Research Report

Development and Maintenance of Standardized Cross Setting Patient Assessment Data for Post-Acute Care

Summary Report of Findings from Alpha 1 Pilot Testing

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Preface

The Centers for Medicare & Medicaid Services (CMS) contracted with the RAND Corporation to identify and/or develop standardized items for use in post-acute care patient assessment instruments. RAND was tasked by CMS with developing and testing items within seven areas of focus that fall under the assessment categories and domains delineated in the Improving Medicare Post-Acute Care Transformation Act of 2014: (1) vision and hearing; (2) cognitive status; (3) depressed mood; (4) pain; (5) care preferences; (6) medication reconciliation; and (7) bladder and bowel continence.

This report presents results of the first Alpha 1 feasibility test of a proposed set of items for assessing each of these focus areas. Conducted between August and October 2016, the test is one of two Alpha tests that will be completed by mid-2017 to assess the feasibility of proposed items. The results of these small-scale feasibility tests will be combined with ongoing stakeholder feedback to inform a national Beta test designed to determine how well the items perform when implemented across post-acute care settings.

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Table of Contents

Preface iii
Research Team iv
Tables vii
Summary ix
Acknowledgments xiii
Abbreviations xiv
Chapter One. Background 1
Chapter Two. Data Collection Methods 5
Chapter Three. Analytic Methods and Results 14
Chapter Four. Results for Vision and Hearing 18
Chapter Five. Results for Cognitive Status 24
Chapter Six. Results for Mood 32
Chapter Seven. Results for Pain 42
Chapter Eight. Results for Care Preferences 48
Chapter Nine. Results for Medication Reconciliation 55
Chapter Ten. Results for Bladder and Bowel Continence 65
Chapter Eleven. General Feedback from Assessors 73
Appendix A. Alpha 1 Assessment Protocol 74
Appendix B. Assessor Feedback Interview Protocol 102
Appendix C. Item History and Current Usage 105
References 108

Tables

Table 4.1. Interrater Reliability of Vision and Hearing Items 19
Table 4.2. Frequency Distribution of Responses to Vision and Hearing Items, by Assessors 20
Table 4.3. Average Time Spent (in Minutes) Completing Vision and Hearing Items, by PAC Setting 21
Table 5.1. Frequency Distributions of Responses to Cognitive Functioning Items, by Assessors Within Each PAC Setting 26
Table 5.2. Average Time Spent (in Minutes) Completing Cognitive Function Items, by PAC Setting 27
Table 5.3. Percentage of Cases in Which Assessors Agreed to Conduct the Trail Making Task 27
Table 5.4. Interrater Reliability of Cognitive Function Items 28
Table 5.5. Pearson Correlations Between the BIMS Composite Score and Each of the Four Executive Function Items 28
Table 5.6. Crosstabs of BIMS Composite with Executive Functioning Items Among the Facility Staff 28
Table 5.7. Executive Functioning Score Distribution According to BIMS Classification Category (Facility Staff, All Settings Combined) 29
Table 6.1. Interrater Reliability for the Items of the Patient/Resident Mood Interview 34
Table 6.2. Symptom Presence and Frequency Distribution of Responses to the Mood Interview Items 35
Table 6.3. Feasibility of Administering the Patient/Resident Mood Interview in PAC Settings: Average Time to Complete 39
Table 6.4. Feasibility of Administering the Mood Items: Clarity of Instructions 39
Table 6.5. Feasibility of Administering the Mood Items: Number of Assessors that Properly Followed Skipping Rules 39
Table 7.1. Interrater Reliability of Pain Items 44
Table 7.2. Pain Items: Frequency Distributions of Responses, by Item and Assessor Type 44
Table 7.3. Pain Items: Frequency of Research Nurse and Facility Staff Adherence to Assessment Skip Rules 46
Table 7.4. Average Time Spent (in Minutes) Completing Pain Items by PAC Setting 47
Table 8.1. Interrater Reliability for Care Preferences Items 50
Table 8.2. Frequency Distribution of Responses to Care Preferences Items 50
Table 8.3. Average Time Spent Completing Care Preferences Items, by PAC Setting 53
Table 9.1. Frequency Distribution of Responses to Medication Reconciliation Items 57
Table 9.2. Interrater Reliability of Medication Reconciliation Items 60

Table 9.3. Dependence of Interrater Agreement on Concordance of Information Source 61
Table 9.4. Average Time Spent (in Minutes) Completing Medication Reconciliation Items, by PAC Setting 61
Table 9.5. Feasibility of Administering Medication Reconciliation Items: Number of Assessors Who Properly Followed Skipping Rules..... 62
Table 10.1. Interrater Reliability of Bladder and Bowel Items..... 67
Table 10.2. Frequency Distribution of Responses to Bladder and Bowel Items, by Assessors ... 67
Table 10.3. Average Time Spent (in Minutes) Completing Bladder and Bowel Items, by PAC Setting 71
Table 10.4. Percentage of Research Nurses and Facility Staff Who Adhered to Assessment Skip Rules 71

Summary

The Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014 aims to improve post-acute care (PAC) reporting and services by requiring collection, transmission, and reporting of standardized patient/resident assessment data across the four PAC settings—Home Health Agencies (HHAs), Inpatient Rehabilitation Facilities (IRFs), Long-Term Care Hospitals (LTCHs), and Skilled Nursing Facilities (SNFs). The Centers for Medicare & Medicaid Services (CMS) contracted with the RAND Corporation to identify and/or develop standardized items to include in the PAC patient assessment instruments. RAND was tasked by CMS with developing and testing items within seven areas of focus that fall under the assessment categories and domains delineated in the IMPACT Act: (1) vision and hearing; (2) cognitive status; (3) depressed mood; (4) pain; (5) care preferences; (6) medication reconciliation; and (7) bladder and bowel continence.

This report presents results of the first Alpha 1 feasibility test of a proposed set of items for assessing each of these focus areas. Conducted between August and October 2016, the test is one of two Alpha tests that will be completed by mid-2017 to assess the feasibility of proposed items. The results of these small-scale feasibility tests will be combined with ongoing stakeholder feedback to inform a national Beta test designed to determine how well the items perform when implemented across PAC settings.

For this test, the Alpha 1 instrument was completed with 133 patients: 37 receiving services in an HHA setting, 34 in an IRF, 31 in an LTCH, and 31 in an SNF. All patients were assessed twice (once by a facility nurse and once by a research nurse) so that agreement between these two assessors, or interrater reliability (IRR), could be determined.

Metrics Used

We briefly summarize the metrics used to assess items in the Alpha 1 test before summarizing results for various items. All items were assessed on at least two metrics: IRR and feasibility. IRR was calculated using Cohen's kappa for categorical variables or weighted kappa for ordinal variables, as appropriate.[1] Feasibility was assessed with the time required to complete the items for each content area, as well as qualitative feedback provided by assessors on the clarity of item instructions and difficulties they encountered with item administration. Some

[1] Jacob Cohen, "A Coefficient of Agreement for Nominal Scales," *Educational and Psychological Measurement*, Vol. 20, No. 1, 1960, pp. 37–46.

content areas had additional goals for assessment, such as fidelity of assessors in skipping certain items as required by the instructions, or sources of data that assessors used to complete the items.

Results of the Alpha 1 Test

The seven content areas assessed in the Alpha 1 test can be divided into three categories:

1. The first category, which included *depressed mood, pain, and bladder and bowel continence*, worked nearly perfectly: The items were both reliable and feasible to implement. They will require **little if any modification** and can proceed to Beta testing in their current form.
2. The second category—for *vision and hearing, cognitive status, and care preferences*—evidenced minor issues with reliability or feasibility. Some of the items in these content areas will require **minor adjustments**, and they may need to be retested in the Alpha 2 phase to prepare them for Beta testing.
3. The third category, which consisted of *medication reconciliation*, was being tested for the first time. Not surprisingly, the medication reconciliation items demonstrated the most limitations with respect to reliability and feasibility. This content area will require considerable **refinement and retesting** in the Alpha 2 phase to prepare for Beta testing.

Category 1: Depressed Mood, Pain, and Bladder and Bowel Continence

IRR. We assessed IRR for this group of items using Cohen's kappa for categorical variables and weighted kappa for ordinal variables. IRR on mood and pain items was always above 0.9 and frequently perfect. Bladder and bowel continence items also generally achieved high IRR, although some of these items (e.g., catheter use) are not applicable to a majority of patients. Rates of bowel and bladder continence issues varied considerably across care settings.

Feasibility. The items in this group were highly feasible to administer and took minimal time to complete. The mood items took between one and three minutes to administer if only the Patient Health Questionnaire (PHQ)-2 was needed, and up to six minutes if the more comprehensive PHQ-9 was also needed. The pain items took approximately one minute to administer when there was no pain, and approximately three minutes to administer when there was pain. The bladder and bowel items took less than two minutes for interview items; the time to complete noninterview items varied widely across care settings.

Assessor feedback. Assessors suggested minor improvements in these content areas. They wanted additional training about how to score the PHQ-2 and the PHQ-9. Assessors reported that the bladder and bowel continence items were straightforward and easy to use. However, they suggested ways to improve them. For example, some assessors suggested that the word *continence* can be hard for some patients to understand and favored using a more easily understood term (e.g., *accidents* or *leaking*) when discussing bladder and bowel items with patients/residents. Assessors also asked for clarification on how to score bladder and bowel continence items when family and patient accounts do not match.

The items from these three content areas have been used in PAC settings for many years, and most have undergone extensive prior testing, validation, and use. They will require few, if any, modifications in future rounds of testing.

Category 2: Vision and Hearing, Cognitive Status, and Care Preferences

IRR. The results for vision and hearing indicate moderate to almost perfect agreement between assessors as measured by IRR. Highest reliability was recorded for use versus nonuse of a hearing aid (Cohen's kappa = 0.92); reliability was somewhat lower for use versus nonuse of glasses (0.69). Cognitive status items generally showed excellent IRR, and assessors came to very similar decisions about whether to skip to the next item in the instrument. The care preferences section had perfect or near-perfect IRR on all items.

Feasibility. Assessors reported that the items were easy to administer. The hearing and vision items each took about one minute to complete. Completing the cognitive section took approximately four minutes, and administering the care preferences items took six to seven minutes.

Assessor feedback. Assessors felt that both the item wording and the scoring criteria for some vision and hearing items needed clarification. There was some confusion about at what point in the assessment patients/residents should be asked the date of their most recent vision or hearing test. The confusion suggests a need to clarify the instructions, user manual, and training materials for these items.

Assessors noted some challenges in administering cognitive status items and asked for additional clarification about how to administer and score the *Trail Making Task*, the *Complex Sentence Repetition Task*, and the *Serial 7's Task*.

Assessors had two specific suggestions for improving the care preferences section. They requested wording changes to Item A4b (regarding who should be involved in making health care decisions for the patient) to make it easier for patients to understand. Second, for Items A3a–A3d ("How important is it to you to be physically active…to be mentally or intellectually involved…to be emotionally healthy…to be socially involved?"), assessors recommended collapsing the levels "not very important" and "not very important at all" because patients had difficulty distinguishing between these shades of meaning.

Category 3: Medication Reconciliation

Items in the third group, which focused solely on medication reconciliation, were being tested for the first time.

IRR. The medication reconciliation category had by far the lowest IRR of any of the items being tested. Kappas for paired assessments were below 0.3 on many items.

Feasibility. Assessors found these items challenging to complete, and they took substantially more time to complete than items in other areas: about 15 to 20 minutes, on average.

Assessor feedback. Assessors commented that the medication reconciliation items, more than any other area, required a "learning curve." They found that their ability to locate the necessary information relatively quickly and accurately improved over time. Assessors identified several opportunities for improvement, including unclear instructions for Item B1 ("Did the post-acute care provider obtain lists of current medications from more than one information source?"), the compound structure of Item B6 ("Did the post-acute care provider address all high-risk discrepancies or potential adverse drug events within…"), and insufficient information in the instructions to determine which medications would be considered high-risk in some cases. Part of the challenge for this content area was the need to look for information across multiple data sources. The data sources that were used to answer the questions varied considerably across patients, assessors, and care settings.

The items in medication reconciliation will require the most refinement in future testing. We will revise the items using the quantitative results and qualitative feedback described in this report. Specifically, revised items will focus on discrepancies between medication lists rather than potential adverse drug events, which Alpha testing found were difficult to identify without clinical judgment. Information about specific drug classes will be sought as well. As assessors gain more experience completing these items, it is likely that the time needed to complete them will decrease somewhat, and the accuracy (and therefore the IRR) may improve. We have also reduced the number of items in this content area, further reducing administration time.

In sum, the medication reconciliation items have been refined and recast into 12 patient-focused assessment items that will be retested. Details about the performance of medication reconciliation items and the changes to specific items can be found in Chapter Nine.

Conclusion

The Alpha 1 testing phase was successfully completed, in that all items were pilot tested among 133 patients. Items from all content areas were assessed on IRR and feasibility; items from some content areas were assessed on other metrics. Items have now been revised, when necessary, based on the findings of the Alpha 1 test. Alpha 2 testing is under way with the updated, revised items.

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Finally, we thank Justin Timbie of RAND and Trudy Mallinson of George Washington University for their thoughtful review of the report.

Abbreviations

BIMS	Brief Interview for Mental Status
CARE	Continuity Assessment Record and Evaluation
CMS	Centers for Medicare & Medicaid Services
EMR	electronic medical record
HHA	Home Health Agency
ICC	intracluster correlation
IMPACT	Improving Medicare Post-Acute Care Transformation
IRF	Inpatient Rehabilitation Facility
IRF-PAI	Inpatient Rehabilitation Facility–Patient Assessment Instrument
IRR	interrater reliability
LCDS	Long-Term Care Hospital Continuity Assessment Record and Evaluation Data Set
LTCH	Long-Term Care Hospital
MDS	Minimum Data Set
OASIS	Outcomes and Assessment Information Set
PAC	post-acute care
PAC PRD	Post-Acute Care Payment Reform Demonstration
pADE	potential adverse drug event
PHQ	Patient Health Questionnaire
SD	standard deviation
SME	subject-matter expert
SNF	Skilled Nursing Facility
TEP	technical expert panel

Chapter One. Background

Overview

The Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014 aims to improve post-acute care (PAC) reporting and services by requiring the collection, transmission, and reporting of standardized patient/resident assessment data across PAC settings. The intent of the Act is to facilitate care coordination and data interoperability while improving discharge planning and patient/resident outcomes for Medicare beneficiaries. The types of PAC providers covered by the IMPACT Act of 2014 are Home Health Agencies (HHAs), Inpatient Rehabilitation Facilities (IRFs), Long-Term Care Hospitals (LTCHs), and Skilled Nursing Facilities (SNFs).

The implementation of a core set of standardized items across PAC settings, facilitated by health information technology, has important implications for Medicare patients, families, providers, policymakers, and payers. At the *patient/resident* level, standardized items promote the collection of high-quality, reliable information important for achieving person-centered outcomes and goals, guiding choice of PAC providers, and improving assessment and care coordination. Item standardization can help support seamless care transitions by allowing meaningful, clinically relevant information that travels with patients/residents as they move from one care setting to the next. At the *provider* level, standardization enhances data exchangeability and improves the efficiency of data sharing. Data that are reusable, informative, interoperable, and consistent across care settings can help providers make optimal discharge placements from acute care, thus improving transitions to PAC settings. At the *national* level, standardized items make it possible to measure and compare quality, outcomes, patient/resident acuity, and resource use longitudinally and consistently across PAC settings, thus guiding policies and PAC payment reform based on patient/resident populations. Ultimately, standardized assessment across PAC settings will help promote efficiency and a focus on patient-centered care while improving Medicare beneficiaries' long-term outcomes.

Approach

The goal of the project is to identify and develop standardized items for implementation in the PAC patient assessment instruments. The major contract activities are

- information gathering for item development and consensus building (literature review and stakeholder input, e.g., technical expert panels [TEPs] and focus groups)
- pilot (Alpha) testing
- national (Beta) testing.

The portion of the IMPACT Act that pertains to this report is Section 2(a), which requires the Centers for Medicare & Medicaid Services (CMS) to develop, implement, and maintain standardized patient/resident assessment items for PAC settings, which are to be nested within the four existing PAC

assessment instruments. Each instrument will continue to have unique items selected for their special relevance to that setting; however, the IMPACT Act of 2014 mandates, at a minimum, standardized items within each of five specified clinical assessment domains:

- functional status, such as mobility and self-care
- cognitive function and mental status
- special services, treatments, and interventions (e.g., need for ventilator, dialysis, chemotherapy, and total parenteral nutrition)
- medical conditions and comorbidities (e.g., diabetes, heart failure, and pressure ulcers)
- impairments (e.g., incontinence; impaired ability to hear, see, or swallow).

The RAND Corporation examined several content areas within the categories and domains specified in the IMPACT Act. In consultation with CMS, we selected these content areas because they would help meet the mandate of the IMPACT Act while also having high potential, if implemented, to support harm prevention, cost reduction, and improved patient/resident and family experiences. To initiate this work, RAND established the following content area–specific work teams:

- impairments: vision and hearing
- cognition and mental status: cognitive status
- cognition and mental status: depressed mood
- medical conditions: pain
- care preferences
- medication reconciliation
- impairments: bladder and bowel continence.

In addition, we established a cross-category work team to address workflow, interoperability, and care transitions. Each work team was led by RAND researchers and included clinicians and academic researchers with expertise in PAC settings as advisers. RAND staff led the research activities but actively collaborated with clinical and academic advisers on an ongoing basis.

Work teams were overseen by project leadership. The RAND project team was led by Project Director Maria Orlando Edelen, Ph.D. (RAND), and Project Co-Director Barbara Gage, Ph.D. (George Washington University), with clinical content support from Debra Saliba, M.D., M.P.H. (RAND). The Lead Statistician in this effort was Susan Paddock, Ph.D. (RAND). Sangeeta Ahluwalia, Ph.D. (RAND) led assessor training, and Emily Chen, Ph.D. (RAND) coordinated key stakeholder activities, such as TEPs and public comment.

Alpha 1 Feasibility Testing

This report summarizes the results of the first Alpha 1 feasibility test, a field test of the feasibility of a proposed set of items for measuring each of the seven identified content areas of health status for Medicare beneficiaries (i.e., vision and hearing, cognitive status, depressed mood, pain, care preferences, medication reconciliation, and bladder and bowel continence). Feasibility tests have circumscribed aims, in that they do not typically have sufficient statistical power to support hypothesis

testing. The major goals of a feasibility test are to assess the feasibility of the proposed items and to identify opportunities to improve them based on feedback.

Candidate items were identified through an environmental scan, which included a literature review, input from the clinical communities serving the PAC populations, and a TEP. This field test is one of two Alpha tests that will be conducted by mid-2017 to test the feasibility of proposed items. The results of this Alpha 1 test, together with the forthcoming Alpha 2 test, will inform a national Beta test to measure item performance when used in any of the four PAC settings: LTCHs, IRFs, SNFs, and HHAs. Unlike Alpha feasibility testing, Beta testing involves a much larger sample size, as the intent is to provide sufficient power for hypothesis testing and for more-precise estimates of item performance.

Previous Testing of Some Items

The Alpha 1 feasibility test was focused on gathering information about items that had not previously been tested across PAC settings. One prior study that evaluated the performance of many items that CMS is considering as candidates for cross-PAC standardization was the Post-Acute Care Payment Reform Demonstration (PAC PRD). The PAC PRD, authorized by the Deficit Reduction Act of 2005, was a first step toward harmonizing items across PAC settings. In the PAC PRD, Congress directed CMS to address the relative costliness and outcomes of similar types of Medicare beneficiaries discharged to different PAC settings. As part of meeting this objective, the Demonstration developed a uniform patient assessment instrument, called the Continuity Assessment Record and Evaluation (CARE) tool, to collect data on the medical, functional, and cognitive status of patients at admission or discharge from a PAC setting. The CARE tool was tested across PAC settings in over 200 providers in 11 geographically diverse markets, resulting in 455 patient assessments that formed the basis for robust interrater and cross-setting reliability estimates for most items in the CARE tool.

Some items that were present in the CARE tool, and were therefore tested during the PAC PRD, were also included in this Alpha 1 feasibility test—not to test them again, since their reliability and validity had already been established, but to provide context for other items being tested. For example, the Alpha 1 feasibility test included an item (Item D2b) asking about a vision exam in patients with severely diminished vision. We accordingly included an item to first assess whether vision was, in fact, diminished (Item D2a), which had already been validated during the PAC PRD. Similarly, we wanted to assess whether patients/residents who scored below a certain threshold on the Brief Interview for Mental Status (BIMS) could skip three proposed cognitive items (Items F5, F6, and F7, the *Trail Making*, *Serial 7's*, and *Complex Sentence Repetition* Tasks, respectively). If patients scoring below a certain threshold on the BIMS were uniformly unable to complete these cognitive items, then such patients could skip them, potentially streamlining testing. However, if some patients were able to complete these items despite having a low BIMS score, then it would be necessary for all patients to complete them.

Items that were previously validated during the PAC PRD are clearly identified as such when they are introduced in the text. For such items, we do not report information about their performance as we do with the items that are being tested as part of the Alpha 1 feasibility study. Instead, these items are used to provide context about how to interpret the items that are being tested.

Organization of This Report

The remainder of this report is organized as follows:

- Chapter Two presents the methods RAND used to conduct the Alpha 1 feasibility test and collect data.
- Chapter Three presents an overview of analytic methods and results from the feasibility test.
- Chapters Four through Ten focus, respectively, on the analysis methods and results for each of the seven content areas: vision and hearing; cognitive status; depressed mood; pain; care preferences; medication reconciliation; and bladder and bowel continence. For each content area, we begin with a brief description of the items and summarize the testing objectives and analytic approach.
- Chapter Eleven presents general feedback from the assessors across the seven content areas.

Chapter Two. Data Collection Methods

In this chapter, we describe the methods used in conducting the Alpha 1 feasibility test. The chapter is divided into eight sections: (1) Information Gathering; (2) Selection and Development of Items for Testing; (3) Market and Facility Selection and Recruitment; (4) Feasibility Test Assessor Training; (5) Data Collection; (6) Help Desk; (7) Monitoring; and (8) Data Security.

Additional information relevant to the methods discussed in this chapter can be found in Appendixes A and B.

Information Gathering

We conducted four main information-gathering activities: literature review, focus groups, the TEP, and meetings with federal subject-matter experts (SMEs). Detailed information about the methods of and findings from these information-gathering activities can be found in our earlier report.[1]

Literature Review and Identification of Items

We conducted a literature review for each content area to identify key articles regarding current or potential items for each topic area. To guide the review, each work team developed an organizing framework to describe the focus, context, and potential impact of standardized cross-setting assessment for its category.

Work teams also identified candidate items for use in PAC settings. These items were categorized as follows:

- *current items*, which are used in one or more of the four existing PAC assessments
- *interim items*, which have been tested in each of the four PAC settings and can be moved forward into implementation on a relatively rapid time line
- *ideal items*, which have not yet been implemented across PAC settings but have desirable characteristics that would support their use across PAC settings (e.g., support person-centered high-quality care, improve information transfer during care transitions, allow for reusable data, promote interoperability).

Focus Groups

RAND conducted multidisciplinary provider focus groups that included physicians, advanced practice nurses, registered nurses, physical and occupational therapists, speech and language pathologists, pharmacists, social workers, and chaplains who represented each of the four PAC settings. In addition, we conducted one consumer focus group for current or former PAC patients/residents,

[1] RAND Corporation, *Technical Expert Panel Summary/Expert Input Report: Development and Maintenance of Post-Acute Care Cross-Setting Standardized Patient Assessment Data*, Santa Monica, Calif.: RAND Corporation, June 2016.

caregivers, ombudsmen, and patient advocacy group representatives. Each focus group consisted of seven to 11 participants who met in person for approximately five hours of facilitated discussion. Participants were selected to achieve diversity across disciplines, geographic locations, experience in rural and urban settings, and to balance representation of facilities or agencies based on affiliation and profit status.

Technical Expert Panel

RAND convened a 16-member TEP on April 7 and 8, 2016, in Baltimore, Maryland, to provide input on current, interim, and ideal items and feedback on the strengths of and barriers to PAC data-item standardization. TEP members were selected for their expertise in PAC settings and to ensure balanced representation of individual disciplines, experience, and PAC settings. At the TEP meeting, members participated in discussions and rated potential items.

Meeting with Federal Subject-Matter Experts

On May 13, 2016, CMS convened a six-hour in-person and teleconference meeting with federal agency SMEs, CMS staff overseeing RAND's contract, and RAND's research team. The meeting included presentations by RAND on findings from the literature review, feedback from the TEP, themes identified in the focus groups, and proposed next steps.

Explanation of Hierarchy of Items

Before describing the development of items for Alpha 1 testing, it is important to explain the hierarchical organization of items. Individual *items* are at the bottom of the hierarchy. *Item clusters* refer to items that are closely related thematically: These items can be identified based on their grouped numbering, such as items F4a, F4b, and F4c. These three items, which refer to whether the patient recalled three words, form an item cluster. Not all items can be grouped into item clusters; some items stand alone. Finally, all the items covering a single broad topic (cognitive testing, bladder and bowel function, etc.) are termed a *content area*.

Selection and Development of Items for Testing

Based on the information-gathering activities, CMS, clinical advisers, and work teams identified a set of items for consideration as potential candidates for standardization. Prior to finalization for Alpha 1 feasibility testing, RAND conducted 24 cognitive interviews for newly developed care preferences, pain, and medication reconciliation items with PAC provider staff (for medication reconciliation) and patients/residents (for care preferences and pain). PAC provider staff interviewees provided services to the four PAC settings, and patient/resident interviews were conducted at three PAC settings: SNFs, IRFs, and LTCHs.

During the cognitive interviews, respondents were administered the items and asked to provide a response. Follow-up questions were then asked to gauge why respondents answered in the way they did, what they understood about the question, and what difficulties, if any, they faced in answering the

question. After the medication reconciliation cognitive interviews were complete, results were analyzed and summarized for the clinical advisers. For the care preferences and pain items, the research team content area leads, survey research experts, and interviewers met after each day of testing to review any problems identified with the items during the interviews and revised the items accordingly. Category leads also worked with their clinical advisers to make revisions. These revisions were tested in the subsequent interviews to see if the identified issues had been resolved. Information from cognitive interviews was used to improve the wording, structure, and response choices of proposed items and to reduce burden prior to Alpha 1 testing. The items tested in Alpha 1 were

- six items or item clusters within the vision and hearing area
- five items or item clusters within cognitive status
- one item cluster within depressed mood
- six items or item clusters within pain
- four items or item clusters within care preferences
- 12 items or item clusters within medication reconciliation
- eight items or item clusters within bladder and bowel continence.

A summary table of the origins and history of the items can be found in Appendix C. For each group of items, this table covers whether the items are currently in use, and, if so, in which PAC settings; what evidence exists for the feasibility and reliability/validity of the items; and how the items were altered for our Alpha 1 test, if at all.

Market and Facility Selection and Recruitment

Data collection occurred at 12 community-based care providers, three from each setting (SNF, HHA, IRF, and LTCH). Data were collected by two types of assessors: facility staff (who deliver direct care at the facility) and research nurses (who were hired by the evaluation effort to collect data). While RAND was in charge of item design and the analysis of results, the data collection portion of the Alpha 1 test also involved two subcontractors: Abt Associates ("Abt") was in charge of facility recruitment and data processing, and Qualidigm led the recruitment of the research nurses and management of the coordination between research and facility data collectors.

Alpha 1 feasibility testing was conducted in one East Coast market (Hartford, Connecticut), which was selected due to the strength of the study team's connections in this region. SNFs and HHAs, which are numerous in the market, were eligible to be selected if they were within a 90-minute drive-time radius of downtown Hartford. IRFs and LTCHs, which are somewhat less common, were eligible to be selected if they were within a two-hour drive-time radius of downtown Hartford. PAC facilities also had to be large enough to ensure that the targeted number of assessments per facility for the Alpha 1 test could be achieved; specifically, IRFs and LTCHs with at least 100 discharges annually, SNFs with at least 100 annual total stays, and HHAs with at least 100 episodes annually met this criterion.

Within the Hartford market, 20 eligible providers across the four types (LTCH, IRF, SNF, and HHA) were randomly selected from Medicare administrative files for potential recruitment. LTCH facilities were pulled from the fiscal year 2016 LTCH Final Rule Impact File; IRF facilities were

identified using the fiscal year 2016 IRF Patient Assessment Instrument Final Rule Impact File; and SNF and HHA facilities were identified from CMS's 2016 utilization and payment public use files, with data covering calendar year 2013.[2]

From this random selection of 20 facilities, Abt recruited two SNFs, two HHAs, two LTCHs, and two IRFs. Fifteen double-coded assessments were targeted per facility, or 120 assessments total. Although assessing feasibility of collecting data on the items was a primary goal of Alpha 1, we note that having 120 assessments total would allow for testing with 80 percent power (alpha = 0.05 level) whether intracluster correlations (ICCs) of ordinal and continuous items indicated relatively high (ICC = 0.70) versus low (ICC = 0.40) reliability. We would have similar power to explore whether dichotomous items were relatively more reliably assessed (e.g., kappa = 0.7 or 0.8) versus less reliably assessed (e.g., kappa = 0.40). Of the eight facilities recruited, seven were using an electronic medical record (EMR) at the time of the assessment, while one was not. Upon CMS's approval of the recruitment materials, Abt mailed a letter and fact sheet to the major provider associations requesting that the organizations pass along the information to their members. Prior to the mailing, RAND reached out to the provider associations by telephone to personally request their support of the project. Approximately two days after the mailing of the letter and fact sheet, Abt sent the letter, fact sheet, and invitation to participate to selected PAC providers. Abt staff then called each PAC provider to answer questions and arrange for a convenient time for a conference call to discuss the field test.

Feasibility Test Assessor Training

To prepare for feasibility testing of the proposed Alpha 1 items, RAND convened a weeklong training of research nurses using a Train-the-Trainer model. The research nurses were trained on the assessment of the proposed items, data collection procedures, and the training method itself. Upon completion of the Train-the-Trainer session, the research nurses led subsequent training of facility staff from facilities and agencies in the test market participating in Alpha 1 data collection.

In addition to training, RAND created a user manual to accompany the Alpha 1 data collection instrument, which specified how the items were to be collected and scored. This user manual was based largely on similar materials that had accompanied the items upon which the Alpha 1 items had been based; for new items, user manual material was written de novo. Revision of this user manual, based upon feedback and results, has continued into the Alpha 2 and Beta testing phases.

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[2] The 2016 LTCH Final Rule Impact File contains data on all IRFs used to examine the impacts of annual changes in the payment system. See CMS, "Data Files," web page, September 15, 2016. The 2016 Inpatient Rehabilitation Facility–Patient Assessment Instrument (IRF-PAI) Final Rule Impact File contains data on all LTCHs used to examine the impacts of annual changes in the LTCH Prospective Payment Systems. See CMS, "Long-Term Care Hospital PPS," web page, August 17, 2015a. For the 2013 data, see CMS, "Utilization and Payment Public Use Files on Home Health Agencies for Calendar Year 2013," web page, 2013a; CMS, "Utilization and Payment Public Use Files on Skilled Nursing Facilities for Calendar Year 2013," web page, 2013b.

Research Nurse Selection and Training

Data collection for the feasibility test was conducted by both the research nurses and participating staff at the test facilities and agencies to evaluate interrater reliability (IRR). Qualidigm recruited four nurses (unaffiliated with the test facilities and agencies) from the Hartford area to serve as the feasibility test research nurses. Qualidigm identified qualified nurses for consideration through LinkedIn, professional trade groups and associations, and its own extensive database. There were two primary criteria for selection of research nurse participants: (1) the nurse must have worked in at least one of the four PAC settings (SNF, HHA, IRF, or LTCH), and (2) the nurse must have direct experience administering and completing the relevant assessment tool for that setting:

- SNF: the Minimum Data Set (MDS) 3.0
- HHA: Outcomes and Assessment Information Set (OASIS-C-1/ICD-10)
- IRF: IRF-PAI
- LTCH: LTCH CARE Data Set (LCDS) v3.00).

The four selected research nurses were based within a 90-minute driving distance of Hartford.

To prepare the research nurses to administer the Alpha 1 assessment and train facility staff from participating facilities and agencies for the feasibility test, a Train-the-Trainer session was held at RAND's office in Santa Monica, California, on July 25 through 29, 2016. Category leads at RAND, under the direction of Sangeeta Ahluwalia and in close partnership with their clinical advisers, developed all necessary training materials and exercises pertaining to the Alpha 1 test items. All training materials were also reviewed by the project's workforce advisory team and CMS, who provided guidance on setting-specific issues that were addressed in the instruction manual and training, and by our project leadership team.

During the five-day Train-the-Trainer session, the four research nurses were provided with two days of classroom presentations related to the proposed items and practice exercises designed to increase research nurses' comfort level and confidence with administering the items. Two days were dedicated to local facility visits, where research nurses were able to practice administering the items with patients, and debriefing with each other to understand and address potential challenges with data collection, especially as they differed across setting types. A final day was devoted to continued debriefing and a structured Questions and Answers session, as well as a Train-the-Trainer module, where research nurses received training and practice on how to train facility staff on the proposed items and the Alpha 1 data-collection process. During the training, assessors were instructed to code the responses completely independently and to not compare their records even after the exercise was completed. Despite this instruction, it is possible that some co-raters were influenced by one another, and this limitation should be taken into consideration when interpreting results of kappa tests, which assume independence of raters.

The research nurse training was led by RAND staff members, with clinical experts providing support on content area–specific presentations. For example, a clinical adviser presented the training module on candidate items for medication reconciliation. Members of RAND's workflow and content area advisory teams also attended to supplement the training and address workflow questions. These advisers also

accompanied the research nurses on practice data collection facility visits, guiding the process, providing constructive feedback to the research nurses, and collecting valuable information pertaining to workflow that was incorporated into the user manual and accompanying materials. Members of the RAND Survey Research Group led presentations and exercises on data confidentiality and safeguarding, scientific misconduct, general interviewing skills, and training approaches for the research nurses to deploy during the facility staff training.

Facility Staff Training

Upon completion of the Train-the-Trainer session, the four research nurses returned to Hartford to train staff from participating facilities and agencies on the items for the Alpha 1 feasibility test. The eight-hour facility staff training occurred on August 17, 2016, in Wethersfield, Connecticut. A dry run of the facility staff training occurred on August 16 to provide the research nurses with additional practice presenting their assigned sections, with several RAND project leaders and staff also in attendance to provide support.

Facility staff participants included up to three staff members from each participating Alpha 1 test facility. A total of 17 staff participants attended the training. The primary criterion for the selection of facility staff was that they must have direct experience administering and completing the relevant assessment tool for at least one of the four PAC settings (see the list of assessment tools in the "Research Nurse Selection and Training" section).

The facility staff training began with an introduction to the project goals and objectives, and a detailed review of the Alpha 1 test assessment tool and accompanying user manual. After reviewing Alpha 1 test materials, the research nurses took turns presenting on general interviewing procedures and data confidentiality, safeguarding, and quality control. Subsequent presentations focused on the proposed items with the aim of increasing facility staff comfort levels and confidence in administering the Alpha 1 assessment tool. There was a dedicated presentation for each content area, including coding examples, and opportunity was provided for the facility staff to practice administering the items. The facility staff training ended with an overview of the Alpha 1 feasibility test data-collection procedures, to be implemented when staff members returned to their home facilities and agencies.

Data Collection

The Alpha 1 data collection took place from August to October 2016. Research nurses were given full access to the medical records at each site prior to the start of data collection, most commonly in the form of "surveyor" access, where the full record was readable but not editable. Facility staff at each site worked with the research nurses to provide them with the necessary orientation to that site's records systems. The data-collection target was 15 completed assessments from each of the eight participating PAC providers (two providers for each of the four PAC settings), or a total of 120 assessments. To be eligible for the Alpha 1 test, a patient/resident must have been admitted to the facility under a new Medicare Part A covered admission. Transfers out for less than three days and resumptions of care were not considered a new Medicare admission and were thus excluded. Patients/residents who were unable

to communicate (verbally or otherwise) were also excluded, because of the need to test direct patient/resident interview items. Research nurses worked with the facility staff at each provider location to identify eligible patients/residents to be included in testing.

A final total of 125 assessments were completed by the end of the data-collection period, with four additional assessments (19 total) conducted at a single IRF and one additional assessment (16 total) conducted at a single LTCH. Two of the test facilities or agencies had delays in initiating data collection due to internal factors such as existing workload, competing regulatory priorities, and staff availability; one SNF completed its first Alpha 1 assessment in Week Five of the data-collection period, and one HHA completed its first Alpha 1 assessment in Week Six. Both sites caught up on their data collection by Week Seven, with seven assessments completed at the SNF and nine assessments completed at the HHA. By the end of the data-collection period, all sites had completed the required 15 assessments. The Alpha 1 assessment protocol can be found in Appendix A.

As noted above, to evaluate IRR, two assessment forms were completed for each participating patient/resident, one by the research nurse and one by the facility staff. One assessor communicated interview questions to the patient/resident while both the research nurse and the facility or agency staff member coded responses. Cue cards, listing response options in large text on a single page, were shown to the patient/resident after each interview question. At the end of each day of data collection, each research nurse collected all the completed forms from the facility staff and placed them in a secure location (a locked storage container provided by Qualidigm). At the end of each week of data collection, the research nurse used the photocopier at the appropriate PAC provider to make a copy of each assessment form. The original paper assessment forms were kept in a secure storage container during the data-collection period, and copies were sent to Abt via FedEx, using pre-addressed shipping envelopes that were provided by RAND to ensure that shipments could be tracked. Upon receipt of the assessment forms, the Abt data manager reviewed each form for legibility and completeness of administrative information (e.g., assessment identification number clearly written on the top of each page; all pages of the form submitted). The Abt data manager notified Qualidigm via email about any issues with received assessment forms, and Qualidigm was responsible for communicating with the research nurses to obtain any unclear information. In only one instance was unclear information received—the assessment identification number was incorrectly written at the top of one page of the assessment form in question. The matter was resolved within a 48-hour time frame through direct contact with the research nurse, who was able to confirm the correct assessment number.

The Abt data manager scanned completed paper assessment forms on an Abt scanner and uploaded the output to Abt's secure file transport server, where staff from Abt's survey subsidiary, SRBI, accessed the forms. Research nurses retained the original paper assessment forms in a locked storage container until notified by Qualidigm that the forms had been reviewed, deemed complete and legible, and successfully uploaded to the Abt secure server. At that time, the research nurses sent the completed forms to Qualidigm via FedEx for their secure destruction. Qualidigm staff documented the receipt of each assessment number in a database, after which the forms were shredded using Infoshred, a secure shredding service.

Debrief Interviews

A critical part of evaluating the candidate items during the feasibility test was a structured debrief interview conducted by RAND staff to gather information from the assessors (i.e., both research nurses and the facility staff) to understand their general experience of administering the assessment, including the clarity of the assessment materials (e.g., instruction manuals and assessment form); ease of use; the ability of patients/residents to understand the questions; nurse and facility staff level of comfort in asking the questions; and potential challenges to assessment administration. This information was collected by RAND during three postassessment debrief interviews of research nurses and two debrief interviews of facility staff involved in the Alpha 1 feasibility test. Research nurse interviews were conducted at the end of Week Two of data collection, at the end of Week Five, and after data collection was completed; facility staff interviews were conducted at the end of Weeks Three and Seven. The interviews were conducted at various points throughout the data-collection period to ensure the team's ability to identify and address early challenges and to learn about challenges that persisted throughout data collection or that came up as data collection progressed. Telephone interviews were conducted in groups and were led by a trained qualitative research facilitator. The assessor feedback interview protocol can be found in Appendix B.

Help Desk

RAND established a help desk website at the outset of the feasibility test to provide assistance to the research nurses and facility staff data collectors. This website allowed the research nurses to submit questions pertaining to the data-collection process (which could originate from the nurses directly or from the facility staff communicating questions or issues to the nurses) and receive a response within 24 hours. Submitted questions were received by RAND project support staff, triaged to the appropriate project team member, and addressed as appropriate. Submitted questions and their responses were cataloged by RAND, incorporated into a Frequently Asked Questions document, and reviewed with the research nurses during weekly monitoring calls led by RAND and Qualidigm (see the next section on "Monitoring"). The help desk website also provided links to data-collection resource materials, including copies of the forms, the data-collection manual, data management tools, and contact information for each of the research nurses. A total of 14 questions were submitted to the help desk; many other questions were discussed during weekly conference calls with the research nurses and the research team, and therefore research nurses may not have felt a need to submit them to the formal help desk.

Monitoring

RAND monitored the data-collection process throughout the Alpha 1 feasibility testing. Weekly monitoring calls between RAND, Qualidigm, and research nurses were held to discuss progress, address problems arising during data collection, and make clarifications to the data-collection process as needed. Research nurses kept a detailed tracking sheet of completed assessments, which was shared with RAND

and Qualidigm during the weekly monitoring calls and also reported out to CMS at weekly meetings. Weekly conference calls were also held between RAND, Abt, and Qualidigm project staff to evaluate progress of data collection and review the status of assessment forms received (incomplete or illegible, complete, uploaded, and ready for shredding).

Data Security

All research nurses abided by data security requirements and complied with all procedures and processes in the collection, storage, and transport of any confidential data collected. All research nurses and research staff working on this project had undergone Collaborative Institutional Training Initiative training on conducting human subjects research and confidentiality and were asked to sign a Confidentiality Acknowledgement, which was kept on file by RAND and provided to each participating facility or agency before any research nurses visited the premises. All research nurses were required to carry a copy of the study-specific data safeguarding plan as well as a copy of the signed confidentiality agreement when visiting each facility or agency. As part of the confidentiality agreement, all research nurses and research staff working on this study agreed not to transfer any confidential data to any outside parties without the express written permission of CMS.

Analytic File Creation

Abt SRBI entered all completed assessment data into an Access database that could be converted to SAS. When data entry was completed, the data file was uploaded to the secure server for RAND to access. On a monthly basis, a preliminary file was shared with RAND to allow detection of any major problems with individual items.

Chapter Three. Analytic Methods and Results

In this chapter, we provide a brief overview of the results that will be discussed in more detail in Chapters Four through Ten. While each of those chapters includes a description of the methods used for the specific item, in this chapter we also provide an overview of the approach used across items to assess IRR and feasibility of administration.

Methods Used to Assess Interrater Reliability and Feasibility of Administration

For all of the content areas, there were at least two goals for the Alpha 1 assessment: to assess IRR and to assess the feasibility of administering the items. Within each chapter, IRR is always presented as Goal 1, and feasibility as Goal 2. For these two goals, we used a similar approach for all items. Some content areas had other goals for assessment, such as the fidelity with which skip patterns were followed and whether the information sources used to complete the items differed among assessors. When other goals were present, they are identified as Goals 3 and higher for that content area.

Interrater Reliability

To determine whether items could be completed with acceptable IRR, for each item we calculated the level of agreement between paired assessors' judgments (research nurse and facility staff assessors). We used Cohen's kappa for the categorical variables and weighted kappa for the ordinal variables.

Feasibility of Administration

To evaluate the feasibility of administration, we examined the time spent to complete the items (provided via nurse and staff self-report of the start and end times for each section as an estimate of the number of minutes to complete each section), and calculated the number of cases in which the research nurse and/or facility staff left the item missing or indicated "Unable to assess/no response." We also relied on what nurses told us when prompted during the debriefing interview to discuss the clarity of definitions and instructions.

Variation Across Settings

To investigate setting-by-setting variation in the reliability and ease of administration of the items, we calculated all statistics by setting as well as across the four settings. In most cases, we lacked sufficient sample size to systematically perform statistical hypothesis testing, which is not a goal of feasibility testing, as explained in Chapter One. In evaluating the feedback that nurses provided during the debriefing interviews, we attempted to discern whether setting differences were evident. Further details on the specific methods used are given in the relevant methods section for each content area.

Methods Used to Analyze Debriefing Interview Feedback

Detailed notes from the debriefing interviews were analyzed from a content-oriented perspective. Common themes and key issues were identified when either multiple assessors commented that they had a similar experience, or it seemed likely that an issue noted by one nurse could recur and noticeably affect the assessment. Comments were initially categorized by the assessment category they addressed or as pertaining to the assessment as a whole. For some of these categories, comments were further subdivided, such as by data element or item, patient factors, and suggestions for training. When examples were available from the debriefing interviews, they were included in the summaries to further illustrate comments.

Number of Completed Assessments

The entire assessment protocol was completed for a total of 133 patients: 37 for the HHA setting, 34 for IRF, 31 for LTCH, and 31 for SNF. All patients were double-assessed (by a facility nurse and a research nurse) to allow for calculation of IRRs.

Results by Category

In general, the Alpha 1 pilot testing of the items demonstrated that many of the items performed acceptably in terms of IRR and feasibility. This result pertains mainly to those items that have already been used and validated in PAC over decades. However, some newer items seem to be in need of additional clarification and refinement to achieve acceptable performance.

The sections below briefly describe the results for each content area and recommendations for further refinement.

Vision and Hearing

Vision and hearing items showed moderate to excellent IRR and were generally feasible to administer. Assessors commented on a need to clarify coding instructions for some items.

Next Steps

- Item instructions on the assessment form will be revised for these items to clarify the assessment protocol and rating criteria.
- Training materials and the user manual for these items will also be revised to improve clarity.

Cognitive Status

Assessors noted some challenges in administering these items and asked for additional clarification about how to administer and score the *Trail Making Task*, the *Complex Sentence Repetition Task*, and the *Serial 7's Task*. Assessors also achieved a high degree of uniformity regarding which items to skip. Cognitive status items took approximately four minutes to administer, while the BIMS took an additional 3.4 minutes.

Next Steps

- Provide additional clarification about how to administer and score the *Trail Making Task*, the *Complex Sentence Repetition Task*, and the *Serial 7's Task*.
- Due to the assessment challenges for both patients/residents and assessors, these items may be reduced or replaced.

Depressed Mood

Mood items generally showed excellent IRR and were highly feasible to administer. Assessors achieved a high degree of uniformity regarding which items to skip.

Next Steps

- We will provide additional training on how to score the Patient Health Questionnaire (PHQ)-2 and the PHQ-9.

Pain

Pain interview items achieved a high IRR and were highly feasible to administer.

Next Steps

- The pain interview items performed well and do not appear to require any further changes.

Care Preferences

Care preferences items achieved a high IRR and were feasible to administer. Care preferences took between six and seven minutes to administer, making it the second-most time-consuming content area.

Next Steps

- Assessors suggested that Item A4b ("Which of the following statements best describes the way in which you would like decisions about your health care to be made?") be reworded. Upon further review, and noting substantial overlap with one of the other items in Care Preferences, we decided to remove this item rather than revise it.
- For items A3a–3d ("How important is it to you to be physically active…mentally or intellectually involved…emotionally healthy…socially involved?"), assessors recommended collapsing the levels "not very important" and "not important at all," because patients/residents had difficulty understanding the distinction. We chose to retain both response levels, because this format has been widely used for many years across many settings.

Medication Reconciliation

Medication reconciliation items raised more issues regarding IRR than any other content area, with most items having kappas below 0.3 between paired assessments. Assessors found these items challenging to complete, and the time required for administration was the longest of any content area (between 15 and 20 minutes). Assessors identified several items that needed clarification of instructions or editing of item wording. Some of these findings can be explained by the facts that these items are

being tested for the first time here, and that medication reconciliation is an inherently complex topic. The items in this content area will require the most refinement in future rounds of testing.

Next Steps

- Clarify instructions for Item B1 ("Did the post-acute care provider obtain lists of current medications from more than one information source?").
- Item B6 ("Did the post-acute care provider address all high-risk discrepancies or potential adverse drug events within…") was noted to have a compound structure (asks two separate questions) and was therefore modified for Alpha 2 testing (it no longer asks about potential adverse drug events).
- Provide additional information to facilitate assessors' applying the Beers Criteria, a widely used set of criteria for identifying potentially inappropriate medications for elderly people.

Bladder and Bowel Continence

Bladder and bowel continence items generally achieved high IRR, although it should be noted that some of these items are not applicable to a majority of patients. Assessors felt that these items were straightforward and feasible to administer. Assessors achieved a high degree of agreement on which items to skip.

Next Steps

- Some assessors commented that patients may not understand the word "continence." In response to these comments, we added suggested language to the user manual that should be used when discussing bladder and bowel continence with patients/residents (i.e., "accidental leakage"; "bladder or bowel accidents").
- We provided additional guidance about how to score these items when patient and family accounts of continence do not match.

Chapter Four. Results for Vision and Hearing

This is the first of seven chapters that report on the results of the Alpha 1 feasibility test by content area. This chapter focuses on the vision and hearing items.

Sensory limitations can contribute to confusion in new settings, increase isolation, exacerbate mood disorders, and impede accurate assessment of other medical conditions, such as cognitive impairment.[1] Assessments of vision and hearing have several potential benefits: PAC patients/residents who have a sensory impairment and receive the appropriate intervention have a decreased risk of falls,[2] fewer disruptive behaviors and depressive symptoms,[3] increased mobility and sociability, and improved ability to communicate. Improving documentation of sensory impairments also has the potential to improve rehabilitation outcomes and care transitions for PAC patients/residents, including transition from a PAC setting to the community.

This chapter begins by describing the vision and hearing items and provides a description of the testing objectives and analytic approach. We then provide results from the feasibility test and end with a brief summary.

Description of Items

The vision and hearing items can be found in Appendix A, Sections D and E. The items in this content area assess (1) vision and hearing impairments (included for context only; not evaluated for feasibility); (2) date of most recent testing for sensory impairments among those severely impaired; and (3) use of vision or hearing aids among patients/residents in PAC settings. Assessors may utilize multiple sources of information for each of these items, including review of the patient/resident chart, staff observations, patient/resident response, and conversation with the family or caregiver.

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[1] Vincent A. Campbell, John E. Crews, David G. Moriarty, Matthew M. Zack, and Donald K. Blackman, "Surveillance for Sensory Impairment, Activity Limitation, and Health-Related Quality of Life Among Older Adults—United States, 1993–1997," *MMWR Surveillance Summaries*, Vol. 48, No. 8, December 17, 1999; Piers Dawes, Richard Emsley, Karen J. Cruickshanks, David R. Moore, Heather Fortnum, Mark Edmondson-Jones, Abby McCormack, and Kevin J. Munro, "Hearing Loss and Cognition: The Role of Hearing Aids, Social Isolation and Depression," *PLOS One*, Vol. 10, No. 3, 2015; William J. Strawbridge, Margaret I. Wallhagen, Sarah J. Shema, and George A. Kaplan, "Negative Consequences of Hearing Impairment in Old Age: A Longitudinal Analysis," *Gerontologist*, Vol. 40, No. 3, 2000.

[2] Rebecca Q. Ivers, Robyn Norton, Robert G. Cumming, Meg Butler, and A. John Campbell, "Visual Impairment and Risk of Hip Fracture," *American Journal of Epidemiology*, Vol. 152, No. 7, 2000; Ellen E. Freeman, Beatriz Muñoz, Gary Rubin, and Sheila K. West, "Visual Field Loss Increases the Risk of Falls in Older Adults: The Salisbury Eye Evaluation," *Investigate Ophthalmolology and Visual Science*, Vol. 48, No. 10, 2007.

[3] Barry W. Rovner and Mary Ganguli, "Depression and Disability Associated with Impaired Vision: The MoVIES Project," *Journal of the American Geriatric Society*, Vol. 46, No. 5, 1998.

Vision Items

For vision, the first item assesses whether the patient/resident regularly uses glasses or other corrective lenses. The second item assesses the patient's/resident's ability to see in adequate light and was tested in the PAC PRD; as such, it was included in testing for context only, and results are not presented here. The third item asks the assessor to document the date of the last vision test by an optometrist or health care professional if the patient's/resident's *Ability to See* was coded as *severely impaired*.

Hearing Items

The hearing items follow a similar pattern, starting with an assessment of whether the patient/resident uses a hearing aid regularly. The second item assesses the patient's/resident's ability to hear with a hearing aid or hearing appliance and was tested in the PAC PRD; as such, it was included in testing for context only, and results are not presented here. Finally, the third item documents the date of the last hearing test by an audiologist or health care professional if the patient's/resident's *Ability to Hear* was coded as *severely impaired*.

Testing Objectives and Analytic Approach

Our main objectives in testing the vision and hearing items were (Goal 1) to determine whether the items could be completed with acceptable IRR, and (Goal 2) to evaluate the feasibility of administration of items. To accomplish Goal 1, we calculated the level of agreement between paired assessors' judgments about each item. IRR was calculated for each item. To accomplish Goal 2, we examined the time spent to complete the items for vision and hearing, and calculated the number of cases in which the research nurse assessor and facility staff left the item missing or indicated "Unable to assess/no response." We also relied on what nurses told us during the debriefing interview when prompted to discuss the clarity of definitions and instructions.

Results

IRR was moderate to high for vision and hearing items across a total of 133 pairs of observations (see Table 4.1). The highest reliability was recorded for use versus non-use of a hearing aid (overall Cohen's kappa = 0.92), while reliability was somewhat lower for use versus non-use of glasses (0.69).

Table 4.1. Interrater Reliability of Vision and Hearing Items

	Setting				
Item Content	**HHA (N = 37)**	**IRF (N = 34)**	**LTCH (N = 31)**	**SNF (N = 31)**	**Overall (N = 133)**
Use of glasses (D1)[a]	0.75	0.77	0.52	0.63	0.69
Use of hearing aid (E1)[a]	0.84	1.0	0.71	1.0	0.92

NOTE: [a]IRR assessed by Cohen's kappa.

Frequency of vision and hearing responses are broken down in Table 4.2 by assessor type and question. In general, facility staff and research nurses had similar findings in terms of binary variables, such as use of glasses (85 percent versus 86 percent overall, respectively) or use of a hearing aid (16 percent versus 17 percent, respectively). However, there was some discrepancy across assessors with respect to administration of the *Date of last vision test* and *Date of last hearing test* items for individuals who were coded as having severe impairments on *Ability to See* and *Ability to Hear,* respectively. For example, research nurses administered the *Date of last vision test* and *Date of last hearing test* items in 100 percent of instances where a patient/resident was coded as having severe vision or hearing impairment, respectively. In contrast, facility staff administered these items for 67 percent (vision test) and 0 percent (hearing test) of cases where the patient/resident was coded as having severe impairment. This suggests differential item administration and/or scoring by the two categories of assessors, and a likely need for additional training and clarification to improve scoring by facility staff. It was rare for the assessors to document ability to see and ability to hear as severely impaired and, therefore, the date of the last vision or hearing test was applicable in only a few cases.

Table 4.2. Frequency Distribution of Responses to Vision and Hearing Items, by Assessors

	HHA (N = 37)		IRF (N = 34)		LTCH (N = 31)		SNF (N = 31)		Overall (N = 133)	
Item	**R**	**F**	**R**	**F**	**R**	**F**	**R**	**F**	**R**	**F**
Use of glasses (D1)										
Answered yes (percentage)	84	76	85	85	90	87	87	93	86	85
Missing (number)	0	0	0	0	0	0	1	1	1	1
Ability to see (D2a)										
Adequate (percentage)	76	81	73	74	84	85	53	90	72	82
Mildly to moderately impaired (percentage)	22	17	27	26	16	11	47	7	27	16
Severely impaired (percentage)	3	3	0	0	0	4	0	3	1	2
Unable to assess/Unknown (number)	0	0	1	0	0	0	0	0	1	0
Missing/responses out of range (number)	0	1	1	0	0	4	1	1	2	6
Date of last vision test (D2b)										
Reported (number)	1	1	0	0	0	1	0	0	1	2
Use of hearing aid (E1)										
Answered yes (percentage)	8	11	15	15	14	16	30	30	16	17
Missing (number)	0	0	0	0	2	0	1	1	3	1
Ability to hear (E2a)										
Adequate (percentage)	59	65	67	70	65	72	33	73	56	70
Mildly to moderately impaired (percentage)	38	35	33	30	35	28	67	23	43	29

Item	HHA (N = 37)		IRF (N = 34)		LTCH (N = 31)		SNF (N = 31)		Overall (N = 133)	
	R	F	R	F	R	F	R	F	R	F
Severely impaired (percentage)	3	0	0	0	0	0	0	3	1	1
Unable to assess/Unknown (number)	0	0	0	0	0	0	0	0	0	0
Missing (number)	0	0	1	1	0	0	1	1	2	2
Date of last hearing test (E2b)										
Reported (number)	1	0	0	0	0	0	0	0	1	0

NOTES: R = research nurse. F = facility staff. *Percentage* rows tabulate responses to each item across all possible answer categories; responses sum to 100 percent. *Number* rows show the number of times each item was unknown, missing, or similar. Responses tabulated in number rows are not part of the denominator for calculating percentages.

Time spent on the vision and hearing assessment is presented in Table 4.3. While there was some variation across settings, the entire vision and hearing assessment was completed in an average of 1.6 minutes per patient.

Table 4.3. Average Time Spent (in Minutes) Completing Vision and Hearing Items, by PAC Setting

	HHA (N = 37) Mean (SD)	IRF (N = 34) Mean (SD)	LTCH (N = 31) Mean (SD)	SNF (N = 31) Mean (SD)	Overall (N = 133) Mean (SD)
By research nurse					
Vision	1.4 (1.4)	0.8 (1.1)	0.6 (0.6)	0.7 (0.8)	0.9 (1.0)
Hearing	0.6 (0.8)	0.4 (0.5)	0.4 (0.5)	0.4 (0.6)	0.4 (0.6)
By facility staff					
Vision	1.3 (1.2)	0.8 (1.1)	2.7 (11.4)	0.7 (0.8)	1.3 (5.5)
Hearing	0.6 (0.8)	0.4 (0.5)	0.4 (0.5)	0.5 (0.8)	0.5 (0.6)

NOTE: SD = standard deviation.

Feedback from Assessors

Assessors (both research nurses and facility staff) generally agreed that the vision and hearing section was clear and easy to complete. However, research nurses identified six areas for comment or recommendations that we discuss further below.

Accuracy of patient self-assessments. The most common issue raised by the research nurses regarding the vision and hearing section was that on several occasions it was difficult to determine how accurate patients' self-assessments of their vision and hearing were. They explained that some patients would say they can hear well; however, it would become apparent throughout the interview that they have difficulty hearing as they struggled to hear the interview questions. Consequently, the nurses would need to return to item E2a ("Ability to hear, with hearing aid or hearing appliance if normally used") and revise their answers. The research nurses recommended moving this section to the end of the assessment so the assessor could evaluate the patient's vision and hearing throughout the assessment and have sufficient information to code the items at the end.

Clarity of scoring rules for *Ability to See*. Research nurses said that in the user manual, the examples for when to code "mild to moderately impaired" for item D2a ("Ability to see in adequate light, with glasses or other visual appliances") are not helpful and should be improved. Although this

item was assessed in PAC PRD, the user manual could be modified in the future to improve clarity and utility for assessors.

Need for a writing sample. Research nurses also recommended that in the future, it may be useful to have a laminated writing sample (i.e., a newspaper excerpt) that assessors can keep with them to use for the vision assessment.

Need to assess whether patients have aids with them today. Another concern from the research nurses was that many patients say they use glasses or hearing aids; however, they did not have them at the time of the assessment and this information is not captured. They suggested adding an item to ask if the patients have their glasses and hearing aids with them at the time that the *Ability to Hear* and *Ability to See* items are completed. Of note, the *Hearing, Speech, and Vision* section of the MDS currently includes items to assess whether hearing aids or corrective lenses were used when the resident completed the hearing (*Ability to Hear*) and vision (*Ability to See*) assessments. It is likely that these items would be feasible to standardize across other PAC assessments.

Wording of the Items *Ability to see* and *Ability to hear*. One research nurse commented that she found the wording of the *Ability to See* and *Ability to Hear* items to be confusing. Using *Ability to See* as an example, she said the phrase "with glasses or other visual appliances" made her question whether the item should be asked only if the patient uses glasses or other visual appliances. Although these items were previously tested in PAC PRD, and showed high acceptability and feasibility across PAC settings, it is possible that future modifications to training materials and the user manual could benefit assessors and improve ease of administration.

Research nurses report that facility staff may skip some items. Several assessors commented that they observed facility staff skipping items in the vision and hearing section. One said, "At this point, people are skipping questions; there is interview error." Another stated, "The facility staff member didn't ask the patient if she wore a hearing aid and then just asked 'how's your hearing?'" This may be reflected in the observed rates of administering the *Date of last hearing test item* by facility staff (0 percent, when *Ability to Hear* was coded as severely impaired). This may suggest a need to improve the user manual, training materials, and/or assessment form in order to clarify when and how the items in this section should be administered to patients/residents.

Summary of Findings: Vision and Hearing

IRR. The results indicate moderate to almost perfect agreement between assessors as measured by IRR. Although data were sparse, discrepancies were observed across research and facility staff with respect to the administration of the *Date of last vision test* and *Date of last hearing test* items. This suggests a need to clarify training materials, the user manual, and instructions on the assessment form to ensure consistency in administering and rating these items.

Feasibility of Use. The time required to complete the items was modest: approximately one minute each for hearing and for vision. While the overall impression from the qualitative feedback is that the items worked well, some items were singled out as needing clarification of language and criteria, notably *Ability to See* and *Ability to Hear*. This result is surprising, given that these items performed

well in the PAC PRD, but may indicate a need to improve training materials and the user manual for these items.

Overall, the results of the Alpha 1 feasibility test indicate that the items in this content area are consistent and feasible, although several opportunities to improve them were identified.

Chapter Five. Results for Cognitive Status

This chapter describes the cognitive status items, the testing objectives and analytic approach, and results from the feasibility test.

Patients/residents in PAC settings are at risk for a number of cognitive impairments that can affect nearly every aspect of their lives.[1] As people age, changes within the brain create mild impairments in memory and information processing. Declines in cognitive function vary across individuals and can include changes in executive function, memory, and language capabilities. Conducting cognitive assessments is critically important to screen for cognitive impairment, rate the severity of a disorder, and to develop a care plan and monitor progression.[2]

Description of Items

The cognitive status items can be found in Appendix A, Section F. The Alpha 1 feasibility test contained items from the BIMS (which is a measure of recall with and without prompting, and of temporal orientation), and three executive function tasks (*Trail Making*, *Serial 7's*, and *Complex Sentence Repetition*). Although cross-setting feasibility data is already available for the BIMS based on the PAC PRD, it was included in Alpha 1 specifically to investigate the benefit of assessing executive functions in addition to the content currently assessed with the BIMS. The Alpha 1 test also allowed us to test whether a skip pattern is appropriate after administration of the BIMS for later data collection.

Executive Functioning Items

The Alpha 1 feasibility test assessed several items related to executive functioning.

The *Trail Making Task* is a neuropsychological test of visual attention and task switching. The patient/resident is instructed to accurately connect a set of dots. The task provides information about visual search ability, scanning, mental flexibility, attention, and executive functioning.

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[1] Rebecca G. Logsdon, Laura E. Gibbons, Susan M. McCurry, and Linda Teri, "Assessing Quality of Life in Older Adults with Cognitive Impairment," *Psychosomatic Medicine*, Vol. 64, No. 3, 2002; Susan E. Campbell, D. Gwyn Seymour, William R. Primrose, Joanna E. Lynch, Edmund Dunstan, Mireia Espallargues, Giovanni Lamura, Peter Lawson, Ian Philp, Elizabeth Mestheneos, Barbara Polityńska, and Ismo Raiha, "A Multi-Centre European Study of Factors Affecting the Discharge Destination of Older People Admitted to Hospital: Analysis of In-Hospital Data from the ACMEplus Project," *Age and Ageing,* Vol. 34, No. 5, 2005; Raphael J. Heruti, Ayala Lusky, Rachel Dankner, Haim Ring, Mark Dolgopiat, Vita Brell, Shalom Levenkrohn, and Abraham Adunsky, "Rehabilitation Outcome of Elderly Patients After a First Stroke: Effect of Cognitive Status at Admission on the Functional Outcome," *Archives of Physical Medicine and Rehabilitation*, Vol. 83, No. 6, 2002.

[2] Valerie T. Cotter, "Alzheimer's Disease: Issues and Challenges in Primary Care," *Nursing Clinics of North America*, Vol. 41, No. 1, 2006; Maud J. L. Graff, Myrra J. M. Vernooij-Dassen, Marjolein Thijssen, Joost Dekker, Willibrord H. L. Hoefnagels, and Marcel G. M. Olde Rikkert, "Community Based Occupational Therapy for Patients with Dementia and Their Care Givers: Randomised Controlled Trial," *BMJ*, Vol. 333, No. 7580, 2006.

Item F5a indicates whether or not the *Trail Making Task* was attempted: yes ("1") or no ("0"). When the *Trail Making Task* is not attempted, item F5b allows the assessor to record the reason it was not attempted: visual impairment ("1") or functional impairment, such as being unable to hold a pen or pencil ("2").

The *Serial 7's Task* assesses attention, mental tracking, and the ability to sustain focus while performing a cognitive operation over repeated trials. The version of this task used in Alpha 1 involves asking the patient/resident to subtract 7 from 90 and to "keep going" until he or she has correctly subtracted 5 numbers. The patient's/resident's responses are coded on a 4-point scale based on the number of correct numbers reported ("3" for four or five numbers, "2" for two or three numbers, "1" for only one number, and "0" for no numbers).

Complex Sentence Repetition involves the immediate repetition of complex auditory sentences. The intent is to assess the central executive component of working memory—the ability of the patient to store, manipulate, and carry out a task. Alpha 1 contained two complex sentences that were developed by a member of the cognitive status advisory group. The two sentences are "After the bell rang, the man standing on the stairs quickly exited the building," and "Though he typically watches westerns, lately he has preferred watching comedies." Patients are given two opportunities to get each sentence exactly correct, which receives a score of "1." If the patient cannot repeat the sentence precisely given two tries, the score for that sentence is "0."

Testing Objectives and Analytic Approach

The main objectives in testing the cognitive items were: (Goal 1) to determine whether ratings of executive function items can be made with acceptable IRR; (Goal 2) to assess the feasibility of item administration; (Goal 3) to understand the benefit of assessing executive function in addition to the content assessed with the BIMS; and (Goal 4) to explore whether a skip pattern may be appropriate after administration of the BIMS for later data collections.

To accomplish Goal 1, we calculated the level of agreement between paired assessors' ratings of each item. We used Cohen's kappa as an index of IRR for categorical items, weighted kappa for ordinal items, and Pearson's correlation for the overall composite BIMS score. We also calculated the percentage of cases in which paired assessors' codes on items F1a ("Was the cognitive interview attempted?") and F5a ("Was the Trail Making Task attempted?") would have led to the same decision to transition to the next item.

To accomplish Goal 2, we looked at frequency distributions for items within and across the four settings. We also examined the amount of missing data per item and the timing of cognitive function items.

To accomplish Goal 3, we examined correlations between the BIMS items and the overall composite BIMS score with each of the four executive function items.

To accomplish Goal 4, we attempted to determine to what extent patients/residents who start the BIMS items (F2–F4c) could continue on to the executive function items or should have instead skipped to Section G. For example, were patients/residents who were scored as "severely impaired" on the

composite BIMS able to complete any of the three executive functioning items correctly? If so, which ones? To what extent did patients/residents with "moderate impairment" vary in answering the executive function items correctly? We expected the executive functioning items to be most useful for providing additional information about cognitive functioning for those who were rated "intact" on the BIMS. We examined the BIMS scores for those residents able to complete 0 to 4 executive functioning items to determine whether there was a cutoff point on the composite BIMS score that would indicate which patients/residents should be asked to complete the executive functioning items or should instead skip to Section G.

Qualitative data obtained during the debriefing interviews were used to evaluate difficulties encountered in administering any of the cognitive items. This information was used to improve future training instructions for interviewers.

Results

Table 5.1 shows the raw results for each cognitive assessment item, overall and broken down by setting. There was variation in item responses across settings; for example, the *Trail Making Task* was correct in 54 percent of instances on average in the IRF setting, whereas in other settings it was 30 percent correct or lower. This likely reflects actual differences in patient status between these different settings. This table also suggests that some of these items may be harder for patients to complete than others, based on the scores. For example, with sentence repetition (Items F7a and F7b), there were more correct answers for the first sentence than the second, implying that the second sentence may be more challenging.

Table 5.1. Frequency Distributions of Responses to Cognitive Functioning Items, by Assessors Within Each PAC Setting

	HHA (N = 37)		IRF (N = 34)		LTCH (N = 31)		SNF (N = 31)		Overall (N = 133)	
Item	**R**	**F**	**R**	**F**	**R**	**F**	**R**	**F**	**R**	**F**
Trail Making Task attempted (F5a)										
Yes (percentage)	95	97	97	100	97	94	100	100	97	98
Missing (number)	0	0	0	0	0	0	1	1	1	1
Reason not attempted (F5b)										
Vision impairment (percentage)	50	100	100	0	0	0	0	0	50	25
Functional impairment (percentage)	0	0	0	0	100	50	0	0	25	25
Other (percentage)	50	0	0	0	0	50	0	100	25	50
Trail making correct (F5c)										
Yes (percentage)	26	33	58	50	30	28	20	21	34	34
Missing (number)	2	1	1	0	1	2	1	2	5	5
Subtraction task (F6)										
No numbers were correctly said or no answer (percentage)	33	42	21	26	26	23	17	17	24	28
Correctly said one number (percentage)	17	11	6	10	23	20	27	27	18	17
Correctly said two or three numbers (percentage)	11	11	32	29	29	33	40	43	27	28

Item	HHA (N = 37) R	HHA (N = 37) F	IRF (N = 34) R	IRF (N = 34) F	LTCH (N = 31) R	LTCH (N = 31) F	SNF (N = 31) R	SNF (N = 31) F	Overall (N = 133) R	Overall (N = 133) F
Correctly said four or five numbers (percentage)	39	36	41	35	23	23	17	13	31	28
Missing (number)	1	1	0	3	0	1	1	1	2	6
Repeats sentence 1 (F7a)										
Sentence was not exactly correct or no answer (percentage)	49	51	41	35	59	55	47	48	48	47
Sentence was exactly correct (percentage)	51	49	59	65	41	45	53	52	52	53
Missing (number)	2	2	0	0	2	2	1	2	5	6
Repeats sentence 2 (F7b)										
Sentence was not exactly correct or no answer (percentage)	80	83	82	82	90	90	93	93	86	87
Sentence was exactly correct (percentage)	20	17	18	18	10	10	7	7	14	13
Missing (number)	2	2	0	0	2	1	1	1	5	4

NOTES: R = research nurse. F = facility staff. *Percentage* rows tabulate responses to each item across all possible answer categories; responses sum to 100 percent. *Number* rows show the number of times each item was unknown, missing, or similar. Responses tabulated in the number rows are not part of the denominator for calculating percentages.

Table 5.2 shows that the cognitive status items (including both BIMS and executive function items) took 7.4 minutes to complete, on average, with relatively little variation across settings. Based on results from the MDS 3.0 development, the BIMS takes approximately 3.4 minutes to complete; thus, we estimate that the executive function items were administered in approximately four minutes.

Table 5.2. Average Time Spent (in Minutes) Completing Cognitive Function Items, by PAC Setting

	HHA (N = 37) Mean (SD)	IRF (N = 34) Mean (SD)	LTCH (N = 31) Mean (SD)	SNF (N = 31) Mean (SD)	Overall (N = 133) Mean (SD)
By research nurse	6.6 (2.8)	6.5 (1.8)	8.2 (2.8)	8.6 (4.5)	7.4 (3.2)
By facility staff	6.6 (2.4)	6.5 (1.8)	8.2 (2.8)	8.5 (4.52)	7.4 (3.1)

Table 5.3 shows that when one assessor attempted the *Trail Making Task*, the other assessor was over 95 percent likely to also judge that the patient was fit to attempt that task—a fact that differed little across settings.

Table 5.3. Percentage of Cases in Which Assessors Agreed to Conduct the Trail Making Task

	HHA (N = 37)	IRF (N = 34)	LTCH (N = 31)	SNF (N = 31)	Overall (N = 133)
Trail Making Task attempted (F5a = 1) (percentage)	95	97	94	97	95

Table 5.4 shows that interrater agreement for executive function items was extremely high, with the lowest Cohen's kappa across all settings at 0.80.

Table 5.4. Interrater Reliability of Cognitive Function Items

Items	HHA (N = 37)	IRF (N = 34)	LTCH (N = 31)	SNF (N = 31)	Overall (N = 133)
Trail making correct (F5c)[a]	0.80	0.88	0.92	1.00	0.89
Subtraction task (F6)[b]	0.92	0.90	0.86	0.84	0.89
Repeats sentence 1 (F7a)[a]	0.94	0.88	0.93	1.00	0.94
Repeats sentence 2 (F7b)[a]	0.91	1.00	1.00	1.00	0.97

NOTE: [a]IRR assessed by Cohen's kappa. [b]IRR assessed by weighted kappa.

Table 5.5 shows that there was only a modest degree of correlation between the BIMS composite score and the four executive function items. The highest correlation was between the BIMS composite score and the subtraction task score (0.49), followed by the BIMS composite score and the *Trail Making Task* (0.35). These results suggest that there is added benefit of assessing executive functioning in addition to the content assessed with the BIMS.

Table 5.5. Pearson Correlations Between the BIMS Composite Score and Each of the Four Executive Function Items

	Trail Making Correct (F5c) (n = 128)	Subtraction Task Score (F6) (n = 127)	Sentence 1 Correct (F7a) (n = 127)	Sentence 2 Correct (F7b) (n = 129)
BIMS composite score	0.35*	0.49*	0.28*	0.19*

NOTE: An asterisk denotes significance at the $p < 0.05$ level.

Table 5.6 shows the relationship between the overall degree of cognitive impairment based on the BIMS score and performance on individual executive function items. As would be expected, patients with overall cognitive impairment performed worse on each of the executive function items. The executive functioning items provided additional information about cognitive function for those who were "intact" on the BIMS as well as some additional information for those who were "moderately impaired" on the BIMS.

Table 5.6. Crosstabs of BIMS Composite with Executive Functioning Items Among the Facility Staff

	BIMS Composite Score		
Executive Function Items	Intact (N = 97)	Moderately Impaired (N = 29)	Severely Impaired (N = 6)
Trail Making attempted (F5a)			
No (percentage)	1	3	17
Yes (percentage)	99	97	83
Trail Making correct (F5c)			
No (percentage)	58	89	100
Yes (percentage)	42	11	0
Subtraction task score (F6)			
No numbers correctly said or no answer	17	52	67
Correctly said only 1 number	16	14	33
Correctly said 2 or 3 numbers	29	31	0

Executive Function Items	BIMS Composite Score		
	Intact (N = 97)	Moderately Impaired (N = 29)	Severely Impaired (N = 6)
Correctly said 4 or 5 numbers	37	3	0
Sentence 1 correct (F7a)			
No (percentage)	38	70	83
Yes (percentage)	62	30	17
Sentence 2 correct (F7b)			
No (percentage)	82	100	100
Yes (percentage)	18	0	0

NOTE: "Intact" = BIMS score greater than 12; "Moderately impaired" = BIMS score 8–12; and "Severely impaired" = BIMS score less than 8.

We created an overall executive function score ranging from 0 to 4 reflecting the number of executive functioning items answered correctly. Table 5.7 shows the distribution of executive functioning scores according to the level of impairment based on the BIMS. While the executive functioning performance of patients with a moderately or severely impaired BIMS score was almost uniformly poor, we did see a considerable range of executive functioning scores among those with an "intact" level of cognitive function as measured by the BIMS. It seems, therefore, that the executive functioning items provide added discrimination among this rather large group.

Table 5.7. Executive Functioning Score Distribution According to BIMS Classification Category (Facility Staff, All Settings Combined)

Executive Function Score	BIMS Classification		
	Intact (N = 97)	Moderately Impaired (N = 29)	Severely Impaired (N = 6)
0 (N = 48)	24	19	5
1 (N = 34)	28	8	1
2 (N = 22)	20	2	0
3 (N = 19)	19	0	0
4 (N = 6)	6	0	0

NOTE: "Intact" = BIMS score > 12; "Moderately impaired" = BIMS score 8–12; "Severely impaired" = BIMS score < 8.

Feedback from Assessors

Questions About Scoring the *Trail Making Task*. Both research nurses and facility staff described situations in which they were unsure of how to score the *Trail Making Task*. In one situation, although a patient/resident drew the line backwards, he correctly drew the line from "E" to "5" to "D" and so on. Another patient/resident could not use his hands, but he correctly described how the line should be drawn. In both cases, the person administering the item did not feel the scoring rules were sufficiently clear about how to score the effort. Research nurses also mentioned that in some situations, it was

unclear whether patients/residents had trouble completing the task due to poor vision or cognitive impairment.

High Respondent Burden for the *Trail Making Task*. Assessors also described the *Trail Making Task* as one that frequently frustrated patients/residents. One facility staff member described a situation in which a patient/resident became distressed after he asked if he was doing the task correctly and the staff member could not answer his question. Similarly, a research nurse noted that a patient/resident became upset during the *Trail Making Task* because he was having trouble completing it correctly and ended the assessment.

Complex Sentence Repetition Task. There were four main types of comments about this task. First, some research nurses explained that when the sentences have to be repeated three times, some patients/residents begin to realize that they are repeating them incorrectly and become frustrated. Second, facility staff occasionally made comments suggesting that they needed additional orientation for instances in which patients/residents make mistakes on the *Complex Sentence Repetition Task*. This is an example of the test working as intended, not a problem to be solved. For example, research nurses noted that many patients/residents would repeat the first sentence correctly, but repeat the second sentence incorrectly; however, such a mistake is the type of cognitive issue the task was designed to identify. Third, some research nurses noted that they observed their facility partners administering the *Complex Sentence Repetition Task* incorrectly, by, for example, coding an item after asking the patient/resident to repeat the sentence one time and then continuing to ask the patient/resident to repeat it a second and third time, or by asking the patient/resident to repeat the sentence only once, even if the patient/resident repeated it incorrectly. Fourth, research nurses also noted that in the instructions, the word "remember" seems out of place, since the assessor has not yet asked the patient to remember anything. In summary, these findings imply that facility staff and research nurses may need additional training on the *Complex Sentence Repetition Task*.

Patients/Residents Providing the Correct Answer on the *Serial 7's Task* Without Doing the Subtraction. The research nurses commented that when completing the *Serial 7's Task*, patients/residents would sometimes say the correct answer, but it seemed that they had done so by guessing. In this situation, the nurses were unsure how to code the answer. However, it is not the assessor's job to consider how the patient/resident arrived at a response, only whether the response is correct. Therefore, this should be considered as a topic for clarification or education in the future.

General Comments About the Cognitive Status Section. The research nurses suggested that the instructions could be clearer for deciding whether to stop the assessment if the patient/resident does not appear to have adequate cognitive abilities. They expressed concern that, without proper clarification on this point, nurses may incorrectly conclude that a patient is not suitable for assessment.

Summary of Findings: Cognitive Status

IRR. IRR was excellent across items, as measured by different assessors on the same patient. In addition, we found that assessors came to very similar decisions about whether to skip the *Trail Making Task*. In summary, the cognitive items performed well in terms of IRR.

Feasibility of Use. Very few items were missing, suggesting that the items are feasible to administer. Completing the cognitive section took approximately four minutes, with an additional 3.4 minutes needed to complete the BIMS. In the qualitative feedback, the assessors asked for additional clarification about the *Trail Making Task*, the *Complex Sentence Repetition Task*, and the *Serial 7's Task*. These results suggest that there is a need to clarify the instructions for the proposed executive functioning items.

Independence of Executive Functioning and BIMS Items. We found that the BIMS score and executive functioning items were correlated weakly, suggesting that there is unique information gathered in each. In fact, we observed a relatively wide range of performance on the executive functioning items among the many patients with an "intact" BIMS score, suggesting that the added items provide additional discrimination in this group.

Skip Pattern. There was no clear BIMS score below which one could skip the executive functioning items, although only one out of six severely impaired patients/residents was able to answer any of the executive functioning items correctly. Conversely, we observe that the executive functioning items do provide additional discrimination among the many patients/residents who have an intact BIMS score.

Overall, the results of the Alpha 1 testing indicate that the items in the cognitive status content area perform with acceptable IRR. We found that it may be necessary to administer both the BIMS and the executive functioning items, regardless of the score on either section. We found some issues associated with training, suggesting that assessors need additional clarification of the instructions for some items.

Chapter Six. Results for Mood

This chapter describes the mood items, the testing objectives and analytic approach, and results from the feasibility test.

Depression is the most common mental health problem in older adults and is particularly common in PAC settings.[1] Undetected depression can lead to degraded physical and mental health and functioning, increased medical care utilization and costs, reduced quality of life, and premature death.[2] It can also exacerbate other chronic medical conditions, compromise treatment participation and compliance, slow recovery from injuries and surgeries, and lead to rehospitalization.[3] Although depression often goes undetected, prognosis is good when there is prompt recognition and treatment.[4] Studies have also shown that treating depression in older adults likely results in long-term cost savings.[5]

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[4] George S. Alexopoulos, Ira R. Katz, Charles F. Reynolds, Daniel Carpenter, and John P. Docherty, "Pharmacotherapy of Depression in Older Patients: A Summary of the Expert Consensus Guidelines," *Journal of Psychiatric Practice,* Vol. 7, No. 6, 2001.

[5] Jurgen Unutzer, Lingqi Tang, Sabine Oishi, Wayne Katon, John W. Williams, Jr., Enid Hunkeler, Hugh Hendrie, Elizabeth H. B. Lin, Stuart Levine, Lydia Grypma, David C. Steffens, Julie Fields, and Christopher Langston, "Reducing Suicidal Ideation in Depressed Older Primary Care Patients," *Journal of the American Geriatrics Society,* Vol. 54, No. 10, 2006.

Description of Items

The mood items can be found in Appendix A, Section G. The Patient/Resident Mood Interview is derived from the well-validated and commonly used nine-item PHQ-9, which assesses each of the nine criteria for major depressive disorder outlined in the *Diagnostic and Statistical Manual of Mental Disorders*.[6] The first two items of the PHQ-9 make up the PHQ-2, another well-validated and commonly used depression screener that assesses only the two cardinal criteria for major depression (described later).[7] To balance the greater ease of administration of the PHQ-2 with the greater informativeness of the PHQ-9, the Patient/Resident Mood Interview incorporates a transition between the two assessments, such that only patients/residents who screen positive on the PHQ-2 are administered the lengthier PHQ-9.

In completing the Patient/Resident Mood Interview as laid out in the Alpha 1 protocol, clinicians administer the first two items of the interview, which correspond to the PHQ-2, and then make a determination about whether to end the interview or continue administering the remaining seven items, which, together with the items from the PHQ-2, constitute the PHQ-9. Each item has a symptom presence component and a symptom severity component, the latter of which is administered only if a symptom is judged to be present. Severity is quantified based on the number of days in the past 14 days the patient/resident has experienced this symptom. Possible severity levels are never or one day, two to six days (or "several" days), seven to 11 days (or half or more of the days), and 12 to 14 days (nearly every day).

In cases in which all nine items of the Patient/Resident Mood Interview are administered, the clinician finalizes the assessment by calculating a total score, which involves summing the symptom severity ratings. There are two sets of missing data instructions embedded in the Patient/Resident Mood Interview that clinicians must follow. The first involves entering a value of nine in the symptom presence box and a dash (–) in the symptom frequency box if the patient/resident does not provide a comprehensible response about symptom presence to an item. The second involves ending the interview once the patient/resident fails to respond to three questions about symptom presence.

Testing Objectives and Analytic Approach

Our main objectives in testing the Patient/Resident Mood Interview were (Goal 1) to determine whether ratings of symptom presence and severity can be made with acceptable IRR; (Goal 2) to assess the feasibility of administering the interview; (Goal 3) to evaluate the ease of decisionmaking about whether to transition from the first two items of the Patient/Resident Mood Interview to the remaining seven items, and to assess the clarity of instructions regarding this transition; and (Goal 4) to evaluate

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[6] Kurt Kroenke, Robert L. Spitzer, Janet B. W. Williams, "The PHQ-9: Validity of a Brief Depression Severity Measure," *Journal of General Internal Medicine,* Vol. 16, No. 19, 2001; American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders*, 5th ed., Arlington, Va., 2013.

[7] Bernd Lowe, Kurt Kroenke, and Kerstin Grafe, "Detecting and Monitoring Depression with a Two-Item Questionnaire (PHQ-2)," *Journal of Psychosomatic Research,* Vol. 58, No. 2, 2005.

the clarity of instructions about how to calculate the total score and how to handle missing data on symptom presence and severity.

To accomplish Goal 1, we calculated the level of agreement between paired assessors' judgments about symptom presence and severity. IRR was calculated for each item of the Patient Mood Interview. We used Cohen's kappa as an index of IRR for the symptom presence ratings. We used the weighted kappa for assessing IRR for the symptom severity ratings.

To accomplish Goal 2, we examined the time taken to complete the first two items of the Patient/Resident Mood Interview (corresponding to the PHQ-2) and (for the subset of patients for whom it applied) the time taken to complete all nine items (corresponding to the PHQ-9).

To accomplish Goals 3 and 4, we relied on both the paired ratings and the qualitative data obtained during the debriefing interviews. For example, to evaluate the ease of decisionmaking about whether to transition from the first two items of the Patient/Resident Mood Interview to the remaining seven items, we calculated the percentage of cases in which paired assessors' codes on Items G1a2 ("About how often have you been bothered by having little interest or pleasure in doing things?") and G1b2 ("About how often have you been bothered by feeling down, depressed, or hopeless?") would have led to the same decision to transition or not and the percentage of time that the lead interviewer made the correct decision to administer the remaining seven items. We also relied on what nurses told us during the debriefing interview when prompted to discuss the clarity of transition instructions. To investigate setting-by-setting variation in the reliability and ease of administration of the item, we calculated all statistics by setting as well as across the four settings. Likewise, in evaluating the feedback that nurses provided during the debriefing interviews, we attempted to discern, informally, whether setting differences were evident.

Results

Table 6.1 shows the IRR for items in the Patient/Resident Mood Interview across 133 sets of paired observations. In general, IRR was excellent—almost always above 0.90, and frequently perfect. Table 6.2 shows the responses for the individual items, stratified by assessor type and care setting. Table 6.3 shows the time to complete the mood items. In general, it took between one and three minutes to complete the first two items of the Patient Mood Interview and between five and six minutes to complete all nine items.

Table 6.1. Interrater Reliability for the Items of the Patient/Resident Mood Interview

	Symptom Presence[a]					Symptom Frequency[b]				
Patient/Resident Mood Interview Item	**HHA (N = 37)**	**IRF (N = 34)**	**LTCH (N = 31)**	**SNF (N = 31)**	**Overall (N = 133)**	**HHA (N = 37)**	**IRF (N = 34)**	**LTCH (N = 31)**	**SNF (N = 31)**	**Overall (N = 133)**
Little interest or pleasure in doing things (G1a1, G1a2)	0.93	1.00	1.00	1.00	0.98	1.00	1.00	0.89	1.00	0.96

Patient/Resident Mood Interview Item	Symptom Presence[a]					Symptom Frequency[b]				
	HHA (N = 37)	IRF (N = 34)	LTCH (N = 31)	SNF (N = 31)	Overall (N = 133)	HHA (N = 37)	IRF (N = 34)	LTCH (N = 31)	SNF (N = 31)	Overall (N = 133)
Feeling down, depressed, or hopeless (G1b1, G1b2)	0.94	1.00	1.00	1.00	0.98	1.00	1.00	N/A	0.94	0.95
Sleep disturbances (G1c1, G1c2)	1.00	1.00	1.00	1.00	1.00	1.00	1.00	N/A	1.00	N/A
Feeling tired or having little energy (G1d1, G1d2)	1.00	1.00	1.00	1.00	1.00	1.00	1.00	0.89	1.00	0.96
Poor appetite or overeating (G1e1, G1e2)	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	0.81	0.94
Feeling bad about yourself (G1f1, G1f2)	N/A	1.00	1.00	0.79	0.87	N/A	1.00	1.00	1.00	1.00
Trouble concentrating (G1g1, G1g2)	N/A	1.00	1.00	1.00	1.00	N/A	1.00	1.00	0.87	0.93
Psychomotor disturbances (G1h1, G1h2)	N/A	1.00	1.00	1.00	1.00	N/A	1.00	1.00	1.00	1.00
Thoughts of suicide or death (G1i1, G1i2)	N/A	1.00	1.00	1.00	1.00	N/A	1.00	1.00	N/A	1.00

NOTE: Cells with N/A indicate that not all response categories were endorsed by both nurses; thus, IRR cannot be computed.
[a]IRR assessed by Cohen's kappa. [b]IRR assessed by weighted kappa.

Table 6.2. Symptom Presence and Frequency Distribution of Responses to the Mood Interview Items

Item	HHA (N = 37)		IRF (N = 34)		LTCH (N = 31)		SNF (N = 31)		Overall (N = 133)	
	R	F	R	F	R	F	R	F	R	F
Little interest or pleasure in doing things (G1a1)										
Yes (percentage)	27	24	38	38	67	67	37	37	41	40
Missing (number)	0	0	0	0	1	1	1	1	2	2
If "yes" above, frequencies (G1a2)										
0. Never or 1 day (percentage)	10	0	8	8	10	5	9	9	9	6
1. 2–6 days (several days) (percentage)	60	67	46	46	50	55	27	27	46	49
2. 7–11 days (half or more of the days) (percentage)	0	0	23	23	25	20	36	36	22	21
3. 12–14 days (nearly every day) (percentage)	30	33	23	23	15	20	27	27	22	25
Skipped* (number)	27	28	21	21	11	11	20	20	79	80

	HHA (N = 37)		IRF (N = 34)		LTCH (N = 31)		SNF (N = 31)		Overall (N = 133)	
Item	**R**	**F**	**R**	**F**	**R**	**F**	**R**	**F**	**R**	**F**
Missing (number)	0	0	0	0	0	0	0	0	0	0
Feeling down, depressed, or hopeless (G1b1)										
Yes (percentage)	38	35	41	41	67	67	63	63	51	50
Missing (number)	0	0	0	0	1	1	1	1	2	2
If “yes” above, frequencies (G1b2)										
0. Never or 1 day (percentage)	31	25	8	8	5	5	6	5	11	9
1. 2–6 days (several days) (percentage)	46	50	54	54	75	70	50	47	58	56
2. 7–11 days (half or more of the days) (percentage)	0	0	23	23	20	20	17	21	16	17
3. 12–14 days (nearly every day) (percentage)	23	25	15	15	0	5	28	26	16	17
Skipped* (number)	23	24	20	20	11	11	12	12	66	67
Missing (number)	1	1	0	0	0	0	0	0	1	1
Unknown (number)	0	0	1	1	0	0	1	0	2	1
Sleep disturbances (G1c1)										
Yes (percentage)	40	40	67	67	70	70	73	75	66	67
Skipped* (number)	31	31	25	25	21	21	20	19	97	96
Missing (number)	1	1	0	0	0	0	0	0	1	1
Unknown (number)	0	0	0	0	0	0	0	0	0	0
If “yes” above, frequencies (G1c2)										
0. Never or 1 day (percentage)	0	0	0	0	14	0	0	0	4	0
1. 2–6 days (several days) (percentage)	50	50	57	50	43	57	22	22	40	42
2. 7–11 days (half or more of the days) (percentage)	0	0	29	33	14	14	22	22	20	21
3. 12–14 days (nearly every day) (percentage)	50	50	14	17	29	29	56	56	36	38
Skipped* (number)	35	35	28	28	24	24	23	22	110	109
Missing (number)	0	0	0	0	0	0	0	0	0	0
Unknown (number)	0	0	0	0	0	0	0	0	0	0
Feeling tired or having little energy (G1d1)										
Yes (percentage)	80	80	78	80	90	90	92	85	86	86
Skipped* (number)	31	31	25	25	21	21	20	19	97	97
Missing (number)	1	0	0	0	0	0	0	0	1	1
Unknown (number)	0	0	0	0	0	0	0	0	0	0
If “yes” above, frequencies (G1d2)										
0. Never or 1 day (percentage)	0	0	14	14	11	11	0	0	7	6
1. 2–6 days (several days) (percentage)	0	0	0	0	22	22	20	18	13	13

Item	HHA (N = 37)		IRF (N = 34)		LTCH (N = 31)		SNF (N = 31)		Overall (N = 133)	
	R	F	R	F	R	F	R	F	R	F
2. 7–11 days (half or more of the days) (percentage)	25	25	43	43	44	33	30	36	37	35
3. 12-14 days (nearly every day) (percentage)	75	75	43	43	22	33	50	45	43	45
Skipped* (number)	33	33	27	27	22	22	21	20	103	102
Missing (number)	0	0	0	0	0	0	0	0	0	0
Poor appetite or overeating (G1e1)										
Yes (percentage)	20	20	56	56	80	80	64	67	60	61
Skipped* (number)	31	31	25	25	21	21	20	19	97	96
Missing (number)	1	1	0	0	0	0	0	0	1	1
Unknown (number)	0	0	0	0	0	0	0	0	0	0
If “yes” above, frequencies (G1e2)										
0. Never or 1 day (percentage)	0	0	0	0	0	0	0	0	0	0
1. 2–6 days (several days) (percentage)	100	100	20	20	0	0	29	25	19	18
2. 7–11 days (half or more of the days) (percentage)	0	0	40	40	50	50	43	50	43	45
3. 12-14 days (nearly every day) (percentage)	0	0	40	40	50	50	29	25	38	36
Skipped* (number)	36	36	29	29	23	23	24	23	112	111
Missing (number)	0	0	0	0	0	0	0	0	0	0
Feeling bad about yourself (G1f1)										
Yes (percentage)	0	20	33	33	20	25	64	67	34	41
Skipped* (number)	31	31	25	25	21	21	20	19	97	96
Missing (number)	1	1	0	0	0	0	0	0	1	1
Out of Range (number)	0	0	0	0	0	1	0	0	0	1
Unknown (number)	0	0	0	0	0	1	0	0	0	1
If “yes” above, frequencies (G1f2)										
0. Never or 1 day (percentage)	0	100	0	0	0	0	0	0	0	7
1. 2–6 days (several days) (percentage)	0	0	33	33	0	0	57	50	42	36
2. 7–11 days (half or more of the days) (percentage)	0	0	67	67	100	100	29	38	50	50
3. 12-14 days (nearly every day) (percentage)	0	0	0	0	0	0	14	13	8	7
Skipped* (number)	37	36	31	31	29	29	24	23	121	119
Missing (number)	0	0	0	0	0	0	0	0	0	0
Trouble concentrating (G1g1)										
Yes (percentage)	0	0	33	33	30	30	82	75	43	42
Skipped* (number)	31	31	25	25	21	21	20	19	97	96
Missing (number)	1	1	0	0	0	0	0	0	1	1
Unknown (number)	0	0	0	0	0	0	0	0	0	0

	HHA (N = 37)		IRF (N = 34)		LTCH (N = 31)		SNF (N = 31)		Overall (N = 133)	
Item	**R**	**F**	**R**	**F**	**R**	**F**	**R**	**F**	**R**	**F**
If “yes” above, frequencies (G1g2)										
0. Never or 1 day (percentage)	0	0	0	0	0	0	0	0	0	0
1. 2–6 days (several days) (percentage)	0	0	0	0	33	33	67	56	47	40
2. 7–11 days (half or more of the days) (percentage)	0	0	67	67	0	0	11	22	20	27
3. 12-14 days (nearly every day) (percentage)	0	0	33	33	67	67	22	22	33	33
Skipped* (number)	37	37	31	31	28	28	22	22	118	118
Missing (number)	0	0	0	0	0	0	0	0	0	0
Psychomotor disturbances (G1h1)										
Yes (percentage)	0	0	44	44	40	50	36	27	34	33
Skipped* (number)	31	31	25	25	21	21	20	19	97	100
Missing (number)	1	1	0	0	0	0	0	0	1	1
Out of range (number)	0	0	0	0	0	1	0	0	0	1
Unknown (number)	0	0	0	0	0	1	0	1	0	2
If “yes” above, frequencies (G1h2)										
0. Never or 1 day (percentage)	0	0	0	0	25	25	0	0	9	9
1. 2–6 days (several days) (percentage)	0	0	25	25	0	0	33	33	18	18
2. 7–11 days (half or more of the days) (percentage)	0	0	50	50	50	50	33	33	45	45
3. 12-14 days (nearly every day) (percentage)	0	0	25	25	25	25	33	33	27	27
Skipped* (number)	37	37	30	30	27	27	27	28	121	122
Missing (number)	0	0	0	0	0	0	1	0	1	0
Thoughts of suicide or death (G1i1)										
Yes (percentage)	0	0	22	22	11	14	10	8	12	12
Skipped* (number)	31	31	25	25	21	21	20	19	97	96
Missing (number)	1	1	0	0	0	0	1	0	2	1
Out of range (number)	0	0	0	0	0	1	0	0	0	1
Unknown (number)	0	0	0	0	1	2	0	0	1	2
If “yes” above, frequencies (G1i2)										
0. Never or 1 day (percentage)	0	0	0	0	0	0	100	100	25	25
1. 2–6 days (several days) (percentage)	0	0	100	100	100	100	0	0	75	75
2. 7–11 days (half or more of the days) (percentage)	0	0	0	0	0	0	0	0	0	0
3. 12-14 days (nearly every day) (percentage)	0	0	0	0	0	0	0	0	0	0
Skipped* (number)	37	37	32	32	30	30	30	30	129	129
Missing (number)	0	0	0	1	0	0	0	0	0	0

NOTES: R = research nurse. F = facility staff. An asterisk denotes skipped answers, which are appropriately missing based on prior answers and programmed skip patterns. *Percentage* rows tabulate responses to each item across all possible answer

categories. Responses sum to 100 percent. *Number* rows show the number of times each item was unknown, missing, or similar. Responses tabulated in number rows are not part of the denominator for calculating percentages.

Table 6.3. Feasibility of Administering the Patient/Resident Mood Interview in PAC Settings: Average Time to Complete

	HHA Mean (SD)	IRF Mean (SD)	LTCH Mean (SD)	SNF Mean (SD)	Overall Mean (SD)
Time taken to complete the first two items (in minutes)					
By research nurse	1.5 (1) N = 4	2.5 (0.7) N = 2	3.71 (4.3) N = 7	4 (4.2) N = 2	3 (3.2) N = 15
By facility staff	2 (0) N = 3	2.5 (0.7) N = 2	3.71 (4.3) N = 7	4 (4.2) N = 2	3.21 (3.2) N = 14
Time taken to complete all nine items (in minutes)					
By research nurse	6 (N/A) N = 1	5.3 (1.37) N = 6	5.7 (1.9) N = 7	6.6 (6.2) N = 7	5.9 (3.7) N = 21
By facility staff	6 (N/A) N = 1	5.3 (1.37) N = 6	5.9 (2.19) N = 7	6.4 (6.19) N = 7	5.9 (3.7) N = 21

NOTE: SD = standard deviation.

Table 6.4 shows that, across 133 sets of paired assessments, assessors had a high level of agreement about when to transition to a longer interview based on initial findings of depression in the early questions. Overall, instructions about documenting missing data were followed 95 percent of the time.

Table 6.4. Feasibility of Administering the Mood Items: Clarity of Instructions

	HHA (N = 37)	IRF (N = 34)	LTCH (N = 31)	SNF (N = 31)
Cases for which assessors' codes for A2 and B2 would have led to the same decision to transition to longer interview (percentage)	100	100	100	97
Cases for which facility staff made the correct decision to transition to the longer interview (percentage)	97	97	97	90
Missing data instructions for calculating total score properly followed	100	93	97	92

Table 6.5 shows the proportion of times that assessors properly followed skipping rules in the mood section. Skips were correctly performed in the great majority of instances.

Table 6.5. Feasibility of Administering the Mood Items: Number of Assessors that Properly Followed Skipping Rules

Skip Item	Total Eligible to Skip	Skipped Completely*	Skipped Partially	Did not Skip Any
G1a and G1b (If neither G1a2 nor G1b2 are greater than or equal to 2, should skip G1c-G1i)				
Research nurse (total N = 133)	97	95	1	1
Facility staff (total N = 133)	96	91	5	0

NOTE: The relevant items should have been skipped completely.

Feedback from Assessors

The assessors noted six issues or recommendations for the mood section.

Patients Forget Time Frame. Research nurses and facility staff both commented that they often had to remind patients/residents of the time frame the item was referring to.

Assessor Discomfort with Some Items. Both groups stated that they were uncomfortable asking some questions, including Item G1f, "Feeling bad about yourself—or that you are a failure or have let yourself or your family down," and Item G1i, "Thoughts that you would be better off dead, or of hurting yourself in some way." However, they noted that while these questions may surprise patients/residents or be thought-provoking, patients/residents did not have too much difficulty answering them.

Need for Additional Training on Administration and Scoring of the Patient/Resident Mood Interview. Although the facility staff did not express any difficulties administering and scoring the Patient/Resident Mood Interview, the research nurses noted some problems faced by facility staff. According to these accounts, some facility staff would ask all the symptom presence items first, then continue to the symptom frequency items, which is not correct. Additionally, it was noted that some facility staff would forget to sum the responses to the first two items and complete the remaining seven items, even though the patient's/resident's responses to the first two items indicated a need to complete the full interview. The research nurses thought that additional training and/or changes to the format of the section may remedy these issues.

Wording Suggestions. The facility staff suggested adding better "lead in" text to Item G1 ("Over the last two weeks, have you been bothered by…"), because the current wording can make it seem out of place and awkward.

Tips on When to Show the Cue Card. The research nurses said they refrain from showing patients/residents the cue card until they finish asking the question; otherwise patients/residents often focus on the cue card instead of the question.

Need for Adequate Probing. Lastly, the research nurses noted that some patients/residents switch their answers to something that signals depression if the assessor probes enough. Probing is allowed within the user manual but should be done only to clarify the intent of the patient, not to challenge it. This implies a need for education, quality control, and clarification of instructions to ensure that the amount of probing on this item is uniform across assessments and that probing is aimed only at achieving clarification and not at challenging a patient's/resident's initial response.

Summary of Findings: Mood

IRR. Interrater agreement on mood items was excellent—always above 0.90 and frequently perfect.

Feasibility/Ease of Use. The first two mood items took between one and three minutes to administer; an additional three minutes was required when it was necessary to administer all nine items. Assessors offered some comments about how to improve various aspects of the administration of the mood section, including a desire for additional training about how to score the assessment.

Clarity of Instructions and Skip Items. Assessors had a very high level of agreement about when to skip to the next section. Overall, as might be expected given the extensive validation already performed for the PHQ-2 and the PHQ-9, they performed well here and do not seem to require changes.

Chapter Seven. Results for Pain

This chapter describes the pain items, the testing objectives and analytic approach, and results from the feasibility test.

Pain affects a significant proportion of patients/residents in PAC settings.[1] Inattention to or mismanagement of pain can significantly affect care management and is associated with decreased quality of life, poor outcomes, and reduced participation in rehabilitation therapies.[2] Pain management can relieve symptoms, but accurate pain assessment is an essential precondition to managing pain. Asking about pain helps to maintain standards of care and improves treatment planning and care management for patients/residents in PAC settings.[3]

Description of Items

The pain items can be found in Appendix A, Section H. Items in this content area address patients'/residents' self-reports of the experience of pain and pain relief. Interviewers are instructed to administer these items to all patients who are capable of communicating, using visual aids to assist patients/residents in responding. As with other sections in the assessment, these items follow skip patterns and termination rules based upon patient/resident responses.

These items assess the following dimensions of pain:

- **Pain presence**. This item (Item H1) identifies the presence of pain. A positive response to this item prompts further questions about the nature of the pain; the absence of pain prompts the assessor to end the section. This item was tested previously in PAC PRD; as such, it was included in testing for context only and was not evaluated for feasibility.
- **Pain frequency**. This item (Item H2) assesses frequency of pain, which is an important characteristic of pain and pain management, and provides a basis for evaluating treatment need and response. Possible responses are *rarely or not at all*, *occasionally*, *frequently*, *almost constantly*, and *unable to answer*.
- **Pain effect on sleep.** This item (Item H3) assesses frequency of pain interference with sleep, which can help to gauge the effects of pain on quality of life and can also provide insight into

[1] American Geriatrics Society Panel on the Pharmacological Management of Persistent Pain in Older Persons, "Pharmacological Management of Persistent Pain in Older Persons," *Pain Medicine,* Vol. 10, No. 6, 2009; Bruce A. Ferrell, Betty R. Ferrell, and Dan Osterweil, "Pain in the Nursing Home," *Journal of the American Geriatrics Society,* Vol. 38, No. 4, 1990.

[2] Nancy Wells, Chris Pasero, and Margo McCaffery, "Improving the Quality of Care Through Pain Assessment and Management," in R. G. Hughes, ed. *Patient Safety and Quality: An Evidence-Based Handbook for Nurses*, Rockville, Md.: Agency for Healthcare Research and Quality, 2008, Chapter 17.

[3] Wen-Chieh Lin, Terry Y. Lum, David R. Mehr, and Rovert L. Kane, "Measuring Pain Presence and Intensity in Nursing Home Residents," *Journal of the American Medical Directors Association,* Vol. 7, No. 3, 2006; Albert, J. Lukas, Bruce Barber, P. Johnson, and Stephen J. Gibson, "Observer-Rated Pain Assessment Instruments Improve Both the Detection of Pain and the Evaluation of Pain Intensity in People with Dementia," *European Journal of Pain,* Vol. 17, No. 10, 2013.

the patient's/resident's sleep-pain cycle (e.g., bidirectional relationship between sleep disturbance and pain exacerbation). Possible responses are *rarely or not at all*, *occasionally*, *frequently*, *almost constantly*, and *unable to answer*.

- **Pain interference with activities**. These items (Items H4a and H4b) assess the extent to which pain interferes with (a) therapy-related activities (only asked of patients/residents to whom rehabilitation therapies have been offered) and (b) nontherapy-related activities. Possible responses are *rarely or not at all*, *occasionally*, *frequently*, *almost constantly*, and *unable to answer*.
- **Pain severity.** This item (Item H5) assesses pain severity, which is an important characteristic of pain and pain management. Pain severity provides a basis for evaluating pain treatment need and response and provides information to help plan an optimum regimen of pain therapy (e.g., to identify optimum schedule/dosage/modality of pain treatment). Possible responses are *mild*, *moderate*, *severe*, *very severe/horrible*, and *unable to answer*.
- **Pain relief.** This item (Item H6) assesses the extent to which current strategies relieve the pain, which provides a basis for assessing the adequacy of the pain management regimen and for evaluating treatment need and response to pain treatment. Possible responses are *no relief*, *some relief*, *quite a bit of relief*, *very much relief*, *not applicable* (patient/resident has not received pain treatments or medications in the past three days), and *unable to answer*.

Testing Objectives and Analytic Approach

Our main objectives in testing the pain interview items (excluding *pain presence*, which was included only for context) were: (Goal 1) to determine whether ratings of each item can be made with acceptable IRR; and (Goal 2) to evaluate feasibility, i.e., the ease of completion and clarity of instructions about how to administer these items (e.g., confusing terminology or item phrasing, adherence to skip patterns, discontinuation rules).

To accomplish Goal 1, we calculated the level of agreement between paired assessors' coding of patient/resident responses to each item. IRR was calculated for each item of the pain interview assessment. We used Cohen's unweighted kappa as an index of IRR for ratings on pain presence. We used the weighted kappa for assessing IRR for pain items with ordinal response scales (i.e., all items except pain presence).

To accomplish Goal 2, we utilized qualitative data based upon feedback that nurses provided during the debriefing interviews and assessed differences across settings. We examined the time spent to complete the items, the frequency with which response options were endorsed by the research nurse assessor and facility staff assessor, and evidence for adherence to skip logic and discontinuation rules by comparing percentages of correct adherence to item administration rules (i.e., for each item, percentage of cases correctly skipped) by both the research nurse and facility staff assessor. To investigate setting-by-setting variation in the reliability and ease of administration of the items, we calculated all statistics by setting as well as across the four settings.

Results

Table 7.1 shows IRR overall and by setting for each pain item. Interrater agreement was nearly perfect for all items, suggesting that different assessors are able to obtain extremely similar results in terms of the pain items.

Table 7.1. Interrater Reliability of Pain Items

Item	HHA (N = 37)	IRF (N = 34)	LTCH (N = 31)	SNF (N = 31)	Overall (N = 133)
Pain frequency (H2)	0.96	1.00	1.00	0.91	0.97
Pain effect on sleep (H3)	1.00	1.00	1.00	1.00	1.00
Pain interference—therapy activities (H4a)	1.00	1.00	1.00	1.00	1.00
Pain interference—other activities (H4b)	1.00	1.00	1.00	1.00	1.00
Pain severity (H5)	1.00	0.96	0.94	1.00	0.98
Pain relief (H6)	0.96	1.00	1.00	0.88	0.96

NOTE: For all items, IRR was assessed by weighted kappa.

Table 7.2 shows the frequency of responses to each item, overall and by setting. Responses to pain items were generally similar across settings. As was suggested by the IRR analysis, there were few if any differences between pain assessments by facility staff and research nurses.

Table 7.2. Pain Items: Frequency Distributions of Responses, by Item and Assessor Type

	HHA (N = 37)		IRF (N = 34)		LTCH (N = 31)		SNF (N = 31)		Overall (N = 133)	
Item	R	F	R	F	R	F	R	F	R	F
Pain presence (H1)										
Yes (percentage)	75	75	85	85	67	67	80	73	77	75
Missing (number)	1	1	0	0	1	1	1	1	3	3
Pain frequency (H2)										
Rarely (percentage)	4	4	3	3	5	5	4	9	4	5
Occasionally (percentage)	33	30	21	21	40	40	35	36	31	31
Frequently (percentage)	30	33	41	41	30	30	35	27	34	34
Almost constantly (percentage)	33	33	34	34	25	25	26	27	30	31
Skipped* (number)	9	9	5	5	10	10	6	8	30	35
Missing (number)	1	0	0	0	1	0	2	0	4	0
Pain effect on sleep (H3)										
Rarely (percentage)	56	56	28	28	30	30	52	47	41	41
Occasionally (percentage)	30	30	34	34	45	45	22	24	32	33
Frequently (percentage)	15	15	34	34	15	15	17	19	21	22
Almost constantly (percentage)	0	0	3	3	10	10	9	10	5	5
Skipped* (number)	9	9	5	5	10	10	6	8	30	32
Missing (number)	1	1	0	0	1	1	2	1	4	3

Item	HHA (N = 37)		IRF (N = 34)		LTCH (N = 31)		SNF (N = 31)		Overall (N = 133)	
	R	F	R	F	R	F	R	F	R	F
Unable to answer/no response (number)	0	0	0	0	0	0	0	1	0	1
Pain interference—therapy activities (H4a)										
Rarely (percentage)	93	93	62	62	69	69	86	89	75	75
Occasionally (percentage)	7	7	24	24	13	13	14	11	16	16
Frequently (percentage)	0	0	14	14	13	13	0	0	7	8
Almost constantly (percentage)	0	0	0	0	6	6	0	0	1	1
Skipped* (number)	21	22	5	5	13	12	8	11	47	50
Missing (number)	1	1	0	0	1	1	2	1	4	3
Unable to answer/no response (number)	0	0	0	0	1	2	0	1	1	3
Pain interference—other activities (H4b)										
Rarely (percentage)	62	63	61	59	53	53	74	73	63	62
Occasionally (percentage)	23	22	11	11	37	37	13	14	20	20
Frequently (percentage)	15	15	21	22	5	5	9	9	14	14
Almost constantly (percentage)	0	0	7	7	5	5	4	5	4	4
Skipped* (number)	9	9	5	5	10	10	6	8	30	32
Missing (number)	2	1	0	0	1	1	2	1	5	3
Out of range (number)	0	0	0	1	0	0	0	0	0	1
Unable to answer/no response (number)	0	0	1	1	1	1	0	0	2	2
Pain severity (H5)										
Mild (percentage)	26	26	3	7	5	5	14	14	12	13
Moderate (percentage)	37	37	31	28	50	45	41	38	39	36
Severe (percentage)	30	30	41	41	30	35	32	33	34	35
Very severe/horrible (percentage)	7	7	24	24	15	15	14	14	15	15
Skipped* (number)	9	9	5	5	10	10	6	8	30	32
Missing (number)	1	1	0	0	1	1	3	1	5	3
Unable to answer/no response (number)	0	0	0	0	0	0	0	1	0	1
Pain relief (H6)										
No relief (percentage)	11	15	0	0	11	11	5	9	6	8
Some relief (percentage)	44	41	45	45	37	37	41	41	42	41
Quite a bit of relief (percentage)	33	33	48	48	26	26	41	41	38	38
Very much relief (percentage)	11	11	7	7	26	26	14	9	13	12

	HHA (N = 37)		IRF (N = 34)		LTCH (N = 31)		SNF (N = 31)		Overall (N = 133)	
Item	**R**	**F**	**R**	**F**	**R**	**F**	**R**	**F**	**R**	**F**
Skipped* (number)	9	9	5	5	10	10	6	8	30	32
Missing (number)	1	1	0	0	1	1	2	1	4	3
Not applicable—patient/resident has not received pain treatments or medications in the past three days (number)	0	0	0	0	1	1	1	0	2	1

NOTES: R = research nurse. F = facility staff. An asterisk denotes that skipped answers are appropriately missing based on prior answers and programmed skip patterns. *Percentage* rows tabulate responses to each item across all possible answer categories; responses sum to 100 percent. *Number* rows show the number of times each item was unknown, missing, or similar. Responses tabulated in *number* rows are not part of the denominator for calculating percentages.

Table 7.3 shows the frequency with which assessors adhered to assessment skip rules. Adherence to skip rules was extremely high (greater than or equal to 90 percent) in all settings, with few differences between research nurses and facility staff, suggesting that skip instructions were clear and easy to follow.

Table 7.3. Pain Items: Frequency of Research Nurse and Facility Staff Adherence to Assessment Skip Rules

	HHA (N = 37)		IRF (N = 34)		LTCH (N = 31)		SNF (N = 31)		Overall (N = 133)	
Adherence to skip rules	**R**	**F**	**R**	**F**	**R**	**F**	**R**	**F**	**R**	**F**
Where *pain presence* (H1) = 0 or 9, skipped items H2–H6 (percentage)	100	100	100	100	100	100	97	97	99	99
Where *pain interference–therapy activities* (H4) = 0 or 9, skipped item H4a (percentage)	96	100	100	100	95	90	100	91	98	96

NOTE: R = research nurse. F = facility staff.

Table 7.4 shows that the average time to complete the pain assessment was approximately three minutes, with little variation across settings.

Table 7.4. Average Time Spent (in Minutes) Completing Pain Items by PAC Setting

	HHA Mean (SD)	IRF Mean (SD)	LTCH Mean (SD)	SNF Mean (SD)	Overall Mean (SD)
By research nurse					
Where *Pain Presence* coded "No" (H1 = 0)	0.7 (0.5) N = 9	2 (1.4) N = 5	0.7 (0.5) N = 10	0.5 (0.6) N = 6	0.9 (0.9) N = 30
Where *Pain Presence* coded "Yes" (H1 = 1)	3.5 (1.3) N = 28	3.5 (1.9) N = 29	3.8 (2.2) N = 21	3.9 (2.9) N = 25	3.6 (2.1) N = 103
By facility staff					
Where *Pain Presence* coded "No" (H1 = 0)	0.7 (0.5) N = 9	2 (1.4) N = 5	0.7 (0.5) N = 10	1.1 (1.6) N = 8	1 (1.1) N = 32
Where *Pain Presence* coded "Yes" (H1 = 1)	3.5 (1.3) N = 28	3.4 (1.9) N = 29	3.8 (2.2) N = 21	4.0 (3.0) N = 23	3.6 (2.1) N = 101

Feedback from Assessors

The assessors noted two issues or recommendations for the pain section.

Positive Views of Pain Items. The research nurses repeatedly commented that the pain section was straightforward, and that they experienced few challenges completing it. The research nurses predicted that this section would likely show the highest reliability.

Pain With and Without Medication. The only issue raised by one research nurse was that some patients/residents would say they did not have pain, but this was discordant with what was written in the patient's/resident's medical record. The facility staff noted that patients/residents often asked if the questions referred to pain present with or without medication, so clarifying this may be helpful.

Summary of Findings: Pain

IRR. Interrater agreement on pain items was excellent—always above 0.90, and frequently perfect.

Feasibility of Use. The pain items took approximately one minute to administer when there was no pain, and approximately three minutes to administer when there was pain. Assessors' comments generally reflected the fact that the pain items were straightforward to administer and highly consistent across assessors. In summary, the pain items performed as well as, or better than, any other content area and do not appear to require any further changes.

Chapter Eight. Results for Care Preferences

This chapter describes the results for care preferences, the testing objectives and analytic approach, and results from the feasibility test.

Assessment of patient preferences for care in PAC settings is critical to informing a patient-centered care plan and developing a plan for successful care transitions.[1] Information about care preferences can also be used to contextualize the progress toward established milestones and goals and can help to create a person-centered experience in PAC settings.

Description of Items

The Care Preferences items can be found in Appendix A, Section A. The Care Preferences items cover four related topics: (1) Documentation of a Decisionmaker; (2) Involvement of Family and Friends in Care Decisions; (3) Goals of Care; and (4) Preferences for Involvement in Decisionmaking.

The *Documentation of a Decisionmaker* item (Item A1, "Does the patient/resident have a designated Health Care Agent?") is adapted from the PAC PRD. The current item has been modified to reflect a shift toward a "Health Care Agent," as opposed to a more general decisionmaker, and contains other minor wording changes. The PAC PRD item was demonstrated to have strong IRR.[2] However, this item has not been assessed in its current proposed form. This item is the only one in this content area to be assessed through medical record review. The item determines whether there is information in the medical record pertaining to a surrogate health care decisionmaker.

The *Involvement of Family and Friends in Care Decisions* item (Item A2, "How important is it to you to have your family or a close friend involved in discussions about your care?") is currently in use in SNF settings through the MDS 3.0 Resident Assessment Instrument (version 1.13), where it has been demonstrated to have very high IRR.[3] This item is assessed through patient interview. The assessment is based on a single question with a Likert scale response, prompting respondents to use a scale from *not important at all* to *very important*. Assessors are given a final option for respondents who are unable to

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[1] Rosalie A. Kane, "Goals of Home Care: Therapeutic, Compensatory, Either, or Both?" *Journal of Aging and Health*, Vol. 11, No. 3, 1999; Robert L. Kane and Rosalie A. Kane, "What Older People Want From Long-Term Care, and How They Can Get It," *Health Affairs*, Vol. 20, No. 6, 2001; Carol J. Whitlatch, Rich Piiparinen, and Lynn Friss Feinberg, "How Well Do Family Caregivers Know Their Relatives' Care Values and Preferences?" *Dementia*, Vol. 8, No. 2, 2009; Judith E. Arnetz, I. Almin, K. Bergstrom, Y. Franzen, and H. Nilsson, "Active Patient Involvement in the Establishment of Physical Therapy Goals: Effects on Treatment Outcome and Quality of Care," *Advances in Physiotherapy,* Vol. 6, No. 2, 2004.

[2] Barbara Gage, Melissa Morley, Laura Smith, Melvin J. Ingber, Anne Deutsch, Tracy Kline, Jill Dever, Judith Abbate, Richard Miller, Brieanne Lyda-McDonald, Cynthia Kelleher, Danielle Garfinkel, Joshua Manning, Christopher M. Murtaugh, Margaret Stineman, and Trudy Mallison, *Post-Acute Care Payment Reform Demonstration,* Research Triangle Park, North Carolina: RTI International, 2012.

[3] CMS, "CARE Tool Institutional Admission," October 2015b.

respond, choose, or who indicate that while the construct may be "important," it is not relevant or actionable (e.g., no living family or friends).

The *Goals for Care* items (Items A3a–A3d, "How important is it to you to be physically active…mentally or intellectually involved…emotionally healthy…socially involved?") are new and were developed during the information-gathering phase of the project based on literature review, expert consultation, and cognitive testing. No data about performance (i.e., validity or IRR) exist for these four items. These items are assessed through patient/resident interview. The items ask about the importance of a patient's/resident's physical activity, intellectual involvement, emotional health, and social involvement. The assessments are based on a Likert-type response scale, prompting respondents to use a scale from *not important at all* to *very important*. Assessors are given two final options for respondents who are unable to respond, or who indicate that, while the construct may be "important," it is not relevant or actionable (e.g., there is no possibility of regaining physical activity).

The two *Preferences for Involvement in Decisionmaking* items (Items A4a and A4b, which cover how much information the respondent wishes to know about his or her health care and who the respondent wants to be involved in making his or her health care decisions) are based on existing protocols that were identified in the literature as being in use in a variety of contexts, but not in PAC. The first item, which relates to the extent of information preference, derives from a larger eight-item questionnaire used in a research study for which no testing was done. The second item, on the involvement of others in the decisionmaking process, is a modified version of the Control Preferences Scale, which has been used in a range of health care settings and has demonstrated good face validity, although no evidence of reliability or validity from PAC settings currently exist.[4]

The two *Preferences for Involvement in Decisionmaking* items, as included in the Alpha 1 protocol, are administered through patient/resident interview. First, the item assessing the amount of information patients/residents like to know about the "details of [their] illness and treatment" is administered. Responses include a short spectrum of categorical options from *not to know or to know very little* to *know as much as [they] can*. The second item prompts patients to think about how they prefer to make health care decisions by referencing different individuals or groups of people who might be involved. Patients/residents can indicate a preference for making health care decisions alone, with any combination of family and/or health care professionals, or other (with a write-in option). Both items include an option for patients/residents who are unable to or do not respond.

Testing Objectives and Analytic Approach

Our main objectives in testing the Care Preferences items were (Goal 1) to determine whether items perform with acceptable IRR; and (Goal 2) to assess basic item feasibility, including clarity of instructions. To accomplish Goal 1, we calculated the level of agreement between paired assessments. We used Cohen's kappa for nominal category responses and the weighted kappa to calculate IRR for

[4] Lesley F. Degner, Jeff A. Sloan, Peri Venkatesh, "The Control Preferences Scale," *Canadian Journal of Nursing Research,* Vol. 29, No. 3, 1997.

ordered categorical responses. To accomplish Goal 2, we used the completion time for the items, and the qualitative feedback from assessors.

Results

Table 8.1 shows IRR for Care Preferences items. Agreement was uniformly high for paired observations across all items and across settings; no item had an overall IRR below 0.90.

Table 8.1. Interrater Reliability for Care Preferences Items

Item	HHA (N = 37)	IRF (N = 34)	LTCH (N = 31)	SNF (N = 31)	Overall (N = 133)
Documentation of surrogate decisionmaker (A1)	1.00	0.82	0.93	0.78	0.90
Involvement of family and friends in care decisions (A2)	1.00	1.00	1.00	1.00	1.00
Physical activity (A3a)	N/A[a]	1.00	1.00	1.00	0.98
Intellectual involvement (A3b)	1.00	1.00	1.00	0.94	0.98
Emotional health (A3c)	1.00	1.00	0.93	1.00	0.98
Social involvement (A3d)	0.96	1.00	1.00	1.00	0.99
Preference for knowledge about care (A4a)	1.00	1.00	1.00	1.00	1.00
Involvement in decisionmaking (A4b)	1.00	0.95	1.00	N/A[a]	0.96

NOTE: IRR assessed by Cohen's kappa or weighted kappa, as appropriate.
[a]Cells with N/A indicate that not all response categories were endorsed by both nurses and facility staff; thus, IRR cannot be computed.

Table 8.2 shows the breakdown of responses to items across settings and between research nurses and facility staff. For most items, responses were consistent across settings and between facility and research staff. For a few items, there was marked variation across care settings, especially for Item A1 ($\chi^2 = 57.89$, $p < 0.05$), "Does the patient/resident have a designated Health Care Agent…AND is there legal documentation in the medical record?" Only 3 percent of patients in the HHA setting met this criterion, compared with approximately 50 percent of LTCH patients, with the other settings recording results in between. This likely reflects an actual difference in how often these details are recorded across different settings. Despite this variation among settings, results obtained by different types of assessors (research versus facility) were highly consistent across the entire category.

Another such difference occurred on Item A4a ("Do you prefer to know as much as you can about the details of your illness and treatment, prefer some information, or prefer not to know or to know very little?"). Only 69 percent of patients in the HHA setting wished to know "as much as I can" about their care, whereas this figure was 90 percent or higher in all other settings ($\chi^2 = 20.32$, $p < 0.05$).

Table 8.2. Frequency Distribution of Responses to Care Preferences Items

	HHA (N = 37)		IRF (N = 34)		LTCH (N = 31)		SNF (N = 31)		Overall (N = 133)	
Item	**R**	**F**	**R**	**F**	**R**	**F**	**R**	**F**	**R**	**F**
Does the patient/resident have a designated Health Care Agent as authorized under state law to make health care decisions in the event that he/she is unable to make his or her own decisions AND there is legal documentation in the medical record? (A1)										
Yes (percentage)	3	3	18	25	50	55	10	6	19	22

Item	HHA (N = 37)		IRF (N = 34)		LTCH (N = 31)		SNF (N = 31)		Overall (N = 133)	
	R	F	R	F	R	F	R	F	R	F
Missing (number)	1	1	1	2	1	0	1	0	4	3
Involvement of family and friends in care decisions (A2)										
Very important (percentage)	69	69	77	77	79	79	91	78	76	75
Somewhat important (percentage)	22	22	17	17	10	10	12	11	16	16
Not very important (percentage)	6	6	7	7	7	7	4	4	6	6
Not important at all (percentage)	3	3	0	0	3	3	4	7	2	3
Missing (number)	1	1	0	0	1	1	1	1	3	3
N/A (important but cannot do or no choice) (number)	0	0	4	4	1	1	3	3	8	8
No response (number)	0	0	0	0	0	0	1	0	1	0
Physical activity (A3a)										
Very important (percentage)	58	58	67	67	78	78	78	78	69	69
Somewhat important (percentage)	32	32	27	27	22	22	15	15	25	25
Not very important (percentage)	10	6	6	6	0	0	4	4	5	4
Not important at all (percentage)	0	3	0	0	0	0	4	4	1	2
N/A (important but cannot do or no choice) (number)	5	5	1	1	3	3	3	3	12	12
Missing (number)	1	1	0	0	1	1	1	1	3	3
Intellectual involvement (A3b)										
Very important (percentage)	77	77	85	85	70	70	79	75	78	77
Somewhat important (percentage)	20	20	15	15	30	30	14	18	20	20
Not very important (percentage)	3	3	0	0	0	0	4	4	2	2
Not important at all (percentage)	0	0	0	0	0	0	4	4	1	1
N/A (important but cannot do or no choice) (number)	1	1	0	0	0	0	1	1	2	2
Missing (no response)/out of range (number)	1	1	0	0	1	1	2	2	4	4
Emotional health (A3c)										
Very important (percentage)	81	81	79	79	80	77	86	86	81	81
Somewhat important (percentage)	19	19	21	21	17	20	14	14	18	18

Item	HHA (N = 37)		IRF (N = 34)		LTCH (N = 31)		SNF (N = 31)		Overall (N = 133)	
	R	F	R	F	R	F	R	F	R	F
Not very important (percentage)	0	0	0	0	0	0	0	0	0	0
Not important at all (percentage)	0	0	0	0	3	3	0	0	1	1
N/A (important but cannot do or no choice) (number)	0	0	0	0	0	0	1	1	1	1
Missing (no response) (number)	1	1	0	0	1	1	1	1	3	3
Social involvement (A3d)										
Very important (percentage)	54	57	84	84	71	71	69	69	69	70
Somewhat important (percentage)	34	31	12	12	25	25	24	24	24	23
Not very important (percentage)	9	9	3	3	4	4	7	7	6	6
Not important at all (percentage)	3	3	0	0	0	0	0	0	1	1
N/A (important but cannot do or no choice) (number)	1	1	2	2	1	1	1	1	5	5
Missing (no response) (number)	1	1	0	0	2	2	1	1	4	4
Preference for knowledge about care (A4a)										
To know as much as you can (percentage)	69	69	91	91	90	90	90	90	85	85
Some information (percentage)	25	25	9	9	10	10	7	7	13	13
Not to know or to know very little (percentage)	6	6	0	0	0	0	3	3	2	2
Missing (number)	1	1	0	0	1	1	1	1	3	3
Involvement in decisionmaking (A4b)										
You alone (percentage)	11	11	0	0	4	3	3	3	5	5
Health care professional to make decision for you (percentage)	8	8	3	3	0	0	0	3	3	4
You and your family member(s) (percentage)	6	6	29	32	29	28	38	43	24	26
You and a health care professional to decide together (percentage)	3	3	12	12	4	3	7	3	6	5
You, a health care professional and your family members(s) to decide together (percentage)	69	69	56	53	64	62	52	47	61	58
Other (percentage)	3	3	0	0	0	3	0	0	1	2
N/A (important but cannot do or no choice) (number)	4	0	0	0	1	1	1	0	6	1

	HHA (N = 37)		IRF (N = 34)		LTCH (N = 31)		SNF (N = 31)		Overall (N = 133)	
Item	**R**	**F**	**R**	**F**	**R**	**F**	**R**	**F**	**R**	**F**
Missing (no response)/out of range (number)	0	1	0	0	2	1	1	1	3	3

NOTES: R = research nurse. F = facility staff. *Percentage* rows tabulate responses to each item across all possible answer categories; responses sum to 100 percent. *Number* rows show the number of times each item was unknown, missing, or similar. Responses tabulated in number rows are not part of the denominator for calculating percentages.

Table 8.3 shows the amount of time needed to complete the Care Preferences section. In general, the section was completed in approximately 6 minutes total, a figure which differed little across settings and between research nurses and facility staff.

Table 8.3. Average Time Spent Completing Care Preferences Items, by PAC Setting

	HHA (N = 37) Mean (SD)	IRF (N = 34) Mean (SD)	LTCH (N = 31) Mean (SD)	SNF (N = 31) Mean (SD)	Overall (N = 133) Mean (SD)
Time to complete the first section, Item A1 (in minutes)					
By research nurse	0.2 (0.6)	0.8 (1.8)	1.3 (2)	0.3 (0.9)	0.6 (1.5)
By facility staff	0.6 (2.1)	1.7 (1.4)	0.9 (1.0)	0.9 (1.0)	1.0 (1.5)
Time to complete the second section, Items A2–A4b (in minutes)					
By research nurse	5.1 (2.0)	4.8 (1.4)	5.6 (2.6)	5.8 (2.9	5.3 (2.3)
By facility staff	4.9 (1.9)	4.8 (1.4)	5.6 (2.6)	5.8 (2.9)	5.3 (2.3)

Feedback from Assessors: Care Preferences

Assessors identified three items for comment in the Care Preferences section:

Lead-in Text to Care Preferences Section Needs Improvement. Several research nurses stated that the lead-in to the first question in the care preferences section is awkward and does not flow well. They suggested that adding another sentence could help clarify.

Unclear Answer Options for Item A4b. Item A4b ("Which of the following statements best describes the way in which you would like decisions about your health care to be made?") was the one most frequently mentioned as problematic. The purpose of the item is to ask patients how they want to make decisions about their health care. Several assessors noted that these responses were too lengthy and redundant and difficult for assessors to read. It was also difficult for patients/residents to select an answer. Some patients/residents would choose an answer to Item A4b before the assessor finished reading the options. The assessors stated that, with the help of cue cards, most patients/residents were eventually able to choose an answer. Still, several facility staff said that the answer to this item can sometimes be vague, and that patients/residents do not seem sure of their choice. The facility staff suggested that one potential fix may be to delete answer 3, since they thought it assumes that the patient's/resident's questions have been answered by a health care professional; therefore it is the same as answer 5. The facility staff also added that such small differences in wording between the answer options are particularly challenging for patients/residents who are fatigued. In addition, one facility staff member noted that a patient/resident had a very emotional reaction to this item.

Unclear Answer Options for Items A3a–A3d. For Items A3a–A3d ("How important is it to you to be physically active…mentally or intellectually involved…emotionally healthy…socially involved?"), assessors recommended simplifying the answer options, since patients/residents often could not discriminate between *not very important* and *not important at all*. Additionally, two facility staff members said that patients/residents did not understand what the answer option *important, but can't do or no choice* meant, although another facility staff member said she had patients who chose that answer without any trouble.

Summary of Findings: Care Preferences

IRR. Across the entire care preferences section, items performed well in terms of IRR, with perfect or near-perfect interrater agreement on all items.

Feasibility of Use. Items were also generally judged to be feasible across the entire care preferences content area. This category took from six to seven minutes to administer in full. Assessors thought the items in Care Preferences worked well but had two specific suggestions to improve them. First, Item A4b ("Which of the following statements best describes the way in which you would like decisions about your health care to be made?") was perceived to be awkwardly worded, and assessors (both research nurses and facility staff) requested wording changes to make it easier for patients to understand. Second, for Items A3a–A3d ("How important is it to you to be physically active…mentally or intellectually involved…emotionally healthy…socially involved?"), assessors (both research nurses and facility staff) recommended collapsing the levels *not very important* and *not very important at all*, because patients appeared to have difficulty distinguishing between these shades of meaning.

Chapter Nine. Results for Medication Reconciliation

This chapter describes the medication reconciliation items, the testing objectives and analytic approach, and results from the feasibility test.

Approximately 75 percent of medication errors during transitions in care are preventable, and medication reconciliation, the process of obtaining a patient's multiple medication lists and reconciling any discrepancies, is a cost-effective way to promote patient safety by reducing errors and resulting adverse drug events. Medication reconciliation was adopted by the Joint Commission as a National Patient Safety Goal in 2005.[1] The five steps in the Joint Commission's medication reconciliation process are (1) develop a list of current medications; (2) develop a list of medications to be prescribed; (3) compare medications on the two lists; (4) make clinical decisions based on the comparisons; and (5) communicate the new list to the patient and appropriate caregivers.[2] Studies repeatedly show that formal medication reconciliation can improve quality of life and reduce morbidity and mortality.[3] Development of standardized items is essential for improving patient care at points of transition and reducing medication errors.

Description of Items

The Medication Reconciliation items can be found in Appendix A, Section B. These items were developed to measure whether and how medication reconciliation was conducted. The goal was to create a standardized set of items that assess the medication reconciliation process with clear definitions of each step to better explicate processes for providers aiming to improve care, ease care transitions, facilitate audits for assessment and adherence, and support future development of appropriate provider-level quality measures. This standardized process should include identifying medications (including dose, route, and frequency) from all sources, assigning responsibility for obtaining this information, and reconciling any discrepancies. It should also include communication back to patients, providers, and pharmacies.

Existing tools found through an extensive literature review were either copyrighted, did not address PAC settings, did not address the five steps above, or did not have sufficient reliability and validity in

[1] The Joint Commission, *Comprehensive Accreditation Manual for Hospitals*, Chicago, Ill., 2015.

[2] The Joint Commission, 2015; Kenneth S. Boockvar, Heather Carlson LaCorte, Vincent Giambanco, Bella Fridman, and Albert Siu, "Medication Reconciliation for Reducing Drug-Discrepancy Adverse Events," *American Journal of Geriatric Pharmacotherapy,* Vol. 4, No. 3, 2006.

[3] Thomas Delate, Elizabeth A. Chester, Troy W. Stubbings, and Carol A. Barnes, "Clinical Outcomes of a Home-Based Medication Reconciliation Program After Discharge from a Skilled Nursing Facility," *Pharmacotherapy,* Vol. 28, No. 4, 2008; Yuhua Bao, Huibo Shao, Tara F. Bishop, Bruce R. Schackman, and Martha L. Bruce, "Inappropriate Medication in a National Sample of U.S. Elderly Patients Receiving Home Health Care," *Journal of General Internal Medicine,* Vol. 27, No. 3, 2012.

published studies. Thus, our team developed new medication reconciliation items with input from five clinical advisers.

- The first item (Item B1) asks whether lists of medications were procured from more than one information source. The rate of discrepancies may be higher when there are multiple medication lists, so this is important to determine. Possible responses are *no*, *yes*, *not applicable because the patient/resident is not taking any medications*, and *unknown/missing information*.
- The second item (Item B2) addresses indication for medications, or the reason why the medication is being taken. While many people have recommended indication-based prescribing, medications are still frequently listed without the reason they were prescribed, making it harder to evaluate medication appropriateness. Responses include *yes*, *no*, and *unknown/missing information*.
- The next seven items (Items B3–B9) ask about medication discrepancies and potential adverse drug events (pADEs), and whether high-risk drugs were involved. The items also ask about the time frame in which high-risk discrepancies and pADEs were identified by the PAC, conveyed to a physician or physician-designee, and addressed by that person.
- The last three items (Items B10–B12) measure communication between key parties about medications. One item relates to communication with the patient/resident or his or her caregiver, and another two to communication with primary care providers and the patient's/resident's pharmacy. As noted above, communication is an important part of the medication reconciliation process and has not been captured comprehensively in any other tool.

Testing Objectives and Analytic Approach

Our main objectives were (Goal 1) to determine whether the ratings of medication reconciliation items could be made with acceptable IRR; (Goal 2) to determine the feasibility of completing the items; (Goal 3) to evaluate the clarity of instructions on rating the items and utility of definitions provided in the user manual; (Goal 4) to determine the consistency of information sources used to complete the items; (Goal 5) to assess whether the concordance or discordance of information sources influence the IRR (as described in the first objective); and (Goal 6) to determine whether results are consistent across care settings, an objective that spans all the analyses.

To assess Goal 1, we report the results for each item, including missing values, in Table 9.1. For example, to evaluate consistency of response to a question about communication with patients and family, we explored the percentage of cases in which paired assessors' codes agreed on that question. We also calculated the level of agreement between paired assessors' judgments. IRR was calculated for each item. We used Cohen's kappa as an index of IRR for the symptom presence ratings and weighted kappa for the ordered categorical ratings.

To assess Goal 2, we relied on both the time of administration and the qualitative feedback from assessors obtained during the debriefing interviews.

Goal 3 was ascertained based on conversations with nurses during the debriefing interviews when prompted to discuss the clarity of instructions. To investigate setting-by-setting variation in the reliability and ease of administration of the item, we calculated all statistics by setting and across the

four settings. Likewise, in evaluating the feedback that nurses provided during the debriefing interviews, we attempted to discern whether setting differences were evident.

To further elaborate on Goals 4 and 5, we asked assessors to identify the source(s) of data used to answer each item. This enabled us to conduct IRR measurements taking into account whether the assessors were using the same source (thus measuring interpretation) or different sources (thus comparing whether different sources seem to provide the same answers).

For Goal 4, we determined the consistency of information sources by exploring the responses to questions regarding the information source used to answer each question. This helped us explore, for Goal 5, whether cases of low IRR were due to different information sources or different interpretation of the same source. Goal 6 was accomplished through stratification of all analyses by care setting.

Results

Results in the medication reconciliation content area revealed more-serious issues with reliability than any other category, which was not unexpected as these are all new items. Table 9.1 shows the breakdown of responses to items in the medication reconciliation content area across settings and between research nurses and facility staff.

Research nurses and facility staff often differed considerably on medication reconciliation items; due to the relatively large differences, we tested some for statistical significance. For example, on item B9 (PAC addressed physician recommendations within 24 hours), 95 percent of research nurses answered yes, compared with 89 percent of facility staff ($t = 9.93$, $p < 0.05$). Sometimes there were marked differences between assessor types within a single setting. For example, on item B3 ("Did the review identify any medication discrepancies?"), in the SNF setting, 70 percent of research nurses answered in the affirmative, compared with 24 percent of facility staff ($t = 2.98$, $p < 0.05$).

Table 9.1. Frequency Distribution of Responses to Medication Reconciliation Items

	HHA (N = 37)		IRF (N = 34)		LTCH (N = 31)		SNF (N = 31)		Overall (N = 133)	
Item	**R**	**F**	**R**	**F**	**R**	**F**	**R**	**F**	**R**	**F**
List from more than one source (B1)										
Yes (percentage)	74	32	85	74	84	94	100	58	86	65
Missing (number)	1	0	0	0	0	0	0	0	1	0
Unknown/missing information/lack of documentation (number)	1	6	0	0	0	0	0	0	1	6
Prescriber included indication (B2)										
Yes (percentage)	6	9	3	6	42	42	48	55	24	27
Missing (number)	1	0	0	0	0	0	0	0	1	0
Unknown/missing information/lack of documentation (number)	1	4	0	0	0	0	0	0	1	4
Identified medication discrepancy (B3)										
Yes (percentage)	45	49	48	35	68	94	70	24	57	50

	HHA (N = 37)		IRF (N = 34)		LTCH (N = 31)		SNF (N = 31)		Overall (N = 133)	
Item	**R**	**F**	**R**	**F**	**R**	**F**	**R**	**F**	**R**	**F**
Missing (number)	1	0	0	0	0	0	0	0	1	0
Unknown/missing information/lack of documentation (number)	3	2	1	0	0	0	1	2	5	4
Identified potential adverse events (B4)										
Yes (percentage)	73	82	15	47	94	84	84	48	65	65
Missing (number)	1	1	0	0	0	0	0	0	1	1
Unknown/missing information/lack of documentation (number)	3	2	0	0	0	0	0	0	3	2
Discrepancy involved “high-risk” drug (B5)										
Yes (percentage)	68	83	52	70	94	80	96	71	81	77
Missing (number)	6	0	3	0	0	1	1	0	10	1
Skipped* (number)	6	5	14	11	0	0	4	14	24	30
Unknown/missing information/lack of documentation (number)	3	2	0	0	0	0	0	0	3	2
PAC addressed all discrepancies (B6)										
24 hours after admission (percentage)	65	56	78	50	97	76	80	83	82	65
48 hours after admission (percentage)	10	15	11	19	0	0	12	17	7	11
72 hours after admission (percentage)	5	13	0	13	0	12	0	0	1	6
Not addressed within three days of admission (percentage)	20	30	11	19	3	12	8	0	10	18
Missing (number)	4	0	3	0	0	0	1	0	8	0
Skipped* (number)	13	10	22	18	2	6	5	19	42	53
PAC addressed discrepancies with patient or caregiver (B7)										
Yes (percentage)	80	79	13	0	14	11	24	20	34	35
Missing (number)	3	0	3	0	0	1	1	0	7	1
Skipped* (number)	13	10	22	18	2	6	5	19	42	53
Unknown/missing information/lack of documentation (number)	6	13	1	7	15	15	0	7	22	42
Contacted physician for high-risk discrepancies (B8)										
No (percentage)	18	5	50	78	7	38	0	27	12	30
No, done but not within 24 hours (percentage)	12	25	0	0	0	0	5	9	4	11
Yes (percentage)	71	70	50	22	93	63	95	64	84	59
Missing (number)	3	0	3	0	0	0	1	0	7	0
Skipped* (number)	13	10	22	18	2	6	5	19	42	53
Not applicable (number)	4	7	1	7	0	9	3	1	8	24
PAC addressed physician recommendations in 24 hours (B9)										
No (percentage)	13	40	0	20	0	0	0	0	5	11

Item	HHA (N = 37)		IRF (N = 34)		LTCH (N = 31)		SNF (N = 31)		Overall (N = 133)	
	R	F	R	F	R	F	R	F	R	F
No, done but not within 24 hours (percentage)	0	0	0	0	0	0	0	0	0	0
Yes (percentage)	88	60	100	80	100	100	100	100	95	89
Missing (number)	3	0	3	0	0	0	1	0	7	0
Skipped* (number)	16	11	26	25	4	12	5	22	51	70
Not applicable (number)	10	21	0	4	0	9	3	2	13	36
PAC communicated reconciled medication to patient (B10)										
Yes (percentage)	81	96	5	0	12	21	20	33	29	43
Missing (number)	3	0	0	0	0	0	1	0	4	0
Out of range (number)	1	0	0	0	0	0	0	0	1	0
Skipped* (number)	6	5	14	11	0	0	4	14	24	30
Not applicable (number)	2	0	0	0	0	0	0	0	2	0
Unknown/missing information/lack of documentation (number)	4	8	1	6	6	12	1	8	12	34
PAC communicated reconciled medication to PCP (B11)										
Yes (percentage)	67	67	71	22	94	86	100	93	83	65
Missing (number)	3	0	0	0	0	0	1	0	4	0
Skipped* (number)	6	5	14	11	0	0	4	14	24	30
Not applicable (number)	2	0	0	0	0	0	0	0	4	0
Unknown/missing information/lack of documentation (number)	5	14	3	5	15	17	3	2	26	38
PAC communicated reconciled medication to pharmacy (B12)										
Yes (percentage)	4	11	80	30	94	80	100	93	67	45
Missing (number)	3	0	0	0	0	0	1	0	4	0
Skipped* (number)	6	5	14	11	0	0	4	14	24	30
Not applicable (number)	1	0	0	0	0	0	0	1	1	1
Unknown/missing information/lack of documentation (number)	3	5	0	3	15	16	1	2	19	26

NOTES: R = research nurse. F = facility staff. An asterisk denotes that skipped answers are appropriately missing based on prior answers and programmed skip patterns. *Percentage* rows tabulate responses to each item across all possible answer categories; responses sum to 100 percent. *Number* rows show the number of times each item was unknown, missing, or similar. Responses tabulated in the number rows are not part of the denominator for calculating percentages.

Table 9.2 shows the IRR for items in the medication reconciliation content area, across 133 pairs of observations. While a few items achieved relatively high kappa scores (e.g., 0.83 overall for Item B10 (PAC communicated the reconciled medication list to the patient or the patient's caregiver) and 0.71 overall for Item B2 (Prescriber included an indication for each medication on the list), most items had low kappas—usually below 0.50 and often below 0.30. In some settings, especially the LTCH, negative kappas were recorded for some items, indicating agreement worse than chance. We also conducted a sensitivity analysis combining *No* and *Don't know* responses, because assessors reported that there was inconsistency in how different assessors handled lack of documentation in some cases. This analysis led

to better agreement on many items, but worse agreement on others. We plan to simplify answer choices and improve training for the next round of testing to address this issue.

Table 9.2. Interrater Reliability of Medication Reconciliation Items

Agreement Among Yes Versus No Responses	HHA (N = 37)	IRF (N = 34)	LTCH (N = 31)	SNF (N = 31)	Overall (N = 133)
List from more than one source (B1)[a]	0.11	0.12	–0.10	N/A	0.06
Prescriber included indication (B2)[a]	0.78	–0.04	0.87	0.49	0.71
Identified medication discrepancy (B3)[a]	0.87	0.14	0.25	0.03	0.35
Identified potential adverse events (B4)[a]	0.71	0.32	–0.10	0.05	0.37
Discrepancy involved "high-risk" drug (B5)[a]	0.57	0.05	–0.11	0.25	0.20
PAC addressed all discrepancies (B6)[b]	N/A	N/A	N/A	N/A	0.20
PAC addressed discrepancies with patient or caregiver (B7)[a]	0.00	N/A	–0.13	1.00	0.52
Contacted physician for high-risk discrepancies (B8)[b]	N/A	N/A	–0.13	N/A	–0.10
PAC addressed physician recommendations in 24 hours (B9)[a]	1.00	N/A	N/A	N/A	1.00
PAC communicated reconciled medication to patient (B10)[a]	0.64	N/A	0.77	0.36	0.83
PAC communicated reconciled medication to PCP (B11)[a]	0.21	0.15	0.00	N/A	0.23
PAC communicated reconciled medication to pharmacy (B12)[a]	0.46	0.10	0.00	N/A	0.57

NOTES: Cells with N/A indicate that not all response categories were endorsed by both nurses; thus, IRR cannot be computed.
[a]IRR assessed by Cohen's kappa.
[b]IRR assessed by weighted kappa.

We examined whether information sources used to answer the medication reconciliation questions were consistent by item and setting, using exact and partial consistency calculations. Exact consistency means that the assessors identified exactly the same sources of information. Partial consistency means that the assessors used at least one source of information in common, but also that there could be at least one other source of information that one of the assessors used and the other did not. Logically, every case of exact consistency of information would also qualify as (at least) partial consistency of information sources.

Exact consistency of data sources was achieved in about half of cases across most items, with some items higher and some lower. Predictably, partial consistency was achieved more often than exact consistency across items, although the magnitude of the difference varied by item. There were differences among settings on some items; for example, exact consistency was achieved less often in the HHA setting compared with other settings for Items B1–B4 (items about identifying discrepancies or pADEs).

Table 9.3 shows the difference in terms of interrater agreement based on whether the assessors used precisely the same information sources (exact consistency) versus all others. Predictably, IRR was higher when the information sources matched (kappa = 0.43) compared with when they did not (0.28).

Table 9.3. Dependence of Interrater Agreement on Concordance of Information Source

	HHA Mean (SD), Min to Max	IRF Mean (SD), Min to Max	LTCH Mean (SD), Min to Max	SNF Mean (SD), Min to Max	Overall Mean (SD), Min to Max
Mean IRR for cases where different information sources were used	0.29 (0.39), –0.14 to 0.86	–0.21 (0.53), –1.00 to 0.17	–0.02 (0.25), –0.25 to 0.40	0.34 (0.45), 0.00 to 1.00	0.28 (0.30), –0.13 to 0.69
Mean IRR for cases where the sources were exactly matched	0.55 (0.44), 0.00 to 1.00	0.10 (0.15), –0.05 to 0.38	0.30 (0.46), –0.07 to 1.00	0.07 (0.29), –0.24 to 0.53	0.43 (0.34), –0.08 to 1.00

Table 9.4 shows the number of minutes taken to complete the medication reconciliation section by facility staff and research nurses. Across all settings combined, research nurses took an average of 20.8 minutes to complete this section, with a minimum of two minutes and a maximum of 195 minutes. Facility staff took an average of 15.6 minutes, with a minimum of one minute and a maximum of 139 minutes. Facility nurses may have taken somewhat less time to complete this section, on average, because of greater familiarity with the electronic record system. It is noteworthy that the time burden to complete this section was many times greater than any other section, attesting to the general difficulty of scoring this section using available information.

Table 9.4. Average Time Spent (in Minutes) Completing Medication Reconciliation Items, by PAC Setting

	HHA (N = 37) Mean (SD)	IRF (N = 34) Mean (SD)	LTCH (N = 31) Mean (SD)	SNF (N = 31) Mean (SD)	Overall (N = 133) Mean (SD)
Research nurse	15.1 (7.6)	19.4 (16.0)	23.8 (10.4)	25.9 (32.6)	20.8 (19.1)
Facility staff	11.5 (10.9)	14.9 (7.5)	20.6 (13.5)	16.9 (25.9)	15.6 (15.5)

Table 9.5 shows the number of assessors who properly followed skipping rules. There were some skips that were not properly followed—most notably, the instruction to end the section if the responses to Items B3 ("Did the review identify any medication discrepancies?") and B4 ("Did the review identify any potential adverse drug events?") were both *no*. This finding suggests a need to clarify or emphasize the instructions on the data collection form, and a possible need for additional assessor training on this point.

Table 9.5. Feasibility of Administering Medication Reconciliation Items: Number of Assessors Who Properly Followed Skipping Rules

Skip Item	Total Eligible to Skip	Skipped Completely (Correctly)*	Skipped Partially	Did not Skip Any
B1 (End Section)				
Research nurse (total N = 133)	0			
Facility nurse (total N = 133)	0			
B4 (End Section)				
Research nurse (total N = 133)	24	9	15	
Facility nurse (total N = 133)	30	19	11	
B5 (Skip to B10)				
Research nurse (total N = 133)	18	13	3	2
Facility nurse (total N = 133)	23	13	6	4
B8 (Skip to B10)				
Research nurse (total N = 133)	8	8		
Facility nurse (total N = 133)	5	5		

NOTE: An asterisk denotes that the relevant items should have been skipped completely.

Feedback from Assessors

Both research nurses and facility staff cited numerous difficulties in completing the medication reconciliation section.

Time-Consuming. In keeping with the numerical results, assessors commented that this was the most time-consuming section. Some attributed this to the number of items and the length of time it took to find answers in the EMR. Several assessors commented that they most often referred to the user manual for this section. In response to this feedback, answer choices were simplified. The removal of questions regarding pADEs should also ease burden.

Role of Experience and the "Learning Curve." Experience was cited as a key factor that added to the challenge of this section. Assessors agreed that this section would be easier for individuals who have more experience dealing with medications and looking at the EMR, whereas staff members such as therapists who have less experience in those areas have more difficulty. The issue of "experience" was also raised regarding the fact that facility staff have more experience with their EMRs than the research nurses; therefore, the facility staff may be able to find information that research nurses miss. The research nurses added that a good orientation to the EMR is essential in reducing these disparities. This issue is not likely to impact the implementation phase, because items will presumably be used by assessors with a good working knowledge of the EMR in most cases. When using the user manual, both groups said that they were most frequently looking up the definition of "potential adverse drug events" and how to code related items. They added that the user manual was helpful in clarifying these questions. These issues will be addressed in the extensive training planned for the next round that will include sample patient records.

Unclear Instructions for Item B1. Regarding Item B1 ("Did the post-acute care provider obtain lists of current medications from more than one information source?"), several assessors asked whether

the patient's home medication list could be considered an information source. This will be clarified in training for the next round of testing.

Compound Structure of Item B6. This item reads, "Did the post-acute care provider address all high-risk discrepancies or potential adverse drug events within…" The nurses recommended separating discrepancies and pADEs into discrete items because it is possible that a doctor addressed one and not the other, which the current item does not capture. In light of this feedback, we have removed questions regarding pADEs and instead focus on discrepancies.

Additional Information Sources Identified. Facility staff commented that, in addition to getting information from the medical record for this section, they also got information from discharge summaries, doctors, and nurses. They said that gathering information from multiple sources was not a challenge. These sources were added to the testing item.

Use of Beers Criteria Varied. Some facility staff noted that there was inconsistency in the extent to which assessors referred to the Beers Criteria because of the use of "for example" in the item. In addition, there were a few occasions where they used their phones to look up the Beers Criteria online rather than using study-provided materials. This section of the assessment was modified to enable recording the highest-risk drug classes in a way that minimized judgment by the assessor.

Difficulty Completing for Patients on Many Medications. Assessors commented that this section was more difficult to complete for patients who were taking a lot of medications, which is especially prevalent in LTCHs. The focus on high-risk medications aims to minimize burden.

Request for Additional Opportunities for Practice. The research nurses recommended providing additional opportunities for medication reconciliation practice by going through the assessment with the cue cards during the training process. This is planned as part of training for the next round of testing.

Discussion of Findings: Medication Reconciliation

The performance of items in the medication reconciliation content area was different from any other content area. There are several explanations for this discrepancy. First, most items in this area are brand new, and others were adapted from related items that have been used but in their current form are also new, so none have been previously tested in their current form. Second, while the content area of medication reconciliation is extremely important to patient safety and outcomes, and is therefore worth considerable effort to assess, it is an inherently complicated task. Third, most assessors had little or no experience completing related items in the past through such other instruments as MDS, OASIS, IRF-PAI, or LCDS because these instruments had not contained an analogous section. This accounts for what assessors described as a "steep learning curve" for completing these items. Fourth, many of the challenges to completing the medication reconciliation items are external to the items themselves and are due to imperfections in clinical documentation.

Our plan for improving the medication reconciliation section includes revising some of the items, with the help of the quantitative results and qualitative feedback discussed in this report. It is also likely that as assessors become more experienced with completing these items, the time to complete them will decrease somewhat, and the accuracy (and therefore the IRR) may improve somewhat. Finally, it is also

likely that assessing medication reconciliation is simply more complicated than some of the other domains and will always take more time and achieve somewhat lower scores on IRR, even after we optimize the items. Given the importance of this content area to patient outcomes, it is likely still highly worthwhile to complete these items, despite the effort involved. Also, to the extent that improved medical records will facilitate the completion of this section by making it easier to record and to locate relevant information, the existence of this section is likely to encourage improved design of medical record systems in meaningful ways.

Summary of Findings: Medication Reconciliation

IRR. There were issues with IRR for many of the items in this content area. Kappas for interrater concordance were low for most items, often below 0.30.

Feasibility/Ease of Use. The medication reconciliation items were perceived by assessors as challenging to administer and required by far the most time of any content area (between 15 and 20 minutes).

Clarity of Instructions. Assessor feedback identified several opportunities for improvement, including unclear instructions for Item B1 ("Did the post-acute care provider obtain lists of current medications from more than one information source?"), compound structure of Item B6 ("Did the post-acute care provider address all high-risk discrepancies or potential adverse drug events within…"), and insufficient information given in the instructions to determine Beers Criteria in some cases.

Consistency of Data Sources. It was clear that part of the challenge for this content area was the need to look for information across multiple data sources, with considerable variability between patients, assessors, and care settings.

Influence of Data Source Concordance on IRR. We found that IRR was somewhat higher when the information sources matched (kappa = 0.39) than when they did not (0.29).

Whether Results Differ by Setting. We found considerable differences between care settings for the results of the medication reconciliation items.

Chapter Ten. Results for Bladder and Bowel Continence

This chapter describes the bladder and bowel continence items, the testing objectives and analytic approach, and results from the feasibility test.

Impaired bowel and bladder continence are common conditions that, if unaddressed, can affect patients' activities of daily living, rehabilitation outcomes, skin integrity, and overall quality of life.[1] Incontinence is also associated with a host of negative outcomes, including sleep difficulties, inactivity, social isolation, and depression.[2] Changes in continence can signal important changes in health status, making transfer of information at care transitions particularly important.

Description of Items

The bladder and bowel items can be found in Appendix A, Section C. They assess patients'/residents' bladder and bowel functioning with respect to two primary content areas: (1) bladder and bowel device utilization, and (2) patients'/residents' bladder and bowel continence. Items consist of items modified from items tested in PAC PRD and new items developed using clinical and technical expert input. Multiple sources of information, including medical record review, direct patient/resident observation, facility staff interviews, and patient/resident and caregiver interviews are used to complete these items. Similar to other sections in the assessment, these items follow skip patterns and termination rules based upon patient/resident responses.

Items are administered separately for bladder and bowel. The bladder items begin with an item to assess device use (such as an indwelling catheter, Item C1a). If the assessor determines the patient/resident has a bladder device, she or he then completes three newly developed items (Items C1b, C1c, and C1d) to indicate the type(s) of device(s), timing of indwelling or external catheter placement, reason for an indwelling or external catheter placement, and the patient's need for assistance to manage the equipment or devices. Item C2a asks how frequently the patient/resident has incontinent events. If

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[1] C. Seth Landefeld, Barbara J. Bowers, Andrew D. Feld, Katherine E. Hartmann, Eileen Hoffman, Melvin J. Ingber, Joseph T. King, W. Scott McDougal, Heidi Nelson, Endel John Orav, Michael Pignone, Lisa H. Richardson, Robert M. Rohrbaugh, Hilary C. Siebens, and Bruce J. Trock, "National Institutes of Health State-of-the-Science Conference Statement: Prevention of Fecal and Urinary Incontinence in Adults," *Annals of Internal Medicine,* Vol. 148, No. 6, 2008.

[2] Ingrid Nygaard, Carolyn L. Turvey, Trudy L. Burns, Elizabeth Crischilles, and Robert Wallace, "Urinary Incontinence and Depression in Middle-Aged United States Women," *Obstetrics and Gynecology,* Vol. 101, No. 1, 2003; Jeanette S. Brown, Eric Vittinghoff, Jean F. Wyman, Katie L. Stone, Michael C. Nevitt, Kristine E. Ensrud, and Deborah Grady, "Urinary Incontinence: Does it Increase Risk for Falls and Fractures? Study of Osteoporotic Fractures Research Group," *Journal of American Geriatrics Society*, Vol. 48, No. 7, 2000; Joseph G. Ouslander, Barbara Greengold, and Sophia Chen, "External Catheter Use and Urinary Tract Infections Among Incontinent Male Nursing Home Patients," *Journal of the American Geriatrics Society,* Vol. 35, No. 12, 1987; Ellen H. Elpern, Kathryn Killeen, Alice Ketchem, Amanda Wiley, Gourang Patel, and Omar Lateef, "Reducing Use of Indwelling Urinary Catheters and Associated Urinary Tract Infections," *American Journal of Critical Care,* Vol. 18, No. 6, 2009.

the patient/resident had incontinent events, Item C2b then asks whether the patient/resident had bladder incontinent events prior to the hospitalization.

Similar to bladder items, the bowel items begin with an item to assess device use (Item C3a). If the patient has an indwelling or external bowel device, the assessor indicates when the device was first placed and whether the patient/resident needs assistance to manage equipment or devices (Items C3b and C3c). Item C4a then asks about how frequently the patient/resident has incontinent events; if any incontinent events are identified, Item C4b asks whether the patient/resident had events prior to the hospitalization. In addition to assessing device use and incontinent events, patients/residents and caregivers are each asked if the patient/resident had experienced any incontinent events and then, if yes, they are asked about their perspective of the problem or burden associated with incontinent events (Items C5–C8).

Testing Objectives and Analytic Approach

Our main objectives in testing the bladder and bowel items were (Goal 1) to determine whether items can be completed with acceptable IRR; (Goal 2) to evaluate the feasibility/ease of administration of items and use of multiple data sources; and (Goal 3) to evaluate the ease of administration and clarity of instructions regarding skip patterns throughout the items.

To accomplish Goal 1, we calculated the level of agreement between paired assessors' judgments about each of the items. IRR was assessed using Cohen's kappa for categorical variables and weighted kappa for ordinal variables.

To accomplish Goal 2, we examined the frequency of response options for each item (including *unable to assess* or *missing*) and the total time spent to complete the items in this section. In addition, we examined the percentage of cases in which the frequency of incontinent events documented from medical record review and/or staff observations matched the patient/resident and/or caregiver report of incontinent events. We also examined the qualitative data from the research nurses and facility staff when prompted to discuss challenges they faced in finding the necessary information in the medical record, pulling data from multiple sources, resolving any conflicting information across multiple sources, and whether they were able to easily identify the reason that a catheter was initially placed.

To accomplish Goal 3, we calculated the percentage of cases in which the research nurse and facility staff correctly followed each of the skip patterns and relied on what nurses told us during the debriefing interviews regarding coding and instructions. To investigate setting-by-setting variation in the reliability and ease of administration of the item, we calculated all statistics by setting and across the four settings. In evaluating the feedback the nurses provided during the debriefing interviews, we attempted to discern, informally, whether setting differences were evident.

Results

Table 10.1 shows the IRR of bladder and bowel items. Many items did not have sufficiently complete information to calculate kappa, at least in some settings, due to a preponderance of missing data. This was largely anticipated, due to lower rates of device use or incontinence in some settings, and

the use of skip logic in this section. However, a number of the items that were assessed had perfect or near-perfect concordance.

Table 10.1. Interrater Reliability of Bladder and Bowel Items

	HHA (N = 37)	IRF (N = 34)	LTCH (N = 31)	SNF (N = 31)	Overall (N = 133)
Bladder, device use (C1a)[a]	N/A	0.84	1.00	1.00	0.96
Bladder, when device first placed (C1b)[b]	N/A	N/A	1.00	N/A	N/A
Bladder, reason catheter placed (C1c)[b]	N/A	1.00	1.00	N/A	1.00
Bladder, need for assistance with device (C1d)[a]	N/A	1.00	N/A	N/A	0.61
Bladder, frequency of incontinent events (C2a)[b]	0.83	0.49	0.80	0.66	0.73
Bladder, prior incontinent events (C2b)[a]	N/A	1.00	0.00	N/A	0.54
Bladder, patient/resident report of burden severity (C5)[a]	1.00	1.00	1.00	1.00	1.00
Bladder, patient/resident report of burden severity (C5a)[b]	0.58	1.00	1.00	1.00	0.90
Bladder, caregiver report of burden severity (C6)[a]	1.00	1.00	1.00	N/A	1.00
Bladder, caregiver report of burden severity (C6a)[b]	N/A	1.00	1.00	N/A	1.00
Bowel, device use (C3a)[a]	N/A	N/A	1.00	1.00	1.00
Bowel, when device first placed (C3b)[b]	N/A	N/A	1.00	N/A	1.00
Bowel, need for assistance with device (C3c)[a]	N/A	N/A	N/A	N/A	N/A
Bowel, frequency of incontinent events (C4a)[b]	0.84	0.36	N/A	1.00	N/A
Bowel, prior incontinent events (C4b)[a]	N/A	N/A	N/A	N/A	0.00
Bowel, patient/resident report of burden severity (C7)[a]	1.00	0.93	1.00	1.00	0.98
Bowel, patient/resident report of burden severity (C7a)[b]	1.00	1.00	1.00	1.00	1.00
Bowel, caregiver report of burden severity (C8)[a]	1.00	1.00	1.00	N/A	1.00
Bowel, caregiver report of burden severity (C8a)[b]	N/A	1.00	1.00	N/A	1.00

NOTE: Cells with N/A indicate that not all response categories were endorsed by both nurses; thus, IRR cannot be computed.
[a]IRR assessed by Cohen's kappa.
[b]IRR assessed by weighted kappa.

Table 10.2 shows the frequency of responses for items in the bladder and bowel content area across 133 pairs of observations. There were notable differences across settings on some items. For example, bladder device use (Item C1a) was more common in the LTCH setting (23 percent) than the IRF or SNF settings (both below 13 percent) or the HHA setting (0 percent). Agreement between research nurses and facility staff in assessing these items was very good in terms of the two assessor groups obtaining similar overall proportions.

Table 10.2. Frequency Distribution of Responses to Bladder and Bowel Items, by Assessors

	HHA (N = 37)		IRF (N = 34)		LTCH (N = 31)		SNF (N = 31)		Overall (N = 133)	
	R	F	R	F	R	F	R	F	R	F
Bladder, device use (C1a)										
Yes (percentage)	0	0	9	12	23	23	6	6	9	10
Missing (number)	1	2	0	0	0	0	0	0	1	2
Bladder, type of device (C1a_1 to C1a_6)[a]										
Indwelling urethral catheter (percentage)	0	0	100	67	17	25	100	50	44	44
Other indwelling catheter (percentage)	0	0	0	0	17	40	0	0	14	22

	HHA (N = 37)		IRF (N = 34)		LTCH (N = 31)		SNF (N = 31)		Overall (N = 133)	
	R	F	R	F	R	F	R	F	R	F
External catheter (percentage)	0	0	100	33	17	25	0	0	25	22
Urostomy (percentage)	0	0	0	0	0	0	0	0	0	0
Intermittent catheterization (percentage)	0	0	0	50	50	50	50	50	50	50
Other (percentage)	0	0	0	0	0	0	0	0	0	0
Skipped* (number)	36	35	31	30	24	24	29	29	120	118
Bladder, when device first placed (C1b)										
In current setting (percentage)	0	0	0	25	0	0	3	0	0	11
Prior setting (percentage)	0	0	67	50	67	75	100	100	71	67
Prior to hospitalization (percentage)	0	0	33	25	33	25	0	0	29	22
Missing (number)	1	2	0	0	3	3	0	1	4	6
Skipped* (number)	36	35	31	30	24	27	29	29	120	118
Unknown (number)	0	0	0	0	1	0	1	0	2	0
Bladder, reason catheter placed (C1c)										
Retention (percentage)	0	0	67	67	33	25	100	100	57	50
Skin protection (percentage)	0	0	0	0	0	0	0	0	0	0
Comfort care (percentage)	0	0	0	0	0	0	0	0	0	0
Other (percentage)	0	0	33	33	67	75	0	0	43	50
Missing (number)	1	2	0	1	3	3	0	1	4	7
Skipped* (number)	36	35	31	30	24	24	29	29	120	118
Unknown (number)	0	0	0	0	1	0	1	0	2	0
Bladder, need for assistance with device (C1d)										
Yes (percentage)	0	0	67	75	83	100	100	100	82	92
Missing (number)	1	2	0	0	1	0	0	1	2	3
Skipped* (number)	36	35	31	30	24	24	29	29	120	118
Bladder, frequency of incontinent events (C2a)										
No events (percentage)	68	69	67	76	60	62	50	55	61	66
Less than daily (percentage)	6	9	24	21	7	17	17	29	13	19
Daily (percentage)	9	9	9	3	10	3	7	10	9	6
More than daily (percentage)	18	14	0	0	23	17	27	6	17	9
Unknown (number)	1	0	0	0	1	0	1	0	3	0
Missing (number)	0	2	0	0	0	2	0	0	0	4
Bladder, prior incontinent events (C2b)										
Yes (percentage)	100	100	50	58	67	75	100	71	74	77
Missing (number)	5	2	1	0	1	2	1	2	8	6
Skipped* (number)	23	24	22	26	18	18	15	17	78	85
Unknown (number)	6	2	1	1	6	3	7	5	20	11
Bladder, patient/resident report of incontinent event (C5)										
Yes (percentage)	31	31	47	47	47	47	50	50	43	43
Missing (number)	1	1	0	0	1	1	1	1	3	3
Bladder, patient/resident report of problem (C5a)										

	HHA (N = 37)		IRF (N = 34)		LTCH (N = 31)		SNF (N = 31)		Overall (N = 133)	
	R	F	R	F	R	F	R	F	R	F
No problem (percentage)	27	9	6	6	0	0	7	7	9	5
Small problem (percentage)	27	36	31	31	29	29	27	27	29	30
Moderate problem (percentage)	9	9	25	25	36	36	40	40	29	29
Big problem (percentage)	36	45	38	38	36	36	27	27	34	36
Missing (number)	1	1	0	0	1	1	1	1	3	3
Skipped* (number)	25	25	18	18	16	16	15	15	74	74
Bladder, caregiver report of incontinent event (C6)										
Yes (percentage)	18	22	27	21	27	31	100	50	27	27
Missing (number)	14	16	4	10	6	9	18	22	42	57
Not applicable (number)	12	12	4	2	10	6	12	4	38	24
Unknown/missing information/lack of documentation/not applicable (number)	0	0	4	3	0	0	0	1	4	4
Bladder, caregiver report of problem in context of overall care (C6a)										
No problem (percentage)	100	100	40	0	0	0	0	0	33	18
Small problem (percentage)	0	0	20	33	25	20	0	0	17	18
Moderate problem (percentage)	0	0	40	67	50	60	100	100	42	55
Big problem (percentage)	0	0	0	0	25	20	0	0	8	9
Missing (number)	14	16	4	10	6	9	18	23	42	58
Out of range (number)	0	0	0	1	0	0	0	0	0	1
Skipped* (number)	21	19	24	20	21	17	12	7	78	63
Unable to assess/no response (number)	0	0	1	0	0	0	0	0	1	0
Bowel, device use (C3a)										
Yes (percentage)	0	0	0	0	13	13	3	3	4	4
Missing (number)	2	3	0	0	0	0	0	1	2	4
Bowel, when device first placed (C3b)										
In current setting (percentage)	0	0	0	0	0	0	0	0	0	0
Prior setting (percentage)	0	0	0	0	75	75	100	100	80	80
Prior to hospitalization (percentage)	0	0	0	0	25	25	0	0	20	20
Missing (number)	2	3	0	0	0	0	0	1	2	4
Skipped* (number)	35	34	34	34	27	27	30	29	126	124
Bowel, need for assistance with device (C3c)										
Yes (percentage)	0	0	0	0	100	100	100	100	100	100
Missing (number)	2	3	0	0	0	0	0	1	2	4
Skipped* (number)	35	34	34	34	27	27	30	29	126	124
Bowel, frequency of incontinent events (C4a)										
No events (percentage)	88	91	85	88	64	63	90	90	82	83
Only once (percentage)	0	0	15	12	18	20	3	3	9	9
More than once (percentage)	12	9	0	0	18	13	7	7	9	7
No bowel output (percentage)	0	0	0	0	0	3	0	0	0	1

	HHA (N = 37)		IRF (N = 34)		LTCH (N = 31)		SNF (N = 31)		Overall (N = 133)	
	R	F	R	F	R	F	R	F	R	F
Missing (number)	2	4	0	0	0	1	0	0	2	5
Unknown (number)	1	0	1	1	1	0	2	1	5	2
Not applicable (number)	0	0	0	0	2	0	0	1	2	1
Bowel, prior incontinent events (C4b)										
Yes (percentage)	0	100	33	100	50	100	50	0	42	90
Missing (number)	4	5	0	1	2	1	1	1	7	8
Skipped* (number)	30	30	28	29	50	20	26	27	104	106
Unknown/missing information/lack of documentation/not applicable (number)	3	0	0	1	5	6	2	2	10	9
Bowel, patient/resident report of incontinent event (C7)										
Yes (percentage)	14	14	32	29	37	37	17	17	25	24
Missing (number)	1	1	0	0	1	1	1	1	3	3
Bowel, patient/resident report of problem (C7a)										
No problem (percentage)	0	0	8	0	9	9	0	0	6	3
Small problem (percentage)	20	20	8	10	18	18	0	0	12	13
Moderate problem (percentage)	20	20	25	30	27	27	25	25	25	27
Big problem (percentage)	60	60	58	60	45	45	75	75	56	57
Missing (number)	1	1	0	0	1	1	2	1	4	3
Out of range (number)	0	0	0	0	0	0	0	1	0	1
Skipped* (number)	31	31	23	24	19	19	25	25	98	99
Bowel, caregiver report of incontinent event (C8)										
Yes (percentage)	30	38	23	20	27	33	100	50	27	29
Missing (number)	16	18	4	11	8	10	27	25	55	64
Not applicable (number)	11	11	4	2	8	6	3	4	26	23
Unknown/missing information/lack of documentation/not applicable (number)	0	0	4	1	0	0	0	0	4	1
Bowel, caregiver report of problem in context of overall care (C8a)										
No problem (percentage)	100	100	40	25	0	0	0	0	36	33
Small problem (percentage)	0	0	40	50	25	20	0	0	21	25
Moderate problem (percentage)	0	0	20	25	75	80	50	0	36	42
Big problem (percentage)	0	0	0	0	0	0	50	0	7	0
Missing (number)	16	18	4	11	8	10	26	26	54	65
Skipped* (number)	18	16	25	19	19	16	3	5	65	56

NOTES: R = research nurse. F = facility staff. An asterisk denotes that skipped answers are appropriately missing based on prior answers and programmed skip patterns. *Percentage* rows tabulate responses to each item across all possible answer categories; responses sum to 100 percent. *Number* rows show the number of times each item was unknown, missing, or similar. Responses tabulated in number rows are not part of the denominator for calculating percentages.
[a]Each item is independent of the others; percentages do not sum to 100 percent due to rounding.

Table 10.3 shows the average time spent, in minutes, to assess bladder and bowel function items. The interview items uniformly took less than two minutes on average in all settings. However, there

were marked differences among settings in how long it took to complete the noninterview items, from as little as 2.9 minutes in the HHA setting to as much as 9.3 minutes in the LTCH setting.

Table 10.3. Average Time Spent (in Minutes) Completing Bladder and Bowel Items, by PAC Setting

	HHA (N = 37) Mean (SD)	IRF (N = 34) Mean (SD)	LTCH (N = 31) Mean (SD)	SNF (N = 31) Mean (SD)	Overall (N = 133) Mean (SD)
By research nurse					
Bladder/bowel noninterview items (C1a–C4b)	2.9 (4.9)	3.2 (1.9)	9.3 (16.0)	4.9 (11.5)	5.0 (10.2)
Bladder/bowel interview items (C5–C8a)	1.4 (1.6)	2.3 (2.7)	1.9 (1.7)	1.4 (1.1)	1.7 (1.9)
By facility staff					
Bladder/bowel noninterview items (C1a–C4b)	2.7 (4.2)	3.3 (2.0)	8.8 (12.1)	4.0 (3.2)	4.7 (7.1)
Bladder/bowel interview items (C5–C8a)	1.5 (1.7)	2.3 (2.7)	1.9 (1.7)	1.4 (1.1)	1.8 (1.9)

Table 10.4 shows the proportion of instances in which skip rules were followed correctly, across items and settings, and stratified by assessor type. Research nurses and facility staff correctly followed the skip rules for almost all patient/residents.

Table 10.4. Percentage of Research Nurses and Facility Staff Who Adhered to Assessment Skip Rules

	HHA		IRF		LTCH		SNF		Overall	
	R	F	R	F	R	F	R	F	R	F
Where *bladder, device use (C1a)* = 0, items C1a (type of device[a])–C1d are missing	100	100	97	100	100	100	97	86	98	97
Where *bladder, continence* (C2a) = 0 or 8, item C2b is missing	88	100	97	97	93	100	100	90	95	97
Where *bowel, device use* (C3a) = 0, items C3b and C3c missing	100	100	100	100	100	100	100	97	100	99
Where *bowel, incontinence* (C4a) = 0, 3, or 8, item C4b is missing	93	97	93	100	100	100	100	100	96	99
Where *bladder, patient report of incontinent events* (C5) = 0 or 9, item C5a is missing	100	100	100	100	100	100	100	100	100	100
Where *bladder, caregiver report of incontinent events* (C6) = 0, 8, or 9, item C6a is missing	100	100	100	95	100	100	100	86	100	97
Where *bowel, patient report of incontinent events* (C7) = 0 or 9, item C7a is missing	100	100	96	96	100	100	100	96	99	98
Where bowel, caregiver report of incontinent events (C8) = 0, 8, or 9, item C8a is missing	100	100	96	100	100	100	100	100	98	100

NOTE: R = research nurse. F = facility staff.
[a]Indwelling urethral catheter, other indwelling catheter, external catheter, or intermittent catheterization.

Feedback from Assessors

In general, facility staff stated that they found the bladder and bowel continence section to be easy to complete and reported few issues with it. However, they noted three issues with this section.

Conflicting Patient/Resident and Caregiver Accounts. Assessors often got conflicting information from patients/residents and caregivers and had to determine which information source was more reliable.

Inconsistent Information in the Medical Record. Some nurses said information about frequency of incontinence is not always available in the medical record in settings such as an SNF. In the home health setting, information about bladder and bowel continence may not be available in the medical record by day three.

Some Patients Do Not Understand the Word "Continence." For example, one patient interpreted it to mean "constipation." While the research nurses were able to explain what "continence" is to patients/residents, they recommended replacing "continence" with a word or phrase that patients/residents will more easily understand.

Summary of Findings: Bladder and Bowel Continence

IRR. Interrater agreement on bladder and bowel items was excellent for the subset of items where it could be assessed. However, some items do not apply to a majority of patients/residents—such as catheter use—meaning that IRR cannot be assessed for those items. Similarly, we found that rates of bowel and bladder continence issues varied considerably across care settings.

Feasibility/Ease of Use. The bladder and bowel items took less than two minutes for interview items, although the time to complete noninterview items varied widely, sometimes by setting.

Clarity of Instructions and Skip Items. Assessors' comments generally reflected the fact that the bladder and bowel items were straightforward to administer and highly consistent across assessors. However, the assessors suggested that the word "continence" can be hard for some patients to understand and favored using a more easily understood term (e.g., "accidents" or "leaking") when administering interview assessment items to patients/residents. Also, assessors felt they would benefit from clarification on how to score these items when family and patient accounts of bladder and bowel continence do not match.

In summary, the bladder and bowel continence items were viewed as straightforward by assessors and generally performed quite well across settings, although sparse data in some settings resulted in inability to calculate IRR for a handful of items. Based upon assessor feedback, the user manual and training materials for these items will be modified slightly to improve clarity and utility for assessors, and language for some interview items may be modified to ease interpretation.

Chapter Eleven. General Feedback from Assessors

In this chapter, we describe general comments received from assessors (both research nurses and facility staff) about the assessment and the training.

General Comments on the Assessment

The following represent general comments from the assessors, which related to all content areas. Assessors noted six main factors that influenced the assessment as a whole: (1) patient/resident factors, such as fatigue or cognitive impairment; (2) staff experience with the assessment; (3) technical glitches; (4) skill with EHR use; (5) the challenge of timing each section separately; and (6) difficulty finding family members when they were needed to help answer items.

Patient/Resident Factors. Assessors said that when patients/residents were cognitively impaired or fatigued, it was noticeably more difficult to complete the assessment. The research nurses noted that it was important to be able to recognize when a patient/resident might be tired and need a break.

Staff Experience with the Assessment. Many research nurses stated that facility staff members became more fluid and facile with the assessment as they gained additional practice in using it. Conversely, when facility staff members had not done an assessment recently, they found it more difficult. Several research nurses said that debriefing with their partners after interviews to discuss challenges and questions had been particularly helpful in improving assessment skills.

Technical Glitches. The research nurses commented that sometimes questions would be skipped accidentally because pages would stick together or facility staff would skip the "testing only" items. One nurse said she and her partners set up a system to mitigate these errors by asking each other at the end of a section if there was anything else they needed to cover.

Skill with EHR Use. Research nurses highlighted the importance of easy access to the EHR and a good orientation to it. Research nurses who needed assistance accessing the EHR said it created extra hassle and scheduling, and they often felt rushed while searching it because someone else was involved in the process.

Challenge of Timing Each Section Separately. Research nurses shared that it was difficult to time each section separately. Even after a section has nominally been completed, additional information about that section frequently arose on further searching the EMR for information about other items. Instead of separate timing for each section of the assessment, research nurses recommended recording the total time spent reviewing the medical record across sections. The challenge of timing each section separately is unique to the testing phase and will not be a problem when these items are actually in use.

Difficulty Finding Family Members. Several research nurses noted that it was often difficult to find family members if they were not in the room, which made it difficult to answer caregiver response items.

IMPACT ACT of 2014—ALPHA TESTING 1.0
PATIENT/RESIDENT ASSESSMENT FORM
RAND CORPORATION

ITEMS REQUIRING MIXED DATA SOURCES
(medical records, staff interview, patient/resident report)

Instructions: The following items utilize multiple sources of information. As feasible, all relevant sources should be identified and used to complete this section of the assessment. Begin with a review of the patient/resident chart. Facility staff and research nurses should complete these items separately. Do not discuss the sources used or your coding of any item with each other. **Refer to the user manual for specific questions pertaining to the assessment of these items.**

Day 1 (Date of admission): ___ ___ / ___ ___ / 2016
(A day begins at 12:00 a.m. and ends at 11:59 p.m.)

Day 3 (earliest assessment date): ___ ___ / ___ ___ / 2016

Day 4 (latest assessment date): ___ ___ / ___ ___ / 2016

Date of Chart Review: ___ ___ / ___ ___ / 2016

SECTION A START TIME (HH:MM) ___ ___: ___ ___ AM / PM

SECTION A CARE PREFERENCES	
Advance Care Directives: Use medical record data only to answer this question	
A1. Does the patient/resident have a designated Health Care Agent as authorized under state law to make healthcare decisions in the event that he/she is unable to make his or her own decisions **AND** there is legal documentation in the medical record?	
Enter Code ☐	0. No 1. Yes (Specify type of legal documentation):_____

SECTION A END TIME (HH:MM) ___ ___: ___ ___ AM / PM

SECTION B START TIME (HH:MM) ___ ___: ___ ___ AM / PM

SECTION B MEDICATION RECONCILIATION	
B1. Did the post-acute care provider obtain lists of current medications from more than one information source?	
Enter Code ☐	0. No 1. Yes 8. N/A; Patient/Resident is not taking any medications **[END SECTION]** 9. Unknown; missing information sources or lack of documentation
[For testing only] **B1a**. **What information sources did you use to answer B1?** Circle all that apply.	
a. Patient response b. Family caregiver response c. Asked the provider responsible for medication reconciliation d. Reviewed paper or electronic documents present in the facility/agency (please describe in detail, e.g. Plan of Care, Nursing Note, Medication Administration Record, Incident Report/Log): _____ e. Other (please describe in detail): _____	
B2. Did the prescriber include an indication for each medication on the list or multiple lists obtained from the information sources?	

Enter Code ☐	0. No 1. Yes 9. Don't know; missing information sources or lack of documentation

[For testing only] **B2a**. **What information sources did you use to answer B2?** Circle all that apply.

a. Patient response

b. Family caregiver response

c. Asked the provider responsible for medication reconciliation

d. Reviewed paper or electronic documents present in the facility/agency (please describe in detail, e.g. Plan of Care, Nursing Note, Medication Administration Record, Incident Report/Log):

_____

e. Other (please describe in detail):

_____

B3. Did the review identify any medication discrepancies?

Enter Code ☐	0. No 1. Yes 9. Unknown; missing information sources or lack of documentation

[For testing only] **B3a**. **What information sources did you use to answer B3?** Circle all that apply.

a. Patient response

b. Family caregiver response

c. Asked the provider responsible for medication reconciliation

d. Reviewed paper or electronic documents present in the facility/agency (please describe in detail, e.g. Plan of Care, Nursing Note, Medication Administration Record, Incident Report/Log):

_____

e. Other (please describe in detail):

_____

B4. Did the review identify any potential adverse drug events?

Enter Code ☐	0. No [if no to both #B3 and #B4, END SECTION] 1. Yes 9. Unknown; missing information sources or lack of documentation

[For testing only] **B4a**. **What information sources did you use to answer B4?** Circle all that apply.

a. Patient response

b. Family caregiver response

c. Asked the provider responsible for medication reconciliation

d. Reviewed paper or electronic documents present in the facility/agency (please describe in detail,

e.g. Plan of Care, Nursing Note, Medication Administration Record, Incident Report/Log):

_____

e. Other (please describe in detail):

_____

B5. Did any discrepancies or potential adverse drug events involve "high-risk" drugs, defined as medications that are anti-coagulants, anti-diabetics, opioids, anti-psychotics, anti-microbials, or are listed in the Beers Criteria, for example?

Enter Code	
☐	0. No [if no proceed to #B10] 1. Yes 9. Unknown; missing information sources or lack of documentation

[For testing only] **B5a**. **How did you answer B5?** Circle all that apply.

a. **I used my clinical judgment** to identify whether any of the drugs that were involved in the documented discrepancies or potential adverse drug events were classified as one or more of the "high-risk" drug classes, or on the Beers Criteria list

b. **I looked up the "high-risk" drug classes or Beers Criteria** list to identify whether any of the drugs that were involved in the documented discrepancies or potential adverse drug events were classified as one or more of the "high-risk" drug classes, or on the Beers Criteria list

c. **Other** (write in how it was determined that the discrepancy(ies) or potential adverse drug event(s) were classified as a "high-risk" drug):

_____

B6. Did the post-acute care provider address all high-risk discrepancies or potential adverse drug events within:

Enter Code	
☐	1. 24 hours after admission 2. 48 hours after admission 3. 72 hours after admission 4. Not addressed within 3 days of admission

[For testing only] **B6a**. **What information sources did you use to answer B6?** Circle all that apply.

a. Patient response

b. Family caregiver response

c. Asked the provider responsible for medication reconciliation

d. Reviewed paper or electronic documents present in the facility/agency (please describe in detail, e.g. Plan of Care, Nursing Note, Medication Administration Record, Incident Report/Log):

_____

e. Other (please describe in detail):

_____

B7. Did the post-acute care provider address high-risk discrepancies or potential adverse drug events by involving the patient/resident or patient's/resident's family/formal caregiver?

Enter Code ☐	0. No 1. Yes 9. Don't know**;** missing information sources or lack of documentation

[For testing only] **B7a**. **What information sources did you use to answer B7?** Circle all that apply.

a. Patient response

b. Family caregiver response

c. Asked the provider responsible for medication reconciliation

d. Reviewed paper or electronic documents present in the facility/agency (please describe in detail, e.g. Plan of Care, Nursing Note, Medication Administration Record, Incident Report/Log):

_____

e. Other (please describe in detail):

_____

B8. Did the post-acute care provider contact a physician (or physician-designee) about all high-risk discrepancies and potential adverse drug events within 24 hours after identification of the first medication issue?

Enter Code ☐	0. No, the physician was not contacted [if so, proceed to #B10] 1. No, the physician was contacted but not within 24 hours after identification of high-risk discrepancies and potential adverse drug events 2. Yes 8. N/A; The assessment is being completed less than 24 hours after identification of the first medication issue [if so, proceed to #B10] 9. Unknown**;** missing information sources or lack of documentation

[For testing only] **B8a**. **What information sources did you use to answer B8?** Circle all that apply.

a. Patient response

b. Family caregiver response

c. Asked the provider responsible for medication reconciliation

d. Reviewed paper or electronic documents present in the facility/agency (please describe in detail, e.g. Plan of Care, Nursing Note, Medication Administration Record, Incident Report/Log):

_____

e. Other (please describe in detail):

_____

B9. After the physician (or physician-designee) responded, did the post-acute care provider complete the physician (or physician-designee) prescribed/recommended actions within 24 hours in response to all high-risk discrepancies and potential adverse drug events?

Enter Code ☐	0. No, the actions were not completed 1. No, the actions were completed but not within 24 hours after the physician responded 2. Yes 9. Unknown**;** missing information sources or lack of documentation or lack of documentation

[For testing only] **B9a**. **What information sources did you use to answer B9**? Circle all that apply.

a. Patient response

b. Family caregiver response

c. Asked the provider responsible for medication reconciliation

d. Reviewed paper or electronic documents present in the facility/agency (please describe in detail, e.g. Plan of Care, Nursing Note, Medication Administration Record, Incident Report/Log):

_____

e. Other (please describe in detail):

_____

B10. Did the post-acute care provider communicate the reconciled medication list to the patient/resident or patient's/resident's family/formal caregiver?

Enter Code ☐	0. No 1. Yes 8. N/A; The physician(s) did not respond and therefore there was no reconciled list 9. Unknown**;** missing information sources or lack of documentation

[For testing only] **B10a**. **What information sources did you use to answer B10?** Circle all that

apply.

a. Patient response

b. Family caregiver response

c. Asked the provider responsible for medication reconciliation

d. Reviewed paper or electronic documents present in the facility/agency (please describe in detail, e.g. Plan of Care, Nursing Note, Medication Administration Record, Incident Report/Log):

_____

e. Other (please describe in detail):

_____

B11. Did the post-acute care provider communicate the reconciled medication list to all of the patient's/resident's primary care providers?

Enter Code ☐	0. No 1. Yes 8. N/A; The physician(s) did not respond and therefore there was no reconciled list 9. Unknown**;** missing information sources or lack of documentation

[For testing only] **B11a**. **What information sources did you use to answer B11?** Circle all that apply.

a. Patient response

b. Family caregiver response

c. Asked the provider responsible for medication reconciliation

d. Reviewed paper or electronic documents present in the facility/agency (please describe in detail, e.g. Plan of Care, Nursing Note, Medication Administration Record, Incident Report/Log):

_____

e. Other (please describe in detail):

_____

B12. Did the post-acute care provider communicate the reconciled medication list to the patient's/resident's primary pharmacy?

Enter Code ☐	0. No 1. Yes 8. N/A ; The physician(s) did not respond and therefore there was no reconciled list 9. Unknown**;** missing information sources or lack of documentation

[For testing only] **B12a**. **What information sources did you use to answer B12?** Circle all that apply.

a. Patient response

b. Family caregiver response

c. Asked the provider responsible for medication reconciliation

d. Reviewed paper or electronic documents present in the facility/agency (please describe in detail, e.g. Plan of Care, Nursing Note, Medication Administration Record, Incident Report/Log):

_____

e. Other (please describe in detail):

_____

SECTION B END TIME (HH:MM) ___ ___: ___ ___ AM / PM

SECTION C START TIME ___ ___: ___ ___ AM / PM

SECTION C BLADDER AND BOWEL

Bladder – Device Use

C1a: Does this patient/resident use an external or indwelling urinary catheter, have a urostomy, or require intermittent urinary catheterization?

Enter Code ☐

0. No **[SKIP to C2a: Frequency of Incontinent Events]**
1. 1. Yes

IF yes, indicate device(s): (For each device, enter 1 if Yes; enter 0 if No.)

☐ Indwelling urethral catheter

☐ Other indwelling catheter (include suprapubic catheter and nephrostomy tube)

☐ External catheter (include condom catheter)

☐ Urostomy

☐ Intermittent catheterization

☐ Other

C1b: If patient/resident has indwelling or external CATHETER, at what point was device first placed?

Enter Code ☐

1. In current setting?
2. Prior setting?
3. Prior to hospitalization for this illness/exacerbation?
9. Unknown

C1c: If patient/resident has an indwelling or external CATHETER, what is the reason the device was put in place?

Enter Code ☐

1. Retention
2. Skin Protection (i.e.; presence of Stage 3 or 4 pressure ulcer)
3. Comfort Care (e.g.; to promote patient comfort at the end of life)
4. Other
(specify):_____
9. Unknown

C1d: If patient/resident has a bladder device **(C1a=1; Yes)**: Does the patient/resident need assistance to manage equipment or devices related to bladder care for ANY reason (e.g., cognitive impairment/mental status, physical limitation, medical issue, etc.)?

Enter Code ☐

0. No
1. Yes

Bladder – Incontinence

C2a: Indicate the frequency of incontinent events.

Enter Code ☐

0. No incontinent events during the assessment period **[SKIP to C3a: Bowel Device Use]**
1. Incontinent events less than daily (on only one or two days during the assessment period)
2. Incontinent events daily (at least once a day during the assessment period)
3. Incontinent events more than daily (more than once a day on each day during the assessment period)
8. Not applicable (e.g., patient/resident has indwelling catheter or no urine output due to renal failure) **[Please proceed to C3a: Bowel Device Use]**
9. Unknown

C2b: If the patient/resident has incontinent events **(C2a=1, 2, or 3)**, did the patient/resident have incontinent events immediately prior to the hospitalization for current illness or exacerbation?

Enter Code ☐

0. No
1. Yes
9. Unknown

Bowel – Device Use

C3a: Does this patient/resident use an indwelling or external device (ostomy or other fecal diversion appliance)?

Enter Code
☐
0. No **[SKIP to C4a: Frequency of Incontinent Events]**
1. Yes

C3b: IF patient/resident has indwelling or external bowel device (e.g., ileostomy, colostomy), at what point was device first placed?

Enter Code
☐
1. In current setting?
2. Prior setting?
3. Prior to hospitalization for this illness/exacerbation?
9. Unknown

C3c: If patient/resident has an indwelling or external bowel device **(C3a=1;Yes):** Does the patient/resident need assistance to manage equipment or devices related to bowel care for ANY reason (e.g., cognitive impairment/mental status, physical limitation, medical issue, etc.)?

Enter Code
☐
0. No
1. Yes

Bowel – Incontinence

C4a: Indicate the frequency of incontinent events.

Enter Code
☐
0. No incontinent events during the assessment period **[End Section]**
1. Incontinent event only once during the assessment period
2. Incontinent events more than once during the assessment period
3. No bowel output during the assessment period **[End Section]**
8. Not applicable (e.g., patient/resident has a colostomy) **[End Section]**
9. Unknown

C4b: If the patient/resident has incontinent events **(C4a=1 or 2)**, did the patient/resident have incontinent events immediately prior to the hospitalization for current illness or exacerbation?

Enter Code
☐
0. No
1. Yes
9. Unknown

SECTION C END TIME (HH:MM) ___ ___: ___ ___ AM / PM

SECTION D START TIME (HH:MM) ___ ___: ___ ___ AM / PM

SECTION D VISION

D1. Does the patient/resident use glasses (or other corrective lenses) regularly?

Enter Code ☐

0. No
1. Yes

D2a. Ability to See in Adequate Light (with glasses or other visual appliances)

Enter Code ☐

1. Adequate: Sees fine detail, for example, regular print in newspapers/books
2. Mildly to Moderately Impaired: Can identify objects; may see large print
3. Severely Impaired: No vision or object identification questionable
9. Unable to assess/Unknown

D2b. Date of last vision test by an optometrist/health care professional? [Training manual specified this item only applies to patients/residents determined to be Severely Impaired in vision]

_ _ / _ _ _ _ (Month/Year)

SECTION D END TIME (HH:MM) ___ ___: ___ ___ AM / PM

SECTION E START TIME (HH:MM) ___ ___: ___ ___ AM / PM

SECTION E HEARING

E1. Does the patient/resident use a hearing aid (or other hearing appliance) regularly?

Enter Code ☐

0. No, the patient/resident does **NOT** use a hearing aid/appliance regularly.
1. Yes, the patient/resident uses a hearing aid/appliance regularly.

E2a. Ability to Hear (with hearing aid or hearing appliance, if normally used)

Enter Code ☐

1. Adequate: Hears normal conversation without difficulty
2. Mildly to Moderately Impaired – Difficulty hearing in some environments or speaker may need to increase volume or speak distinctly.
3. Severely Impaired: Absence of useful hearing
9. Unable to assess/Unknown

E2b. Date of last hearing test by an audiologist/health care professional? [Training manual specified this item only applies to patients/residents determined to be Severely Impaired in vision]

_ _ / _ _ _ _ (Month/Year)

SECTION E END TIME (HH:MM) ___ ___: ___ ___ AM / PM

ITEMS REQUIRING DIRECT PATIENT/RESIDENT RESPONSE

Instructions: The following items are patient/resident reported. The only source of information that should be used to assess these items is direct patient interview. These items should be completed *after* conducting a review of the patient's/resident's medical record and completing any assessment items requiring medical record review. **Refer to the user manual for specific questions pertaining to the assessment of these items.**

Day 1 (Date of admission): ___ ___ / ___ ___ / 2016
(A day begins at 12:00 a.m. and ends at 11:59 p.m.)

Day 3 (earliest assessment date): ___ ___ / ___ ___ / 2016

Day 4 (latest assessment date): ___ ___ / ___ ___ / 2016

Date of Patient/Resident Assessment: ___ ___ / ___ ___ / 2016

SECTION F START TIME (HH:MM) ___ ___: ___ ___ AM / PM

SECTION F COGNITIVE STATUS			
Interview Attempted			
Enter Code ☐	**F1a. Interview Attempted?** 0. No (**Complete F1b and then SKIP to C6: Bladder Incontinence** 1. Yes (**Continue to F2**)	Enter Code ☐	**F1b. Indicate reason that the interview was not attempted.** 1. Unresponsive or minimally conscious 2. Unable to make self understood 3. No interpreter available
Brief Interview for Mental Status			
Enter Code ☐	**F2. Repetition of Three Words** **Ask Patient/Resident:** "I am going to say three words for you to remember. Please repeat the words after I have said all three. The words are: sock, blue and bed. Now tell me the three words." Number of words repeated by patient/resident after first attempt: 3. Three 2. Two 1. One 0. None or no answer		
After the patient's/resident's first attempt say: "I will repeat each of the three words with a cue and ask you about them later: sock, something to wear; blue, a color; bed, a piece of furniture." **You may repeat the words up to two more times.**			

Enter Code ☐	**F3a. Year, Month, Day** **Ask Patient/Resident:** "Please tell me what year it is right now." Patient's/Resident's answer is: 3. Correct 2. Missed by 1 year 1. Missed by 2 to 5 years 0. Missed by more than 5 years or no answer
Enter Code ☐	**F3b. Ask Patient/Resident:** "What month are we in right now?" Patient's/Resident's answer is: 2. Accurate within 5 days 1. Missed by 6 days to 1 month 0. Missed by more than 1 month or no answer
Enter Code ☐	**F3c. Ask Patient/Resident:** "What day of the week is today?" Patient's/Resident's answer is: 1. Accurate 0. Incorrect or no answer
F4. Recall **Ask Patient/Resident:** "Let's go back to the first question. What were those three words that I asked you to repeat?" **If unable to remember a word, give cue (i.e., something to wear; a color; a piece of furniture) for that word.**	
Enter Code ☐	**F4a**. Recalls "sock?" 2. Yes, no cue required 1. Yes, after cueing ("something to wear") 0. No, could not recall or no answer

Enter Code ☐	**F4b**. Recalls "blue?" 2. Yes, no cue required 1. Yes, after cueing ("a color") 0. No, could not recall or no answer
Enter Code ☐	**F4c**. Recalls "bed?" 2. Yes, no cue required 1. Yes, after cueing ("a piece of furniture") 0. No, could not recall or no answer

Trail Making Task – HAND SHEET TO PATIENT/RESIDENT **Instruct the patient/resident:** "Please draw a line, going from a number to a letter in ascending order. Being here [point to '1'] and draw a line from '1' then to 'A' then to '2' and so on. End here [point to 'E']."			
Enter Code ☐	**F5a. Trail Task Attempted?** 0. No (**Complete F5b and then SKIP to F6: Serial 7 Subtraction Task**) 1. Yes **(Continue to F5c)**	Enter Code ☐	**F5b. Indicate reason that the Trail Task was not attempted.** 1. Vision impairment 2. Functional impairment (e.g., unable to hold pen/pencil) 3. Other_____
Enter Code ☐	**F5c. Trail Making** 1. Successfully drew the pattern without drawing any lines that cross 0. Had lines that crossed, were incorrect, or missing.		
Serial 7 Subtraction Task			

Enter Code ☐	**F6. Ask patient/resident: "**Now, I will ask you to count backward from 90 by 7, and then keep counting backward by seven until I tell you to stop." **You may provide this instruction twice if necessary. Provide an example if necessary, such as "If I were to count backward from 25 by 5, and then keep going, I would say '25', '20', '15', '10', '5', and '0'.** Assessor Notes: 90 ___ ___ ___ ___ 3. Correctly said four or five numbers 2. Correctly said two or three numbers 1. Correctly said only one number 0. No numbers were correctly said or no answer
Complex Sentence Repetition	
Enter Code ☐	**F7a. Instruct patient/resident**: "I am going to read you a sentence. Repeat it after me, exactly as I say it. Remember, do not begin until I have given you the whole sentence [pause]: *After the bell rang, the man standing on the stairs quickly exited the building*." **If the response is not exactly correct say, "Let's try that again" and repeat the sentence. If the response is still not exactly correct, repeat the sentence a final time.** 1. Sentence was exactly correct 0. Sentence was not exactly correct or no answer
Enter Code ☐	**F7b. Instruct patient/resident:** "Now I am going to read you different sentence. Repeat it after me, exactly as I say it. Remember, do not begin until I have given you the whole sentence [pause]: *Though he typically watches westerns, lately he has preferred watching comedies."* **If the response is not exactly correct say, "Let's try that again" and repeat the sentence. If the response is still not exactly correct, repeat the sentence a final time.** 1. Sentence was exactly correct 0. Sentence was not exactly correct or no answer

SECTION F END TIME (HH:MM) ___ ___: ___ ___ AM / PM

SECTION G START TIME (HH:MM) ___ ___: ___ ___ AM / PM

SECTION G MOOD			
Patient Mood Interview (PHQ©)			
Ask patient/resident: "Over the last 2 weeks, have you been bothered by . . . ?" **If symptom is present, enter 1 (yes) in Column 1, Symptom Presence**			
If yes in Column 1, then ask the patient/resident: "About how often have you been bothered by this?" **Read and show the patient/resident a card with the symptom frequency choices. Indicate response in Column 2, Symptom Frequency**			
G1. Symptom Presence 0. **No** (enter 0 in Column 2) 1. **Yes** (enter 0-3 in Column 2) 9. **No response** (enter a dash [–] in Column 2)	**G2. Symptom Frequency** 0. **Never or 1 day** 1. **2-6 days** (several days) 2. **7-11 days** (half or more of the days) 3. **12-14 days** (nearly every day)	**G1. Symptom Presence**	**G2. Symptom Frequency**
		Enter Scores in Boxes ↓	↓
G1a1, G1a2: Little interest or pleasure in doing things		☐ a1	☐ a2
G1b1, G1b2: Feeling down, depressed, or hopeless		☐ b1	☐ b2
IF **either** A2 or B2 is **2 or 3**, **CONTINUE** **asking the questions below. If not, END the interview and SKIP to H1: Pain Presence.**			
G1c1, G1c2: Trouble falling asleep or staying asleep, or sleeping too much		☐ c1	☐ c2
G1d1, G1d2: Feeling tired or having little energy		☐ d1	☐ d2
G1e1, G1e2: Poor appetite or overeating		☐ e1	☐ e2
G1f1, G1f2: Feeling bad about yourself – or that you are a failure or have let yourself or your family down		☐ f1	☐ f2
G1g1, G1g2: Trouble concentrating on things, such as reading the newspaper or watching television		☐ g1	☐ g2

G1h1, G1h2: Moving or speaking so slowly that other people could have noticed. Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual	☐ h1	☐ h2
G1i1, G1i2: Thoughts that you would be better off dead, or of hurting yourself in some way	☐ i1	☐ i2

PHQ-9 TOTAL: Add values in boxes a2, b2, c2, d2, e2, f2, g2, h2 and i2 →	☐
If the patient/resident has not responded to 3 questions in Column 1, END the interview and enter a dash in the Total Box. Then SKIP to H1: Pain Presence.	

SECTION G END TIME (HH:MM) ___ ___: ___ ___ AM / PM

SECTION H START TIME (HH:MM) ___ ___: ___ ___ AM / PM

SECTION H PAIN

H1: Pain Presence

Enter Code ☐

Ask Patient/Resident - "Have you had pain or hurting any time during the last 3 days?"

0. No **[SKIP to A2: Care Preferences]**
1. Yes
9. Unable to answer or no response **[SKIP to A2: Care Preferences]**

H2: Pain Frequency

Enter Code ☐

Ask Patient/Resident - "How often during the past 3 days have you had pain or hurting?"

1. Rarely or not at all
2. Occasionally
3. Frequently
4. Almost constantly
9. Unable to answer or no response

H3: Pain Effect on Sleep

Enter Code ☐

Ask Patient/Resident - "During the past 3 days, how often has pain limited your ability to sleep?

1. Rarely or not at all
2. Occasionally
3. Frequently
4. Almost constantly
9. Unable to answer or no response

H4: Pain Interference - Therapy Activities

Enter Code ☐

Ask Patient/Resident - "During the past 3 days, have you been offered any rehabilitation therapies (e.g., physical therapy, occupational therapy, speech therapy) by your care providers?"

0. No **[SKIP to H4b: Pain Interference-Other Activities]**
1. Yes **[Proceed to H4a: Pain Interference-Therapy Activities]**
9. Unable to answer or no response **[SKIP to H4b: Pain Interference-Other Activities]**

H4a: Pain Interference - Therapy Activities

Enter Code ☐

If yes: Ask Patient/Resident – "During the past 3 days, how often have you limited your participation in rehabilitation therapy sessions due to pain?"

1. Rarely or not at all
2. Occasionally
3. Frequently
4. Almost constantly
9. Unable to answer or no response

H4b: Pain Interference - Other Activities

Enter Code ☐

Ask Patient/Resident - "During the past 3 days, how often have you limited your participation in other activities (**excluding** rehabilitation therapy sessions) due to pain?"

1. Rarely or not at all
2. Occasionally
3. Frequently
4. Almost constantly
9. Unable to answer or no response

H5: Pain Severity

Enter Code ☐

Ask Patient/Resident - "Please rate the intensity of your **worst** pain over the last 3 days."

1. Mild
2. Moderate
3. Severe
4. Very severe, horrible
9. Unable to answer or no response

H6: Pain Relief

Enter Code ☐

Ask Patient/Resident – " During the past 3 days how much relief have you felt from pain due to pain treatments or medications?"

1. No relief
2. Some relief
3. Quite a bit of relief
4. Very much relief
8. Not applicable- patient/resident has not received pain treatments or medications in the past 3 days
9. Unable to answer or no response

SECTION H END TIME (HH:MM) ___ ___: ___ ___ AM / PM

SECTION A START TIME (HH:MM) ___ ___: ___ ___ AM / PM

SECTION A CARE PREFERENCES

Involvement of Family/friends in Care Decisions

A2. Ask Patient/Resident – "It is important for us to understand how you'd like your family or friends involved in your care. How important is it to you to have your family or a close friend involved in discussions about your care?"

Enter Code ☐

1. Very important
2. Somewhat important
3. Not very important
4. Not important at all
5. Important, but can't do or no choice
9. No response or non-responsive

Goals for Care

Say to Patient/Resident: "**Now we are going to talk about the goals you might have for your life.** The following are four goals that are important to some people. We want to know how important each of these goals is to you. The four goals are about your physical activity, intellectual involvement, emotional health and social involvement."

Enter Code ☐

A3a. Ask Patient/Resident: "How important is it to you to be physically active? By physically active, I mean staying fit or doing physical activities you typically enjoy."

1. Very important
2. Somewhat important
3. Not very important
4. Not important at all
5. Important, but can't do or no choice
9. No response or non-responsive

Enter Code ☐

A3b. **Ask Patient/Resident:** "How important is it to you to be mentally or intellectually involved? By mentally or intellectually involved, I mean things like being able to remember day-to-day things, being able to process information quickly, or being able to switch back and forth between tasks."

1. Very important
2. Somewhat important
3. Not very important
4. Not important at all
5. Important, but can't do or no choice
9. No response or non-responsive

Enter Code ☐

A3c. **Ask Patient/Resident:** "How important is it to you to be emotionally healthy? By emotionally healthy, I mean things like having a positive outlook, feeling satisfied with your life, and feeling like you are able to enjoy yourself."

1. Very important
2. Somewhat important
3. Not very important
4. Not important at all
5. Important, but can't do or no choice
9. No response or non-responsive

Enter Code ☐

A3d. **Ask Patient/Resident:** "How important is it to you to be socially involved? By being socially involved, I mean things like being able to spend time with friends and family, go to events, and feeling like you have good relationships with people in your life."

1. Very important
2. Somewhat important
3. Not very important
4. Not important at all
5. Important, but can't do or no choice
9. No response or non-responsive

Preferences for Involvement in Decision Making Questionnaire

A4a. Ask Patient/Resident: "I'd like to talk to you about how you prefer to be involved in your care. Everyone copes with their illness differently. Do you prefer to know as much as you can about the details of your illness and treatment, prefer some information, or prefer not to know or to know very little?"

Enter Code ☐

1. To know as much as you can
2. Some information
3. Not to know or to know very little
9. No response or non-responsive

A4b. **Ask Patient/Resident:** "The way in which you would like to make decisions about your healthcare is important for us to know. Which of the following statements best describes the way in which you would like decisions about your healthcare to be made?"

Enter Code ☐

1. For you alone to make the decision
2. For a healthcare professional to make the decision for you, taking into account your personal wishes
3. For you and your family member(s) to decide together after your questions have been answered
4. For you and a healthcare professional to decide together after your questions have been answered
5. For you, a healthcare professional and your family members(s) to discuss and decide together
6. Other (Specify):_____
9. Unable to answer or non-responsive

SECTION A END TIME (HH:MM) ___ ___: ___ ___ AM / PM

SECTION C START TIME ___ ___: ___ ___ AM / PM

SECTION C BLADDER AND BOWEL

Bladder – Incontinence

C5: Ask patient/resident: "Have you experienced any bladder incontinent events (or "accidents" or "leaking of urine") during the past 3 days?"

Enter Code ☐

0. No **[SKIP to C6: Caregiver Perspective]**
1. Yes
9. Unable to assess/no response **[SKIP to C6]**

C5a: If patient/resident reports experiencing incontinent events **[If C5 = 1]**, **Ask Patient/Resident –** "How big of a problem or burden are incontinent events (or "accidents," "leaking") to you?"

Enter Code ☐

1. No problem
2. Small problem
3. Moderate problem
4. Big problem
9. Unable to assess/no response

C6: Ask caregiver: "Has the patient/resident experienced any bladder incontinent events (or "accidents" or "leaking of urine") during the past 3 days?"

Enter Code ☐

0. No **[SKIP to C7: Patient/Resident Perspective-Bowel Incontinent Events]**
1. Yes
8. Not applicable (i.e. caregiver not present) **[SKIP to C7]**
9. Unable to assess/no response **[SKIP to C7]**

C6a: If patient/resident experiences bladder incontinent events **[If C6=1]**, **Ask Caregiver –** "How big of a problem are the patient's/resident's bladder incontinent events in the context of their overall care?"

Enter Code ☐

1. No problem
2. Small problem
3. Moderate problem
4. Big problem
9. Unable to assess/no response

Bowel - Incontinence

C7: Ask patient/resident: "Have you experienced any bowel incontinent events (or "accidents" or "leaking of stool") during the past 3 days?"

Enter Code ☐

0. No **[SKIP to C8: Caregiver Perspective]**
1. Yes
9. Unable to assess/no response **[SKIP to C8]**

C7a: If patient/resident experiences incontinent events **[If C7 = 1]**, **Ask Patient/Resident –** "How big of a problem or burden are incontinent events (or "accidents"; "leaking") to you?"

Enter Code ☐

1. No problem
2. Small problem
3. Moderate problem
4. Big problem
9. Unable to assess/no response

C8: Ask caregiver: "Has the patient/resident experienced any bowel incontinent events (or "accidents" or "leaking of stool") during the past 3 days?"

Enter Code ☐

0. No **[End section]**
1. Yes
8. Not applicable (i.e. caregiver not present) **[End section]**
9. Unable to assess/no response **[End section]**

C8a: If patient/resident experiences incontinent events **[If C8=1]**, **Ask Caregiver –** "How big of a problem are the patient's/resident's bowel incontinent events in the context of their overall care?"

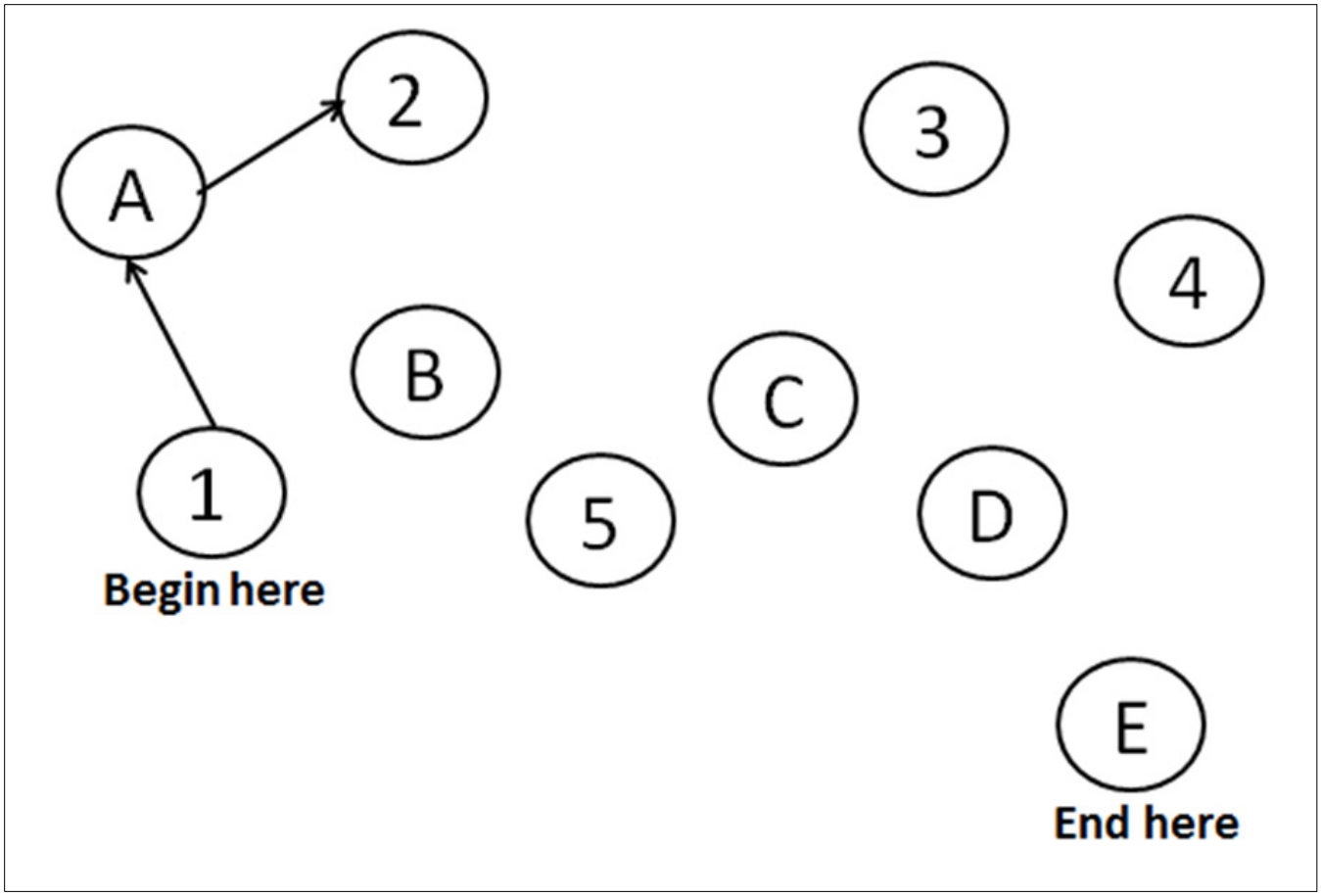
Enter Code ☐

1. No problem
2. Small problem
3. Moderate problem
4. Big problem
9. Unable to assess/no response

SECTION C END TIME ___ ___: ___ ___ AM / PM

SECTION F: Trail Making Task

"Please draw a line, going from a number to a letter in ascending order. Being here [point to '1'] and draw a line from '1' then to 'A' then to '2' and so on. End here [point to 'E']."



Appendix B. Assessor Feedback Interview Protocol

Introduction*: Please read out loud the following introduction before beginning the interview and record all responses.*

[*Introduction*] Thank you for taking the time to participate in this interview in addition to all of your other study-related responsibilities. My name is [XXX] and I'll be facilitating this discussion today. My job is to collect information from all of you today regarding the data collection process and your use of the assessment tool and user manual. I'll also be in charge of making sure everyone has a chance to contribute their thoughts and will try to keep us on schedule and our discussion on track. [XXX] is also on the line to ask follow-up questions, as is [XXX], who will be taking notes as we go so that we don't lose any of the valuable information you share with us. In addition, we also have: [introduce others or ask them to introduce themselves and their project role very quickly].

[*Purpose*] I will be asking you to share your experiences of collecting the data, any challenges that emerged when collecting the data and if/how these were addressed, your thoughts regarding potential changes to the assessment tool, and your perception of the adequacy of the training for preparing you for this effort. The main purpose of this debrief is to help us identify any changes we should make to the assessment materials (e.g., clarification of the instructions for a particular item, changes in the formatting or structure of the assessment form), or to the training materials (e.g., if we should teach trainees about particular challenges and how to address them in practice). This is the first of three discussions I will have with you over the course of this Alpha 1 data collection effort, so if there is something you forget to bring up today, there will be two additional times to bring up issues. You are also welcome to share information with me and Jason via email in between our discussions so you do not forget issues you want to discuss.

Are there any questions? Ok, let's begin.

< **BEGIN** >

1. To begin, let's do a quick tally of how many assessments and in what settings each of you have completed to date (prompt them to include but differentiate practice assessments from actual assessments).
2. Thinking of these assessments, can someone describe an assessment that went really smoothly? What do you think made this assessment easy to conduct/complete? (Prompt them to think of patient characteristics, the staff person's aptitude or engagement, or familiarity with the assessment tool.)

3. Now I want you to think about a fairly challenging assessment you've completed with your partner. What do you think made this assessment so challenging to conduct/complete? (Prompt them to think of patient characteristics, the staff person's aptitude or engagement, or familiarity with the assessment tool.)
    - What steps did you and your partner have to take to mitigate these challenges? Or, what steps should be taken in the future to mitigate these types of challenges?
    - Were any of these challenges unique to the setting (i.e., IRF, LTCH, HHA, or SNF)?
4. Okay, now let's talk about the assessment form and user manual specifically:
    - When did you find yourself referencing the user manual (Prompt for what issues, which domains/items, and at what point the manual was checked, e.g., during, before, or after the assessment)?
        i. [for the identified times the user manual was referenced] To what extent was it helpful? Confusing? Do you have any suggestions for improvements or additions regarding the user manual?
    - To what extent have you encountered challenges with the assessment form itself? (Probe for confusing sections or layout, clarity of instructions, length, and time to complete.)
    - Do you feel the facility staff was well prepared to conduct the assessments? Did you observe any challenges they faced?
    - What, if any, additional tools/materials would have helped you train the facility staff during the training that you conducted at Qualidigm?
    - Looking back at the facility staff training you provided at Qualidigm, given what you have experienced in conducting the assessments so far, what would you recommend we change about facility staff training?
5. Now let's talk through each of the domains specifically. What were some of the challenges you encountered while completing the assessments for each of these domains?
    - **Let's start with Cognition** (probe for patient characteristics, time, data entry process, coding/scoring, the assessment tool itself, physical space and environmental issues [e.g., lack of privacy, interruptions, background noise])
        i. **Please describe any challenges you encountered that you think were setting-specific.**
    - **Now let's switch to Mood** (probe for patient characteristics, time, data entry process, coding/scoring, the assessment tool itself, physical space and environmental issues [e.g., lack of privacy, interruptions, background noise])
        i. Were the instructions on how to decide whether or not to proceed to the final seven items of the Patient Mood Interview clear? What difficulties did you experience, if any, deciding whether or not to proceed?
        ii. What questions on the Patient Mood Interview were most difficult for you to ask? What made asking those questions difficult?
        iii. What difficulties did you experience interpreting patients' answers to the questions on the Patient Mood Interview?
        iv. What difficulties, if any, did you have in calculating the PHQ-2 and PHQ-9 total scores?
        v. **Please describe any challenges you encountered that you think were setting-specific.**

- **Now let's turn to Medication Reconciliation** (probe for patient characteristics, time, data entry process, coding/scoring, the assessment tool itself, physical space and environmental issues [e.g., lack of privacy, interruptions, background noise])
    i. Describe any challenges you encountered with accessing and using the medical records to answer the assessment questions.
    ii. Did you need to speak with others (facility staff, patient's family members) to complete the assessment and, if so, were there any challenges with doing so?
    iii. Describe any "problem" assessment questions—what were the specific challenges associated with this question and how did you or could we resolve this issue? (Probe for whether the wording of the questions, the coding options, and the instructions and definitions in the user manual were clear or need clarification/correction.)
    iv. **Please describe any challenges you encountered that you think were setting-specific.**
    v. **To what extent did the EHR help or hinder you in completing this section?**
- **Let's talk about Care Preferences** (probe for patient characteristics, time, data entry process, coding/scoring, the assessment tool itself, physical space and environmental issues [e.g., lack of privacy, interruptions, background noise])
    i. **Please describe any challenges you encountered that you think were setting-specific.**
- **Now let's talk about Hearing and Vision** (probe for patient characteristics, time, data entry process, coding/scoring, the assessment tool itself, physical space and environmental issues [e.g., lack of privacy, interruptions, background noise])
    i. **Please describe any challenges you encountered that you think were setting-specific.**
- **Now let's switch to Pain** (probe for patient characteristics, time, data entry process, coding/scoring, the assessment tool itself, physical space and environmental issues [e.g., lack of privacy, interruptions, background noise])
    i. **Please describe any challenges you encountered that you think were setting-specific.**
- **Now let's switch to Bladder and Bowel Continence** (probe for patient characteristics, time, data entry process, coding/scoring, the assessment tool itself, physical space and environmental issues [e.g., lack of privacy, interruptions, background noise])
    i. **Please describe any challenges you encountered that you think were setting-specific.**

6. In general, for domains or items that require multiple sources of information to complete the assessment, what sources did you tend to use or have access to? What types of challenges did you encounter with these questions?
7. Do you have any other observations or thoughts about the process that you would like to share?

Appendix C. Item History and Current Usage

Item Name	Use in PAC Setting	Reliability/Validity	Data Sources Eligible for Coding
Vision and hearing			
Glasses/corrective lenses	new		patient interview, direct observation
Ability to see in adequate light	PAC PRD, MDS	The PAC PRD found substantial agreement for IRR across settings for this data element (kappa of 0.74).	patient interview, direct observation
Last vision test	new		medical record, nurse and nursing assistant notes, staff interview, caregiver interview
Hearing aid	new		patient interview, direct observation
Ability to hear	New, similar to item in MDS		patient observation
Last hearing test	new		medical record, nurse and nursing assistant notes, staff interview, caregiver interview
Cognitive Function and Mental Status			
BIMS	PAC PRD, MDS	The BIMS was tested in the PAC PRD, where it was found to have substantial to almost perfect agreement for IRR (kappa range of 0.71 to 0.91).	patient interview
Trail making	new		patient interview
Serial 7	new		patient interview
Complex sentence repetition	new		patient interview
Mood			
PHQ-2 to PHQ-9	MDS (mod)	The PHQ-2 was tested in the PAC PRD, where it was found to have almost perfect agreement for IRR (kappa range of 0.84 to 0.91) when tested in all four PAC settings. The PHQ-9 has also been shown to be a reliable and valid screening tool in older adults, home health, skilled nursing facilities, and rehabilitation populations.	patient interview

Item Name	Use in PAC Setting	Reliability/Validity	Data Sources Eligible for Coding
Pain			
Pain presence	PAC PRD, MDS	PAC PRD version demonstrated substantial to almost perfect agreement for IRR in all four PAC settings (kappa range of 0.79 to 0.88)	patient interview
Pain frequency	MDS		patient interview
Pain effect on sleep	PAC PRD, MDS (mod)	PAC PRD version showed good feasibility and reliability across PAC settings	patient interview
Pain interference—therapy activities	PAC PRD (mod)	PAC PRD version showed good feasibility and reliability across PAC settings	patient interview
Pain interference—other activities	PAC PRD, MDS (mod)	PAC PRD version showed good feasibility and reliability across PAC settings	patient interview
Pain severity	PAC PRD, MDS	PAC PRD version demonstrated substantial to almost perfect agreement for IRR in all four settings (kappa range of 0.79 to 0.88)	patient interview
Pain relief	new		patient interview
Care Preferences			
Advanced care directives	PAC PRD, MDS (mod)	PAC PRD version shown to be feasible across PAC settings	medical record
Involvement of family/friends	PAC PRD, MDS (mod)	PAC PRD version found to be feasible and reliable across PAC settings	patient interview
Goals for care	new		patient interview
Preferences for involvement in decisionmaking	new		patient interview
Medication Reconciliation			
Medication reconciliation data element cluster	new		patient interview
Bladder and Bowel			
Bladder—device use	PAC PRD, MDS	PAC PRD version showed good feasibility and reliability across PAC settings	medical record, nurse and nursing assistant notes, direct observation, caregiver interview, patient interview
Bladder—incontinence	New, similar to items in PAC PRD, MDS, IRF-PAI, LCDS		medical record, nurse and nursing assistant notes, direct observation, caregiver interview, patient interview
Bladder—incontinence interview	new		patient interview, caregiver interview

Item Name	Use in PAC Setting	Reliability/Validity	Data Sources Eligible for Coding
Bowel—device use	PAC PRD, MDS	PAC PRD version showed good feasibility across PAC settings	medical record, nurse and nursing assistant notes, direct observation, caregiver interview, patient interview
Bowel—incontinence	New, similar to item in PAC PRD		medical record, nurse and nursing assistant notes, direct observation
Bowel—incontinence interview	New, similar to items in PAC PRD, MDS, IRF-PAI, LCDS, OASIS		patient interview, caregiver interview

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