PACE/COCOA-B
Final Report

A Project to Develop an
Outcome-based Continuous Quality Improvement System and Core Outcome and Comprehensive Assessment (COCOA-B)Data Set
for the Program of All-Inclusive Care for the Elderly (PACE)

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TABLE OF CONTENTS

Chapter			Page
1.	BACKGROUND AND OVERVIEW OF PROCESS		9
	A.	Clinical Panel Reviews of Initial Draft Outcome Indicators	10
	B.	Essential Outcome Indicators for PACE OBCQI	11
	C.	Quantifying the Draft Outcome Indicators	12
	D.	Preliminary Feasibility Test of Possible Data Items for OBCQI	14
	E.	Specifying Potential Risk Factors and Associated Data Items	15
	F.	Development of the Core Comprehensive Assess. Data Set And Integration with the OBCQI Data Set	17
	G.	Master Clinician Review and Refinement of the Integrated Data Set	19
	H.	Integral Involvement of the PACE Community, CMS, and State Representatives	20
2.	OVERVIEW OF EMPIRICAL TESTING AND SUMMARY OF INITIAL FIELD TEST PHASES		21
	A.	Overview of Field Test Activities	21
	B.	Feasibility Test	24
	C.	Reliability Test	28
3.	COCOA-B SYSTEMATIC FIELD TEST: IMPLEMENTING THE COCOA-B DATA SYSTEM AT 13 PACE SITES		37
	A.	Introduction	37
	B.	Systematic Field Test Overview	37
	C.	Overview of SYFT COCOA-B Data Encoded at the Research Center	40
	D.	COCOA-B Data Quality	43
	E.	Findings from the SYFT	47
4.	EMPIRICAL BASIS FOR RECOMMENDED OUTCOME MEASURES AND OTHER FINDINGS FROM THE SYSTEMATIC FIELD TEST		49
	A.	Introduction	49
	B.	Definition of Outcome Measures	49
	C.	Selection of Outcome Measures for PACE OBCQI	50
	D.	Additional SYFT Experiences and Findings	72
5.	ADDITIONAL TABLES AND REFERENCES		74
	A.	Outcome Measures, Data Sets, and Reports	74
	B.	References	84

Technical Appendices (These files are posted separately)

1A Terminology and Concepts Related to OBCQI 1A.1

2A Original PACE Demonstration Sites 2A.1

2B Clinical Panel, Master Clinician Review Panel, and Advisory Committee Members 2B.1

2C Data Sets Reviewed and Relevant Literature Used in OBCQI/COCOA-B Developmental Work 2C.1

2D Conceptual Domains Used in OBCQI/COCOA Developmental Work 2D.1

3A Feasibility Test Version of the COCOA Data Set 3A.1

3B Reliability Test Version of the COCOA Data Set 3B.1

3C Reliability Statistics for the COCOA Data Set 3C.1

3D Supplemental Core Comprehensive Assessment Items 3D.1

4A Systematic Field Test Version of the COCOA-B Data Set 4A.1

4B COCOA-B Data Item Integration Guidelines 4B.1

4C Data Collection Protocols for the Systematic Field Test 4C.1

4D Illustrative Participant Characteristics Report 4D.1

4E COCOA-B Data Validation Checks (SYFT Version) 4E.1

4F Data Submission and Data Quality Reports 4F.1

5A Specifications for Tier 1 and Tier 2 Outcome Measures 5A.1

5B Potential Risk Factors for Tier 1 Outcome Measures 5B.1

5C COCOA-B Risk Factors and Participant Characteristic Measures Specifications (SYFT Version) 5C.1

6A The COCOA-B Data Set: Contractor-Recommended Data Set for PACE Quality Monitoring and OBCQI 6A.1

6B Proposed Guidelines for Assigning COCOA-B Clinical Data Items 6B.1

FORWARD

Health care provision, particularly to patients requiring long-term, chronic care, often is fragmented and poorly coordinated across providers, programs, and payers. PACE is designed to overcome these problems through an integrated program of comprehensive medical and social services coordinated and largely provided by a group of specialists functioning as a caregiving team. PACE participants are impaired and frail elderly who are nursing home eligible. A high percentage of the PACE population has a significant degree of cognitive impairment; according to the National PACE Association (2002), 62% of PACE and pre-PACE enrollees suffer from cognitive deficits. Continued community residence is the goal for most PACE participants, with an emphasis on frequent attendance at an adult day health center. The complexity of providing such a comprehensive program of care to the frail elderly, and maintaining them in the community whenever possible, creates a corresponding need to monitor the quality of care provided on an ongoing basis.

After more than a decade operating as a federally supported demonstration project, the Program of All-Inclusive Care for the Elderly (PACE) is now recognized as a permanent provider under Medicare and a state option under Medicaid. More than two dozen sites serving Medicaid and dually-eligible patients currently are in operation nationwide. Approximately 17,000 persons are being served through the various sites. The Balanced Budget Act of 1997 (BBA [P.L. 105-33]) in establishing PACE as a permanent provider also mandated that the quality of care that PACE enrollees receive be monitored.

In 1997, the Centers for Medicare and Medicaid Services (then HCFA) contracted with the University of Colorado Center for Health Services Research (CHSR) to develop a quality assurance system for PACE and its frail elderly participants. In 1999, CMS (then HCFA) published an interim final rule that described a planned reporting system for PACE that was envisioned to be quite similar to the quality performance reporting system now mandatory for home health agencies that serve Medicare beneficiaries.

By the time the CHSR project, funded through contracts with CMS, ended in 2004 it had created a set of outcome measures and a complex system of "Outcome-Based Continuous Quality Improvement (OBCQI)." The contract also encompassed development of a set of data elements with which to both evaluate participants at two points in time and compare (across sites) participant health status, home and environmental circumstances, and socio-demographic factors. After measures were tested, a number of potential elements were eventually omitted. At the end of the contract, the contractor named the data collection/participant assessment form that emerged **"Core Outcome and Comprehensive Assessment – Basic (COCOA-B) Data Set."** The contractor also created a preliminary method for risk adjusting outcome data so comparisons could be made among sites. PACE sites provided feedback to the contractor, during testing phases of the contract.

Prior to release of a final rule that will delineate federal expectations for the Quality Assessment and Performance Improvement Program (QAPI) that the PACE Program is required to implement, CMS is posting the COCOA-B data collection tool for individual PACE sites to use, if they choose to implement this method to collect and analyze data for their own participants. The data collection instrument, COCOA-B, was developed with federal funds and is in the public domain, so anyone is free to use it as they wish. In addition to the data collection instrument, we are posting additional background analyses conducted during the course of the contract.

At the time of posting of this document, January 2006, the Centers for Medicare and Medicaid Services is neither requiring the use of the COCOA-B assessment tool nor the submission of data. PACE sites will have latitude to choose whatever type of instrument they want to use to assess participants' status and needs. Each site can also determine how best to ensure the quality of its services. We expect that PACE organizations will continue to explore the most effective manner in which to apply quality measures to improve participant outcomes and will develop alternative or additional measures, as needed. PACE sites will be notified by CMS if requirements change in the future.

Materials that follow are excerpted from a report submitted by the University of Colorado Center for Health Services Research. The report and all materials were created under contract with CMS. We have retained most of the original, lengthy report and appendices for the use of PACE sites that participated in development and testing work and may be interested in descriptions of methodology and findings. Chapters and tables in the narrative report have been renumbered to accommodate edits. Recommendations are those of the University of Colorado Center for Health Services Research and do not reflect CMS policy.

Some assumptions and recommendations by the contractor have been omitted because they presume creation and maintenance of a central database, creation of outcome reports, and implementation of comparative analyses of the various PACE sites. While language has been edited to clarify that statements represent the contractor's view and not CMS policy, there may be residual content or tone that reflect the contractor's perspective, recommendations, or assumptions. Individual sites would probably implement the concepts of risk adjustment and outcome based continuous quality improvement differently than the methods described in this report if their focus were to be on assessing their own performance and quality over time.

The following acronyms are used throughout the report and the related appendices.

Acronyms

BBA	Balanced Budget Act of 1997
CMS	Centers for Medicare & Medicaid Services
COCOA	Core Outcome and Comprehensive Assessment Data Set
COCOA-B	Core Outcome and Comprehensive Assessment Data Set-Basic
COMIRB	Colorado Multiple Institutional Review Board
CQI	Continuous Quality Improvement
DHC	Day Health Center
DIR	Data Inconsistency Report
DQCC	Data Quality and Collection Coordinator
DRR	Data Receipt Reports
EMR	Medical Record System
FIM	Functional Independence Measure
HIPAA	Health Insurance Portability and Accountability Act of 1996
IRB	Institutional Review Board
MDS	Minimum Data Set
MMSE	Mini Mental Status Examination
NPA	National PACE Association
OASIS	Outcome Assessment and Information Set
OBCQI	Outcome-Based Continuous Quality Improvement
OBQI	Outcome-Based Quality Improvement
OBRA	Omnibus Reconciliation Act of 1986
OMB	Office of Management and Budget
PACE	Program of All-Inclusive Care for the Elderly
PCR	Patient Characteristics Report
PHS	PACE Health Survey
QAPI	Quality Assessment and Performance Improvement
RTI	Research Triangle Institute
SCC	Site Clinical Contact
SYFT	Systematic Field Test
TO	Target Outcome
UFR	Up Front Review

[1] COCOA-B is the reduced version of the core outcome and comprehensive assessment (COCOA) data set and is the data set the CMS contractor recommended. The larger COCOA data set contains additional data items that may be useful for participant assessment.

TABLE 1: OUTCOME TAXONOMY

Health Status Outcome Measures reflect change in a participant's condition that is (potentially) due to the provision of care. Health status outcomes refer to change in physiologic conditions, functional abilities, symptoms distress, cognitive abilities, or emotional conditions that are intrinsic to the participant.

Utilization Outcome Measures reflect health services use (or nonuse) potentially attributable (possibly iatrogenically) to the health care under consideration.

Instrumental Outcome Measures reflect nonphysiologic or nonfunctional outcomes of care that are intrinsic to the participant, the participant's family/informal caregiver, or their behavior (e.g., decrease in loneliness) -- however, the instrumental outcome is not typically the primary reason for, or the intended end result of, the care provided.

Consumer-Centered Measures are a special category of Instrumental Outcome Measures that relate to participant and/or informal caregiver satisfaction with care provided, including end of life care.

TABLE 2: OUTCOME INDICATOR AND MEASURE SELECTION CRITERIA

1. Clinical meaningfulness, perceived importance of the measure for OBCQI determined by our clinical staff and review panels;
2. Interrater reliability of data items needed to compute the measures;
3. Diversity of measures by different dimensions of health including functional, physiologic, behavioral/emotional, cognitive status;
4. Minimal redundancy of clinical information content within the entire measure set;
5. Validity: measure sensitivity to site-level differences in quality of care;
6. Validity: measure capacity to detect differences between participant groups or sites whose outcomes are hypothesized to vary;
7. Validity: clinical meaningfulness of interrelationships among outcome measures;
8. Validity: clinical meaningfulness of the relationships between outcome measures and risk factors or case mix variables;
9. Sufficient prevalence (statistically) so outcome measures do not signify extremely rare nor extremely common events;
10. Minimal statistical redundancy among measures, so that individual measures each can be shown to convey unique information;
11. Utility of the data items used to compute outcome measures in terms of meaningfulness and face validity of items for assessment and care planning for participants;
12. Minimal ability of providers to "game" the measure in the data collection process;
13. Probability that the measure can be used to promote constructive changes in care behaviors;
14. Minimization of administrative or data collection burden;
15. Multiplicity of services subsumed by the outcome thereby reducing the data items and measures needed for OBCQI; and
16. Multiplicity of clinical, assessment, management, administrative, fiscal, and reporting purposes that can be served by items and measures.

TABLE 3: CONTRACTOR - RECOMMENDED OUTCOME MEASURES[A] FOR THE COCOA-B/OBCQI SYSTEM

TIER 1 - EMPIRICALLY SUPPORTED MEASURES

HEALTH STATUS OUTCOMES

Physiologic Status and Symptom Management
Decrease[b] in Nutritional Risk
Improvement in Urinary Continence
Improvement in Dyspnea
Improvement in Edema
Increase[c] in Pain Interfering with Daily Activities
Decline in Edema
Percent of Participants Immunized for Influenza

Functional Status
Decrease in Number of Activities Limited by Health
Decline in Management of Oral Medications

Emotional/Mental Health Status

Decrease in Depression/Depressive Symptoms
Decrease in Self-Report of Loneliness
Decrease in Number of Behavior Problems
Increase in Depression/Depressive Symptoms

Cognitive Functioning
Improvement in Ability to Understand Others
Improvement in Ability to Speak to Others
Decline in Ability to Speak to Others

INSTRUMENTAL OUTCOMES

Participant Quality of Life

Improvement in Satisfaction with Frequency of Social Interactions
Decline in Satisfaction with Frequency of Social Interactions

Knowledge and Adherence
Improvement in Therapy Adherence

Informal Caregiver Quality of Life

Decrease in Informal Caregiver Stress
Improvement in Informal Caregiver Coping
Increase in Informal Caregiver Stress

CONSUMER-CENTERED MEASURES

Participant Satisfaction

Satisfaction with Staff Communications
Satisfaction with Day Health Center Services
Satisfaction with Transportation
Satisfaction with Obtaining Needed Services/Assistance

Informal Caregiver Satisfaction

Satisfaction with Provider-Family Communications
Satisfaction with Transportation

End Of Life Care
Percent of Participants with a Signed Advance Directive

TIER 2 - MEASURES FOR FURTHER INVESTIGATION

HEALTH STATUS OUTCOMES

Physiologic Status and Symptom Management
Decrease in Pain Interfering with Daily Activities
Decline in Dyspnea
Decline in Urinary Continence

Functional Status
Improvement in Ambulation
Improvement in Management of Oral Medications
Improvement in Transferring
Decline in Ambulation
Decline in Transferring
Increase in Number of Activities Limited by Health

Emotional/Mental Health Status

Increase in Self-Report of Loneliness
Increase in Number of Behavior Problems

Cognitive Functioning
Decline in Ability to Understand Others

UTILIZATION OUTCOMES

Hospitalization

Percent of Participants Hospitalized
Percent of Participants Readmitted to the Hospital

Nursing Home Placement
Percent of Permanent Nursing Home Admissions
Number of Nursing Home Days

Emergency Care Services

Percent of Participants Receiving Emergency Care

INSTRUMENTAL OUTCOMES	
Participant Quality of Life	**Informal Caregiver Quality of Life**
Improvement in Self-Rated Quality of Life Decline in Self-Rated Quality of Life	Decline in Informal Caregiver Coping
Knowledge and Adherence Decline in Therapy Adherence	

[a] Four types of measures are included in the set of OBCQI outcome measures: Health Status Outcomes, Utilization Outcomes, Instrumental Outcomes, and Consumer-Centered Measures. Outcomes are further grouped by domain (with the exception of Utilization Outcome measures), as follows: Health Status Outcomes include outcomes related to physiologic and symptom management, functional status, emotional/mental health status, and cognitive functioning; Instrumental Outcomes include outcomes related to participant quality of life, informal caregiver quality of life, and knowledge and adherence; and Consumer-Centered Measures consist of participant satisfaction, informal caregiver satisfaction, and end of life care measures. All measure types and domains are not necessarily represented in each of the outcome tiers.

[b] Decrease measures indicate improvement in a health status area. For example, Decrease in Nutritional Risk indicates less risk and therefore improved status.

[c] Increase measures indicate decline in a health status area. For example, Increase in Pain Interfering with Daily Activities indicates more pain and therefore declined status.

The contractor-recommended COCOA-B data set consists of the 102 data items necessary to compute and riskadjust the 50 Tier 1 and Tier 2 outcome measures. To facilitate data collection by the interdisciplinary team and other staff, COCOA-B is composed of four clinical item sets and five nonclinical item sets. The clinical items are grouped by primary recommended discipline, including primary care provider, nursing, rehabilitation therapy, and social work item sets. To reduce data collection burden and increase the accuracy of the data, the COCOA-B clinical items could be integrated into existing clinical assessment materials at PACE sites. The nonclinical item sets include tracking and demographic items, participant and informal caregiver satisfaction questionnaires, a utilization form, and a brief disenrollment form.

Data Collection Processes

Contractor-recommended data collection processes for the COCOA-B clinical item sets are summarized in Table 4. Areas for further investigation or resolution are noted (by bulleted points) below selected protocols. Processes for the nonclinical item sets are summarized in Table 5.

The COCOA-B Data Set that the contractor has recommended for PACE Quality Monitoring and OBCQI can be found in its entirety in Appendix 6A.

TABLE 4: Key Data Collection Processes for COCOA-B Clinical Item Sets

1. Integration: PACE sites integrate COCOA-B data items and data collection processes into current site assessment materials and practices. The contractor/developer of COCOA-B did not intend fit as an "add-on."
   - Assist sites with modifying existing EMR systems to include the COCOA-B data items (sites developing new systems should incorporate COCOA-B from the outset).
   - Develop a program to promote greater convergence of multiple applications of COCOA-B data and reduce site-level data collection burden (work with states, others).
2. Assessment/Data Collection Intervals: Sites collect COCOA-B at initial assessment of a newly enrolled participant and at six-month intervals thereafter, for all participants.
   - Analyses could be conducted to compare the effectiveness of various assessment/data collection intervals to maximize the accuracy of outcome measurement.
3. Significant Change in Condition: The six-month COCOA-B reassessment schedule should remain in place whether or not a change occurs in the midst of the interval.
4. Assessment Completion Period: Members of the interdisciplinary team should complete the COCOA-B clinical assessments/item sets for an individual participant (for a single assessment period) within a 21-day period.
   - Analyses could be conducted to examine the hypothesis that participant condition generally remains stable during a 21-day time period. The assessment completion period could be limited further, if appropriate.
   - It may be useful to define a range for the occasional outlier and to intermittently monitor sites to ensure that the 21-day window is adhered to on a routine basis.
5. Discipline Designation: Sites may follow guidelines regarding recommended discipline or staff type for collecting each COCOA-B data item as part of routine, ongoing assessment activities. Examine cross-discipline reliability to determine whether responses to COCOA-B data items vary by clinical discipline. If significant and consistent variation is identified for some items, consider assigning a single, required discipline to such items to avoid inaccurate cross-site comparisons of outcomes due to discipline-based variability rather than true status of participants.
6. Permanent Nursing Home Residents: Site care providers complete all COCOA-B clinical items on permanent nursing home residents at the scheduled six-month intervals, adhering to established (site-specific) discipline assignments.
7. Temporary Nursing Home Residents: Site care providers complete all COCOA-B clinical items on temporary nursing home or transitional housing residents at or near the scheduled six-month intervals. Scheduled assessments can be postponed until the participant is no longer in temporary nursing home or transitional housing, if within the 21-day assessment window.
8. Hospitalized Participants: Sites complete the COCOA-B assessment on hospitalized participants at or near the scheduled six-month intervals. Scheduled assessments can be postponed until the participant has been discharged from the hospital, if within the 21-day assessment window.
9. Cognitively Impaired Participants: Sites complete the majority of COCOA-B data items based on care provider assessment, and should use the (generally) same assessment approach for participants with or without cognitive impairment. For the subset of items that require direct participant response (e.g., self-report of loneliness, self-rated quality of life), care providers should administer the items to all participants and mark the designated checkbox if the participant is unable to respond due to cognitive impairment.

TABLE 5: Overview of Data Collection Processes for Nonclinical Item Sets

1. Participant Tracking and Demographic Items: Administrative or other staff members at sites complete all data items in this item set at initial assessment (or first COCOA-B reassessment after programwide implementation). At each six-month reassessment time point, sites provide updated information, if any, or indicate on the form that no changes have occurred for these items since the prior assessment.
2. Participant Satisfaction Questionnaire (PSQ): Sites collect annually on all or a subset of their participant population (by verbal administration of the questionnaire). Ideally, an individual who does not provide direct care to participants administers the questionnaire to participants.
3. Caregiver Satisfaction Questionnaire (CSQ): Sites collect annually on all or a subset of their informal caregiver population (by verbal administration or a mailed questionnaire). Ideally, an individual who does not provide direct care to participants administers the questionnaire to participants (if verbal administration is implemented).
4. Utilization Form: Medical records or other administrative staff use this form to record all inpatient services used by site participants during a given month.
5. Disenrollment Form: Site staff complete this form for each participant who disenrolls from a PACE program due to death or other reasons

SOURCES CONTRIBUTING TO IDENTIFICATION OF INITIAL RANGE OF OUTCOME INDICATORS

1. *Geriatric and Gerontologic Literature Review*: As an initial step in outcome indicator development, project staff reviewed published and unpublished literature in several areas of health status. The purpose of this review was to identify outcome and health status indicators and measures that might be useful for constructing PACE outcome indicators. In identifying such indicators, literature pertaining to the frail elderly population was given special attention.
2. *Programmatic Review*: To obtain background information on the PACE program and quality assurance and quality improvement activities at PACE sites, a review of published and unpublished literature was conducted. In addition, project staff conducted surveys with representative staff at each PACE site to assess and understand the nature and extent of care provided at all PACE sites, including quality assurance and quality improvement activities in place at all sites.
3. *Recommendations of Experts*: The initial recommendations of various clinical and programmatic experts who were consulted during the initial stages of the project also influenced the indicator development process. In addition, the project team's experience in such areas as geriatric medicine, end of life care, and outcome measure development contributed to the initial specification of draft indicators.
4. *Focus Groups*: With the cooperation and assistance of two PACE sites, five participant or family caregiver focus groups were conducted by project staff. The intent of the focus groups was to gather information to develop draft indicators for consumer- or participant-centered outcomes (in addition to the information on this topic obtained from the above three sources). Consumer-centered outcome indicators were integrated into the draft list of outcome indicators. (Further information on the focus group methods and findings is provided in Deliverable 6 for this project; see Kowalsky, Kutner, and Kramer, 1997).
5. *DataPACE*: A review and analysis of extant data items in DataPACE (the minimum data set developed for PACE by On Lok, Inc., 1993) was conducted to facilitate research staff understanding of this data source and to identify potentially useful outcome indicators.

CHAPTER 1

BACKGROUND AND OVERVIEW OF PROCESS

A. Clinical Panel Reviews of Initial Draft Outcome Indicators

After refining the outcome indicator list to a manageable size, the first two of four clinical panels were assembled (in April and July 1998) to further refine the set of indicators to include those most critical for PACE. Sixteen clinical panel members (eight members per panel) were selected to represent the perspectives of various disciplines and various PACE sites (clinical panel members are listed in Appendix 1B).

Panelists were asked to rate the value of each outcome indicator for the purpose of assessing the quality of care provided to PACE participants, regardless of the measurement problems that might be associated with a particular indicator. In addition, the clinical panelists were asked to rate the importance of the indicators from the perspective of all PACE sites and all PACE participants, expanding their view beyond the experiences and participant characteristics of the PACE site with which they were most familiar. Panelists were given the following criteria to consider in determining the importance of each outcome indicator: (1) the likelihood that a significant proportion of participants (i.e., 25% or more) will experience some change in the indicator; (2) the sensitivity of the outcome indicator to detect differences in the quality of care among participants and PACE sites; and (3) the probable acceptance of the outcome indicator by PACE care providers as a valid marker of quality.

The first and second clinical panel reviews followed the same structure and sequence of activities. First, individual panel members were sent a list of over 400 outcome and consumer-centered indicators for review. Panelists were requested to rate the probable utility and substantive value of each outcome indicator based on a 0-2 scale that denoted negligible value, definite value, or extreme importance in assessing quality of care at PACE sites. To ensure that all potential indicators would be considered, panelists also were asked to suggest additional outcome indicators of importance to PACE that were not already on the list. Research Center project staff compiled and summarized panel member responses and developed a composite list of the outcome indicators that received the highest average ratings (also included were selected additional outcome indicators suggested by the panelists). The composite list was sent to the panel members for a second review. From this "refined" list of approximately 130 outcome indicators, panelists were asked to select the 50 outcome indicators that they felt were the most essential for PACE. (Panelists were asked to select only 50 outcome indicators to further narrow the list of key indicators to a manageable number.)

The purpose of the first two clinical panel meetings was to review the composite ratings, the reasons for differences of opinion, and the new outcome indicators suggested by the panelists. (The two clinical panels independently followed the same sequence of activities, beginning with the review of the same set of over 400 indicators; the findings of the two panels ultimately were combined to identify the set of outcome indicators used in subsequent activities to develop the OBCQI data set.) During each meeting, the "top 50" selections of each panelist were tabulated, and outcome indicators that were not either selected or rejected by three-fourths of the panel were identified. These "discrepant" outcome indicators served as the basis of discussion during the meetings. Discussion focused primarily on panelists' opinions regarding the importance of certain indicators relative to the other indicators, and also provided the opportunity to discuss duplication/redundancy in the list of potential outcome indicators. Panelists helped reword

and/or eliminate indicators to minimize ambiguity and overlap in meaning. As a result of these discussions, several outcome indicators were reworded and a few new outcome indicators were added. At the end of each meeting day, panelists were asked to select their top 50 outcome indicators again.

B. Essential Outcome Indicators for PACE OBCQI

Each clinical panel identified a subset of outcome indicators considered to be the most important for PACE, made valuable suggestions for new outcome indicators, and identified several issues important to consider as the development of the OBCQI system for PACE progressed. Research staff also asked the panelists to list possible risk factors for selected indicators. The pooled list of the 50 outcome indicators that received the most support from the two clinical panels provided the foundation for measure development and item specification for initial drafts of the data set to be used for OBCQI.

During the course of the multiphase field test (described later in this report), project staff continuously reassessed the set of outcome indicators in light of findings, including substantial input from PACE care providers, from the field test activities. Prior to the systematic field test, project staff revised the set of outcome indicators to reflect the additional information and experience obtained during the initial phases of the field test. The draft set of 44 outcome indicators, on which the COCOA-B data set used in the systematic field test was based, is presented below. The indicators are organized first by measure type (e.g., Health Status Outcomes) and within type, by conceptual domain (e.g., Functional Status).

TABLE 1.1: DRAFT SET OF OUTCOME INDICATORS FOR PACE OBCQI (BY DOMAIN).[A]

Health Status Outcomes

Physiologic Status and Symptom Management

Pain interfering with daily activities.
Number of prescription medications.
Number of falls resulting in injury.
Pressure ulcers: e.g., presence; number and stage; stage of most problematic.
Nutritional status: e.g., adequacy of diet; weight/height comparisons.
Bladder (or urinary) continence or urinary catheter presence.
Influenza immunization status.
Skin integrity: e.g., presence of open wound.
Physical symptoms other than pain.

Functional Status

Ambulation/locomotion: e.g., walking, wheelchair use.
Extent of regular daily activities participant is not able to accomplish because of health.
Management of oral medications: e.g., ability to safely measure and administer oral medications.
Transferring from bed to chair; or chair to toilet.

Cognitive Functioning

Interpersonal communication ability: e.g., ability to express oneself; ability to hold a conversation.

Emotional/Mental Health Status

Depression or depressive feelings.
Tendency to wander.
Frequency and intensity of behavior problems.

Utilization Outcomes

Hospitalization: percent of participants hospitalized, number of hospital stays over six-month interval, percent of days in hospital over six-month interval.
Readmissions within 30 days after hospital discharge: percent of participants readmitted, number of readmissions.
Nursing home admissions: percent of participants admitted to nursing home, number of nursing home stays, percent of days in nursing home over six-month interval.
Emergent care utilization: occurrence or number of emergency department visits or emergent physician visits.

Instrumental Outcomes

Participant Quality of Life

Self-rated overall quality of life.
Satisfaction with social interaction/contact with friends and family: e.g., amount, quality.

Informal Caregiver Quality of Life

Caregiver reported psychological well being: e.g., emotional reactions to caregiving such as stress (feeling overwhelmed, tense); coping.

Knowledge and Adherence

Adherence to medications.

Consumer-Centered Measures

Participant Satisfaction with Care

Participant satisfaction with the PACE program overall.
Participant satisfaction with provider-participant communication.
Participant satisfaction with involvement in care decisions.
Participant satisfaction with transportation services: e.g., timeliness, safety.
Participant satisfaction with obtaining needed assistance/treatment from program: e.g., medications, assistive devices, staff assistance.
Participant satisfaction with Day Health Center services: e.g., meals, activities.

Informal Caregiver Satisfaction with Care

Caregiver satisfaction with the PACE program overall.
Caregiver satisfaction with provider-family communication.
Caregiver satisfaction with involvement in care decisions.
Caregiver satisfaction with transportation services: e.g., timeliness, safety.
Caregiver satisfaction with obtaining needed assistance/treatment from program: e.g., medications, assistive devices, staff assistance for participant.
Caregiver satisfaction with Day Health Center services: e.g., meals, activities.

End of Life

Participant care consistent with own preferences about end of life decisions: e.g., participant choice of treatment, preferred type of care elicited and followed by providers.
Satisfaction with comfort care provided.
Satisfaction with provider communication and information giving at the end of the participant's life.
Emotional well being of participant as it relates to acceptance of end of life.
Presence and discussion of signed advance directive (DNR; Living Will; Durable Power of Attorney for Health Care).
Satisfaction with overall care/overall treatment of illness during end of participant's life.
Emotional well being of caregiver as it relates acceptance of end of participant's life.

[a] Outcome indicators related to participant and informal caregiver knowledge were eliminated prior to the systematic field test due to difficulties encountered with measuring these outcomes without placing significant burden on participants, informal caregivers, and care providers.

C. Quantifying the Draft Outcome Indicators

During the initial outcome indicator specification process, concerns about measuring the indicators were deliberately deferred. Only after paring down the expansive range of potential outcome indicators to those most important and relevant to PACE was it appropriate to undertake the challenge of quantifying the indicators. The 50 outcome indicators that received the most support from the first two clinical panels served as the focus of initial outcome measure and data item specification activities.

Practical issues were integral to outcome measure and data item specification and, later, empirical testing phases of the project. Hence, measurement difficulties resulted in the elimination of selected indicators, despite their potential clinical relevance. For example, indicators related to participant and informal caregiver knowledge ultimately were eliminated, due to difficulties encountered with measuring these outcomes without placing significant burden on participants, informal caregivers, and care providers.

In the proposed OBCQI approach, outcome measures are recommended for presentation as percentages of participants who have improved or declined in a particular health status or other area (e.g., quality of life). Improvement and decline are measured by comparing the value of each data item at reassessment with an earlier time point, including enrollment in the PACE program. For example, when measuring improvement, a dichotomous variable is created, equal to "1" if the value of the item shows improvement at the later time point, and equal to "0" otherwise. To illustrate, if a participant's performance in ambulation is recorded as "4" [does not walk, but uses wheelchair with assistance] at enrollment and measured as "1" on the scale [walks, but receives some human assistance or uses assistive device] at a later assessment time point, then the participant would be given a value of "1" for the ambulation outcome measure, indicating improvement.

Improvement and decline measures are proposed given the nature of the population served by PACE and the relatively rare expectation for continuous improvement in health status, the high percentage of participants who likely will stabilize (making stabilization measures less likely to be of comparative value), and the inevitable decline in health status for the majority of participants during their enrollment in PACE.

The specification of draft outcome measures and data items is logical to undertake concurrently since outcome measures are defined to some extent by the data item(s) used to assess the indicator. This can be illustrated using the example in which a scale (or data item) measuring the severity of dyspnea was used to quantify the outcome indicator of change in dyspnea. The potential outcome measure was defined based on whether the participant's rating on the numeric scale for severity of dyspnea changed (i.e., reflecting improved status, no change in status, or worse status) between the baseline and follow-up assessment time point. Because of this relationship between an outcome measure and the data items used to operationalize the measure, it is efficient to address the specification of outcome measures and associated data items simultaneously.

Because numerous approaches exist for measuring a single outcome indicator, a major goal in initial data item specification activities was to identify and document a limited number of data item options that appeared to be the most relevant and useful possibilities for measuring the outcome indicators identified as important for PACE. (The term "data item option" is used to refer to either a single data item or a group of items that could be used together to measure a single outcome indicator.)

Specification of data items began with the careful review of data sets identified as relevant to the frail elderly PACE population. Project staff examined existing data sets to identify data items that could be used or adapted to measure each of the selected outcome indicators. The primary data sets included in the review were DataPACE, MDS, OASIS, and the Functional Independence Measure (FIM). These data sets were of particular interest due to their potential relevance to the PACE population or similar populations (e.g., nursing home residents, home health care patients), and their widespread use in clinical settings. If these data sets did not include possible data items for an outcome indicator, additional data sources were used to generate potential items (particularly for the outcome indicators related to end of life, quality of life, and participant and caregiver satisfaction with care). A list of data sets reviewed during OBCQI/COCOA-B developmental work is presented in Appendix 2C. For some outcome indicators, no existing data item options were identified, or existing options did not completely or directly address the indicator. In such cases, clinical and research staff from the project team created new data items to measure the indicator. Relevant research was taken into account when developing these data items. Newly developed items were tested and evaluated along with the other data item options, as described below.

Criteria that were considered in selecting potential data items are listed in Table 1.2. (Data items were further evaluated during field testing particularly with regard to criteria 3-6.) After documenting the multiple potential data item options per outcome indicator, the options were winnowed down through preliminary feasibility testing (conducted at four PACE sites, prior to integration of the data items for OBCQI and core comprehensive assessment and clinical panel review.

TABLE 1.2: Preliminary Data Item Selection Criteria.

1. Frequency and breadth of use (including the estimated number of individuals to whom the instrument/item has been administered, and/or number of separate projects in which the instrument/item has been used);
2. Type of population with which the instrument has been used (i.e., relevance of the clinical setting to the PACE population);
3. Reliability and validity of data items;
4. Level of precision/sensitivity of the item to measure change in the PACE participant or informal caregiver;
5. Time required to accurately administer the instrument/item; and
6. Acceptability to clinicians, PACE care providers in particular (including clinical meaningfulness as well as practical issues).

Detailed information on the initial data item specification activities can be found in Deliverables 15-19 for this project (Kaehny et al, 1999). Data items specified during this developmental phase were revised throughout the project, based on qualitative and quantitative findings of the field test activities.

D. Preliminary Feasibility Test of Possible Data Items for OBCQI

As noted, several options for data items were identified for each outcome indicator. Once these items were identified, a small-scale feasibility test was undertaken to identify the most appropriate data items for measuring each outcome indicator, based on PACE care provider feedback and what was learned by using the data items in the PACE population and setting. In addition to providing input regarding the most effective data item(s) to measure a particular indicator, care providers also were asked to give feedback regarding the most appropriate discipline/staff member to collect each data item.

Multidisciplinary care providers from four PACE sites[1] participated in the two phases of the OBCQI feasibility test. (The OBCQI feasibility test was conducted prior to the contract modification to develop a core comprehensive assessment data set, which is described in Section C. Considerably more extensive field testing was later completed using the COCOA data set, encompassing data items for OBCQI and core comprehensive assessment. During phase one of the OBCQI feasibility test, care providers were asked to review and evaluate one to ten (usually about four) data item options presented for each outcome indicator, based on their knowledge and experience with providing care to PACE participants. An anticipated respondent (e.g., nurse, social worker, PACE participant, informal caregiver) was suggested for each data item option. After considering an individual data item option, the care provider was asked to answer a set of evaluation questions related to that option (e.g., whether the wording of the item was appropriate for the PACE population and setting, whether the anticipated respondent for the item was appropriate, etc.). After reviewing and commenting on each of the data item options for an individual outcome indicator, the care provider responded to a set of questions regarding the outcome indicator; for example, which data item option would be most effective and appropriate, whether the indicator applies to particular participant subgroups (e.g., cognitively impaired individuals).

Using the input from the first phase of the feasibility test, project staff reduced the number of data item options for each outcome indicator. Under phase two, participating care providers each assessed five PACE participants using the remaining one to four data item options per outcome indicator. Each option was tested and evaluated by PACE care providers in terms of availability of needed data, accuracy, and the time burden of data collection using that option. Questions on the validity of the data item option and whether the option would adequately capture change in participant (or informal caregiver) status over time also were included for each data item option. After evaluating each of the data item options presented for an outcome indicator, care providers were asked to select the option they considered to be the most effective and appropriate for measuring the outcome in the PACE population and setting.

The findings from the OBCQI feasibility test were used to select the draft data items for measuring outcomes and to identify the discipline assigned to complete the items. For some outcome indicators, more than one data item option still remained due to lack of consensus on the most appropriate option; further input was subsequently elicited from the third clinical panel where more detailed and interactive discussion could occur. The next steps were to identify potential risk factors for the draft outcomes under consideration and subsequently specify draft data items for measuring the risk factors. The data items for measuring outcomes and data items for measuring risk factors together created the draft data set for OBCQI.

[1] Participating sites were Palmetto SeniorCare, Providence Elder Place, Sutter Senior Care, and Total Longterm Care.

E. Specifying Potential Risk Factors and Associated Data Items

Early in the project, the importance of risk adjustment was discussed and supported by the first two clinical panels and the project Advisory Committee (members are listed in Appendix 2B). These groups expressed concern about the variation among PACE sites, which could affect interpretation of outcomes and thus weaken the OBCQI process. The need to effectively address variation in participant characteristics across sites is a major justification for risk adjustment. If the system were to accurately and validly compare outcomes across sites, the OBCQI system would have to take into account differences across sites.

The terms case mix adjustment and risk adjustment both refer to methods of ensuring that important differences in participant characteristics, related to disease and disability as well as other covariates or circumstances that can influence health status over time, are taken into consideration when comparing outcomes between two groups of participants. This may be accomplished through stratification (e.g., grouping participants according to conditions or circumstances that influence outcomes such as orthopedic or cardiac conditions), statistical adjustment (e.g., standardization, multivariate modeling, regression, statistical clustering, grouping algorithms, or multivariate matching) or both. On this project, we use the term risk adjustment for any of these activities that entail taking participant characteristics into consideration to adjust outcomes, since the term case mix adjustment tends to be used most often with respect to cost and resource consumption. Risk adjustment is important for outcome comparisons because participant characteristics related to the natural progression of disease and disability for PACE participants at one site could be different from those at another site. Such discrepancies in risk factors could account for outcome differences between two sites unless risk adjustment is performed.

Other past and ongoing Research Center projects have involved significant work on risk-adjustment methodologies, particularly for home health and nursing home care received by the elderly. This work contributed important information and insights to the development of risk factors and risk adjustment methods for PACE OBCQI. Early in the project, attention to risk adjustment was limited, as it was important to first determine the outcome indicators, measures, and data items to be used in the data set prior to focusing on the identification of data items that might be necessary to risk adjust outcomes. However, initial efforts to identify risk factors began during the early developmental activities, as described below. (Analytic findings as they relate to progress made in identifying potentially effective risk-adjustment approaches are discussed in Chapter 3.)

Preliminary input was obtained from the first two clinical panels on possible risk factors[2] for selected potential outcome indicators. The purpose of this task was to generate ideas from PACE care providers regarding the factors, other than the care provided by PACE, that might influence participant outcomes and thus might need to be taken into account when measuring outcomes. Because the intent was simply for panelists to brainstorm ideas, the structure for the task was informal and the time frame for completion was brief. Nevertheless, the clinical panel input was valuable as a preliminary first step toward identifying potential risk factors for a subset of the outcome indicators under consideration for OBCQI.

[2] A risk factor was defined for clinical panelists as follows: A risk factor for a particular outcome is a participant/caregiver condition or circumstance that (positively or negatively) influences the likelihood of a participant/caregiver attaining the outcome. These conditions do NOT include antecedent care.

Capitalizing on the substantial work on risk-adjustment methodologies conducted in other Research Center projects (e.g., for computing adult home care outcomes), project staff identified the outcomes used in home care projects that are the same or similar to the outcomes currently being considered for PACE. The risk factors relevant to those outcomes were enumerated and were added to the compilation of the clinical panels' suggested risk factors for PACE outcomes (duplicates were eliminated).

Using this larger set of potential risk factors, project staff identified the risk factors related to the greatest number of PACE outcome domains. This approach was implemented to help generate a potential "core set" of risk factors that could be relevant to many of the outcomes being measured and still maintain a reasonable data collection burden. Although all desirable risk factors cannot necessarily be included in the data items to be collected under OBCQI, it is important to bear in mind that all data items that will ultimately be used to measure PACE outcomes will be potential risk factors as well. The set of potential risk factors influencing PACE outcomes was refined as part of the systematic field test data analysis activities, as discussed in Chapter 4.

Third Clinical Panel Review of Data Items

A third clinical panel composed of PACE care providers and external researchers with expertise in measurement issues (members are listed in Appendix 1B) was assembled to review and help establish the draft OBCQI data set. Prior to the third clinical panel meeting, panel members received the set of potential risk factors and the possible data item options for assessing the risk factors. The panel members provided written input regarding the various options, helping project staff specify data items for measuring risk factors in the draft OBCQI data set. Draft data items for measuring outcome indicators and risk factors then were reviewed and discussed by the third clinical panel.

As discussed above, multiple data item options for measuring outcome indicators were tested during the OBCQI feasibility test at four PACE sites. The results of the feasibility test were used to assist in the selection of the most appropriate data items for measuring each of the outcome indicators under consideration. In working to select the "best" data items for use with the PACE population and setting, numerous data item-level issues were identified; for example, whether the wording of participant-response data items might be overly complex for the average participant to comprehend; whether conceptual components such as hearing and cognitive ability should be more distinctly separated in an item assessing a participant's ability to understand others. These issues were brought to the third clinical panel for discussion and resolution. The third clinical panel review and discussion also addressed the selection of the most appropriate data item option for each of the outcome indicators with more than one data item option still under consideration.

Clinical panel members reviewed the draft data items and accompanying issues prior to the meeting, to facilitate an efficient and productive panel discussion. The panel meeting focused on resolving relatively straightforward issues quickly, to allow time for more intensive discussion of conceptual and operational issues. The third clinical panel meeting was an integral step toward establishing the initial draft of the OBCQI data set.

F. DEVELOPMENT OF THE CORE COMPREHENSIVE ASSESSMENT DATA SET AND INTEGRATION WITH THE OBCQI DATA SET

1. Project Modification

In 1999, the OBCQI project was modified to include the development of a set of core comprehensive assessment data items to be used uniformly across PACE sites for evaluating and documenting participant health status, home and environmental circumstances, and sociodemographic factors. The purpose of the newer component of the project was to develop a set of core comprehensive assessment data items to be used by PACE care providers to assess participants at the time of enrollment and at specified time intervals or under certain circumstances thereafter.

Although the OBCQI and core comprehensive assessment components of the project originally were conceived as independent efforts, the data items developed for these two purposes were integrated into a single data set, the core outcome and comprehensive assessment, or COCOA, data set for PACE. The COCOA data set was designed to facilitate thorough measurement and risk adjustment of participant outcomes, provide the information needed to describe and analyze case mix and utilization at individual PACE sites and for the PACE program as a whole, and enhance the process of participant assessment and care planning by PACE staff. The integration of the two components reduced the data collection burden placed on PACE care providers and participants and strengthened the utility of the data set for outcome measurement and assessment.

2. Developing the Core Comprehensive Assessment Data Set (COCOA)

Development of the draft core comprehensive assessment data items followed similar steps to those taken in the development of the draft OBCQI data items, described above. The initial stage in development involved the identification of information that expert care providers agree is essential to establish the foundation for assessment and care planning for every PACE participant. Three information acquisition tasks were conducted concurrently to identify information that is essential to PACE participant assessment. As part of the first information acquisition task, Research Center staff obtained and reviewed assessment materials and protocol documentation from the original 12 PACE demonstration sites (i.e., those with dual Medicare and Medicaid capitation as of 1997) and interviewed representatives from nine of those sites regarding assessment practices (a list of the 12 PACE demonstration sites is provided in Appendix 2A). The second task involved a review of the geriatric and gerontologic assessment literature and identification of assessment practices of non-PACE community-based long-term care programs that focus largely on the frail elderly. To complete the third information acquisition task, Research Center staff obtained information from state government representatives regarding the existing and planned state data requirements for PACE sites (and/or Medicaid managed care programs), with the intent of addressing as many common data needs as possible with the core comprehensive assessment data set. (Products 2, 3, and 4 for this project provide further information on each of the three information acquisition tasks; see Mottram et al., 1999; Jordan et al., 1999; and Brega et al., 1999, respectively.)

Research Center staff reviewed and synthesized the information gathered through these tasks to identify a draft set of 225 “data elements” pertaining to health or health status that appeared to be essential to assessment of PACE participants (e.g., ability to ambulate, diagnoses, bladder incontinence, dementia). The data elements were organized into a set of conceptual domains, similar to the classification system established to organize the outcome indicators for

OBCQI. The domains for the core comprehensive assessment elements included Functional Health Status, Physiologic Status and Symptom Management, Emotional/Mental Health Status, Cognitive Health Status, Quality of Life/Social Support, Home Environment/Living Arrangements, Utilization of Health Care Services, and End of Life issues. These domains are a subset of the OBCQI domains, with the excepted addition of the Home Environment/Living Arrangements domain. (Appendix 2D presents a table delineating the sets of domains reflected in the draft OBCQI data set, draft core comprehensive assessment data set, integrated COCOA data set, and COCOA-B data set.)

To help identify the essential assessment elements to form the basis of the core comprehensive assessment data set for PACE, the draft set of data elements underwent two rounds of review by an external clinical panel of PACE clinicians and administrators (see Appendix 1B, External Clinical Panel list for members). Panel members rated each data element to indicate whether they considered the element essential for the assessment of all participants. The draft set of data elements was revised in response to panelist feedback, resulting in a set of 164 data elements considered to be essential for assessment of PACE participants.

The next developmental step, data item specification, involved the development or identification of specific measurement approaches (i.e., data items and scales) with which to operationalize the core assessment data elements. Research Center staff used information obtained from reviews of PACE site assessment materials, the geriatric and gerontologic assessment literature (including existing data sets), state data requirements, and DataPACE to identify data items for use in measuring each element. In addition, to reduce data collection burden, relevant data items from the draft OBCQI data set were reviewed and included in the initial list of potential data items for core comprehensive assessment.

Once potential data items had been identified, Research Center clinical and research staff conducted a preliminary review of multiple data item options for each data element. A total of 587 data items were selected for initial review. Reviewers provided input regarding whether each data item should be retained and suggested wording changes, item presentation revisions, and new data items. In addition, staff made suggestions regarding the discipline(s) most appropriate to assess each data item. Initial reviews of the items included in each domain (or broad category of items) were conducted by two to five Research Center staff members.

Data item preferences and comments from reviewers were analyzed and consolidated by Research Center staff. This information was used to eliminate or revise data items deemed inadequate for assessment. This process of internal review resulted in a set of 254 data items, which was then reviewed by a fourth clinical panel for the project composed of eight PACE clinicians (listed under Fourth Clinical Panel in Appendix 2B). Based on information gathered from panel members' written comments and discussion at the clinical panel meeting, data items were further revised to arrive at the preliminary draft core comprehensive assessment data set. This process of review and revision consisted primarily of integrating suggested wording changes to data items for clarity or increased precision, revising data item presentation, and consolidating/integrating similar data items. After revising and consolidating data items, the preliminary draft core comprehensive assessment data set consisted of 161 data items, of which 50 items also were part of the draft OBCQI data set.

3. Integration of OBCQI and Core Comprehensive Assessment Data Items

The integration of the data items for OBCQI and the data items for core comprehensive assessment into the single COCOA data set began during the assessment data item selection

process when efforts were made to use OBCQI data items, when appropriate, for measuring assessment data elements. The integration of the two data sets was of key importance in minimizing data collection burden for PACE care providers and participants. After finalizing items for the preliminary draft core comprehensive assessment data set, the remaining OBCQI data items (those data items not already incorporated) were integrated into the data set. The preliminary draft COCOA data set, including all data items needed for OBCQI and core comprehensive assessment purposes, was comprised of 210 data items. (More detailed information on the core comprehensive assessment data elements, data item specification process, and creation of the integrated data set is presented in Product 6 for this project; see Kaehny, Donelan-McCall, and Mottram, 2000.)

G. MASTER CLINICIAN REVIEW AND REFINEMENT OF THE INTEGRATED DATA SET

Following the integration of the OBCQI and core comprehensive assessment data items, the preliminary draft of the combined data set underwent review by nearly 100 PACE care providers. Master clinicians representing six disciplines involved in the PACE interdisciplinary teams (i.e., primary care, nursing, rehabilitation therapy, social work, recreational therapy, and dietitians) were recruited from each of the original 12 PACE demonstration sites. For purposes of this activity, a "master clinician" was defined as an extremely competent clinician who is expert at assessment and possesses a thorough understanding of the operation and goals of the PACE program. The objective of the master clinician review was to obtain feedback from a more extensive group of experienced PACE clinicians regarding the usefulness and practicality of the proposed draft items for assessment. The master clinician review was initiated after the fourth clinical panel meeting, based on the recommendation of the eight clinical panel members to involve a larger PACE audience in reviewing and evaluating the data set prior to implementing the data set in field testing.

Ninety-eight clinicians (listed under Master Clinician Review in Appendix 2B) reviewed assessment items relevant to their particular disciplines. The reviewers provided input on the usefulness of the items for participant assessment; suggested data item revisions, eliminations, and additions; and made recommendations regarding which discipline should be responsible for collecting each item. Research Center project staff used this input to revise the data items and develop a set of 12 data collection forms (e.g., Social Work Form, Nursing Form) to be completed by various members of the interdisciplinary team during the feasibility test of the COCOA data set. The decision to assign the clinical data items to particular disciplines and create discipline-specific data collection forms (rather than implementing data collection using one large form) was in keeping with current assessment practices at PACE sites.

The master clinician reviewers did not necessarily agree upon a single, most appropriate discipline for collecting each data item (multiple different disciplines often were recommended for a single item). In keeping with this varied input, and in the interest of providing each discipline with a complete set of assessment items from that discipline's perspective, project staff included some data items in multiple COCOA forms for testing in the feasibility test. For example, both the Social Work Form and Recreational Therapy Form used during the feasibility test included a data item assessing participant social activities. An important objective of the feasibility test, therefore, was to evaluate the value and necessity of including data items on more than one discipline's assessment form.

The master clinician review was the final developmental phase completed before transitioning to empirical testing of the integrated data set. The draft COCOA data set resulting from the master clinician review (and implemented in the feasibility test) included 212 data items. Following

chapters describe the methods and findings (including modification and reduction of the data set) of the empirical testing phases.

H. INTEGRAL INVOLVEMENT OF THE PACE COMMUNITY, CMS, AND STATE REPRESENTATIVES

The process of obtaining and integrating external feedback, particularly from the PACE community, was central to the developmental activities that produced the full COCOA data set, the focused COCOA-B data set, and the associated data collection and implementation protocols. In addition to the four clinical panel meetings, the OBCQI feasibility test, the external panel review, and the master clinician review, all of which preceded the multiphase field test of the integrated data set, the subsequent field test phases were designed to emphasize the solicitation of feedback from the care providers participating at each of the involved PACE sites. This care provider feedback heavily influenced the revision of the data set and operational procedures after each phase of testing.

The project Advisory Committee was an additional source of PACE community members whose input helped direct the development and refinement of the data set and associated data collection and implementation protocols. The Advisory Committee, which was composed of PACE clinical leaders (primarily medical directors) and administrative leaders (e.g., administrators, quality assurance directors), state government representatives, NPA leadership, and CMS staff, gathered on ten occasions during the course of the project.

CHAPTER 2

OVERVIEW OF EMPIRICAL TESTING AND SUMMARY OF INITIAL FIELD TEST PHASES

A. OVERVIEW OF FIELD TEST ACTIVITIES

With the preliminary draft of the COCOA data set complete, the project transitioned from developmental work to the empirical testing phase. The multiphase field test began with a feasibility test of the integrated COCOA data set at three sites, followed by reliability testing at three additional sites. The reduced data set, COCOA-B, was then implemented at 13 dually-capitated sites under the systematic field test (SYFT).

1. Objectives of the Multiphase Field Test

The overall objectives of the field test were to 1) assess the feasibility and utility of implementing the data set and data collection protocols in the context of the PACE care delivery system; 2) evaluate the reliability of the data items to assess whether the items consistently and dependably measure the health status and well being of PACE participants and selected factors related to informal caregivers; 3) develop and evaluate the outcome measures and preliminary risk adjustment methodology; 4) obtain feedback from PACE care providers on the data items and data collection protocols; and 5) identify areas for improvement and subsequently refine the data items and operational procedures based on care provider input and empirical findings.

2. Field Test Timeline and Participating Sites

The time frame and participating PACE sites for each phase of the field test are noted in Table 2.1. The time periods between the field test phases were devoted to synthesizing care provider feedback, conducting qualitative and quantitative analyses, revising the data set and protocols based on the analytic and operational findings of the prior phase, and preparing materials for Institutional Review Boards (IRBs) for participation of sites in the subsequent field test phase. Six PACE sites that participated in the SYFT also participated in one or both of the previous testing phases.

3. Significant Challenges Encountered

a. *Obtaining Necessary Clearances and Approvals*: Substantial time and resources were committed by Research Center staff to meet the requirements of the Colorado Multiple Institutional Review Board (COMIRB), eight site-related IRBs, and newly imposed HIPAA regulations, in addition to obtaining and renewing OMB clearance of the data set. The process of obtaining site-associated IRB approval for eight PACE sites resulted in delays to the timeline for field test activities and, on one occasion (the two-site feasibility test), resulted in a significant alteration to the testing protocols due to IRB constraints.

TABLE 2.1: Overview of Field Test Schedule and Participating Sites.

Test Phase		Test Dates	# Sites	PACE Sites
A.	**Feasibility Test**			
1.	Pilot Feasibility Test	3/01 - 7/01	1	Total Longterm Care
2.	Two-Site Feasibility Test	8/01 - 3/02	2	Elder Service Plan of East Boston Palmetto SeniorCare[a]
B.	**Reliability Test**	6/02 - 12/02	3	Comprehensive Care Management[a] Community Care for the Elderly Henry Ford Center for Senior Independence[a]
C.	**Systematic Field Test**	4/03 - 12/03	13	Total Longterm Care Elder Service Plan of East Boston Palmetto SeniorCare[a] Comprehensive Care Management[a] Community Care for the Elderly Henry Ford Center for Senior Independence[a] Center for Elders Independence Sutter SeniorCare[a] On Lok Senior Health Services[a] Elder Service Plan of the Cambridge Health Alliance[a] Upham's Elder Service Plan ViaHealth Independent Living for Seniors[a] TriHealth SeniorLink[a]

[a] Eight sites required approval from a site-associated IRB prior to participation in field test activities.

The IRB requirement to obtain informed consent from participants and informal caregivers prior to data collection activities posed a significant problem for many of the field test sites. Designated staff members at each site were responsible for obtaining informed consent (and for the SYFT, HIPAA authorization as well) from all participants and informal caregivers prior to their participation. The consent procedure, often including verbatim reading of the somewhat lengthy, technically worded consent form (developed to meet IRB requirements) was time consuming, resource intensive, and, at times, confusing or overwhelming to the PACE frail elderly participants and their informal caregivers.

The requirement to obtain informed consent limited the number and diversity of participants who could be involved in the various testing phases, compromising the representative nature of the data. Due to IRB protocols, particular groups of individuals were excluded from participation in the various field test phases, including participants who could not speak English, Chinese, or Spanish (as project resources limited the capacity to translate the consent forms into additional languages) and individuals who were cognitively impaired but did not have a proxy who could consent on their behalf.

As described above, meeting IRB requirements resulted in delays to the field test timeline, frustration and excessive time investment on the part of care providers and participants, and a smaller and less representative participant sample for the field test. However, these difficulties would be resolved if COCOA-B data collection were not part of a research and developmental effort (which requires IRB approval) but instead were a CMS requirement for operational PACE sites.

b. *Timing of the SYFT and Competing Site Priorities*: The timing of the SYFT (both in terms of preparatory activities and the data collection period) was challenging for PACE sites, given the completion of permanent provider applications, CMS site visits, and state readiness

reviews at many sites during the same general time period. Additional site-level conflicts included the completion of activities to comply with HIPAA regulations, implementation of the federal risk adjustment methodology for payment and encounter reporting requirements, other data reporting requirements (e.g., state requirements), openings of new centers, and staff shortages. These factors resulted in data collection delays for some sites and, for others, the decision to decline participation in the SYFT.

Several of the competing priorities faced by sites during the SYFT were specific to the time period (e.g., efforts related to permanent provider applications, CMS site visits, and HIPAA implementation). Others (e.g., opening new centers, managing staff shortages) could be assumed to be intermittent issues. Managing both COCOA-B data reporting and state data requirements will be a challenge for many sites.

4. Implementation Activities for All Field Test Phases

a. *Training PACE Site Staff*: During this project, two training approaches were implemented. For the feasibility and reliability test phases, Research Center staff conducted on-site training involving all participating site staff. A train-the-trainer approach was implemented for the SYFT, whereby Research Center staff trained site representatives at a national training meeting, which included basic instruction on training remaining site staff upon the representatives' return to their home sites. Training manuals were developed for each phase of testing. Revisions to content and presentation were based on lessons learned from prior field test phases.

b. *Coordination of Field Test Activities at the PACE Site:* To facilitate adherence to data collection protocols and to coordinate data collection activities, each site identified a Data Quality and Collection Coordinator (DQCC) who served as a liaison between the site and the Research Center. The DQCC was responsible for coordinating site staff training, ensuring compliance with data collection protocols, managing the flow of data between the site and the Research Center, and coordinating communication between Research Center staff and site staff with regard to questions, concerns, or updates to data collection protocols. Several sites selected multiple DQCCs to coordinate activities, particularly if the site had multiple locations or several interdisciplinary teams. Each site was assigned a Research Center contact responsible for communicating changes in data collection protocols to the sites, communicating with sites on their data submission status and data quality concerns, and answering site questions.

c. *Obtaining Feedback From PACE Staff Members*: As mentioned previously, one objective of each field test phase was to obtain feedback from PACE care providers and other staff members based on their experiences implementing the data set and data collection protocols. Site staff received structured evaluation questions intended to elicit feedback on such areas as the utility of the data items for assessment and care planning, relevance of the data item wording for the PACE population, appropriateness of the discipline assigned to collect each item, and general recommendations for improving the utility of the item sets. Suggestions for improving or streamlining implementation activities (e.g., the training session and materials provided, the consent process, etc.) also were encouraged. Care provider feedback was carefully reviewed after each phase of the field test and was used in conjunction with analytic findings to guide the revision of the data items and data collection protocols (e.g., the discipline assigned to collect each data item) prior to the subsequent phase of testing.

B. FEASIBILITY TEST

1. Objectives and Methods

The feasibility test, composed of a pilot followed by a two-site feasibility test, was designed to examine the feasibility of implementing the initial draft COCOA data set and data collection protocols as part of routine site assessment activities at a limited number of PACE sites, permitting project staff to refine the data set and protocols prior to more rigorous testing phases. This phase of testing was the first time the draft COCOA data items, organized into 12 data collection forms. The data collection forms used in the feasibility test are contained in Appendix 3A.

The key objectives of the feasibility test were: a) to implement the draft COCOA forms and data collection protocols in the PACE care delivery context; b) to obtain feedback from PACE care providers on the COCOA forms and data collection protocols based on their experience with completing the forms for PACE participants; and c) to identify issues and subsequently refine the forms and data collection protocols based on care provider feedback and the observations of Research Center project staff, in preparation for subsequent field testing. An additional, ongoing goal of the field test as a whole was to reduce the overlap of data items across COCOA forms, where appropriate. Feedback was solicited from care providers regarding the necessity or usefulness of retaining data items on more than one discipline's COCOA form, as well as input regarding the most appropriate single discipline for collecting each item.

The pilot feasibility test was conducted during March through August 2001 at one center of Total Longterm Care, the Denver PACE site. Because the pilot feasibility test was completed during a seven-month waiting period for OMB clearance, data collection was restricted to only nine participants. Although the OMB review period delayed the planned schedule for the two-site feasibility test, this circumstance also resulted in flexibility during the pilot feasibility test that allowed both the PACE site and the Research Center to identify and resolve obstacles as data collection progressed, increasing the effectiveness of the pilot as a learning experience. Project staff also had the opportunity to evaluate potential approaches to reducing the time required for various field test activities.

Care providers from one interdisciplinary team participated in the pilot feasibility test. The participating team members included primary care providers (one physician and one nurse practitioner), clinic and home health nurses, social workers, rehabilitation therapists, recreational therapists, and dietitians, as well as intake and medical records staff. The data collection responsibilities of each staff type for both the pilot and two-site feasibility test are noted in Table 2.2. The Center Director acted as the DQCC for the pilot feasibility test, serving as the liaison between the Research Center and the PACE site and coordinating the completion of activities at the site. The discipline-specific clinical COCOA forms were completed as part of regularly scheduled participant assessments, with the remaining forms (e.g., satisfaction questionnaires, End of Life Questionnaire) completed outside of routine assessment, as noted in Table 2.2.

TABLE 2.2: Overview of COCOA Data Collection for Feasibility Test.[a]

COCOA Form	Responsible Staff	Data Collection Approach
Intake	Intake staff	Record information from current documentation
Home Environment Assessment (HEA)	Pilot: Home health nurse Two-Site: Social worker, rehab therapist, or home health nurse	Complete during home visit
Primary Care Provider	Physician Nurse Practitioner	Complete during routine reassessment
Nursing	RN (not LPN)	Complete during routine reassessment
Rehabilitation Therapy	Occupational Therapist Physical Therapist	Complete during routine reassessment
Dietitian	Dietitian	Complete during routine reassessment
Social Work	Social Worker	Complete during routine reassessment
Recreational Therapy	Recreational Therapist Activities Coordinator	Complete during routine reassessment
Participant Satisfaction Questionnaire (PSQ)	Pilot: Research Center staff member Two-Site: Site staff member who does not provide direct participant care	Administer to participant in private room at PACE site
Caregiver Satisfaction Questionnaire (CSQ)	Pilot: Not implemented Two-Site: Individual who does not provide direct participant care	Administer to informal caregiver over the phone or in private room at PACE site
Utilization	Medical records staff	Record information from current documentation
End of Life (EOL) Questionnaire	Social worker or home health nurse	Mail to primary informal caregiver 2 to 4 months after death of participant, with two options for completion (written, mailed response or telephone interview)

[a] This table summarizes the data collection approach for both components of the feasibility test. Where specific approaches differed between the two phases, the different approaches are noted.

The two-site feasibility test was held from August 2001 through March 2002 at the Elder Service Plan (ESP) of the East Boston Neighborhood Health Center in Boston, Massachusetts, and Palmetto Senior Care (PSC) in Columbia, South Carolina. The two sites were recruited with the intent of site staff completing each COCOA form on 20 participants or, for some forms, 20 informal caregivers (at each site). Due to difficulties and extended delays associated with IRB review required for PSC, it became necessary for PSC staff to participate in an intensive review of the COCOA data items and data collection protocols rather than the intended data collection activities.

Care providers from the interdisciplinary teams at three centers affiliated with the East Boston PACE site participated in the feasibility test activities. The participating team members included primary care providers, clinic and home health nurses, social workers, rehabilitation therapists,

recreational therapists, and dietitians, as well as intake and medical records staff. The Center Manager at the main center acted as the DQCC across the three centers, serving as the liaison between the Research Center and the PACE site and coordinating the completion of activities at the three centers. Consistent with data collection protocols from the pilot feasibility test, discipline-specific forms were completed as part of regularly scheduled participant assessments, with the remaining forms completed outside of routine assessment.

2. Summary of Findings From the Pilot and Two-Site Feasibility Test Phases

At the conclusion of the two-site feasibility test, the COCOA data and care provider feedback generated from the pilot feasibility test and two-site feasibility test were synthesized and carefully reviewed by project staff at the Research Center. Because of the experience and perspective gained by the Total Longterm Care and East Boston care providers by using the COCOA forms to assess participants (rather than only reviewing the forms), the feedback from these care providers was weighed more heavily than that of the Palmetto SeniorCare reviewers. The operational experience, observations, and findings from the feasibility test involvement of all three sites, however, helped shape the design and plans for the next phase of testing and guided the revision of the draft COCOA data items and forms, in preparation for the reliability test.

Table 2.3 summarizes the number of participants (or, where appropriate, informal caregivers) for whom each COCOA form was completed during the feasibility test. For the pilot feasibility test, the intention was to complete each form for nine participants (or informal caregivers for the End-of-Life [EOL] Questionnaire). The target number for the two-site feasibility test was 20 participants (or informal caregivers) per form, at each site. Given the modified participation of Palmetto SeniorCare, the two-site feasibility test column in the table shows only the data collected by East Boston staff.

As shown in Table 2.3, participating staff submitted close to the goal number for many of the forms during the pilot and two-site feasibility test phases. Difficulties were encountered during the two-site feasibility test with achieving the target number for three forms in particular: the Home Environment Assessment (HEA) Form, the Caregiver Satisfaction Questionnaire (CSQ), and the End of Life (EOL) Questionnaire. The high number of missing HEA Forms was the result of confusion at the site regarding the discipline responsible for completing the form, due to a flexible protocol that allowed completion of the form by any of the four discipline types that typically conducted home visits (home health nurses, social workers, occupational therapists, and physical therapists). This flexible approach was suggested by pilot feasibility test care providers who felt that assigning the HEA for completion only by the home health nurse (as in the pilot feasibility test) forced home visits by that discipline for the purpose of completing the form, rather than allowing any of the aforementioned disciplines to complete the form during a home visit already planned for other purposes. Interestingly, instead of facilitating HEA data collection during the two-site feasibility test, this more flexible approach resulted in confusion and, ultimately, the completion of fewer HEAs (only seven of the intended 20). Because of continued support from PACE care providers for the more discipline-neutral approach to the HEA, the same approach was retained for the reliability test, with strong emphasis during training sessions on the potential for confusion in this area and the recommendation that site staff establish a mechanism to ensure completion of the HEA for all assigned participants.

TABLE 2.3: Number of COCOA Forms Completed During the Pilot and Two-Site Feasibility Tests.

COCOA Form	Pilot[a]	Two-Site[b, c]
Intake	9	14
Home Environment Assessment	9	7
Primary Care Provider	9	19
Nursing	9	16
Rehabilitation Therapy	9	20
Dietitian	9	20
Social Work	9	18
Recreational Therapy	9	21
Utilization	9	19
Participant Satisfaction Questionnaire (PSQ)	9	17
Caregiver Satisfaction Questionnaire (CSQ)[d]	--	12
End of Life Questionnaire (EOL)	7	7

[a] The target number of completed forms (for each form) was nine for the pilot feasibility test.

[b] Given the modified participation of one of the two sites, this column shows only the data collected at the site able to undertake data collection during the two-site feasibility test.

[c] The target number of completed forms (for each form) was 20 for the two-site feasibility test.

[d] The Caregiver Satisfaction Questionnaire was not completed during the pilot feasibility test.

The primary obstacle to completing the target number of CSQs, as identified by site staff, was difficulty with scheduling a time for the call. Because many informal caregivers are employed or are otherwise away from the home during business hours, site staff and informal caregivers found it difficult to make initial contact and coordinate their schedules for conducting the CSQ. Although the CSQ protocols required verbal administration, the EOL Questionnaire involved two options for participation—either telephone discussion with a familiar site staff member or the privacy and convenience of a written questionnaire—providing the opportunity for informal caregivers to select the method with which they were most comfortable. The two options also were intended to increase the response rate for the questionnaire. During the pilot feasibility test, seven of nine informal caregivers participated in the EOL Questionnaire (two by phone interview, five by mail) and seven of 20 informal caregivers responded (all by mail) during the two-site feasibility test. Given the relatively small sample size for the feasibility test, the data collection protocols for the CSQ and EOL Questionnaire were retained for the reliability test, with the intention that project staff would continue to evaluate the potential administration methods for these two questionnaires to identify the approach that would provide a good response rate and reduce burden for site staff.

Care providers involved in the two feasibility test phases generated a substantial volume of feedback related to the draft data items. Common suggestions were related to wording changes to render the verbiage more relevant and/or appropriate for the PACE population and setting. For participant-response items, wording suggestions related to simplifying the language to increase the likelihood of participants understanding item meaning. Additional response options were suggested for some data items, to more accurately reflect the status of participants assessed using the forms. Many of the item-specific comments, particularly those raised by multiple care providers, were implemented by project staff to enhance the utility and accuracy of the data items prior to reliability testing. Criteria used to determine when to implement a

suggested change included the frequency with which the suggestion was raised across care providers and sites, and the clinical and/or practical basis for the suggested revision.

As a result of the data item revision process, data items were eliminated from discipline-specific forms, multiple data items were modified in terms of wording, response options, and/or format, and a limited number of new items were added to the data set. Much of the duplication of data items across forms was eliminated. For the majority of the duplicative items, the item was still retained on at least one form, reducing the overlap of items across forms, but not eliminating items from the entire data set (only five items were eliminated from the data set as a result of the feasibility test). Reducing the degree of overlap among data items across the discipline-specific forms was a major objective of the feasibility test. To facilitate the reduction of overlap across disciplines, care providers were asked to identify the single most appropriate discipline for each item, particularly those currently included across forms. Not surprisingly, given the overlap of relevant clinical areas across disciplines, conflicting feedback was received. For example, the data items addressing alcohol use received support for collection by both social workers and primary care providers. Although many care providers agreed that the overlap should be minimized or eliminated, consensus on the most appropriate discipline for each item was not reached in the written evaluation comments. Efforts therefore were made by project staff during the item revision process to select the discipline(s) most frequently suggested. In situations where opinions varied so widely that no clear indication existed, the data items remained on more than one form, to permit invitation for further input in the next phase of testing.

C. RELIABILITY TEST

1. Objectives and Overview

The primary objective of the reliability test was to evaluate and enhance the reliability of the data items, or the capacity of the items to consistently and dependably measure the health status and well being of PACE participants (as well as selected factors related to informal caregivers). The reliability analyses focused on whether the individuals responding to the COCOA data items (whether care providers, participants, or informal caregivers) interpreted and answered the data items in the same way, given the same information. Project staff analyzed the data collected by the participating PACE sites and identified the data items that showed strong reliability and the data items showing less consistency. Data items in the latter group were modified to enhance their reliability. Research Center project staff also solicited feedback from care providers regarding their experiences using the COCOA data items and data collection protocols including input on data item wording, clarity, and relevance; discipline assignment; data item order and logical flow of skip patterns; and utility of training materials and data collection protocols.

Three of the original 12 demonstration sites were recruited to participate in the reliability test. Data collection protocols required that sites assign pairs of care providers of the same discipline to complete each COCOA form for the same participant (or informal caregiver) within a 24-hour period. Each site was asked to complete pairs of each COCOA form for 30 eligible participants and informal caregivers. One site elected to complete the entire set of COCOA forms for the same (smaller) group of participants, while two sites elected to complete subsets of COCOA forms for a larger number of participants (e.g., only the Primary Care Provider, Nursing, and Social Work Forms were completed for a participant—with the other COCOA forms being completed for other participants). Although the latter approach resulted in data collection on more participants than originally anticipated (n=135), each data item was tested with only a subset of the participants.

2. Data Collection: Sample and Methods

The participants involved in the reliability test were English speaking, enrolled in the PACE program for at least four months, in attendance at the day health center at least once a month, and available for assessment on consecutive days (assessments could be conducted at different locations, e.g., day health center and the participant's residence).

Reliability data were collected from 44 informal caregivers, (i.e., nonpaid family or community members who provide assistance to a participant at least once a month) primarily for the CSQ but also on a small number of other caregiver-response data items. Informal caregivers were eligible to participate if they were English speaking, provided care to participants who had been enrolled in the PACE program for at least four months, were available to respond to caregiver response items on consecutive days, and were able to respond to the majority of the caregiver response items (i.e., not cognitively impaired).

The version of the COCOA data set (revised based on findings from the feasibility test) used for the reliability test consisted of 242 data items, organized into the same twelve discipline- and content-specific forms used in the feasibility test, as noted in Table 2.2. After careful consideration, the End of Life Questionnaire was not included in the reliability test due to the subject matter of the questionnaire and the data collection protocols (the questionnaire is mailed to informal caregivers of deceased participants). The reliability version of the COCOA data set is presented in Appendix 2B.

As described in Section B.2, some data item overlap across discipline-specific forms remained during the reliability test. To further reduce duplication across COCOA forms, one objective of the reliability test was to determine the discipline that provided the most reliable responses when a COCOA data item was collected by more than one discipline.

The interrater reliability study design called for independent assessments of PACE participants by two different clinicians (or PACE site staff) during separate assessments. Pairs of care providers of the same discipline completed the draft COCOA forms for PACE participants and, if applicable, their informal caregivers (e.g., two social workers completed the COCOA Social Work Form for the same participant). Each pair of clinicians (or PACE staff) independently conducted their assessment of and completed the same COCOA form for the same participant or informal caregiver within a 24-hour period. This time limit was enforced to minimize the likelihood that the participant's condition would change measurably from one assessment to the next. Ninety-one percent of the COCOA pairs were completed within the 24-hour timeframe. Continuity in the location (e.g., day health center, participant's home) or time of day (e.g., morning, afternoon) for the administration of the two assessments was not a required protocol. Therefore, the participant may have been assessed at the day health center by the first clinician and assessed in the participant's home by the second clinician.

To ensure that assessments were truly independent, clinicians participating as a pair did not communicate with each other about the participants, nor did they review each other's completed COCOA forms. Clinicians were permitted to discuss participant status with other members of the interdisciplinary team, as this approach to assessment is standard within the PACE care delivery system.

3. Reliability Data Analysis and Findings

The reliability analysis was conducted using the COCOA data exactly as recorded by PACE care providers. Data items that were left blank or reported as unknown, not applicable, or unavailable due to a participant's cognitive impairment were excluded from the main analysis. These exclusions resulted in a data set consisting of pairs of valid analytic responses, permitting the calculation of meaningful weighted kappa statistics for the ordinal variables in the COCOA data set.

For each data item, four measures of interrater reliability were calculated: percent agreement, Cohen's kappa without weighting, weighted kappa, and Pearson's correlation. The unweighted or simple kappa is commonly used as a measure of rater agreement for nominal measurement. It represents the degree to which the actual proportion of cases on which raters agree (exactly) exceeds the percentage agreement that would be expected under the assumptions of statistical independence (or no association between the paired values). The weighted kappa is appropriate for measures that employ an interval or ordinal scale, where the magnitude of discrepancies between raters should be taken into account. For dichotomous measures, the weighted kappa and unweighted kappa are equivalent. The Fleiss-Cohen version of weighted kappa, which uses the squared differences in scale values for weighting, is used in the analysis reported here for all ordinal and interval scale measures since it imposes a greater penalty for large discrepancies between paired values. For multiple response items, reliability was assessed for each response category.

The kappa coefficient can take on values ranging from -1.00 to 1.00, with 1.00 representing perfect agreement on all cases by two raters. A scheme for interpreting kappa coefficients has been suggested by Landis and Koch (1977) and has been adopted by a number of researchers. This scheme attaches the following labels to value ranges: greater than 0.80 = almost perfect agreement; greater than 0.60 = "moderate" agreement; greater than 0.20 but no greater than 0.40 = "fair" agreement; 0.20 or less = "slight" agreement. For a few COCOA data items, the item variance for the reliability cases was zero for one or both raters, meaning that all participants were assessed as falling into a single category on that item. The kappa coefficient is undefined under these conditions, so percent agreement is reported alone. In addition to those cases where the item variance is zero for one or both raters, the percent agreement statistic also is reported when more than 95% of cases for both raters fell into a single category since the kappa coefficient may be rather unstable and, therefore, misleading when an item has a highly skewed distribution.

For the Diagnoses and Severity Index data item (C0240), standard reliability statistics were not suitable given that the numbers have no real numeric meaning in terms of scale (i.e., they are nothing more than a means of identification) and that each rater reported multiple diagnoses for a participant. Therefore, a slightly different analytic approach was used when assessing the reliability of this data item. Diagnoses were compared using the first three digits of ICD-9-CM codes, thereby reducing the specificity of the diagnosis and, instead, identifying general agreement on a diagnosis. For each rater and each diagnosis reported for each participant, a measure was created to indicate whether the diagnosis also had been reported by the other rater (e.g., a "match" was indicated if both Rater 1 and Rater 2 recorded diagnosis of diabetes (ICD-9 code 250) for participant "Smith"; "no match" was indicated if only one of the raters recorded a diagnosis of diabetes for participant "Smith"). Once the count of matching diagnoses was complete, a sample-level match rate equal to the number of diagnoses matched by the other rater across all participants divided by the total number of diagnoses reported by both raters across all participants was created. For example, if Rater 1 reported a total of

25 diagnoses across all assessments and Rater 2 reported a total of 20 diagnoses across all assessments, the denominator for the match rate would be 45. If the raters matched on 15 of the diagnoses (e.g., Rater 1 reported 15 of the same diagnoses as Rater 2 and Rater 2 reported 15 of the same diagnoses as Rater 1), the numerator for the match rate would be 30. This would result in a sample-level match rate of 67.67%.

For the analyses of the severity ratings and acute/chronic indicators associated with the diagnoses, standard reliability statistics were computed but only for those index values associated with diagnoses that were reported by both raters. Again, we report sample-level statistics so, for all the diagnoses across all participants reported by both raters, these statistics represent how well the associated severity ratings and acute/chronic indicators match.

Table 2.4 presents the reliability statistics for the data items that were retained in the recommended COCOA-B data set. (Reliability statistics for all quantitative COCOA data items can be found in Appendix 3C.) For data items that were included on more than one COCOA form and therefore collected by more than one discipline pair, the strongest reliability statistic is presented (e.g., for the data item assessing dyspnea [C0420], the reliability statistic for the primary care provider pairs rather than the nursing or rehabilitation therapy pairs is presented). Sixty-four percent of the data item responses retained in COCOA-B were demonstrated to have "moderate" agreement (reliability coefficient $\geq$.60) during this phase of testing. The majority of the data items, particularly those with reliability coefficients less than .60, were revised prior to the SYFT based on results of the reliability test (including reliability findings and care provider input) to strengthen the reliability and clarity of the data items. Because many of the data items have undergone some degree of revision since the reliability test phase of the project (including those with reliability coefficients >.60), further reliability testing of the COCOA-B data items is strongly recommended. However, as the majority of the data items were determined to be reliable and items that demonstrated poor reliability were either revised or removed from the data set, further testing could be conducted as part of implementation (i.e., testing would not necessarily need to be conducted prior to implementation). It is recommended that work should continue over time to update and improve the reliability of all data items.

TABLE 2.4: COCOA-B Data Item Reliability (by Response Category).

Data Item		Reliability Statistic[a,b,c]
C0050	Enrollment Date	88.2%
C0070	Gender	0.89
C0080	Date of Birth	97.9%
C0100_2	Medicare Entitlement	97.6%
C0110_2	Medicaid Eligibility	0.62
C0120	Ethnicity	NA[d]
C0130	Race	
	American Indian or Alaska Native	97.9%
	Asian	100.0%
	Black or African-American	100.0%
	Hispanic or Latino	100.0%
	Native Hawaiian or Pacific Islander	100.0%
	Non-Hispanic White	97.9%
	Unknown	100.0%
C0140	Marital Status	0.90
C0150	Highest Level of Education Completed	0.92
C0160	Primary Language and English Fluency	
	Primary Language	NA
	English Fluency	
	Spoken	-0.06
	Reading	0.48

TABLE 2.4: COCOA-B Data Item Reliability (by Response Category). (Cont'd)

Data Item		Reliability Statistic[a,b,c]
C0240	Diagnosis and Severity Index	
	Diagnosis	58.7%
	Severity Rating	0.17
	Acute or Chronic	97.7%
C0250	Overall Prognosis	0.31
C0260	Life Expectancy	0.24
C0270	Participant Pain	
	Any Pain	0.58
	Severity of Pain	0.67
	Frequency of Pain	0.66
	Pain Interfering with Daily Activities	0.49
	Intractable Pain	0.23
C0290	Pressure Ulcers	
	Pressure Ulcer	97.1%
	Number of Pressure Ulcers - Stage 1	ID[e]
	Number of Pressure Ulcers - Stage 2	ID
	Number of Pressure Ulcers - Stage 3	ID
	Number of Pressure Ulcers - Stage 4	ID
	Non-observable Pressure Ulcer	ID
	Stage of Most Problematic Pressure Ulcer	ID
	Status of Most Problematic Pressure Ulcer	ID
C0320	High Risk Factors[f]	
	Heavy smoking	0.86
	Obesity	0.47
	Alcohol dependency	0.70
	Drug dependency	96.0%
	None of the above	0.72
C0350	Flu Immunization Status	0.60
C0360	Vision	0.44
C0370	Hearing	0.65
C0410	Nutritional Risk	0.43
C0420	Dyspnea	0.62
C0430	Edema	
	Edema: Legs	
	None	0.48
	Right leg	0.44
	Left leg	0.59
C0440	Bladder Continence/When Urinary Continence Occurs	
	Bladder Continence	0.69
	When Urinary Incontinence	0.56
C0450	Urinary Tract Infection	98.5%
C0460	Bowel Incontinence Frequency	0.58
C0470	Number of Falls/Number of Falls Resulting in Injury	
	Number of Falls	0.77
	Number of Falls Resulting in Injury	0.85
C0490	Management of Oral Medications	0.81
C0500	Adherence to Medications	0.04
C0510	Adherence to Therapy/Medical Interventions	NA
C0520	Self-Report of Health Status	0.65
C0530	Activity Difficulties[g]	NA
C0540	Help from Another Person for Activities[g]	NA
C0550	Lifting or Carrying Objects[g]	NA
C0560	Walking a Quarter of a Mile[g]	NA
C0570	Day Health Center Attendance[g]	NA
C0580	Current Residence	0.74
C0590	Participant Lives With	
	Lives alone	0.91
	Spouse or significant other	98.6%

TABLE 2.4: COCOA-B Data Item Reliability (by Response Category). (Cont'd)

Data Item		Reliability Statistic[a,b,c]
	Other family member	0.86
	Friend	100.0%
	Paid family caregiver	100.0%
	Paid help	95.8%
	Other	0.70
C0600	Informal (Unpaid) Caregivers	
	No informal caregiver	96.0%
	Relatives, friends, or neighbors outside the home	0.38
	Person residing in home	0.91
C0610	Number of Informal Caregivers	NA
C0620	Frequency of Caregiver Assistance	0.52
C0630	Type of Caregiver Assistance:	
	Type of Informal Caregiver Assistance Received	
	ADL assistance	0.36
	IADL assistance	0.44
	Transportation	NA
	Environmental support	0.33
	Psychosocial support	0.36
	Advocates participant's involvement in medical care	0.40
	Financial agent	0.36
	Health care agent	0.52
C0650	Advance Directives	
	Signed	0.54
	Discussed with PACE	0.55
C0660	Frequency of Participant's Anxiety	0.39
C0670	Participant Stress/Concerns	
	Participant Stress: Major Life Changes	NA
	Participant Stress: Severity	NA
C0680	Depression, Depressive Symptoms, and Social Isolation	
	Depression or Depressive Symptoms:	
	Decreased Energy	0.47
	Slow Thinking, Language, Behavior	92.9%
	Decreased Appetite	0.31
	Expressions of Worthlessness or Futility	97.1%
	Crying Spells	92.9%
	Consistent Sadness	97.1%
	Sleep Disturbances	0.58
	Fear of Death	NA
	Withdrawn/Isolated	NA
C0690	Frequency of Behavior Problems	
	Verbal Disruption	0.72
	Physical Aggression	0.77
	Disruptive, Infantile, Regressive	0.75
	Delirium, Confusion, Delusional	0.72
	Agitated	0.87
	Withdrawn/Isolated	0.36
C0700	Wandering	0.76
C0710	Cognitive Functioning[f]	0.63
C0720	Memory Deficit	
	Familiar persons/places	0.52
	Recall events	0.60
	Supervision required	NA
	None of the above	NA
C0730	Judgment	0.70
C0740	Ability to Understand Others	0.67
C0750	Ability to Express Thoughts, Wants, Needs	0.77
C0760	Satisfaction with Amount of Interaction/Contact	0.22
C0780	Socialization/Isolation	
	Communication with Friends or Family	0.53

TABLE 2.4: COCOA-B Data Item Reliability (by Response Category). (Cont'd)

Data Item		Reliability Statistic[a,b,c]
	Feel Lonely	0.60
C0790	Self-Rated Quality of Life	0.44
C0800	Satisfaction with Care Provided for Pain	
	Staff Attention to Pain Control	90.9%
	Wait for Pain Medication	90.0%
	Staff Should Do More to Control Pain	0.49
C0810	Caregiver Stress	0.67
C0820	Caregiver Coping	
	Caregiver Coping: Difficulty	0.63
	Caregiver Coping: Need for a Break	0.71
C0840	Endurance	0.50
C0850	Ambulation/Locomotion	0.84
C0860	Transferring	0.77
C0870	Bathing	0.67
C0880	Grooming	0.73
C0890	Dressing Upper Body	0.90
C0900	Dressing Lower Body	0.86
C0910	Toileting	0.76
C0920	Feeding or Eating	0.73
C0930	Planning and Preparing Light Meals	0.85
C0940	Shopping	0.71
C0950	Housekeeping	0.71
C0960	Laundry	0.78
C0970	Telephone Use	0.81
C0980	Transportation	NA
C0990	Functional Rehabilitative Prognosis	0.29
C1010	Structural Barriers in Participant's Residence	
	Structural Barriers	
	None	0.49
	Stairs from inside to outside	0.63
	Stairs in home that must be used	0.51
	Stairs in home that are optional	0.55
	Narrow or obstructed doorways	-0.09
	Narrow or obstructed walkways	93.2%
	Other	0.37

[a] For data items that appeared on more than one COCOA form, the strongest reliability statistic is presented.

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

[c] The sample size for each data item with a corresponding reliability coefficient varied from 20 to 80 reliability pairs, depending on the number of valid analytic pairs for each data item.

[d] The "NA" notation signifies that the data item or the specific response option was added to the COCOA-B data set after the reliability test phase of the project. For those data items/responses reliability statistics are not available.

[e] The "ID" notation signifies that insufficient data were obtained during the reliability test to compute valid reliability coefficients for the data item or response option.

[f] This item was added for risk adjustment purposes after the reliability test phase of the project. The item was obtained from the OASIS data set and therefore the OASIS reliability coefficient is reported (see Hittle et al., 2003 for a review of OASIS reliability).

[g] The item was added to COCOA-B for the SYFT from the PACE Health Survey (PHS) to examine the feasibility of integrating items necessary for payment into the COCOA-B data system.

The inclusion of several data items on multiple discipline-specific COCOA forms implemented during the reliability test allowed comparative reliability analyses to be conducted across disciplines for this subset of data items. Reliability statistics for these data items are presented,

by discipline, in Table 3.5. The results of this cross-discipline analysis helped inform discipline assignments for these data items during the SYFT.

TABLE 2.5: CROSS-DISCIPLINE RELIABILITY FINDINGS FOR SELECTED DATA ITEMS.[A]

		Reliability Statistic[b,c]					
	Data Item	PCP	RN	REHAB	SW	RD	RT
C0360	Vision	.44	.41				
C0370	Hearing	.53	.65				
C0380	Height and Weight						
	Height		70.0%			95.8%	
	Weight		60.3%			70.8%	
C0390	Hydration (Oral Fluid Intake)						
C0420	Dyspnea	0.62	0.53	0.48			
C0440	Bladder Continence/When Urinary Incontinence Occurs						
	Bladder Continence	0.60	0.69				
	When Urinary Incontinence Occurs	0.07	0.56				
C0460	Bowel Incontinence Frequency		0.36				
C0470	Falls/Falls Resulting in Injury						
	Number of Falls	0.75	0.77	0.61			
	Number of Falls Resulting in Injury	0.75	0.56	0.85			
C0660	Frequency of Anxiety	0.39			0.20		
C0690	Frequency of Behavior Problems						
	Verbal Disruption				0.72		0.12
	Physical Aggression				0.77		0.12
	Disruptive, Infantile, Regressive				0.75		0.09
	Delirium, Confusion, Delusional				0.72		0.46
	Agitated				0.87		0.38
	Withdrawn/Isolated				0.14		0.36
C0700	Wandering				0.70		0.76

[a] The inclusion of several data items on multiple discipline-specific COCOA forms implemented during the reliability test permitted comparative reliability analyses across disciplines for these data items. Reliability results by discipline are presented in this table.

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

[c] The number of valid analytic pairs for each data item varied from 24 to 80.

4. Data Item Revision and Creation of the COCOA-B Data Set

Over 100 data items were eliminated from the data set after the reliability test, resulting in a set of 134 items intended for measuring and risk adjusting participant outcomes while providing a uniform set of basic assessment items across PACE sites. The reduced data set, referred to as COCOA-B, was created in response to multiple converging factors. Key influencing factors included empirical findings and care provider feedback from the feasibility and reliability test phases, input from the project Advisory Committee and National PACE Association leadership, administrative and payment considerations, and concerns related to burden and practicality. The data items from the COCOA data set that were not retained for the COCOA-B data set are presented in Appendix 3D (the original sources of the data items also are documented in the

appendix). Although some of the data items were eliminated due to poor reliability, many items could not be retained in the smaller data set simply because they were not critical to the objectives of the COCOA-B data set, although still useful for assessment purposes. The data items could serve as a valuable resource for PACE sites working to develop or revise assessment materials. Sites could add desired data items to supplement their assessment materials (which will encompass the COCOA-B data items and other site-specific assessment items).

In addition to the substantial reduction of the data set, many of the remaining data items were revised to enhance their reliability and utility for outcome measurement and assessment. Data item overlap across disciplines was eliminated entirely (other than a small set of tracking items), and discipline assignments for the data items were modified based on the reliability test experience (e.g., findings from cross-provider reliability analyses, input from care providers, and observations of site staffing patterns). Implementation activities for the systematic field test, such as the training program and steps to initiating data collection, also were refined based on the reliability test experience.

CHAPTER 3

COCOA-B SYSTEMATIC FIELD TEST: IMPLEMENTING THE COCOA-B DATA SYSTEM AT 13 PACE SITES

A. INTRODUCTION

After significant revisions to the data set and data collection protocols based on findings from the first two phases of the field test, the larger scale systematic field test (SYFT) of the COCOA-B\OBCQI data system was undertaken from June through November 2003. Operational aspects of the SYFT are presented in this chapter. (Analytic findings from the SYFT related to the development and testing of the outcome measures and preliminary risk adjustment methodology are described in Chapter 4.) Section B provides an overview of the SYFT, including objectives, site recruitment, COCOA-B clinical item integration, site training, selection of participants and informal caregivers, and data collection protocols. Section C provides an overview of the data received during the SYFT, including a summary of participant characteristics for the SYFT sample. The procedures established to ensure high quality data during the SYFT and data problems encountered are reviewed in Section D. Finally, Section E provides a summary of major operational findings from the SYFT.

B. SYSTEMATIC FIELD TEST OVERVIEW

1. Objectives of the Systematic Field Test

The overall objectives of the SYFT were to 1) support the integration of the COCOA-B data items and data collection protocols into routine site activities; 2) test and evaluate the accuracy of the COCOA-B data items and their effectiveness for computing outcome measures for OBCQI; 3) develop a preliminary risk adjustment methodology for the creation of outcome reports; 4) develop initial drafts of site-specific risk-adjusted outcome reports (not planned for distribution to PACE sites) and participant characteristic reports, and 5) evaluate and revise the draft COCOA-B data items, outcome measures, and data collection protocols based on empirical findings, site staff input, and experience obtained during the SYFT.

2. Site Recruitment

Seventeen PACE sites were contacted regarding participation in the SYFT, including all 12 of the original demonstration sites. Four sites were unable to participate due to factors such as CMS provider visits and staffing constraints. Of the 13 sites that agreed to participate, 10 were original demonstration sites and three were more recently established PACE sites. (The 13 SYFT sites are listed in Chapter 2, Table 2.1.) The composition of established and newer PACE sites permitted an examination of potential differences in operational challenges related to implementing the COCOA-B data system within a given site.

3. COCOA-B Form Integration Process

After agreeing to participate in the SYFT, the first major site activity was to integrate the COCOA-B data items into existing clinical assessment materials. (The COCOA-B data set used during the SYFT is presented in Appendix 4A.[3]) Although the COCOA-B data set was designed

[3] Four items, administered under two conditions (participant response and nurse assessed) were added to the COCOA-B data set prior to the SYFT. These items were developed by another CMS contractor, Research Triangle

primarily for computing and risk adjusting outcomes, the data set also was developed to meet multiple purposes, including participant assessment and care planning. The clinical data items are intended to be integrated into existing site assessment materials. Integration means that items on a site's assessment form that are substantive duplicates of COCOA-B data items are replaced with COCOA-B data items; COCOA-B items should not be simply added on to the beginning or end of an existing assessment form, but should be interspersed with existing items in a manner that creates a logical and clinically appropriate flow to the assessment.

In addition to the COCOA-B clinical data items integrated into site assessment materials, the COCOA-B data set implemented during the SYFT included subsets of data items intended to serve as stand-alone data collection instruments, including Participant Tracking and Demographic Items, a Participant Satisfaction Questionnaire, Caregiver Satisfaction Questionnaire, End of Life Questionnaire, Inpatient Utilization Form, and Disenrollment Form.

To facilitate the form integration process and to ensure adherence to SYFT data collection processes, each clinical data item was assigned to a specific discipline; in a few cases, alternate disciplines for data collection were permitted. The approach of assigning COCOA-B data items to specific disciplines fits with the interdisciplinary team approach emphasized under the PACE model and reduces the data collection burden for any one discipline.

Ten sites integrated the COCOA-B data items into their existing assessment materials, and three sites were unable to integrate due to state data reporting requirements (e.g., OASIS data collection) and/or existing electronic medical record systems (EMRs).[4] Sites received instructional materials on the integration process, and to ensure data integrity, all integrated forms were reviewed and approved by Research Center staff. Instructional information distributed to SYFT sites to support the COCOA-B data item integration process (including discipline assignments), is provided in Appendix 4B.

4. Site Training

To ensure an understanding of the overall objectives of the project and increase adherence to SYFT data collection protocols, two to four representatives from each of the participating SYFT sites attended a two-day training in Denver prior to the start of data collection. Due to financial and logistical considerations, a train-the-trainer approach was employed whereby those attending the training in Denver were responsible for training all other staff involved in SYFT data collection at their site.

The SYFT training focused on the outcome-based continuous quality improvement methodology, the development and utility of the COCOA-B data set, COCOA-B form integration, SYFT data collection protocols/processes, obtaining participant and informal caregiver consent to participate in the SYFT, methods to ensure data quality, and approaches to training site staff. Training manuals were developed and provided to sites in both hardcopy and electronic formats to facilitate site-level training.

Institute (RTI), and are the four items used to compute a frailty adjuster for potential use in risk-adjusted payment. During the SYFT, the Research Center worked as a subcontractor to RTI to examine the feasibility of integrating th data items (that would be necessary for payment) into the COCOA-B data collection system.

[4] The following sites integrated the COCOA-B data items into their existing site assessment forms: Center for Elders Independence, Community Care for the Elderly, Elder Service Plan of East Boston, Elder Service Plan of the Cambridge Health Alliance, Henry Ford Center for Senior Independence, Sutter SeniorCare, Total Longterm Care, TriHealth SeniorLink, Upham's Elder Service Plan, and ViaHealth Independent Living for Seniors.

5. Participant and Informal Caregiver Recruitment

To ensure sufficient data for evaluating of the risk-adjusted outcome measures, the SYFT was designed to involve all site enrollees. Due to staffing constraints and other site limitations (e.g., EMRs, OASIS data collection), a few sites were unable to involve all enrollees and therefore included only a subset of their participants (e.g., participants from one center).

Because SYFT COCOA-B data collection was conducted as a developmental effort and not a CMS requirement, informed consent and HIPAA authorization had to be obtained for each participating individual prior to any data collection involving the individual. Consent and HIPAA authorization therefore were obtained from participating individuals or the primary informal caregiver, family member, or legal proxy (depending on state law) for participants who were unable to consent due to cognitive impairment or required a proxy signature due to physical impairment. Due to issues related to obtaining consent, the following individuals were not eligible to participate in the SYFT:

- participants/informal caregivers who did not speak/understand English, Spanish, or Chinese well enough to be able to understand the consent and authorization forms in those languages;
- participants who were cognitively impaired to the extent that they could not consent and did not have a proxy/informal caregiver to consent on their behalf; and
- informal caregivers who were cognitively impaired to the extent that they could not consent on their own behalf (proxy consent was not allowable for informal caregivers).

While consent was reported to be a burdensome process for site staff, the vast majority of participants and informal caregivers who were asked to take part in the SYFT agreed to participate.

6. Data Collection Protocols

To ensure that data were collected in a systematic and reliable manner, data collection protocols were implemented during the SYFT. A summary of the SYFT data collection protocols is presented below. Documentation of the detailed data collection protocols that were provided in the SYFT training manual is provided in Appendix 4C.

a. COCOA-B Clinical Item Sets - One of the key objectives of the SYFT was to test and evaluate the accuracy of the outcome measures specified earlier in the project. In order to compute the majority of participant outcomes, COCOA-B data must be available for a participant at two points in time.[5] Toward this goal, sites participating in the SYFT were asked to collect complete COCOA-B clinical data on all participants due for assessment (based on each site's assessment schedule) during the SYFT and to reassess the participants three to four months later (depending on state data reporting requirements). The majority of the SYFT sites elected to reassess participants at four-month intervals; therefore, participants assessed in June and July 2003 were to be reassessed in October and November 2003, respectively.

Based on prior discussions with PACE site staff, it was our presumption that clinical assessments were completed by the interdisciplinary team members within two weeks of a participant's assessment due date. Therefore, no specified time requirement for completing the set of clinical assessments was established in the SYFT data collection protocols. Sites were asked to complete assessments based on the site's established protocols for participant assessment.

[5] A few of the outcome measures selected for PACE require data at a single time point (e.g., Percent of Participants Immunized for Influenza).

All COCOA-B data items were to be completed unless specific instructions (e.g., an item should be skipped due to a response to a previous item) were indicated. Each discipline was asked to review each completed form before submitting the form to the Research Center. The site Data Quality and Collection Coordinator was asked to conduct a second form review to ensure all data were complete and free of logical inconsistencies. After this second review, the form was submitted to the Research Center for electronic encoding.

b. *Utilization Form:* Sites were asked to complete the Inpatient and Emergency Services Utilization Form for all participants who were admitted to an inpatient facility or seen at an emergency department during each month of the SYFT. In addition, participants who were admitted in prior months but continued to reside in an inpatient facility during the designated month were to be included in the list. Sites were asked to submit the form to the Research Center by the 10th of the following month (e.g., the Utilization Form for June should have been submitted to the Research Center by July 10). As with all COCOA-B data collected during the SYFT, identifiable utilization data could not be submitted for participants without a valid consent and HIPAA authorization form.
c. *Satisfaction Questionnaires (Participant and Informal Caregiver):* Sites were asked to administer the Participant Satisfaction Questionnaire and Caregiver Satisfaction Questionnaire to 50% of eligible participants and informal caregivers during July and August 2003, respectively. It was anticipated that sites would have resolved issues related to start-up activities for administration of the COCOA-B clinical item sets, and therefore, resources would be available to manage data collection activities for the satisfaction questionnaires by this time. In an effort to maximize the validity of the responses, sites were asked to have the questionnaires administered by staff or volunteers who did not provide direct care to participants. The PSQ was administered to each participant in a face-to-face interview, whereas the CSQ could be administered either in person or by telephone. Sites were asked to review the forms for logical inconsistencies before submitting completed questionnaires to the Research Center.
d. *End of Life Questionnaire*: End of Life Questionnaires were mailed to primary informal caregivers of deceased participants, two to four months after the participant's death. Informal caregivers were asked to complete the questionnaires and return them (either to the PACE site or Research Center) using an enclosed prepaid envelope.

C. OVERVIEW OF SYFT COCOA-B DATA ENCODED AT THE RESEARCH CENTER

Due to site resource constraints, it was determined that COCOA-B data entry activities would occur at the Research Center and not at the PACE sites. Therefore, hardcopy COCOA-B forms were submitted to the Research Center where forms with valid consent and HIPAA authorization were electronically encoded into a data entry system developed for the SYFT.[6] During the period of the SYFT, data were received and encoded for 1,799 participants and 365 informal caregivers across all 13 SYFT PACE sites. A total of 16,521 forms were encoded at the Research Center. Table 3.1 presents the total number of forms submitted, by form type. It should be noted that sites were permitted to assign several of the COCOA-B data items to a variety of staff members and therefore the number of submitted forms varied by site. For example, the number of Pharmacist Forms submitted to the Research Center is relatively small

[6] COCOA-B forms received at the Research Center without valid consent and HIPAA authorization could not be encoded and were destroyed. Forms for 14 participants and seven informal caregivers were destroyed due to missing or invalid consent or HIPAA authorization. As the number of participants and information caregivers whose forms were destroyed represents less than one percent of the participants and less than two percent of the informal caregivers in the SYFT sample, it is anticipated that the exclusion of these individuals will not have an effect on the project findings.

because only one site assigned a subset of COCOA-B data items for completion by the site pharmacist. These data items also were collected by all other sites, but those sites assigned the items to a discipline other than the pharmacist.

TABLE 3.1: SUMMARY OF SYFT COCOA-B DATA ENCODED AT THE RESEARCH CENTER.

COCOA-B Forms	Number of Forms
Participant Tracking and Demographic Items	2,057
Primary Care Provider (PCP)	2,019
Nursing (RN)	1,935
Nursing - Home Care (RN-HC)	269
Social Work (SW)	2,199
Rehabilitative Therapy (Rehab)	1,532
Occupational Therapy (OT)	382
Physical Therapy (PT)	257
Recreational Therapy (RT)	115
Pharmacist (Pharm)	53
Dietitian (RD)	803
Home Safety (HomeSafety)	384
Mini Mental Status Examination (MMSE)	404
Utilization (Util)	3,102
Disenrollment (Dis)	44
End of Life Questionnaire (EOL)	46
Participant Satisfaction Questionnaire (PSQ)	601
Caregiver Satisfaction Questionnaire (CSQ)	319
All Forms	**16,521**

There was considerable variability in the volume of data submitted by each site, irrespective of site census. For example, one moderately sized PACE site was unable to begin data collection until September and submitted data on only five participants, whereas a smaller PACE site began data collection in June and submitted data for 95 of their participants. The numbers of involved participants and COCOA forms submitted by site are presented in Table 3.2.

Also presented in Table 4.2 are the number of participants with complete COCOA-B clinical data for their initial SYFT assessment and the number of participants with valid outcome pairs (i.e., data collected at two time points). As mentioned previously, one of the key objectives of the SYFT was to test and evaluate the accuracy of the participant outcome measures specified earlier in the project. To accomplish this goal, individual COCOA-B clinical item sets (e.g., primary care provider, nursing) were grouped together for each participant to create one or more complete COCOA-B assessment(s) based on each site's form integration approach. For example, a complete COCOA-B clinical assessment for a participant at Site A might include a Primary Care Provider Form, Nursing Form, Social Work Form, and Rehabilitative Therapy Form, whereas a complete COCOA-B assessment at Site B might include a Primary Care Provider Form, Nursing Form, Social Work Form, Occupational Therapy Form, Physical Therapy Form, and Dietitian Form. After creating complete COCOA-B assessments, participants with COCOA-B assessment data at two time points were included in the participant outcome analysis file.

TABLE 3.2: Number of Participants, Forms, Complete COCOA-B Assessments and Outcome Pairs (by Site)

Site[a]	Participants	COCOA-B Forms	Complete COCOA-B Assessments	Outcome Pairs
A	296	3454	239	77
B	297	3589	177	69
C	65	774	9	4
D	168	1395	108	49
E	312	1547	84	10
F	200	1844	159	65
G	5	26	0	0
H	115	927	44	35
I	35	311	5	4
J	48	504	46	44
K	28	145	1	1
L	159	1524	119	60
M	71	481	31	19
All Sites	**1799**	**16521**	**1022**	**437**

[a] To maintain site and participant confidentiality, sites have been assigned a random identifier.

Initially, criteria for inclusion in the outcome analyses required participants to have complete COCOA-B assessment data at two time points. However, due to the significant amount of data missing for the second assessment a less stringent inclusion criterion was applied. To be included in the analysis file for the development and testing of the outcome measures, participants had to have a complete COCOA-B assessment at the first assessment time point and at least one COCOA-B clinical item set at the follow-up assessment time point. The requirement for complete COCOA-B assessment data at the first assessment time point could not be amended as data items necessary for computing risk factors are selected from the first assessment time point. As a result of implementing the less rigorous definition for inclusion in the SYFT outcome analysis file, the constellation of participants varies for any given outcome measure (participants were excluded from individual outcome measures when second time point data were missing).

As indicated in Table 3.2, 437 participants had valid outcome pairs and therefore were included in the data set used to develop and evaluate the participant outcome measures and preliminary risk adjustment methodology (described in detail in Chapter 4). Additionally, 1,045 participants (1,022 participants with complete COCOA-B data at their first assessment time point and 23 participants with complete COCOA-B data at their second assessment time point) were included in a larger data set used to compute a limited number of outcome measures that required data at one point in time only (e.g., Percent of Participants with a Signed Advance Directive) and to generate participant characteristic reports provided to PACE sites after completion of the SYFT.

The participant characteristics reports distributed to participating SYFT sties can be used to assess and compare similarities and differences between one site's participant population and that of the other PACE sites involved in the SYFT. An example of the participant characteristics report and accompanying documentation sent to participating sites can be found in Appendix 3D. A summary of participant characteristics for the SYFT sample is provided in Table 3.3. Participants who enrolled in the SYFT were predominately female (73.4%), with an average age of 78.2 years. Most participants lived either alone or with others in a private

residence (74.5%). The majority of SYFT participants were categorized as dependent in living skills (63.7%), and 25.7% of participants were categorized as dependent in personal care skills.

TABLE 3.3: SYFT Sample: Summary of Participant Characteristics.[a]

	N	Mean	SD
Demographics			
Age (average in years)	986	78.16	10.14
Gender: Female (%)	983	73.4%	0.44
Marital Status: Married (%)	975	17.5%	0.38
Race/Ethnicity: Asian (%)	983	5.4%	0.23
Race/Ethnicity: Black or African American (%;	984	35.0%	0.48
Race/Ethnicity: Hispanic or Latino (%)	984	5.9%	0.24
Race/Ethnicity: Non-Hispanic White (%)	983	52.6%	0.50
Length of Enrollment			
< 1 Year (%)	919	28.8%	0.45
1-3 Years (%)	919	35.1%	0.48
3-5 Years (%)	919	17.3%	0.38
> 5 Years (%)	919	18.7%	0.39
Current Living Situation			
Lives Alone (%)	1041	32.3%	0.47
Home With Others (%)	1039	42.2%	0.49
Group Living Situation (%)	1040	16.3%	0.37
Nursing Home (%)	1042	2.5%	0.16
Assisting Persons			
Residing in Home (%)	1042	33.3%	0.47
Residing Outside Home (%)	1041	48.1%	0.50
Paid Help (%)	1041	4.8%	0.21
Frequency of Assistance (0-5, scale avg.)	771	2.62	1.79
Type of Informal Caregiver Assistance			
ADL/IADL (%)	1041	60.4%	0.49
Environmental Support (%)	1041	69.3%	0.46
Participant Advocacy (%)	1040	57.7%	0.49
Advance Directives			
Signed Living Will (%)	1033	73.2%	0.44
Prognoses			
Overall Prognosis (0-2, scale avg.)	1026	1.00	0.40
Functional Rehab Prognosis (0-2, scale avg.)	1025	1.05	0.39
Respiratory Status			
Dyspnea (0-4, scale avg.)	1026	0.73	0.94
Edema			
Legs/Feet (%)	1013	33.2%	0.47
Immunizations			
Flu Immunization (%)	1011	85.2%	0.36
Elimination Status			
UTI Within Past 14 Days (%)	1031	2.3%	0.15
Urinary Incontinence (%)	1028	54.9%	0.50
Incontinent Day and Night (%)	1016	38.3%	0.49
Urinary Catheter (%)	1045	1.0%	0.10
Bowel Incontinence (0-6, scale avg.)	1041	0.59	1.29
Pain			
Severity of Pain (0-10, scale avg.)	949	2.35	3.26
Pain Interfering with Activity (0-4, scale avg.)	1025	0.85	1.11
Intractable Pain (%)	1021	6.3%	0.24

	N	Mean	SD
Falls			
Fall Resulting in Injury (%)	1034	10.2%	0.30
Sensory Status			
Vision Impairment (0-2, scale avg.)	1042	0.47	0.55
Hearing Impairment (0-2, scale avg.)	1040	0.30	0.46
Language Comprehension Impairment (0-2, scale avg.)	1040	0.78	0.99
Language Expression Impairment (0-2, scale avg.)	1035	0.76	1.05
Current Diagnoses			
Infections/parasitic diseases (%)	1045	5.0%	0.22
Neoplasms (%)	1045	4.8%	0.21
Endocrine/nutrit./metabolic (%)	1045	59.2%	0.49
Blood diseases (%)	1045	13.3%	0.34
Mental diseases (%)	1045	56.2%	0.50
Nervous system diseases (%)	1045	54.0%	0.50
Circulatory system diseases (%)	1045	84.2%	0.36
Respiratory system diseases (%)	1045	20.6%	0.40
Digestive system diseases (%)	1045	44.2%	0.50
Genitourinary system diseases (%)	1045	21.2%	0.41
Skin/subcutaneous diseases (%)	1045	8.4%	0.28
Musculoskeletal system diseases (%)	1045	60.3%	0.49
Ill-defined conditions (%)	1045	36.7%	0.48
Fractures (%)	1045	1.7%	0.13
Other injury (%)	1045	1.7%	0.13
Iatrogenic conditions (%)	1045	0.6%	0.08
ADL Disabilities			
Grooming (0-3, scale avg.)	1042	0.93	0.95
Upper Body Dressing (0-3, scale avg.)	1042	0.82	1.00
Lower Body Dressing (0-3, scale avg.)	1041	0.95	1.05
Bathing (0-5, scale avg.)	1039	2.20	1.28
Toileting (0-5, scale avg.)	1041	1.25	1.37
Transferring (0-5, scale avg.)	1041	0.96	0.83
Ambulation (0-5, scale avg.)	1043	1.19	1.04
Eating (0-5, scale avg.)	1041	0.40	0.71
Dependence in Personal Care (%)	1037	25.7%	0.44
Impaired Ambulation/Mobility (%)	1040	23.4%	0.42
IADL Disabilities			
Light Meal Preparation (0-2, scale avg.)	1038	1.14	0.89
Transportation (0-2, scale avg.)	1040	0.96	0.25
Laundry (0-2, scale avg.)	1034	1.55	0.74
Housekeeping (0-4, scale avg.)	1040	2.75	1.48
Shopping (0-3, scale avg.)	1034	2.03	0.98
Phone Use (0-5, scale avg.)	1013	1.38	1.83
Management of Oral Meds (0-2, scale avg.)	1031	1.23	0.67
Dependence in Living Skills (%)	1028	63.7%	0.48
Neuro/Emotional/Behavioral Status			
Moderate Cognitive Disability (%)	1041	25.3%	0.43
Severe Anxiety Level (%)	1024	17.5%	0.38
Depressive Symptoms Occurring > Monthly (0-10, scale avg	1044	1.97	2.25
Behavioral Problems > Monthly (%)	1042	23.2%	0.42
Wandering (%)	1037	1.6%	0.13
Adherence to Treatment			
Poor Adherence to Medications (%)	1033	1.4%	0.12
Poor Adherence to Therapy/Interventions (%)	893	5.4%	0.23
Nutritional Risk			
Nutritional Risk (%)	1045	21.5%	0.41

[a] Analysis based on all SYFT participants with complete COCOA-B clinical data for at least one assessment.

Characteristics of SYFT participants are similar to those reported for the general PACE population by the National PACE Association (NPA, 2004), with a few notable exceptions; SYFT participants were younger, less likely to reside in a nursing home, and showed less cognitive impairment.

D. COCOA-B DATA QUALITY

1. Ensuring Data Quality

OBCQI is a data-driven system, meaning that the OBCQI activities are highly dependent on data collection and analysis. In order to maintain an OBCQI system comprised of valid outcome

measures, high quality data on individual participants are imperative. Preventing data quality problems will result in data that more accurately represent the types of participants sites care for and ensure the validity of the outcome measures. Assuring precise and uniform data was, therefore, a critical goal of the SYFT. Several procedures (noted below) were implemented at participating PACE sites and the Research Center to ensure that quality COCOA-B data would be available for developing the outcome measures and risk adjustment methodology for PACE.

a. *Tracking of COCOA-B Forms* - PACE site Data Quality and Collection Coordinators were asked to track the completion of all participant assessments to ensure that participants were assessed by all disciplines according to their site's assessment schedule and that the data were submitted to the Research Center in a timely manner.
b. *Up Front Review (UFR)* - PACE staff members were instructed to conduct an up front review of each completed COCOA-B form, checking the form for such problems as missing responses, inconsistencies within and across items, and multiple responses to single response items. After completing the UFR, the form was submitted to the Data Quality and Collection Coordinator who conducted a second UFR before submitting the completed COCOA-B form to the Research Center. The UFR process was established to decrease the number of assessments with errors submitted to the Research Center.
c. *Data Validation Reports* - After each COCOA-B form was encoded at the Research Center, a series of data validation checks was performed and if any errors were identified, a Data Inconsistency Report (DIR) was generated. DIRs provide a written record of all data problems identified on a specific COCOA-B form. Research Center staff reviewed the DIRs to ensure that no errors were the result of data entry errors. If data entry errors were identified, the assessment information was corrected in the database. Preferably, DIRs would have been sent to SYFT sites to resolve any remaining data problems; however, we were unable to implement this process during the SYFT due to Research Center and site resource constraints. A comprehensive listing of all data validation checks can be found in Appendix 4E.
d. *Data Receipt Reports (DRRs)* - Data Receipt Reports provide a comprehensive listing of all COCOA-B forms encoded at the Research Center for each participant at a PACE site. Research Center staff used these reports during the SYFT as a resource for identifying missing COCOA-B forms prior to regularly scheduled site calls. The DRRs were sent to sites after the completion of the SYFT as part of Data Quality and Submission Reports (see Appendix 4F for a sample Data Quality and Submission Report, including the Data Receipt Report). Data Quality and Submission Reports (including DRRs) could be used by PACE sites to identify missing COCOA-B forms, determine the most common data errors, and monitor (and remediate) other data quality issues, such as timely completion of participant assessments.

2. Data Quality Problems Encountered

Although several initiatives were implemented to obtain quality data, numerous problems were encountered as described in this section.

a. *Missing COCOA-B Clinical Data* - A number of participants were missing at least one COCOA-B clinical form (often an entire COCOA-B assessment was missing) and therefore could not be included in the analysis files. Sites indicated several reasons for missing COCOA-B item sets, as described below.
    - Site assessment protocols did not require the entire interdisciplinary team to be involved in the assessment of participants residing in nursing homes; therefore,

certain COCOA-B clinical item sets (integrated into site clinical assessments) were not completed for nursing home participants.

- At some sites, participants who were not receiving therapy services (physical or occupational therapy) were not assessed using the COCOA-B Rehabilitative Therapy items (which were integrated into site rehabilitative therapy forms).
- Due to tracking and timing difficulties, several COCOA-B forms were never completed and/or submitted to the Research Center.

b. COCOA-B Forms Submitted with Errors - Across all PACE sites participating in the SYFT, 79.3% of the COCOA-B clinical item sets were submitted without any errors. Sites varied in the quality of their submitted data, with one site submitting 56.3% of their assessments without errors while the most error-free site submitted 92.5% of their assessments without errors. The 20 most common errors across all sites are presented in Table 3.4 (a comprehensive listing of all data quality checks is provided in Appendix 4E).

TABLE 3.4: Twenty Most Common Errors Identified on COCOA-B Clinical Forms During the SYFT.

Error Message	Data Item	Total Forms	Number (Percent) of Forms with Error
For C0240 (Diagnosis and Severity Index), the severity rating for ICD-9 code (value) should not be blank.	C0240	2019	178 (8.82%)
For C0240 (Diagnosis and Severity Index), an Acute or Chronic designation for ICD-9 code (value) should not be blank.	C0240	2019	176 (8.72%)
C0380 (Height) cannot be blank.	C0380	2000	145 (7.25%)
C0430 (Edema: Sacral) cannot be blank.	C0430	2024	141 (6.97%)
C0430 (Edema: Facial) cannot be blank.	C0430	2024	137 (6.77%)
C0100_2 (Medicare Entitlement) cannot be blank.	C0100	2057	108 (5.25%)
Since the response to C0040 (Reason for Assessment) is "2-Reassessment," C0800_1 (Satisfaction with Care Provided for Pain) should not be blank.	C0040, C0800	2199	106 (4.82%)
Since "NA-No informal caregiver" is not checked, C0830 (Caregiver Support) should not be blank.	C0830, C0830	2199	93 (4.23%)
Since the response to C0650_1 (Advance Directives) is "0-No," C0650_2 (Advance Directives: Discussion) should be blank.	C0650	2206	93 (4.22%)
Since "NA-No informal caregiver" is not checked, C0810 (Caregiver Stress) should not be blank.	C0810, C0810	2199	90 (4.09%)
Since "NA-No informal caregiver" is not checked, C0820_1 (Caregiver Coping) should not be blank.	C0820, C0820	2199	90 (4.09%)
Since "NA-No informal caregiver" is not checked, C0820_2 (Caregiver Coping) should not be blank.	C0820, C0820	2199	89 (4.05%)
C0350 (Flu Immunization Status) cannot be blank.	C0350	2004	81 (4.04%)
Since the response to C0040 (Reason for Assessment) is "2-Reassessment," C0170 (Inpatient Facilities) should be blank.	C0040, C0170	2057	83 (4.04%)
C0380 (Weight) cannot be blank.	C0380	2000	80 (4.00%)
Since the response to C0040 (Reason for Assessment) is "2-Reassessment," C0180 (Formal Services Received) should be	C0040, C0180	2057	78 (3.79%)

TABLE 3.4: Twenty Most Common Errors Identified on COCOA-B Clinical Forms During the SYFT. (Cont'd)

Error Message	Data Item	Total Forms	Number (Percent) of Forms with Error
blank.			
C0100_1 (Medicare Number) cannot be blank.	C0100	2057	68 (3.31%)
The (value) entered for C0240 (Diagnosis and Severity Index) is not a valid ICD-9 code.	C0240	2019	66 (3.27%)
C0310_a4 (MMSE: Today's date) cannot be blank.	C0310	2095	67 (3.20%)
C0510 (Adherence to Therapy/Medical Interventions) cannot be blank.	C0510	2018	62 (3.07%)

c. *Excessive Completion Period for COCOA-B Clinical Item Sets* - The assessment completion period is defined as the number of days between the earliest and the latest Date Assessment Completed (C0050) for the group of COCOA-B clinical forms required to assess a participant at a single point in time. For example, if the Primary Care Provider Form was completed for a participant on 5/5/2003, the Nursing Form completed on 5/10/2003, the Social Work Form completed on 5/15/2003, and the Rehabilitative Therapy Form completed on 5/16/2003, the assessment completion period for the participant would be 11 days (the number of days from 5/5/2003 to 5/16/2003). Assessment completion period was calculated only for those participants with complete COCOA-B assessments. The mean, standard deviation, and range (reported in days) within each site and across all sites are provided in Table 3.5.

As displayed in Table 3.5, the assessment completion period ranged significantly from site to site. The average assessment completion period across all sites was 20.6 days—a timeframe that far exceeds the 14-day time frame presumed prior to the SYFT for completing a participant assessment. To capture the true health status of a participant at a single point in time, it is imperative that sites work toward completing assessments in a timely manner.

d. *Problems Encountered with Utilization Data Collection* - Sites were permitted to submit identifiable utilization data only for those participants with valid consent and authorization forms. As a result, site staff had to cross-reference consent records to determine whether a specific encounter could be submitted to the Research Center. The process of cross-referencing utilization records with consent information was perceived as burdensome by some sites, resulting in missing utilization data. Other sites decided to postpone submission of utilization data until late in the SYFT when they had already obtained consent for most of their participants.

TABLE 3.5: DESCRIPTIVE STATISTICS FOR ASSESSMENT COMPLETION PERIOD (IN DAYS) DURING THE SYFT.

Site ID	Mean	Std. Dev.	Range
A	18.8	11.4	2-85
B	18.0	12.0	1-70
C	27.7	7.4	19-43
D	18.4	16.8	1-80
E	27.2	19.6	1-81
F	18.9	11.9	0-70
G	8.0	-	8-8
H	18.9	16.3	1-70
I	30.0	23.6	7-56
J	29.1	16.8	8-72
K	60.0	-	60-60
L	20.2	10.4	0-63
M	34.8	20.2	7-79
All Sites	**20.6**	**14.2**	**0-85**

In addition to problems encountered with the amount of utilization data submitted, sites varied considerably in their interpretation of several of the response options on the Utilization Form. Most notably, Admission Type (C1250) was defined differently across sites based on state and PACE site definitions and provision of housing options.

Finally, the brief time period allocated for the SYFT was insufficient for capturing utilization events occurring after assessments with COCOA-B clinical data items (a necessary condition for computing utilization outcome measures). Due to the significant impact of these issues on the quantity and quality of the utilization data, it was determined that the utilization data collected during the SYFT would not be suitable for the development of utilization outcome measures. Problems related to utilization data collection during the SYFT are largely an artifact of the data collection and consent protocols that were unique to this testing phase. Difficulties encountered with regard to response options have been addressed through revisions to the data items. The contractor recommends that the revised utilization data items be retained in the COCOA-B data system and that future work includes further testing of utilization outcome measures.

E. FINDINGS FROM THE SYFT

In addition to providing data necessary for development and evaluation of the PACE outcome measures and preliminary risk adjustment methodology, the SYFT served to inform decisions regarding implementation activities, data collection protocols, and revisions to the COCOA-B data items. Some of the key findings from the SYFT are highlighted below.

- Under-representation of Nursing Home Participants - Based on COCOA-B assessment data (as presented in Table 3.3), 2.5% of the SYFT PACE participants were residing in a nursing home at the time of their COCOA-B assessment compared to 8.7% of the general PACE participant population, as reported by the National PACE Association (NPA, 2004). Because many of the SYFT sites assessed nursing home participants using only a subset of the COCOA-B data, these participants were underrepresented in the outcome analyses for the SYFT. Clearly defined protocols for assessing nursing home participants would need to be established if implementation were to occur.

- Differences between Demonstration Sites and Newer Sites - Difficulties encountered with implementing COCOA-B into site assessment materials and activities related to COCOA-B data collection and submission were not associated with site maturity and experience. Factors that contributed to successful integration and data collection were related to availability of adequate resources, organized and goal-oriented implementation teams, demonstrated commitment to and support for SYFT activities by site administration, and consistent communication with Research Center staff.
- Electronic Encoding and Transmission of COCOA-B Data at the PACE Sites - One of the most significant factors that directly affected the quality of the data provided during the SYFT was the lack of immediate feedback to sites with regard to COCOA-B data quality issues, including specific data item validation information and reporting of missing COCOA-B forms. Development of a site-level electronic encoding, tracking, and transmission system for COCOA-B data is a critical component to be addressed for national implementation. Such a system should include a data item validation mechanism, COCOA-B tracking reports, and data quality reports.
- Establish Guidelines for Assessment Completion Period - As discussed earlier in the chapter, one unexpected finding from the SYFT was the average time required to complete an assessment for a given participant (20.6 days). To capture the true health status of a participant at a single point in time and facilitate effective care planning, it is imperative that a guideline (as brief as possible) be established for the assessment completion period.
- Translation of Participant Response Items into Other Languages- Fifteen percent of the PACE participants who were involved in the SYFT had limited or no fluency in spoken English. The SYFT sample under-represents the racial, ethnic, and language diversity in the overall PACE population due to the unavailability of consent forms in languages other than English, Chinese, and Spanish, and due to the fact that sites with significant numbers of participants likely to speak other languages did not participate in the SYFT (e.g., the predominantly Spanish-speaking participant population at Bienvivir in El Paso). Therefore, to ensure that participant-response items are presented to all participants in the same way, sites might consider translating participant-response items into the most common languages represented at their site.
- COCOA-B Data Collection Protocol and Data Item Revisions - As with previous testing phases, PACE site staff were asked to provide feedback on all aspects of the SYFT including training, COCOA-B data collection protocols, technical assistance, and comments regarding COCOA-B wording, discipline assignments, and item appropriateness. In conjunction with SYFT empirical findings and Advisory Committee input, care provider feedback was incorporated into decisions regarding revisions to training materials, data collection protocols, and specific COCOA-B data item.

Although a limited number of problems were identified during the SYFT, the overall success of the data collection effort with regard to the quality and quantity of the data submitted to the Research Center is noteworthy. The successful submission of a substantial volume of high quality COCOA-B data allowed project staff to develop and test the outcome measures specified for PACE, as described in Chapter 4. Additionally, the SYFT phase of the field test was invaluable with regard to testing training approaches and materials, developing and refining data collection protocols, establishing a range of COCOA-B data verification checks. implementation.

CHAPTER 4

EMPIRICAL BASIS FOR RECOMMENDED OUTCOME MEASURES AND OTHER FINDINGS FROM THE SYSTEMATIC FIELD TEST

A. INTRODUCTION

Findings from the analyses of the outcome measures examined during the systematic field test (SYFT) are presented in this chapter. The SYFT analyses focused in particular on identifying the outcome measures—among those specified based on several years of developmental work and clinical and PACE community review that would be most effective for purposes of outcome-based continuous quality improvement and quality monitoring. Section B discusses the approach to defining outcome measures for the PACE OBCQI system. The criteria and analytic methods employed that guided selection of the most effective measures, as well as preliminary efforts toward risk adjusting selected measures, are described in Section C. A discussion of additional SYFT findings that underpin the final products is presented in Section D.

B. DEFINITION OF OUTCOME MEASURES

An outcome measure is the precise quantification of an outcome indicator (a construct or attribute of change in health status). For example, the outcome indicator of change in dyspnea gives rise to an outcome measure when a health status scale for dyspnea is used at baseline and follow-up time points. Outcome measures can be presented as the percentage of participants who have improved, stabilized (i.e., not worsened), or declined in a particular health status or other area (e.g., quality of life) from one time point (e.g., enrollment in the PACE program or a reassessment time point for enrolled participants) to the next assessment time point. The feasibility and utility of these three measure types (i.e., improvement, stabilization, and decline measures) for PACE OBCQI were investigated in the SYFT outcome analyses.

Based on the SYFT analyses and consideration of the PACE model and population served, improvement and decline measures were identified as the most useful for PACE OBCQI. Stabilization measures were dropped from consideration because of the low variability displayed within and across sites, reducing the utility of this measure type for comparing site performance over time and across sites, a primary feature of OBCQI. Given the nature of the population served by PACE and the relatively rare expectation for continuous improvement in health status, decline measures were determined to be meaningful (permitting providers to compare relative rates of decline) whereas this type of measure would not be as meaningful in other health care settings where continuous improvement is expected and often is the goal of care.

Using data obtained from the SYFT, health status and instrumental outcome measures were computed between baseline assessments and follow-up assessments completed three to four months after the baseline. Meaningful analysis of utilization measures was limited by multiple factors. Measures of improvement and decline were computed by comparing the value of each data item at follow-up with its value at the baseline time point. (For some measures, improvement is shown by a decrease in an attribute and decline is shown by an increase in an attribute. For example, the measure labeled Increase in Depression or Depressive Symptoms is a measure of decline or worsening.) Participants who could not improve (i.e., who were assessed at the most independent level on a data item scale at the first time point) were excluded from the improvement measures and participants who could not worsen (those assessed at the most dependent level on a scale at the first time point) were excluded from the

decline measures. A dichotomous variable was created, equal to "1" if the value of the item showed change (i.e., improvement or decline) at the later time point, and equal to "0" if no change occurred.

Measures examining patterns of change at three or more time points (rather than between two time points) were considered, but dismissed. Given the constrained time period for the SYFT, data collection was restricted to two time points, precluding our investigation of measures across multiple time points. However, previous work on outcome measurement in home health care has found that outcomes measured at two points in time provided sufficient information for quality improvement efforts (Shaughnessy et al., 1994). Additionally, using these measures simplifies the process of care investigation conducted by site clinical staff as part of the outcome enhancement stage of OBCQI. We therefore recommend outcome measures based on data collected at two time points.

Table 4.1 illustrates the computation of two outcome measures for the outcome indicator of change in dyspnea. If a participant's status on the dyspnea scale is recorded as a "4" [at rest] at baseline and measured as a "2" on the scale [with moderate exertion] at a later time point, then the participant would be given a value of "1" for the dyspnea outcome measure indicating improvement and would be excluded from the decline measure, because he/she is at the most dependent level of the scale (i.e., he/she cannot show decline beyond the scale level "4"). Note that if the participant's status on the dyspnea scale was "0" [never, participant is not short of breath] at baseline, this participant would be excluded from the improvement outcome computation because he/she cannot improve on this measure given our scale. This latter issue is important to note since the number of participants eligible for a specific outcome measure varies as a result of the measure definition.

The consumer-centered measures (i.e., participant and caregiver satisfaction and end of life care measures) and the measure addressing participant immunization status are not outcome measures per se because they do not measure change in status over time. Instead, they are measures based on a single time point and therefore, are not labeled as "improvement" or "decline" measures.

C. SELECTION OF OUTCOME MEASURES FOR PACE OBCQI

1. Overview of Selection Criteria and Assignment to Outcome Tiers

Each outcome measure was evaluated during the early developmental work, empirical testing phase, and when selecting measures for inclusion in the recommended measure set based on the outcome selection criteria presented earlier. During the early phases of the project, criteria related to clinical meaningfulness, diversity, administrative burden, redundancy, multiplicity of services subsumed, and multiplicity of purposes were applied by various clinical and research panels to select and refine an extensive list of potential outcome indicators and measures. As the project shifted to the empirical testing phase, selected empirical criteria in addition to continued clinical review were used to refine the data items and measures, eliminate various measures, and expand others with alternative definitions and approaches. In the final empirical phase (the SYFT), certain criteria were used to classify measures into one of three tiers related to their utility for quality monitoring and OBCQI. (The tier classification system is described below.) For example, those measures that did not demonstrate sufficient prevalence in the participant sample were not included in the Tier 1 list of outcome measures regardless of their clinical significance.

TABLE 4.1: ILLUSTRATIVE OUTCOME MEASURE CALCULATIONS FOR DYSPNEA.

Data Item/Scale

Dyspnea: When is the participant dyspneic or noticeably Short of Breath**?**

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

Improvement Measure

Improvement in Dyspnea: Defined only if the participant can improve (i.e., the participant has a value of 1 or greater at baseline on the above scale).

1 ⇒ Participant scale value is less at follow-up (three to four months[a] from baseline) than scale value at baseline.
0 ⇒ Participant scale value is not less at follow-up than at baseline.

Decline Measure

Decline in Dyspnea: Defined only if the participant can decline (i.e., the participant has a value of 3 or less at baseline on the above scale).

1 ⇒ Participant scale value is greater at follow-up than at baseline.
0 ⇒ Participant scale value is not greater at follow-up than at baseline.

Sample Scale Responses and Outcome Values

Baseline Value	Follow-up Value	Improvement in Dyspnea	Decline in Dyspnea
0	1	NA	1
1	1	0	0
4	2	1	NA

[a] Data collection interval for the SYFT.

The analyses presented in this chapter are a subset of the analytic work undertaken during the course of selecting the recommended set of outcome measures for the PACE quality monitoring and OBCQI system. The selection of the recommended outcome measures was an iterative process that entailed extensive analytic work including (but not limited to) the examination of distributional properties of all outcome measures and risk factors under consideration, assessment of various methods for examining cross-site variability, and examination of alternative risk adjustment methodologies.

The full set of outcome measures evaluated during the SYFT is presented in Table 4.2. Outcome measure specifications can be found in Appendix 5A. The measures presented in the table are grouped into three tiers (tier definitions and assignment criteria are described), then categorized as health status outcomes, utilization outcomes, instrumental outcomes, or

consumer-centered measures. Within these categories, measures are further organized by conceptual domain (e.g., physiologic status and symptom management). Favorable outcomes, if any, (i.e., improvement or decrease measures) are listed first in each domain grouping (when relevant), followed by nonfavorable outcomes (i.e., decline or increase measures).

TABLE 4.2: OBCQI Outcome Measures[a] Developed and Tested During the SYFT (Presented by Tier).

TIER 1 - EMPIRICALLY SUPPORTED MEASURES	
Health Status Outcomes	
Physiologic Status and Symptom Management	**Emotional/Mental Health Status**
Decrease[b] in Nutritional Risk	Decrease in Depression/Depressive Symptoms
Improvement in Urinary Continence	Decrease in Self-Report of Loneliness
Improvement in Dyspnea	Decrease in Number of Behavior Problems
Improvement in Edema	Increase in Depression/Depressive Symptoms
Increase[c] in Pain Interfering with Daily Activities	**Cognitive Functioning**
Decline in Edema	Improvement in Ability to Understand Others
Percent of Participants Immunized for Influenza	Improvement in Ability to Speak to Others
Functional Status	Decline in Ability to Speak to Others
Decrease in Number of Activities Limited by Health	
Decline in Management of Oral Medications	
Instrumental Outcomes	
Participant Quality of Life	**Informal Caregiver Quality of Life**
Improvement in Satisfaction with Frequency of Social Interactions	Decrease in Informal Caregiver Stress
Decline in Satisfaction with Frequency of Social Interactions	Improvement in Informal Caregiver Coping
Knowledge and Adherence	Increase in Informal Caregiver Stress
Improvement in Therapy Adherence	
Consumer-Centered Measures	
Participant Satisfaction	**Informal Caregiver Satisfaction**
Satisfaction with Staff Communications	Satisfaction with Provider-Family Communications
Satisfaction with Day Health Center Services	Satisfaction with Transportation
Satisfaction with Transportation	**End of Life Care**
Satisfaction with Obtaining Needed Services/Assistance	Percent of Participants with a Signed Advance Directive
TIER 2 - MEASURES FOR FURTHER INVESTIGATION[d]	
Health Status Outcomes	
Physiologic Status and Symptom Management	**Emotional/Mental Health Status**
Decrease in Pain Interfering with Daily Activities	Increase in Self-Report of Loneliness
Decline in Dyspnea	Increase in Number of Behavior Problems
Decline in Urinary Continence	**Cognitive Functioning**
Functional Status	Decline in Ability to Understand Others
Improvement in Ambulation	
Improvement in Management of Oral Medications	
Improvement in Transferring	
Decline in Ambulation	
Decline in Transferring	
Increase in Number of Activities Limited by Health	
Utilization Outcomes	
Hospitalization	**Emergency Care Services**
Percent of Participants Hospitalized	Percent of Participants Receiving Emergency Care
Percent of Participants Readmitted to the Hospital	
Nursing Home Placement	
Percent of Permanent Nursing Home Admissions	
Number of Nursing Home Days	

Instrumental Outcomes

Participant Quality of Life
Improvement in Self-Rated Quality of Life
Decline in Self-Rated Quality of Life

Knowledge and Adherence
Decline in Therapy Adherence

Informal Caregiver Quality of Life
Decline in Informal Caregiver Coping

TIER 3 - MEASURES TO BE DROPPED

Health Status Outcomes

Physiologic Status and Symptom Management
Decrease in Falls Resulting in Injury[e]
Improvement in Pressure Ulcers[e]
Improvement in Skin Integrity

Increase in Falls Resulting in Injury[e]
Decline in Pressure Ulcers[e]
Decline in Skin Integrity
Decline in Nutritional Risk

Number of Prescription Medications

Emotional/Mental Health Status
Decrease in Wandering[e]
Increase in Wandering[e]

Instrumental Outcomes

Participant Quality of Life
Improvement in Satisfaction with Quality of Social Interactions

Decline in Satisfaction with Quality of Social Interactions

Knowledge and Adherence
Improvement in Medication Adherence

Decline in Medication Adherence

Informal Caregiver Quality of Life
Improvement in Informal Caregiver Support

Decline in Informal Caregiver Support

Consumer-Centered Measures

Participant Satisfaction
Satisfaction with PACE Program Overall
Satisfaction with Involvement in Decision Making

End of Life Care
Participant's End of Life Wishes Followed
Informal Caregiver Satisfaction with Comfort Care
Informal Caregiver Satisfaction with Communication at End of Life
Participant's Acceptance of End of Life
Informal Caregiver Acceptance of Participant's End of Life
Informal Caregiver Satisfaction with End of Life Care

Informal Caregiver Satisfaction
Satisfaction with PACE Program Overall
Satisfaction with Involvement in Decision Making
Satisfaction with Participant Obtaining Needed Services/Assistance
Satisfaction with Day Health Center Services

[a] Four types of measures are included in the set of OBCQI outcome measures: Health Status Outcomes, Utilization Outcomes, Instrumental Outcomes, and Consumer-Centered Measures. Outcomes are further grouped by domain (with the exception of Utilization Outcome measures), as follows: Health Status Outcomes include outcomes related to physiologic and symptom management, functional status, emotional/mental health status, and cognitive functioning; Instrumental Outcomes include outcomes related to participant quality of life, informal caregiver quality of life, and knowledge and adherence; and Consumer-Centered Measures consist of participant satisfaction, informal caregiver satisfaction, and end of life care measures. All measure types and domains are not necessarily represented in each of the three tiers presented in this table.

[b] Decrease measures indicate improvement in a health status area. For example, Decrease in Nutritional Risk indicates that the participant is at less risk and therefore has improved status.

[c] Increase measures indicate decline in a health status area. For example, Increase in Pain Interfering with Daily Activities indicates that the participant experienced more pain and therefore has declined status.

As noted above, a primary objective of the SYFT analyses was to identify the outcome measures that would be the most effective for quality monitoring and OBCQI. The results of the analyses contributed, along with other considerations (e.g., clinical significance, data collection burden), to the determination of the set of outcome measures recommended as part of the COCOA-B data system. Each measure was classified into one of the three tiers displayed in Table 4.2. Tier 1 (Empirically Supported Measures) represents those measures that had strong

clinical and empirical support and can be recommended based on SYFT findings. Tier 2 (Measures for Further Investigation) represents those measures that had strong clinical support but were lacking in empirical support based on data available from the SYFT. These measures remain promising and are worthy of further empirical investigation with a larger sample size. We therefore recommend that all measures in Tier 1 and Tier 2 remain in the COCOA-B data system until further analyses can be conducted to evaluate the Tier 2 measures (it is anticipated that the utility of the majority of the Tier 2 measures will be empirically supported). Tier 3 (Measures to be Dropped) includes measures that cannot be justified for inclusion in the set of measures recommended for quality monitoring and OBCQI, due to insufficient empirical support and excessive data collection burden.

The primary purpose of this chapter is to demonstrate the statistical properties and utility of the Tier 1 outcome measures. As mentioned previously, the findings presented here are not intended to be a comprehensive account of all analytic work undertaken throughout measure development but to represent the most salient findings that support selection for the Tier 1 outcome measures. Therefore, the majority of the tables present analytic findings for the Tier 1, and to a lesser degree Tier 2, measures only. A brief discussion regarding the outcome measures classified into Tier 3 and the potential implications of dropping these measures is presented at the end of this section.

Prior to analyzing the statistical properties of the outcome measures, an evaluation of the two reassessment intervals (three- versus four-month reassessment intervals) implemented during the SYFT was examined. Two-group comparisons between participants assessed at three- versus four-month intervals were conducted to determine if any of the outcome measures were more sensitive to change at one time interval versus the other. No differences were found between three- and four-month intervals on any of the outcome measures. Therefore, all subsequent outcome analyses involving data from two time points included all participants with complete data at two time points regardless of the outcome interval.

2. Sufficient Prevalence

Sufficient prevalence was considered a necessary condition for inclusion as a Tier 1 measure. Sufficient prevalence was defined in terms of the number of participants eligible for an outcome after measure exclusions (e.g., only participants experiencing pain are eligible for the outcome of Decrease in Pain Interfering with Daily Activities, reducing the sample size for this measure) and the percent of participants that obtained the outcome (based on the outcome measure definition). It is imperative that the measures used for quality monitoring and OBCQI are representative of the PACE population and do not signify extremely rare nor extremely common events. Therefore, sufficient prevalence was considered a necessary condition for inclusion as a Tier 1 measure. Outcome measures with a sample size of less than 85 participants (<20% of the SYFT sample) who were eligible for the outcome and/or measures where less than 15% or more than 85% of the participants obtained the outcome were determined to have insufficient prevalence to be categorized as a Tier 1 measure.

Table 4.3 contains a list of all potential outcome measures (excluding utilization measures) and associated descriptive statistics (mean, standard deviation, and sample size). Descriptive statistics are not presented for a limited number of outcome measures due to data quality problems and/or extremely small sample sizes that resulted in an inability to compute the associated outcome measures. Repeated attempts were employed throughout the multiphase field test to measure these constructs as they were consistently identified as clinically meaningful for PACE participants. Despite these efforts, sufficient data were not obtained for computing the associated outcome measures. Change (improvement and decline) in the number of pressure ulcers illustrates this point. Although change in the number of pressure ulcers was consistently identified as a clinically meaningful outcome measure, less than 4% of

the PACE population presented with any type of wound or skin problem based on data collected during the SYFT.

TABLE 4.3: Descriptive Statistics for SYFT Participant and Informal Caregiver Outcome Measures.[a]

	Mean[b]	Standard Deviation	N
Health Status Outcomes			
Physiologic Status and Symptom Management			
Decrease In:			
Pain Interfering with Daily Activities	58.5%	49.6%	82
Falls Resulting in Injury	85.2%	36.2%	27
Nutritional Risk	19.5%	39.7%	328
Improvement In:			
Pressure Ulcers[c]	--	--	--
Skin Integrity[c]	--	--	--
Urinary Continence	32.8%	47.1%	177
Dyspnea	44.7%	49.9%	152
Edema	43.6%	49.8%	117
Increase In:			
Pain Interfering with Daily Activities	21.1%	40.9%	336
Falls Resulting in Injury	7.7%	26.7%	352
Nutritional Risk	8.0%	27.2%	349
Decline In:			
Pressure Ulcers[c]	--	--	--
Skin Integrity[c]	--	--	--
Urinary Continence	19.4%	39.6%	315
Dyspnea	21.5%	41.2%	330
Edema	17.7%	38.2%	232
Other			
Percent of Participants Immunized for Influenza[d]	85.2%	35.6%	1011
Number of Prescription Medications[c]	--	--	--
Functional Status			
Decrease In:			
Number of Activities Limited by Health	30.9%	46.3%	304
Improvement In:			
Ambulation	12.9%	33.6%	263
Management of Oral Medications	13.4%	34.1%	261
Transferring	11.2%	31.7%	249
Increase In:			
Number of Activities Limited by Health	34.2%	47.5%	304
Decline In:			
Ambulation	11.8%	32.3%	323
Management of Oral Medications	21.4%	41.1%	210
Transferring	17.7%	38.2%	316
Emotional/Mental Health Status			
Decrease In:			
Depression/Depressive Symptoms	56.3%	49.7%	238
Self-Report of Loneliness	41.5%	49.4%	205
Wandering	40.4%	49.6%	47
Number of Behavior Problems	59.8%	49.3%	87
Increase In:			
Depression/Depressive Symptoms	33.8%	47.4%	370
Self-Report of Loneliness	26.7%	44.3%	315
Wandering	6.2%	24.2%	369
Number of Behavior Problems	12.5%	33.2%	367
Cognitive Functioning			
Improvement In:			
Ability to Understand Others	34.0%	47.5%	188
Ability to Speak to Others	31.3%	46.5%	176
Decline In:			
Ability to Understand Others	20.6%	40.5%	360
Ability to Speak to Others	22.6%	41.9%	354

TABLE 4.3: Descriptive Statistics for SYFT Participant and Informal Caregiver Outcome Measures.[a] (Cont'd)

	Mean[b]	Standard Deviation	N
Instrumental Outcomes			
Participant Quality of Life			
Improvement In:			
Self-Rated Quality of Life	24.5%	43.1%	286
Satisfaction with Frequency of Social Interactions	39.4%	49.0%	142
Satisfaction with Quality of Social Interactions	62.1%	48.9%	66
Decline In:			
Self-Rated Quality of Life	21.5%	41.2%	302
Satisfaction with Frequency of Social Interactions	25.1%	43.4%	263
Satisfaction with Quality of Social Interactions	13.0%	33.7%	315
Knowledge and Adherence			
Improvement In:			
Medication Adherence	48.2%	50.4%	56
Therapy Adherence	53.1%	50.2%	98
Decline In:			
Medication Adherence	8.1%	27.3%	309
Therapy Adherence	13.4%	34.1%	239
Informal Caregiver Quality of Life			
Decrease In:			
Informal Caregiver Stress	41.0%	49.3%	173
Improvement In:			
Informal Caregiver Coping	38.4%	48.8%	164
Informal Caregiver Support	37.1%	48.5%	140
Increase In:			
Informal Caregiver Stress	25.4%	43.6%	193
Decline In:			
Informal Caregiver Coping	20.3%	40.3%	202
Informal Caregiver Support	18.6%	39.0%	194
Consumer-Centered Measures[d]			
Participant Satisfaction			
Satisfaction with PACE Program Overall	96.2%	19.1%	476
Satisfaction with Staff Communications	81.4%	38.9%	463
Satisfaction with Involvement in Decision Making	94.8%	22.1%	467
Satisfaction with Day Health Center Services	77.0%	42.1%	449
Satisfaction with Transportation	80.7%	39.5%	411
Satisfaction with Obtaining Needed Services/Assistance	83.8%	36.8%	390
Informal Caregiver Satisfaction			
Satisfaction with PACE Program Overall	95.5%	20.6%	317
Satisfaction with Provider-Family Communications	80.0%	40.0%	306
Satisfaction with Involvement in Decision Making	92.0%	27.0%	316
Satisfaction with Day Health Center Services	88.1%	32.3%	288
Satisfaction with Transportation	78.7%	41.0%	297
Satisfaction with Participant Obtaining Needed Services/Assistance	85.9%	34.8%	207
End of Life Care			
Participant's End of Life Wishes Followed	93.0%	25.8%	43
Informal Caregiver Satisfaction with Comfort Care	84.0%	37.0%	44
Informal Caregiver Satisfaction with Communication at End of Life	97.9%	14.9%	45
Participant's Acceptance of End of Life	95.3%	21.3%	43
Informal Caregiver Acceptance of Participant's End of Life	75.5%	43.5%	45
Informal Caregiver Satisfaction with End of Life Care	95.5%	21.0%	45
Percent of Participants with a Signed Advance Directive[d]	73.2%	44.3%	1033

[a] Outcomes computed based on participant or informal caregiver status at baseline and follow-up. Follow-up assessments were completed at three- or four-month intervals during the SYFT, depending on state data reporting requirements. Preliminary analyses comparing differences between outcome measures computed at three- and four-month intervals showed no differences. Therefore, these analyses include all participants with two data collection time points, regardless of the assessment interval. The exception to this rule is noted in footnote d.

TABLE 4.3: Descriptive Statistics for SYFT Participant and Informal Caregiver Outcome Measures.[a] (Cont'd)

[b] Percent of participants that obtained each outcome.

[c] Outcome measure could not be computed due to insufficient or poor quality data.

[d] Percent of Participants Immunized for Influenza, Percent of Participants with a Signed Advance Directive, and the set of consumer-centered measures are not outcome measures per se (i.e., they are not measures of change over time) but reflect status/satisfaction at a specific point in time. Descriptive statistics for these measures are based on all available data collected and are not limited by the two data collection time point rule that applies to all other outcome measures.

The varying sample sizes for the measures presented in Table 4.3 reflect the case exclusion criteria for each measure, as noted in Table 4.1 and discussed above. For example, the sample (N=82) for the first outcome measure (Decrease in Pain Interfering with Daily Activities) only included those participants who were experiencing pain (and therefore could improve in this area).

Several measures were not classified as Tier 1 measures because either the sample size for the measure was insufficient or the proportion (rate) of participants that obtained the outcome was too small (<15%) or too large (>85%). For example, measures of improvement and decline in ambulation and transferring did not demonstrate sufficient prevalence, based on findings from the SYFT, to warrant inclusion in Tier 1. The rate for Decline in Ambulation was 11.8%, a rate below the 15% criteria required to meet the sufficient prevalence definition. However, it is important to recognize that the reassessment interval during the SYFT was three or four months and that the recommended interval for national implementation is six months. It is likely that the assessment interval used for the SYFT was too brief to detect change in these functional measures and that measures computed over a longer period of time (e.g., six months, one year) would show sufficient prevalence for these critical outcomes of care. The contractor recommends that these and all other Tier 2 measures and their associated data items remain in the COCOA-B data system until further testing can be conducted.

CMS note: The sections below presume that CMS would mandate collection and submission of PACE data by all PACE sites. That approach would have entailed comparison of data/site-specific performance and issuance of comparative reports.

3. Measure Sensitivity to Site-Level Differences in Quality of Care

One objective of this project was to develop a set of outcome measures that could permit individual PACE sites to compare their outcomes with a reference group (e.g., all other PACE sites) and in turn identify (comparatively) exemplary or problematic outcomes for purposes of reinforcement or remediation. Measures that demonstrate little to no variability across sites, albeit potentially informative and clinically meaningful, would generally not be appropriate measures for outcome improvement purposes. Therefore, the Tier 1 measures include primarily measures that demonstrate sufficient cross-site variability, with the exception of a small number of measures with marginal cross-site variability but with sufficient prevalence and adequate potential for risk adjustment. Ideally, cross-site comparisons would be performed adjusting for differences in site participant characteristics (risk adjustment). Although preliminary risk-adjusted models for selected outcome measures are presented later in this chapter, comparisons of risk-adjusted outcome measures could not be conducted for the cross-site variability analyses due to the small samples for several of the SYFT sites. Two approaches to cross-site variability were employed in our analyses, as described below.

The first method examined differences between individual sites and a reference group of all other sites on unadjusted (i.e., not risk-adjusted) outcome measures. Results are presented in

Table 4.4. The table shows, for each outcome, the number (and percentage) of sites that demonstrated a statistically favorable, statistically unfavorable, or no statistical difference when comparing individual site rates to a reference group of all other sites. For example, for the outcome of Decrease in Nutritional Risk, four of the eight sites in the analysis differed significantly from their reference group. Two of the sites had higher (i.e., favorable) rates compared to the reference group and two of the sites had lower (i.e., unfavorable) rates when compared to the reference group. The remaining four sites did not differ significantly from the reference group. For most of the measures categorized as Tier 1 measures, at least one site demonstrated a statistically significant difference from the reference group for that measure.

As envisioned by the contractor, an outcome enhancement phase of OBCQI would begin when sites receive their annual outcome reports and select outcome measures to target for improvement. Sites are encouraged to select measures where their performance is significantly unfavorable (or in some cases significantly favorable) relative to the reference group. Examining the information presented in Table 4.4 in a slightly different manner, we can determine the likely utility of the measures to be used in this critical outcome selection phase, namely that each site has a set of significantly unfavorable and/or significantly favorable outcomes for selection.

TABLE 4.4: Capacity of Outcome Measures to Detect Mean Differences in Site-Level[a] Unadjusted Outcome Rates.[b]

Health Status Outcomes	No. of Sites with Valid Outcome Data	Significant and Favorable Rates	Significant and Unfavorable Rates	Non-Significant Rates
Physiologic Status and Symptom Management				
Decrease In:				
Pain Interfering with Daily Activities	8	0 (0%)	0 (0%)	8 (100%)
Falls Resulting in Injury	6	0 (0%)	0 (0%)	6 (100%)
Nutritional Risk	8	2 (25%)	2 (25%)	4 (50%)
Improvement In:				
Urinary Continence	8	3 (38%)	1 (13%)	4 (50%)
Dyspnea	7	0 (0%)	0 (0%)	7 (100%)
Edema	8	2 (25%)	2 (25%)	4 (50%)
Increase In:				
Pain Interfering with Activities	8	1 (13%)	1 (13%)	6 (75%)
Falls Resulting in Injury	8	0 (0%)	0 (0%)	8 (100%)
Nutritional Risk	8	1 (13%)	0 (0%)	7 (88%)
Decline In:				
Urinary Continence	8	1 (13%)	1 (13%)	6 (75%)
Dyspnea	8	0 (0%)	0 (0%)	8 (100%)
Edema	7	0 (0%)	1 (14%)	6 (86%)
Other				
Percent of Participants Immunized for Influenza	9	2 (22%)	1 (11%)	6 (67%)
Functional Status				
Decrease In:				
Number of Activities Limited by Health	8	1 (13%)	2 (25%)	5 (63%)
Improvement In:				
Ambulation	8	0 (0%)	1 (13%)	7 (88%)
Management of Oral Medications	8	1 (13%)	0 (0%)	7 (88%)
Transferring	8	2 (25%)	0 (0%)	6 (75%)
Increase In:				
Number of Activities Limited by Health	8	1 (13%)	0 (0%)	7 (88%)
Decline In:				
Ambulation	8	0 (0%)	2 (25%)	6 (75%)
Management of Oral Medications	8	0 (0%)	0 (0%)	8 (100%)
Transferring	8	0 (0%)	0 (0%)	8 (100%)
Emotional/Mental Health Status				
Decrease In:				

TABLE 4.4: Capacity of Outcome Measures to Detect Mean Differences in Site-Level[a] Unadjusted Outcome Rates.[b] (Cont'd)

Health Status Outcomes	No. of Sites with Valid Outcome Data	Significant and Favorable Rates	Significant and Unfavorable Rates	Non-Significant Rates
Depression/Depressive Symptoms	8	1 (13%)	1 (13%)	6 (75%)
Self-Report of Loneliness	8	0 (0%)	0 (0%)	8 (100%)
Wandering	7	1 (14%)	0 (0%)	6 (86%)
Number of Behavior Problems	8	0 (0%)	1 (13%)	7 (88%)
Increase In:				
Depression/Depressive Symptoms	8	2 (25%)	1 (13%)	5 (63%)
Self-Report of Loneliness	8	2 (25%)	1 (13%)	5 (63%)
Wandering	8	1 (13%)	1 (13%)	6 (75%)
Number of Behavior Problems	8	1 (13%)	0 (0%)	7 (88%)
Cognitive Functioning				
Improvement In:				
Ability to Understand Others	8	1 (13%)	0 (0%)	7 (88%)
Ability to Speak to Others	8	1 (13%)	1 (13%)	6 (75%)
Decline In:				
Ability to Understand Others	8	2 (25%)	2 (25%)	4 (50%)
Ability to Speak to Others	8	2 (25%)	2 (25%)	4 (50%)
Instrumental Outcomes				
Participant Quality of Life				
Improvement In:				
Self-Rated Quality of Life	8	1 (13%)	0 (0%)	7 (88%)
Satisfaction with Frequency of Social Interactions	8	1 (13%)	0 (0%)	7 (88%)
Satisfaction with Quality of Social Interactions	8	1 (13%)	1 (13%)	6 (75%)
Decline In:				
Self-Rated Quality of Life	8	1 (13%)	1 (13%)	6 (75%)
Satisfaction with Frequency of Social Interactions	8	1 (13%)	2 (25%)	5 (63%)
Satisfaction with Quality of Social Interactions	8	0 (0%)	1 (13%)	7 (88%)
Knowledge and Compliance				
Improvement In:				
Medication Adherence	7	0 (0%)	0 (0%)	7 (100%)
Therapy Adherence	8	0 (0%)	1 (13%)	7 (88%)
Decline In:				
Medication Adherence	8	0 (0%)	0 (0%)	8 (100%)
Therapy Adherence	8	0 (0%)	1 (13%)	7 (88%)
Informal Caregiver Quality of Life				
Decrease In:				
Informal Caregiver Stress	8	0 (0%)	1 (13%)	7 (88%)
Improvement In:				
Informal Caregiver Coping	8	0 (0%)	0 (0%)	8 (100%)
Informal Caregiver Support	8	1 (13%)	1 (13%)	6 (75%)
Increase In:				
Caregiver Stress	8	0 (0%)	0 (0%)	8 (100%)
Decline In:				
Informal Caregiver Coping	8	0 (0%)	0 (0%)	8 (100%)
Informal Caregiver Support	8	1 (13%)	0 (0%)	7 (88%)
Consumer-Centered Measures				
Participant Satisfaction				
Satisfaction with PACE Program Overall	9	0 (0%)	1 (11%)	8 (89%)
Satisfaction with Staff Communications	9	1 (11%)	2 (22%)	6 (67%)
Satisfaction with Involvement in Decision Making	9	0 (0%)	1 (11%)	8 (89%)
Satisfaction with Day Health Center Services	9	1 (11%)	2 (22%)	6 (67%)
Satisfaction with Transportation	9	3 (33%)	2 (22%)	4 (44%)
Satisfaction with Obtaining Needed Services/Assistance	9	1 (11%)	1 (11%)	7 (78%)
Informal Caregiver Satisfaction				
Satisfaction with PACE Program Overall	8	0 (0%)	1 (13%)	7 (100%)

TABLE 4.4: Capacity of Outcome Measures to Detect Mean Differences in Site-Level[a] Unadjusted Outcome Rates.[b] (Cont'd)

Health Status Outcomes	No. of Sites with Valid Outcome Data	Significant and Favorable Rates	Significant and Unfavorable Rates	Non-Significant Rates
Satisfaction with Provider-Family Communications	8	1 (13%)	1 (13%)	6 (75%)
Satisfaction with Involvement in Decision Making	8	2 (25%)	1 (13%)	5 (63%)
Satisfaction with Day Health Center Services	8	1 (13%)	1 (13%)	6 (75%)
Satisfaction with Transportation	8	1 (13%)	2 (25%)	5 (63%)
Satisfaction with Obtaining Needed Services/Assistance	8	1 (13%)	0 (0%)	7 (88%)
End of Life Care				
Percent of Participants with a Signed Advance Directive	9	4 (44%)	3 (33%)	2 (22%)

[a] Sites with fewer than 10 cases were excluded from the analysis.

[b] For each site, a Fisher's exact test was conducted comparing the site rate to the rate for all other sites. A favorable result occurred when the site average was statistically greater than the other sites for improvement (decrease) measures or statistically less than the average for the other sites for decline (increase) measures. Statistical significance was defined as a p-value of 0.10 or less.

Table 4.4 presents the number of Tier 1 outcome measures identified as significant and favorable, significant and unfavorable, and non-significant within each site. Note that all but two sites included in this analysis have both favorable and unfavorable outcome rates (when compared to the reference). The findings depicted in Tables 4.4 and 4.5 demonstrate the cross-site variability of the Tier 1 outcomes, illustrating the utility of these outcomes for sites when selecting measures for outcome enhancement activities.

TABLE 4.5: FAVORABLE AND UNFAVORABLE UNADJUSTED OUTCOME MEASURES (TIER 1) BY SITE.[A]

Site	Number of[b] Valid Outcomes	Significant and Favorable Rates[c,d]	Significant and Unfavorable Rates	Non-Significant Rates
A	29	8 (27.6%)	3 (10.3%)	18 (62.1%)
B	29	1 (3.4%)	5 (17.2%)	23 (79.3%)
C	6	1 (16.7%)	0 (0%)	5 (83.3%)
D	29	3 (10.3%)	4 (13.8%)	22 (75.9%)
E	8	2 (25%)	4 (50%)	2 (25%)
F	29	2 (6.9%)	5 (17.2%)	22 (75.9%)
H	29	3 (10.3%)	4 (13.8%)	22 (75.9%)
J	24	3 (12.5%)	3 (12.5%)	18 (75.0%)
L	27	4 (14.8%)	5 (18.5%)	18 (66.7%)
M	26	5 (19.2%)	0 (0%)	21 (80.8%)

[a] Three sites were excluded from this analysis because of extremely small sample sizes. Therefore, the analysis was conducted on data from 10 sites.

[b] Outcomes with fewer than 10 cases within a site were excluded from the analysis.

[c] For each site, a Fisher's exact test was conducted comparing the site rate to the rate for all other sites. A favorable result occurred when the site rate was statistically greater than the reference for improvement (decrease) measures or statistically less than the reference for decline (increase) measures.

[d] Statistical significance was defined as a p-value of 0.10 or less.

A second approach to assessing the capacity of a measure to detect differences among sites involves examining the amount of variation in the outcome measure explained by the variability among sites. In view of the fact that the overall variance or standard deviation has a within-agency and a between-agency component, this analysis provides an estimate of the between-agency variance (a necessary condition for examining differences across sites). The first column in Table 4.6 presents the proportion of total variability in the measure accounted for by variation among sites, based on a one-way analysis of variance using a random effects model. For example, 18.6% of the variance (a substantial proportion) in the outcome measure Improvement in Urinary Continence is explained by variability between sites. The second column presents the F value from the analysis of variance and the third column presents the p-value or significance level from the analysis of variance. Statistically significant F values indicate that the variation in agency-level effects can be assumed to be nonzero (at p<.10). Based on the findings presented in Table 4.6, for all but seven of the 29 Tier 1 outcome measures, site-level variance can be assumed to be nonzero.

Although the analysis of cross-site variability provides substantial evidence for inclusion of many measures into Tier 1, it is a limitation that the measures could not be adjusted for site differences in participant characteristics prior to conducting these analyses. Therefore, outcome measures with marginal cross-site variability (that met the prevalence criterion) were still considered for inclusion in Tier 1, if they also displayed adequate potential for risk adjustment (as described in Section B.6).

TABLE 4.6: STATISTICAL PROFILE OF SITE VARIATION BY OUTCOME MEASURE.

	$\frac{s_\tau^2}{s_\tau^2 + MSE}$ [b]	F[c]	Significance Level
Health Status Outcomes[a]			
Physiologic Status and Symptom Management			
Decrease In:			
Pain Interfering with Daily Activities	0.000	0.842	0.557
Falls Resulting in Injury	0.000	0.155	0.976
Nutritional Risk	0.115	6.064	0.000
Improvement In:			
Urinary Continence	0.186	5.700	0.000
Dyspnea	0.000	0.939	0.469
Edema	0.173	3.802	0.001
Increase In:			
Pain Interfering with Daily Activities	0.024	1.979	0.058
Falls Resulting in Injury	0.000	0.516	0.823
Nutritional Risk	0.000	0.818	0.573
Decline In:			
Urinary Continence	0.013	1.472	0.177
Dyspnea	0.000	0.941	0.475
Edema	0.027	1.930	0.077
Other			
Percent of Participants Immunized for Influenza	0.016	2.829	0.004
Functional Status			
Decrease In:			
Number of Activities Limited by Health	0.107	5.293	0.000
Improvement In:			
Ambulation	0.009	1.310	0.246
Management of Oral Medications	0.009	1.335	0.234
Transferring	0.052	2.508	0.017
Increase In:			
Number of Activities Limited by Health	0.000	0.825	0.567
Decline In:			

TABLE 4.6: Statistical Profile of Site Variation by Outcome Measure. (Cont'd)

	$\frac{s_\tau^2}{s_\tau^2 + MSE}$ [b]	F[c]	Significance Level
Ambulation	0.019	1.751	0.097
Management of Oral Medications	0.047	2.244	0.032
Transferring	0.000	0.841	0.554
Emotional/Mental Health Status			
Decrease In:			
Depression/Depressive Symptoms	0.028	1.819	0.085
Self-Report of Loneliness	0.000	0.966	0.458
Wandering	0.158	2.133	0.072
Number of Behavior Problems	0.135	2.499	0.023
Increase In:			
Depression/Depressive Symptoms	0.027	2.194	0.034
Self-Report of Loneliness	0.041	2.632	0.012
Wandering	0.036	2.683	0.010
Number of Behavior Problems	0.055	2.797	0.008
Cognitive Functioning			
Improvement In:			
Ability to Understand Others	0.018	1.444	0.190
Ability to Speak to Others	0.093	3.080	0.004
Decline In:			
Ability to Understand Others	0.074	4.445	0.000
Ability to Speak to Others	0.064	3.955	0.000
Instrumental Outcomes			
Participant Quality of Life			
Improvement In:			
Self-Rated Quality of Life	0.000	1.008	0.426
Satisfaction with Frequency of Social Interactions	0.049	1.909	0.073
Satisfaction with Quality of Social Interactions	0.102	1.868	0.092
Decline In:			
Self-Rated Quality of Life	0.071	3.763	0.001
Satisfaction with Frequency of Social Interactions	0.063	3.115	0.004
Satisfaction with Quality of Social Interactions	0.009	1.282	0.259
Knowledge and Compliance			
Improvement In:			
Medication Adherence	0.000	0.390	0.882
Therapy Adherence	0.028	1.295	0.262
Decline In:			
Medication Adherence	0.000	0.527	0.814
Therapy Adherence	0.009	1.144	0.336
Informal Caregiver Quality Of Life			
Decrease In:			
Informal Caregiver Stress	0.020	1.404	0.207
Improvement In:			
Informal Caregiver Coping	0.017	1.325	0.242
Informal Caregiver Support	0.096	2.618	0.015
Increase In:			
Informal Caregiver Stress	0.000	0.827	0.566
Decline In:			
Informal Caregiver Coping	0.000	0.439	0.876
Informal Caregiver Support	0.026	1.588	0.142
Consumer-Centered Measures			
Participant Satisfaction			
Satisfaction with PACE Program Overall	0.000	1.665	0.105

TABLE 4.6: Statistical Profile of Site Variation by Outcome Measure. (Cont'd)

	$\frac{s_\tau^2}{s_\tau^2 + MSE}$ [b]	F[c]	Significance Level
Satisfaction with Staff Communications	0.078	5.246	0.000
Satisfaction with Involvement in Decision Making	0.020	1.706	0.095
Satisfaction with Day Health Center Services	0.084	5.425	0.000
Satisfaction with Transportation	0.076	4.523	0.000
Satisfaction with Obtaining Needed Services/Assistance	0.022	1.989	0.047
Informal Caregiver Satisfaction			
Satisfaction with PACE Program Overall	0.023	2.331	0.032
Satisfaction with Provider-Family Communications	0.037	2.431	0.026
Satisfaction with Involvement in Decision Making	0.079	4.143	0.001
Satisfaction with Day Health Center Services	0.046	2.756	0.013
Satisfaction with Transportation	0.097	4.706	0.000
Satisfaction with Obtaining Needed Services/Assistance	0.016	1.421	0.208
End of Life Care			
Percent of Participants with a Signed Advance Directive	0.267	40.161	0.000

[a] Sites with fewer than 10 cases were excluded from the analysis.

[b] The formula represents the site variability divided by the total variability, which is the sum of site and participant variability. This quantity can be thought of as the proportion of total variability in the responses accounted for by variation among sites.

[c] The F statistic and associated significance level were computed using a one-way analysis of variance model with random effects.

4. Illustrative Findings from Two-Group Comparisons

Two-group comparisons were conducted as part of the analysis to examine the content validity of the Tier 1 outcome measures. Two-group comparisons assess the ability of the measures to detect differences between participant groups (e.g., cognitively impaired versus noncognitively impaired) or types of sites (e.g., original demonstration sites versus newer sites, large sites versus small sites) hypothesized to vary in terms of outcomes. Two-group comparisons by site could not be conducted due to the small sample size in the newer site and small site groups. Tables 4.7, 4.8, and 4.9 contain the results from two-group comparisons of Tier 1 outcome measures based on data collected at baseline and follow-up time points for the following groups: a) participants with informal caregivers versus without informal caregivers; b) participants with cognitive impairment versus without cognitive impairment; and c) participants enrolled in PACE less than a year versus those enrolled for more than a year. Differences between groups were considered to be statistically significant at $p < 0.10$.

TABLE 4.7: Unadjusted Two-Group Comparisons of Tier 1 Outcome Measures: PACE Participants With an Informal Caregiver versus Without an Informal Caregiver.

Outcome Measure	Informal Caregiver Present	No Informal Caregiver	Significance Level[a]
Physiologic Status and Symptom Management			
Decrease in Nutritional Risk	0.230	0.095	0.007*
Improvement in Urinary Continence	0.296	0.429	0.133
Improvement in Dyspnea	0.455	0.431	0.863
Improvement in Edema	0.488	0.303	0.097*
Increase in Pain Interfering with Daily Activities	0.219	0.187	0.632
Decline in Edema	0.197	0.102	0.143
Percent of Participants Immunized for Influenza	0.858	0.831	0.316

Functional Status			
Decrease in Number of Activities Limited by Health	0.305	0.328	0.765
Decline in Management of Oral Medications	0.195	0.283	0.224
Emotional/Mental Health Status			
Decrease in Depression/Depressive Symptoms	0.581	0.508	0.365
Decrease in Self-Report of Loneliness	0.405	0.442	0.745
Decrease in Number of Behavioral Problems	0.620	0.500	0.409
Increase in Depression/Depressive Symptoms	0.337	0.333	1.000
Cognitive Functioning			
Improvement in Ability to Understand Others	0.348	0.300	0.679
Improvement in Ability to Speak to Others	0.306	0.345	0.667
Decline in Ability to Speak to Others	0.243	0.165	0.178
Participant Quality of Life			
Improvement in Satisfaction with Frequency of Social Interactions	0.366	0.475	0.256
Decline in Satisfaction with Frequency of Social Interactions	0.271	0.183	0.181
Knowledge and Adherence			
Improvement in Therapy Adherence	0.548	0.480	0.645
Informal Caregiver Quality of Life			
Decrease in Informal Caregiver Stress	0.407	1.000	0.410
Improvement in Informal Caregiver Coping	0.380	1.000	0.384
Increase in Informal Caregiver Stress	0.255	0.000	1.000
End of Life Care			
Percent of Participants with a Signed Advance Directive	0.724	0.756	0.336

[a] Two-group comparisons were conducted using Fisher's exact test. Statistical significance (*) was defined as a p-value of 0.10 or less.

TABLE 4.8: Unadjusted Two-Group Comparisons of Tier 1 Outcome Measures: PACE Participants with Cognitive Impairment versus Without Cognitive Impairment.[a]

Outcome Measure	Cognitive Impairment	No Cognitive Impairment	Significance Level[b]
Physiologic Status and Symptom Management			
Decrease in Nutritional Risk	0.220	0.187	0.535
Improvement in Urinary Continence	0.196	0.383	0.015*
Improvement in Dyspnea	0.469	0.442	0.843
Improvement in Edema	0.571	0.398	0.128
Increase in Pain Interfering with Daily Activities	0.121	0.242	0.016*
Decline in Edema	0.157	0.186	0.709
Percent of Participants Immunized for Influenza	0.876	0.843	0.190
Functional Status			
Decrease in Number of Activities Limited by Health	0.275	0.322	0.497
Decline in Management of Oral Medications	0.269	0.209	0.455
Emotional/Mental Health Status			
Decrease in Depression/Depressive Symptoms	0.627	0.531	0.205
Decrease in Self-Report of Loneliness	0.452	0.398	0.598
Decrease in Number of Behavioral Problems	0.571	0.632	0.661
Increase in Depression/Depressive Symptoms	0.265	0.365	0.084*
Cognitive Functioning			
Improvement in Ability to Understand Others	0.315	0.362	0.538
Improvement in Ability to Speak to Others	0.292	0.333	0.626
Decline in Ability to Speak to Others	0.187	0.237	0.382
Participant Quality of Life			
Improvement in Satisfaction with Frequency of Social Interactions	0.333	0.404	0.661
Decline in Satisfaction with Frequency of Social	0.237	0.256	0.865

Interactions			
Knowledge and Adherence			
Improvement in Therapy Adherence	0.458	0.562	0.480
Informal Caregiver Quality of Life			
Decrease in Informal Caregiver Stress	0.455	0.383	0.427
Improvement in Informal Caregiver Coping	0.429	0.356	0.410
Increase in Informal Caregiver Stress	0.231	0.266	0.727
End of Life Care			
Percent of Participants with a Signed Advance Directive	0.668	0.754	0.008*

[a] Participants were classified into the cognitive impairment group if COCOA-B item C0710: Cognitive Functioning was marked as 2, 3, or 4. Participants assessed with a 0 or 1 response were assigned to the "without cognitive impairment" group.

[b] Two-group comparisons were conducted using Fisher's exact test. Statistical significance (*) was defined as a p-value of 0.10 or less.

TABLE 4.9: Unadjusted Two-Group Comparisons of Tier 1 Outcome Measures: PACE Participants Enrolled Less Than One Year Versus More Than One Year.

Outcome Measure	Enrolled < 1 Year	Enrolled > 1 Year	Significance Level[a]
Physiologic Status and Symptom Management			
Decrease in Nutritional Risk	0.215	0.184	0.564
Improvement in Urinary Continence	0.394	0.288	0.185
Improvement in Dyspnea	0.520	0.412	0.228
Improvement in Edema	0.451	0.424	0.852
Increase in Pain Interfering with Daily Activities	0.198	0.219	0.681
Decline in Edema	0.262	0.128	0.013*
Percent of Participants Immunized for Influenza	0.771	0.888	0.000*
Functional Status			
Decrease in Number of Activities Limited by Health	0.349	0.288	0.298
Decline in Management of Oral Medications	0.256	0.189	0.297
Emotional/Mental Health Status			
Decrease in Depression/Depressive Symptoms	0.564	0.563	1.000
Decrease in Self-Report of Loneliness	0.416	0.414	1.000
Decrease in Number of Behavioral Problems	0.783	0.531	0.047*
Increase in Depression/Depressive Symptoms	0.346	0.333	0.820
Cognitive Functioning			
Improvement in Ability to Understand Others	0.379	0.323	0.506
Improvement in Ability to Speak to Others	0.400	0.273	0.114
Decline in ability to Speak to Others	0.256	0.208	0.358
Participant Quality of Life			
Improvement in Satisfaction with Frequency of Social Interactions	0.462	0.356	0.219
Decline in Satisfaction with Frequency of Social Interactions	0.270	0.239	0.661
Knowledge and Adherence			
Improvement in Therapy Adherence	0.657	0.460	0.091*
Informal Caregiver Quality of Life			
Decrease in Informal Caregiver Stress	0.514	0.340	0.028*
Improvement in Informal Caregiver Coping	0.446	0.343	0.194
Increase in Informal Caregiver Stress	0.243	0.261	0.866
End of Life Care			
Percent of Participants with a Signed Advance Directive	0.638	0.787	0.000*

[a] Two-group comparisons were conducted using Fisher's exact test. Statistical significance (*) was defined as a p-value of 0.10 or less.

The results from the two-group comparisons demonstrate only a few statistically significant differences. However, the differences that do exist are consistent with what would be expected clinically. In summary, outcomes are better for participants with informal caregivers; participants without cognitive impairment demonstrated better physiologic outcomes but worse emotional/mental health outcomes; and better outcomes are reported for participants in their first year of enrollment in the PACE program.[7] A few specific findings are worth noting. The finding that participants without cognitive impairment are more likely to increase in depression/depressive symptoms may imply that these participants are better able to communicate their feelings as opposed to a true difference between the groups in increasing symptoms of depression. Cognitive impairment likely would be an important risk factor for cross-site comparisons of outcome measures related to emotional/mental health.

Findings related to PACE program enrollment (less than one year versus more than one year) suggest that newly enrolled participants are more likely to decrease in the number of behavior problems and improve in adherence to therapy, and informal caregivers of these participants are more likely to decrease in their stress. These findings are likely attributable to the comprehensive and coordinated care model provided to PACE participants and informal caregivers that notably impact certain outcomes during the initial year in PACE.

5. Interrelationships Among Recommended Outcome Measures

To ensure that the outcome measures selected for PACE OBCQI are diverse, yet independent (or demonstrate very little redundancy), associations between the Tier 1 outcome measures were examined using Pearson correlations and are presented in Table 4.10. Redundancy refers to the extent to which two variables measure the same or similar (underlying) construct. Redundancy between measures would exist if the correlation coefficient approached 1.0. A correlation coefficient as high as 0.50 indicates that only 25% of the variation in one measure is explained in terms of variation in the other measure. For the most part, the correlations presented in Table 4.10 demonstrate very little redundancy; however, the associations between three of the measure pairs did result in correlations greater than .50. Most notably, the association between Improvement in Ability to Speak to Others and Improvement in Ability to Understand Others is correlated at r=.64. In this case, 41% of the variance in the Improvement in Ability to Speak to Others measure is explained in terms of the variation in the Improvement in Ability to Understand Others measure (and vice versa).

As with every phase of outcome measure development work, measures were excluded from Tier 1 when they demonstrated considerable redundancy. Throughout the process of outcome measure development the inclusion (and exclusion) of measures into tiers was consistently balanced against the various outcome measure selection criteria. For example, a measure demonstrating modest redundancy may have been retained due to the likelihood of the measure to capture cross-site variability. As mentioned previously, the process of selecting outcome measures for OBCQI was an iterative process.

6. Preliminary Risk Adjustment

[7] For the comparison between participants enrolled less than a year versus more than one year, two measures showed more favorable results for the participants enrolled more than one year: Percent of Participants Immunized for Influenza and Percent of Participants with a Signed Advance Directive. These two measures are not traditional outcome measures (i.e., measuring change over time) but are process measures reporting incidence rates based on a single data collection time point. It is not surprising that participants enrolled in the PACE program for a longer period of time are more likely to be immunized and have had the opportunity to discuss and complete documentation of advance directives.

The project's early developmental work included initial efforts toward identifying potential risk factors for the outcomes under consideration. This preliminary specification, guided largely by recommendations (based on clinical meaningfulness) from PACE clinical panels and adaptation from statistical modelling used for risk adjusting home health outcomes, permitted the inclusion in the COCOA-B data set of a core set of data items for measuring potential risk factors (many of which also are used to compute outcomes).

After selecting the Tier 1 outcomes, the first step in the development of preliminary risk models was to identify potential risk factors that were both clinically meaningful and statistically significant in relation to the outcome measures. Pearson correlation coefficients were used

TABLE 4.10: BIVARIATE CORRELATIONS AMONG TIER 1 MEASURES.

Correlations (Below Diagonal) and Sample Sizes (Above Diagonal)[a] for Outcome Measures—by Number (in Left Column)[b]

Health Status and Instrumental Outcomes	1	2	3	4	5	6	7	8	9	10	11	12	13	1
1. Decrease in Nutritional Risk	--	(157)	(134)	(106)	(266)	(200)	(244)	(189)	(191)	(157)	(72)	(292)	(156)	(14
2. Improvement in Urinary Continence	0.084	--	(73)	(62)	(155)	(114)	(156)	(100)	(118)	(86)	(46)	(167)	(97)	(8
3. Improvement in Dyspnea	**0.233**	**0.244**	--	(47)	(118)	(86)	(109)	(95)	(91)	(79)	(27)	(130)	(65)	(5
4. Improvement in Edema	**0.240**	0.136	-0.040	--	(107)	(26)	(97)	(79)	(70)	(66)	(19)	(110)	(50)	(4
5. Increase in Pain Interfering w/Daily Activities	0.002	-0.014	-0.115	-0.011	--	(205)	(264)	(178)	(189)	(164)	(72)	(305)	(157)	(14
6. Decline in Edema	0.037	0.034	0.126	**-0.693**	**0.132**	--	(175)	(135)	(140)	(109)	(59)	(212)	(119)	(10
7. Improvement in Activities Limited by Health	0.041	-0.022	0.032	0.029	-0.094	0.029	--	(161)	(178)	(152)	(67)	(279)	(147)	(13
8. Decline in Management of Oral Medications	0.088	-0.085	0.055	0.058	-0.089	**0.144**	**0.159**	--	(128)	(119)	(26)	(197)	(76)	(6
9. Decrease in Depression/Depressive Symptoms	-0.053	**0.213**	0.035	0.141	**0.147**	-0.077	0.045	0.026	--	(155)	(74)	(238)	(136)	(12
10. Decrease in Self-Report of Loneliness	0.091	0.115	0.083	-0.028	0.021	-0.125	-0.108	0.026	**0.250**	--	(42)	(205)	(99)	(8
11. Decrease in Number of Behavior Problems	0.143	0.183	**0.438**	-0.267	0.069	**0.290**	0.069	0.020	0.183	-0.022	--	(87)	(72)	(6
12. Increase in Depression/Depressive Symptoms	0.046	-0.024	0.115	0.020	0.006	**0.169**	0.053	0.033	**-0.652**	**-0.246**	-0.079	--	(188)	(17
13. Improvement in Ability to Understand Others	-0.008	-0.094	0.144	0.199	**0.240**	**0.206**	0.041	-0.010	0.066	-0.026	0.118	-0.002	--	(15
14. Improvement in Ability to Speak to Others	-0.004	0.149	0.082	0.081	**0.180**	**0.299**	0.033	-0.086	**0.193**	**0.194**	0.139	-0.042	**0.641**	-
15. Decline in Ability to Speak to Others	**-0.101**	-0.007	-0.073	0.125	-0.025	-0.006	0.076	0.111	0.024	0.026	-0.145	0.017	**-0.209**	**-0.**
16. Imp. in Satis. w/ Freq. of Social Interactions	0.008	**0.227**	0.014	-0.215	-0.010	0.001	0.139	**0.188**	**0.170**	**0.306**	-0.287	-0.101	0.054	0.1
17. Decline in Satis. w/ Freq. of Social Interactions	0.038	-0.005	0.024	0.026	-0.091	0.019	-0.004	0.007	**-0.184**	-0.105	-0.023	**0.227**	0.011	-0.0
18. Improvement in Therapy Adherence	**0.327**	0.161	0.161	**0.354**	-0.110	-0.060	0.002	-0.112	-0.077	0.000	0.309	0.092	-0.095	-0.1

Informal Caregiver Quality of Life	19	20	21
19. Decrease in Informal Caregiver Stress	--	(155)	(162)
20. Improvement in Informal Caregiver Coping	**0.387**	--	(153)
21. Increase in Informal Caregiver Stress	**-0.393**	**-0.209**	--

Participant Satisfaction	22	23	2
22. Satisfaction w/ Staff Communications	--	(436)	(40
23. Satisfaction w/ Day Health Center Services	**0.121**	--	(38
24. Satisfaction w/ Transportation	**0.291**	**0.137**	-
25. Satis. w/ Obtaining Needed Svcs/Assistance	**0.405**	**0.123**	**0.2**

Informal Caregiver Satisfaction	26	27
26. Satisfaction w/ Provider-Family Communications	--	(288)
27. Satisfaction w/ Transportation	**0.211**	--

Other	28	29
28. % of Participant Immunized for Influenza	--	(1000)
29. % of Participant w/Signed Advance Directive	**0.096**	

[a] Measure-specific sample sizes vary due to outcome definitions and data item exclusions.

[b] Product-moment correlations between outcomes i and j are located in cell (i,j) and are based on the number of participants given in cell (j,i). Statistical significance is not given; however, correlations with statistically significant p-values (i.e., less than 0.10) are in boldface.

as the primary tool for identifying significant associations between outcome measures and potential risk factors (using the set of risk factors previously selected based on clinical review). After close examination of the correlation coefficients along with consideration of the clinical nature of the associations, a table was compiled indicating which, if any, risk factors should be

included in the preliminary risk adjustment analyses (see Appendix 4B for risk factor table and Appendix 5C for measure specifications for all risk factors).

The statistical method used to risk adjust the dichotomous outcome measures was logistic regression, a method widely used in the research literature on risk adjustment for health status outcomes. The logistic regression model is used to predict the probability that the outcome will be achieved based on the values of the risk factors included in the model. The model is estimated using the risk factors identified based on clinical and empirical grounds (as described above) with each risk factor statistically tested in the context of empirically estimating the model. Risk factors were retained in the model if they were significant at $p<.10$. Once an initial model had been estimated, further review was undertaken to ensure that the model was clinically logical and that non-significant coefficients were not present in the model.

Three preliminary logistic regression models for the outcome measures of Improvement in Dyspnea, Decrease in Number of Activities Limited by Health, and Decline in Management of Oral Medications are presented in Table 4.11. Statistical properties of each model including Adjusted R-Square, c Statistic, and Hosmer-Lemeshow goodness of fit statistic are presented in addition to the risk factors with their coefficients and associated corresponding significance levels.

The value reported for adjusted R-square is Nagelkerke's adjusted coefficient of determination. Unlike in ordinary least squares regression, where the R-square value is an estimate of the percent of variance explained by the model, the logistic regression R-square measures the strength of association between the variables in the model and is, therefore, not to be interpreted as a goodness-of-fit statistic. The c Statistic is a measure of how well the logistic equation discriminates when estimating probability values for correct and incorrect responses to the dependent variable (i.e., in this case, the participant achieved the outcome and the participant did not achieve the outcome). The value of the statistic varies between 0.5 (the model's predictions are no better than predictions that would be made by chance) and 1.0 (the model always assigns higher probability values to correct responses). A value of .70 or greater was considered acceptable. The Hosmer-Lemeshow goodness-of-fit statistic is particularly robust for models with continuous covariates. It is based on grouping cases into deciles of risk, from which a chi-square value is computed by comparing the observed probability with the expected probability within each decile. If the goodness-of-fit test statistic (i.e., the significance value) is greater than .05, we fail to reject the null hypothesis that there is no difference, implying that the model's estimates fit the data at an acceptable level.

For each of the three models presented, we have incorporated the data item that corresponds to the attribute of the outcome measure (e.g., Dyspnea is a risk factor for Improvement in Dyspnea). In the case of improvement measures, we have found that the more dependent participants are in terms of the attribute under consideration, the more likely they are to improve. Conversely, the more independent participants are with regard to the outcome attribute, the more likely they are to decline; particularly considering the frailty of the population. For example, the positive coefficient for the dyspnea risk factor in the Improvement in Dyspnea model indicates a greater likelihood of improvement in dyspnea if the participant is at the most severe level for dyspnea. All three models presented in Table 4.11 demonstrate acceptable statistical properties with risk factors that are associated in a clinically logical manner.

TABLE 4.11: PRELIMINARY LOGISTIC REGRESSION MODELS FOR THREE TIER 1 OUTCOME MEASURES.

Model for Improvement in Dyspnea

Adjusted R-Square[a]	0.2256	c Statistic:[b]	0.728
Hosmer-Lemeshow Chi-Square:[c]	4.376	Significance:	0.8223

Independent Variables	Coefficients	Significance Level
Dyspnea	0.4739	0.0493
Race/Ethnicity: Hispanic	1.4844	0.0441
Education Level	-0.3832	0.0350
Feelings of Loneliness	0.2637	0.1033
Diagnosis: Infectious/Parasitic Diseases	2.2190	0.0474
Constant	-0.7476	0.2535

Model for Decrease in Number of Activities Limited by Health

Adjusted R-Square[a]	0.2683	c Statistic:[b]	0.772
Hosmer-Lemeshow Chi-Square:[c]	10.0883	Significance:	0.2644

Independent Variables	Coefficients	Significance Level
Number of Activities Limited By Health	0.1859	<0.0001
Race/Ethnicity: Black	-1.5409	<0.0001
Participant Lives Alone	0.5982	0.0528
Good Rehabilitative Prognosis	1.0871	0.0072
Presence of Intractable Pain	-2.0847	0.0546
Diagnosis: Respiratory System Diseases	0.5999	0.0626
Constant	-3.1162	<0.0001

Model for Decline in Management of Oral Medications

Adjusted R-Square[a]	0.2764	c Statistic:[b]	0.781
Hosmer-Lemeshow Chi-Square:[c]	2.9395	Significance:	0.8905

Independent Variables	Coefficients	Significance Level
Management of Oral Medications	-2.3259	<0.0001
Endurance	0.6715	0.0035
Diagnosis: Musculoskeletal System Diseases	-0.8278	0.0326
Constant	0.0652	0.8751

[a] The value reported is Nagelkerke's adjusted coefficient of determination. Unlike in ordinary least squares regression, where the R-square value is an estimate of the percent of variance explained by the model, the logistic regression R-square measures the strength of association between the variables in the model and is, therefore, not to be interpreted as a goodness-of-fit statistic.

[b] The c Statistic is a measure of how well the logistic equation discriminates when estimating probability values for correct and incorrect responses to the dependent variable (i.e., in this case, the participant achieved the outcome and the participant did not achieve the outcome). The value of the statistic varies between 0.5 (the model's predictions are no better than predictions that would be made by chance) and 1.0 (the model always assigns higher probability values to correct responses).

[c] The Hosmer-Lemeshow goodness-of-fit statistic is particularly robust for models with continuous covariates. It is based on grouping cases into deciles of risk, from which a chi-square value is computed by comparing the observed probability with the

expected probability within each decile. If the goodness-of-fit test statistic (i.e., the significance value) is greater than .05, we fail to reject the null hypothesis that there is no difference, implying that the model's estimates fit the data at an acceptable level..

Presented in Table 4.12 are the statistical properties for the preliminary risk models developed for the Tier 1 measures. Risk adjustment models were developed only for those outcome measures with valid risk factor data. Measures collected at a single point in time did not contain the data items necessary for computing all associated risk factors and therefore, risk models were not developed for the consumer-centered measures or the Percent of Participants Immunized for Influenza and Percent of Participants with Signed Advance Directives measures.

TABLE 4.12: MODEL FIT STATISTICS FOR TIER 1 OUTCOME MEASURES

Outcome Measure	Adjusted R-Square[a]	c Statistic[b]	Hosmer-Lemeshow Chi-Square[c]	Significance Level
Physiologic Status and Symptom Management				
Decrease in Nutritional Risk	0.542	0.863	0.652	0.420
Improvement in Urinary Continence	0.294	0.773	6.461	0.487
Improvement in Dyspnea	0.226	0.728	4.376	0.823
Improvement in Edema	0.303	0.775	6.112	0.527
Increase in Pain Interfering with Activities	0.114	0.696	13.006	0.112
Decline in Edema	0.151	0.717	3.875	0.694
Functional Status				
Decrease in Number of Activities Limited by Health	0.268	0.772	10.088	0.264
Decline in Management of Oral Medications	0.276	0.781	2.940	0.891
Emotional/Mental Health Status				
Decrease in Depression/Depressive Symptoms	0.280	0.767	7.997	0.434
Decrease in Self-Report of Loneliness	0.295	0.774	4.776	0.687
Decrease in Number of Behavior Problems	0.430	0.839	6.858	0.652
Increase in Depression/Depressive Symptoms	0.299	0.780	14.267	0.075
Cognitive Functioning				
Improvement in Ability to Understand Others	0.294	0.806	12.929	0.114
Improvement in Ability to Speak to Others	0.197	0.750	9.217	0.238
Decline in Ability to Speak to Others	0.231	0.737	8.187	0.316
Participant Quality of Life				
Improvement in Satisfaction with Frequency of Social Interactions	0.331	0.784	5.355	0.719
Decline in Satisfaction with Frequency of Social Interactions	0.167	0.723	2.890	0.823
Knowledge and Adherence				
Improvement in Therapy Adherence	0.326	0.808	5.117	0.646
Informal Caregiver Quality of Life				
Decrease in Informal Caregiver Stress	0.232	0.704	0.144	0.931
Improvement in Informal Caregiver Coping	0.228	0.742	0.583	0.999
Increase in Informal Caregiver Stress	0.254	0.750	4.245	0.834

[a] The value reported is Nagelkerke's adjusted coefficient of determination. Unlike in ordinary least squares regression, where the R-square value is an estimate of the percent of variance explained by the model, the logistic regression R-square measures the strength of association between the variables in the model and is, therefore, not to be interpreted as a goodness-of-fit statistic.

[b] The c Statistic is a measure of how well the logistic equation discriminates when estimating probability values for correct and incorrect responses to the dependent variable (i.e., in this case, the participant achieved the outcome and the participant did not achieve the outcome). The value of the statistic varies between 0.5 (the model's predictions are no better than predictions that would be made by chance) and 1.0 (the model always assigns higher probability values to correct responses).

[c] The Hosmer-Lemeshow Chi-Square goodness-of-fit statistic is particularly robust for models with continuous covariates. It is based on grouping cases into deciles of risk, from which a chi-square value is computed by comparing the observed probability with the expected probability within each decile. If the goodness-of-fit test statistic (i.e., the significance value) is greater than .05 (as reported in the significance level column), we fail to reject the null hypothesis that there is no difference, implying that the model's estimates fit the data at an acceptable level.

The potential to successfully risk adjust all Tier 1 measures is evidenced by the findings presented in Table 4.12. Each of the Tier 1 logistic regression models demonstrated an acceptable value for the Adjusted R-square (r^2 >.10), the c Statistic ($c \geq 0.70$) and Hosmer-Lemonshow statistic (non-significant chi-square). The consistency of the findings suggests that the set of risk factors comprised in the COCOA-B data set are useful for successfully risk adjusting the Tier 1 measures. However, due to limitations in sample size (e.g., the number of variables included in model development was limited due to sample size) and population characteristics (e.g., under representation of participants residing in a nursing home), further development and refinement of the risk-adjustment models would be necessary prior to developing final models for PACE OBCQI.

7. Selection of Tier 3 Measures

The Tier 3 measures (Measures to be Dropped) are comprised predominately of two groups of measures: end of life measures and satisfaction measures. Given the importance of end of life care provided by PACE programs, it is notable that six end of life measures were included in Tier 3. These measures were dropped from the recommended COCOA-B data system for several reasons. First, implementing the End of Life Questionnaire, which is mailed to the primary informal caregiver two to four months after the death of a participant, creates additional data collection responsibilities for site staff (whereas the majority of COCOA-B items are intended for integration with routinely conducted participant assessments). Although the questionnaire itself is relatively brief, it requires site staff to track when and to whom the questionnaire packets should be mailed and to customize the questionnaire and cover letter (e.g., completing a subset of questionnaire items to indicate the participant's name and date of death) prior to mailing. During the SYFT and prior phases of the field test, sites consistently found it challenging to identify staff resources to undertake this responsibility, often resulting in eligible informal caregivers not receiving the questionnaire. The response rate for the questionnaire also was relatively low, impeding our ability to effectively analyze the end of life measures (the limited analyses that were conducted found minimal variability across respondents for the majority of the end of life measures). In view of these factors and because the end of life measures are not directly relevant to meeting the requirements of the federal regulations), these measures were assigned to Tier 3. Nonetheless, given the importance of end of life care for the PACE population (supported by PACE clinicians and administrators on a conceptual, if not operational, level throughout the project), the End of Life Questionnaire (included in Appendix 4A) may be a useful resource for sites interested in collecting such data on a voluntary basis.

Satisfaction measures also represent a significant portion of the Tier 3 measures. The primary reason for assigning six of the 12 satisfaction measures (under consideration prior to the SYFT) to Tier 3 was lack of variability across respondents, rendering these measures less effective for comparison purposes. Although six other satisfaction measures did meet the empirical criteria for inclusion in Tier 1, the logistical difficulties encountered during the field test with implementing the two satisfaction questionnaires almost led to the assignment of all 12 satisfaction measures to Tier 3. The value of comparative satisfaction data was consistently supported by the PACE community throughout the project; however, the logistical and resource challenges associated with implementing the Participant Satisfaction Questionnaire and, in particular, the Caregiver Satisfaction Questionnaire were raised multiple times at Advisory Committee meetings and in written evaluation comments from PACE staff members participating in field test activities. Difficulties included lack of staffing resources (the protocols required verbal administration of the questionnaires by individuals who do not provide direct care, to promote a comfortable environment for honest responses regarding care), the time-

intensive nature of scheduling satisfaction interviews (particularly with informal caregivers), removing participants from Day Health Center activities, and language/translation barriers for segments of the population.

Given these difficulties, potential methods to resolve identified challenges might be considered. For example, sites could specify a subset of participants and informal caregivers on whom to collect satisfaction data (e.g., 10% of site enrollment) and the requirement for administration of the questionnaires by an individual who does not provide direct care could be altered. Additional avenues might be to explore the possibility of designating an outside resource to administer satisfaction interviews at PACE sites, or to conduct a focused study to identify the most efficient and effective methods to collect satisfaction data in the PACE setting.

D. ADDITIONAL SYFT EXPERIENCE AND FINDINGS

1. Potential Adverse Event Measures

A few of the outcome indicators that are clinically meaningful but lack sufficient prevalence may be useful for quality monitoring and site quality improvement as adverse event measures. An adverse event measure is defined as a low frequency negative or untoward event that potentially reflects a serious health problem or decline in health status for an individual participant. The potential adverse events discussed "began" as outcome measures, however, their very low frequency prevented their use as standard outcome measures. Because they are regarded as important to include in a site's overall quality measurement program (due to their serious and potentially preventable nature), it may be useful to retain them.

Three measures that could be useful for adverse events for PACE OBCQI and quality monitoring (based on SYFT analyses) are Falls Resulting in Injury, Presence of Pressure Ulcers, and Wandering (straying or becoming lost in the community due to impaired judgment). The average rate across all sites for Falls Resulting in Injury was 10.2%, indicating that 10.2% of the SYFT participants experienced falls that resulted in injury. Although at least some falls resulting in injury may be beyond the control of the PACE site, such a serious quality indicator should warrant investigation of each episode to examine what, if anything, could have been done to prevent the fall and resultant injury. Given that only 3.6% of SYFT participants were reported to have a pressure ulcer and in view of the importance of preventing the development of pressure ulcers, presence of a new pressure ulcer(s) also is recommended as an adverse event to be monitored. (Data items to assess the stage and status of pressure ulcers also have been retained in COCOA-B to permit acquisition of additional information on pressure ulcers. Presence of pressure ulcers at a specified stage or worsening of pressure ulcers over time also could be considered for adverse events.) Similarly, the average percentage of participants that wandered was 1.6%, although some sites had rates as high as 4%. Because the data item used to compute this measure refers to wandering away from home, the Day Health Center or other locations (not just wandering from one room to another within a secured building), it seems that any instance of wandering is potentially dangerous and should be investigated (although, again, it ultimately may be determined that the event was beyond the control of the PACE site). Additional empirical analyses and clinical consideration are recommended to further examine the utility of these potential adverse events and identify other possible adverse events to be monitored.

2. Refinement of Data Collection Protocols and Other SYFT Experience

The SYFT was extremely effective in providing data and experience to guide the project's recommendations for the outcome measures, data set, data collection protocols, and implementation steps if the COCOA-B data system for PACE OBCQI and quality monitoring were implemented. The SYFT, as the culmination of years of developmental work and

preliminary empirical testing, provided an opportunity to test implementation across 13 PACE sites of varying geographic location, size, participant diversity, and experience. Data collection protocols and initial implementation activities (e.g., integrating COCOA-B into existing site assessment materials and practices, training, technical assistance) were tested and evaluated, allowing project staff to identify areas for refinement. The project team and site staff were able to identify challenges and, in many cases, resolve them during the SYFT.

CHAPTER 5

ADDITIONAL TABLES

A. CONTRACTOR-RECOMMENDED OUTCOME MEASURES, COCOA-B DATA SET, AND ILLUSTRATIVE REPORTS

1. Recommended Outcome Measures for PACE Quality Monitoring and OBCQI
the draft outcome measures specified during the developmental and preliminary empirical testing phases of the project were evaluated during the SYFT to assess their effectiveness for OBCQI and quality monitoring. Following the SYFT, the measures were organized into three tiers reflecting their utility for the COCOA-B data system based on statistical, clinical, and other considerations (e.g., data collection burden). The 50 measures included in Tier 1 and Tier 2 compose the set of outcome measures recommended for implementation as part of the COCOA-B data system. All of the measures were supported clinically throughout the project. The 29 Tier 1 measures were found to meet empirical criteria for selection of outcome measures, based on findings from the SYFT. The 21 measures in Tier 2 did not demonstrate sufficient empirical evidence based on the SYFT data analyses for effective outcome measures but remain promising and are worthy of further empirical investigation with a larger sample of PACE participants than was obtained during the SYFT. We therefore recommend that all of the data items necessary for measuring both Tier 1 and Tier 2 outcome measures remain in the COCOA-B data system. The set of recommended measures (Tier 1 and Tier 2 measures) is presented in Table 5.2.

The recommended measures (Tier 1 and Tier 2 measures) consist of 28 health status outcomes addressing participant physiologic, functional, emotional/mental health, and cognitive status; 10 instrumental outcomes related to participant and informal caregiver quality of life, and participant knowledge and adherence; 5 utilization measures addressing hospital, emergency care, and nursing home use; and 7 consumer-centered measures related to participant and informal caregiver satisfaction and end of life care. The measures are the result of a detailed developmental and testing process that included extensive, ongoing involvement of the PACE community in the initial specification and refinement activities and the subsequent empirical testing phases.

Twenty four of the measures evaluated during the SYFT were assigned to Tier 3 and are not recommended for inclusion in the COCOA-B data system. Although these measures were initially supported on a conceptual level by clinical and administrative PACE community members as potentially effective for OBCQI, the measures are difficult to justify for inclusion in the recommended measure set due to insufficient empirical support, excessive data collection burden cited by PACE community members, and/or other considerations identified during the course of field testing. (Discussion of the empirical criteria and other factors that led to classification of the Tier 3 measures is presented in Chapter 4.)

TABLE 5.2: CONTRACTOR-RECOMMENDED OUTCOME MEASURES[A] FOR THE COCOA-B/OBCQI SYSTEM

Tier 1 – CLINICALLY AND EMPIRICALLY SUPPORTED Measures

HEALTH STATUS OUTCOMES

Physiologic Status and Symptom Management
Decrease[b] in Nutritional Risk
Improvement in Urinary Continence
Improvement in Dyspnea
Improvement in Edema
Increase[c] in Pain Interfering with Daily Activities
Decline in Edema
Percent of Participants Immunized for Influenza

Functional Status
Decrease in Number of Activities Limited by Health
Decline in Management of Oral Medications

Emotional/Mental Health Status

Decrease in Depression/Depressive Symptoms
Decrease in Self-Report of Loneliness
Decrease in Number of Behavior Problems
Increase in Depression/Depressive Symptoms

Cognitive Functioning
Improvement in Ability to Understand Others
Improvement in Ability to Speak to Others
Decline in Ability to Speak to Others

INSTRUMENTAL OUTCOMES

Participant Quality of Life

Improvement in Satisfaction with Frequency of Social Interactions
Decline in Satisfaction with Frequency of Social Interactions

Knowledge and Adherence
Improvement in Therapy Adherence

Informal Caregiver Quality of Life

Decrease in Informal Caregiver Stress
Improvement in Informal Caregiver Coping
Increase in Informal Caregiver Stress

CONSUMER-CENTERED MEASURES

Participant Satisfaction

Satisfaction with Staff Communications
Satisfaction with Day Health Center Services
Satisfaction with Transportation
Satisfaction with Obtaining Needed Services/Assistance

Informal Caregiver Satisfaction

Satisfaction with Provider-Family Communications
Satisfaction with Transportation

End of Life Care
Percent of Participants with a Signed Advance Directive

Tier 2 – Measures for Further Investigation[D]

HEALTH STATUS OUTCOMES

Physiologic Status and Symptom Management
Decrease in Pain Interfering with Daily Activities
Decline in Dyspnea
Decline in Urinary Continence

Functional Status
Improvement in Ambulation
Improvement in Management of Oral Medications
Improvement in Transferring
Decline in Ambulation
Decline in Transferring
Increase in Number of Activities Limited by Health

Emotional/Mental Health Status

Increase in Self-Report of Loneliness
Increase in Number of Behavior Problems

Cognitive Functioning
Decline in Ability to Understand Others

UTILIZATION OUTCOMES

Hospitalization	**Emergency Care Services**
Percent of Participants Hospitalized Percent of Participants Readmitted to the Hospital	Percent of Participants Receiving Emergency Care
Nursing Home Placement Percent of Permanent Nursing Home Admissions Number of Nursing Home Days	

INSTRUMENTAL OUTCOMES

Participant Quality of Life	**Informal Caregiver Quality of Life**
Improvement in Self-Rated Quality of Life Decline in Self-Rated Quality of Life	Decline in Informal Caregiver Coping
Knowledge and Adherence Decline in Therapy Adherence	

[a] Four types of measures are included in the set of OBCQI outcome measures: Health Status Outcomes, Utilization Outcomes, Instrumental Outcomes, and Consumer-Centered Measures. Outcomes are further grouped by domain (with the exception of Utilization Outcome measures), as follows: Health Status Outcomes include outcomes related to physiologic and symptom management, functional status, emotional/mental health status, and cognitive functioning; Instrumental Outcomes include outcomes related to participant quality of life, informal caregiver quality of life, and knowledge and adherence; and Consumer-Centered Measures consist of participant satisfaction, informal caregiver satisfaction, and end of life care measures. All measure types and domains are not necessarily represented in each of the outcome tiers.

[b] Decrease measures indicate improvement in a health status area. For example, Decrease in Nutritional Risk indicates less risk and therefore improved status.

[c] Increase measures indicate decline in a health status area. For example, Increase in Pain Interfering with Daily Activities indicates more pain and therefore declined status.

2. Contractor-Recommended COCOA-B Data Set

The COCOA-B data set recommended for implementation contains the 102 data items necessary to compute and risk adjust the Tier 1 and Tier 2 outcome measures. The data items that compose the recommended COCOA-B data set are listed in Table 5.3 (the data set is provided in Appendix 6A).

TABLE 5.3: CONTRACTOR-RECOMMENDED COCOA-B DATA SET: LIST OF DATA ITEMS

	C0#	Item Name
CLINICAL RECORD ITEMS		
1.	C0010	Site ID
2.	C0020	Participant ID
3.	C0030	Participant Name
4.	C0040	Reason for Assessment
5.	C0050	Date Assessment Completed
6.	C0055	Scheduled Month of Assessment
PARTICIPANT TRACKING AND DEMOGRAPHIC ITEMS		
7.	C0060	Program Enrollment Date (Date PACE Services Began)
8.	C0070	Gender
9.	C0080	Date of Birth
10.	C0090	Participant Social Security Number
11.	C0100	Medicare Number and Entitlement (C0100_1; C0100_2)
12.	C0110	Medicaid Number and Eligibility (C0110_1; C0110_2)
13.	C0120	Ethnicity
14.	C0130	Race
15.	C0140	Marital Status
16.	C0150	Highest Level of Education Completed
17.	C0160	Primary Language and English Fluency (C0160_1; C0160_2)
DISENROLLMENT ITEMS		
18.	C0190	Disenrollment Date
19.	C0200	Disenrollment Due to Death
20.	C0210	Date of Death

TABLE 5.3: Recommended COCOA-B Data Set: List of Data Items. (Cont'd)

	C0#	Item Name
21.	C0220	Reason for Disenrollment
22.	C0230	Referred to Following Disenrollment
PRIMARY CARE PROVIDER		
23.	C0240	Diagnosis and Severity Index
24.	C0250	Overall Prognosis
25.	C0260	Life Expectancy
26.	C0270	Participant Pain (C0270_1 to C0270_5)
NURSING		
27.	C0290	Pressure Ulcers (C0290_1 to C0290_4)
28.	C0320	High Risk Factors
29.	C0350	Flu Immunization Status
30.	C0360	Vision
31.	C0370	Hearing
32.	C0410	Nutritional Risk
33.	C0420	Dyspnea
34.	C0430	Edema
35.	C0440	Bladder Continence/When Urinary Incontinence Occurs (C0440_1; C0440_2)
36.	C0450	Urinary Tract Infection
37.	C0460	Bowel Incontinence Frequency
38.	C0470	Number of Falls/Number of Falls Resulting in Injury (C0470_1; C0470_2)
39.	C0490	Management of Oral Medications
NURSING (cont'd)		
40.	C0500	Adherence to Medications
41.	C0510	Adherence to Therapy/Medical Interventions
42.	C0520	Self-Report of Health Status
43.	C0530	Activity Difficulties
44.	C0540	Help from Another Person for Activities
45.	C0550	Lifting or Carrying Objects
46.	C0560	Walking a Quarter of a Mile
SOCIAL WORK		
47.	C0570	Day Health Center Attendance
48.	C0580	Current Residence
49.	C0590	Participant Lives With
50.	C0600	Informal (Unpaid) Caregivers
51.	C0610	Number of Informal Caregivers
52.	C0620	Frequency of Caregiver Assistance
53.	C0630	Type of Caregiver Assistance
54.	C0650	Advance Directives (C0650_1; C0650_2)
55.	C0660	Frequency of Participant's Anxiety
56.	C0670	Participant Stress/Concerns (C0670_1; C0670_2)
57.	C0680	Depression, Depressive Symptoms, and Social Isolation
58.	C0690	Frequency of Behavior Problems
59.	C0700	Wandering
60.	C0710	Cognitive Functioning
61.	C0720	Memory Deficit
62.	C0730	Judgment
63.	C0740	Ability to Understand Others
64.	C0750	Ability to Express Thoughts, Wants, Needs
65.	C0760	Satisfaction with Amount of Interaction/Contact
66.	C0780	Socialization/Isolation (C0780_1; C0780_2)
67.	C0790	Self-Rated Quality of Life
68.	C0800	Satisfaction with Care Provided for Pain (C0800_1 to C0800_3)
69.	C0810	Caregiver Stress
70.	C0820	Caregiver Coping (C0820_1; C0820_2)
REHABILITATION THERAPY		
71.	C0840	Endurance
72.	C0850	Ambulation/Locomotion
73.	C0860	Transferring
74.	C0870	Bathing
75.	C0880	Grooming
76.	C0890	Dressing Upper Body
77.	C0900	Dressing Lower Body
78.	C0910	Toileting
79.	C0920	Feeding or Eating
80.	C0930	Planning and Preparing Light Meals
81.	C0940	Shopping
82.	C0950	Housekeeping
REHABILITATION THERAPY		
83.	C0960	Laundry
84.	C0970	Telephone Use
85.	C0980	Transportation
86.	C0990	Functional Rehabilitative Prognosis
87.	C1010	Structural Barriers in Participant's Residence
PARTICIPANT SATISFACTION		
88.	C1020	Satisfaction with Communication with Site Staff
89.	C1030	Satisfaction with Services, Help
90.	C1040	Satisfaction with Other Services
CAREGIVER SATISFACTION		
91.	C1070	Caregiver Satisfaction with Communication with Site Staff
92.	C1080	Caregiver Satisfaction with Services, Help
93.	C1090	Caregiver Satisfaction with Other Services
UTILIZATION		
94.	C1250	Type of Admission
95.	C1260	Admission Date
96.	C1270	Discharge Date
97.	C1280	Length of Stay
98.	C1290	Number of ICU or CCU Days
99.	C1300	Discharge Disposition
100.	C1310	Primary and Secondary Discharge Diagnoses (C1310_1; C1310_2)
101.	C1320	Hospital Admission Reason
102.	C1330	Nursing Home Admission Reason

The data set was revised based on empirical findings and qualitative input resulting from the SYFT, including the elimination of 32 data items (e.g., data items intended only for computing Tier 3 outcome measures and that were not useful for risk adjusting other measures). The data items eliminated from COCOA-B after the SYFT are listed in Table 5.4.

TABLE 5.4: Data Items Eliminated from COCOA-B Based on Systematic Field Test Findings and Other Input.

C0#	Item Name
PARTICIPANT TRACKING AND DEMOGRAPHIC ITEMS	
C0170	Inpatient Facilities Last 14 Days
C0180	Formal Services Prior to Enrollment
PRIMARY CARE PROVIDER	
C0280	Surgical Wounds
C0300	Stasis Ulcers
C0310	Standardized Mini Mental Status Examination (MMSE)
NURSING	
C0330	Therapies at Home
C0340	Respiratory Treatments at Home
C0380	Height and Weight
C0390	Hydration (Oral Fluid Intake)
C0400	Skin Turgor (Hydration)
C0480	Number of Prescription Medications
SOCIAL WORK	
C0640	Financial Concerns
C0770	Satisfaction with Quality of Interaction/Contact
C0830	Caregiver Support
REHABILITATION THERAPY	
C1000	Safety Hazards in Participant's Residence

C0#	Item Name
PARTICIPANT SATISFACTION	
C1050	Satisfaction with Care in the Last Four Months
C1060	Recommend (PACE Site) to Friend or Family
CAREGIVER SATISFACTION	
C1100	Caregiver Satisfaction with Care in the Last Four Months
C1110	Caregiver Recommend (PACE Site) to Friend or Family
END OF LIFE	
C1120	Caregiver Relationship to Participant
C1130	Caregiver Name
C1140	Caregiver Gender
C1150	Caregiver Ethnicity
C1160	Caregiver Race
C1170	Location Last Two Weeks of Life
C1180	Extent Wishes Followed
C1190	Staff Efforts to Control Pain
C1200	Program Staff Open and Forthcoming
C1210	Program Staff Sensitive, Respectful
C1220	Participant Feelings of Peace Last 2 Weeks
C1230	Caregiver Feelings of Peace Last 2 Wks of Life
C1240	Caregiver Satisfaction with End of Life Care

Table 5.5 provides a summary of the number of data items and indicators/measures included in the data set at each phase of the field test. This table illustrates the progression of the data set from a fairly large (albeit more comprehensive for assessment purposes) data set used for the feasibility and reliability test phases of the project to the more streamlined, final recommended COCOA-B data set resulting from the systematic field test.

TABLE 5.5: NUMBER OF DATA ITEMS AND OUTCOME INDICATORS/MEASURES BY PROJECT PHASE

	Data Items	Outcome Indicators/Measures[a]
Initial Draft COCOA Data Set (Master Clinician Review)	210	50 Indicators
COCOA Feasibility Test	212	50 Indicators
COCOA Reliability Test	242	50 Indicators
COCOA-B Systematic Field Test	134	43 Indicators; 74 Measures
COCOA-B Data Set (Recommended)	102	50 Measures; 3 Adverse Event Measures

[a] The original list of 50 outcome indicators was broadly quantified into over 100 measures (e.g., Change in ambulation could be quantified into at least three separate measures including Improvement in Ambulation, Stabilization in Ambulation, and Decline in Ambulation). The quantification of indicators into measures did not take place formally until after the reliability test phase of the project as data item reliability was a necessarily condition for quantifying outcome indicators into measures. If an item could not be retained in the data set due to issues of reliability, then the underlying measure could not be calculated.

To facilitate data collection by the interdisciplinary team and other PACE site staff, the COCOA-B data items are organized into four clinical item sets (grouped by preferred discipline for data collection), including primary care provider, nursing, rehabilitation therapy, and social work staff, and five nonclinical item sets (tracking and demographic items, participant and informal caregiver satisfaction questionnaires, a utilization form, and a brief disenrollment form). Although the clinical items have been grouped under the heading of particular disciplines, responsibility for data collection for each data item can be assigned by individual PACE sites; our recommended approach for assigning the items for integration into clinical assessment materials is discussed in Section D.5 in this chapter.

With the goal of a manageable and parsimonious data set, each COCOA-B data item has been retained for at least one specific purpose, and in many instances, for multiple (potential) purposes. Table 5.6 summarizes the currently identified application(s) for each item, including participant tracking information, outcome measurement/quality monitoring, risk adjustment, adverse event monitoring, participant characteristic reporting, and payment adjustment. The item applications noted in the table are based on the SYFT analyses and current expectations. Additional or alternative applications for each item likely will be identified if further analyses are conducted to validate and refine outcome measures and risk models, as adverse event definitions are finalized. Additional needs (not represented in Table 5.6) that also could be met through the COCOA-B/OBCQI system include site-level quality assessment and performance improvement (QAPI) efforts, state reporting requirements (if approved by states), and site-specific quality improvement and other informational needs.

TABLE 5.6: Intended Application(s) of Each COCOA-B Data Item.[a]

	C0#	Item Name	Tracking Identifier	Outcome Measurement	Risk Adjustment	Adverse Event	Participant Characteristics	Payment Frailty Adjuster[b]	Other[c]
CLINICAL RECORD ITEMS									
1.	C0010	Site ID	X						
2.	C0020	Participant ID	X						
3.	C0030	Participant Name	X						
4.	C0040	Reason for Assessment	X						
5.	C0050	Date Assessment Completed	X		X		X		
6.	C0055	Scheduled Month of Assessment	X						
PARTICIPANT TRACKING AND DEMOGRAPHIC ITEMS									
7.	C0060	Program Enrollment Date (Date PACE Services Began)			X		X		
8.	C0070	Gender			X		X		
9.	C0080	Date of Birth			X		X		
10.	C0090	Participant Social Security Number	X						
11.	C0100	Medicare Number and Entitlement (C0100_1; C0100_2)	X		X				
12.	C0110	Medicaid Number and Eligibility (C0110_1; C0110_2)	X		X				
13.	C0120	Ethnicity			X		X		

TABLE 5.6: Intended Application(s) of Each COCOA-B Data Item.[a] (Cont'd)

	C0#	Item Name	Tracking Identifier	Outcome Measurement	Risk Adjustment	Adverse Event	Participant Characteristics	Payment Frailty Adjuster[b]	Other[c]
14.	C0130	Race			X		X		
15.	C0140	Marital Status			X		X		
16.	C0150	Highest Level of Education Completed			X				
17.	C0160	Primary Language and English Fluency (C0160_1; C0160_2)							X
DISENROLLMENT ITEMS									
18.	C0190	Disenrollment Date	X						
19.	C0200	Disenrollment Due to Death							X
20.	C0210	Date of Death	X						
21.	C0220	Reason for Disenrollment							X
22.	C0230	Referred to Following Disenrollment							X
PRIMARY CARE PROVIDER									
23.	C0240	Diagnosis and Severity Index			X		X		
24.	C0250	Overall Prognosis			X		X		
25.	C0260	Life Expectancy			X				
26.	C0270	Participant Pain (C0270_1 to C0270_5)		X	X		X		
NURSING									
27.	C0290	Pressure Ulcers (C0290_1 to C0290_4)				X			
28.	C0320	High Risk Factors			X				
29.	C0350	Flu Immunization Status		X	X		X		
30.	C0360	Vision			X		X		
31.	C0370	Hearing			X		X		
32.	C0410	Nutritional Risk		X	X		X		
33.	C0420	Dyspnea		X	X		X		
34.	C0430	Edema		X	X		X		
35.	C0440	Bladder Continence/When Urinary Incontinence Occurs (C0440_1; C0440_2)		X	X		X		
36.	C0450	Urinary Tract Infection					X		
37.	C0460	Bowel Incontinence Frequency			X		X		
38.	C0470	Number of Falls/Number of Falls Resulting in Injury (C0470_1; C0470_2)			X	X	X		
39.	C0490	Management of Oral Medications		X	X		X		
40.	C0500	Adherence to Medications			X		X		
41.	C0510	Adherence to Therapy/Medical Interventions		X	X		X		
42.	C0520	Self-Report of Health Status			X				
43.	C0530	Activity Difficulties		X				X	
44.	C0540	Help from Another Person for Activities						X	
45.	C0550	Lifting or Carrying Objects						X	
46.	C0560	Walking a Quarter of a Mile						X	
SOCIAL WORK									
47.	C0570	Day Health Center Attendance			X				
48.	C0580	Current Residence			X		X		
49.	C0590	Participant Lives With			X		X		
50.	C0600	Informal (Unpaid) Caregivers			X		X		
51.	C0610	Number of Informal Caregivers			X				
52.	C0620	Frequency of Caregiver Assistance			X		X		

TABLE 5.6: Intended Application(s) of Each COCOA-B Data Item.[a] (Cont'd)

	C0#	Item Name	Tracking Identifier	Outcome Measurement	Risk Adjustment	Adverse Event	Participant Characteristics	Payment Frailty Adjuster[b]	Other[c]
53.	C0630	Type of Caregiver Assistance			X		X		
54.	C0650	Advance Directives (C0650_1; C0650_2)		X	X		X		
55.	C0660	Frequency of Participant's Anxiety			X		X		
56.	C0670	Participant Stress/Concerns (C0670_1; C0670_2)			X				
57.	C0680	Depression, Depressive Symptoms, and Social Isolation		X	X		X		
58.	C0690	Frequency of Behavior Problems		X	X		X		
59.	C0700	Wandering			X	X	X		
60.	C0710	Cognitive Functioning			X		X		
61.	C0720	Memory Deficit			X				
62.	C0730	Judgment			X				
63.	C0740	Ability to Understand Others		X	X		X		
64.	C0750	Ability to Express Thoughts, Wants, Needs		X	X		X		
65.	C0760	Satisfaction with Amount of Interaction/Contact		X	X				
66.	C0780	Socialization/Isolation (C0780_1; C0780_2)		X	X				
67.	C0790	Self-Rated Quality of Life		X					
68.	C0800	Satisfaction with Care Provided for Pain (C0800_1 to C0800_3)							X
69.	C0810	Caregiver Stress		X	X				
70.	C0820	Caregiver Coping (C0820_1; C0820_2)		X					
REHABILITATION THERAPY									
71.	C0840	Endurance			X				
72.	C0850	Ambulation/Locomotion		X	X		X		
73.	C0860	Transferring		X	X		X		
74.	C0870	Bathing			X		X		
75.	C0880	Grooming			X		X		
76.	C0890	Dressing Upper Body			X		X		
77.	C0900	Dressing Lower Body			X		X		
78.	C0910	Toileting			X		X		
79.	C0920	Feeding or Eating			X		X		
80.	C0930	Planning and Preparing Light Meals			X		X		
81.	C0940	Shopping			X		X		
82.	C0950	Housekeeping			X		X		
83.	C0960	Laundry			X		X		
84.	C0970	Telephone Use			X		X		
85.	C0980	Transportation		X			X		
86.	C0990	Functional Rehabilitative Prognosis			X		X		
87.	C1010	Structural Barriers in Participant's Residence			X				
PARTICIPANT SATISFACTION									
88.	C1020	Satisfaction with Communication with Site Staff		X					
89.	C1030	Satisfaction with Services, Help		X					
90.	C1040	Satisfaction with Other Services		X					
CAREGIVER SATISFACTION									
91.	C1070	Satisfaction with Communication with Site Staff		X					
92.	C1080	Satisfaction with Services, Help		X					
93.	C1090	Satisfaction with Other Services		X					
UTILIZATION									

TABLE 5.6: Intended Application(s) of Each COCOA-B Data Item.[a] (Cont'd)

	C0#	Item Name	Tracking Identifier	Outcome Measurement	Risk Adjustment	Adverse Event	Participant Characteristics	Payment Frailty Adjuster[b]	Other[c]
94.	C1250	Type of Admission	X	X	X		X		
95.	C1260	Admission Date	X	X	X				
96.	C1270	Discharge Date	X	X	X				
97.	C1280	Length of Stay		X	X				
98.	C1290	Number of ICU or CCU Days							X
99.	C1300	Discharge Disposition							X
100.	C1310	Primary and Secondary Discharge Diagnoses (C1310_1; C1310_2)							X
101.	C1320	Hospital Admission Reason		X	X		X		
102.	C1330	Nursing Home Admission Reason		X	X		X		

[a] The item applications noted in the table are based on the SYFT analyses and current expectations.

[b] Items C0530-C0560 were included in the SYFT under a subcontract with Research Triangle Institute, a CMS contractor developing a frailty adjuster for potential payment of PACE sites. The items have been retained in the recommended data set. Although not marked for this purpose, many of the rehabilitation therapy items also could be useful in calculating a frailty adjuster for payment, if CMS wanted to pursue this concept.

[c] Eight data items retained in the data set currently are not used for the purposes noted in this table (the primary purposes of the data set). The items were retained for site-level descriptive information and/or because of their potential utility for additional outcome measures and risk models.

3. Reports from COCOA-B Data

Outcome reports and participant characteristics reports could be created and used by individual sites to compare of the site's own data from one year (or other period) to the next. An example of a participant characteristic report (appearing in the format of reports distributed to the PACE sites that participated in the SYFT) is presented in Appendix 4D.

Participant characteristic reports can be generated from COCOA-B data, reflecting information on a variety of dimensions including demographic, environmental, social support, and health status characteristics of site participants.

Given the limited period of time allocated for field test activities and the relatively small sample size for the SYFT, only preliminary work was conducted on the development of outcome reports. Adverse event reports also could be produced using the COCOA-B data. Three adverse event measures of potential value for PACE quality monitoring were identified based on the SYFT analyses. The three measures, falls resulting in injury, presence of pressure ulcers, and wandering demonstrated low prevalence in the SYFT analyses, but may be important to include in sites' overall quality measurement programs due to their serious and potentially preventable nature.

An array of additional statistical reports could be created using the COCOA-B data for multiple purposes, including site-specific areas of inquiry. For example, reports could be generated to identify trends in particular groups or types of participants (e.g., participants with and without informal caregivers; participants with and without cognitive impairment; participants at particular centers within a site) or to link specific health status outcomes with health service utilization outcomes.

4. Potential Resource for Sites: Supplemental Core Comprehensive Assessment Items
As noted previously in this report, COCOA-B is a subset of a larger data set (COCOA) developed under this project. The full COCOA data set was designed to include data items necessary for two purposes: a) to measure and risk adjust outcomes, and b) to provide a standardized core comprehensive assessment across PACE sites. As the multiphase field test of COCOA progressed, concerns related to administrative burden and practicality were highlighted and it became necessary to substantially reduce the size, and therefore the focus, of the data set to maximize efficiency, minimize burden, and still retain a data set that would be useful for multiple purposes. The COCOA-B data set focuses in particular on providing the information necessary to measure and risk adjust outcomes for quality monitoring and OBCQI purposes. Data items not considered critical to this purpose were eliminated resulting in the more focused and manageable COCOA-B data set.

The developmental process that resulted in the full COCOA data set strengthened the data items retained in COCOA-B (e.g., increased the utility of the items for participant assessment) and produced a set of additional data items of potential utility to new PACE sites as they develop materials for participant assessment or for established sites that may wish to modify their site-specific assessment materials. The supplemental core comprehensive assessment data items that were not retained in COCOA-B are presented in Appendix 3D. It should be noted that the supplemental data items were not revised based on findings from the reliability test and were not included in the SYFT; therefore, these items were not as widely tested as the items retained in COCOA-B. Because a substantial subset of the full COCOA data set was removed when creating COCOA-B, the supplemental core comprehensive assessment data items should not be considered a full core comprehensive assessment.

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