☐ 5 - Patient nonresponsive or unable to speak.

(M0420) Frequency of Pain interfering with patient's activity or movement:

- ☐ 0 - Patient has no pain or pain does not interfere with activity or movement
- ☐ 1 - Less often than daily
- ☐ 2 - Daily, but not constantly
- ☐ 3 - All of the time

(M0430) Intractable Pain: Is the patient experiencing pain that is not easily relieved, occurs at least daily, and affects the patient's sleep, appetite, physical or emotional energy, concentration, personal relationships, emotions, or ability or desire to perform physical activity?

- ☐ 0 - No
- ☐ 1 - Yes

INTEGUMENTARY STATUS

(M0440) Does this patient have a **Skin Lesion** or an **Open Wound**? This excludes "OSTOMIES."

☐ 0 - No **[If No, go to *M0490*]**
☐ 1 - Yes

(M0445) Does this patient have a **Pressure Ulcer**?

☐ 0 - No **[If No, go to *M0468*]**
☐ 1 - Yes

(M0450) Current Number of Pressure Ulcers at Each Stage: (Circle one response for each stage.)

Pressure Ulcer Stages		Number of Pressure Ulcers				
a)	Stage 1: Nonblanchable erythema of intact skin; the heralding of skin ulceration. In darker-pigmented skin, warmth, edema, hardness, or discolored skin may be indicators.	0	1	2	3	4 or more
b)	Stage 2: Partial thickness skin loss involving epidermis and/or dermis. The ulcer is superficial and presents clinically as an abrasion, blister, or shallow crater.	0	1	2	3	4 or more
c)	Stage 3: Full-thickness skin loss involving damage or necrosis of subcutaneous tissue which may extend down to, but not through, underlying fascia. The ulcer presents clinically as a deep crater with or without undermining of adjacent tissue.	0	1	2	3	4 or more
d)	Stage 4: Full-thickness skin loss with extensive destruction, tissue necrosis, or damage to muscle, bone, or supporting structures (e.g., tendon, joint capsule, etc.)	0	1	2	3	4 or more
e)	In addition to the above, is there at least one pressure ulcer that cannot be observed due to the presence of eschar or a nonremovable dressing, including casts? ☐ 0 - No ☐ 1 - Yes					

(M0460) Stage of Most Problematic (Observable) Pressure Ulcer:

☐ 1 - Stage 1
☐ 2 - Stage 2
☐ 3 - Stage 3
☐ 4 - Stage 4
☐ NA - No observable pressure ulcer

(M0464) Status of Most Problematic (Observable) Pressure Ulcer:

☐ 1 - Fully granulating
☐ 2 - Early/partial granulation
☐ 3 - Not healing
☐ NA - No observable pressure ulcer

(M0468) Does this patient have a **Stasis Ulcer**?

☐ 0 - No **[If No, go to *M0482*]**
☐ 1 - Yes

(M0470) Current Number of Observable Stasis Ulcer(s):

☐ 0 - Zero
☐ 1 - One
☐ 2 - Two
☐ 3 - Three
☐ 4 - Four or more

(M0474) Does this patient have at least one **Stasis Ulcer that Cannot be Observed** due to the presence of a nonremovable dressing?

☐ 0 - No
☐ 1 - Yes

(M0476) Status of Most Problematic (Observable) Stasis Ulcer:

☐ 1 - Fully granulating
☐ 2 - Early/partial granulation
☐ 3 - Not healing
☐ NA - No observable stasis ulcer

(M0482) Does this patient have a **Surgical Wound?**

☐ 0 - No **[If No, go to *M0490*]**
☐ 1 - Yes

(M0484) Current Number of (Observable) Surgical Wounds: (If a wound is partially closed but has more than one opening, consider each opening as a separate wound.)

☐ 0 - Zero
☐ 1 - One
☐ 2 - Two
☐ 3 - Three
☐ 4 - Four or more

(M0486) Does this patient have at least one **Surgical Wound that Cannot be Observed** due to the presence of a nonremovable dressing?

☐ 0 - No
☐ 1 - Yes

(M0488) Status of Most Problematic (Observable) Surgical Wound:

☐ 1 - Fully granulating
☐ 2 - Early/partial granulation
☐ 3 - Not healing
☐ NA - No observable surgical wound

RESPIRATORY STATUS

(M0490) When is the patient dyspneic or noticeably **Short of Breath**?

- ☐ 0 - Never, patient is not short of breath
- ☐ 1 - When walking more than 20 feet, climbing stairs
- ☐ 2 - With moderate exertion (e.g., while dressing, using commode or bedpan, walking distances less than 20 feet)
- ☐ 3 - With minimal exertion (e.g., while eating, talking, or performing other ADLs) or with agitation
- ☐ 4 - At rest (during day or night)

(M0500) **Respiratory Treatments** utilized at home: **(Mark all that apply.)**

- ☐ 1 - Oxygen (intermittent or continuous)
- ☐ 2 - Ventilator (continually or at night)
- ☐ 3 - Continuous positive airway pressure
- ☐ 4 - None of the above

ELIMINATION STATUS

(M0510) Has this patient been treated for a **Urinary Tract Infection** in the past 14 days?

- ☐ 0 - No
- ☐ 1 - Yes
- ☐ NA - Patient on prophylactic treatment
- ☐ UK - Unknown

(M0520) **Urinary Incontinence or Urinary Catheter Presence:**

- ☐ 0 - No incontinence or catheter (includes anuria or ostomy for urinary drainage) **[If No, go to *M0540*]**
- ☐ 1 - Patient is incontinent
- ☐ 2 - Patient requires a urinary catheter (i.e., external, indwelling, intermittent, suprapubic) **[Go to *M0540*]**

(M0530) **When** does **Urinary Incontinence** occur?

- ☐ 0 - Timed-voiding defers incontinence
- ☐ 1 - During the night only
- ☐ 2 - During the day and night

(M0540) **Bowel Incontinence Frequency:**

- ☐ 0 - Very rarely or never has bowel incontinence
- ☐ 1 - Less than once weekly
- ☐ 2 - One to three times weekly
- ☐ 3 - Four to six times weekly
- ☐ 4 - On a daily basis
- ☐ 5 - More often than once daily
- ☐ NA - Patient has ostomy for bowel elimination
- ☐ UK - Unknown

(M0550) Ostomy for Bowel Elimination: Does this patient have an ostomy for bowel elimination that (within the last 14 days): a) was related to an inpatient facility stay, or b) necessitated a change in medical or treatment regimen?

- ☐ 0 - Patient does not have an ostomy for bowel elimination.
- ☐ 1 - Patient's ostomy was not related to an inpatient stay and did not necessitate change in medical or treatment regimen.
- ☐ 2 - The ostomy was related to an inpatient stay or did necessitate change in medical or treatment regimen.

NEURO/EMOTIONAL/BEHAVIORAL STATUS

(M0560) Cognitive Functioning: (Patient's current level of alertness, orientation, comprehension, concentration, and immediate memory for simple commands.)

- ☐ 0 - Alert/oriented, able to focus and shift attention, comprehends and recalls task directions independently.
- ☐ 1 - Requires prompting (cuing, repetition, reminders) only under stressful or unfamiliar conditions.
- ☐ 2 - Requires assistance and some direction in specific situations (e.g., on all tasks involving shifting of attention), or consistently requires low stimulus environment due to distractibility.
- ☐ 3 - Requires considerable assistance in routine situations. Is not alert and oriented or is unable to shift attention and recall directions more than half the time.
- ☐ 4 - Totally dependent due to disturbances such as constant disorientation, coma, persistent vegetative state, or delirium.

(M0570) When Confused (Reported or Observed):

- ☐ 0 - Never
- ☐ 1 - In new or complex situations only
- ☐ 2 - On awakening or at night only
- ☐ 3 - During the day and evening, but not constantly
- ☐ 4 - Constantly
- ☐ NA - Patient nonresponsive

(M0580) When Anxious (Reported or Observed):

- ☐ 0 - None of the time
- ☐ 1 - Less often than daily
- ☐ 2 - Daily, but not constantly
- ☐ 3 - All of the time
- ☐ NA - Patient nonresponsive

(M0590) Depressive Feelings Reported or Observed in Patient: (Mark all that apply.)

- ☐ 1 - Depressed mood (e.g., feeling sad, tearful)
- ☐ 2 - Sense of failure or self reproach
- ☐ 3 - Hopelessness
- ☐ 4 - Recurrent thoughts of death
- ☐ 5 - Thoughts of suicide
- ☐ 6 - None of the above feelings observed or reported

(M0600) Patient Behaviors (Reported or Observed): (Mark all that apply.)

- ☐ 1 - Indecisiveness, lack of concentration
- ☐ 2 - Diminished interest in most activities
- ☐ 3 - Sleep disturbances
- ☐ 4 - Recent change in appetite or weight
- ☐ 5 - Agitation
- ☐ 6 - A suicide attempt
- ☐ 7 - None of the above behaviors observed or reported

(M0610) Behaviors Demonstrated <u>at Least Once a Week</u> (Reported or Observed): (Mark all that apply.)

- ☐ 1 - Memory deficit: failure to recognize familiar persons/places, inability to recall events of past 24 hours, significant memory loss so that supervision is required
- ☐ 2 - Impaired decision-making: failure to perform usual ADLs or IADLs, inability to appropriately stop activities, jeopardizes safety through actions
- ☐ 3 - Verbal disruption: yelling, threatening, excessive profanity, sexual references, etc.
- ☐ 4 - Physical aggression: aggressive or combative to self and others (e.g., hits self, throws objects, punches, dangerous maneuvers with wheelchair or other objects)
- ☐ 5 - Disruptive, infantile, or socially inappropriate behavior (**excludes** verbal actions)
- ☐ 6 - Delusional, hallucinatory, or paranoid behavior
- ☐ 7 - None of the above behaviors demonstrated

(M0620) Frequency of Behavior Problems (Reported or Observed) (e.g., wandering episodes, self abuse, verbal disruption, physical aggression, etc.):

- ☐ 0 - Never
- ☐ 1 - Less than once a month
- ☐ 2 - Once a month
- ☐ 3 - Several times each month
- ☐ 4 - Several times a week
- ☐ 5 - At least daily

(M0630) Is this patient receiving **Psychiatric Nursing Services** at home provided by a qualified psychiatric nurse?

- ☐ 0 - No
- ☐ 1 - Yes

ADL/IADLs

For M0640-M0800, complete the "Current" column for all patients. For these same items, complete the "Prior" column only at start of care and at resumption of care; mark the level that corresponds to the patient's condition 14 days prior to start of care date (M0030) or resumption of care date (M0032). In all cases, record what the patient is *able to do*.

(M0640) Grooming: Ability to tend to personal hygiene needs (i.e., washing face and hands, hair care, shaving or make up, teeth or denture care, fingernail care).

Prior Current

- ☐ ☐ 0 - Able to groom self unaided, with or without the use of assistive devices or adapted methods.
- ☐ ☐ 1 - Grooming utensils must be placed within reach before able to complete grooming activities.
- ☐ ☐ 2 - Someone must assist the patient to groom self.
- ☐ ☐ 3 - Patient depends entirely upon someone else for grooming needs.
- ☐ UK - Unknown

(M0650) Ability to Dress Upper Body (with or without dressing aids) including undergarments, pullovers, front-opening shirts and blouses, managing zippers, buttons, and snaps:

Prior Current

- ☐ ☐ 0 - Able to get clothes out of closets and drawers, put them on and remove them from the upper body without assistance.
- ☐ ☐ 1 - Able to dress upper body without assistance if clothing is laid out or handed to the patient.
- ☐ ☐ 2 - Someone must help the patient put on upper body clothing.
- ☐ ☐ 3 - Patient depends entirely upon another person to dress the upper body.
- ☐ UK - Unknown

(M0660) Ability to Dress Lower Body (with or without dressing aids) including undergarments, slacks, socks or nylons, shoes:

Prior Current

- ☐ ☐ 0 - Able to obtain, put on, and remove clothing and shoes without assistance.
- ☐ ☐ 1 - Able to dress lower body without assistance if clothing and shoes are laid out or handed to the patient.
- ☐ ☐ 2 - Someone must help the patient put on undergarments, slacks, socks or nylons, and shoes.
- ☐ ☐ 3 - Patient depends entirely upon another person to dress lower body.
- ☐ UK - Unknown

(M0670) Bathing: Ability to wash entire body. **Excludes grooming (washing face and hands only).**

Prior Current

- ☐ ☐ 0 - Able to bathe self in shower or tub independently.
- ☐ ☐ 1 - With the use of devices, is able to bathe self in shower or tub independently.
- ☐ ☐ 2 - Able to bathe in shower or tub with the assistance of another person:
  (a) for intermittent supervision or encouragement or reminders, OR
  (b) to get in and out of the shower or tub, OR
  (c) for washing difficult to reach areas.
- ☐ ☐ 3 - Participates in bathing self in shower or tub, but requires presence of another person throughout the bath for assistance or supervision.
- ☐ ☐ 4 - Unable to use the shower or tub and is bathed in bed or bedside chair.
- ☐ ☐ 5 - Unable to effectively participate in bathing and is totally bathed by another person.
- ☐ UK - Unknown

(M0680) Toileting: Ability to get to and from the toilet or bedside commode.

Prior	Current			
☐	☐	0	-	Able to get to and from the toilet independently with or without a device.
☐	☐	1	-	When reminded, assisted, or supervised by another person, able to get to and from the toilet.
☐	☐	2	-	Unable to get to and from the toilet but is able to use a bedside commode (with or without assistance).
☐	☐	3	-	Unable to get to and from the toilet or bedside commode but is able to use a bedpan/urinal independently.
☐	☐	4	-	Is totally dependent in toileting.
☐		UK	-	Unknown

(M0690) Transferring: Ability to move from bed to chair, on and off toilet or commode, into and out of tub or shower, and ability to turn and position self in bed if patient is bedfast.

Prior	Current			
☐	☐	0	-	Able to independently transfer.
☐	☐	1	-	Transfers with minimal human assistance or with use of an assistive device.
☐	☐	2	-	Unable to transfer self but is able to bear weight and pivot during the transfer process.
☐	☐	3	-	Unable to transfer self and is unable to bear weight or pivot when transferred by another person.
☐	☐	4	-	Bedfast, unable to transfer but is able to turn and position self in bed.
☐	☐	5	-	Bedfast, unable to transfer and is unable to turn and position self.
☐		UK	-	Unknown

(M0700) Ambulation/Locomotion: Ability to SAFELY walk, once in a standing position, or use a wheelchair, once in a seated position, on a variety of surfaces.

Prior	Current			
☐	☐	0	-	Able to independently walk on even and uneven surfaces and climb stairs with or without railings (i.e., needs no human assistance or assistive device).
☐	☐	1	-	Requires use of a device (e.g., cane, walker) to walk alone or requires human supervision or assistance to negotiate stairs or steps or uneven surfaces.
☐	☐	2	-	Able to walk only with the supervision or assistance of another person at all times.
☐	☐	3	-	Chairfast, unable to ambulate but is able to wheel self independently.
☐	☐	4	-	Chairfast, unable to ambulate and is unable to wheel self.
☐	☐	5	-	Bedfast, unable to ambulate or be up in a chair.
☐		UK	-	Unknown

(M0710) Feeding or Eating: Ability to feed self meals and snacks. **Note: This refers only to the process of eating, chewing, and swallowing, not preparing the food to be eaten.**

Prior	Current			
☐	☐	0	-	Able to independently feed self.
☐	☐	1	-	Able to feed self independently but requires: (a) meal set-up; OR (b) intermittent assistance or supervision from another person; OR (c) a liquid, pureed or ground meat diet.
☐	☐	2	-	Unable to feed self and must be assisted or supervised throughout the meal/snack.
☐	☐	3	-	Able to take in nutrients orally and receives supplemental nutrients through a nasogastric tube or gastrostomy.
☐	☐	4	-	Unable to take in nutrients orally and is fed nutrients through a nasogastric tube or gastrostomy.
☐	☐	5	-	Unable to take in nutrients orally or by tube feeding.
☐		UK	-	Unknown

(M0720) Planning and Preparing Light Meals (e.g., cereal, sandwich) or reheat delivered meals:

Prior	Current		
☐	☐	0	- (a) Able to independently plan and prepare all light meals for self or reheat delivered meals; OR (b) Is physically, cognitively, and mentally able to prepare light meals on a regular basis but has not routinely performed light meal preparation in the past (i.e., prior to this home care admission).
☐	☐	1	- Unable to prepare light meals on a regular basis due to physical, cognitive, or mental limitations.
☐	☐	2	- Unable to prepare any light meals or reheat any delivered meals.
☐		UK	- Unknown

(M0730) Transportation: Physical and mental ability to safely use a car, taxi, or public transportation (bus, train, subway).

Prior	Current		
☐	☐	0	- Able to independently drive a regular or adapted car; OR uses a regular or handicap-accessible public bus.
☐	☐	1	- Able to ride in a car only when driven by another person; OR able to use a bus or handicap van only when assisted or accompanied by another person.
☐	☐	2	- Unable to ride in a car, taxi, bus, or van, and requires transportation by ambulance.
☐		UK	- Unknown

(M0740) Laundry: Ability to do own laundry -- to carry laundry to and from washing machine, to use washer and dryer, to wash small items by hand.

Prior	Current		
☐	☐	0	- (a) Able to independently take care of all laundry tasks; OR (b) Physically, cognitively, and mentally able to do laundry and access facilities, but has not routinely performed laundry tasks in the past (i.e., prior to this home care admission).
☐	☐	1	- Able to do only light laundry, such as minor hand wash or light washer loads. Due to physical, cognitive, or mental limitations, needs assistance with heavy laundry such as carrying large loads of laundry.
☐	☐	2	- Unable to do any laundry due to physical limitation or needs continual supervision and assistance due to cognitive or mental limitation.
☐		UK	- Unknown

(M0750) Housekeeping: Ability to safely and effectively perform light housekeeping and heavier cleaning tasks.

Prior	Current		
☐	☐	0	- (a) Able to independently perform all housekeeping tasks; OR (b) Physically, cognitively, and mentally able to perform all housekeeping tasks but has not routinely participated in housekeeping tasks in the past (i.e., prior to this home care admission).
☐	☐	1	- Able to perform only light housekeeping (e.g., dusting, wiping kitchen counters) tasks independently.
☐	☐	2	- Able to perform housekeeping tasks with intermittent assistance or supervision from another person.
☐	☐	3	- Unable to consistently perform any housekeeping tasks unless assisted by another person throughout the process.
☐	☐	4	- Unable to effectively participate in any housekeeping tasks.
☐		UK	- Unknown

(M0760) Shopping: Ability to plan for, select, and purchase items in a store and to carry them home or arrange delivery.

Prior Current

☐ ☐ 0 - (a) Able to plan for shopping needs and independently perform shopping tasks, including carrying packages; OR
(b) Physically, cognitively, and mentally able to take care of shopping, but has not done shopping in the past (i.e., prior to this home care admission).

☐ ☐ 1 - Able to go shopping, but needs some assistance:
(a) By self is able to do only light shopping and carry small packages, but needs someone to do occasional major shopping; OR
(b) Unable to go shopping alone, but can go with someone to assist.

☐ ☐ 2 - Unable to go shopping, but is able to identify items needed, place orders, and arrange home delivery.

☐ ☐ 3 - Needs someone to do all shopping and errands.

☐ UK - Unknown

(M0770) Ability to Use Telephone: Ability to answer the phone, dial numbers, and effectively use the telephone to communicate.

Prior Current

☐ ☐ 0 - Able to dial numbers and answer calls appropriately and as desired.

☐ ☐ 1 - Able to use a specially adapted telephone (i.e., large numbers on the dial, teletype phone for the deaf) and call essential numbers.

☐ ☐ 2 - Able to answer the telephone and carry on a normal conversation but has difficulty with placing calls.

☐ ☐ 3 - Able to answer the telephone only some of the time or is able to carry on only a limited conversation.

☐ ☐ 4 - Unable to answer the telephone at all but can listen if assisted with equipment.

☐ ☐ 5 - Totally unable to use the telephone.

☐ ☐ NA - Patient does not have a telephone.

☐ UK - Unknown

MEDICATIONS

(M0780) Management of Oral Medications: Patient's ability to prepare and take all prescribed oral medications reliably and safely, including administration of the correct dosage at the appropriate times/intervals. **Excludes injectable and IV medications. (NOTE: This refers to ability, not compliance or willingness.)**

Prior Current

☐ ☐ 0 - Able to independently take the correct oral medication(s) and proper dosage(s) at the correct times.

☐ ☐ 1 - Able to take medication(s) at the correct times if:
(a) individual dosages are prepared in advance by another person; OR
(b) given daily reminders; OR
(c) someone develops a drug diary or chart.

☐ ☐ 2 - Unable to take medication unless administered by someone else.

☐ ☐ NA - No oral medications prescribed.

☐ UK - Unknown

(M0790) Management of Inhalant/Mist Medications: Patient's ability to prepare and take all prescribed inhalant/mist medications (nebulizers, metered dose devices) reliably and safely, including administration of the correct dosage at the appropriate times/intervals. **Excludes all other forms of medication (oral tablets, injectable and IV medications).**

Prior	Current			
☐	☐	0	-	Able to independently take the correct medication and proper dosage at the correct times.
☐	☐	1	-	Able to take medication at the correct times if: (a) individual dosages are prepared in advance by another person, OR (b) given daily reminders.
☐	☐	2	-	Unable to take medication unless administered by someone else.
☐	☐	NA	-	No inhalant/mist medications prescribed.
☐		UK	-	Unknown

(M0800) Management of Injectable Medications: Patient's ability to prepare and take all prescribed injectable medications reliably and safely, including administration of correct dosage at the appropriate times/intervals. **Excludes IV medications.**

Prior	Current			
☐	☐	0	-	Able to independently take the correct medication and proper dosage at the correct times.
☐	☐	1	-	Able to take injectable medication at correct times if: (a) individual syringes are prepared in advance by another person, OR (b) given daily reminders.
☐	☐	2	-	Unable to take injectable medications unless administered by someone else.
☐	☐	NA	-	No injectable medications prescribed.
☐		UK	-	Unknown

EQUIPMENT MANAGEMENT

(M0810) Patient Management of Equipment (includes ONLY oxygen, IV/infusion therapy, enteral/parenteral nutrition equipment or supplies): Patient's ability to set up, monitor and change equipment reliably and safely, add appropriate fluids or medication, clean/store/dispose of equipment or supplies using proper technique. **(NOTE: This refers to ability, not compliance or willingness.)**

☐	0	-	Patient manages all tasks related to equipment completely independently.
☐	1	-	If someone else sets up equipment (i.e., fills portable oxygen tank, provides patient with prepared solutions), patient is able to manage all other aspects of equipment.
☐	2	-	Patient requires considerable assistance from another person to manage equipment, but independently completes portions of the task.
☐	3	-	Patient is only able to monitor equipment (e.g., liter flow, fluid in bag) and must call someone else to manage the equipment.
☐	4	-	Patient is completely dependent on someone else to manage all equipment.
☐	NA	-	No equipment of this type used in care **[If NA, go to *M0825*]**

(M0820) Caregiver Management of Equipment (includes ONLY oxygen, IV/infusion equipment, enteral/parenteral nutrition, ventilator therapy equipment or supplies): Caregiver's ability to set up, monitor, and change equipment reliably and safely, add appropriate fluids or medication, clean/store/dispose of equipment or supplies using proper technique. **(NOTE: This refers to ability, not compliance or willingness.)**

- ☐ 0 - Caregiver manages all tasks related to equipment completely independently.
- ☐ 1 - If someone else sets up equipment, caregiver is able to manage all other aspects.
- ☐ 2 - Caregiver requires considerable assistance from another person to manage equipment, but independently completes significant portions of task.
- ☐ 3 - Caregiver is only able to complete small portions of task (e.g., administer nebulizer treatment, clean/store/dispose of equipment or supplies).
- ☐ 4 - Caregiver is completely dependent on someone else to manage all equipment.
- ☐ NA - No caregiver
- ☐ UK - Unknown

THERAPY NEED

(M0825) Therapy Need: Does the care plan of the Medicare payment period for which this assessment will define a case mix group indicate a need for therapy (physical, occupational, or speech therapy) that meets the threshold for a Medicare high-therapy case mix group?

- ☐ 0 - No
- ☐ 1 - Yes
- ☐ NA - Not applicable

EMERGENT CARE

(M0830) Emergent Care: Since the last time OASIS data were collected, has the patient utilized any of the following services for emergent care (other than home care agency services)? **(Mark all that apply.)**

- ☐ 0 - No emergent care services **[If no emergent care, go to *M0855*]**
- ☐ 1 - Hospital emergency room (includes 23-hour holding)
- ☐ 2 - Doctor's office emergency visit/house call
- ☐ 3 - Outpatient department/clinic emergency (includes urgicenter sites)
- ☐ UK - Unknown **[If UK, go to *M0855*]**

(M0840) Emergent Care Reason: For what reason(s) did the patient/family seek emergent care? **(Mark all that apply.)**

- ☐ 1 - Improper medication administration, medication side effects, toxicity, anaphylaxis
- ☐ 2 - Nausea, dehydration, malnutrition, constipation, impaction
- ☐ 3 - Injury caused by fall or accident at home
- ☐ 4 - Respiratory problems (e.g., shortness of breath, respiratory infection, tracheobronchial obstruction)
- ☐ 5 - Wound infection, deteriorating wound status, new lesion/ulcer
- ☐ 6 - Cardiac problems (e.g., fluid overload, exacerbation of CHF, chest pain)
- ☐ 7 - Hypo/Hyperglycemia, diabetes out of control
- ☐ 8 - GI bleeding, obstruction
- ☐ 9 - Other than above reasons
- ☐ UK - Reason unknown

DATA ITEMS COLLECTED AT INPATIENT FACILITY ADMISSION OR AGENCY DISCHARGE ONLY

(M0855) To which **Inpatient Facility** has the patient been admitted?

- ☐ 1 - Hospital **[Go to *M0890*]**
- ☐ 2 - Rehabilitation facility **[Go to *M0903*]**
- ☐ 3 - Nursing home **[Go to *M0900*]**
- ☐ 4 - Hospice **[Go to *M0903*]**
- ☐ NA - No inpatient facility admission

(M0870) Discharge Disposition: Where is the patient after discharge from your agency? **(Choose only one answer.)**

- ☐ 1 - Patient remained in the community (not in hospital, nursing home, or rehab facility)
- ☐ 2 - Patient transferred to a noninstitutional hospice **[Go to *M0903*]**
- ☐ 3 - Unknown because patient moved to a geographic location not served by this agency **[Go to *M0903*]**
- ☐ UK - Other unknown **[Go to *M0903*]**

(M0880) After discharge, does the patient receive health, personal, or support **Services or Assistance**? **(Mark all that apply.)**

- ☐ 1 - No assistance or services received
- ☐ 2 - Yes, assistance or services provided by family or friends
- ☐ 3 - Yes, assistance or services provided by other community resources (e.g., meals-on-wheels, home health services, homemaker assistance, transportation assistance, assisted living, board and care)

Go to *M0903*

(M0890) If the patient was admitted to an acute care **Hospital**, for what **Reason** was he/she admitted?

- ☐ 1 - Hospitalization for emergent (unscheduled) care
- ☐ 2 - Hospitalization for urgent (scheduled within 24 hours of admission) care
- ☐ 3 - Hospitalization for elective (scheduled more than 24 hours before admission) care
- ☐ UK - Unknown

(M0895) Reason for Hospitalization: (Mark all that apply.)

- ☐ 1 - Improper medication administration, medication side effects, toxicity, anaphylaxis
- ☐ 2 - Injury caused by fall or accident at home
- ☐ 3 - Respiratory problems (SOB, infection, obstruction)
- ☐ 4 - Wound or tube site infection, deteriorating wound status, new lesion/ulcer
- ☐ 5 - Hypo/Hyperglycemia, diabetes out of control
- ☐ 6 - GI bleeding, obstruction
- ☐ 7 - Exacerbation of CHF, fluid overload, heart failure
- ☐ 8 - Myocardial infarction, stroke
- ☐ 9 - Chemotherapy
- ☐ 10 - Scheduled surgical procedure
- ☐ 11 - Urinary tract infection
- ☐ 12 - IV catheter-related infection
- ☐ 13 - Deep vein thrombosis, pulmonary embolus
- ☐ 14 - Uncontrolled pain
- ☐ 15 - Psychotic episode
- ☐ 16 - Other than above reasons

Go to *M0903*

(M0900) For what **Reason(s)** was the patient **Admitted** to a **Nursing Home**? **(Mark all that apply.)**

- ☐ 1 - Therapy services
- ☐ 2 - Respite care
- ☐ 3 - Hospice care
- ☐ 4 - Permanent placement
- ☐ 5 - Unsafe for care at home
- ☐ 6 - Other
- ☐ UK - Unknown

(M0903) Date of Last (Most Recent) Home Visit:

__ __ / __ __ / __ __ __ __
month day year

(M0906) Discharge/Transfer/Death Date: Enter the date of the discharge, transfer, or death (at home) of the patient.

__ __ / __ __ / __ __ __ __
month day year

SUPPORTING DOCUMENT 5:

IMPLEMENTING OUTCOME-BASED QUALITY IMPROVEMENT

in Volume 3 of the report series entitled:

OASIS and Outcome-Based Quality Improvement in Home Health Care:
Research and Demonstration Findings, Policy Implications,
and Considerations for Future Change

for the three interrelated studies:

The National Medicare Quality Assurance and Improvement Demonstration
The New York State Outcome-Based Quality Improvement Demonstration
A Project to Assist Home Care Providers to Effectively Use Patient Outcomes

February 2002

OVERVIEW

It is important for the home care clinical manager to understand and have exposure to the fundamental principals for establishing and maintaining a successful Outcome-Based Quality Improvement (OBQI) program for improving patient care delivery. This supporting document is the second of three separate manuals for home care providers, written with the support of the Robert Wood Johnson Foundation (Grant No. 031950). A manual for home care administrators and a manual for clinicians, examining their roles in the development and maintenance of an OBQI program, constitute the first and third documents in this series. This manual for home care clinical managers contains methods for maintaining data collection and encoding processes, and reviews the basic concepts of the outcome enhancement process.

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Preface

The Health Care Financing Administration (HCFA) Conditions of Participation requiring Outcome and Assessment Information Set (OASIS) data collection (Health Care Financing Administration, U.S. Department of Health and Human Services, June 18, 1999, *Federal Register* 64[117]:32984-32991) were released during a time when the home health industry was undergoing radical changes in Medicare payment. Because of the timing of the OASIS requirement, there was and continues to be significant confusion in the industry about the nature and purpose of OASIS. OASIS was designed primarily to help agencies systematically and continually improve outcomes of care for their patients. Why is OASIS necessary? Why is it critical to ensure that OASIS data accurately reflect patient status at the time of assessment? This manual addresses these issues and provides background information on the history and development of OASIS.

OASIS provides home health agencies information about their patients at a level of detail that was previously unattainable. These data can provide agencies with powerful tools for evaluating agency performance, marketing, strategic planning, management decisions, and determining payment under the Prospective Payment System (PPS). Perhaps more importantly, OASIS-derived outcome reports can be used for outcome-based quality improvement (OBQI). Using OBQI, many home care agencies have demonstrated significant improvements in patient outcomes, such as decreased hospitalization rates.

This manual provides home care clinical managers and Quality Improvement (QI) coordinators with the fundamental principles for establishing and maintaining a successful OBQI program. This manual does not provide detailed information on how to implement quality improvement/performance improvement (QI/PI) programs, presuming that most clinical managers and QI coordinators are familiar with the principles of QI/PI. Likewise, the manual only briefly discusses OASIS data collection protocols, since this material is included in HCFA's *OASIS User's Manual* (which was written largely by our staff). Rather, the focus is on how to move forward with implementing OBQI after data collection, encoding, and transmission activities have been put into place in an agency. In this manual, methods for maintaining data collection and encoding systems and for ensuring the quality of OASIS are explored. Examples of reports that can be derived from OASIS data are provided, along with definitions of statistical terms. The fundamental concepts of the outcome enhancement process (i.e., how agencies can use outcome data for performance improvement) are explained in detail. Additionally, the role of clinical managers and QI coordinators in a successful OBQI program is examined. Appendix A contains a troubleshooting guide for implementing OBQI, derived from demonstration agency experiences. Definitions of selected terms for OASIS implementation can be found in Appendix B.

This manual is part of a three-manual series for home care providers, written with the support of the Robert Wood Johnson Foundation (Grant No. 031950). A manual for home care administrators and a manual for clinicians examining their roles in the development and maintenance of OBQI programs constitute the first and third documents in this series.

Chapter 1
Overview

The introduction of the OASIS dataset and Outcome-Based Quality Improvement (OBQI) in the late 1990s represented a turning point in the evolution of home health care in the United States. For the first time, home health agencies were able to demonstrate the effectiveness of the clinical services they provide to patients in a valid, objective manner using Outcome and Assessment Information Set (OASIS)-derived outcome reports. Although OASIS-based reports are used for many purposes, including payment under PPS, one of the most well tested (and most important) uses for outcome data is improving agency performance through OBQI. This chapter is devoted to providing clinical managers and quality improvement coordinators with a basic understanding of the historical development of OASIS and OBQI and key concepts of the OBQI process.

A. Why is OASIS Necessary?

While processes of care vary across home health agencies and patients, the overall goal is universal. That goal is to provide patients with high-quality health care services that result in improvement or stabilization of patients' health status. Since outcomes are basically changes in health status between two time points (such as admission and discharge), the fundamental purpose of home health care is to optimally influence outcomes.

How can the outcomes of care be measured? Traditionally, care providers have identified patient-specific goals and evaluated patient outcomes by assessing whether goals were met. While that approach is useful when developing and evaluating plans of care for individual patients, there are drawbacks. For example, care providers can be inconsistent in setting goals for patients. One care provider may set low goals, while another care provider may always set higher goals. In addition, the evaluation of whether a patient has achieved his or her goals is often subjective. As with setting goals, care providers can be inconsistent in evaluating whether a patient achieved goals.

The subjectivity inherent in the process of setting goals and evaluating goal achievement makes aggregation of these data to an agency level futile. For example, if Agency A advertised that 75% of their patients met goals, while Agency B indicated that 50% of their patients met goals, can one feel confident that Agency A provided superior care? Or is it more likely that the difference between the two agencies is due to inconsistency in how goals were set and evaluated?

To measure the impact of an agency's care in terms of patient outcomes, it is necessary to collect high-quality standardized data at specific times during a patient's care episode. Accurate data collected in a consistent manner across all patients can be analyzed at the agency level. Agency-level data can then be aggregated further to regional and national levels. OASIS was developed over the course of many years for the purpose of validly and reliably measuring outcomes of home care patients. The precisely defined OASIS scales (an illustrative OASIS item is provided in Figure 1) and

standardized data collection time points allow accurate measurement of changes in health status. Definitions of each scale level are provided in terms that are at the same time understandable to care providers and highly specific. The specificity of the scales for OASIS items increases interrater reliability, the assurance that scoring is consistent across care providers.

FIGURE 1: Illustrative OASIS Item.

(M0560): Cognitive Functioning: (Patient's current level of alertness, orientation, comprehension, concentration, and immediate memory for simple commands.)

0 - Alert/oriented, able to focus and shift attention, comprehends and recalls task directions independently.
1 - Requires prompting (cueing, repetition, reminders) only under stressful or unfamiliar conditions.
2 - Requires assistance and some direction in specific situations (e.g., on all tasks involving shifting of attention), or consistently requires low stimulus environment due to distractibility.
3 - Requires considerable assistance in routine situations. Is not alert and oriented or is unable to shift attention and recall directions more than half the time.
4 - Totally dependent due to disturbances such as constant disorientation, coma, persistent vegetative state, or delirium.

B. OASIS Development

OASIS was carefully designed over a period of approximately 15 years as an instrument to assess and enhance health outcomes of home care patients (Table 1 summarizes key points about the development of OASIS).

TABLE 1: OASIS Development.

- Developed over a period of approximately 15 years
- Designed for measuring and enhancing patient outcomes
- Developed with input from home care clinicians
- Designed to include more detailed versions of routine assessment items
- Tested in hundreds of home health agencies

Initially, home care experts (e.g., nurses, physicians, therapists, social workers, administrators) specified a set of outcomes, chosen from the most important domains of health status, for the purpose of evaluating the effectiveness of care. From this set of patient outcomes, OASIS data items were derived. These data items were further tested in hundreds of agencies across the country and refined for the fundamental purpose of enhancing health outcomes on behalf of home care patients.

OASIS requires the collection of the same type of clinical information that health care providers have always collected as part of a routine comprehensive assessment. To achieve the precision necessary to calculate outcomes, however, this health status information is collected in more detail. For example, clinicians have always assessed Activities of Daily Living (ADLs). However, a variety of scales for ADLs were utilized (sometimes within the same agency), and response scales often required vague,

subjective responses such as "independent," "needs moderate assistance," or "dependent." The same information about ADLs is required by OASIS, but the clinician must choose from a more detailed scale that precisely describes the patient's level of independence or dependence in the context of the home environment.

In the mid-1990s, after an initial ten years of OASIS research and development, the National Medicare Quality Assurance Demonstration was funded to assess the utility of using OASIS-derived outcomes for home health provider and regulatory applications. The program involved 54 home health agencies in 26 states and was implemented to serve as a prototype for a national program. The participants included small, medium, and large agencies, both rural and urban agencies, and home care agencies representing a variety of ownership types. The New York State Department of Health (NYSDOH) implemented a state-level OBQI demonstration patterned after this national demonstration. This program was eventually expanded to include 65 home care agencies (both certified and noncertified). The more than 100 agencies participating in the two demonstration programs successfully integrated into their day-to-day operations all facets of OASIS data collection, monitoring, processing, and transmission.

C. Benefits of OASIS Data

With the advent of national OASIS data collection, home care agencies have the opportunity to precisely measure the impact of care on patients. If data are collected and encoded accurately, the resulting reports provide powerful information. For example, agencies can use data demonstrating the effectiveness of home care services to justify the need for the services, for marketing purposes, to satisfy certification and accreditation requirements, and to target staff development activities. OASIS data also provide a foundation for OBQI, a systematic method for improving quality of care. QI Coordinators from demonstration projects found that OBQI allows them to focus their activities, increasing efficiency of QI/PI programs.

In addition to the benefits for agencies, other home care stakeholders will also benefit from OASIS data. Payment under the Medicare PPS is determined using OASIS data. Outcome information will be used to supplement the survey and certification program. In the future, outcome data will be available for consumers of home health care (e.g., patients, physicians) to use when selecting home care providers. Ultimately, care for home health patients nationally will be enhanced by improved patient care techniques that are identified and promulgated by agencies using OBQI.

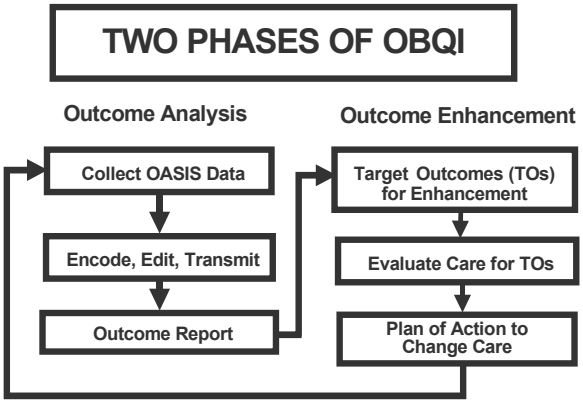
D. Using OASIS Data for Outcome Enhancement

There are two phases to the OBQI process (see Figure 2). The first phase, the outcome analysis phase, consists of OASIS data collection and analysis to generate agency level reports. As defined in the June 18, 1999 *Federal Register*, OASIS data must be collected for all home care patients 18 and older with the exception of patients receiving antepartum and postpartum services[1], patients receiving personal care services

[1] With the July 3 2000 publication of the PPS Final Rule, HCFA required that OASIS data be collected for disabled maternity patients and patients under 18. These data are not encoded and transmitted to State Agencies.

only, and patients receiving only housekeeping/chore services. Data are then encoded and transmitted to State Agencies.

FIGURE 2: Two Phases of OBQI.



OASIS data reflecting patient status are collected at standard time points, checked for accuracy and completeness, encoded, and transmitted to a central repository (e.g., State Agencies). During analyses, data are aggregated to produce agency-level reports, including outcome and case mix reports (examples are provided in Chapter 3). Outcome reports allow an agency to assess its performance in terms of how the health status of patients changed between home care admission and follow-up timepoints (typically discharge). Agency performance is reflected by a variety of end-result outcomes such as Improvement in Ambulation/Locomotion, Stabilization in Speech or Language, Improvement in Status of Surgical Wounds, Stabilization in Anxiety, etc., and utilization outcomes such as Acute Care Hospitalization. Case mix reports contain information about demographic, environmental, social support, and health status characteristics of agency patients on admission and resumption of care following an inpatient stay. Both of these reports provide a comparison of agency data relative to a national reference or benchmark sample and from the agency's own data from one year to the next.

The second phase of the OBQI process is the outcome enhancement phase. In this phase, agencies select target outcome(s), evaluate the care processes linked to the target outcome(s), and develop a plan of action to improve or maintain selected outcome(s). Table 2 lists the steps of the outcome enhancement phase in more detail.

TABLE 2: Steps of the Outcome Enhancement Phase.

1. Interpret outcome and case mix reports
2. Select target outcome(s)
3. Investigate care processes affecting target outcome(s)
4. Identify problems/strengths and best practices
5. Develop action plan to enhance (improve or maintain) the target outcome(s)
6. Implement action plan
7. Monitor action plan
8. Evaluate effect of action plan on outcomes in subsequent reports

When outcome reports are received, agencies interpret reports and select one or two target outcomes that merit further investigation, typically because they are significantly different than reference data (either inferior or superior). Once target outcomes are selected, a QI team investigates care processes linked with the target outcomes. During the investigation, the team identifies best practices associated with the outcome and determines whether clinicians utilized those best practices when providing patient care. Once the investigation is completed, the team summarizes its findings by developing statements of problems or strengths and identifying corresponding best practices that become the focus of an action plan to enhance the target outcome. The action plan is a road map for change, including specific details on educating care providers regarding best practices and promoting their use in patient care delivery. It also includes strategies for monitoring the effectiveness of the plan. Once the action plan is developed, it is then implemented by the QI team or other designated staff. The action plan should be implemented within a short time frame (e.g., one month) after the outcome report is received so that changes in patient outcomes can be observed on the subsequent outcome report. Monitoring activities should be conducted throughout the next data collection period to evaluate the success of action plan activities and to determine the need for revisions to the plan (e.g., activities to reinforce the importance of using best practices). The effectiveness of the action plan in terms of changing care practice is ultimately evaluated by reviewing the subsequent outcome report for changes in the target outcome(s).

E. The Power of OBQI

Findings from agencies participating in the national OBQI demonstration project highlight the power of the system. For the sake of evaluating the potential effectiveness of OBQI, all agencies participating in the national demonstration were required to focus on the common target outcome of hospitalization. Agencies were free to select an additional target outcome. Statistical analyses compared hospitalization rates between Year 1 and Year 2, with adjustments for case mix differences that may have existed for the two groups of patients between the first and second years. Collectively, the Year 1 hospitalization rate for agencies was 31.4%, compared with a Year 2 hospitalization rate of 28.3%.* The decrease of 3.1 percentage points is statistically significant and translates into an overall rate of decrease from Year 1 to Year 2 of approximately 10%. Nationally, in non-demonstration settings, there was no comparable reduction in hospital rates. The other (nonhospitalization) outcomes of demonstration agencies also showed significant improvement (Shaughnessy, 1999). The same outcome trends in hospitalization rates and other targeted outcomes were found for the New York demonstration.

Many agencies have demonstrated that, done correctly, OBQI can lead to enhanced care delivery and improved patient outcomes. Collecting and transmitting high-quality OASIS data are only the beginning. By using outcome information in QI/PI programs, agencies can identify and subsequently implement changes in care delivery that can result in improved health outcomes.

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*[These were preliminary results; see Volume 2 of the 2002 four-volume final report for (analogous) findings based on the entire demonstration program data set.]

F. Characteristics of Agencies Successfully Implementing OBQI

As with any systematic change, implementing an OBQI program can be challenging. Agency staff can easily lose the "big-picture" perspective of what they hope to accomplish as they focus on the details of implementing OBQI. Home care agencies that successfully implement OBQI have several characteristics in common (see Table 3).

TABLE 3: Characteristics of Agencies Successfully Implementing OBQI.

- Maintain a strong, long-term commitment to principles of QI
- Understand value of information that can be obtained from OASIS data
- Ensure high-quality data
- Establish and maintain internal structures and processes that recognize and demonstrate the value of OBQI
- Support continuous development and change as OBQI evolves

Agencies that maintain a strong, long-term commitment to the principles of QI are best prepared to overcome minor obstacles in order to achieve the goal of improved patient care. Agency administrators and staff with an understanding of and appreciation for the information they will obtain from OASIS data are better able to justify the time and resource expenditures necessary to obtain and utilize outcome and case mix information. OASIS data collection may be perceived as a burden if agencies view it solely as necessary for regulatory compliance. However, OASIS data used for OBQI can be a powerful tool for improving patient care.

In a data-driven system, the quality of reports is only as good as the quality of the data that were collected and encoded. To ensure that outcome reports accurately reflect the impact of care, agencies must be willing to develop systems to ensure the quality of OASIS data, such as data audit programs (described in more detail in Chapter 2). With the emphasis on OASIS data collection and transmission processes, occasionally agencies forget the importance of systems to support the outcome enhancement phase of OBQI. Successful agencies establish and maintain the internal structure and processes that recognize and demonstrate the value of each step of the OBQI process, and involve staff at all levels in planning, implementation, and evaluation activities. Finally, agencies must build flexibility into systems as they implement an OBQI approach. It is necessary to acknowledge that OBQI will evolve over time, and successful agencies are willing and able to support continuous development and change. With careful preparation and planning, adequate resources, and management support, agencies can truly make an investment in better care and better outcomes.

Chapter 2

Implementing and Maintaining OASIS Data Collection, Encoding, and Transmission Systems

As discussed in Chapter 1, the first phase of OBQI consists of gathering, encoding, and transmitting OASIS data to a central database (e.g., State Agency) for analysis. Prior to the January 25, 1999 release of the Final Rule for OASIS data collection, encoding, and transmission (HCFA, 1999), HCFA made the *Outcome and Assessment Information Set User's Manual* available to home health agencies. Along with the manual, which provided detailed instructions on OASIS data collection, HCFA provided agencies with specifications for data entry and electronic transmission. Workshops were offered by State OASIS educational and automation coordinators and responses to frequently-asked questions were posted on HCFA's OASIS Web site (http://www.hcfa.gov/medicaid/oasis/oasishmp.htm). The final regulation for the mandatory use and collection of OASIS data for all patients receiving skilled services from home health agencies, and for the encoding and transmission of data for Medicare and Medicaid patients was published June 18, 1999.

A. Integration of OASIS into Clinical Documentation

OASIS was never intended to be a comprehensive patient assessment. The data items provide consistency and detail for many aspects of clinical assessments, but must be supplemented with other clinical information (i.e., vital signs, breath sounds, etc.). Agencies following the HCFA guidelines integrate OASIS items into agency clinical documentation forms or software. This involves "cutting and pasting" OASIS items into forms (carefully following appropriate skip patterns) and eliminating duplicate clinical items. Many choose to use sample clinical records that HCFA provided on their OASIS Web site.

OASIS integration serves several purposes. It streamlines data collection for clinicians and minimizes or eliminates any additional time needed to complete patient assessments at required time points. It also reinforces the fact that OASIS data items are not intended to be used as a survey instrument, but as a routine and integral part of the comprehensive assessment. As discussed previously, OASIS items are not new assessment items, but are more specific versions of data that have always been gathered during clinical assessments. Clinicians continue to use traditional methods of assessment (typically a combination of observation and interview) to collect OASIS data and record their findings on clinical assessment forms. Another purpose of OASIS integration is to promote data quality. Since OASIS items are part of the legal medical record, clinicians are accountable for the accuracy and completeness of OASIS data.

B. Implementing Phase I of OBQI

To operationalize OASIS data collection and transmission, agencies systematically evaluate existing forms and processes (e.g., clinical documentation, paper flow, data entry for billing information, etc.) and make refinements or develop new processes to

ensure compliance with the HCFA Conditions of Participation (see Table 4). Once clinical assessment forms integrating OASIS are finalized, clinicians must be educated on the data items and time points for OASIS data collection. Tracking systems must be developed to ensure that data are collected at the required time points. Processes should be established for reviewing OASIS data prior to data entry and ensuring that missing or inaccurate data are corrected within a seven-day "lock" period. Agency policies regarding assessments and clinical competencies should be evaluated and revised as needed. Data entry software must be obtained and staff trained to encode and transmit OASIS data.

TABLE 4: Tasks to be Accomplished During OBQI Phase I Implementation.

- Revise clinical assessment forms to include OASIS data items
- Educate clinicians on new forms and OASIS data collection time points
- Develop tracking systems to ensure data are collected at required time points
- Establish OASIS review processes
- Evaluate and revise policies as needed
- Obtain OASIS data entry software
- Educate data entry staff

Agencies typically identify one or more staff members to liaison with State OASIS educational and technical coordinators and to work with agency staff to ensure successful implementation. Because OASIS data collection and management affects many different agency departments (e.g., clinical staff, administration, medical records, information systems, etc.), most agencies use a team approach to implement these changes.

C. Maintaining and Refining OASIS Data Collection, Encoding, and Transmission Processes

An OASIS data collection and reporting period is one year, and several months are needed after the end of the reporting period to produce outcome and case mix reports from those data. It is not uncommon in the middle and/or end of a data reporting period for agencies to lose the momentum associated with the early months of data collection. It is critical, however, that the data gathered during the entire year be complete and accurate so that reports will be meaningful. Clinical managers and QI coordinators should frequently acknowledge and reinforce the importance of the work field and office staff are doing related to data collection, encoding, and transmission.

All agencies, even those with years of OBQI experience, should periodically evaluate structures and processes for managing OASIS data (see Table 5). Processes for data collection, tracking, verification of the completeness and accuracy of the data, corrections to the data, and encoding and transmitting the data to the State Agency should be assessed. Each process should be reviewed for efficiency, effectiveness, identification of problems, and opportunities for system refinements.

TABLE 5: OASIS-Related Processes and Systems Needing Review.

- Data collection
- Tracking systems for OASIS assessments
- Data quality checks
- Process for obtaining corrections for incomplete or inaccurate OASIS data
- Data entry
- Data transmission

As a result of the review, agencies often find processes that can be improved. For example, some agencies may identify the need to further modify clinical documentation forms or to provide additional training for field clinicians or data entry personnel. Others may determine there is a need to include statements about OASIS data collection in competency guidelines. Agencies may determine that intake personnel can obtain some OASIS data (i.e., patient demographic information) to streamline the data collection process.

When evaluating data collection systems, it is common for agencies to identify issues with data tracking and follow-up of problematic data. It can be challenging to ensure that data are collected, checked for accuracy, revised (if necessary), and encoded within the required seven days. One possible system refinement is to implement up-front reviews to identify missing or inaccurate data before they are encoded. Other potential modifications include revising policies to require that clinicians submit all paperwork within 24 hours of their visit or changing "hospital hold" policies (i.e., policies allowing patients who are readmitted to inpatient facilities to remain on service). Agencies can often improve efficiency by integrating OASIS tracking processes with other agency tracking systems (e.g., billing systems). Agencies using manual tracking systems may consider implementing computerized systems.

Regardless of the agency's policies and systems, the importance of monitoring processes cannot be overemphasized. Agencies that fall behind in their efforts to acquire and manage data can face large "clean-up" efforts, requiring significant resources to catch up with data entry and transmission.

D. Assuring Data Quality

Since OASIS data are used for many purposes, agencies must strive to have the highest quality data possible. Clinical managers and QI Coordinators are often responsible for ensuring that the OASIS data collected in their agency are complete and accurate. Edit checks in Home Assessment Validation and Entry (HAVEN) and other OASIS data entry software were developed to identify problems in the data. Data audits, however, are the responsibility of the agency and should be conducted on a routine basis to ensure that data are collected accurately and encoded correctly. Chapter 12 of the HCFA *OASIS User's Manual* (HCFA, 1998) recommends several data audit techniques (see summary in Table 6).

TABLE 6: Data Quality Audits.

	Type of Audit	Frequency	# Patients or Records	Evaluation of
1.	Check OASIS data entered into software against corresponding paper version of assessment form.	Quarterly	Approx. 20 records	Accuracy of data entry
2.	Clinical Record Review: Compare OASIS assessment to documentation from visits conducted within 2-3 days of the OASIS assessment.	Quarterly	Approx. 10 records (5 admission records; 5 D/C records)	Accuracy of assessment and OASIS data recording
3a.	Two visits – Two clinicians: One clinician conducts and records OASIS assessment; within 24 hours another clinician conducts and records OASIS assessment. The two OASIS data sets are compared.	Quarterly	Approx. 5 patients	Accuracy of assessment and OASIS data recording
	and/or			
3b.	One visit – Two clinicians: One clinician conducts OASIS assessment and records OASIS data; a second clinician observes assessment and records OASIS data. The two OASIS data sets are compared.	Quarterly	Approx. 5 patients	Accuracy of assessment and OASIS data recording

One type of audit involves a check of encoded data against the corresponding paper version of the assessment form. This audit can be conducted for a sample of approximately 20 records on a quarterly basis and is a useful method for assessing data entry errors. Another audit technique is to conduct clinical record reviews, comparing an OASIS assessment to documentation from other visits occurring within approximately two to three days of the comprehensive assessment. Although some discrepancies between the OASIS assessment and other visits may reflect changes in the patient, large differences in patient status may be due to inaccurate recording of OASIS data items. A third audit strategy consists of two clinicians conducting separate visits to the patient within a short time frame (e.g., 24 hours), collecting OASIS data during both visits. Often agencies choose to have this occur during supervisory visits or with patients scheduled for daily visits. The OASIS responses from the two clinicians are then compared for discrepancies. Alternatively, two clinicians can be present during a comprehensive assessment. In this method, one clinician conducts the assessment while the other clinician observes. Both clinicians complete OASIS items. The responses for each clinician are then compared and discrepancies are discussed.

Data quality audits promote an understanding of the importance of accurate data and provide clinical managers and QI coordinators an opportunity to identify staff education needs. Many QI coordinators choose to conduct audits as part of their overall QI/PI program, using data accuracy as a quarterly QI indicator. In addition, managers often find that data audits provide an excellent tool for evaluating assessment skills of clinicians and data entry skills of clerical staff.

Chapter 3

Preparing for OASIS Reports

As discussed previously, maintaining motivation during the period of time (at least one year) that elapses between the beginning of the data collection period and the generation of OASIS reports can be challenging. Even the most visionary and dedicated clinician can become complacent during this period when the results of the hard work of data collection are not yet evident. One way to remind staff of the end result of data collection efforts and prepare them to interpret agency reports is to provide samples of OASIS-derived reports.

Several reports can be generated from OASIS data. Outcome reports allow agencies to assess their performance in terms of the impact of their care delivery on patients' health status. Evaluation of outcomes in comparison to reference samples (e.g., a national database) and to the agency's own data over time allows identification of specific areas of patient care that warrant attention, either because they need improvement or because they are exemplary and deserve reinforcement or replication. Adverse event outcome reports provide information on several low-frequency outcomes (e.g., Emergent Care for Falls or Accidents). Case mix reports provide detailed information about characteristics of patients admitted to an agency and can be used for strategic planning and other management decisions. Patient tally reports give patient-specific information on outcomes, case mix attributes, and raw OASIS responses. Many agencies generate other reports from OASIS data (e.g., a listing of patient primary diagnoses) for their own unique purposes.

Reports similar to agency outcome, adverse event outcome, and case mix reports will likely be generated by HCFA on an annual basis. Agencies choosing to create their own additional OASIS-derived reports, such as patient tally reports or other special reports, can use OASIS data entered into HAVEN or other data entry software. Brief explanations and examples of some of these reports are provided in this chapter.

A. Reports from OASIS Data

1. Outcome Reports

Outcome reports provide graphical information on the end-result and utilization outcomes of an agency's patients. End-result outcomes are changes in patient status between two points in time (usually admission and discharge). Utilization outcomes specify use of other health services (e.g., acute care hospitalization) typically reflecting a change in patient health status over time. Figure 3 provides an excerpt from a sample outcome report for the imaginary Faircare Home Health Services. It provides results for several OASIS-based outcomes for a 12-month time period. Alongside those outcomes are comparisons to outcomes of a reference sample of agencies and to the agency's own outcomes from a previous time period.

To produce the report, outcomes are calculated for individual patients, then aggregated to the agency level as the percentage of patients that achieved each outcome. To interpret the report, it is important to understand the following definitions (Appendix B provides additional definitions).

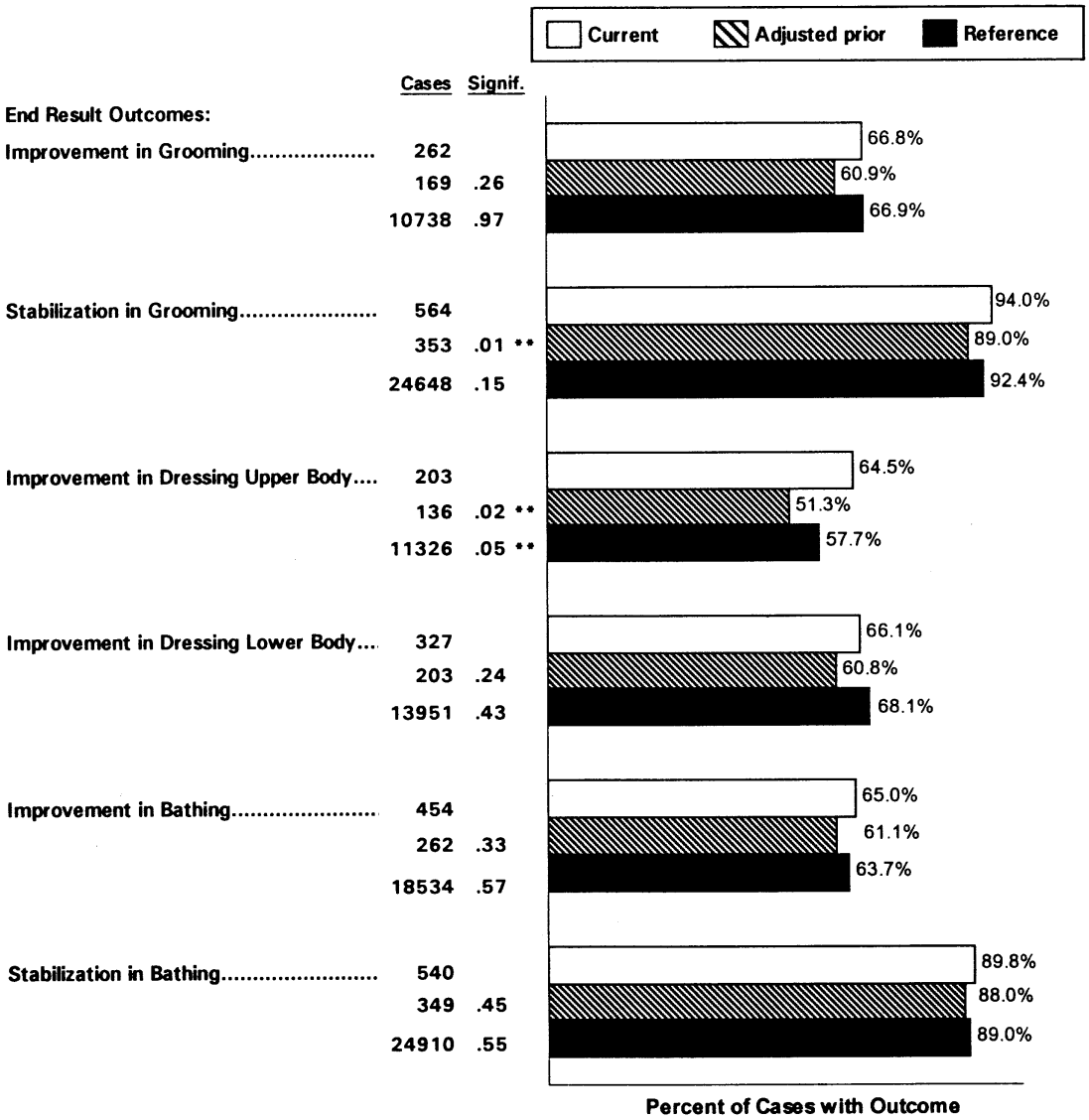
FIGURE 3: Outcome Report. [excerpt]

Agency: Faircare Home Health Services
Number of Cases in Current Period: 599
Number of Cases in Prior Period: 374
Number of Cases in Reference Sample: 26044

Date Report Printed: 02/28/2001
Current Period: 01/01/2000-12/31/2000
Prior Period: 01/01/1999-12/31/1999

All Patients' Outcome Report

Risk Adjusted



* The probability is 10% or less that this difference is due to chance, and 90% or more that the difference is real.

** The probability is 5% or less that this difference is due to chance, and 95% or more that the difference is real.

An **Improvement (Outcome) Measure** corresponding to a specific health status attribute (such as ambulation or dyspnea) is a dichotomous measure, having two levels. The measure takes on the value 1 if the patient improves or the value 0 if the patient does not improve.

An improvement measure *cannot be computed* if the patient's health is optimal for the attribute of interest at Start of Care (SOC) since the patient cannot possibly improve or achieve a more optimal level of health status according to the scale being considered. For example, a patient who is never short of breath would not be included in the calculation of the outcome measure Improvement in Dyspnea (shown in Figure 4).

FIGURE 4: Illustrative OASIS Item.

(M0490): **Dyspnea:** When is the patient dyspneic or noticeably **Short of Breath**?

0 - Never, patient is not short of breath
1 - When walking more than 20 feet, climbing stairs
2 - With moderate exertion (e.g., while dressing, using commode or bedpan, walking distances less than 20 feet
3 - With minimal exertion (e.g., while eating, talking, or performing other ADLs) or with agitation
4 - At rest (during day or night)

To illustrate calculation of an improvement measure, imagine that patient's condition improved by changing from level 2 to level 1 on the OASIS data item M0490 for dyspnea. In that situation, the dichotomous outcome measure "Improvement in Dyspnea" would take on the value 1. If the patient changed from level 2 to level 4, or started at 2 and remained at 2, the measure would take on the value 0. If the patient did not have dyspnea at SOC (level 0), then the health status is optimal according to this scale for dyspnea, and the improvement measure would not be computed for this patient. When calculating the agency-level outcome measure, the sum of patients with a value of 1 is the numerator. The sum of patients who could have improved (i.e., were not at the optimal level of health status according to the scale) is the denominator. The rate of patients improving is reported as a percentage. For example, in Figure 3, 66.8% of Faircare's patients who could have improved in grooming actually showed improvement.

A **Stabilization (Outcome) Measure** corresponding to a specific health status attribute (such as ambulation or dyspnea) is a dichotomous measure that takes on the value 1 if the patient does not worsen (i.e., improves or remains the same) and takes on the value 0 if the patient worsens according to the scale for the health status attribute under consideration.

A stabilization measure *cannot be computed* if the patient's health is at the most severely impaired level for the attribute of interest at SOC (i.e., the patient's condition cannot worsen according to the scale being considered). Using the OASIS item for dyspnea as an example (see Figure 4), a patient experiencing dyspnea at rest (during day or night) is not able to worsen according to the OASIS scale for dyspnea, and thus is excluded from calculation of the measure "Stabilization in Dyspnea."

To illustrate, if a patient began at level 2 at SOC and remained at level 2 at follow-up for the dyspnea scale, the dichotomous outcome measure "Stabilization in Dyspnea" would take on the value 1. If the patient changed from level 2 to level 1, the measure

would again take on the value 1. If the patient changed from level 0 to level 3, the measure would take on the value 0. If the patient was rated at the most extreme level of disability for the dyspnea scale (level 4) at SOC, the stabilization measure would not be computed for this patient.

When calculating the agency-level stabilization measure, the sum of patients with a value of 1 is the numerator. The sum of patients who could have stabilized (i.e., were not at the most severely impaired level of health status according to the scale) is the denominator. The rate of patients stabilizing is reported as a percentage. For example, in Figure 3, 94.0% of Faircare's patients who could have stabilized in grooming actually showed stabilization.

Significance is the statistical probability that the computed outcome difference would have occurred if the two groups being compared were really the same, in terms of outcomes (Shaughnessy and Crisler, 1995). It may be easier to understand if you consider statistical significance the probability (measured in percentages) that the difference in outcomes between your agency and reference data is due to chance. If the significance is greater than .10, then the possibility is high that the difference was due to chance. If the significance is less than .10, however, the possibility that the difference in outcomes is due to chance is low. In the illustrative outcome report shown in Figure 3, the difference between the current and adjusted prior finding for the outcome "Stabilization in Grooming" has a statistical significance level of .01. Thus, we can be 99% sure that the difference is real and not due to chance.

Outcome reports are most meaningful when outcomes are adjusted for case mix differences and comparisons are made to reference data. **Risk adjustment** is a statistical method of minimizing differences between groups in order to make valid outcome comparisons. For example, differences in the age of patients can have a strong influence on outcomes. If the average age of patients admitted to your agency is 85, compared with the average age of 65 for reference sample patients, differences in the outcomes might be accounted for by this fact alone. Risk adjustment takes such case mix differences into account when one agency's outcomes are compared with those of a reference sample. It is not essential, however, when comparing an agency's outcomes for different time periods if case mix remains relatively stable.

2. Adverse Event Outcome Reports

Adverse event outcome reports provide information on low-frequency negative or untoward events that potentially reflect a serious health problem or decline in health status for an individual patient. Because these are low-frequency events, they do not lend themselves to the types of analysis used for outcome reports. Figure 5 is an excerpt from an illustrative tabular adverse event outcome report. The **Agency Incidence** is the percentage of the agency's patients for whom the adverse event occurred. The **Reference Incidence** is the percentage of reference sample patients for whom the adverse event occurred. For example, in Figure 5, 2.0% of Faircare's patients received emergent care due to a fall or accident at home compared with 1.7% of the patients in the reference sample. Many agencies use adverse event outcome reports in Quality Assurance (QA) PI programs, often examining every case to determine if the adverse event could have been avoided. These efforts, however, should complement, not substitute for, outcome enhancement activities to improve or maintain end-result or utilization outcomes.

FIGURE 5: Adverse Event Outcome Report. [excerpt]

Agency: Faircare Home Health Services **Date Report Printed: 02/28/2001**
Number of Cases in Current Period: 300 **Report Period: 01/01/2000 – 12/31/2000**
Reference Sample: 11183

Adverse Event Outcome Report

Emergent Care for Falls or Accidents

Complete Data Cases 300 **Number of Events 6** **Agency Incidence 2.0%** **Reference Incidence 1.7%**

Patient ID	Branch	SOC/ROC	DC/Tran	Patient ID	Branch	SOC/ROC	DC/Tran
100000041	1	02/16/97	05/21/97	100000231	1	07/20/97	11/21/97
100000107	3	04/01/97	07/01/97	100000582	2	10/03/97	01/03/98
100000167	3	05/04/97	10/30/97	100000649	2	12/01/98	01/05/98

Emergent Care for Wounds or Infections

Complete Data Cases 280 **Number of Events 4** **Agency Incidence 1.4%** **Reference Incidence 1.9%**

Patient ID	Branch	SOC/ROC	DC/Tran	Patient ID	Branch	SOC/ROC	DC/Tran
100000041	1	02/16/97	05/21/97	100000169	3	05/04/97	10/30/97
100000105	3	04/01/97	07/01/97	100000257	1	07/20/97	11/21/97

Development of Urinary Tract Infections

Complete Data Cases 250 **Number of Events 10** **Agency Incidence 4.0%** **Reference Incidence 2.3%**

Patient ID	Branch	SOC/ROC	DC/Tran	Patient ID	Branch	SOC/ROC	DC/Tran
100000017	3	02/15/97	04/17/97	100000254	3	07/10/97	09/20/97
100000116	1	04/10/97	07/07/97	100000464	2	07/13/97	09/10/97
100000191	1	05/23/97	10/14/97	100000549	1	09/03/97	01/05/98
100000213	2	05/29/97	08/14/97	100000580	2	09/23/97	01/05/98
100000226	3	06/20/97	11/24/97	100000637	2	11/21/97	01/04/98

NOTE: Incidence = [(Number of Events)/(Complete Data Cases)], computed separately for each measure.
SOC/ROC = Start of Care or Resumption of Care.

3. Case Mix Reports

Case mix reports contain information on the demographics, environmental and social support characteristics, and health status of patients admitted to the home care agency. It is a "snapshot" of the characteristics of patients at Start of Care or Resumption of Care (SOC/ROC). As with outcome reports, comparisons to a reference sample and to data from a previous data collection period are provided.

In the illustrative case mix report excerpt presented in Figure 6, the average age of Faircare patients is 75.9 compared with an average age of 70.7 for a prior reporting period and 73.0 for the reference group. Instead of presenting the actual significance levels between current and prior data comparisons, one asterisk indicates a statistical significance level of .05; while two asterisks indicate a statistical significance level of .01. For comparisons between current and reference data, one dagger indicates a statistical significance level of .01; two daggers indicate a statistical significance level of .001. Monitoring case mix over time can be helpful for budgeting, resource allocation, and program development.

FIGURE 6: Case Mix Report. [excerpt]

Agency: Faircare Home Health Services
Number of Cases in Current Period: 901
Number of Cases in Prior Period: 601
Number of Cases in Reference Sample: 37765

Date Report Printed: 02/28/2001
Current Period: 01/01/2000-12/31/2000
Prior Report Period: 01/01/1999-12/31/1999

All Patients' Case Mix Profile at Start of Care/Resumption of Care
All Patients

	Means				
	Current	Prior[1]		Reference[2]	
Demographics					
Age (average in years)	75.9	70.7	**	73.0	‡
Gender: Female (%)	68.2%	69.4%		62.7%	‡
Race: Black (%)	0.4%	1.7%	*	13.0%	‡
Race: White (%)	98.8%	97.5%		82.7%	‡
Race: Other (%)	0.8%	0.8%		4.3%	‡
Payment Source					
Any Medicare (%)	93.7%	80.4%	**	82.8%	‡
Any Medicaid (%)	8.3%	12.9%	**	14.6%	‡
Any HMO (%)	3.8%	3.0%		8.8%	‡
Medicare HMO (%)	2.2%	1.3%		3.8%	†
Any third party (%)	17.9%	19.9%		20.2%	
Current Residence					
Own home (%)	74.7%	74.1%		79.3%	‡
Family member home (%)	22.5%	20.5%		13.8%	‡
Current Living Situation					
Lives alone (%)	27.4%	28.6%		29.2%	
With family member (%)	65.8%	66.7%		63.5%	
With friend (%)	1.6%	1.3%		1.6%	
With paid help (%)	4.1%	2.3%		5.0%	
Assisting Persons					
Person residing in home (%)	60.5%	57.0%		55.1%	‡
Person residing outside home (%)	36.0%	44.3%	**	53.4%	‡
Paid help (%)	10.5%	9.3%		14.0%	†
Primary Caregiver					
Spouse/significant other (%)	29.8%	31.0%		31.9%	
Daughter/son (%)	35.3%	33.0%		26.0%	‡
Other paid help (%)	6.3%	3.7%	*	6.5%	
No one person (%)	19.2%	21.7%		23.2%	†

[1] The asterisks represent the significance levels of the current and prior data comparisons.
[2] The daggers represent the significance levels of the current and reference data comparisons.

4. Patient Tally Reports

Patient tally reports give information on individual patient case mix characteristics, outcomes, and raw OASIS data responses. An excerpt of an illustrative patient tally report is presented in Figure 7. An "x" under the outcome heading indicates that the patient achieved the outcome, an "o" indicates the patient did not achieve the outcome, and a "-" means that the outcome was not calculated for the patient. In the illustrative tally report, patient 1012-06 achieved the outcome "Stabilization in Bathing," but did not achieve the outcome "Improvement in Ambulation." A report with individual patient data is extremely helpful to agencies using OBQI. As part of the outcome enhancement

phase, agencies target one or two specific outcomes for investigation. The tally report assists QI/PI teams in identifying patients who achieved the target outcome vs. those patients who did not achieve the target outcome. HCFA may eventually provide these reports for agencies. Agencies, however, can produce their own tally reports by extracting patient-level data from OASIS data entry software files using database software. Using definitions for improvement and stabilization outcomes, agencies can isolate individuals who were eligible for and achieved specific outcomes.

FIGURE 7: Patient Tally Report. [excerpt]

Agency: Faircare Home Health Services

All Patients' Illustrative Tally Report: Outcomes

Date Report Printed: 02/28/2001

Report Period: 01/01/2000-12/31/2000		**Functional Activities**									
		Activities of Daily Living									
Patient ID	Start of Care Date	Improv in grooming	Stabil in grooming	Improv in dressing upper body	Improv in dressing lower body	Improv in bathing	Stabil in bathing	Improv in toileting	Improv in transferring	Stabil in transferring	Improv in ambulation
1012-06	03/21/00	-	x	-	-	o	x	-	-	x	o
1036-03	02/22/00	-	-	-	-	-	-	-	-	-	-
1036-04	03/07/00	-	x	x	x	x	x	-	x	x	o
1048-04	04/21/00	x	x	o	o	x	x	x	o	x	o
1122-02	05/30/00	x	x	x	x	x	x	x	-	o	o
1139-02	04/05/00	-	x	-	-	o	x	-	-	x	o
1148-04	05/07/00	o	x	o	o	o	x	o	-	o	o
1286-02	07/29/00	-	x	-	-	o	x	-	-	x	o
1287-07	05/09/00	-	x	-	-	-	x	-	-	x	o
1323-04	04/15/00	-	o	o	o	o	x	-	o	x	o
1328-02	08/08/00	-	x	-	-	o	x	-	x	x	o
1338-06	02/20/00	-	x	-	x	o	x	-	-	o	o
1338-07	11/06/00	-	x	-	-	o	x	-	o	x	o
1382-02	11/13/00	-	x	-	-	x	x	-	-	o	o
1383-02	02/06/00	-	x	-	-	-	x	-	-	x	-
1392-03	02/22/00	-	-	-	-	-	-	-	-	-	-
1403-04	02/12/00	-	x	-	-	o	x	-	o	x	o
1403-05	07/11/00	-	x	-	-	x	x	x	-	x	o
1413-02	07/01/00	-	-	-	-	-	-	-	-	-	-
1425-05	04/21/00	-	x	-	-	o	o	-	-	o	o
1425-06	09/18/00	-	-	-	-	-	-	-	-	-	-
1425-07	12/01/00	-	-	-	-	-	-	-	-	-	-

5. Agency-Defined Reports

Many agencies choose to specify other types of reports from OASIS data. These agencies collaborate with staff members or consultants who have database experience to extract the desired information from OASIS data entry software files. Examples of reports that agencies have developed include summary reports on primary diagnoses or the number of patients with specific third-party payers. Other helpful report variables may be length of service or number of patients hospitalized. Agencies can add information to OASIS-derived reports such as services provided and the number of visits made in an episode to generate utilization profiles (Lee, 1999; McCann, 1999). These agency-defined reports provide useful information for strategic planning, budgeting, and other management activities.

When specifying reports, it is important to be as precise as possible. For example, should report variables be presented as numbers, percentages, or rates? Query variables should be clearly defined with the specific OASIS data item related to the query. If more than one variable is needed, then it may be helpful to separate the query into its smallest components. For example, suppose a report is needed for patients over 65 with a primary or secondary diagnosis of hip fracture. For this report, it would be helpful to specify two queries: Query 1: List all patients over 65; Query 2: Of those patients, list the patients with a primary or secondary diagnosis of hip fracture. Once reports have been clearly defined, then they can be generated from database software. If OASIS data were entered into HAVEN software, the data files are stored on the computer in a Microsoft Access™ database. From that file, the data are accessible for queries and reports. For OASIS data entered into other software, agency staff should contact their software vendor for assistance in defining and generating reports.

B. Linking Outcome and Cost Data

Once agencies have become proficient at collecting outcome data and using outcomes for quality improvement activities, they will be able to use this information to determine the costs of delivering care related to specific outcomes. For example, did patients who achieved the outcome for "Improvement in Bathing" have more visits than patients who did not improve in bathing? These data can help administrators and managers make decisions on how to best invest limited resources in patient care. For example, an agency with poor outcomes could assess if they are providing an adequate number of visits. Figure 8 shows an example of a resource consumption report that agencies may ultimately use in conjunction with outcome reports. In this example, Faircare may not be providing enough visits to achieve excellent health outcomes.

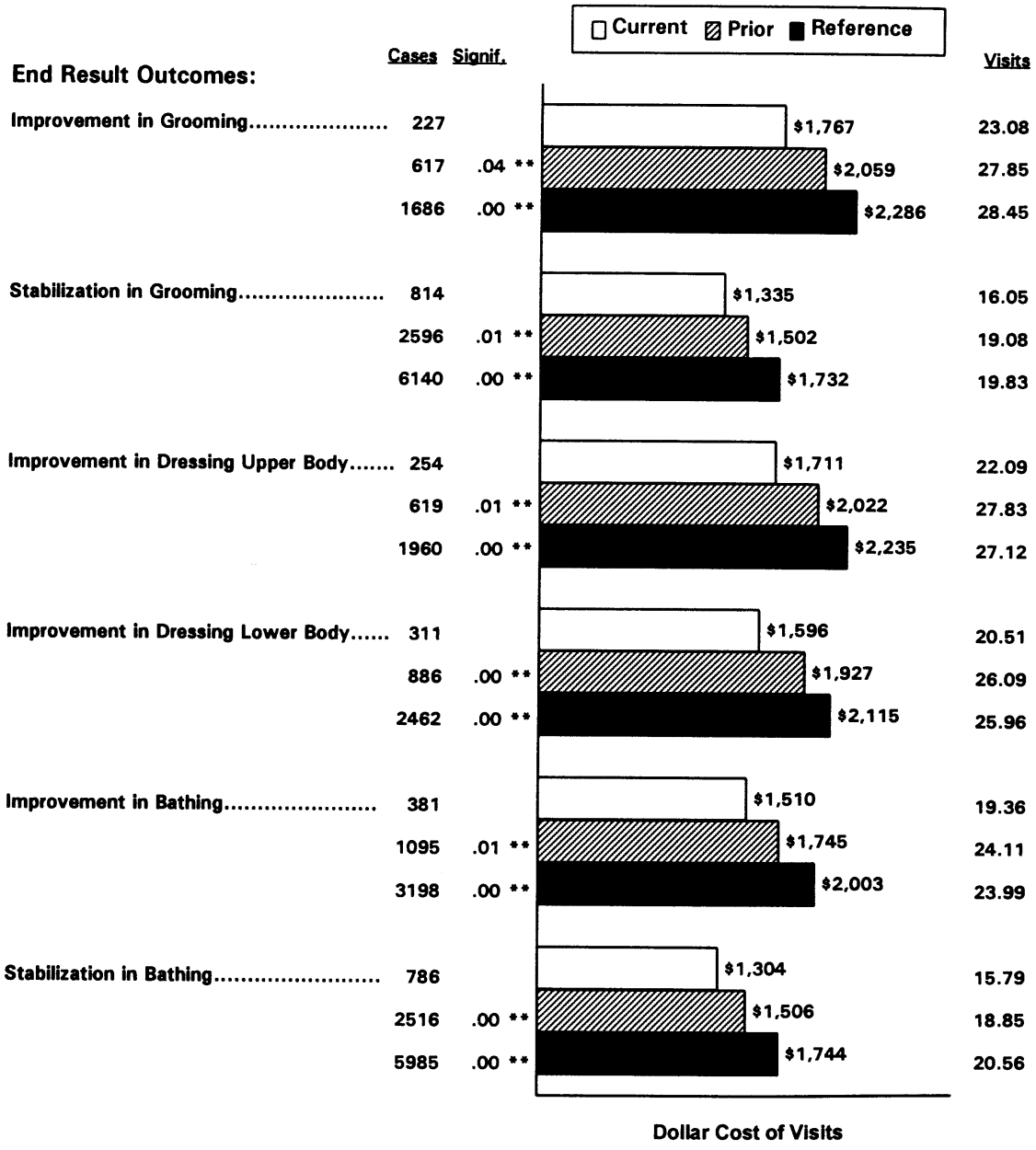
FIGURE 8: Resource Consumption Report. [excerpt]

Agency: Faircare Home Health Services
Number of Cases in Current Period: 1256
Number of Cases in Prior Period: 3048
Number of Cases in Reference Sample: 9784

Date Report Printed: 03/31/1998
Current Period: 02/01/1997 - 01/31/1998
Prior Period: 02/01/1996 - 01/31/1997

All Patients' Resource Consumption Profile (By Outcome)

Unadjusted



* The probability is 10% or less that this difference is due to chance, and 90% or more that the difference is real.
** The probability is 5% or less that this difference is due to chance, and 95% or more that the difference is real.

As OBQI evolves, the focus will be on how to deliver superior care in the most cost-effective manner possible. As Figure 9 illustrates, OASIS data collection is just the beginning.

FIGURE 9: Linking Outcomes to Resources.

OASIS is the vehicle for assessing clinical outcomes. Clinical outcome data can be evaluated in relation to the processes of care provided to patients. Clinicians then can use best practices consistently to achieve specific outcomes. When the resources necessary to achieve outcomes are determined and managed along with care delivery, the end result should be cost-effective, high-quality care.

Chapter 4
Implementing OBQI Phase II: Outcome Enhancement

The outcome enhancement phase of OBQI begins after agencies receive outcome reports. During this phase, agency staff review outcome and case mix reports and select one or two outcomes that merit further investigation because they are significantly different (i.e., inferior or superior) than comparison outcomes. Selected agency staff, such as an interdisciplinary QI/PI team, investigate processes of care that produced the target outcomes. As a result of findings from the investigation, a plan of action to improve problematic care processes or to reinforce excellent care techniques is developed, implemented, and monitored. The subsequent outcome report allows the agency to evaluate the effect of the action plan on patient outcomes.

A. Principles of CQI and OBQI

The OBQI process is based on key principles of continuous quality improvement (CQI) (summarized in Table 7). Agencies committed to CQI are generally able to successfully implement OBQI. Agencies using these principles are determined to meet their customer needs and expectations. They strive to continuously and accurately measure the effectiveness of the care that clinicians provide and to focus on problematic processes, rather than individuals, when something goes wrong. While investigating problems, they analyze procedural difficulties, including potential problems with inter-departmental communications and relationships. Allocation of resources for QI activities such as ensuring data quality, interpreting outcome reports, investigating care processes related to outcomes, and implementing action plans to expand the use of best practices is a priority. These agencies strive to use systematic methods as they investigate opportunities for improvement and implement activities designed to enhance quality.

TABLE 7: Key Principles of CQI.

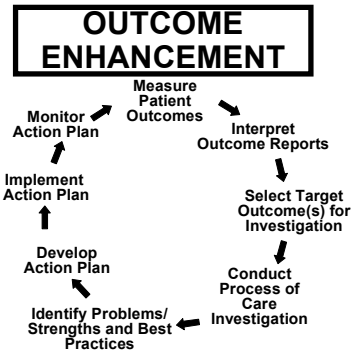
- Recognize all internal and external customers and commit to meeting customer needs and expectations
- Focus on problematic processes rather than assign blame to individuals
- Assess relationships between departments when evaluating problematic processes
- Commit adequate resources to quality improvement efforts
- Strive to adequately and accurately measure performance
- Use systematic methods for quality improvement

Agencies that are fully committed to principles of CQI believe that providing the highest quality of care possible is their responsibility to patients and critical to their own viability (Joint Commission on Accreditation of Healthcare Organizations, 1996). Most also find that the return on investment of QI/PI efforts, when done correctly, is well worth the expense.

B. The Outcome Enhancement Process: Step by Step

The outcome enhancement phase of OBQI consists of seven steps, linking back to OASIS data collection and measurement of patient outcomes. These steps should be performed in a short period of time (e.g., within one month after receiving the outcome report), to maximize the likelihood that any changes in outcomes due to outcome enhancement activities will be evidenced on the subsequent outcome report. Figure 10 illustrates the steps of the outcome enhancement process, which are discussed in more detail below.

FIGURE 10: The Outcome Enhancement Process.



1. Interpreting Outcome Reports

Prior to receiving outcome reports, many agencies identify a team of staff members to interpret the reports. The team should be provided with sample reports and interpretive documentation and allowed to practice interpreting reports if time permits.

Team members should also be aware of reactions to outcome reports that home care agency staff frequently experience. When first presented with reports, it is not uncommon for agency staff to experience "data shock." It is often the first time that agencies see the results of their care presented in report format, and the amount and detail of information in OASIS reports can seem overwhelming. Many times staff react in a defensive manner, questioning the quality of the data and the validity of the analysis. Reactions may include statements such as, "The data must have been wrong because I know our patients get good care," and "Our patients are so different than those from other agencies, I'm sure that explains our outcomes." It is important for the team to quickly move past initial reactions so the remaining steps of the outcome enhancement phase can be completed in a timely manner.

Team leaders may find it necessary to remind themselves and others of the actions taken during the data collection effort to ensure data quality. If reports are risk adjusted, the team leader may find it helpful to remind the team that differences between the agency and the reference sample are taken into account in the analysis.

2. Selecting Target Outcomes

The next step of the process is to identify one or two outcomes for further investigation. It is recommended that agencies limit the number of target outcomes to ensure that the relevant care processes can be thoroughly investigated and action plans developed and implemented within approximately one month after receiving the outcome report. Several criteria should be applied during the process of selecting target outcomes (see Table 8).

TABLE 8: Criteria for Selecting Target Outcomes.

- Statistical significance
- Number of cases
- Magnitude of the outcome difference
- Relevance to agency's goals
- Clinical significance
- Agency's ability to influence outcome

One of the most important criteria to consider when selecting target outcomes is statistical significance. As explained in Chapter 3, if the difference between an agency's outcome and the corresponding reference outcome is statistically significant, we can presume that the difference is a true difference. Agencies should also consider the number of cases included in the outcome measure calculation. If only a small number of cases were used (i.e., fewer than 30), the outcome results may not be representative of the agency's patient caseload and should therefore be interpreted cautiously.

The magnitude of the outcome difference, or the actual percentage point difference between the agency's outcome and the reference outcome, should also be considered. For example, an outcome that is different than the reference outcome by 15 percentage points may be more important than one that differs by only 3 percentage points, even if both differences are statistically significant. Additional criteria for selecting target outcomes are the outcome's importance or relevance to agency goals, clinical significance, and the agency's ability to influence the outcome by changing care behaviors (Shaughnessy & Crisler, 1995).

3. Investigating Care Processes

Once a target outcome is selected, agencies typically form an interdisciplinary QI/PI team to examine the care associated with the outcome. The team systematically investigates the care provided to patients, comparing it to a gold standard to determine whether appropriate care processes were used. The "gold standard" may be agency-specific and is often a clinical pathway or a standard protocol for care for specific types of patients. For example, a "gold standard" for care of cardiac patients may include twice-weekly weight checks for evidence of fluid retention. The team would investigate whether patients who worsened in dyspnea actually received twice-weekly weight checks during the home care episode.

The team should carefully evaluate the completeness, appropriateness, and accuracy of assessments, care plans, teaching, clinical interventions, interdisciplinary communication, and evaluation of patient response to teaching or interventions provided during the patient's home care episode. The team may use a tally report (such as the illustrative tally report provided in Chapter 3) to identify patients for record review. In order to identify patterns of care, approximately 10-15 records should be reviewed for patients that achieved the outcome, and the same number of records for patients who did not achieve the outcome. The care provided for each group of patients should be examined and compared. Many familiar CQI tools and techniques may be used during the investigation. Agencies have found that methods such as brainstorming, flow-charting, clinical record review, clinician interviews, and cause-and-effect diagramming can be particularly helpful when evaluating processes of care.

Agencies choosing a target outcome that is superior to reference data follow similar steps to identify care processes associated with the excellent outcome. This presents some unique challenges, since agencies are typically not accustomed to examining why the care they provide results in exemplary outcomes. However, as agencies become familiar with OBQI processes, it is likely that more will choose to investigate outcomes that compare favorably to reference data.

4. *Identifying Problems/Strengths and Best Practices*

During the investigation, the QI/PI team identifies specific problematic care practices needing remediation and strengths needing reinforcement. When summarizing findings, the team should list the problems and strengths in a specific, succinct statement. Following the problem or strength statement, corresponding best practices that should be used in care delivery should be identified. For example, a problem statement, "Clinicians do not consistently assess pain at every visit," could be followed by the corresponding best practice, "Clinicians will assess pain by requesting patients with pain to rate its intensity on a scale of 0 - 10 (0 = no pain; 10 = intolerable pain)." Best practices corresponding to strength statements may be very similar. For example, a strength statement, "Clinicians consistently contact the physician when post-op patients have oral temperatures of 100.5 F or greater," may be followed by the corresponding best practice, "Clinicians will continue to consistently contact the MD for post-op patients with oral temperatures of 100.5 F or greater."

Statements of problems, strengths, and best practices should be focused on patient care. Statements may include any component of patient care including assessment, care or teaching plans, clinical interventions, teaching strategies, interdisciplinary coordination, and follow-up or evaluation. It is important to recognize that changes in how care is provided have the strongest impact in terms of improving patient outcomes. Although the quality of documentation should also be evaluated and addressed, changes in the way care is documented without concurrent changes in care delivery will not likely affect the end result outcomes for patients.

5. *Developing an Action Plan*

Problems or strengths and best practices become the foundation for a plan of action. The action plan is the roadmap for change, a systematic strategy to educate staff on best

practices and to promote their use in care delivery. Figure 11 is an abbreviated example of an action plan (complete action plans list team members by name and typically include more intervention activities). When developing the action plan, the QI/PI team should clearly specify the target outcome, problem and/or strength statements, and best practices. The team should then identify specific actions for bringing about change. These may include approaches such as developing or refining policies or procedures, standardized care plans, teaching guides, or critical pathways; securing new equipment; developing or expanding specialty programs; staff education programs; consulting with experts; updating clinical competency guidelines; or implementing mentoring programs. Research suggests that a layered approach to intervention strategies (i.e., using more than one method) is often the most effective (Davis, et al., 1995).

Figure 11: Illustrative Plan of Action.

Plan of Action for Continuous Quality Improvement

Outcome Report Date 1/3/2001 Plan of Action Date 1/17/2001

Target Outcome Addressed by Plan of Action:

Improvement in Management of Oral Medications.

Identified Problem or Strength:

When a deficit in management of oral medications due to poor manual dexterity is identified, the teaching plan rarely addresses issues with manual dexterity.

Care Behaviors or Processes Selected as Best Practices (Prioritized):

For patients with poor manual dexterity leading to deficits in oral medication management, clinicians will plan and teach alternate methods for managing medications (e.g., using flip-top medication planners.)

Intervention Actions (Prioritized):

Action	Time Frame		Responsible Person(s)	Monitoring Approaches (and Frequency)
	Start	Finish		
a. Revise medication teaching guide to include a section for documenting teaching of alternate methods for managing oral medications for patients with poor manual dexterity.	1/18/01	1/24/01	Peggy	QI team will review revised guide 1/26/01
b. Disseminate new medication teaching guide to clinicians via in-house mail	1/26/01	1/28/01	Mark	Supervisors to speak to each clinician to ensure he/she received medication teaching guide by 2/2/01.
c. Discuss teaching plan in Staff Meeting.	2/2/01	2/2/01	Jean	Discussions will be documented in staff meeting notes.

Evaluation:

a: Review of Plan:
Date: 03/1/2001
Responsible Person(s) Peggy, Mark, Jean

b: Next outcome report:
Date:_____
Result:_____
Next Step(s):

Results:

c: Monitoring Activities:

(1) Activity: Quarterly clinical record review to determine if clinicians are documenting in the new section of the medication management form.
Date completed:
Findings:
Response:

(2) Activity: Discussions of clinical record review findings in quarterly QI meeting and subsequently in a staff meeting.
Date completed:
Findings:
Response:

Specific time frames and responsible individuals should be identified for each intervention action to ensure that the plan is implemented. For each intervention action, a specific monitoring activity to determine if the action was carried out according to the plan should be listed. Using the example in Figure 11, if a new medication guide was disseminated, a monitoring approach could be that supervisors speak directly to each clinician to ensure they received the new guide. In addition to monitoring each individual change strategy, a plan for reassessing (monitoring) the overall implementation of action plan should be identified. In the illustrative action plan, an overall plan monitoring activity is quarterly clinical record review to determine if clinicians utilize the new medication teaching guide.

6. Implementing the Action Plan

Activities to change or reinforce care practices should be implemented according to the plan. As previously mentioned, these activities should be implemented as completely as possible within one month of receiving the outcome reports. This short time frame permits several months for the changes to coalesce in the agency, and allows time for the impact of the care process changes on the target outcome to be measured for the subsequent outcome report. Although it may not be possible to comprehensively implement the action plan within one month, all activities should be initiated within the month. Because data collection time periods are typically one year, most agencies will find it necessary to reinforce the intervention strategies throughout the OASIS data collection period. This may involve issuing reminders to clinicians of the goal of improving or maintaining target outcomes (e.g., during staff meetings, in newsletters, supervisory meetings, etc.), or reinforcement of specific strategies if monitoring activities determine a need for such reinforcement.

7. Monitoring the Action Plan

The QI/PI team should evaluate whether each intervention action was implemented completely and within planned timeframes, using the monitoring activities specified in the plan. This evaluation should occur approximately one month after the implementation of the plan. The overall plan should be evaluated (monitored) at three months and periodically (e.g., quarterly) during the subsequent data reporting period to evaluate if best practices are being utilized in care delivery. For example, if the QI/PI team implemented a new medication teaching guide, quarterly record reviews can be used to determine if field staff are using the guide appropriately. If the action plan is not resulting in changes in care practices, refinements or revisions (e.g., additional intervention strategies) may be developed and implemented. Regular monitoring and modifications to the action plan as needed increase the likelihood that target outcomes will be improved or at least maintained.

8. Measurement of Patient Outcomes

In an OBQI system, the effectiveness of outcome enhancement activities is ultimately measured in terms of changes in target outcomes. By comparing the target outcome results over time, the agency will be able to objectively assess whether they have been able to improve or maintain outcomes. Thus, the outcome enhancement activities lead back into measurement of patient outcomes, continuing the OBQI cycle.

Chapter 5
Successfully Implementing an OBQI Program

Clinical managers and QI coordinators typically carry the primary responsibility for implementing OBQI in a home care agency. A comprehensive understanding of all OBQI components is necessary before moving forward with OBQI implementation. The detailed information in Chapters 2-4 provides a solid foundation for understanding how OBQI works. In addition to understanding the process, however, managers are responsible for "setting the stage" for OBQI at an organizational level (see Table 9).

TABLE 9: Responsibilities of Clinical Managers and QI Coordinators.

- Create an environment conducive to OBQI
- Work with administrators to secure necessary resources
- Educate staff on fundamentals of OBQI
- Evaluate and refine structures and processes supporting OBQI
- Ensure data quality
- Prepare agency for outcome enhancement activities
- Anticipate and respond to evolutionary changes to OBQI

This involves creating an environment conducive to OBQI (including motivating staff at all levels) and working with administrators to secure necessary resources. Managers and QI coordinators are often responsible for educating staff on all aspects of OBQI and evaluating and refining structures and processes for data collection, encoding, transmission, and outcome enhancement. As discussed in Chapter 2, clinical managers and QI Coordinators are usually responsible for assessing and ensuring that OASIS data are of the highest quality. They are accountable for preparing the agency for outcome enhancement activities and ensuring that those activities are conducted. When implementing OBQI programs, they should also anticipate that OBQI will evolve over time, and should be prepared to make changes to their systems as needed. Several of these management responsibilities are discussed in more detail below.

A. Providing an Environment Conducive to OBQI

Implementing OBQI requires an agency-wide commitment to evaluating performance regularly in terms of patient outcomes and to improving patient care on an ongoing basis. In OBQI, the focus is on the patient, not on agency staff. For many agencies, this requires a shift from a culture based on administrative needs to a culture focused on patient needs. The importance of leadership "buy-in" to this concept cannot be underestimated. It is the responsibility of agency managers to lay the groundwork for a culture conducive to OBQI by emphasizing the usefulness of OASIS and by highlighting its direct and indirect benefits for the agency and patients.

Clinical managers and QI coordinators should maintain open communications with staff about the purpose of collecting data and share with them the various OASIS-derived reports to reinforce the high value placed on OBQI. Participation in OASIS data collection and OBQI activities are professional responsibilities for all home care clinicians. As such, performance standards should reflect an expectation that clinicians be competent in conducting comprehensive assessments (including collection of OASIS data items) and that they participate in OBQI teams and activities. This focus on professional accountability can empower staff to actively identify opportunities for change and improvements in patient care.

B. Acquiring Resources Necessary for OBQI Implementation

Implementation of OBQI requires agencies to make a commitment to allocating sufficient resources for data collection, tracking, encoding, and transmission activities, as well as outcome enhancement activities. To monitor the quality of OASIS data, clinical managers and QI coordinators should work with agency administrators to ensure that resources are dedicated for data audit activities. Managers wishing to generate reports from OASIS data (beyond reports that HCFA will ultimately provide) will need to ensure the availability of appropriate resources and personnel with database expertise. When outcome reports are received, interdisciplinary QI/PI teams must be allocated sufficient time to implement outcome enhancement activities.

Many agencies have developed creative approaches to minimize costs. One demonstration agency videotaped a simulated patient assessment. The videotape was used periodically to evaluate assessment competencies and to train clinicians in OASIS data collection. Several agencies used interdisciplinary teams to brainstorm ideas on how they could combine OBQI functions with other agency functions. For example, one agency used OASIS items to develop an acuity score to screen patients for potential physical therapy referrals. Others combined OASIS data audits with clinical supervisory visits to accomplish several goals during a single patient visit. One agency implementing OBQI used outcomes to identify the need for specific clinical pathways (Polzien, Kendall, and Hindlang, 1998). These examples illustrate how OBQI functions can be integrated into existing functions in a manner that is both efficient and cost-effective.

C. Preparing for the Outcome Enhancement Phase of OBQI

With planning and foresight, most agencies can easily integrate outcome enhancement activities into existing QI/PI programs. Once agencies are capable of collecting and transmitting OASIS data consistently, clinical managers and QI coordinators should begin to prepare the agency for outcome enhancement activities (see Table 10).

TABLE 10: Planning for Outcome Enhancement Activities.

- Identify team members.
- Initiate teambuilding activities.
- Familiarize staff with outcome and case mix reports.
- Educate QI/PI team members on outcome enhancement process.
- Allow time for practice exercises to reinforce outcome enhancement concepts.

Identification of multidisciplinary QI/PI team members and initiation of team-building activities is a good way to prepare staff for receiving OASIS-based reports and conducting outcome enhancement activities. If necessary, QI/PI teams should be introduced to general QI/PI concepts and tools and to the fundamentals of OBQI. Sample statistical outcome and case mix reports should be used to educate team members on interpreting reports. It may be helpful to lead QI/PI teams through mock record reviews or staff interviews during practice process of care investigations. Following practice investigations, teams should practice developing problem statements, corresponding best practices and plans of action. Providing these and other educational opportunities for staff in advance of receiving agency outcome reports can facilitate a smooth, streamlined approach to outcome enhancement activities. By preparing staff for interpreting OASIS reports and outcome enhancement activities, clinical managers can pave the way for a successful OBQI program.

D. Maintaining and Refining OBQI

Just as home care has evolved over time, OBQI will also evolve. Updated versions of OASIS will be released periodically, with corresponding changes in data entry software. As the home health industry collectively gains experience with OASIS and OASIS-derived reports, new and creative approaches to accomplishing the goals of OBQI will be generated. For example, agencies and vendors will likely develop the ability to generate a variety of management reports from OASIS data. In all probability, clinical best practices for specific OASIS-derived outcomes will be identified and made available to the industry. As the case mix of home health patients changes over time, new outcome measures may be developed.

OBQI requires an ongoing commitment to evaluating performance and striving to improve care. Clinical managers and QI coordinators should ensure that agencies build flexibility into the system as they implement and maintain an OBQI approach. OBQI processes should be evaluated regularly and refinements made as needed. Agencies should be prepared to incorporate changes in OASIS data items and data entry software as revisions are released. Clinical managers and QI coordinators should network with colleagues and monitor industry publications to keep abreast of new developments and to share ideas and approaches maintaining OBQI programs. By sharing their experiences, agencies have an opportunity to contribute to the ongoing development and evolution of OBQI nationally.

Chapter 6
Summary

Although OASIS and OBQI involve some complex implementation steps and require attention to many details, a few key points (many of which are new to home health agencies) capture the essentials:

- OBQI represents a turning point in the evolution of home health care in the United States, allowing agencies to demonstrate the effectiveness of the services they provide in a valid, objective manner using OASIS-derived reports.

- OBQI is two-phase system. The first phase is the outcome analysis phase, consisting of data collection and analysis. The second phase, the outcome enhancement phase, includes interpreting outcome and case mix reports, selecting target outcomes, investigating care processes linked to outcomes, and developing, implementing, and monitoring a plan to improve or maintain outcomes.

- OBQI is a data-driven system, and the quality of reports (and thus their value to agencies) is related directly to the quality of OASIS data collection and encoding. Achieving and maintaining high-quality OASIS data collection is, therefore, a critical internal agency function.

- OASIS, implemented solely to meet regulatory compliance, will likely be perceived as a burden. OASIS data used in OBQI and other management decisions will prove to be a powerful tool for patient care and agency operations.

- To effectively implement OBQI, agencies must have a strong commitment at all levels to QI principles, an understanding of the types of output that can be generated from OASIS data, the realization that internal agency structures and processes must recognize and demonstrate the value of OBQI, and the ability to support ongoing development and change.

- Sharing examples of OASIS-derived reports can help motivate staff during the beginning of the data collection period. Sharing these reports can also be helpful in preparing the agency for outcome enhancement activities.

- A comprehensive understanding of all the components of OBQI is necessary before moving forward with OBQI implementation. In addition, clinical managers and QI coordinators must "set the stage" at an organizational level by providing an environment conducive to OBQI, working with administrators to obtain the necessary resources, educating staff on OBQI activities, and overseeing those activities.

- Just as home care continues to evolve over time, so will OBQI. Agencies must be prepared to respond to revisions in OASIS and data entry software. By networking with colleagues and sharing experiences, clinical managers and QI coordinators become part of the ongoing development of OBQI.

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Appendix A

Troubleshooting Guide for Implementing OBQI

SITUATIONS	HOW AGENCIES HAVE RESPONDED
Our OBQI program doesn't seem to be going anywhere -- we started collecting and transmitting OASIS data but there isn't any direction to the program.	• Review which individuals are involved in your OASIS program. When staff at all levels of the organization, especially administration, are knowledgeable about OASIS and committed to data quality and continuous QI/PI, the program becomes more directed.
Everyone in our agency is really "down" about OASIS.	• Listen to the approach or language that key staff use. • Try to identify specific problems. For example, were comprehensive assessments not being completed for patients prior to OASIS? Is staff trying to read every OASIS question to patients, expecting patients to respond with the correct OASIS response? Are your assessment forms difficult to use? Does staff understand the "output" of OASIS -- outcome and case mix reports? • Encourage staff to talk with others about how attitude can influence the success of a program. Those responsible for implementing and maintaining OASIS should portray an upbeat, realistic approach.
Even though certified home health agencies are required to do OASIS data collection and submit to the state, there doesn't seem to be much interest or investment in OBQI.	• Explain that OASIS data collection is part of a continuous process. It is only one part of OBQI. It is, however, where clinicians have direct control over measuring what happens to patients.
Our agency has a constant rate of staff turnover. There are wide variations in understanding and practical application of OASIS data collection, especially among clinical staff.	• Include OASIS assessment policies and procedures in orientation. • Tape an assessment and have new clinical staff view the tape during orientation. • Follow the tape by having new clinicians complete an assessment form and review answers with a supervisor who can structure additional orientation as needed. • Pair new clinicians with clinicians that have excellent assessment skills and apply OASIS accurately.

SITUATIONS	HOW AGENCIES HAVE RESPONDED
We don't know whether our staff is completing OASIS correctly.	• Utilize data audit strategies recommended in Chapter 12 of the OASIS User's Manual. • Have supervisors make home visits with each of your clinicians. The clinician and the supervisor complete separate assessment forms and then compare their observations after the home visit. • Convene multidisciplinary case conferences to discuss assessments and compare the discussion with what was recorded. • Develop clinical competency statements for the comprehensive assessment and accurate completion of OASIS items. • Review clinical forms to be certain that OASIS items are appropriately integrated. • Gather clinicians to discuss or elicit feedback on certain data items or sets of items. • Utilize HCFA's OASIS Web site' for frequently asked questions.
The nurses and therapists at our agency don't seem to be "on the same page" when talking about their OASIS assessments.	• Have nurses and therapists view taped assessments together and discuss their approaches to assessments and completion of OASIS.
Is there anything we can do to assure data quality of our OASIS assessment forms?	• Assign someone at the agency to check the forms monthly for accuracy. • Ensure copies are clearly produced and complete forms. • Use Chapter 12 of the *OASIS Users Manual* to integrate data checks and clinical record data checks into existing utilization review processes. Incomplete documentation by clinicians may occur when the forms are not accurate.
How can we know that the data being encoded is accurate?	• Designate someone in your organization to routinely and randomly compare the completed assessment documentation with OASIS data entered by each of your data entry staff. A double-check is helpful to identify training needs of data entry staff.

SITUATIONS	HOW AGENCIES HAVE RESPONDED
Clinicians are saying that what they are recording is not what is being encoded.	• Assess how data entry staff deals with questions or problems in interpreting OASIS documentation by clinicians. Do they guess at illegible handwriting? Help data entry staff know what to do and who to contact when questions arise.
We can't plan to have staff meetings very often for training on OBQI activities, especially with budget constraints under PPS.	• Consider having an OASIS newsletter or an OASIS "corner" in your current newsletter. • Videotape meetings at which OASIS and OBQI information are presented and make tapes available for staff to view individually. • Include OASIS- and OBQI-specific information and updates in paychecks. Bulletin boards, posters, e-mail, and voicemail are good communications methods. Ongoing communication is critical for staff to understand and remain informed on OBQI.
Our staff reacts defensively to the outcome report.	• This is a normal reaction. Acknowledge it but move past initial reactions quickly into OBQI activities. • Review data collection protocols and the concept of risk adjustment (if necessary). • Communicate clearly and support the staff when they receive the outcome report.
Our QI team has difficulty selecting target outcomes.	• Reinforce the need to limit outcome enhancement activities to one or two target outcomes. • Review and use the criteria (in Chapter 4) for selecting target outcomes.
Our QI team is unable to identify problematic or superior care processes linked with the target outcome.	• Generate ideas through brainstorming with key people closest to the process. • Encourage the QI team to look at care processes by asking them to list one to three things they would do for a patient with that problem. • Use standardized review criteria for consistency when reviewing records or conducting staff interviews.

SITUATIONS	HOW AGENCIES HAVE RESPONDED
Our QI team is having difficulty implementing the action plan we developed for our target outcome.	• Review the action plan to make sure it contains a specific problem or strength statement and clearly stated best practices. • Make sure that each action plan activity has timelines and responsible persons identified. Clearly stated action plans with three to five intervention activities have the best chance of being implemented successfully.
Why is it important to identify specific individuals by name on the plan of action?	• Promote direct accountability by selecting those individuals closest to the process associated with each intervention action. Only identifying "QI Team" or "Management Team" often hinders timely implementation of a plan of action. Outcome enhancement activities can reach a dead end if no individuals feel responsible.
Our QI team implemented the action plan but no changes occurred on the subsequent outcome report.	• Use monitoring strategies throughout the year to verify that clinicians used the best practices identified in the action plan. • Provide reminders throughout the year about the goal of improving the target outcome. • Involve clinical staff from the beginning in OBQI activities and solicit their input and feedback as part of the monitoring.
Time frames for development and implementation of the action plans are so short. It seems we just received our outcome report and within a month, our action plan had to be fully up and running.	• Restrict target outcomes to one to two to facilitate implementation and maintain momentum with OBQI activities. This maximizes the time available to implement best practices so that the improvement(s) in patient outcomes can be reflected on the subsequent outcome report.
How should we go about establishing a QI team to develop, implement, and monitor plans of action?	• Elicit volunteer support by suggesting to key staff that their involvement is highly desirable because of their knowledge of a particular process. • Include clinicians, administrative staff, and managers and supervisors, as well as new and long-time employees. • Limit the group to a manageable number to promote efficiency and timeliness.

Appendix B
Definitions of Selected Terms

Adverse Event Outcome Report: A graphical or tabular document that provides information on low-frequency or untoward events that potentially reflect a serious health problem or decline in health status for an individual patient. Because they are low-frequency events, they do not lend themselves to the type of analysis used for outcome reports. An example is provided in Figure 5.

Case Mix Report: A graphical or tabular document that provides average values for patient attributes at start of care. Comparative data are provided for: (1) agency case mix for a prior time period (if available) and (2) case mix for a reference sample of patients from other agencies. An example is provided in Figure 6.

Data Encoding: Entry of data from a paper (clinical record) form into software that contains the appropriate data entry fields for the form. Data entry of OASIS items typically consists of entering a single numeric value corresponding to the response selected on the form.

Data Tracking: The process of keeping track of the various records that constitute an episode of care for an individual patient according to the OASIS data collection protocols. In order to compute outcome measures, it is necessary to have complete data from start of care, follow-up time points, and discharge. This includes transfers to inpatient facilities and resumption of care after inpatient stays. Tracking systems (whether paper- or computer-based) rely on key patient identifying information to match the records that form an episode of care. Key identifying information in the OASIS includes patient ID number, Medicare number, last name, date of birth, and start of care date.

Data Transmission: Electronic submission of OASIS data to the state agency, as required by the HCFA Conditions of Participation for Medicare-certified agencies.

End-Result Outcomes: Changes in health status between two or more time points. An example is "Improvement in Ambulation."

HAVEN: The Home Assessment and Validation Entry software provided by HCFA for agencies to use (optionally) for encoding OASIS data.

Improvement Measures: End-result outcome measures calculated for patients who improve in an outcome over time. Patients who cannot possibly improve since they are already at the highest (most independent) level of an OASIS data item scale are excluded from the calculation of this measure. An example is "Improvement in Pain Interfering with Activity."

Outcome: A change in patient health status between two or more time points. Outcomes are changes that are intrinsic to the patient and can be positive, negative, or neutral changes in health status.

Outcome and ASsessment Information Set (OASIS): A set of data items developed largely for purposes of measuring (and risk adjusting) patient outcomes in home health care. OASIS items include sociodemographic, physiologic and mental/behavioral/ emotional health status, functional status, and service utilization information. Since the OASIS is used for measuring outcomes, most data items are obtained at start of care and follow-up time points (i.e., every 60 days and discharge). The OASIS is not a comprehensive assessment but is intended to be integrated into agency clinical record forms. Periodic revisions will be made to the data set.

Outcome-Based Quality Improvement (OBQI): A two-phase quality improvement approach, premised on the principle that patient outcomes are central to continuous quality improvement. The first phase, the outcome analysis phase, begins with collecting uniform patient health status data and culminates with an outcome report that reflects agency performance by comparing the agency's outcomes with those of a reference group of patients (which could be patients from a prior period at the same agency). The second phase (or the outcome enhancement stage) consists of selecting target outcomes for follow-up. It entails conducting an investigation to determine key care behaviors that influenced these target outcomes, culminating with the development and implementation of a plan of action to remedy substandard care practices or reinforce exemplary care practices. The effects of implementing the plan of action are evaluated in the next outcome report.

Outcome Analysis: The first phase of OBQI, consisting of collecting and analyzing OASIS data to produce outcome and case mix reports.

Outcome Enhancement: The second phase of OBQI, consisting of selecting target outcome(s), conducting an investigation to determine key care behaviors that influenced the target outcome(s), and developing and implementing a plan of action to remedy substandard care practices or to reinforce exemplary care practices.

Outcome Measure: A quantification of a change in health status between two or more time points. In OBQI, outcome measures are computed using OASIS data from start of care and from subsequent time points or discharge. Two common types of outcome measures used in OBQI pertain to Improvement in or Stabilization of a specific health status attribute. An example is Improvement in Ambulation between start of care and discharge.

Outcome Report: A graphical or tabular document that compares an agency's patient outcomes for a given time period with: (1) analogous agency-level outcomes for a prior time period (if available) and (2) outcomes for a reference sample of patients from other agencies. An outcome report contains information on selected outcome measures either for all patients in the agency or for patients with specific conditions. An example is included in Figure 3.

Patient Tally Report: A tabular document that provides individual patient case mix characteristics, outcomes, and raw OASIS data. An example is provided in Figure 7.

Resource Consumption Report: A graphical or tabular document that provides information on resources consumed for specific outcomes. An example is provided in Figure 8.

Risk Adjustment: The process of minimizing the effects of risk factor differences when comparing outcome findings between two groups of patients. Two common risk adjustment methods are grouping/stratification and (multivariate) statistical procedures.

Risk Factor: A patient condition or circumstance that (positively or negatively) influences the likelihood of a patient attaining the outcome. An example is rehab potential for the outcome "Improvement in Ambulation."

Significance: The statistical probability that the computed outcome difference would have occurred if the two groups being compared were really the same, in terms of outcomes.

Stabilization Measures: End-result outcome measures calculated for patients who do not worsen over time (e.g., patients who improve or stay the same). Patients who cannot possibly worsen since they are already at the lowest (most impaired) level of an OASIS data item scale are excluded from the calculation of these measures. An example is "Stabilization in Grooming."

Utilization Outcomes: Types of health care utilization that reflect changes in health status over time. An example is unplanned hospitalization.