VOLUME 1

POLICY AND PROGRAM OVERVIEW

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

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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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VOLUME 1

POLICY AND PROGRAM OVERVIEW

A. POLICY AND CLINICAL BACKGROUND

1. The Roles of Medicare and Medicaid

Medicare-certified home health care in the United States has its genesis in community and public health nursing in the late 19th and early 20th centuries.[1-4] The original tenet that a variety of health services can be more effectively and efficiently provided in patient's home environment rather than institutional settings still underpins home health care today. Significant changes understandably have occurred in the manner in which such care is provided, organized, managed, financed, and regulated. The catalyst for the most significant and sweeping set of changes was the passage of the Medicare and Medicaid Amendments to the Social Security Act in 1965 (P.L. 89-97). Today, home health care is a well-defined benefit for Medicare recipients needing intermittent in-home skilled nursing, physical and occupational therapy, speech-language pathology, medical social work, and home health aide services. Home care is also a Medicaid benefit that varies from state to state, typically including these and other skilled services plus additional services such as personal care.

Because Medicare is the dominant payer for skilled home health care in the United States, its policies and practices strongly shape how home health care is provided. In particular, Medicare's approaches to quality monitoring and improvement, payment, patient and provider eligibility, and cost and utilization monitoring profoundly influence the practice of home health care in both the public and private sectors. Although Medicaid is not as large a payer as Medicare for home care services nationally, it is the more dominant payer in selected states and also exerts significant influence on how home care is organized and practiced. Frequently, state-level Medicaid policies and practices build on, modify, and extend Medicare home health practices for certified agencies. Owing to the pervasiveness of Medicare as a federal program, the discussion later in this report frequently focuses on Medicare patients and practices. As used in this report, the term "home health care" refers to the aforementioned services for which Medicare beneficiaries are eligible, while the term "home care" encompasses these services as well as all other home or community-based services that might possibly be provided under the rubric of state Medicaid programs.

2. Uniqueness of Home Health Care

Given a choice between in-home and institutional care, patients and their families nearly always prefer in-home care. Because of this preference and the fact that the patient's home environment is more conducive to a sense of well being, positive motivation, and constructive communication with family members and friends, most believe the home environment to be optimal when it is possible and practical to provide care in this setting.

Home care tends to be educational in nature because professional providers are physically present in the home on a limited basis. Patients and their informal caregivers must frequently be oriented or trained to recognize and respond to possible negative changes in physiologic, emotional, cognitive, and functional conditions. Teaching occurs in areas such as administering medications; monitoring the status of surgical and other types of wounds; evaluating and responding to symptoms of cardiac, circulatory, and pulmonary problems or diseases; managing patient and informal caregiver stress; providing assistance in activities of daily living (ADLs) and instrumental activities of daily living (IADLs); managing medical equipment; and encouraging and assisting with nutritional and exercise regimens. Patients and informal caregivers often should be educated about home safety and how to respond to circumstances that may require emergent care, including when and how to most effectively access providers of emergent care.

Because of the intermittent nature of home health care and home care in general, patient and informal caregiver adherence to treatment regimens is more difficult to ensure and monitor than in institutional long-term and acute care settings. It is a commonly held belief that patient and informal caregiver motivation play a far more powerful role in home care than in most health care settings. Thus, another challenge for home care providers is how to contribute to and enhance such motivation. This is an issue in other settings as well, but it can be exceptionally pivotal in home care.

Unlike other types of care, the provider is a guest in the patient's home. At any given time, the provider is usually attempting to maintain a schedule of several visits per day; communicate with patients, physicians, and other agency staff; and yet provide in-home services that are responsive to the unique needs of patients and informal caregivers. With many noteworthy exceptions, communications between skilled nurses (or other home health agency staff) and physicians often fall short of what would be desirable. When such communication is inadequate, it is often due to the busy schedules on the part of both physicians and home care providers, an ingrained history of relatively ineffective communication, and the structure of the payment systems for physician care and home health care. The nature of communications that occur between patients and providers during the intervals between in-home visits is important, as efforts are now being made by providers to reduce the number of visits under the current prospective payment system (PPS). Telecommunication is becoming more frequent in home health care as telehealth approaches receive more attention.

In various ways and for a number of patients, home care is the "last resort" for avoiding nursing home care or placement in institutional long-term care. Home care can take on immeasurable importance for many individuals whose quality of life and personal identity are intertwined with remaining at home rather than being placed in a nursing home. An extremely significant enabling condition for patients to remain at home is the ability to function and maintain sufficient independence in such domains as in-home mobility, meal preparation, medication administration, telephone use, dressing, toileting, and bathing. In no small way, the ultimate or bottom-line purpose of home care (and home health care) is to assist individuals to remain or become as independent as realistically possible in such functional areas.

This is true not only for individuals seeking to avoid nursing home placement, but for nearly all individuals who receive home care -- they implicitly and sometimes explicitly view home care as a way to compensate for or enhance their presently constrained functional capacity so that they might cope better or more independently in their home environment. Even more technical and skilled services such as wound care, physical therapy, and psychological counseling often have as their longer run objective independence in one or several domains of functioning.

In all, the nature, environment, and interpersonal circumstances of home care delivery are unique. It is extremely difficult and challenging to monitor the quality and effectiveness of care provided in the home. For this reason, monitoring patient outcomes is particularly useful in home care. Because the interval over which home care is provided should be characterized by improvement, stabilization, or a minimal rate of decline in functioning, health and functional status should be measured at a minimum of two time points: start of care and discharge. This is necessary to monitor change in health status over the care interval and evaluate the effectiveness of care. Changes in health status or patient outcomes can then be measured across large groups of patients cared for by a particular agency in order to judge whether its home care is effective relative to other agencies'. Monitoring health or functional status, such as ability to ambulate, at a single point in time is not sufficient for this purpose.

3. Vulnerability of Our Home Care Population

Many of the over four million[5] predominantly elderly individuals who receive home care in the United States are highly vulnerable to inadequacies in and even potential exploitation through our home care delivery system. While no doubt exists that home care is a valuable benefit for patients, the age and frailty of this population[6] combined with the very attribute that defines such care -- its provision in the patient's home -- are the primary reasons for this vulnerability. Unlike care provided in clinics or institutional settings, the approaches that can be maintained or called upon as needed to monitor shortcomings in home-based care are perforce costly, more complex, and less likely to be undertaken. For long-term care provided in nursing homes and inpatient rehabilitation facilities, the resident or patient's condition can be and often is monitored by several providers, both skilled and paraprofessional if needed, on a daily basis. For home care, depending on need and the type(s) of care being provided, a patient may be receiving intermittent care from a single provider. Rarely is it around-the-clock care and rarely are other professional providers continuously available to assess patient health status and conduct on-site monitoring and management of the care being provided by their staff. Thus, while quality assessment can be and is done in home care, it is far more challenging and must rely on procedures and activities often different from those in institutional settings. As a result, for many home care agencies, quality monitoring is not sufficiently effective.

Another factor complicating the process of care provision in the home is the fact that informal support plays a crucial role as an adjunct to patient treatment. Some home care patients have no informal caregivers living with them. Even when such caregivers are available, they usually are not aware of how to properly assist in monitoring and

meeting selected technical, skilled, and even personal care needs of the patient. Combined with the fact that patients and their caregivers, if present, are frequently elderly, sometimes cognitively impaired, and often functionally disabled, these circumstances can and sometimes do result in exacerbations of both chronic and acute conditions. When this occurs, it is often more difficult for home care providers to monitor and respond to patient problems as quickly as providers in other care settings.

Such vulnerability leads to problems, deficiencies in care, and in selected well-publicized instances over the past few years, even cases of scandalous neglect and patient abuse. The factual nature of such problems is borne out by various reports and legal cases.[7-13] Concerns about the vulnerability of the home care population have been voiced for some time, going at least as far back as the late 1980's when those in positions of authority and oversight, including members of Congress, were exhorted to more closely examine the "black box" of home care.[14] The most appropriate stance on such issues, however, should not result in finger pointing at the home care industry which most would agree is comprised of a mix of organizations and individuals that span the range from highly competent and altruistically motivated to, in some cases, those egregiously unconcerned about their patients. Rather, we should acknowledge the degree to which a wide variety of home care patients are vulnerable and make certain that appropriate steps are taken to minimize the negative ramifications of this vulnerability. In doing so, we should ensure that home care agencies have tools and methods of direct value for identifying and solving quality problems. The information generated by such tools and methods should be useful for as many agency-level, clinical, managerial, and administrative purposes as possible. At the same time, such information should allow the Medicare and Medicaid programs as well as the general public to better understand and evaluate the quality of home health care.

It is noteworthy that the recently implemented PPS for Medicare home health care, which pays agencies a predetermined amount for an episode of care (adjusting to some extent for variation in patient admitting characteristics as well as local labor costs), has the unintended consequence of increasing considerably patient vulnerability. Specifically, since the dollar amount an agency will be paid for an episode of care is preset, there is an incentive at the individual patient level to attempt to provide care in such a manner that it costs less (preferably considerably less purely from the perspective of profit) than the payment amount. It is not difficult to envision the many circumstances where needed care could be minimized or even withheld from patients because of this incentive, and the challenges inherent in monitoring whether all of the services needed are actually being provided in the home. In view of these challenges, neither is it difficult to understand that monitoring patient outcomes would be useful to assess the effectiveness of home care services in terms of their positive or negative impacts on patient well being. Outcome measures (changes in patient health status between the start and end of care) can form a reasonable foundation for monitoring whether one home care agency or even a group of providers is, on average, performing (exceptionally) better than, about the same as, somewhat more poorly than, or egregiously more poorly than other agencies or providers -- in order to (1) validly monitor what is happening as home care is being provided to this vulnerable population and (2) to identify and remedy inadequacies in home care delivery.

4. Historical Shifts in Supply, Utilization, and Cost of Medicare Home Health Care

By removing several restrictions on the provision and supply of home health care, the Omnibus Budget Reconciliation Act of 1980 (P.L. 96-499) encouraged home health utilization and enabled more hospital-based and proprietary home health agencies to participate in Medicare, resulting in an increase from 2924 agencies in 1980 to 5695 agencies in 1990.[15, 16] Implementation of Medicare prospective payment for hospitals based on diagnosis-related groups (DRGs) served as a catalyst for hospital patients to be discharged "quicker and sicker," thereby increasing the case mix intensity of patients admitted to home health care by the mid-to-late 1980s.[17] As a result of a l987 legal challenge, clarification of Medicare coverage of intermittent home health care in 1989 spurred growth to 10,577 agencies by 1997.[18, 19] This was accompanied by increases in Medicare home health care visits from 36 million in 1987 to 256 million in 1997, the average number of visits per patient from 23 in 1987 to 73 in 1997, and Medicare home health expenditures from $2.6 billion in 1987 to $16.7 billion in 1997.[19, 20]

In response to these increases, Congress enacted a sweeping set of changes in Medicare payment for home health care through the Balanced Budget Act of 1997 (P.L. 105-33). This legislation imposed limits and decreases in payment that were implemented under the Interim Payment System (IPS) for certified providers of home health care until PPS could be implemented, which occurred in October 2000. Within just two years, by 1999, IPS resulted in more than a 50% reduction in total visits to 112 million, a decline of over 40% in visits per patient to 42, and a greater than 50% decrease in Medicare expenditures on home health care to $7.9 billion.[21] Agency closures and withdrawals from the Medicare program reduced the number of agencies by almost one-third to 7146 by the end of 2000.[22]

As these wide swings in the supply, use, and cost of home health services were occurring, particularly in the 1990's, concerns regarding the lack of evidence on patient-level effects of home health care were heightening.[23, 24] CMS, termed the Health Care Financing Administration (HCFA) at that time, did not have objective information on the value of such care to assess the effects of these substantial swings on Medicare beneficiaries and other home health patients (under the Conditions of Participation, the Medicare program is expected to monitor the quality of care for all patients, not simply Medicare patients, who receive home care from certified agencies).[25, 26] Physicians, hospital discharge planners, and case managers lacked evidence on the effectiveness of home health care in their communities that would assist in making referral decisions. Most importantly, those who administered the Medicare and Medicaid programs, other payers, home care clinical managers, physicians, other individual clinicians, and administrators at home health agencies were unable to assess the outcomes of home health care for their patients. There was no uniform, accurate outcome-based information to isolate possible quality problems and target quality improvement efforts as payment lessened under IPS and was based later on per-case reimbursement, which, as noted, can create perverse incentives to underserve patients.

5. The Challenge Confronting the Centers for Medicare & Medicaid Services

As the administering body for the Medicare and Medicaid programs, CMS has a considerable range of responsibilities to several constituencies. No responsibilities, of course, are more important than those to individual Medicare beneficiaries and recipients of Medicaid services. In the home health care field today, the vulnerability of the patient population, uniqueness of home health care, and events of the last two decades, particularly the payment system changes in recent years, point to and amplify the need for CMS to plan and maintain well-designed programs and administrative practices. Such programs must be responsive to the now increased needs of Medicare and Medicaid patients for home health services of adequate quality. In fact, quality should progressively improve beyond its current level. This program development must be sufficiently visionary so it transcends the problems unique to the present policy climate and encourages long-term effectiveness as well as efficiency within the home health care delivery system. This is no small challenge, particularly in view of current political issues fostered by provider responses to the considerable reductions in payment and Medicare expenditures on home health care between 1997 and 2000. Nonetheless, it is imperative to meet this challenge in a manner that endures and ensures quality care on behalf of the millions enrolled in the Medicare and Medicaid programs.

Since Medicare programs and practices in the home health care field set the pace for home care nationally, this challenge translates into (1) continuing with planned and extant programs that presently or will soon better serve beneficiary needs, (2) changing other program features to more effectively serve such needs, and (3) perhaps most importantly, developing and implementing an overall framework or system for continued evolution and refinement that encourages and supports regular improvements over the course of time. The purpose of this report to CMS is to present and discuss findings from a 15-year research and development program that recently resulted in the completion of two home health care demonstrations that shed extensive light on ways for CMS to meet this challenge.

The remainder of this volume summarizes the outcome improvement approach used in the demonstrations, and findings about its impacts on patient outcomes (Section B); presents information that facilitates understanding the nature of the findings and their implications (Section C); summarizes present concerns about OASIS in view of recent payment system changes and analyzes such concerns in the context of agency and CMS responsibilities and programs (Section D); and concludes with practical considerations for CMS in addressing the challenge of how to ensure that quality home health care can be efficiently and effectively provided (Section E). Together, Sections D and E address how the quality improvement methodology and the uniform data set needed to implement it are of value to providers as well as patients.

At this writing, most in the home health industry are not sufficiently aware of the advantages of the outcome-based quality improvement (OBQI) approach as a solution to many current problems in areas such as quality monitoring and improvement, clinical management, patient mix monitoring, public relations and marketing, patient assessment and care planning, utilization and cost monitoring, cost-effective care provision,

accreditation, and feedback to physicians and hospital discharge planners. For CMS, the implications of OBQI and OASIS data are discussed in Section E in the context of several programmatic applications including (1) patient outcome evaluation and monitoring, (2) tracking adverse patient events, (3) evaluating changes or shifts in the types of patients being served by home health providers regionally and nationally, (4) public or consumer reporting, (5) progressive refinement toward more equitably adjusting outcome measures and PPS payment rates for case mix differences among home health agencies, (6) implementing outcome-based applications in survey and certification, (7) monitoring program integrity, (8) facilitating the involvement of Quality Improvement Organizations (QIOs), previously known as Peer Review Organizations (PROs), in outcome enhancement, and (9) more efficiently determining patient-level program eligibility.

B. THE OUTCOME-BASED QUALITY IMPROVEMENT DEMONSTRATIONS IN HOME HEALTH CARE

1. Rationale for the Demonstrations

Since its inception, the continuous quality improvement (CQI) movement has shaped quality management efforts in the United States' health care system.[27-30] CQI changed our orientation from traditional quality assurance directed at satisfying prespecified standards for the structure, processes, and (occasionally) outcomes of health care to an orientation that emphasizes continuous enhancement of health and health care from year to year[31-34] and, to a greater extent than before, the impacts of care on the well being of patients (patient outcomes).[35-37] Salient features of an effective CQI program include (1) an emphasis on clinically useful and sensitive indicators of quality that can be measured across time periods, (2) ongoing reporting of statistical information on such measures that permits timely comparisons of present with past performance, and (3) sufficient clarity and meaningfulness of findings so that clinicians, managers, and payers can encourage or implement changes in care behaviors to improve quality or reinforce exemplary care.

Anticipating the need for outcome-related information that might encourage CQI in home health care, HCFA, in conjunction with the Robert Wood Johnson Foundation and later the New York State Department of Health, embarked on a research and development program in the late 1980s to assess the feasibility and utility of measuring the outcomes of home health care. This 15-year program evolved through several overlapping stages of research, development, pilot testing, clinical and methodological review, and demonstration and evaluation activities. The findings reported here pertain to the recently completed OBQI demonstration trial and evaluation stage of this program. Most of the material in this section is paraphrased or extracted from Volume 2, which contains further detail on methodologies and cross-references to documents that provide clinical and technical information on OBQI and the demonstrations. The following subsections (2-5) highlight selected features of the initial research and key results from the demonstration component of this program.

2. Outcome Measures and Needed Data

At the outset of the research program that ultimately led to the demonstrations, a draft set of outcomes was refined through several rounds of external review by researchers in the long-term care field and nationally recognized clinical experts from all disciplines involved in home health care. The reviews were designed to evaluate each outcome in terms of its clinical validity and utility, importance to patient health, and expected measurement precision. Data items to measure the resulting outcomes were developed thereafter using extant data sets, refining existing data items as needed, and developing new items when others were nonexistent or inadequate. The final data set for measuring and risk adjusting outcomes was named the Outcome and Assessment Information Set (OASIS) for home health care. The items in this data set were developed in this research program for measuring, evaluating, and ultimately improving patient outcomes. Thus, the development of OASIS was driven by outcome measures, outcome measurement, and the need to adjust outcome measures for case mix differences among home health agencies. The conceptual and empirical research that resulted in the OASIS data set is summarized in the introductory narrative to the OASIS Chronicle that appears in Volume 4 of this report series. This data set was designed to be integrated into a home health agency's start-of-care and follow-up patient assessment forms, replacing like items with OASIS items.

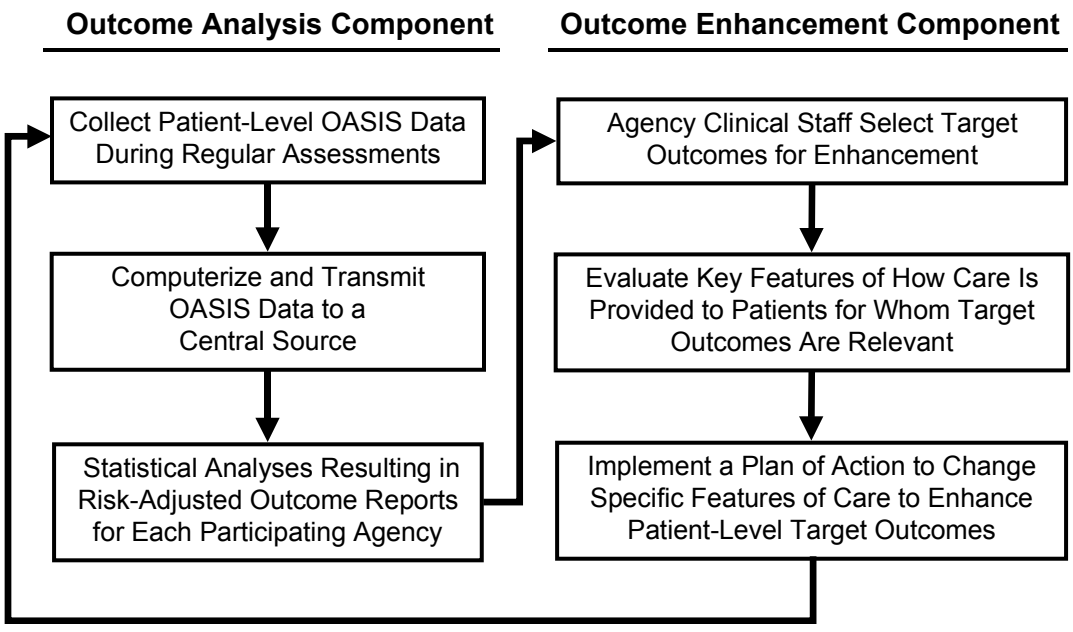
In order to measure outcomes in the initial research and development studies, and consistent with the timing of Medicare (plan-of-care) recertification, OASIS items were completed at start of care for each adult (18 years or older), nonmaternity patient and approximately every 60 days until and including time of discharge. The 60-day interval, which resulted from testing data collection intervals of varying lengths, was optimal for the combined objective of provider efficiency and clinical and statistical utility of outcome measurement. Data items could, therefore, be used effectively for assessing patient home care needs, care planning, measuring outcomes as changes in health status between start of care and follow-up points, and risk adjusting outcome measures to take into consideration case mix differences between an agency's patients and its comparison group.

For the sake of parsimony and clinical utility, 41 outcome measures were used in the subsequent OBQI demonstrations. These included (1) functional outcomes such as improvement in ambulation/locomotion, improvement in toileting, improvement in management of oral medications, and improvement in eating, as well as stabilization in bathing and stabilization in light meal preparation; (2) physiologic outcomes such as improvement in status of surgical wounds, improvement in dyspnea, and improvement in urinary incontinence, as well as stabilization in speech or language; (3) emotional/ behavioral/cognitive outcomes such as improvement in anxiety level and stabilization in cognitive functioning; and (4) selected utilization outcome measures such as acute care hospitalization.

3. Outcome-Based Quality Improvement

The essential features of the CQI applications framework employed in the OBQI demonstration trials were developed and refined in a pilot project involving several home health agencies in the early 1990s. This framework includes the outcome analysis and outcome enhancement components depicted in Figure 1. The outcome analysis component begins with collecting (as part of routine patient assessment), computerizing, and transmitting OASIS data to a central source (the University of Colorado in the case of the demonstrations). Outcome, case mix, and adverse event reports are returned to each agency on an annual basis. Most important is the All Patients' Outcome Report that permits agency staff to analyze their patient outcomes aggregated to the agency level. This report provides a risk-adjusted comparison of agency performance (1) relative to a national reference or benchmark population and (2) from one year to the next. The case mix profile report contains an overview of the agency's admitting case mix for the current time period or year relative to the agency's prior time period and the (national) reference group. The adverse event report provides a profile of low-frequency adverse patient outcomes such as emergent care for hypo/hyperglycemia. A complete copy of the outcome report series for a hypothetical agency is found in Supporting Document 6 in Volume 3.

FIGURE 1: OBQI Applications Framework.



In the second component of the OBQI applications framework, outcome enhancement, each agency is given considerable latitude to conduct its own CQI activities. These include process-of-care investigations that culminate in the development and implementation of plans of action specifying how care behaviors will be changed to enhance

outcomes. Upon conclusion of the first demonstration year, each demonstration agency received an outcome report showing its performance that year relative to all demonstration agencies (no prior comparison was possible the first year). After reviewing the report, various methods were implemented by agency staff to assess and change specific care behaviors related to target outcomes of their choosing. Agencies produced written plans of action for their target outcomes at the beginning of the second demonstration year. For each such outcome, these plans documented the target outcome, care behaviors being targeted, how and when they would be changed, who would be responsible for implementing the changes, and how the changes would be monitored on a continuing basis. The outcome enhancement process was repeated at the start of each succeeding demonstration year when the annual outcome report was received.

Accurate and uniform data on patient health status are critical for OBQI. The collection and use of OASIS data for this purpose introduced far more rigor into the assessment process than had been customary in many of the demonstration agencies. Further, the OBQI approach is novel in the sense that it entails a considerably different type of thinking and philosophy than typically used by home care providers for quality assurance. Such thinking requires analysis that links care to specific outcomes to facilitate managing and coordinating changes in care behaviors involving multiple providers. Training programs that focused on incorporating OASIS into comprehensive assessments and using OBQI to evaluate and enhance patient outcomes were an important component of the pilot and demonstration projects.

4. The OBQI Demonstrations

After the initial research, including developing and empirically testing outcome measures and OASIS data items over a period of several years, as well as a pilot to assess the feasibility of OBQI, two large-scale demonstration trials were designed. Hospitalization was selected as the most pivotal outcome on which to concentrate OBQI efforts since it could be readily evaluated for non-OBQI patients as well as on a pre/post basis for OBQI patients. Therefore, incorporated into the demonstration and evaluation design was the request that demonstration agency staff choose hospitalization as one of their two target outcomes each year (a few agencies selected more than two target outcomes). Hospitalization was a recommended target outcome for four reasons. First, it is important substantively, because if a patient's condition changes or declines to a point where inpatient hospital care is necessary, it is likely that a serious change in health status has occurred. Second, if providers could improve (i.e., lower) hospitalization rates, it would strongly suggest OBQI could be effective. Hospitalization is a difficult outcome to impact in view of the multiplicity of factors that influence it, the frequent need for various clinical staff of the home care agency to be involved, and the need to have physician input and involvement in the process. Thus, hospitalization cannot be easily impacted without often involving and influencing the care behaviors of several providers. Third, in keeping with the research design, having all agencies attempt to improve a single outcome (which encompasses a number of potential health status changes) would facilitate homogeneous pre/post and intervention/nonintervention comparisons of the effectiveness of OBQI. Fourth, reducing hospitalization rates can have substantial impacts on (lowering) the total cost of care while at the same time reflecting enhanced

patient outcomes and, hence, systemwide cost-effectiveness. For the second target outcome, agencies were free to choose from any of the remaining outcome measures in their outcome reports. They were provided with written guidelines and training on how to select an outcome for improvement based on outcome report findings.

Three comparative approaches were incorporated into the research design. First, a pre/post comparison of risk-adjusted outcomes was to be undertaken from one demonstration year to the next for patients pooled across all demonstration agencies. Second, for the most important outcome, hospitalization, a randomly selected comparison group of non-OBQI Medicare home health care patients from the same states as the OBQI Medicare patients would be used to assess whether changes or trends in hospitalization rates for OBQI Medicare patients were different. Third, since the OBQI methodology involves selecting specific target or OBQI outcomes, a comparison of improvements or changes in such outcomes with improvements or changes in (uncorrelated) nontarget outcomes would be undertaken.

In accord with this demonstration design and evaluation plan, HCFA sponsored a National OBQI Demonstration trial between 1995 and 2000, with funding from both HCFA and the Robert Wood Johnson Foundation. This National Demonstration involved 54 home health agencies from 27 states. If successful, the demonstration approach could serve as a prototype for a national OBQI program for all Medicare-certified home health agencies. The national OBQI trial was designed to establish a methodology and template to (1) collect uniform (OASIS) data on all adult, nonmaternity home health patients to measure and report patient outcomes; (2) utilize outcome measures for CQI in home health care; and (3) provide a foundation for an approach to enhancing patient outcomes that could lead to a more efficient systemwide approach to performance improvement in home health care.

Patterned after HCFA's national OBQI demonstration in late 1995, the New York State Department of Health implemented a statewide OBQI demonstration that began with 19 agencies and would eventually involve 33 certified agencies as well as 24 non-certified agencies. Like the National Demonstration, this six-year program was administered by the University of Colorado Center for Health Services Research. After training by Research Center staff, the agencies participating in the two demonstration trials integrated into their day-to-day operation all facets of OASIS data collection, monitoring, processing, and transmission, as well as all components of OBQI.

5. Findings on OBQI Impacts

The demonstration results are based on 157,548 predominantly elderly adult patients admitted over three years to the 54 OBQI agencies in the National Demonstration, 105,917 patients admitted over four years to the original 19 OBQI agencies (i.e., those certified agencies participating for all four years) in the New York State Demonstration, and 248,621 patients admitted over three years to non-OBQI control agencies in the 27 demonstration states. The time periods for each cycle of outcome reporting in the demonstration were approximately 12 months and were termed Years 1, 2, 3, and 4 (Year 4 pertained only to the New York State Demonstration).

The hospitalization results summarized in this paragraph are all statistically significant and based on risk-adjusted outcome analyses that compensated for possible case mix changes that might have occurred from year to year during both demonstration trials (see Volume 2 for further details). For the National Demonstration, the pooled hospitalization rates for all patients declined steadily over three years of the demonstration, from 32.5% in the first year to 25.3% in the third year. This case mix- or risk-adjusted net decrease of 7.2 percentage points (i.e., the risk-adjusted decline from 32.5% to 25.3%) in hospitalization rates for the National Demonstration resulted in an overall relative rate of decline of 22% over the three-year demonstration period. Analogous decreases in risk-adjusted hospitalization rates occurred for the New York State Demonstration patients. The consistent decline in hospitalization rates from 30.1% in the first year to 22.2% in the fourth year produced a net decrease of 7.9 percentage points for a four-year overall relative rate of decline of 26%.

The hospitalization rate changes for non-OBQI Medicare home health care patients in the demonstration states were based on a 5% random sample of Medicare patients admitted to the nondemonstration agencies in these 27 states. The findings showed only small changes in hospitalization rates for non-OBQI patients in the demonstration states between Year 1 and Year 2 of the demonstration period (a net decrease of 0.4%). The change between Year 2 and Year 3 (a net decrease of 0.3%) also was small compared to the substantially larger hospitalization decreases attained in the demonstrations. The net decrease was less than one percentage point over the three demonstration years. Since the 5% claims file for Medicare home health care patients did not permit a representative sample from non-OBQI agencies in New York State, claims analyses were not undertaken for non-OBQI patients in New York State.

The risk-adjusted results for target outcomes other than acute hospitalization for all patients paralleled and reinforced the hospitalization findings. The percent improvement for all such outcomes across the pooled National Demonstration patients from Year 1 to Year 2 was 7.7%. The analogous percent improvement for (uncorrelated) comparison outcomes was 1.4% over this period. The percent improvement in target outcomes from Year 2 to Year 3 was 5.8%, compared with a 1.1% improvement rate in comparison outcomes over the same period for the National Demonstration agencies. The New York State results demonstrated analogous statistically significant changes in the nonhospitalization target outcomes relative to changes in comparison outcomes over the successive four years of this demonstration. For each pair of consecutive years in the New York State Demonstration, the percent improvement in target outcomes was approximately 6.0% and the comparison outcome improvement rate was approximately 1.0%.

The favorable outcomes of demonstration agencies were broadly based but did not occur universally in every demonstration agency. Between 70% and 90% of the agencies favorably and significantly impacted their target outcomes from one year to the next (i.e., for each pair of adjacent years), although the individual agencies that significantly influenced either hospitalization or other target outcomes were not always the same for each pair of years.

C. DISCUSSION OF THE DEMONSTRATION FINDINGS

1. Magnitude of the Impacts of OBQI

The 22% and 26% relative rates of decline in hospitalization over the three- and four-year outcome reporting cycles of the National and New York State Demonstrations were not only of considerable magnitude, but they were unparalleled by changes in hospitalization rates for non-OBQI patients in the national demonstration states over the same period of time. Analogously, the rates of improvement for OBQI target outcome measures, which averaged between 5% and 7% per year, were unparalleled by the approximately 1% rates of change in nontarget outcomes, highlighting the effectiveness of the outcome enhancement component of OBQI that focuses on changing care behaviors for target outcomes.

In general, (1) the magnitude of the effects of OBQI, (2) the large numbers and variety of patients and providers involved which ensured breadth of experience and statistical power, (3) the consistency of the pre/post and study/control findings for hospitalization rates, (4) the agreement between the hospitalization and health status outcome results, (5) the parallel findings for the two separate demonstration trials, (6) the continual successes of outcome enhancement for the vast majority of agencies throughout the demonstration, and (7) the information conveyed by clinical staff (discussed shortly) about the value of OBQI -- combine to indicate a pervasively favorable impact of OBQI on patient outcomes. The magnitude of the improvements in hospitalization rates and other outcomes was substantial, particularly since home health clinicians had never undertaken this type of quality improvement. Further, the latter stages of these demonstrations were conducted during a time of unprecedented and radical decline in payment (under IPS) accompanied by large reductions in visits per patient and serious threats to agency survival. Thus, these OBQI impacts on patient outcomes were attained despite a marked decrease in patient care revenues.

2. Home Health Agency Training, Problems, and Support for OBQI

a. OASIS and OBQI Training: At selected central locations, staff members (typically two) from each demonstration agency participated in two training programs. Initial training was focused on integrating OASIS into clinical records and monitoring data collection, and the second dealt with interpreting outcome reports and conducting the outcome enhancement component of OBQI upon receipt of the reports. The staff members who attended the training sessions were, in turn, responsible for training the remainder of the staff at their respective agencies. No payments for participating in the demonstrations were available to OBQI agencies.

b. Agency Challenges and Problems: The most significant challenges faced by the demonstration agencies were fourfold. First, the novelty of conceptualizing and using patient outcomes as performance indicators required a transition from the traditional mindset with which home care clinicians tend to approach patient care. Practitioner education and training typically focus on processes of care (i.e., how to provide care) and rarely deal explicitly with systematically evaluating the effectiveness of care through

rigorous and statistical analysis of patient outcomes. This initially led several clinicians to question OASIS and the emphasis on collecting uniform data to measure outcomes. During the second year of OBQI clinicians typically made the transition to an outcome-oriented mindset and better understood the need for OASIS data. Second, collecting uniform patient status data required agency clinical staff to conduct more precise assessments. Because home care agency staff tend to be vigorously independent, use of standard language in assessments was not always well-received. Administrative support for the long-term value of the data assisted clinicians to work through this change process. Third, despite considerable automation advances in most domains of health care, a large portion of the home health industry was not automated in terms of clinical records and other aspects of patient care during the demonstration period (this continues to be true in many agencies today). As a result, computerization and transmission of OASIS data, which would not have been a new concept in many health care settings, required not only additional time and resources, but orientation to a more data driven management approach (which the home care field was slowly moving toward in any event). Paraphrasing some demonstration agency staff, "OBQI has forced us into the computer age, better now than later." Adaptations to the new automation requirements, when they did not occur fairly quickly, occurred during the second year of OBQI, after the first round of outcome reports. Fourth, as already discussed, the impacts of IPS were demoralizing to administrative and clinical management staff as well as to most clinicians, who gradually became aware of the substantial revenue declines in their agencies during the latter part of the demonstration period. The fact that they persisted with OBQI as a means of monitoring and improving outcomes was a testament to the commitment to patient care that had emerged at these agencies (or that already existed and was reinforced during the demonstrations), and to their belief in the cost effectiveness of OBQI.

Some agencies had specific difficulties with OASIS or the OBQI approach. The more significant problems that occurred at a few agencies typically resulted from either inadequate attention to efficiently integrating OASIS into the day-to-day assessment and data collection routines of clinical staff, or from technically flawed or inefficient implementation and maintenance of systems for computerizing and transmitting OASIS data. Interestingly, but not surprisingly, staff at the relatively few agencies that failed to implement and properly integrate OASIS and OBQI (in accord with the protocols and guidelines provided during training) complained vociferously to demonstration project staff at the University of Colorado about the burden of OASIS data collection and transmission, as well as other aspects of OBQI. However, virtually no attrition in agency participation during the demonstration period occurred and, by the end of this period, the relatively few "complaining agencies" had been reduced to two or three in both demonstration projects combined as acceptance of the OBQI approach increased.

c. Emerging Support for OBQI Over Time: Communication with clinical and administrative staff from OBQI agencies continued throughout the demonstration projects. In addition to clarifying issues and resolving technical problems on an ongoing basis, University of Colorado project staff received considerable feedback about OBQI. The responses to OBQI were nearly always positive, particularly in the later years of the demonstration trials, after (1) OASIS had been thoroughly integrated into assessment and clinical record keeping, (2) computerization and data transmission issues had been

addressed, and (3) agencies received the first round of outcome reports. By the end of the demonstration trials, staff at numerous OBQI agencies had commented on the value of being able to rigorously monitor patient outcomes, use the various reports (including adverse event and case mix reports as well as outcome reports) to isolate and resolve problems on behalf of individual patients and groups of patients, access reports on case mix and the care needs of patients for staffing and clinical management purposes, compare outcomes with utilization to assess cost effectiveness, and continually enhance patient outcomes.

3. Reasons for OBQI Successes in the Demonstrations

After the demonstrations concluded, the staff of most participating agencies continued to use OBQI. As already discussed, demonstration agency staff generally exhibited a strong sense of ownership of OBQI (and OASIS), reflected by the manner in which they adapted OBQI to their agencies' day-to-day operations. Several factors accounted for the successes of the OBQI demonstration programs. First, information obtained, analyzed, and used in feedback reports is precise, understandable, and of practical value for clinicians. Second, when implemented correctly, requisite data items and CQI activities can be integrated into and replace current items and activities rather than add substantially to the day-to-day operational routine of clinical staff. Third, the OBQI applications framework encourages clinical staff and quality improvement coordinators to be rigorous and innovative in areas such as (1) choosing target outcomes; (2) isolating important care behaviors to change in their agency or care environment; (3) writing a focused plan of action documenting target care behaviors to change, how to change them, who is responsible for changes, how changes will be implemented and monitored, and when these various activities are to occur; and (4) motivating other clinicians to change and ensuring that changed behaviors continue. Such factors serve as the basis for providing informative feedback to clinicians and give rise to a flexible and pragmatic approach to enhancing outcomes.

An important feature of the OBQI framework is that it does not rely exclusively on a formula-driven approach such as clinical guidelines, care maps, or clinical paths for specific patient problems (although these can be used in the process-of-care investigation). Rather, it relies on practical feedback of a statistical nature and, most importantly, challenges clinicians to exercise sound judgement and innovation to isolate strengths and weaknesses in care behaviors or practices within the context of their specific agency or clinical group. As OBQI continues, it is likely that additional findings and conclusions will be available on specific clinical, technical, and coordinative approaches used by home care providers to enhance outcomes. As agencies gain more experience with OBQI, the body of knowledge about methods used to enhance patient outcomes is expected to continue to grow.

4. Evolution and Purpose of OASIS

In order to provide background information to inform debate on OASIS and its applications over the next several years, the following several paragraphs present key points about OASIS and its history. The preceding material in this volume has

summarized the major impacts of using OASIS data to enhance patient outcomes through the application of the OBQI framework. This subsection repeats a few earlier points and focuses exclusively on OASIS, summarizing why and how it was developed.

a. OASIS Purpose, Content, and Research: The purpose of OASIS rests with the primary reason why (home) health care is provided. Stripping away issues such as regulation, payment, cost, utilization, and staffing, health care is provided to benefit people. Since outcomes are basically changes in health status between two time points (such as start of care and discharge from care), the fundamental purpose of health care is to positively influence patient outcomes. OASIS was carefully designed for measuring and ultimately enhancing patient outcomes.

All (non-identifier) items in OASIS were derived by first specifying a set of patient outcomes considered critical by home care experts (e.g., nurses, physicians, therapists, social workers, administrators) for evaluating the effectiveness of care. These outcomes were chosen from the most important domains of health status addressed by home care providers. Most data items in OASIS were developed, tested in hundreds of agencies, and refined for measuring outcomes in order to evaluate and enhance the effectiveness of home care. This has been and remains the fundamental purpose of OASIS.

The general categories of data and health status items in OASIS include demographics and patient history, living arrangements, supportive assistance, sensory status, integumentary (skin) status, respiratory status, elimination status, neuro/emotional/ behavioral status, activities of daily living, medications, equipment management, and information collected at inpatient facility admission or agency discharge. Each of these general categories was deemed necessary to properly measure and evaluate those patient outcomes judged to be most pivotal in examining the effectiveness of home care. To properly measure outcomes as changes in patient health status over time, most OASIS data items are designed to be collected at start of care and every two months thereafter until and including time of discharge.

Not only were several multidisciplinary clinical panels convened to substantively review and revise sets of the most important outcome measures, but OASIS data items and measurement methods also were reviewed by multidisciplinary panels of research methodologists, clinicians, home care managers, and policy analysts. As OASIS data items were employed in research projects and subsequently in demonstration projects, reliability and validity testing was undertaken with a view toward enhancing accuracy and utility. Selected items, including some that were added (after the initial research was completed) at the request of industry representatives, remain problematic in terms of precision or accuracy and should be regarded as candidates for future revision. The OASIS Chronicle in Volume 4 reviews each item and provides recommendations for future refinements that would best occur at scheduled intervals of every few years.

b. Guiding Principles for OASIS Development and Refinement: OASIS is the only major data set ever developed for a large component of our health care delivery system that has been focused first and foremost on measuring and improving outcomes on behalf of patients. This is the primary principle that has guided the evolution of OASIS over its 15-year history. A set of seven additional operating principles, which

evolved iteratively during the early stages of OASIS development, became established as basic tenets of the OASIS developmental process and its various applications; they can serve as guidelines for the continued evolution of OASIS. The seven guiding principles (secondary to the above guiding principle of outcome enhancement) are:

- OASIS should be a precise, uniform data set tailored to the unique features of home health care. This data set should be an integral part of the comprehensive assessments providers routinely conduct in their daily operations (as required by the Medicare Conditions of Participation).

- Scientific methods and standards must be employed in all phases of OASIS development and ongoing refinement.

- Development and continued evolution of OASIS should be consistent with the conceptually derived and clinically validated applications framework, termed Outcome-Based Quality Improvement.

- OASIS data items should be useful for measuring or risk adjusting each measure in a system of outcomes that serves as the basis for reports that are understandable and of practical value to clinicians, managers, and home care agencies in general.

- The agency-level applications of OASIS should constitute a system that fosters self-improvement, evolution, and provider ownership over the course of time.

- Modifications to the OASIS data system should be undertaken carefully and rigorously, after analyzing the system impacts of such changes and empirically testing them prior to their implementation.

- In addition to the primary objective of enhancing outcomes of home care, continued development and refinement of the OASIS data system should anticipate possible current and emerging applications in areas such as informing consumers, clinical management, agency marketing, monitoring and remedying fraud and abuse, facilitating voluntary accreditation, developing progressively better outcome measures for clinical and evaluative purposes, improving case mix adjustment for payment, improving risk adjustment for outcome measurement, increasing efficiency and effectiveness of survey and certification, detecting discrimination and access barriers to home care, determining impacts of payment policies, and monitoring the needs of recipients of home care.

These principles were used in guiding research and operational activities that entailed empirically testing several versions of OASIS data items and outcomes in more than 400 home care agencies, with the input of more than 1200 home care providers, managers, and administrators. Input also was received from Medicare and Medicaid officials, policy analysts, consumer representatives, and representatives from other governmental and nongovernmental organizations with interests in (possible) OASIS applications. The current OASIS data items constitute those deemed most essential for implementing an effective outcome enhancement and quality assurance system at the

home health agency level -- one that also can serve as the foundation for strengthening the quality improvement and assurance approaches for the entire Medicare program (and state-level Medicaid programs).

D. RECENT PROGRAM DEVELOPMENTS AND PRESENT CONCERNS

1. National Developments in OASIS and OBQI Program Applications

Owing to preliminary findings from the OBQI demonstrations and the value of OASIS data for case mix adjusting payment rates under PPS, in mid-1999 HCFA mandated OASIS data collection for skilled level patients at all certified agencies, and electronic transmission (to state agencies) of such data for Medicare and Medicaid patients. CMS is now moving forward with planning for OBQI nationally. CMS's national orientation and training programs for OASIS data collection and OBQI are patterned after analogous programs used in the demonstration trials. Under nationwide implementation, training and data management programs have been and will continue to be administered at the state level. OASIS data are transmitted to a state agency and then to a central national repository for outcome reporting and case mix adjusting payment rates. At this writing, (1) case mix and adverse event reports have been made available electronically to all certified agencies in the United States, (2) OASIS data have been used for case mix adjustment during the first year of prospective payment, and (3) planning has been completed for national OBQI training and for the first round of risk-adjusted outcome reports for all certified agencies in early 2002.

The national outcome reports will serve as the basis for voluntary OBQI activities at the agency level. They also will assist the Medicare survey and certification process by providing more specific information to identify strong home health programs that need relatively little attention as well as programs in need of greater improvement. A pilot program is underway to facilitate the involvement of QIOs in assisting home health agencies to implement and use OBQI for outcome enhancement. This program also builds on the training and technical assistance approaches used in the demonstration trials. In addition to OASIS applications developed by CMS, OASIS-based outcome measures are now being used by many accredited home health agencies participating in the Joint Commission on Accreditation of Healthcare Organizations' ORYX program that focuses on performance indicators.

As experience is gained with outcome reports designed for home health agency use, current CMS plans assume that some version of OASIS-based outcome reports will be available to the public. While public reporting on performance of health care providers is controversial in some sectors, a general tendency toward such reporting is apparent.[38, 39] Initial experience with OBQI reports for all certified agencies would be a reasonable prerequisite before public reporting is implemented and, according to publicly released CMS plans, home health agencies will be able to acquire this experience prior to the release of consumer reports.

2. Concerns Expressed about OASIS

a. Payment System Changes as a Catalyst for OASIS Concerns: While nearly all non-identifier OASIS items are used for OBQI, only selected OASIS data items currently are used to case mix adjust per-episode payments under the recently implemented PPS for certified agencies. Some industry representatives have suggested reducing OASIS to only those items currently used for payment and eliminating other OASIS items used for OBQI (and for potential future refinements to case mix adjustment of payment rates). The demonstration findings suggest this would be a disservice to patients, providers, and payers concerned about quality monitoring and improvement. It is, however, understandable that concerns have arisen related to the burden of OASIS data collection, encoding, and transmission on the part of home health agencies.

These concerns (discussed in more detail shortly) also have resulted in suggestions to eliminate OASIS altogether, reduce the frequency of data collection, or restrict the types of patients on whom OASIS data are collected. One reason for industry concern is the fact that Medicare revenues for home health care were reduced by over 50% under IPS between 1997 and 2000. Another is the unfortunate but factual coincidence that the national mandate for OASIS data collection occurred toward the end of this period. The powerful impact of IPS on the home care industry is evident from the fact that nearly one-third of all home health agencies closed or withdrew from the Medicare program between 1997 and 2000. In all, the inopportune announcement of HCFA's OASIS mandate during the concluding, most severe phase of IPS produced the understandable conclusion by many in the industry that OASIS was a designed accompaniment of IPS, or at least a harbinger of additional governmental paperwork and burden that would further complicate rather than solve problems in the future.

In addition, because OASIS was to be used for case mix adjustment under a home health care prospective payment system that was Congressionally mandated to immediately follow IPS, certified home health agencies were required to implement OASIS data collection and transmission in accord with an extremely ambitious schedule. These two factors -- the conclusion of IPS concurrent with the OASIS mandate and the ambitious implementation schedule for OASIS (announced in January and June 1999 regulations) -- led to far more concern about OASIS than otherwise would have been the case.

b. Natural Resistance to Change Despite Pre-IPS Receptivity: Three versions of OASIS had been released for public review and reaction during the four years prior to the implementation of IPS; all received a generally positive reaction. In fact, a number of nondemonstration agencies had voluntarily implemented OASIS and OASIS-based quality improvement prior to the HCFA mandate. Before the shift to IPS took place, the home health industry was generally supportive of OASIS and exhibited a sense of ownership of this data set that was developed specifically with the needs of home care agencies in mind. This support was evidenced by the statements and activities of individual agencies, state provider associations, and national provider associations (such as the National Association for Home Care), which sponsored a variety of educational programs for their members on improving quality through outcome measurement and OASIS applications during the mid-1990s.

Change is difficult, particularly if it affects the very infrastructure of an organization in the context of increasingly scarce resources. It is from the vantage point of being required to establish a new data system and way of thinking with far fewer dollars from the dominant payer that many in the home health care industry are commenting about OASIS today. There is a tendency to view the OASIS data set simply as a set of items that requires a given amount of space on paper and has a given number of boxes to check. This view results in criticism of the data items and questions about why they are collected. Some even blame the home care nursing shortage on OASIS, despite the fact that the shortage is at least as severe in several other modalities of health care (e.g., the hospital field) in which OASIS is not a factor. Unfortunately, in the wake of IPS and now under PPS, many in the home care field have little understanding of how and why OASIS has evolved, what this data set is going to be used for, its significant value to home care agencies and their patients, its utility for making resource allocation and staffing decisions, and its long-term merits for the Medicare and Medicaid programs -- which merits, in turn, will benefit the industry.

c. Concerns about the Burdens of Data Collection, Encoding, and Transmission: As indicated, various concerns have been voiced about the burden of OASIS data collection. A number of clinicians and industry representatives point out that the OASIS data set requires more pages than previously were contained in patient assessment forms. Some also contend that OASIS substantially increases assessment time. In addition to assessment or data collection burden, the concern has been raised that computerizing and encoding OASIS data is a new burden particularly because many agencies heretofore did not computerize clinical records. Even for those that did, electronic transmission of patient health status data was not required. Hence, the contention has been made that the new PPS was not designed to cover adequately the cost of OASIS data collection, encoding, and transmission.

d. Suggestions to Restrict OASIS Data Collection to Selected Patients: The requirement to collect OASIS data that was issued in 1999 pertains to all adult, non-maternity skilled care patients (excluding, for example, patients receiving only personal care), regardless of payer, admitted to Medicare-certified home health agencies. Agencies are free to collect OASIS data for all other nonskilled or personal care patients if they choose to do so. Only data on Medicare and Medicaid skilled patients are required to be transmitted to the state and subsequently to the OASIS national repository. When procedures to ensure sufficient confidentiality are finalized and a final regulatory notice is issued, current plans call for transmitting OASIS data on all other skilled care (i.e., non-Medicare and non-Medicaid) patients. OASIS data on non-Medicare and non-Medicaid patients presently transmitted to the state must have masked identifiers.

The 1999 mandate indicates no decision has been made regarding potential OASIS requirements for nonskilled care patients. Further information has not been released on this topic. In view of the earlier concerns voiced about burden, some suggestions have been made to eliminate the OASIS requirement for Medicaid skilled patients and other non-Medicare skilled patients, and not to pursue OASIS data collection for any other types of patients, including but not restricted to Medicaid personal care patients.

e. Requests to Reduce OASIS Based on Interrater Reliability or Validity: In the interest of reducing a number of OASIS data items, concerns have been expressed that selected items are unreliable and should be eliminated. As will be discussed shortly, some of the concerns about reliability are reasonable and speak to either refinement of selected items or even elimination of a few items if they cannot be improved sufficiently. Questions have also been raised about the clinical and analytic validity of OASIS in searching for items to recommend for deletion.

3. Analysis of Concerns Expressed about OASIS

a. Lack of Awareness about the Value of OASIS: As the home health agencies participating in OBQI demonstrations discovered, OASIS represents a significant solution to numerous problems, including those caused by IPS. Because OASIS was developed primarily for home care providers, one of its aforementioned guiding principles was that OASIS and its outcome enhancement applications must be of practical value and mesh with the day-to-day operations of home care agencies. It must yield reports and tools that agency staff can use to evaluate their own effectiveness in investing resources on behalf of their patients. Reports had to be sufficiently practical and understandable so that agencies can change and reallocate resources, both to produce better outcomes and to control and minimize costs in doing so. That this is possible has been shown under the OBQI demonstration programs.

OASIS can be used by agency staff to monitor potential changes in case mix so that approaches to care can be altered systematically in accord with the changing needs of patients. In addition to the forthcoming risk-adjusted outcome reports, agencies can now access adverse event outcome reports reflecting the frequency with which a variety of untoward events (such as emergent care for wound infection or deteriorating wound status, development of a urinary tract infection, or substantial decline in management of oral medications) occur. Such events can be monitored efficiently through OASIS, providing agencies with critical information in order to investigate where they occur for individual patients. Further, OASIS not only can result in management decisions on how best to invest limited resources in patient care, but it also can contribute to reducing total health system costs through enhanced outcomes, such as reduction in hospitalization rates for home care patients.

The main point that emerges from the present climate of concern about OASIS is twofold. First, OASIS is far less a part of the problem than it is a significant component of the solution. The fact that it is popular with those who have implemented and used it for a reasonable period of time is a testament to its utility, even in a financially constrained environment. Second, because the home health industry has been overwhelmed by and preoccupied with the effects of payment changes and constraints, most individuals have not had the opportunity to assess the value of OASIS for multiple purposes. Therefore, the fact that OASIS, in reality, represents both intermediate and long-run solutions to current problems is largely unknown in the home care industry.

b. OASIS Burden in Light of Proper Implementation and Needed Change:

Demonstration Experience: None of the agencies in the aforementioned demonstration programs, in which agencies received no financial assistance to implement or maintain the OASIS data system, withdrew because of OASIS-related burdens or costs. This also was true for nearly all nondemonstration agencies that voluntarily implemented OASIS before the federal mandate. It has become clear, however, that agencies that do not properly implement OASIS from the perspectives of (1) efficient integration of data items into the current assessment, (2) adequate training and orientation of staff, (3) adequate communication with staff regarding the purposes and value of OASIS, and (4) anticipating the natural resistance that occurs on the part of clinical staff to any such change, will naturally struggle and, in many instances, perceive that OASIS represents an extremely costly or burdensome undertaking.

Long-Standing Medicare Requirement: In keeping with the primary responsibility of the Medicare program to its beneficiaries, the Medicare Conditions of Participation have long included the requirement that services provided by a home health agency follow a plan of care, which must have the following attributes:

> Standard: Plan of care. The plan of care developed in consultation with the agency staff covers all pertinent diagnoses, including mental status, types of services and equipment required, frequency of visits, prognosis, rehabilitation potential, functional limitations, activities permitted, nutritional requirements, medications and treatments, and any safety measures to protect against injury, instructions for timely discharge or referral, and any other appropriate items. (Source: CFR 42-484.18, revision effective August 1991)

In order to establish a plan of care with these attributes, a clinician must complete what is referred to as a comprehensive assessment. The most recent regulation clarifies this responsibility and makes it more specific and uniform by requiring that a comprehensive assessment include OASIS.[25] The new regulation clarifies the comprehensive assessment requirements, including assessments at two-month follow-up time points in addition to discharge and start of care. It is important to note this is not an OASIS requirement; rather, it is a clarified comprehensive assessment requirement that is mandated for Medicare beneficiaries. Research and demonstration experience has shown that many agencies were not previously meeting the comprehensive assessment requirement even at start of care. Now that it has been re-emphasized in the most recent regulation, clarifying that items such as those in OASIS should be included, some agencies necessarily require more time to conduct patient assessments that are superior to the assessments conducted previously.

Inaccurate Perception of OASIS and Data Collection Burden: A significant misconception about OASIS is that it is a ponderous data set including numerous new items that substantially increase time spent in assessing patients. In fact, OASIS contains very few new items that were not already part of agencies' clinical records -- assuming that valid comprehensive assessments were already being conducted. The OASIS items are typically more precisely worded than comparable items previously included in agencies' assessment forms. This precision, in turn, enhances the accuracy of assessment, improves care planning, and permits uniform evaluation of patient outcomes.

OASIS items should replace, rather than augment, items that were previously in agencies' clinical records. A typical clinical record resulting from a valid comprehensive assessment includes over 200 items. Using OASIS items instead of extant items means that half of the items in an agency's clinical record are replaced. Although more paper is usually added to the assessment form with OASIS, the total number of items is relatively unchanged, and they typically require no more time for data collection. That is, once a provider is familiar with the items, it is often only necessary for a particular option (e.g., level on a health status scale) to be checked, without making narrative notes regarding the patient's condition.

Research and demonstration experience indicates that when assessments containing OASIS items are used, there is a shift in the amount of time spent completing assessments in patients' homes versus time spent on out-of-home activities (such as documentation, form completion, and care coordination activities that do not have to be done during home visits). A time study found that, for clinicians who previously had been conducting valid comprehensive assessments, the increased time spent in patients' homes when using forms that included OASIS items was offset by less out-of-home time because the objective and systematic checklist format of OASIS items eliminated the need for extensive narrative documentation. Therefore, despite the fact that OASIS items occupy more space on paper, they do not necessarily increase total provider time spent in completing and documenting an assessment unless the assessment approach had previously been inadequate.

Conclusions Regarding Different Types of OASIS Burdens: In summary, several concerns regarding OASIS-related burden are inappropriate or unfounded. However, others are not. There are valid start-up costs related to training, forms development, and integration of OASIS into day-to-day operations of agency clinical activities. There is a learning process or learning curve that is real. Such costs should be or should have been adequately covered. It is not clear this has been the case. Time required to computerize and transmit OASIS data, even if the free CMS software (i.e., HAVEN) is used, is a new cost incurred by many agencies. Whether Medicare should pay for the costs of computerization or encoding such data (apart from subsequent transmission) is a dilemma. Some more technologically advanced agencies had already concluded that computerization of clinical information was a cost-effective clinical and business strategy prior to the OASIS mandate. Data transmission, however, is a requirement that follows directly from the recent federal regulation. Although it is not strictly an OASIS-driven cost, the clarification that comprehensive assessments must be done at follow-up points may increase staff time for some agencies that had previously not been thoroughly documenting health status at such time points. Despite the fact that certified agencies have now been collecting, encoding, and transmitting OASIS data for some time, it seems appropriate to revisit some of these costs and assess whether they are adequately covered under the current payment system.

c. Restricting OASIS to Specific Patients in View of CMS and Agency Responsibilities: Some reasonable concerns underpin the suggestions to minimize the types of patients to which the OASIS mandate should pertain. The suggestions regarding skilled patients and nonskilled (i.e., personal care) patients, while often presented together, are

basically quite different and should be analyzed separately. Deliberations on issues related to OASIS data for skilled care patients should take into consideration the research and demonstration experience.

Demonstration Experience: All home care agencies in the demonstrations as well as other agencies that implemented OBQI in the late 1990s collected data on all patients regardless of payer source. One of the primary advantages in doing so, from an agency's perspective, is receiving outcome and related reports on its entire caseload. This permits managers to make better informed decisions about resource management on behalf of patients, taking an agency's total cost structure and total utilization picture into consideration. From a clinical viewpoint, agency staff are not required to use different forms for different types of patients. This uniformity helps in designing agency-wide (and therefore more efficient) approaches to care planning, care coordination, and the provision and monitoring of care -- particularly for skilled care patients.

CMS Oversight Mandate: Beyond agency-specific considerations, the responsibility of CMS to monitor the quality of care provided by home health agencies certified by Medicare was discussed in Section A. This responsibility is well established within the Social Security Act [Sec. 1861(o)(6) and Sec. 1891(b)]. It is not limited to patients for whom the payer is Medicare or Medicaid. The rationale for this, in part, rests with the principle that when the federal government takes on the responsibility to certify home health to provide care to Medicare beneficiaries, it also must assume the responsibility to ensure that CMS payment practices and other procedures do not adversely or differentially impact Medicare and non-Medicare patients.

Cause for Concern about Quality: As has been discussed, under the current payment environment (PPS), as well as the immediately preceding payment system (IPS), there is little doubt that patterns of care have changed in the vast majority of home health care agencies across the country. What has happened to both Medicare and non-Medicare patients in terms of outcomes is relatively unknown except for selected anecdotes and relatively sketchy information about service provision. Available information suggests that while the total number of home health care visits dropped between 1997 and 1999, the number of deficiencies in care increased over this same period.[40] Thus, because strong incentives exist under PPS to reduce services, it is possible that a number of agencies may provide less adequate care to Medicare patients. Agencies interested primarily in profit maximization will have the incentive to admit as many Medicare patients as possible, minimizing services provided so as to maximize profit under PPS. This can result not only in inferior outcomes for Medicare patients, but in reduced access for non-Medicare skilled care patients in particular (e.g., lower admission rates for particular types of patients whose care is costly relative to payments received) since profits may not be as substantial for non-Medicare patients.

The Need to Monitor Outcomes for Skilled Care Patients: Without OASIS data collected on Medicare and non-Medicare skilled care patients alike, PPS may create an undetected two-class home health care delivery system for public- vs. nonpublic-pay (skilled care) patients. We may not learn definitively of this system or how to remedy it until it has caused many years of damage. Because home care serves a highly vulnerable

population, this is an extremely serious concern. Further, public or consumer reporting on outcome indicators based only on Medicare patients will not be nearly as informative to consumers as reporting based on an agency's entire caseload, or at least its skilled care caseload. Therefore, it would not be advisable to eliminate Medicaid patients from the current reporting requirement. Further, it would be beneficial to proceed with data transmission for non-Medicare and non-Medicaid skilled care patients as soon as methods to ensure confidentiality of data for such patients are sufficiently developed.

Proceeding Deliberately with Nonskilled or Personal Care Patients: The most valid concerns raised in restricting OASIS data collection appear to be those that focus on nonskilled care patients. For patients receiving exclusively services that are not regarded as skilled, the OASIS data set, developed primarily for measuring outcomes of skilled home health care services, may better serve assessment and outcome monitoring objectives if it is tailored more uniquely to the characteristics and care needs of nonskilled care patients. Because little is known about the outcomes of patients receiving only nonskilled care, specific information is lacking to guide refinements in this regard. Therefore, it appears reasonable to delay a decision on requiring a (possibly revised) version of OASIS for personal care patients.

d. Reliability Considerations and Potential Revisions to OASIS Through Continued Reliability Analyses: It is not the intent in this volume to delve into detail on individual data items. Volume 4 contains information on reliability (and validity) for every OASIS data item, along with a recommendation for continued use or change. Supporting Document 2 in Volume 3 contains the findings from a recent reliability study. Some general points about reliability are appropriate, however. First, three separate OASIS interrater reliability studies have been conducted in the recent past. Prior to these studies, preliminary reliability and consistency analyses contributed to the initial wording, format, and instructions associated with most OASIS data items.

Description of Interrater Reliability through Independent Assessments: Each of the three recent interrater reliability studies had its own unique design, sample size, and research approach. Two of the three studies used independent interrater assessments, and one used concurrent interrater assessments. For most fields in which interrater reliability research is appropriate, the independent assessment approach is regarded as preferable and most appropriate. This approach involves two separate raters (assessors) collecting information on the same patient at two different time points. The time points should be as close together as possible, and the raters are not expected to share information about the patient. A potentially serious weakness with this approach can arise if the two assessments are excessively far apart in time (in order to avoid patient fatigue or due to travel logistics and time constraints) because patients' health status can change between the two time points, particularly for Medicare home health patients who are often characterized by acute, unstable conditions. Longer time periods between assessments are less problematic with chronic care patients, such as non-Medicare home care patients or nursing home patients, whose conditions are more stable over time. The maximum preferred time interval between independent assessments for skilled home care patients is 24 hours. To the extent that this time interval is exceeded by an interrater reliability study design, it tends to produce biased reliability coefficients that underestimate true interrater reliability because change in patient condition over time is not sufficiently controlled.

Description of Interrater Reliability through Concurrent Assessments: The concurrent interrater reliability approach entails one rater (assessor) conducting the patient assessment and the other rater listening and observing, without commenting or communicating in any way during the assessment and without sharing information with the primary assessor after the assessment. Both raters or assessors record the assessment information independently. The weakness associated with this approach is that the secondary assessor is constrained to the approach and style of the first assessor. This would tend to create a bias in the direction of inflated reliability. However, this can be offset by the fact that the perceptual and interpretive skills of the two individuals can be sufficiently different so their recordings are more disparate when one is constrained only to the cues resulting from the other's communication style instead of his or her own communication style (which might be more likely to produce closer assessment ratings to the first assessor). Thus, the concurrent assessment approach may yield inaccurate reliability estimates due to these factors, but the direction of the inaccuracy is less clear.

Error Introduced through Inexperienced Assessors: A challenge in both types of interrater reliability approaches (i.e., independent and concurrent assessments) is that uncontrolled variation can be introduced when the assessors are not sufficiently trained and experienced in the application of the proper assessment techniques and data items. This variation in rater ability superimposes noise or random error that exacerbates the (true) unreliability of the item(s) being tested, tending to result in underestimates of actual item-specific reliability coefficients.

Designs of the Two OASIS Reliability Studies that Used Independent Assessment: One OASIS interrater reliability study that has received wide circulation to date is an independent assessment reliability study which allowed for up to three-day intervals between assessments and employed a number of assessors with varying degrees of ability and experience in using OASIS. Based on these design characteristics, it is likely that the reliability estimates from this study underestimate the true reliability of OASIS items. The interrater reliability results for OASIS data items in the OASIS Chronicle found in Volume 4 are based primarily on an independent assessment approach that used a smaller sample of patients, but a more rigorous design, permitting a maximum of 24 hours between assessments that were conducted by a limited number of trained clinicians.

Overview of Findings: Interrater reliability for the vast majority of OASIS items, particularly most items used for important applications in outcome measurement and risk adjustment of outcome measures, is adequate and, in many areas, excellent. However, some items are unreliable and either should be eliminated or not used until their reliability is improved -- as suggested in Volume 4.

e. Validity of OASIS and OBQI: Validity is at least as important as reliability for most OASIS applications. The more consequential types of validity for the OASIS data set, in view of the primary focus on enhancing patient outcomes, are consensual and predictive/convergent validity. Briefly, most items underwent several rounds of review by expert clinical and research panels who focused on their utility for both patient assessment and outcome measurement or risk adjustment. This approach to consensual validity was complemented by validation through empirical testing that resulted from using the

OASIS-derived outcome measures in the OBQI demonstrations, where they were judged useful by hundreds of clinicians for patient assessment and care planning purposes, as well as outcome enhancement.

Convergent or predictive validity was assessed through hypothesis testing which involved estimating risk-adjusted models for each outcome measure. Models typically included between 10 and 50 risk factors whose signs and coefficients were consistent and clinically meaningful across all models. The fact that the entire OASIS-based system of outcome measures and risk factors led to an integrated quality improvement approach that was validated through outcome enhancement, and which was widely accepted by home care providers, is perhaps the strongest form of validation. Some of the concerns expressed about clinical acceptability of specific OASIS data items are addressed in Volume 4. It is important to note here, however, that clinical utility and validity were given the highest priority throughout the development and testing phases of OASIS, as documented in Volume 3 of this report.

f. The Potential Burdens if Extensive Changes Are Made to OASIS in the Near Future: It is important to recognize that OASIS data collection and reporting have been in place for a reasonable period of time. Therefore, changing OASIS, the nature of the assessments, or the protocols involved in collecting OASIS information has a substantial cost for home health agencies. A significant burden would result from changing assessment forms and data collection procedures, retraining, altering data encoding or computerization procedures, changing software, and revising data monitoring and reporting methods. Most of this burden would be borne by home health agency staff. Hence, even moderate changes in OASIS at this time likely will bring about a significant negative response by many clinical staff and home health agency administrators, especially staff from the extremely large number of agencies that currently are collecting and using such data and have heretofore not complained to CMS. It is possible that the negative response about these new burdens would exceed the concerns currently being expressed about OASIS burden.

Equally important, OASIS cannot be simply pared down without several negative ramifications for CMS applications. Reductions in items or data collection time points, specifically if they include any of (numerous) pivotal items, could require significant changes in terms of (1) risk adjustment for outcome measures needed for public reporting and agency-level outcome reporting, (2) CMS evaluation of quality of care for Medicare beneficiaries, (3) future refinements of the initial case mix adjustment approach for prospective payment, (4) outcome-based survey and certification applications, (5) revisions to software and software systems, (6) the various data management and statistical systems currently in place, (7) program safeguard and integrity activities, and (8) emerging responsibilities of QIOs under their Seventh Scope of Work. Just as consequential would be the reduced opportunities for improved clinical management, enhanced outcomes, and more effective administration in home health agencies -- as well as lessened opportunities for physicians, discharge planners, and case managers to make more informed referral decisions.

E. RECOMMENDATIONS ON EVOLUTION AND REFINEMENT OF OASIS APPLICATIONS

1. A Continuous Quality Improvement System Whose Underlying Data Set Has Multiple Applications

a. The Overarching Goal: The research and developmental program that has given rise to OBQI and OASIS should be viewed realistically. To date, the program has focused on establishing the feasibility and utility of a CQI approach to ensuring that home health care patient outcomes are evaluated continually and improved where necessary. The OBQI methodology designed for this purpose was developed, tested, and shown to be successful on a large scale over a period of several years. The research efforts were targeted at developing a CQI system that works at the home health agency level, and never wavered in this regard. The overall goal was to develop an approach to evaluating and continuously improving quality that would serve multiple purposes for home health agencies, simultaneously contributing to improving CMS quality monitoring systems. If properly implemented and maintained at a national level, OBQI has the strong potential to accomplish this goal. Consequently, and especially in view of the incentives to deleteriously withhold or reduce services under PPS, the decision to move forward with promoting OBQI on a national basis is not only evidence-based, but it is targeted at solving the most serious problems facing home care patients today.

b. Information Dissemination and Infrastructure Changes: The ramifications of the decision to implement OBQI nationally are many. It is important that the home health industry fully understand what OBQI is, including the intermediate and long-term purposes it serves. As national OBQI training and information promulgation begin, the extent to which OBQI fosters not only greater effectiveness of home health care, but also can lead to increased efficiency and improved staff morale -- should be made known. All should recognize that this process, including collecting and transmitting the necessary data as well as receiving and analyzing outcome reports, takes time to settle in, and, as with any systemic change, will not necessarily be well received during its implementation and accommodation stages within every home health agency.

To implement OBQI, infrastructure changes within both individual home health agencies and CMS programs are necessary. Many changes have begun and new programs are moving forward. They are accompanied by natural resistance from home care providers that is manifest in different ways. It is tempting to try to return to older, more comfortable ways of doing business, providing care, monitoring quality, and regulating home health care. It also is natural to attempt to simplify as much as possible various components of the process being changed to make them at least closely resemble prior approaches and activities. Yet, to return to prior practices or to retain current methods that are becoming outdated is not possible. An approach akin to OBQI must be implemented on a nationwide basis in response to growing concerns about the quality of home health care.

c. A New and Different Era of Medicare Home Health Care: Regardless of the arguments surrounding quality, one indisputable fact necessitates this change -- namely,

prospective payment for Medicare home health care. Because of PPS, Medicare home health care has changed significantly and permanently. Acceptance of per-case payment for an episode of patient care and acceptance of the accompanying freedom to blend the types and volume of services that comes with such payment translate into specific responsibilities. In particular, providers also must accept responsibility and accountability for patient outcomes that occur over episodes of care for which payment is received. Further, CMS must accept responsibility and accountability for ensuring that adequate information is available to evaluate outcomes of care across payment episodes, preferably in a manner that is useful to home health providers as well as for external monitoring and regulatory purposes. PPS has ushered in not only a new era of financing home health care under Medicare, but also a new era of accountability. It would be irresponsible for agencies not to be accountable for patient outcomes under this payment approach, just as it would be irresponsible for CMS not to evaluate such outcomes on behalf of Medicare beneficiaries and other patients whose care can be influenced by PPS. In short, it is impossible to return to or rely on past practices of monitoring and evaluating quality in view of the powerful incentives under this payment system that likely will continue for decades to come.

2. Accepting the Need for Refinements and Proceeding with Applications

a. Moving Past OASIS as a Goal Unto Itself: As a methodology for evaluating and continually improving patient outcomes of home health care, OBQI has considerable potential for the Medicare program and individual home health agencies. Unfortunately, it has not been OBQI, but OASIS that has occupied center stage to date. Although understandable because a uniform data system must be implemented first, the preoccupation with OASIS has come to be a distraction and even an impediment to properly understanding and implementing OBQI. Obviously, maintaining the OASIS data system should not be viewed as a goal unto itself. Neither should CMS staff nor anyone involved in the development of OASIS be defensive about its weaknesses. It exists to serve the primary purpose of a national OBQI approach that will benefit patients, agencies, and CMS, but to do so effectively, OASIS itself must evolve. Selected shortcomings in OASIS were apparent by the end of the demonstration program. OBQI and OASIS had been refined and had evolved over the preceding decade with changes carefully introduced during the demonstrations so that they would be minimally disruptive to ongoing operations. This experience made it clear that OBQI, including OASIS, must be implemented and guided dynamically, recognizing that not only is it targeted at continually improving quality, but that doing so necessitates continually improving the approach itself.

The need to use specific and reasonably precise information on patient status to case mix adjust payment was obviously an immediate catalyst for the implementation of the OASIS data system in 1999-2000. Equally important, however, was the need to have a reasonably accurate and uniform data system in place to serve the aforementioned responsibilities and accountabilities on the part of providers and CMS to evaluate patient outcomes under this payment system. Although delaying implementation of OASIS would have made possible further refinements to this already useful data set, this would have been inappropriate, if not impossible. Delaying for the sake of improvements to a

system that was already known to be feasible and effective for its intended purposes would have precluded the timely attainment of the most important goal, outcome monitoring and enhancement, which by that time had become an imperative due to PPS.

b. Planning for Change: As stated earlier, CMS has a considerable range of responsibilities to several constituencies. Most important among these are its responsibilities to individual Medicare beneficiaries and recipients of Medicaid services. To carry out these responsibilities in the home care field in a balanced, yet effective manner under the current circumstances is a considerable challenge. OBQI offers a tool for helping to meet the challenge, but only if it continues to evolve. OBQI and the several applications that follow from it in the context of CMS programs should have an explicitly recognized and permanent evolutionary component targeted at (1) identifying potential program improvements and (2) implementing improvements in accord with a set of principles that minimize operational impacts while maximizing returns.

3. Suggestions for Moving Forward with OBQI and OASIS Applications

The foundation now exists for a national OBQI program for home health care. The following suggestions are intended to assist in continuing with the implementation and subsequent maintenance of the national OBQI system. It is recognized that various CMS and industry activities and programs have already been implemented. No effort is intended to indicate precisely how these suggestions should be incorporated into activities and programs because decisions on how to do so are best made by those who will administer the programs.

a. OBQI Evolution and Ongoing Information Dissemination: As noted, the inherently changing nature of OBQI necessitates acknowledging the need for ongoing refinement in the form of a CMS program function to guide its evolution. This function can be performed by a standing committee or operational group within CMS that has the aforementioned responsibilities to (1) evaluate potential refinements and (2) design or suggest operational steps for implementing those refinements to OBQI, OASIS, data collection methods, reporting methods, and other components of the overall system as needed. A process for obtaining input from a variety of sources should be established and maintained on an ongoing basis. Potential changes should be carefully weighed and analyzed in terms of the totality of their implications and ripple effects for providers, patients, and existing administrative programs. A preset schedule for implementing change on a deliberate (unhurried) periodic basis, such as every several years, should be followed so that all who are influenced by such change are aware of, can provide input to, and have time to prepare for new developments.

Prior discussion has highlighted what is perhaps the most significant barrier to implementing and maintaining OBQI, including its OASIS data system -- namely, a general lack of awareness of specifics regarding the rationale for and operational components (both agency-level and national) of OBQI. Training and information dissemination programs have been developed to assist with implementation. However, these programs also must be ongoing because of the dynamic and changing nature of OBQI as well as normal staff turnover within the home health care delivery system and the Medicare

program. Ongoing training and information dissemination can be Web-based or electronic in nature, or can be accomplished through more traditional approaches. Efforts of this nature can provide the appropriate vehicles for communicating regular changes in the OBQI system and the programs it influences. Training and information dissemination activities should, of course, be conducted by both CMS and industry associations and groups.

b. Reanalyzing Selected Burden Topics: Issues about OASIS-related burdens incurred by Medicare-certified home health agencies have been debated in various forums. As noted in foregoing sections, several of the industry-voiced concerns in this area are overstated, but others may be valid. It would be reasonable to revisit the burden issue, studying carefully and objectively its various facets, and, if appropriate, determining and clarifying precisely how payment might be changed to address valid and recurrent inadequacies in payment due to OASIS-related burden. This analysis should be based on precise information collected in a scientific manner, free of potential biases of self-interest. In conducting such an analysis, it is important to recognize that recent sweeping changes in Medicare payment have permanently altered the cost structure and cost behaviors of agencies and individual clinicians. The financial capacity to absorb change and even the marginal cost of absorbing such change may have been altered since the demonstration program experience. This is more probable when comparing the early years of the demonstration experience with the most recent (OASIS) data system implementation experience, because the demonstration program was implemented not under IPS or PPS, but under the former Medicare cost reimbursement approach for home health care.

c. Revisions Based on Improving Reliability: Although not as directly related to burden, concerns about the reliability of selected OASIS data items also should be carefully addressed. Here again, selected concerns are reasonable and others are the result of inappropriate conclusions or atypical experiences. Volume 4 of this report series, which contains the OASIS Chronicle and recommendations for OASIS refinement, is intended to provide an objective foundation and vehicle for such refinements. This activity is part of the actual process of studying and recommending refinements over the course of time, and would be part of the OBQI evolution program function described earlier.

d. OASIS and Non-Medicare Patients: For the reasons given in Section D on the value of outcome reports pertaining to the entire caseload of an agency, and the statutory requirement that CMS evaluate quality for both Medicare and non-Medicare patients, the recommendation is made that OBQI (and the OASIS data system) should continue to be targeted at all adult, nonmaternity patients who receive skilled care from home health agencies. This would entail continuing with plans to include information on non-Medicare and non-Medicaid skilled patients in OBQI outcome reports when information on confidentiality for such patients during data transmission can be ensured. The incremental cost of encoding and transmitting these additional data should be taken into account.

The final decision for nonskilled patients, however, should continue in abeyance. Revisions to OBQI and OASIS for personal care patients are being developed and will be

empirically tested through a demonstration trial in New York State. The results of that experience as they pertain to both OBQI and OASIS for personal care patients likely will be informative. These results can be evaluated and taken into consideration within the context of the OBQI evolution program function described earlier.

e. OBQI and Systemwide Quality of Care: To realize the full potential of OBQI, home health providers, membership organizations, and CMS should work together to foster the use of outcome and related reports that will be available (electronically) to users on request. These reports for individual agencies and their patients considerably extend the quality assurance approaches that previously have been employed in the home health care field. They will form a provider-driven foundation for the national OBQI system, which will constitute, in essence, an evolving partnership between the home care industry and the Medicare program. This partnership will benefit patients as well as individual agencies and CMS programs that support home health care if OBQI is properly implemented, maintained, and refined.

f. Using Outcomes in the Survey and Certification Process: In addition to informing clinical management and resource allocation decisions within individual agencies, the OBQI data system can and should be used to strengthen and streamline various components of the current home health care survey and certification system, increasing its emphasis on patient outcomes as mandated by the Omnibus Budget Reconciliation Act of 1987 (P.L. 100-203). As outcome reports are generated, it will be possible to lessen the resources devoted to surveying agencies whose outcomes are superior and focus such resources on agencies whose outcomes need improvement.

g. Combined Survey, QIO, and Agency Efforts Focused on Outcome Improvement: With feedback from survey staff, assistance from the staff of QIOs, and by virtue of their own emerging outcome enhancement skills, agencies that seek to focus on improving specific types of patient outcomes will have the information, input, and external assistance to do so. As experience is gained, progressively more information can be shared on how to (1) efficiently evaluate and improve specific patient outcomes, (2) continue to refocus and streamline the survey process, and (3) facilitate QIO assistance with agencies' quality improvement programs. Further, by serving as an OBQI resource for home health agencies, QIOs will gain experience in systematically monitoring outcomes and directly facilitating outcome enhancement.

h. Evaluating PPS Impacts: At the same time, CMS will have and should act on the capacity to evaluate PPS impacts on patient outcomes, case mix changes over time, and case mix-adjusted cost and utilization patterns for both Medicare and (eventually) non-Medicare home health care patients receiving skilled services. An evaluation should be undertaken of whether PPS has produced a two-class delivery system for Medicare versus non-Medicare patients, analyzing risk-adjusted patient outcomes, case mix-adjusted use and costs, and trends in case mix that might reflect differential changes in access to home health care for Medicare and non-Medicare patients.

i. Outcome Reporting for Consumers and Other Purposes: Modifications to the national outcome reporting system can be made to produce reports that are under-

standable to and useful for the general public. Reports for consumers could include initially a subset of the outcomes used for agency-level OBQI. However, the current outcome measures are tailored to OBQI applications largely to provide home care clinicians with information on fairly specific health status outcomes for use in problem identification and resolution. It would be appropriate to develop composite or more aggregate outcome indicators that span several domains of health status for ease of understanding by consumers, either for the initial round of consumer reports or for subsequent refinements.

After sufficient experience has been gained as a result of the first round of outcome reporting under the national OBQI program, other reporting applications would be appropriate. Specifically, the degree to which outcome and case mix reports are useful to physicians should be assessed. It is possible that outcome reports should be stratified by either patient condition or other factors to be more useful for physicians as well as individual agency clinicians and hospital discharge planners or community-based case managers. Outcome and related reports should be generated to examine state-by-state and regional similarities and dissimilarities in outcomes and case mix.

j. Continued Refinements to CMS Program Operations: As the OBQI approach and its data system evolve through the above-mentioned applications at the individual home health agency level, various programmatic components will continue to change. Improvements can be undertaken to render PPS payments more equitable through refinements to the case mix adjustment approach, possibly incorporating additional OASIS data items to produce more sensitive adjustment. Here also, it would seem that refinements to case mix adjustment should only occur deliberately, in accord with a regular, preset schedule. OBQI data system and patient assessment accuracy should continue to improve in accord with Medicare program integrity initiatives in order to minimize fraud and abuse. Improved methods to determine patient eligibility for Medicare and Medicaid services at both start of care and follow-up time points should be systematized in the relatively near future.

As with case mix revisions for payment purposes, refinements and revisions to risk-adjustment methods for outcome measures used in OBQI reports should be undertaken to continually increase the value of outcome reports for providers. Results from periodic reliability studies also can provide input to program integrity and survey and certification efforts to ensure the accuracy of assessments. Merging OASIS data with claims data as well as other agency- and patient-level data will produce a unified data system that can be used for multiple administrative, policy analysis, and research purposes.

4. Closing Comment

As noted earlier, the overarching goal of OBQI and OASIS is to develop a CQI system that works at the home health agency level. At the same time, the OASIS data can be used for multiple additional purposes by agencies and CMS. The foundation for this system is largely in place and can be refined at relatively low cost in a structured manner guided by CMS, to the ultimate benefit of home health patients, providers, and CMS program operations.

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VOLUME 2

RESEARCH AND TECHNICAL OVERVIEW

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

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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.

CONTENTS

ABSTRACT

Objective: To evaluate impacts on patient outcomes of outcome-based quality improvement (OBQI), a continuous quality improvement methodology for home health care (HHC) that uses data from the Outcome and Assessment Information Set (OASIS) to assist providers monitor and enhance patient well being.

Design and Setting: A quasi experimental design with prospective pre/post and study/control components within two multiyear demonstration trials (occurring from 1995 to 2000) in which 73 home health agencies implemented OBQI, receiving several annual cycles of outcome reports to evaluate and enhance patient outcomes.

Participants: 157,548 predominantly elderly adult patients admitted over three years to 54 OBQI agencies from 27 states in the National Demonstration Trial, 105,917 patients admitted over four years to 19 OBQI agencies in the New York State Trial, and 248,621 patients admitted over three years to non-OBQI control agencies in the 27 demonstration states.

Intervention: As a clinical management and administrative intervention, OBQI involves collecting, encoding, and transmitting OASIS patient-level health status data to a central source that provides each OBQI agency with a risk-adjusted outcome report comparing the agency's patient outcomes with those from a reference population and with its own outcomes from the prior period. Target outcomes are selected and focused plans of action implemented to change care behaviors. Outcome changes are evaluated through the next report cycle.

Measurements: Outcome measures include hospitalization rates and improvement and stabilization outcome rates in functional, physiologic, emotional/behavioral, and cognitive health.

Results: For the National and New York State Demonstration Trials, respectively, the risk-adjusted relative rates of decline in hospitalization of 22% and 26% for OBQI patients over the three-year and four-year demonstration periods were significant ($P<.001$) and unparalleled by considerably smaller rates of decline for the non-OBQI patients in the 27 states. The risk-adjusted rates of improvement for OBQI target outcome measures of health status averaged 5% to 7% per year in both demonstration trials, and were significantly greater ($P<.05$) than analogous improvement rates for nontarget comparison outcomes, which averaged about 1% per year.

Conclusions: It is feasible to integrate the programmatic, data collection, data transmission, and outcome enhancement components of OBQI into the day-to-day operations of home health agencies. The aggregate findings and the agency-level evidence available from site-specific communications suggest that OBQI had a pervasive impact on outcome improvement for home health patients. The OASIS data set provides patient-level data for OBQI and is critical for monitoring the outcomes of HHC for both Medicare and non-Medicare patients under a new per-case payment system that has incentives to deleteriously withhold services from patients. This data set can and should be carefully and scientifically refined over time in accord with (1) CMS's responsibilities to patients, (2) the value of OBQI, (3) payment considerations, (4) provider efficiency, (5) Medicare requirements for comprehensive assessments, (6) quality monitoring, and (7) consumer or public reporting. OBQI warrants expansion and refinement in HHC and experimentation in other health care settings.

VOLUME 2

RESEARCH AND TECHNICAL OVERVIEW

This volume is written in journal-article format for purposes of clarity and efficiency (it has been accepted for publication in the *Journal of the American Geriatrics Society*). Certain topics from the journal version were expanded in writing this document in order to provide additional information or cross-references to other volumes.

A. BACKGROUND

Home health care (HHC) is generally regarded as preferable to institutional care by patients and their families. However, little is known about the outcomes of HHC and whether it is possible and practical to measure, monitor, and improve the outcomes of HHC. Our ability to measure outcomes has been particularly problematic since utilization of HHC has changed radically over the past two decades. Because Medicare is the dominant payer for skilled HHC services (skilled nursing, physical and occupational therapies, speech and language pathology, and medical social work) as well as home health aide services that accompany skilled care, its payment and regulatory practices have impacted considerably the types and numbers of home health agencies, practice patterns, utilization, and expenditures. By removing restrictions on the provision and supply of HHC, the Omnibus Budget Reconciliation Act of 1980 (P.L. 96-499) encouraged home health utilization and enabled more hospital-based and proprietary home health agencies to participate in Medicare, resulting in an increase from 2924 agencies in 1980 to 5695 agencies in 1990.[1, 2] Implementation of Medicare prospective payment for hospitals based on diagnosis-related groups (DRGs) served as a catalyst for hospital patients to be discharged "quicker and sicker," thereby increasing the case mix intensity of patients admitted to HHC by the mid-to-late 1980s.[3] As a result of a l987 legal challenge, clarification of Medicare coverage of intermittent HHC in 1989 spurred growth to 10,577 agencies by 1997.[4, 5] This growth was accompanied by increases in Medicare HHC visits from 36 million in 1987 to 256 million in 1997, the average number of visits per patient from 23 in 1987 to 73 in 1997, and Medicare home health expenditures from $2.6 billion in 1987 to $16.7 billion in 1997.[5, 6]

In response to these increases, Congress enacted a sweeping set of changes in Medicare payment for HHC through the Balanced Budget Act of 1997 (P.L. 105-33). This legislation imposed limits and decreases in payment that were implemented under the Interim Payment System (IPS) for certified HHC providers until a per-case prospective payment system (PPS) could be implemented, which occurred in October 2000. By 1999, IPS resulted in more than a 50% reduction in total visits to 112 million, a decline of over 40% in visits per patient to 42, and greater than a 50% decrease in Medicare expenditures on HHC to $7.9 billion.[7] Agency closures and withdrawals from Medicare reduced the number of agencies by almost one-third to 7146 by the end of 2000.[8]

As these wide swings in the supply, use, and cost of home health services were occurring, concerns regarding the lack of evidence on patient-level health effects of such

care were heightening.[9, 10] The federal agency that administered Medicare and Medicaid, the Health Care Financing Administration (HCFA), now CMS, did not have objective information to assess the effects of these changes on Medicare beneficiaries. Physicians, hospital discharge planners, and case managers lacked evidence on the effectiveness of HHC in their communities that would assist in making referral decisions. Payers (including Medicare and Medicaid), home care clinical managers, physicians, other individual clinicians, and administrators at home health agencies were unable to assess the effectiveness of HHC for their patients. Most recently, under IPS and the advent of PPS, data on patient outcomes have become imperative to evaluate patient well being as payment lessened and subsequently was based on per-case reimbursement, which can create perverse incentives to underserve patients.

Since its inception, the continuous quality improvement (CQI) movement has shaped quality management efforts in the United States' health care system.[11-14] CQI changed our orientation from traditional quality assurance directed at satisfying prespecified standards for the structure, processes, and (occasionally) outcomes of health care to an orientation that emphasizes continuous enhancement of health and health care from year to year[15-18] and, to a greater extent than before, the impacts of care on the well being of patients (patient outcomes).[19-21] Salient features of an effective CQI program include (1) an emphasis on clinically useful and sensitive indicators of quality that can be measured across time periods, (2) ongoing reporting of statistical information on such measures that permits timely comparisons of present with past performance, and (3) sufficient clarity and meaningfulness of findings so that clinicians, managers, and payers can encourage or implement changes in care behaviors to improve quality or reinforce exemplary care.

Anticipating the need for outcomes-related information that might enhance CQI, HCFA, in conjunction with the Robert Wood Johnson Foundation and later the New York State Department of Health, embarked on a research and development program in the late 1980s to assess the feasibility and utility of measuring the outcomes of HHC. This 15-year program evolved through several overlapping stages of research, development, pilot testing, clinical and methodological review, demonstration, and evaluation activities. A summary of the more salient research, policy changes, and health care issues that shaped the evolution of this program is contained in Volume 1 and Supporting Document 1 of Volume 3. The findings reported here pertain to the recently completed outcome-based quality improvement (OBQI) demonstration trial and evaluation stage of this program, accompanied by methodological highlights from earlier stages.

B. METHODS

1. Outcome Measures and Data Items

In keeping with Donabedian, a patient health status outcome is defined as a change in health status between two (or more) time points,[22] typically admission and discharge for home health patients. Health status is broadly defined to include functional, physiologic, cognitive, and emotional/behavioral dimensions of health. An initial set of over 500 patient health-status outcomes was specified after reviewing the outcome and

long-term care literature, conducting unstructured discussions on appropriate and useful patient outcomes with clinicians from all disciplines involved in HHC as well as representatives of regulatory and governmental programs, and then surveying home health providers on outcomes. The draft set of outcomes was refined through several rounds of external review by approximately 20 researchers in the long-term care field and 20 nationally recognized clinical experts from all disciplines involved in HHC. The reviews were designed to evaluate each outcome in terms of clinical validity and utility, importance to patient health, and expected measurement precision. Data items to measure the resulting outcomes were then developed using extant data sets, refining existing data items as needed, and developing new items when others were nonexistent or inadequate.

Data items and outcome measures were iteratively refined and reduced through field testing at over 200 home health agencies nationally during a period of several years in which (1) outcome measures continued to be evaluated and revised clinically and empirically, (2) new data items were added to risk adjust outcome measures for case mix differences among patient groups being compared, (3) alternative outcome measurement approaches were examined for their practicality and utility in monitoring and managing impacts of care on patient well being, and (4) a CQI applications framework that would eventually be termed OBQI was developed and pilot tested in several home care agencies.[23] The final data set for measuring and risk adjusting outcomes was termed the Outcome and Assessment Information Set (OASIS) for home health care.[24, 25] This 107-item data set was designed to be integrated into a home health agency's start-of-care (SOC) and follow-up patient assessment forms, replacing like items with OASIS items. Despite the fact that the more precisely worded OASIS data items required more space in assessment forms, agencies already performing a clinically appropriate comprehensive assessment of each patient added little, if any, new content to their SOC assessment form when they replaced extant items with OASIS items. A subsequent (double-blind) time survey showed once clinical staff became familiar with OASIS items, average time required for patient assessments returned to that required before OASIS was used -- for clinicians that had previously been conducting comprehensive assessments as required under Medicare. The time study is discussed in more detail in Supporting Document 2 of Volume 3.

Consistent with Medicare certification requirements, OASIS items were completed at SOC for each adult (18 years or older), nonmaternity patient. OASIS data were collected approximately every 60 days until and including time of discharge. A 60-day interval, which resulted from testing data collection intervals of varying lengths, was optimal for the combined objectives of provider efficiency and clinical and statistical utility of outcome measurement. This length of time allowed the data items to be used effectively for assessing patient home care needs, measuring outcomes as changes in health status between SOC and follow-up points, and risk adjusting outcome measures to take into consideration case mix differences between an agency's patients and its comparison group. For the sake of parsimony and clinical utility, the 41 dichotomous outcome measures enumerated in Table 1 were (and still are) used for OBQI. Every OASIS data item other than patient identifiers is used either to measure or risk adjust at least one, but typically many, of the 41 outcomes. The majority of these are functional

TABLE 1: Outcome Measures Used in OBQI Demonstrations.

Health Status Outcome Measures*

Functional: Activities of Daily Living

Improved in:

- Ambulation/Locomotion
- Dressing Upper Body
- Dressing Lower Body
- Grooming
- Bathing
- Eating
- Toileting
- Transferring

Stabilized in:

- Grooming
- Bathing
- Transferring

Functional: Instrumental Activities of Daily Living

Improved in:

- Management of Oral Medications
- Light Meal Preparation
- Laundry
- Housekeeping
- Shopping
- Telephone Use

Stabilized in:

- Management of Oral Medications
- Light Meal Preparation
- Laundry
- Housekeeping
- Shopping
- Telephone Use

Physiologic

Improved in:

- Pain Interfering with Activity
- Number of Surgical Wounds
- Status of Surgical Wounds
- Dyspnea
- Urinary Tract Infection
- Urinary Incontinence
- Bowel Incontinence
- Speech or Language

Stabilized in:

- Speech or Language

Emotional/Behavioral

Improved in:

- Anxiety Level
- Behavioral Problem Frequency

Stabilized in:

- Anxiety Level

Cognitive

Improved in:

- Confusion Frequency
- Cognitive Functioning

Stabilized in:

- Cognitive Functioning

Utilization Outcome Measures†

- Acute Care Hospitalization
- Discharge to Community
- Emergent Care

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* A patient improves when the scale value for the health attribute under consideration shows an improvement from one time point to the next (i.e., between admission and discharge). If the patient is less disabled or dependent at discharge than at start of care, then the patient has improved and the improvement outcome measure takes on the value "1;" otherwise, it takes on the value "0." If the patient is at the most independent or "healthiest" extreme of the scale, it is impossible to improve, and therefore the measure is not defined for such patients.
A patient stabilizes when the scale value for the health attribute under consideration shows nonworsening in patient condition. If the patient is no more disabled or dependent (that is, has not worsened) at discharge than at start of care, then the patient has stabilized and the stabilization outcome measure takes on the value "1," whereas if the patient worsened, the stabilization measure takes on the value "0." If the patient is not able to worsen according to the scale (i.e., is at the most dependent or "sickest" extreme of the scale), then the measure is not computed for this particular patient because his/her condition cannot worsen. Exclusions result in differing sample sizes for each health status outcome.
As an illustration, the ambulation/locomotion scale in OASIS is specified as follows:
Ability to SAFELY walk, once in a standing position, or use a wheelchair, once in a seated position, on a variety of surfaces.
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.
If the patient is classified at level "0" at start of care, the improvement measure for ambulation/locomotion is not computed. If the patient is classified at level "5," the stabilization measure is not computed.

† Utilization outcomes take on the value "1" if the indicated event occurs; otherwise, they take on the value "0." Unlike the aforementioned improvement and stabilization outcomes, these outcomes are defined for all patients. For example, if the patient is hospitalized (as an inpatient, for a period of at least 48 hours), the hospitalization measure takes on the value "1;" otherwise, it takes on the value "0."

outcomes because of the emphasis in home care on assisting patients to become or remain sufficiently independent to stay in their home environment, avoiding institutional long-term or acute care. The more technical or specific skilled services provided by home health agency staff such as wound care, administering IVs, infection control, cardiac evaluation and monitoring, and cognitive assessment often are directed toward or culminate in assisting patients to (resume) function(ing) as well as possible at home.

Each health status outcome measure is either an improvement or stabilization measure as defined in the first footnote of Table 1. At times, the intent of HHC is to prevent decline or slow the rate of decline in health status. Hence, in addition to improvement measures, Table 1 contains selected stabilization measures that are often necessary to evaluate outcomes. The research considerations and principles that shaped the approaches to outcome measurement in this program are discussed in the article reproduced in Supporting Document 3 (Volume 3).

While it is possible to employ aggregate outcome measures corresponding to multiple domains of health (such as a single global measure encompassing all domains of functioning simultaneously) and thereby to measure outcomes on near-continuous or at least polytomous (ordinal) scales, dichotomous outcomes corresponding to individual domains of health status were chosen for OBQI applications for two reasons. First, they are more readily understood by clinicians (and others). Second, they are more straightforward to use to enhance patient outcomes than more complex composite outcome measures that necessitate determining which specific outcome domains must be further examined to improve the composite measure. The utilization outcomes in Table 1 can be regarded as surrogate health status outcomes. While the 41 outcome measures in this table have been selected for OBQI applications at the present time, research to improve upon these outcomes for OBQI and other applications is ongoing.

Information on reliability of OASIS data items is available in Supporting Document 2 (Volume 3) and elsewhere.[13, 26] An outcome measure was judged to be reliable for OBQI if the underlying data item used to compute the outcome had an interrater reliability coefficient (weighted kappa) greater than 0.60. (The raters included two skilled nurses trained in using OASIS who did duplicate assessments within 24 hours of one another, while randomizing which rater was first, for 66 patients from five agencies.) Only two of the 38 health status outcome measures used in the OBQI outcome reports had coefficients less than 0.60 (both were 0.54). Twenty-five outcome measures had reliability coefficients greater than 0.70. OASIS reliability testing and refinements to improve reliability will continue as CMS and others use OASIS and OBQI nationally. The current version of OASIS, with an explanatory prologue and instructions for using OASIS, is provided in Supporting Document 4 (Volume 3).

2. The Framework for Quality Improvement

The essential features of the CQI applications framework employed in the OBQI demonstration trials were developed and refined in a pilot project involving several home health agencies in the early 1990s. Supporting Document 5 (Volume 3) contains a detailed explanation of OBQI. This framework includes the outcome analysis and

outcome enhancement components depicted in Figure 1. The outcome analysis component begins with collecting, computerizing, and transmitting OASIS data to a central source (the University of Colorado in the case of the demonstrations). Outcome, case mix, and adverse event reports are returned to each agency on an annual basis. Most important is the All Patients' Outcome Report that permits agency staff to analyze their patient outcomes aggregated to the agency level. In the demonstrations, two additional outcome reports for orthopedic and cardiac patients were provided if agency-specific sample sizes were adequate. The outcome reports provide a comparison of agency performance (1) relative to a national reference or benchmark population and (2) from one year to the next. The 41 outcome measures presented in Table 1 were selected from a larger set of outcomes for the all-patient reports. The case mix report contains an overview of the agency's admitting case mix on about 140 case mix factors for the current time period or year relative to the agency's prior time period and the (national) reference group. The adverse event report provides a profile on low-frequency adverse patient outcomes such as emergent care for hypo/hyperglycemia. Incidence rates for such events are too low for meaningful risk adjustment. Their occurrence generally requires review and scrutiny on a case-by-case basis. Figure 2 provides an illustration from an outcome report; the footnotes explain the terms and computations involved. A complete copy of the outcome report series for a hypothetical agency is found in Supporting Document 6, Volume 3. It contains sample outcome, case mix, and adverse event reports as well as a patient satisfaction report included as part of the demonstrations.

FIGURE 1: OBQI Applications Framework.

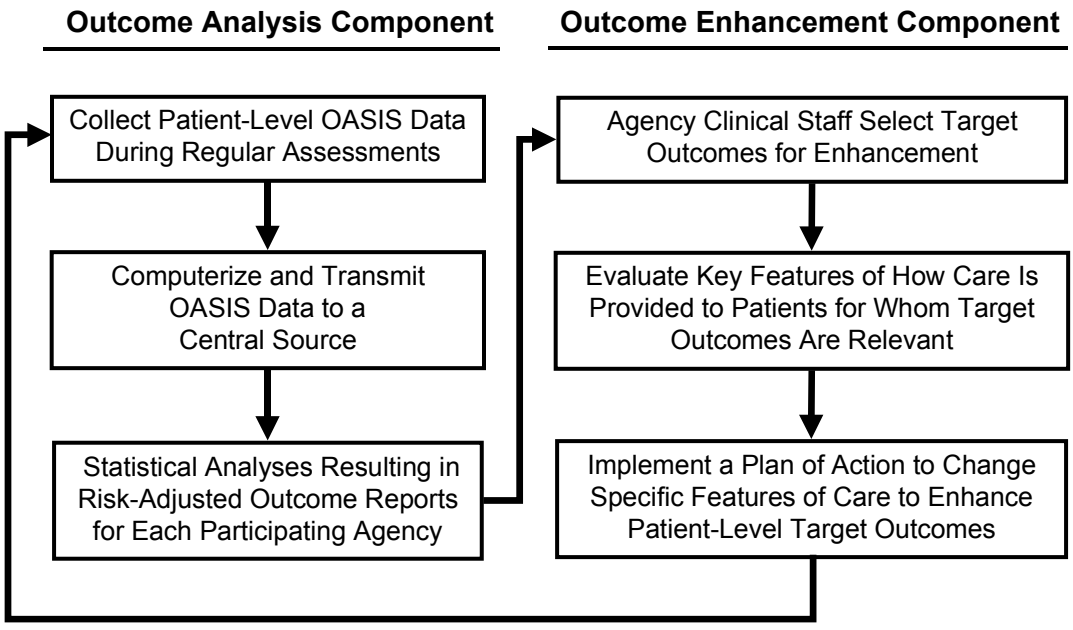
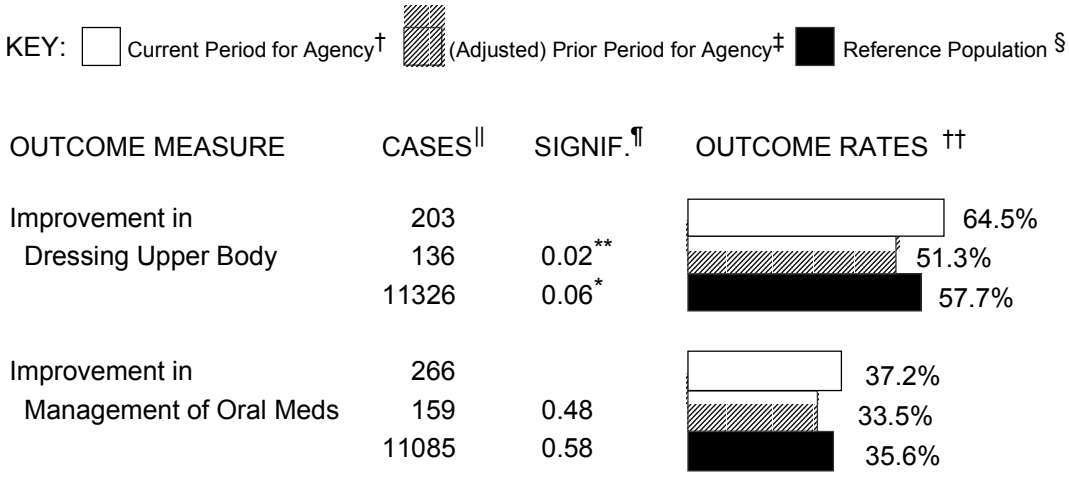


FIGURE 2: Excerpt (Using 2 of 41 Outcomes) from an Agency-Level Risk-Adjusted Outcome Report.



† The unshaded or "current" rates pertain to the actual or observed improvement rates for each outcome during the most recent period (usually about 12 months).

‡ The partially shaded or "(adjusted) prior period" rates are the risk-adjusted comparative rates for the period preceding the most recent one for the given agency and are computed by

$$\hat{y}(\text{adj prior}) = y_p(\text{obsv}) + [\hat{y}_c(\text{pred}) - \hat{y}_p(\text{pred})],$$

where $y_p(\text{obsv})$ = the observed outcome rate for the prior period for the agency; $\hat{y}_c(\text{pred})$ = the predicted rate for the current period obtained by substituting all patients eligible for the outcome for the agency into the outcome's logistic regression model based on pooled data from the prior and current period, and computing the average or rate across all such predicted values; and $\hat{y}_p(\text{pred})$ = the predicted rate for the prior period obtained by substituting all patients eligible for the outcome for the agency into the outcome's logistic regression model based on pooled data from the prior and current period -- and computing the average or rate across all such predicted values. Intuitively, the expression $[\hat{y}_c(\text{pred}) - \hat{y}_p(\text{pred})]$ represents the outcome rate adjustment to the baseline (observed prior) rate that is due to the difference or change in risk factors between the current and prior periods.

§ The darkened or "reference" rates are the risk-adjusted comparative reference sample rates for each outcome computed by calculating the mean of the predicted or expected values for each nonexcluded patient admitted to the agency under consideration. These are obtained by substituting each patient's values for the risk factors into the logistic regression model for that outcome (which was estimated using all patients in the reference sample), and averaging the predicted values across all the agency's (nonexcluded) patients for the outcome.

|| The "cases" column contains the number of patients or outcome episodes for the time period or the reference group to which the bar to the far right of the case count corresponds (in the instance of the reference group, this is the number of cases on which the logistic regression model for the outcome was estimated). The number of cases for each of the three samples reflects the number of patients not excluded from the outcome measure computation for the indicated period or group, using the exclusion criteria given in the first footnote of Table 1.

¶ The "signif." column contains the statistical significance level of the test of the null hypothesis that the outcome rate for the current period is the same as the comparative rate (for either the adjusted prior period or the reference group). For the current vs. adjusted prior comparison, this is the significance level for testing the hypothesis that two sample binomial proportions are the same. In the case of small samples (N<30), it is the significance level for Fisher's exact test, and for larger samples, it is the significance level for the chi-square approximation to this test. In comparing the current vs. reference population rate, it is the significance level for the one-sample binomial test that a sample proportion is equal to a population proportion. Several statistical tests were examined theoretically and experimentally before determining that these two binomial tests are the most informative and sensitive for generating these significance levels. Single and double asterisks are used on the outcome report to convey significance for P<.10 and P<.05, respectively, so that the report can be scanned to determine where there might be significant differences (either favorable or unfavorable) in outcomes.

†† The outcome rates for the two time periods and the reference groups are depicted by the length of the respective bars for the outcome. Their numeric values are given to the right of each bar.

In the second component of the OBQI applications framework, outcome enhancement, each agency is given considerable latitude to conduct its own CQI activities. These include process-of-care investigations that culminate in the development and implementation of plans of action specifying how care behaviors will be changed to enhance outcomes. Upon conclusion of the first demonstration year, each demonstration agency received an outcome report showing its performance during that year relative to all demonstration agencies (no prior period comparison was possible the first year). After reviewing the report, various methods were implemented by agency staff to assess and change specific care behaviors related to target outcomes of their choosing. Thus, agencies produced written plans of action for their target outcomes at the beginning of the second demonstration year. These plans documented the target outcome, care behaviors being targeted, how and where they would be changed, who would be responsible for implementing the changes, and how the changes would be monitored on a continuing basis. The outcome enhancement process was repeated at the start of each succeeding demonstration year when the annual outcome report was received.

Accurate and uniform data on patient health status are critically important to OBQI. In addition, accuracy and uniformity of patient information introduce far more rigor into the assessment process than had been customary in HHC. Further, the OBQI approach entails a considerably different type of thinking and philosophy than typically used by home care providers. Such thinking requires analysis that links care to specific outcomes in managing care behaviors and coordinating changes in care behaviors that involve multiple providers. Separate training programs accompanied the demonstration trials that focused on incorporating OASIS into comprehensive assessments and using OBQI to evaluate and enhance patient outcomes.

3. Demonstration and Evaluation Design

After the developmental research, including a pilot to assess the feasibility of OBQI, two large-scale demonstration trials were designed and implemented. Hospitalization was selected as the most pivotal outcome to evaluate since it would be readily measurable for non-OBQI patients as well as on a pre/post basis for OBQI patients. The other outcomes in Table 1 were selected for the pre/post comparisons for OBQI patients. Mortality was not selected as an OBQI outcome because, for the predominantly elderly population, it is exceptionally difficult to define and risk adjust (low frequency) unexpected mortality. Demonstration agencies were selected from a larger pool of several hundred agencies that expressed interest in OBQI. Demonstration sites included small, medium, and large agencies, both rural and urban, and agencies representing a variety of ownership types. It was not possible to randomize the OBQI intervention because (1) OASIS is an integral part of the OBQI intervention and yet (2) it also would be needed to provide the data to risk adjust and measure outcomes in the non-OBQI group (since sufficiently precise health status data were not uniformly available from clinical records of home health agencies at the time the demonstration trials were implemented). That is, without collecting OASIS data, it would be impossible to compare outcomes in the intervention (OBQI) and nonintervention (non-OBQI) groups. Paradoxically, by collecting such data the nonintervention group would receive a significant portion of the intervention -- namely, a standardized approach to assessment, data

collection, computerization, verification of the accuracy of health status information, and associated training of clinical staff. Unto itself, this standardized approach could influence outcomes by heightening the awareness and possibly the motivation of providers to be more attentive to patient needs. Alternatively, if nonagency staff were to collect OASIS data at SOC and follow-up points, the nonintervention patients would receive different professional/clinical attention at these points than the intervention patients.

As a result, three comparative approaches not involving randomization were incorporated into the research design. First, a pre/post comparison of risk-adjusted outcomes would be undertaken from one demonstration year to the next for patients pooled across all demonstration agencies. Second, for the most important outcome, hospitalization, a randomly selected comparison group of non-OBQI Medicare patients from the same states as the OBQI Medicare patients would be used to assess whether changes in hospitalization rates for Medicare patients (who comprise the majority of HHC patients) under OBQI were different from those for non-OBQI HHC patients in the same states. Third, since the OBQI methodology involves selecting specific target or OBQI outcomes, a comparison of improvements or changes in such outcomes with improvements or changes in (uncorrelated) nontarget outcomes would be undertaken. Statistical power would be exceptionally high (exceeding .95), even for small effects, since the design called for large sample sizes.

In accord with this demonstration design and evaluation plan, HCFA sponsored a national OBQI demonstration trial between 1995 and 2000, with funding from both HCFA and the Robert Wood Johnson Foundation. This national demonstration involved 54 home health agencies from 27 states. If successful, the demonstration approach would serve as the prototype for a national OBQI program for all Medicare-certified home health agencies. The national OBQI trial was designed to establish a methodology and template to (1) collect uniform (OASIS) data on all adult, nonmaternity home health patients to measure and report patient outcomes, (2) utilize outcome measures for CQI in HHC, and (3) provide a foundation for an approach to enhancing patient outcomes, which might lead to a more efficient systemwide approach to performance improvement in HHC.

In late 1995, the New York State Department of Health implemented a statewide OBQI demonstration trial, patterned after HCFA's national OBQI demonstration, that began with 19 and would eventually involve 33 certified agencies and 24 noncertified agencies. Like the National Demonstration, this six-year program was administered by the University of Colorado Center for Health Services Research. After training by Research Center staff, the more than 100 agencies participating in the two demonstration trials integrated into their day-to-day operation all facets of OASIS and outcome data collection, monitoring, processing, transmission, and OBQI. Further specifics on the operational components of both demonstrations are presented in Supporting Document 7, Volume 3.

4. Target Outcomes in the Demonstration

To evaluate effectiveness of OBQI and to encourage agency staff to efficiently channel quality improvement energies, all certified agencies participating in each demonstration were asked to focus their outcome enhancement activities exclusively on two target outcomes (although some agencies chose more than two). Hospitalization was a strongly recommended target outcome during the first round of OBQI for four reasons. First, it is important substantively because if a patient's condition changes or declines to a point where inpatient hospital care is necessary, it is likely that a serious change in health status has occurred. Second, if providers could improve (i.e., lower) hospitalization rates, it would strongly suggest OBQI could be effective, because hospitalization is a challenging outcome to impact in view of the multiplicity of factors that influence it, the frequent need for various clinical staff of the home care agency to be involved, and the need to have physician input and involvement in the process. Thus, hospitalization often cannot be impacted without involving and influencing the care behaviors of several providers. Third, in keeping with the research design, having all agencies attempt to improve a single outcome (which encompasses a number of potential health status changes) would facilitate homogeneous pre/post and intervention/nonintervention comparisons of the effectiveness of OBQI. Fourth, reducing hospitalization rates can have substantial impacts on (lowering) the total cost of care while at the same time reflecting enhanced patient outcomes and, thus, cost-effectiveness. For the second target outcome, however, agencies were free to choose from approximately 80 different outcomes contained in either their standard 41-outcome, all-patient report or, where applicable, two special outcome reports for orthopedic and cardiac patients, respectively. Agencies typically chose outcomes reflecting inferior performance on their part relative to the national reference sample.

5. Risk Adjustment of Outcomes

To compare outcomes for patients from one demonstration agency with outcomes for patients from all demonstration agencies, each outcome measure was risk adjusted using logistic regression (after testing several risk adjustment methods including multivariate standardization, discriminant function analysis, computerized classification methods, the Classification and Regression Tree [CART] methodology, the Group Method of Data Handling [GMDH], and multilevel stratification). The risk adjustment methodology described here represents the starting point for further research that is presently taking place to extend and revise the risk adjustment techniques that will be used to produce outcome reports for all certified home health agencies in the United States.

To estimate and then validate each logistic regression model, the entire pool of patients for a given time period was randomly split into two equal groups, a developmental and a validation sample. For example, for the first demonstration year, the total number of outcome episodes was approximately 40,000, resulting in developmental and validation samples of approximately 20,000 episodes apiece. [The terms "episode," "patient," and "case" are used interchangeably hereafter.] Each of the 41 logistic regression models was estimated using cases exclusively from the developmental sample. This first entailed conceptually and clinically specifying all possible risk factors that might influence the outcome under consideration from the 150 to

160 possible risk factors. Empirical testing using bivariate measures of association (Pearson correlations) and stepwise logistic regression followed in order to address the relationships between candidate risk factors and the outcome measure under consideration. This process included examining some higher order and interaction terms that did not usually contribute more than their first-order counterparts taken separately.

Several iterative steps followed in which the initial version of the logistic regression model was estimated for the outcome, and the coefficients and odds ratios for each risk factor were examined to determine if they were clinically plausible and statistically reasonable. Risk factors with questionable or insignificant coefficients were eliminated, at times substituting another risk factor or a combination of risk factors. Statistical significance was established at $P<.10$ instead of $P<.05$ for individual coefficients since a predictive model rather than an impact assessment (i.e., to assess the impact of specific risk factors) was being developed. Each model was re-estimated a number of times to reach a credible and stable model. Upon completion of this first-stage process, the explanatory power of the model was tested using the independent validation sample. This involved selecting 20 random subsamples (each 25% of the total) from the validation sample and correlating the predicted outcome values with the observed outcome values for each subsample to obtain twenty "R^2" statistics, one for each of the 20 random validation samples. This intuitive R^2 statistic is the squared Pearson correlation between predicted and observed values.[27] It proved to be the most useful statistic in assessing explanatory power of logistic regression models in validation samples relative to developmental samples for this application. Thus, each R^2 reflects the proportion of outcome variance explained by the model in the validation subsample.

A substantial discrepancy between the (similarly computed) R^2 for the developmental sample and the mean R^2 for the validation subsamples, or an unusually large range for the 20 R^2s, indicated that the model likely had been overfit to the developmental sample. That is, the model had been estimated in such a way that its risk factors and coefficients were excessively tailored to the unique rather than the representative characteristics of the developmental sample. If overfitting was identified, re-estimation of the model was then undertaken using the developmental sample. The above steps would be repeated, changing or eliminating the (sometimes multicollinear or highly correlated) risk factors judged to cause the overfit problem, re-estimating model coefficients, then reviewing the model again, until a stable and clinically valid model was obtained for which the developmental sample explanatory power and validation explanatory power were approximately the same. For example, in estimating the initial risk model for hospitalization using the developmental sample, it was possible to attain a developmental R^2 close to .40 by overfitting the model owing to the large number of risk factors available through OASIS. However, validation R^2s for this outcome were usually under .20, which required re-estimation until the developmental and validation R^2s converged between .15 and .19. The 41 separate risk models for each outcome were derived in this manner and used to produce outcome reports for the first year of the demonstration programs that permitted a comparison of observed and expected rates for all outcomes for every agency. Risk models were re-estimated each year in producing several rounds of outcome reports for each home health agency participating in the OBQI demonstrations. Tables 2 and 3 provide illustrations of two risk models estimated for recent outcome report purposes.

TABLE 2: Logistic Regression Model for Risk Adjusting the Outcome of Improvement in Dressing Lower Body.

Risk Factor Measured at SOC/ROC*†	Coefficient‡	Odds Ratio‡	(90% CI)‡
Medicare as a payment source (0-1)	.18	1.19	(1.10-1.29)
Patient lives alone (0-1)	.22	1.24	(1.15-1.34)
ADL assistance provided by caregiver (0-1)	-.22	.80	(0.76-0.86)
Inpatient discharge from hospital (0-1)	.36	1.43	(1.34-1.52)
Inpatient discharge from rehab. facility (0-1)	.28	1.32	(1.20-1.46)
Disruptive/socially inappropriate behavior within past 2 weeks (0-1)	-.26[b]	.77	(0.62-0.96)
Memory loss requiring supervision within past 2 weeks (0-1)	-.11[b]	.90	(0.81-0.99)
Disability in dressing upper body (0-3)	-.09	.92	(0.87-0.96)
Disability in dressing lower body (0-3)	.90	2.46	(2.31-2.62)
Disability in toileting (0-4)	-.10	.90	(0.87-0.94)
Disability in transferring (0-5)	-.20	.82	(0.78-0.86)
Disability in ambulation (0-5)	-.17	.84	(0.80-0.89)
Disability in housekeeping (0-4)	-.06	.94	(0.91-0.98)
Disability in light meal preparation (0-2)	-.07[a]	.93	(0.88-0.99)
Disability in management of oral medications (0-2)	-.19	.83	(0.79-0.87)
Disability in telephone use (0-5)	-.12	.89	(0.87-0.91)
Prior (2 weeks ago) disability in grooming (0-3)	-.08	.93	(0.89-0.97)
Prior (2 weeks ago) disability in ambulation (0-5)	-.07	.93	(0.89-0.97)
Prior (2 weeks ago) disability in laundry (0-2)	-.20	.82	(0.78-0.87)
Moderate recovery prognosis (0-1)	.17	1.19	(1.07-1.32)
Good functional status rehab prognosis (0-1)	.20	1.22	(1.13-1.31)
Stasis ulcer(s) present (0-1)	-.33	.72	(0.59-0.88)
Number of surgical wounds present (0-4)	.12	1.12	(1.08-1.17)
Status of most problematic pressure ulcer (0-3)	-.14	.87	(0.82-0.93)
Acute condition: orthopedic (0-1)	-.23	.80	(0.74-0.85)
Acute condition: ventilator (0-1)	-1.04[b]	.35	(0.13-0.97)
Acute condition: terminal (0-1)	-.35	.71	(0.60-0.84)
Chronic condition: dependence in living skills (0-1)	-.10[b]	.90	(0.82-0.99)
Chronic condition: dependence in personal care (0-1)	-.44	.64	(0.59-0.70)
Chronic condition: urinary incontinence/catheter (0-1)	-.34	.72	(0.66-0.78)
Diagnosis: ill-defined conditions (0-1)	-.08[b]	.93	(0.87-0.99)
Diagnosis: nervous system disorder (0-1)	-.17	.84	(0.77-0.92)
Length of stay: more than 31 days (0-1)	.50	1.65	(1.56-1.75)
Constant	.08		

Developmental sample R^2 = 0.230; Validation sample R^2s for 20 validation subsamples: Minimum = 0.211, Maximum = 0.237, and Mean = 0.224.§

* SOC = Start of Care, ROC = Resumption of Care after inpatient stay. Risk factors pertain to SOC/ROC unless indicated otherwise.

† The number of values in the measurement scale for each risk factor is in parentheses. E.g., the risk factor corresponding to whether the patient lives alone takes on the values 0 and 1; the risk factor corresponding to transferring takes on six values, from 0 through 5, with higher levels depicting greater dependence.

‡ All coefficients/odds ratios are significant at P<.10 using the likelihood ratio test for the hypothesis that the coefficient is zero. For this model, the five coefficients/odds ratios significant for .05<P<.10 are superscripted by "b," the one that is significant for .01<P<.05 is superscripted by "a," and the remainder are significant for P<.01. 90% confidence intervals (CIs) are given and odds ratios are considered significant at P<.10 (rather than the standard 95% CIs and P<.05 since the risk models were not used to assess impacts of risk factors on outcomes, rather the model was used purely for predictive or risk adjustment purposes, resulting in the need to be inclusive).

§ The R^2 values are the squared correlations between predicted and observed values for all patients in the developmental and validation subsamples.

TABLE 3: Logistic Regression Model for the Outcome of Acute Care Hospitalization.

Risk Factor Measured at SOC/ROC*†	Coefficient‡	Odds Ratio‡	(90% CI)‡
Medicare as a payment source (0-1)	.07[a]	1.07	(1.02-1.13)
Inpatient discharge from hospital (0-1)	.30	1.35	(1.30-1.41)
Inpatient discharge from nursing home (0-1)	.20	1.22	(1.10-1.36)
Urinary catheter within past 2 weeks (0-1)	.24	1.27	(1.11-1.45)
Maximum severity rating among all diagnoses (0-4)[§]	.13	1.14	(1.11-1.18)
Number of diagnoses with severity rating ≥ 2 (0-6)[§]	.06	1.07	(1.05-1.08)
Moderate recovery prognosis (0-1)	-.16	.85	(0.80-0.91)
Good rehabilitation prognosis (0-1)	-.29	.75	(0.71-0.78)
Drug dependency at SOC (0-1)	.26[a]	1.30	(1.08-1.55)
Home sanitation hazard (clutter/soil/trash/vermin) (0-1)	.19	1.21	(1.13-1.29)
Patient lives alone (0-1)	.08	1.09	(1.04-1.14)
Patient has unpaid live-in help (0-1)	.08[a]	1.08	(1.02-1.15)
Vision impairment (0-2)	.05[a]	1.05	(1.01-1.09)
Pain interfering with activity (0-3)	.03	1.03	(1.01-1.05)
Stage of most problematic pressure ulcer (0-4)	.14	1.15	(1.10-1.21)
Stage 3-4 pressure ulcer(s) present (0-1)	.25[a]	1.28	(1.05-1.57)
Status of most problematic stasis ulcer (0-3)	.31	1.36	(1.30-1.42)
Surgical wound(s) present (0-1)	-.65	.52	(0.46-0.59)
Status of surgical wound (0-3)	.24	1.27	(1.19-1.36)
Dyspnea (0-4)	.18	1.19	(1.17-1.21)
Urinary catheter (0-1)	.30	1.34	(1.23-1.47)
Bowel ostomy (0-1)	.43	1.54	(1.37-1.74)
Anxiety Level (0-3)	.03[a]	1.03	(1.01-1.06)
Depression scale (0-5)	.09	1.09	(1.06-1.13)
Disability in grooming (0-3)	.08	1.08	(1.06-1.11)
Disability in ambulation (0-5)	.06	1.06	(1.03-1.08)
Disability in bathing (0-5)	.06	1.06	(1.05-1.08)
ADL assistance provided by caregiver (0-1)	-.14	.87	(0.84-0.91)
Prior (2 weeks ago) disability in laundry (0-2)	.13	1.14	(1.10-1.18)
Prior (2 weeks ago) disability in shopping (0-3)	.06	1.07	(1.04-1.10)
Prior (2 weeks ago) disability in transportation (0-2)	.22	1.25	(1.19-1.31)
Acute condition: mental/emotional (0-1)	.43	1.54	(1.38-1.72)
Acute condition: oxygen therapy (0-1)	.22	1.24	(1.17-1.32)
Acute condition: IV/infusion therapy (0-1)	.42	1.52	(1.38-1.66)
Acute condition: enteral/parenteral nutrition (0-1)	.64	1.89	(1.68-2.13)
Acute condition: cardiac/peripheral vascular (0-1)	.29	1.34	(1.28-1.41)
Acute condition: pulmonary (0-1)	.10	1.11	(1.05-1.16)
Acute condition: diabetes mellitus (0-1)	.10[a]	1.10	(1.03-1.78)
Acute condition: gastrointestinal disorder (0-1)	.17	1.19	(1.12-1.26)
Acute condition: contagious/communicable disease (0-1)	.28	1.32	(1.17-1.50)
Chronic condition: dependence in medication administration (0-1)	.18	1.19	(1.14-1.25)
Chronic condition: chronic pain (0-1)	.20	1.23	(1.12-1.34)
Diagnosis: genitourinary system diseases (0-1)	.21	1.23	(1.17-1.30)
Diagnosis: skin/subcutaneous diseases (0-1)	.27	1.31	(1.22-1.41)
Diagnosis: neoplasms (0-1)	.49	1.64	(1.55-1.73)
Diagnosis: endocrine/nutritional/metabolic (0-1)	.25	1.29	(1.23-1.35)
Diagnosis: blood diseases (0-1)	.35	1.41	(1.33-1.50)
Diagnosis: circulatory system diseases (0-1)	.13	1.14	(1.09-1.20)
Length of stay: more than 31 days (0-1)	-.66	.52	(0.50-0.54)
Constant	-2.78		

Developmental sample R^2 = 0.165; Validation sample R^2s for 20 validation subsamples: Minimum = 0.145, Maximum = 0.165, and Mean = 0.155.[§]

* † § See Table 2 footnotes for explanations of these items.

‡For this model, the seven coefficients/odds ratios significant for .01<P<.05 are superscripted by "a," and the remainder are significant for P<.01. See the corresponding footnote in Table 2 for further explanation.

6. Evaluation Approach for Hospitalization Outcomes

Evaluation of the demonstrations was concerned primarily with the impacts of OBQI on patient outcomes and secondarily with the feasibility of implementing the OBQI approach. If outcomes were impacted as a result of the first or succeeding years' outcome reports and outcome enhancement activities, this would suggest that the OBQI framework was feasible to implement and would produce the desired results. The outcome reports provide a straightforward way to evaluate the impacts of each individual agency's OBQI program by comparing target outcome rates for the current period with the risk-adjusted rates for the prior period. To evaluate the general OBQI impact on hospitalization rates (the first target outcome) for all patients, the same approach can be used by pooling data across all OBQI patients, comparing the current period's hospitalization rate with the risk-adjusted rate for the prior period. An alternative, which yields essentially the same results, is to include all risk factors relevant for the hospitalization outcome in a single logistic regression model estimated on the pooled sample of all current and prior period patients in the demonstration, with a dichotomous variable corresponding to the prior vs. the current period. The magnitude and significance of the coefficient or odds ratio for this variable reflect the magnitude and significance of the risk-adjusted mean difference in hospitalization rates for the two periods (years). Since this approach is more commonly used in evaluations of this nature, it was employed to determine pre/post results for adjacent demonstration years and between the first and final demonstration years for each of the two demonstration trials.

To assess intervention (OBQI) vs. nonintervention (non-OBQI) group differences, Medicare claims data were used to determine hospitalization rates for a random sample of non-OBQI Medicare patients in the demonstration states. This permitted a comparison of changes in hospitalization rates over the demonstration time period between OBQI and non-OBQI Medicare home health patients. It was not possible to risk adjust the non-OBQI hospitalization rates for Medicare home health patients, because OASIS data were not available for these patients and the health status data available from claims was not sufficiently comprehensive and consistent. Nonintervention patients were restricted to the demonstration states, and annual changes in unadjusted hospitalization rates were compared for intervention and nonintervention patients in these states using the unequal variance t-test and Wilcoxon test, both of which yielded the same results. As is evident in the findings section (Section D), using unadjusted rates for this comparison proved informative in view of the very close parallels between annual trends in adjusted and unadjusted hospitalization rates for patients on whom OASIS data were available.

7. Evaluation Approach for Other Outcomes

Analysis of changes for the target outcomes other than hospitalization from one year to the next was complicated by the fact that no single target outcome was chosen by a preponderance of agencies. Consequently, findings were combined across different outcomes and standardized for the differences in magnitudes of mean outcome rates across the different outcome measures. This was done by analyzing the risk-adjusted percent change or improvement in each agency's nonhospitalization target outcome rates from one year to the next, averaging the percent changes across all agencies first to

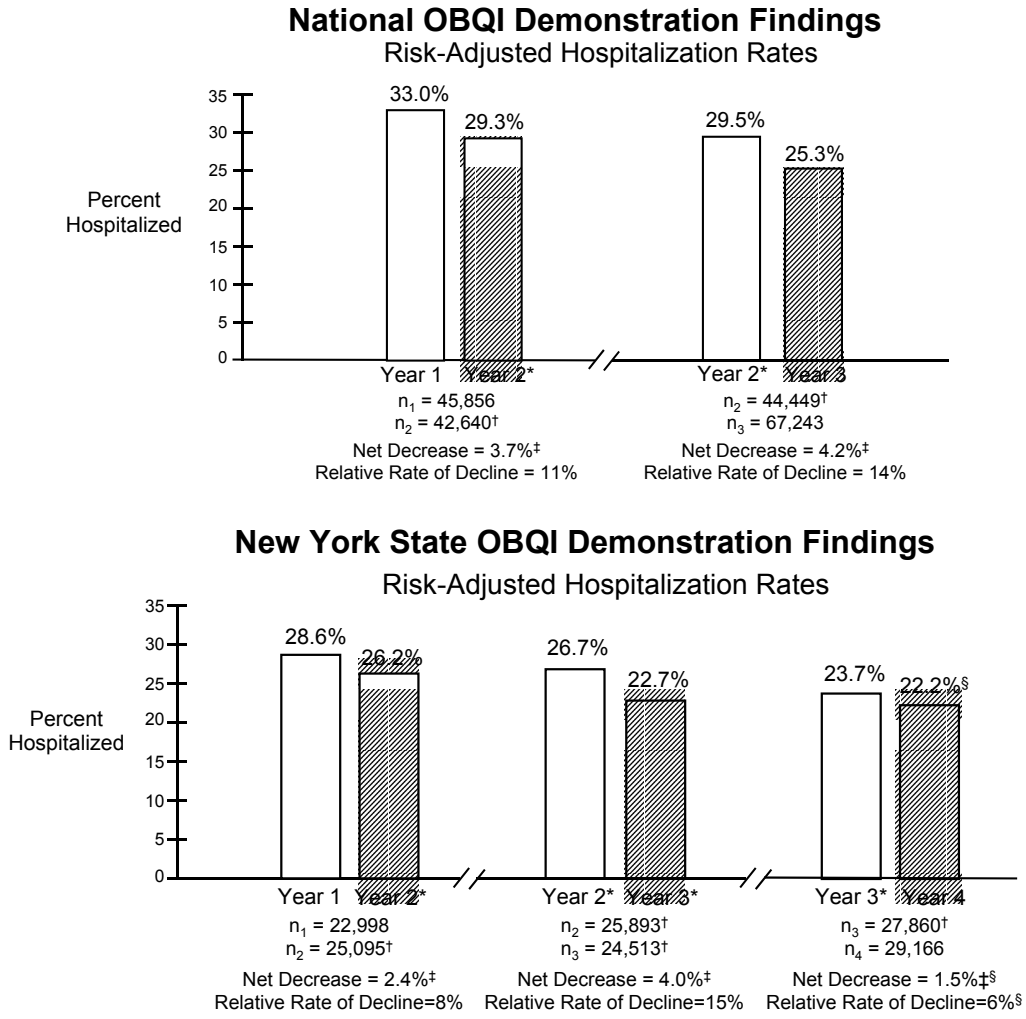
determine whether the average improvement rate exceeded zero for such target outcomes. This average improvement rate (i.e., percent change) for target outcomes also was compared with the average improvement rate for a set of uncorrelated comparison outcomes, because it was appropriate to control for possible concurrent outcome trends resulting from factors other than the structured OBQI methodology. For this purpose it was necessary to use (relatively) uncorrelated comparison outcomes because it is plausible for a plan of action focused on one target outcome to influence other nontarget outcomes by having (desirable) OBQI "spillover" effects. For example, by positively influencing the target outcome of Improvement in Ambulation/Locomotion, it is also possible for an agency to positively influence the outcome of Improvement in Transferring (e.g., bed-to-chair, standing-to-sitting) because these two outcomes are highly correlated. Therefore, within each demonstration agency, a comparison outcome was selected for each (nonhospitalization) target outcome so that it was at most minimally associated or correlated (either positively or negatively) with the target outcome. This permitted the mean percent change (improvement rate) across all national (or New York State) demonstration agencies for nonhospitalization target outcomes to be compared with an analogous mean percent change for comparison outcomes that were uncorrelated with the target outcomes at each agency. Subject to the requirement that improvement measures be compared with improvement measures and stabilization measures be compared with stabilization measures (defined in the first footnote of Table 1), comparison outcomes were selected solely on the basis of low correlation with the target outcome (prior to examining actual change rates at the agency level). The (risk-adjusted) mean percent change for the target outcome sample was compared with the (risk-adjusted) mean percent change for the comparison outcome sample using the two-sample unequal variance t-test and was verified with the two-sample Wilcoxon test.

C. RESULTS

1. Hospitalization Outcome Findings

The time periods for each cycle of outcome reporting were approximately 12 months and were termed Years 1, 2, 3, and (for the New York State Demonstration) 4. OBQI impacts on outcomes were assessed (1) by comparing the outcome changes between pairs of consecutive years for all demonstration agency patients and (2) by comparing year-to-year hospitalization rate changes for OBQI patients with non-OBQI patients in the demonstration states. The results comparing risk-adjusted hospitalization rates for Year 1 vs. Year 2 and Year 2 vs. Year 3 for the National and New York State Demonstrations are presented in Figure 3, along with the Year 3 vs. Year 4 comparison for New York State. For the National OBQI Demonstration, after adjusting for the risk factor differences, the Year 1 hospitalization rate was 33.0%, compared with the Year 2 hospitalization rate of 29.3%. The decrease of 3.7 percentage points is statistically significant ($P<.001$) and translates into a relative rate of decline from Year 1 to Year 2 of 11%. The analogous risk-adjusted decrease from Year 2 to Year 3 was from 29.5% to 25.3% (the first footnote in Figure 3 explains why this Year 2 rate is slightly different from the first Year 2 rate which was compared with Year 1). The decrease of

FIGURE 3: OBQI Impacts on Risk-Adjusted Hospitalization Rates.



* The Year 2 hospitalization rates differ for the Year 1 vs. Year 2 and the Year 2 vs. Year 3 comparisons due to both risk adjustment and the differences in patient-level sample sizes and contributing agencies mentioned in the note below. For the Year 1 vs. Year 2 comparisons, the Year 2 hospitalization rate is the observed rate and the Year 1 rate is risk adjusted, whereas for the Year 2 vs. Year 3 comparisons, the Year 3 rate is the observed rate and the Year 2 rate is risk adjusted. For the New York State findings, this explanation also pertains to the two different Year 3 rates.

†Subject to the following conditions regarding pairs of years, all 54 certified agencies in the National Demonstration contributed to the national findings. The 19 certified agencies that started at the outset of the New York State Demonstration contributed to the New York State findings. Patient-level sample sizes for Year 2 in the Year 1 vs. Year 2 and Year 2 vs. Year 3 comparisons differ because (a few) selected agencies were excluded for certain years owing to data reporting problems or because they started later in the demonstration period than other agencies. If data for a given agency were not available for a specific year, then that agency's patients also were excluded from the comparison year. For example, a few agencies started late in the National Demonstration and provided only Year 2 and Year 3 data. Therefore, their patient-level data were not included in the Year 1 vs. Year 2 comparison, but they were included in the Year 2 vs. Year 3 comparison.

‡All net decreases are statistically significant (P<.001). The significance level for each net decrease corresponds to a test of the hypothesis that the net risk-adjusted decrease in hospitalization rates was zero. It is based on the likelihood ratio test for the significance of the coefficient or odds ratio for the time period dichotomous indicator (e.g., Year 1 vs. Year 2) in the logistic regression model that included all risk factors for hospitalization as well as the time period indicator.

§Hospitalization rates for Year 4 of the New York State Demonstration may have been inflated relative to prior years owing to a federal reporting requirement from which agencies were exempt under the demonstration, although some agencies appear to have complied with the requirement and included hospitalizations between 24 and 48 hours, whereas the demonstration definition was 48 hours or more. This may account in part for the lower net decrease and relative rate of decline from Year 3 to Year 4.

4.2 percentage points is statistically significant (P<.001), yielding a relative rate of decline from Year 2 to Year 3 of 14%. The risk-adjusted net decrease (not shown in Figure 3) of 7.2 percentage points (from 32.5% to 25.3%) in hospitalization rates from Year 1 to Year 3 for the National OBQI Demonstration resulted in an overall risk-adjusted relative rate of decline of 22% over the three-year demonstration period (P<.001).

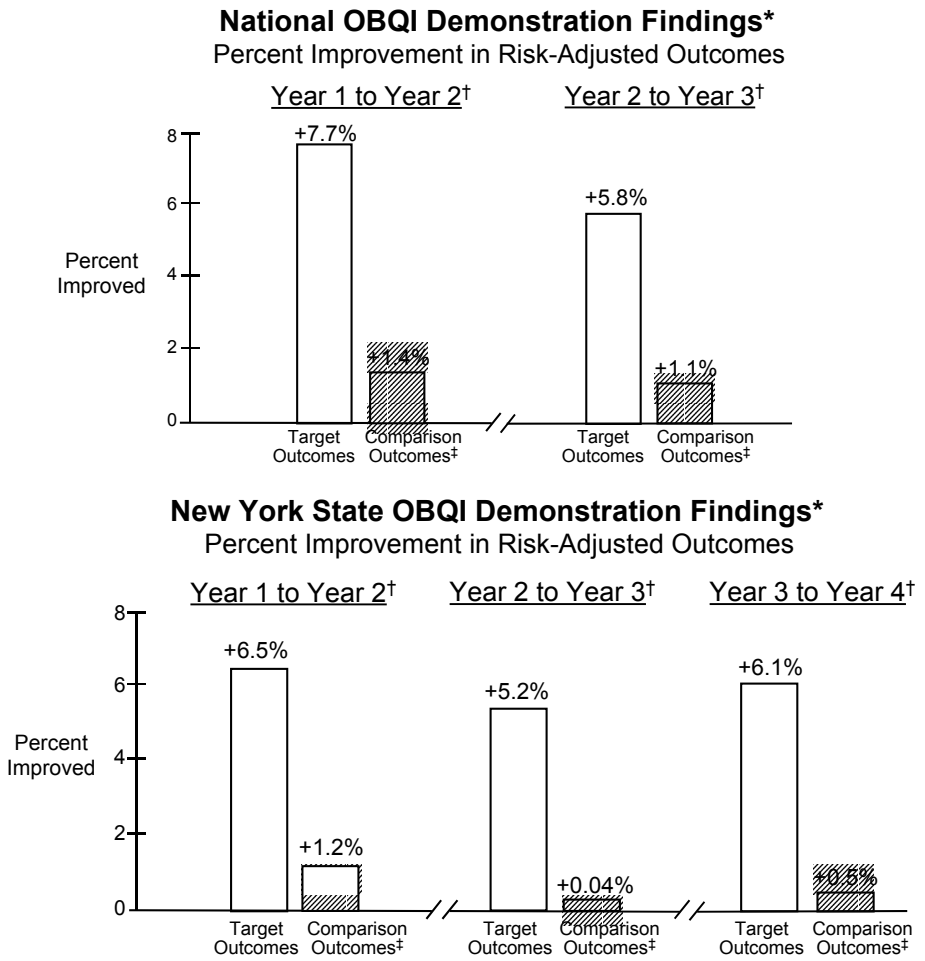
Analogous annual decreases in risk-adjusted hospitalization rates occurred for the New York State OBQI Demonstration patients as shown in the lower portion of Figure 3. All decreases between pairs of adjacent years were significant (P<.001), although the decrease from Year 3 to Year 4 was less than the prior two decreases. Also not shown in Figure 3, the overall risk-adjusted relative rate of decline from Year 1 to Year 3 was 20% (P<.001) and the Year 1 to Year 4 risk-adjusted change in New York (from 30.1% to 22.2%) produced a net decrease of 7.9 percentage points and a four-year overall relative rate of decline of 26% (P<.001). The hospitalization rate changes for non-OBQI Medicare HHC patients in the demonstration states were based on a 5% random sample of Medicare patients admitted to nondemonstration agencies in these states. Sample sizes were 91,679, 81,631, and 75,581 for these non-OBQI patients for Years 1, 2, and 3, respectively, of the National Demonstration Trial. The findings showed only small changes in hospitalization rates for non-OBQI patients in the demonstration states between Year 1 and Year 2 of the demonstration period (a decrease of 0.4%). The change between Year 2 and Year 3 (a decrease of 0.3%) also was small compared to the substantially larger hospitalization decreases attained in the demonstrations. Since the 5% claims file for Medicare HHC patients did not permit a representative sample from non-OBQI agencies in New York State, claims analyses were not undertaken for non-OBQI patients in New York State.

2. Other Target Outcome Findings

The results for target outcomes other than acute hospitalization for all patients are presented in Figure 4. The mean percent improvement (i.e., percent change) in outcome rates across all national demonstration agencies in nonhospitalization risk-adjusted target outcomes from Year 1 to Year 2 was 7.7%. The analogous mean percent improvement for comparison outcomes was 1.4% over this period. The percent improvement in nonhospitalization target outcomes from Year 2 to Year 3 was 5.8%, compared with a 1.1% improvement rate in comparison outcomes over the same period for the national demonstration agencies. Thus, paralleling the findings for the patient-level hospitalization analyses, the agency-level analyses of target outcome improvement rates over these two successive periods of adjacent years resulted in significant outcome enhancements (P<.05) for both time periods. The New York State results presented in Figure 4 demonstrate analogous significant changes (P<.05) in nonhospitalization target outcomes relative to changes in comparison outcomes over the successive periods of adjacent years.

For hospitalization as well as other target outcomes, findings for a minority of the agencies were not significantly favorable. Approximately 70% to 90% of the agencies favorably and significantly impacted their target outcomes from one year to the next, although the individual agencies influencing either hospitalization or other target outcomes were not always the same across years.

FIGURE 4: Combined OBQI Impacts on Risk-Adjusted Target Outcomes Other Than Hospitalization.



* As indicated in the first footnote in Table 1, due to exclusions resulting from the definitions of improvement and stabilization measures, patient-level sample sizes vary by measure for all health status outcomes at each agency. In general, a sample size for a target outcome measure might typically range from a minimum of 30 or 40 patients to a maximum of 1000 patients or more, depending on agency size and case mix. Therefore, patient-level sample sizes vary for both target outcome measures and comparison outcome measures at each agency. In all, for any given pair of years contributing to the percent improvement analyses summarized in this figure, the total patient sample sizes range between 20,000 and 50,000 patients. As indicated below, however, the comparative analyses that resulted in these findings used the home health agency as the unit of analysis (actually an outcome measure for a home health agency was the unit of analysis, since some agencies chose more than one target outcome in addition to hospitalization). For the National Demonstration analyses, this resulted in approximately 60 cases for each of the two year-to-year comparisons. For the New York State Demonstration findings, it resulted in approximately 40 cases for each of the three year-to-year comparisons.

† The mean change (percent improvement) for the target outcome sample was compared with the mean change for the comparison outcome sample using the two-sample unequal variance t-test and the (nonparametric) two-sample Wilcoxon test. Results generally agreed regardless of which type of test was used. All mean differences (for pairs of years) were significant ($P<.05$) despite the fact that a fairly conservative approach was taken to statistical testing since outcome measures at the agency level were employed as the unit of analysis, rather than patients. In this regard, the most important statistical test used was the two-sample unequal variance t-test since it permitted the agency- or measure-level analyses to be weighted by patient sample sizes corresponding to the target and comparison outcomes for each agency.

‡ Comparison outcomes were chosen for each target outcome such that an improvement target outcome would be compared with an improvement comparison outcome, a stabilization target outcome would be compared with a stabilization comparison outcome, and the correlations between target and comparison outcomes were always less than 0.2 (typically far less) so that the variance explained in one outcome by the other would always be less than $(0.2)^2$ or 4%. Illustrative pairings of target and comparison outcomes along with their correlations for the National Demonstration Year 2 to Year 3 percent improvement analyses are: Improvement in Light Meal Preparation (target outcome) paired with Improvement in Urinary Tract Infection (comparison outcome), correlation = .095; Stabilization in Management of Oral Medications (target outcome) paired with Stabilization in Anxiety (comparison outcome), correlation = .103; Improvement in Status of Surgical Wounds (target outcome) paired with Improvement in Management of Oral Medications (comparison outcome), correlation = .046.

D. DISCUSSION

1. Support for OBQI and Its Value to Patients and Providers

Communications with clinical and administrative staff from OBQI agencies continued throughout the demonstration trials. In addition to providing assistance in clarifying issues and resolving technical problems, Research Center staff received considerable feedback about OBQI. The responses to OBQI were nearly always positive, particularly in the later years of the demonstration trials, after OASIS had been thoroughly integrated into assessment and clinical record keeping, computerization and data transmission issues had been addressed, and agencies received the first round of risk-adjusted outcome reports. By the end of the demonstration trials, many agency staff had commented on the value of being able to rigorously and efficiently monitor patient outcomes, use the various reports to isolate and resolve problems for individuals and groups of patients, and continually enhance outcomes. Clinicians and administrators also valued the opportunity to access reports on patient case mix and care needs for staffing and clinical management use, and to assess cost-effectiveness by comparing outcomes with utilization.

In general, (1) the magnitude of the effects of OBQI, (2) the large numbers and variety of patients and providers involved which ensured breadth of experience and statistical power, (3) the consistency of the pre/post and study/control findings for hospitalization rates, (4) the agreement between the hospitalization and health status outcome results, (5) the parallel findings for the two separate demonstration trials, (6) the continual successes of outcome enhancement for the vast majority of agencies throughout the demonstration, and (7) the information conveyed by clinical staff about the value of OBQI -- combine to indicate a pervasively favorable impact of OBQI on patient outcomes. The magnitude of the improvements in hospitalization rates and other outcomes was substantial, particularly since home health clinicians had never undertaken this type of quality improvement. Further, as noted in the introduction, the latter stages of these demonstrations were conducted during a time of unprecedented and radical decline in payment (under IPS) accompanied by large reductions in visits per patient and serious threats to agency survival.

Owing to preliminary findings from the OBQI demonstrations, and the value of OASIS data for case mix adjusting payment rates under PPS, in late 1999 HCFA mandated OASIS data collection for skilled level patients at all certified agencies. CMS is now moving forward with planning for OBQI nationally. While all "nonidentifier" OASIS items are used for OBQI, only selected OASIS data items are used to case mix adjust per episode payments under the newly implemented PPS for certified agencies. Industry representatives concerned exclusively with payment have suggested reducing OASIS to only those items currently used for payment and eliminating other OASIS items used for OBQI (and for potential future refinements to case mix adjustment of payment rates). The demonstration findings suggest this would be a disservice to patients, providers, and payers concerned about quality monitoring and improvement.

The impact of OBQI on hospitalization rates reinforces its value in lowering hospital inpatient expenditures by preventing hospitalization for patients admitted from the community, or rehospitalization of patients admitted from acute hospitals. The findings reported here imply that quality HHC can prevent hospitalization, a premise that had been

called into question by earlier research.[10] The present results are derived more directly from home health programs focused on quality improvement, whereas the earlier research was based on areawide analyses for all home health agencies in metropolitan areas, most of which did not have formal quality improvement programs.

2. Reasons for OBQI Successes and Areas for Continued Development

After the demonstrations were concluded, the staff of most participating agencies continued to use OBQI. Demonstration agency staff generally exhibited a strong sense of ownership of OBQI (and OASIS), reflected by the manner in which they adapted OBQI to their agency's day-to-day operations. Several factors accounted for the successes of the OBQI demonstration programs. First, information obtained, analyzed, and used in feedback reports is precise, understandable, and of practical value for clinicians. Second, when implemented correctly, requisite data items and CQI activities can be integrated into and replace current items and activities rather than add substantially to the day-to-day operational routine of clinical staff. Third, the OBQI applications framework encourages clinical staff and quality improvement coordinators to be rigorous and innovative in areas such as (1) choosing target outcomes; (2) isolating important care behaviors to change in their agency or care environment; (3) writing a focused plan of action documenting target care behaviors to change, how to change them, who is responsible for changes, how changes will be implemented and monitored, and when these various activities are to occur; and (4) motivating other clinicians to change. Such factors serve as the basis for providing informative feedback to clinicians and give rise to a flexible and pragmatic approach to enhancing outcomes.

An important feature of the OBQI framework is that it does not rely exclusively on a formula-driven approach such as clinical guidelines, care maps, or clinical paths for specific patient problems (although these can be used in the process-of-care investigation). Rather, it relies on practical feedback of a statistical nature and, most importantly, challenges clinicians to exercise sound judgement and innovation to isolate strengths and weaknesses in care behaviors or practices within the context of their specific agency or clinical group.

The above conclusions on outcome-enhancing behaviors were obtained by reviewing written plans of action and speaking with clinicians and clinical managers at demonstration agencies in person or by phone. As OBQI research proceeds, additional findings and conclusions will be disseminated on specific clinical, technical, and coordinative methods used by home care providers to enhance outcomes. Future publications will address such methods and provide findings specific to individual outcomes (other than hospitalization), based on subgroups of patients and agencies. The material in Supporting Document 8 (Volume 3) represents a starting point for such information.

When annual risk-adjusted OBQI outcome reports become available for all Medicare-certified home health agencies nationally, they will represent a resource to physicians, case managers, and discharge planners for making referral decisions and ultimately for monitoring patient outcomes. Because the current 41 outcomes span a range of patient health status indicators, it will be possible for physicians to determine the strengths of home health agencies according to different types of outcomes. New

outcomes will become available to augment the original 41. Physicians, other clinicians, and even payers will likely become more active in the OBQI process.

While nonphysician staff played the more significant roles in enhancing quality in most demonstration agencies, it was apparent in several agency-level OBQI programs that physician involvement was substantial and could have a pronounced CQI effect. The potential value of physician involvement has recently been reinforced in a home-based primary care program sponsored by the Department of Veterans Affairs.[28] In general, however, communication between physicians and home health agency staff needs to improve for physician involvement to be truly effective in an HHC-based OBQI environment.

3. A National OBQI Program to Improve the Quality of HHC

CMS's national orientation and training programs for OASIS data collection and OBQI are patterned after analogous programs used in the demonstration trials. Under nationwide implementation, training and data management programs are or will be administered at the state level. OASIS data are transmitted to a state agency and then to a central national repository for outcome reporting and case mix adjusting payment rates. At this writing, (1) case mix and adverse event reports have been made available to all agencies in the United States, (2) OASIS data have been used for case mix adjustment during the first year of prospective payment, and (3) planning is underway for national OBQI training and the first round of risk-adjusted outcome reports for all certified agencies. The outcome reports will serve as the basis for OBQI and CQI at the agency level. They also will assist the Medicare survey and certification process by providing more specific information to identify strong home health programs that need relatively little attention as well as programs in need of greater improvement. A pilot program is underway to facilitate the involvement of Quality Improvement Organizations (QIOs), previously known as Peer Review Organizations (PROs), in assisting home health agencies to implement and use OBQI for outcome enhancement. This program also builds on the training and technical assistance approaches used in the demonstration trials. OASIS-based outcome measures are now being used by many accredited home health agencies participating in the Joint Commission on Accreditation of Healthcare Organization's ORYX program that focuses on performance indicators.

As experience is gained with outcome reports, it is reasonable to assume that some streamlined version of OBQI reports will be available to the public. While public reporting on performance of health care providers remains controversial, a general tendency toward such reporting is apparent.[29, 30] Initial experience with OBQI reports for all certified agencies would be a reasonable prerequisite before public reporting is implemented.

4. Evolution and Refinement

Whether the OBQI effects observed in the demonstration trial can be replicated or approximated more widely or over longer time periods remains to be seen. The OASIS data set, the outcome measures derived and risk adjusted through the OASIS data set, and the total OBQI framework should not be viewed as work completed. Their continued evolution and improvement is imperative. A foundation now exists for a national OBQI program for HHC, but there is much to do. Refinements will be needed intermittently in areas such as revised OASIS data items for OBQI and payment purposes. Improved

interrater reliability for some data items is attainable. Progressively more explanatory power of variation in outcome measures and greater interagency equity can be achieved through improved risk adjustment and enhanced precision of data. New outcome measures can be developed and incorporated into outcome reports and adverse event reports, including composite outcome measures for more general performance evaluation. Gaps and areas to improve will naturally be identified as OASIS, outcome measures, and OBQI principles are used more extensively by home care clinicians, physicians, administrators, survey and certification programs, QIOs, payment programs, accrediting bodies, state governments, federal agencies, and researchers. Obviously, it will be important to secure input from individuals representing these various perspectives to guide the necessary evolution and plan an approach for implementing improvements. Experimentation with the OBQI framework may prove useful and contribute to enhanced CQI in other domains of health care. The implications of the findings presented here for emerging CMS programs and for other applications are discussed in Volume 1.

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