Information-Gathering Report

Hospice Quality Reporting Program – Base Year

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APPENDICES

Table of Acronyms

AHRQ	Agency for Healthcare Research and Quality	IDG	Interdisciplinary Group
CAHPS	Hospice Consumer Assessment of Healthcare Providers and Systems CAHPS® Survey	IRF	Inpatient Rehabilitation Facility
CHC	Continuous home care	LTCH	Long-Term Care Hospital
CPG	Clinical Practice Guidelines	NAHC	National Association for Home Care and Hospice
CMS	Centers for Medicare & Medicaid Services	NHPCO	National Hospice and Palliative Care Organization
COP	Conditions of Participation	NPHI	National Partnership for Hospice Innovation
GIP care	General inpatient care	PGD	Prolonged grief disorder
HIS	Hospice Item Set	QAPI	Quality assurance/performance improvement
HQRP	Hospice Quality Reporting Program	QM	Quality Measure
HOPE tool	Hospice Outcomes & Patient Evaluation tool	SNF	Skilled Nursing Facility
HH	Home Health	TEP	Technical Expert Panel
IMPACT Act	Improving Medicare Post-Acute Care Transformation Act	VNAA	Visiting Nurse Associations of America
IPOS	Integrated Palliative care Outcomes Scale		

Executive Summary

The Centers for Medicare & Medicaid Services (CMS) anticipates expanding the Hospice Quality Reporting Program (HQRP) over the next several years to include additional, meaningful quality measures. Abt Associates, under contract to CMS, is supporting this work, which will be based on a patient assessment instrument that is expected to replace the current Hospice Item Set (HIS) data-collection vehicle. Specifically, this project includes developing a patient assessment instrument and related quality measures that reflect the care needs of people through the dying process, as well as prioritizes the safety and comfort of individuals enrolled in hospice nationwide and promotes person-centered care that emphasizes psychosocial, spiritual, and emotional support.

To measure overall quality of hospice care, CMS can draw upon three complementary sources of information to provide a comprehensive picture: 1) administrative claims; 2) instrument data; and 3) post-bereavement interviews or surveys with hospice primary caregiver/s (Consumer Assessment of Healthcare Providers and Symptoms [CAHPS®] Hospice Survey). To support the development of a patient assessment instrument, we conducted a range of information-gathering activities to identify candidate domains and elements, as well as quality measure constructs based on those domains and elements. In particular, we focused on desired patient outcomes and processes that distinguish high-quality hospice care for the purposes of quality improvement and accountability.

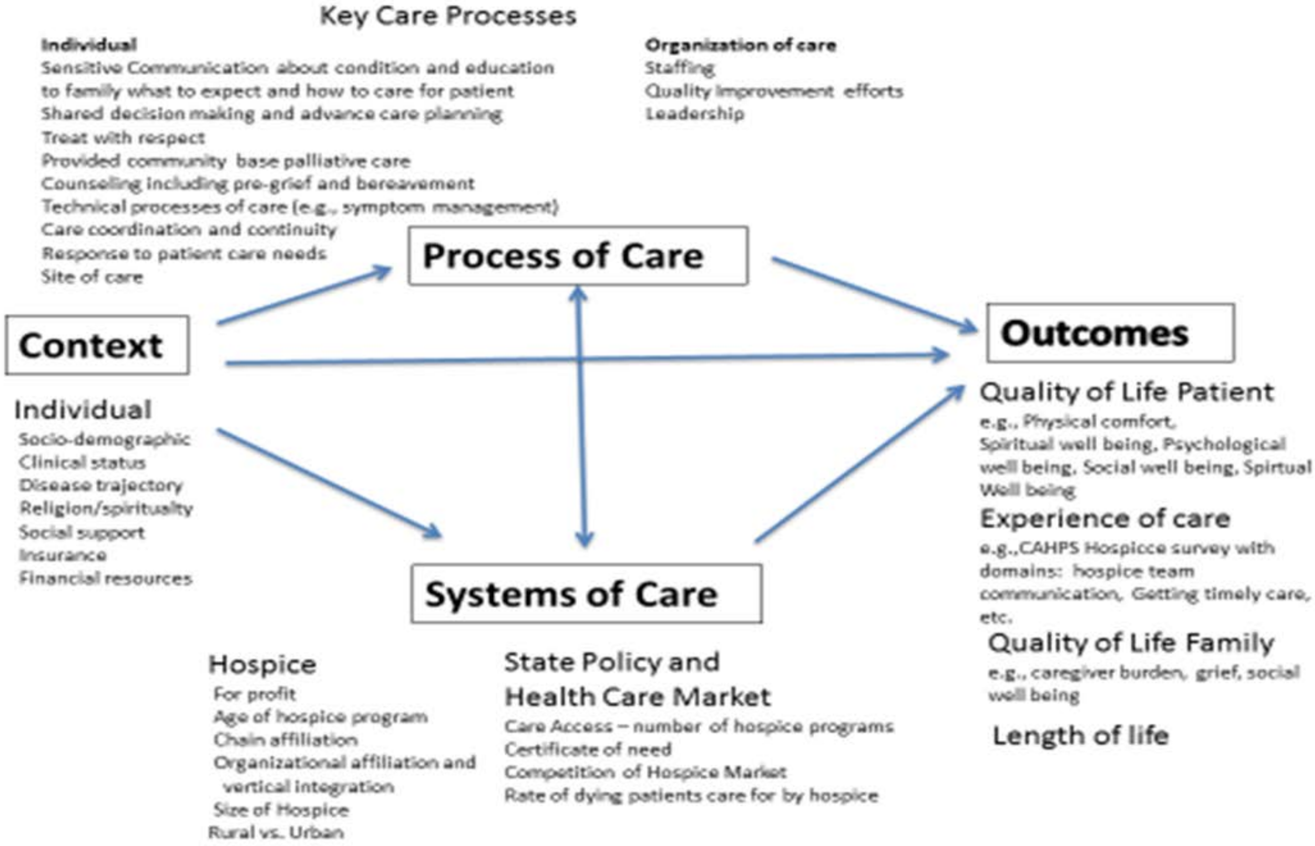
To guide our information-gathering activities to inform hospice quality assessment and measurement, the Abt team formulated the following research questions:

- What are key domains, when assessing hospice quality that can be assessed in a patient assessment instrument completed by hospice staff?
- What quality measures (QMs) will best distinguish hospice performance for the public about the quality of hospice care?
- What are the current gaps in hospice QMs, and which measure concepts will help address these gaps?
- What are patient, family, and other stakeholders' priorities for high-quality hospice care?
- What is the potential for interoperability and electronic health record (EHR) exchange and/or standardization across hospice and/or other post-acute care settings?

Proposed elements of the patient assessment instrument will have three anticipated uses: 1) development or refinement of quality measures, including potential risk adjustment; 2) care planning; and/or 3) refining the payment model, as appropriate. A primary focus in the selection of key domains is alignment with meaningful outcomes of interest, along with supporting process of care measures and potential risk adjustment. The patient assessment instrument will not replace the requirements of the Medicare Hospice Conditions of Participation [COPs][1] regarding comprehensive assessment.

Our research was informed by the conceptual model below illustrating the relationships between care systems, processes, and outcomes, and the contextual factors that impact them. In particular we are mindful of the individual patient characteristics, including socio-demographic factors, disease trajectories, and personal beliefs that are important to providing and measuring patient-centered hospice care.

Figure 1: Hospice Care Conceptual Model[2]



Our information-gathering activities involved obtaining input from a range of stakeholders, through expert interviews, key stakeholder interviews, and focus groups. We also conducted a scan of relevant guidelines, regulation and legislation, and reviews of the hospice literature and extant assessment items and instruments. In line with the requirements of the Measures Management System Blueprint, this report summarizes our findings from these activities. From this work emerged a candidate list of domains recommended for inclusion in the patient assessment instrument. Based on the results of information gathering, we recommend for CMS and the Technical Expert Panel (TEP) to consider the following domains for inclusion in the patient assessment instrument and related quality measures:

- Actively Dying
- Caregiver Well-Being
- Psychological Well-Being
- Social Well-Being
- Physical Symptoms
- Physical Function
- Prognosis and Performance Status
- Spirituality
- Shared Decision-Making and Advance Care Planning

To further expand the evidence base for a patient assessment instrument, we are pursuing additional information-gathering activities. This includes recently completed focus groups with hospice personnel (summarized in a Focus Group Addendum to this report) and cognitive testing to provide input on candidate items for the assessment tool. These activities will also help identify any required modifications for alpha testing of the draft patient assessment instrument, known as the Hospice Outcomes & Patient Evaluation (HOPE) tool.

1. BACKGROUND AND SIGNIFICANCE

Many Americans rely on hospice care for end-of-life support. The Centers for Medicare & Medicaid Services (CMS) pays a per diem for hospice services for more than a million Americans each year.[3] These services are critical to an aging and often vulnerable patient population. CMS continually strives to improve hospice quality and experience of care for beneficiaries within the context of the Meaningful Measures Framework (MMF)[4], which prioritizes high-impact quality measure areas that are meaningful to patients, their families and caregivers. As payment policy shifts from fee-for-service to value-based care, CMS strives to define, measure, and incentivize high-quality hospice care.

CMS anticipates expanding the Hospice Quality Reporting Program (HQRP) over the next several years to include additional meaningful quality measures. The Abt team, under contract to CMS, supports this work, which includes the development of a patient assessment instrument that is expected to replace the current Hospice Item Set (HIS) data-collection vehicle. A primary development goal for the patient assessment instrument is that it reflects both the care needs of people through the dying process as well as prioritizes the safety and comfort of individuals enrolled in hospice nationwide and promotes person-centered care that prioritizes psychosocial, spiritual, and emotional support.

This information-gathering report presents our review of available resources to inform a patient assessment instrument and related quality measures. We present methods and findings from our information-gathering activities, including diverse stakeholder input, review of existing clinical practice guidelines, review of legislation and regulations and their impact on measurement, literature reviews, and a gap analysis of existing instruments and measure. We conclude with recommendations for CMS and a planned Technical Expert Panel (TEP) to consider regarding the development of quality measures supported by the patient assessment instrument, known as the Hospice Outcomes & Patient Evaluation (HOPE) tool.

2. SCOPE

The goal of the patient assessment instrument is to understand the care needs of people through the dying process and to promote the safety and comfort of individuals enrolled in hospice organizations nationwide. The standardized data collected by the Hospice Outcomes & Patient Evaluation (HOPE) assessment tool will support quality measures (QMs) for hospice care throughout the dying process, encourage the delivery of person-centered care, and reflect the CMS Meaningful Measures Framework priorities.

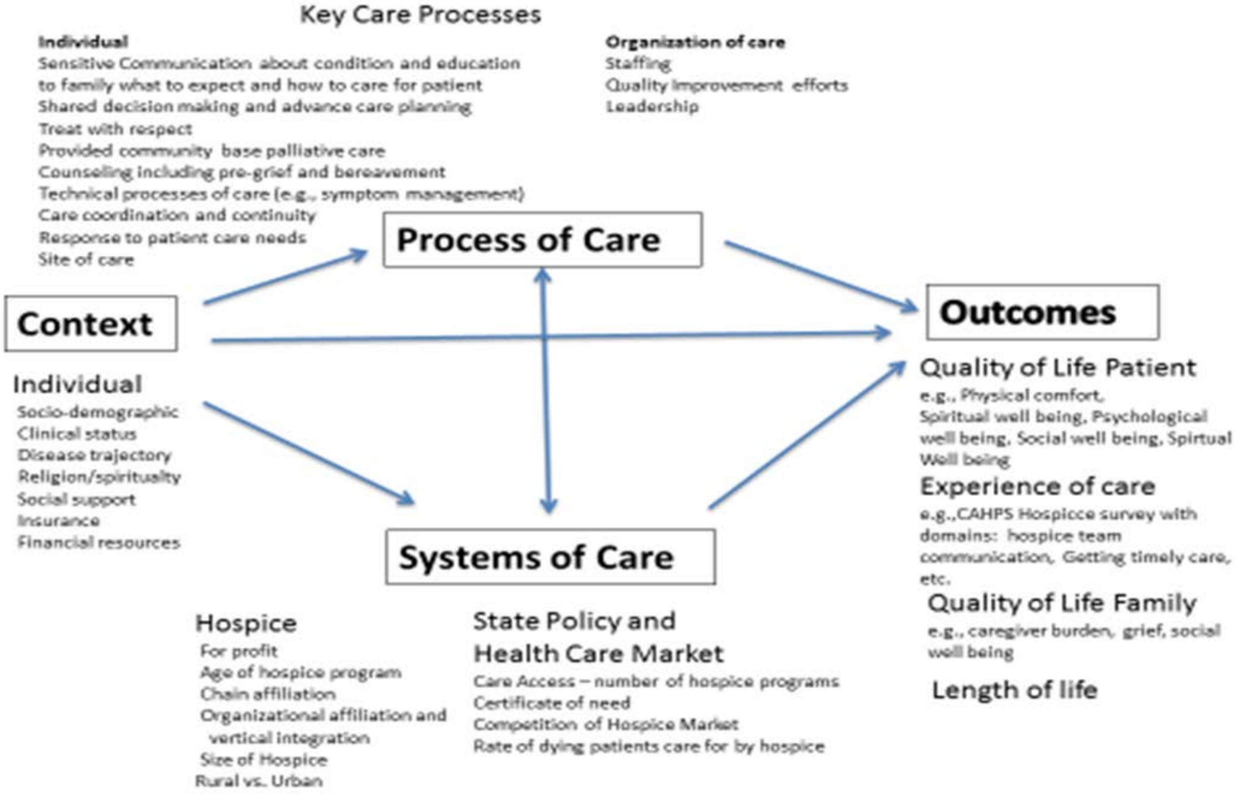
2.1. Research Questions

The Abt team formulated the following research questions to guide the hospice quality assessment and measurement information gathering:

- What are key domains, when assessing hospice quality that can be assessed in a patient assessment instrument completed by hospice staff?
- What quality measures (QMs) will best distinguish hospice performance for the public about the quality of hospice care?
- What are the current gaps in hospice QMs, and which measure concepts will help address these gaps?
- What are patient, family, and other stakeholders' priorities for high-quality hospice care?
- What is the potential for interoperability and electronic health record (EHR) exchange and/or standardization across hospice and other post-acute care settings?

Our research was informed by a conceptual model linking hospice care systems, processes, and outcomes, and identifying important contextual factors (see Figure 1).

Figure 2: Hospice Care Conceptual Model[2]



We initially used this model to help guide our expert interviews, key stakeholder interviews, and focus groups, as well as syntheses of relevant guidelines, legislation, and extant literature reviews. The following domains were explored in our information-gathering activities:

- Actively Dying
- Caregiver Well-Being
- Psychological Well-Being
- Social Well-Being
- Physical Symptoms
- Physical Function
- Prognosis and Performance Status
- Spirituality
- Shared Decision-Making and Advance Care Planning

The selection and prioritization of these domains was informed by stakeholder input, including listening sessions with leading industry associations, organizations, and federal experts in quality and hospice policy and review of federal guidance, clinical practice guidelines (CPGs), regulations and legislation. We also reviewed peer-reviewed and gray literature, as well as existing instruments, items, scales, and tools relevant to hospice care. Our information-gathering activities were focused on applicability to developing outcome measures and process of care measures. The sections below summarize our findings by type of information-gathering activity, starting with the input we obtained from a diverse range of stakeholders.

3. STAKEHOLDER INPUT

3.1. Provider Associations - Listening Sessions

3.1.1 Methods

As part of our information-gathering efforts, the Abt team engaged with a range of hospice stakeholders—from clinical staff to data administrators—to comment on a draft list of assessment domains, the proposed timing of data collection, and more general considerations around hospice quality measurement. In the spring of 2019, the Abt team hosted listening sessions with the following hospice and palliative care provider associations:

- National Hospice and Palliative Care Organization's (NHPCO) Leadership and Advocacy Conference (3 in-person sessions) (April 14-17, 2019)
- Visiting Nurses Association of America (VNAA) (teleconference) (May 14, 2019)
- National Partnership for Hospice Innovation (NPHI) (teleconference) (May 15, 2019)
- National Association for Home Care and Hospice (NAHC) (teleconference) (May 21, 2019)

In each listening session, participants spoke about their experiences with existing data-collection tools—specifically, the Hospice Item Set (HIS) and Hospice Consumer Assessment of Healthcare Providers and Systems (CAHPS®). The CAPHS® is an experience-of-care composite measure, while the HIS is a chart abstraction tool; neither are based on real-time patient assessment.

3.1.2 Results

After reflecting on indicators or metrics of quality of care in their current practices, listening session participants voiced general considerations for a future patient assessment instrument. Below are some key takeaways from these conversations.

- **Alignment with patient goals:** Hospice is unique in that it respects—and encourages—goal-setting among patients and caregivers. This could mean "pain or symptom control," or it could mean something entirely nonclinical—"attending a daughter's wedding," for instance, or "resolving a family issue." Ideally, a patient assessment instrument should capture the extent to which a hospice facilitates such goals.
- **Holistic approach:** Because of the sensitive and all-consuming nature of the dying process, hospice should cater to all needs of a patient—not just the clinical. Specifically, delivering quality hospice care means considering the psychological, spiritual, and cultural profiles of patients and caregivers alike. To facilitate this, an interdisciplinary team—including chaplains and social workers—can provide crucial assistance to clinical staff.
- **Minimal burden**: A patient assessment instrument should avoid placing additional burden on patients and caregivers during what is, presumably, an already difficult experience. Some interviewees were concerned that additional reporting requirements would detract from clinical attention given to the patient. Achieving minimal burden can be interpreted as requiring infrequent assessments. At the same time, any discrete (rather than continuous) assessment has the potential to mischaracterize a patient's evolving condition. A patient may be "looking great" leading up to assessment, and then "take a turn" immediately prior to assessment. Ultimately, a patient assessment instrument should balance the need for complete, timely information with the need to respect patients' and providers' time.
- **Integration into current workflow:** To avoid undue burden, a patient assessment instrument should leverage existing data-collection processes. Ideally, new reporting requirements would be embedded within the electronic health record (EHR) — both to minimize the burden of additional data input and to guard against duplicative questions.

- **<u>Skip patterns:</u>** Despite (or perhaps because of) its standardized nature, a patient assessment instrument should allow for some flexibility in tailoring data collection around a patient's clinical profile. Ideally, a patient assessment instrument should include skip patterns—custom omissions that reduce the collection of unnecessary information.

By speaking with stakeholders at multiple hospice and palliative care provider organizations, the Abt team was able to reaffirm—and reassess—its development of various domains for the patient assessment instrument. These conversations highlighted important on-the-ground considerations from clinicians who, one day, could be users of the HOPE instrument.

3.2. Special Open Door Forum

3.2.1 Methods:

On June 12th, 2019, CMS and the Abt team facilitated a Special Open Door Forum (SODF) to allow a range of hospice stakeholders to comment on the development of the patient assessment instrument. This hour-long conference call is part of a series of quarterly virtual meetings—all open to the public—during which CMS and the Abt team provide status updates about the Hospice Quality Reporting Program, with an emphasis on updates related to the development of the patient assessment instrument, and provide responses to questions from the participants.

More than six hundred hospice stakeholders participated in this teleconference. After listening to a short presentation, participants were encouraged to respond in real time to representatives from the Abt team and CMS. Nine participants—predominantly hospice provider employees—asked their questions and noted their concerns about challenges in developing a patient assessment instrument.

3.2.2 Results

Common themes included the importance of minimizing patient and provider burden during data collection, integrating the instrument within existing clinical workflow, and aligning quality measurement with patients' goals.

In addition, participants raised several open-ended questions:

- How can a required assessment instrument be simultaneously standardized and individualized?
- Considering the different clinical profiles of patients in hospice, will the instrument measure disease-specific care?
- Frequently, patient goals and caregiver goals are not aligned. Which should providers prioritize, particularly in situations when the patient experiences impaired judgement or communication?

The discussion that followed reaffirmed the unique challenges of hospice care, as well as some universal considerations (outlined above) around quality assessment and measurement. The Abt team was able to gauge a broad range of valuable perspectives from this public stakeholder engagement opportunity.

3.3. Federal Stakeholder Meeting

3.3.1 Methods

On June 13th, 2019, CMS and the Abt team facilitated a Federal Stakeholder meeting in order to 1) update federal stakeholders on the status of the patient assessment instrument, and 2) gather comments and reactions to the suggested domains, the challenges, and the practical uses of items under consideration. The meeting lasted two hours and was conducted virtually to allow for large and diverse attendance.

While previous information-gathering efforts via expert input included largely hospice providers—the intended users of the hospice assessment instrument—this federal stakeholder meeting targeted health policy experts and government officials, and included CMS participants from the Center for Clinical Standards and Quality (CCSQ), Center for Medicare, the Center for Medicare and Medicaid Innovation

(CMMI) and the Medicare Payment Advisory Council (MedPAC). This macro perspective meant participants were also able to provide input on instrument details: the ways in which an item's wording might affect payment, for instance, or the potential misalignment of specific items with federal requirements. These specific comments from federal stakeholders reaffirmed many of Abt's broader conceptual categories for the patient assessment instrument.

3.3.2 Results

The table below (Table 1) summarizes key discussion points and recommendations related to each of the topic areas:

Table 1: Summary Points from Federal Stakeholder Meeting on June 13, 2019

Topics	Summary Points
Diagnosis	Recommendation: • Consider a simple check box for diagnoses, in order to capture those that are related to the terminal illness. Key discussion points: • Conditions of Participation (COP) require hospices to determine whether a diagnosis is related or unrelated to terminal illness. This determination must be made in consultation with the attending physician and hospice medical director. • Hospice nurses do not just treat a patient's terminal illness, but rather the entire list of diagnoses. Thus, the listing of all active diagnoses is important to include. • From a payer standpoint, the diagnoses impact what services are paid for and whether a specialist is paid by the hospice or directly from Medicare.
Function	Recommendation: • Review the Functional Assessment Standardized Items (FASI), available in the Data Element Library (DEL). Key discussion points: • The Data Element Library (DEL) contains items for instrumental activities of daily living (IADLs) and activities of daily living (ADLs). The Abt team should consider building upon these if they are already used in nursing home and home health settings.
Living Arrangements	Recommendations: Include information on both living arrangements and the capability of the caregiver. • Reach out to EHR vendors to determine if there are items already being used by the industry that would be applicable to this domain.
Drug Profile	Recommendation: • Draft a section that would capture drugs related to symptom palliation, grouped into four categories: analgesics, antinauseants (antiemetics), laxatives, and antianxiety medications (anxiolytics). Key discussion points: • Mixed feedback as to whether "drug profile" is important to include in the assessment. • On one hand, this domain is important because medications that are not covered require a co-pay for the patient and there is little information about hospice characteristics. Currently, it's difficult to capture which services (including drugs) are being provided. • Drug data could potentially include in future development of QM.
Severity Scale	Recommendation: • Speak with the Data Element Library (DEL) team about how to structure the items in the proposed modified IPOS scale prior to alpha and beta testing.

Topics	Summary Points
Grief	Recommendation: • Remove the detailed scale for Prolonged Grief Disorder (PGD). Perhaps question #3 on the short Interdisciplinary Group (IDG) tool—based on the Integrated Palliative Outcome Scale (IPOS)—could be used in place of the full PGD-12 tool. Key discussion points: • Measuring grief is important. • The assessment instrument and any related measures should consider the role of information provided by the next of kin. . • What are hospices' obligations to address prolonged grief disorder among caregivers? • If hospice does provide a year of post-bereavement services, would it make sense to assess over that year? • Alternate options presented for discussion: o Collect known risk factors (e.g. childhood trauma, substance abuse, etc.) using checkboxes for these items. o Create a quality measure: "have any caregivers been anxious about the patient?" Meanwhile, the offer of social worker, chaplain, or bereavement services could be a process measure. • In addition, hospice staff could assess family concerns using an item from the IPOS and create a process measure that includes whether social worker services were offered during hospice.
Caregiver Burden	Recommendation: • Omit "caregiver burden" from the assessment instrument, as this topic cannot be linked to the Conditions of Participation (COP). However, caregiver burden, in a more global sense, can be captured through data gather for the IDG meeting.
Skin integrity	Recommendation: • Consider developing a quality measure around skin integrity (high rate of this being cited on hospice surveys as indicating a care deficiency). Key discussion points: • It is difficult to hold hospices accountable for wounds that will not heal as a result of the patient's medical condition. (For instance, a cancer patient may also have anorexia and skeletal metastases that result in severe pain.) • CMS cited survey evidence that over 60 percent of hospices have issues with wounds. Because of this concern, consideration should be given to a process measure regarding assessment of skin integrity and development of treatment plans. • Separately, these items might be important for case mix, as they drive resource utilization.
Interdisciplinary Group/Team (IDG/ IDT) Assessment	Recommendation: Proceed with the development of brief assessment completed prior to an IDG. • Check with the DEL team for interoperability of the candidate IDG items. Key discussion points: • The Abt team reviewed several options regarding the use of an assessment instrument prior to the mandated IDG for updating of the care plan: o Option A- collect every 15 days prior to IDG, twice in the first 30 days. o Option B- collect up to the first recertification period (90 day). o Option C- collect prior to each IDG meeting (every 15 days). • CMS is collecting this data for the purposes of public reporting. It is important to know the frequency of data collection required in order to have a large enough denominator, so even the small hospices that potentially would be excluded from public reporting would get captured.
Prognosis	Recommendations: • Determine which validated performance scales are used by hospices currently. Develop a crosswalk across the various scales, if use of a specific scale is not required for data collection.

Participants also encouraged the Abt team to coordinate with CMS Data Element Library (DEL) staff and to gather information from electronic health record (EHR) vendors in order to enhance interoperability and minimize data collection burden. Ultimately, this Federal Stakeholder meeting helped to contextualize the technicalities of a patient assessment instrument within the broader CMS policy landscape. By speaking with a range of policy experts and government officials, the Abt team was able to refine—and reaffirm—its categorization of various domains related to hospice quality assessment.

3.4. Pilot A Tool Debrief

3.4.1 Methods

To supplement forward-looking input about the patient assessment instrument, the Abt team also looked backward—namely, at the experiences of hospices that piloted a similar assessment developed under a previous CMS contract. By soliciting input from testing participants, the Abt team gained valuable insight and considerations for designing and implementing an assessment instrument in the hospice setting.

In early May of 2019, the Abt team conducted two conference-call interviews with 8-10 representatives of hospices that had participated in the pilot testing of an prior draft hospice patient assessment tool—an initiative termed "Pilot A"—during the winter of 2018. To seek diversity of opinion, the Abt team recruited staff from a range of hospices who participated in this testing to provide feedback about various aspects of the pilot implementation. After explaining that this feedback would help guide the development of a patient assessment instrument, the Abt team encouraged interviewees to respond candidly to a series of questions regarding the content, administration, and training associated with the Pilot A tool. Both interviews lasted one hour, and the conference call format allowed participants to respond to each other in a casual and unscripted environment.

3.4.2 Results

Below are some key takeaways from the conversations:

- **Skip patterns:** Interviewees acknowledged the challenge in developing an instrument that is both standardized and flexible—an assessment that captures necessary information, yet allows for tailoring around specific patient and caregiver needs. Based on their experience, Pilot A participants noted the limitations of having the same data collection requirements for patients with various clinical profiles. For example, one interviewee, who administered the Pilot A tool as a nurse, noted the awkwardness around asking an actively dying patient whether s/he "wanted to be re-hospitalized."
- **Recommendation:** A patient assessment instrument should include clear skip patterns to allow for more customization based on individual patient and caregiver characteristics.
- **Alignment with patient goals**: Interviewees emphasized the importance of tailoring hospice care to patient and caregiver needs, and thus considering carefully the length and content of an assessment. Some providers reported deviating from the scripted items—particularly when it was not required to ask questions verbatim—in order to better align with the specific needs of the patient.
- **Recommendation**: Create a flexible instrument that can be tailored to individual circumstances.
- **Minimize burden:** Ideally, a quality assessment instrument should not detract from the care it is trying to measure. Several interviewees voiced concerns about the potential stress on dying patients from collecting assessment data. They cited the subjectivity of some response scales (for instance, categories like "not at all, a little bit, quite a bit"), combined with the back-and-forth between categorical and numerical response options, as sometimes "confusing" to patients and providers alike. Administrators of the Pilot A also described burden associated with required paperwork.
- **Recommendation:** Minimize the data collection burden, including the complexity of response pattern, to facilitate administration.

- **<u>Integration into current workflow:</u>** Many interviewees noted the importance of integrating new assessments into existing EHR systems; otherwise, "they're just an extra thing to worry about." While one hospice representative described using an EHR-compatible tool, the majority of interviewees used a combination of paper and electronic assessments that duplicated, rather than leveraged, existing data collection when participating in the pilot.
- **<u>Recommendation:</u>** Both testing and final administration of a patient assessment instrument should be designed to leverage existing work flows and EHR systems.
- **<u>Training and guidance:</u>** Respondents agreed that increased training efforts prior to instrument testing would have mitigated challenges related to administering the Pilot A tool. When pilot testing began in early 2018, hospices participated in a 90-minute conference call one week prior to implementation. Many interviewees described having a "point person"—typically a nurse—disseminate instructions to other staff after attending the training. Although this delegation "worked well" to spread information, several respondents would have liked more time to prepare for testing following the training, as well as more explanation regarding tool administration—particularly, how to differentiate mandatory sections from those that applied to specific clinical cases. For instance, many hospices recommended that training include clear examples of skippable questions, as well as examples of appropriate responses to questions (for instance, pain while getting dressed falls under the category of "moderate pain").
- **<u>Recommendation:</u>** Training for future hospice assessment instrument testing and implementation should be extensive—both in length and in content – and allow sufficient time to prepare for data gathering after training concludes.

In contrast with other types of expert input, which focused on developing the patient assessment instrument, these Pilot A debrief interviews offered guidance based on lessons learned from past experiences with testing. By speaking with hospice employees who experienced instrument implementation firsthand, the Abt team is better poised to leverage the successes—and learn from the challenges—of past efforts in testing a hospice quality assessment instrument. These findings will be applied to both instrument design and the protocols for alpha and beta testing.

3.5. PCORI Ambassador and Caregiver Interviews

3.5.1 Methods

In addition to interviewing hospice provider employees—people responsible for collecting and submitting patient assessment items—the Abt team sought input from people at the other end of data collection: patients, family members, and caregivers. In July 2019, the Abt team conducted five separate, hour-long phone interviews with members and referred contacts of the Patient Centered Outcomes Research Institute (PCORI) Ambassador Program—a network of volunteers who serve as liaisons between health researchers and the broader community.

For this round of interviews, the Abt team selected ambassadors who had been personally affected by hospice—whether through caring for their own dying relatives or through witnessing the end-of-life experiences of geographically and culturally diverse patient groups. While all interviews were candid and unscripted, the Abt team encouraged each Ambassador to discuss the following topics: their considerations when choosing hospice care, their experiences within the hospice system, and any recommendations they had for systemic hospice improvement.

3.5.2 Results

Below are some key takeaways from these conversations:

What does quality hospice care look like?

- **Routine assistance with daily activities**: For most patients, patient-centered assistance with daily activities—and any accompanying pain, symptoms, and collaborating with the caregiver —is a baseline requirement of hospice care.
- **Responsiveness of staff at any time**: In addition to routine and predictable care, caregivers noted appreciating around-the-clock availability of hospice employees. All interviewees recalled wanting—if not already having—the ability to request and receive care at any time of day.
- **Availability of patient-centered non-medical auxiliary staff**: The participant descriptions of the availability of non-medical support varied from general unavailability of social workers and chaplains to receiving non-medical staff that did not support the caregiver's perspectives and needs. Upon the participants' reflection of their experiences, they raised the importance of the availability and patient- and caregiver centered non-medical auxiliary staff would have likely improved their experience with hospice.
- **Alignment with patient goals**: Because of the non-curative nature of hospice, end-of-life care allows for—and, in fact, necessitates—alignment with patients' requests and goals. This means respecting spiritual, religious, and cultural preferences among patients. It also means treating patients with dignity—something that can be achieved through tailoring healthcare to individual preferences and desires. For instance, one hospice nurse respected her patient's desire to eat dinner on the floor. Another helped her patient with "manicures and makeup"—activities that made her "feel like a lady, and not like a patient." During the last days of life, respondents noted, small acts of kindness can make a big difference.
- **Advanced care planning:** An important component of quality care is the opportunity to discuss and define it. Hospices should encourage—if not facilitate—conversations between caregivers and their loved ones about their preferred end-of-life scenarios. Of course, advance care planning is influenced heavily by one's personal background, and respondents said hospices should recognize the range of patients' and caregivers familiarity and comfort with these conversations. For instance, a couple interviewees had engaged in end-of-life conversations decades prior to their relatives' deaths. Meanwhile, several interviewees noted a cultural or religious tendency to avoid conversations about death—either to reduce anxiety among the dying, or to shield biological descendants from learning potential clues about their own disease trajectories. Ultimately, hospices should encourage these difficult conversations, while respecting the varying levels of comfort around advance care planning.
- **Educational support for caregivers**: Generally, caregivers want to be informed collaborators and decision-makers when their loved one enters hospice. This starts with setting clear expectations. One interviewee, who resorted to calling 911 during a nighttime emergency, wished someone had told her that hospice nurses were on-call at all times. Another wished that hospices distributed "educational toolkits" to inform and empower caregivers from the start. But education should go both ways: caregivers should also be recognized—and utilized—for their deep personal knowledge about the patient. For instance, one interviewee recalled an eighty-page tutorial that he wrote for his hospice staff, which detailed the specific needs and preferences of his dying wife. This gesture, although unconventional, represents a common desire among hospice caregivers to both give and receive educational support.
- **Emotional support for caregivers**: Hospices should provide bereavement support to caregivers once their loved one has passed. Currently, there is no standard protocol: one interviewee noted "no communication or support" after his spouse died; another interviewee was offered grief management

classes, but decided not to partake. Although caregivers experience bereavement differently, support should nevertheless be available to all.

- **Respect for caregivers' needs**: Although not the primary recipients of care, family members nevertheless deserve the same sensitivity given to patients. Unfortunately, many caregivers feel overlooked, rather than included, in the care of their loved ones. One interviewee was annoyed by the numerous unannounced home visits by hospice staff—a component of patient care that assumed this caregiver had no other responsibilities. Ultimately, caregivers should be recognized as beneficiaries, too.

How should quality of care be measured?

- **Minimize burden**: Due to the fundamentally stressful nature of end-of-life care, hospice assessments should be simple, concise, and easy to complete in order to minimize additional burden on patients and caregivers alike. Unfortunately, some interviewees had experiences to the contrary. One remembered his mother's hospice staff appearing "distracted" by all the paperwork; another estimated that the staff spent as much time on paperwork as they did on the patient. The burden was two-fold: not only was there was a lot of information to be collected, but the tools that allowed for such collection were lengthy and distracting. One interviewee even yearned for a "voice recognition software" that allowed hospice staff to maintain eye contact with patients while filling out required documentation.
- **Universal metrics:** If the goal of an assessment instrument is to standardize quality measurement, these instruments should contain universal metrics for responding. For instance, one interviewee noted potential differences in the perception and categorization of pain across ethnicities and cultures—a gap that could be addressed by incorporating simple visuals in an assessment. Although patients are not always able—or required—to fill out a quality assessment themselves, an instrument should nevertheless contain metrics that can be interpreted similarly by a range of respondents.

How should quality hospice care be publicized?

- **Emphasis on choice**: Given the wide range of services and characteristics across hospices, consumers should, if possible, have a choice in the care they receive. In fact, most interviewees claimed that they would have chosen differently had they been informed of the unique and variable features of hospice: characteristics like cultural and religious sensitivity, language of care, responsiveness and availability of staff, and overall patient-centeredness. Of course, "some people may not have any choice" in where they receive hospice—"so what's the point?" Although many patients do, in fact, choose a hospice based solely on geographic proximity, others may benefit from seeing comparative infographics and descriptions when making a decision.
- **Positive promotion**: Before consumers can choose a hospice, they must seek it. Unfortunately, many patients and caregivers neglect to consider hospice due to negative preconceptions about the process. Hospice may seem like a "last ditch effort"; something one needs to be "talked into"; a process without "hope." Meanwhile, many families feel "guilty" about sending their loved one to a hospice—a guilt that may be diminished through increased advertising of home-based services, financial accessibility, and language-based accommodations. Ultimately, death is unpleasant to envision. Due to combination of negative news coverage, cultural stereotypes, and the sheer sound of "hospice"—a word with similarities to "hospital" and "hostile"—many people believe hospice to be painful, rather than pain-reducing.

These five interviews with PCORI Ambassadors, although of a small sample size, complemented the Abt teams other information-gathering activities regarding hospice quality assessment. By speaking with a range of caregivers, family members, and patient advocates, the Abt team learned valuable information about the needs and preferences of those receiving hospice care. Ultimately, these interviews highlighted important considerations about the strengths, gaps, and unintended consequences of quality assessment—a crucial step in aligning the objectives of the patient assessment instrument with its real-world application.

3.6. Expert Interviews

3.6.1 Methods

Throughout the spring of 2019, the Abt team conducted sixteen phone interviews—either individually or in small group sessions—with various hospice subject matter experts (SME). These experts included physicians, nurses, researchers, and federal experts with collective expertise in palliative care, pain, non-verbal dyspnea, prolonged grief disorder, health literacy, data collection, and payment policy. When conducting these thirty-minute interviews, the Abt team tailored its guiding questions according to the background of each expert. Table 2 presents interviewee roles and specialty areas

Table 2: Interviewee Roles and Specialty Areas

Interviewees	Specialty Areas
Physicians, physician researchers	Advanced illness; Chief Medical Officer (CMO) of large for-profit hospice organization, palliative care research; Integrated Palliative Outcome Scale (IPOS); Chief Medical Officer (CMO) of large hospice with Center for Medicare and Medicaid Innovation (CMMI) demonstration
Federal experts - CMS	Survey and certification; hospice Conditions of Participation (COP); hospice payment policy; Hospice Evaluation and Assessment Reporting Tool (HEART) Work Group; Center for Clinical Standards and Quality (QMVIG)
Nurses, nurse researchers	Clinical care; quality improvement; health literacy; non-verbal dyspnea, pain
Other researchers; Chief Executive Officers (CEO)	Prolonged Grief Disorder (PGD); for-profit hospice

3.6.2 Results

Below is a synthesis of key considerations and recommendations from these expert interviews:

- **Actively Dying:** Many patients enter hospice in the last few days of life. A majority of experts interviewed agreed these patients should be viewed through a different lens, and assessed differently. Other experts pointed out that patients and families want to know hospice is available to provide support at this difficult time.
- **Symptom Assessment:** The Abt team is exploring the use of a modified Integrated Palliative Outcome Scale (IPOS) as part of patient assessment. Almost half of the interviews mentioned symptom assessment/management as an important domain. A majority of the interviewees felt the proposed modified IPOS scale aligned with hospice day-to-day operations.
- **Assessment Domains and Other Important Factors:** Draft instrument domains were shared to generate discussion regarding factors for consideration. Experts in the area of payment and regulation supported developing a de novo assessment, noting that while it does not need to be long and arduous, it should show the hospice provider is meeting patient and family/caregiver needs and goals. This feeling was echoed by other hospice experts.

These expert interviews—conducted either individually or in small groups—allowed for targeted, tailored, and candid conversation. By interviewing people with a range of clinical, research, and policy expertise, the Abt team gained valuable insight about specific elements of the patient assessment instrument development, which is a good complement to some of the broader but less targeted feedback gained through public forums.

4. SUMMARY OF CLINICAL PRACTICE GUIDELINES REVIEW

4.1. Methods

Team members conducted a search to identify relevant evidence-based clinical practice guidelines (CPGs) to inform the development of a patient assessment instrument and associated quality measures. CPGs can provide an evidence-based framework for a topic area based on systematic reviews of the literature. The purpose of the search was to answer the question: "What clinical practice guidelines exist that may provide insight on quality hospice practice?" Online publication directories searched included PubMed and the ECRI Guidelines Trust™. Keywords for searches included hospice, palliative care, and end-of-life.

4.2. Results

Based on this search, one directly relevant and high-quality guideline was selected for review.

Guideline name: "National Consensus Project's Clinical Practice Guidelines for Quality Palliative Care, 4th Edition"[5]

Developer: National Coalition for Hospice and Palliative Care

Year Published: 2018

Summary of major recommendations: This guideline makes a number of recommendations for palliative care across all settings of care. The guideline specifies eight domains, each of which contains sub-domains and evidence for best practices. All domains include recommendations based on involving the expertise of an interdisciplinary team (IDT), conducting proper screening and assessment, making appropriate plans of care that honor patient and family preferences, and developing and following plans for ongoing communication and care coordination. The eight domains and a summary of the recommendations are as follows:

1) *Structure and Processes of Care*: This domain stresses the importance of an interdisciplinary team (IDT) and its ideal composition, assessments specifically for palliative care, and outlines typical processes and plans for palliative care.[6]

2) *Physical Aspects of Care*: This domain describes the important elements of a screening and assessment by the IDT for how a patient's symptoms are affecting his or her well-being, quality of life, and functional status. Additionally this domain promotes evidence-based treatment of physical symptoms and recommends involvement in care planning by all persons involved in care, including the patient and caregivers. It also cautions against inappropriate use of opioids.[6]

3) *Psychological and Psychiatric Aspects of Care:* This domain and its sub-domains recommends involvement of a social worker in the IDT; evidence-based screening for and treatment of mental health issues including distress, anxiety, and depression at the end of life; and appropriate planning for managing ongoing care and coordination of care. [6]

4) *Social Aspects of Care:* This domain stresses the impact that social factors have on patient quality of life, and the importance of having an IDT member who can adequately recognize the social determinants of health that may be influencing the patient and family through screening and assessment; additionally, the IDT should create a care plan that addresses identified social needs (examples are homelessness, caregiver capacity, financial vulnerability, functional limitations, and more), as well as a plan for ongoing monitoring and coordination to ensure that care addresses those needs. It also highlights the specific need for pediatric-experienced professionals when dealing with perinatal or pediatric patients. [6]

5) *Spiritual, Religious, and Existential Aspects of Care:* This domain emphasizes respect for patient beliefs and spiritual practices, ideologies, and preferences by the IDT, involvement of a spiritual care specialist, and proper screening and assessment for spiritual needs or distress. [6]

6) *Culture Aspects of Care:* This domain is focused on the values, cultural beliefs, traditional practices, language, and communication preferences of the patient and family, and stresses appropriate staffing to deliver culturally sensitive care, including medical interpreter services where possible. This domain also stresses that assessment should reveal preferences like beliefs about pain and suffering, level of health literacy, and a patient's gender/pronoun identity. [6]

7) *Care of the Patient Nearing the End of Life:* This domain encourages the IDT's familiarization with the signs and symptoms of a patient approaching death, and stresses communication with the patient's family at this time, including identifying concerns in the previously stated domains and providing grief and bereavement support (the level of which is not specified); hospice eligibility and hospital services should be brought into the conversation at this point. The patient's symptoms (including physical, psychological, spiritual, and social) should be addressed during the dying process, and preferences should be honored. After death, the IDT should direct families to appropriate bereavement services. [6]

8) *Ethical and Legal Aspects of Care:* Ethical and legal aspects of care in this domain encompass those unique to the seriously ill or dying population, including the importance of "autonomy, substituted judgement, beneficence, justice, and nonmaleficence." The IDT should be familiar with local, state, and national laws regarding the provision of care. This domain stresses the importance of decision making by the patient where possible and legal, and screening for care preferences is emphasized while acknowledging that preferences may change over time. The IDT should also make use of an ethics team whenever possible.[6]

Table 3 presents sample recommendation statements from the National Consensus Project's Clinical Practice Guidelines for Quality Palliative Care, 4th Edition.

Table 3: Sample Recommendation Statements from the National Consensus Project's Clinical Practice Guidelines for Quality Palliative Care, 4th Edition[5]

Domains for Quality Palliative Care	Sample Recommendation Statements[5]
Structure and processes of care	(Guideline 1.2) comprehensive assessment provides the basis of individualized care plan
Physical aspects of care	(Guideline 2.2) screening and assessment of physical symptoms impact on quality of life, well-being, and functional status
Psychological and psychiatric aspects of care	(Guideline 3.3) treatment of psychological and psychiatric aspects of care is provided through the interdisciplinary team or referral to appropriate professional
Social aspects of care	(Guideline 4.1) the palliative care interdisciplinary team has the needed resources to address the social aspects of care
Spiritual, religious, and existential aspects of care	(Guideline 5.3) the palliative care interdisciplinary team addresses the spiritual aspects of care
Cultural aspects of care	(Guideline 6.1) the palliative care team respects the person's cultural traditions and provides needed resources as translator
Care of the persons nearing the end of life	(Guideline 7.3) the palliative care team develops a care plan that anticipates and treats physical, psychological, spiritual needs and distress in the actively dying person
Ethical and legal aspects of care	(Guideline 8.1) the core principles of bioethics guide care of dying persons and their families

5. REVIEW OF LEGISLATION AND REGULATIONS

5.1. Methods and Results

There are a number of federal regulations, statutes, and other guidance that govern the provision and measurement of hospice services covered by Medicare and Medicaid. The Abt team has reviewed the following legislation, regulations, and other federal guidance as part of our information gathering efforts. Below, we summarize their implications for a patient assessment instrument.

Federal legislation: Tax Equity and Fiscal Responsibility Act (TEFRA) of 1982
Primary agency responsible: Department of Health and Human Services
Year passed (or effective): 1982
Summary of major implications: Section 122 of TEFRA expanded the scope of Medicare to include the coverage for terminally ill beneficiaries that chose to elect the hospice benefit. The legislation established the eligibility criteria and requirements of the program to deliver hospice care. The law also established a framework that authorizes CMS to design the payment system and other requirements through rulemaking to establish federal regulations at 42 Part 418 for conditions of payment and conditions of participation. The Abt team reviewed the foundation of the Medicare hospice legislation to understand the design of a program that considers the beneficiary and caregiver as a unit of care.

Federal legislation: Patient Protection and Affordable Care Act (PPACA) of 2010
Primary agency responsible: U.S. Department of Health and Human Services
Year passed (or effective): 2010
Summary of major implications: The ACA mandates in section 3004 that the "Secretary [is] to establish quality reporting requirements for hospice programs." This requirement established the Hospice Quality Reporting Program (HQRP) — an initiative that not only reports data collected from hospices through the current Hospice Item Set (HIS) and the Hospice Consumer Assessment of Healthcare Providers and Systems (CAHPS®) tool, but that also authorizes CMS to collect patient assessment data. The ACA also established the CMS's Center for Medicare & Medicaid Innovation (hereafter referred to as the Innovation Center) to authorize CMS to design and test "innovative payment and service delivery models to reduce program expenditures . . . while preserving or enhancing the quality of care." For example, the Innovation Center exercised its authority to develop the Medicare Care Choices Model (MCCM) that allows for supportive care services to be provided by hospices without the beneficiary forgoing or waiving Medicare payment for care related to the terminal condition. The Abt team considered data and findings as a result of ACA-initiated programs to inform the development of a patient assessment instrument and related quality measures.

Federal legislation: The Improving Medicare Post Acute Care Transformation (IMPACT) Act
Primary agency Responsible: Department of Health and Human Services
Year published: 2014
Summary of major implications: The IMPACT Act mandates the provision of "standardized post-acute care assessment data for quality, payment, and discharge planning" from Long-Term Care Hospitals (LTCHs), Skilled Nursing Facilities (SNFs), Home Health Agencies (HHAs), and Inpatient Rehabilitation Facilities (IRFs) (H.R. 4994—2). We sought to align the draft patient assessment instrument closely with IMPACT Act requirements where appropriate, including by using standardized items from existing post-acute care instruments, namely the Minimum Data Set (MDS) used in nursing homes, the Outcome and Assessment Information Set (OASIS) used in home health, and the Inpatient Rehabilitation Facility Patient Assessment Instrument (IRF PAI) used in inpatient rehabilitation facilities. To ensure such alignment, the Abt team referred to the CMS Data Element Library (DEL), which compiles data elements from various instruments and their associated information technology (IT) standards into one central location. As part of our review, we considered all possibly applicable items from these instruments across hospice domains for inclusion in the patient assessment instrument, and these are included in the draft instrument where applicable.

Federal regulation: Hospice Wage Index, Payment Rate, and Quality Reporting Proposed and Final Rules from 1983 – 2019, as applicable to the Medicare Hospice Benefit and Quality Reporting Program
Initial year published: 1983
Summary of major implications: Since the implementation of the Medicare hospice benefit in 1983, annual rulemaking updates the payment rates and provides agency policy direction to the public on the hospice benefit. The process of rulemaking provides the public with an opportunity to comment on policy proposals, and the agency consider all comments before issuing the final decisions in the final rule. The Abt team reviewed relevant rules to better understand the evolution of the Medicare hospice benefit, descriptive analysis of hospice utilization, potential policy concerns, and the history of the quality reporting program.

Hospice Conditions of Participation (CoPs) (2008) implications: The Hospice COPs are requirements that Medicare-certified hospices must meet for the purposes of participation and payment. In this rule, CMS requires hospices to have a continuous quality assessment and performance improvement program (QAPI) as part of the Conditions of Participation, but gives hospices the flexibility to design a QAPI based on meaningful data that could identify areas for improvement or reinforce areas with positive performance. This rule incorporates changes made to the Social Security Act and recommendations from stakeholders to focus on “patient-centered, outcome-oriented, and transparent process that promotes quality patient care.” The Hospice COPs also serve as a guide on types of domains that could be considered for measurement and patient assessment instrument items.

Hospice Payment Reform (2014-2019) implications: CMS provides data analysis regarding the utilization of the Medicare hospice benefit in its proposed and final rules. Since the FY 2014 hospice rules and annually thereafter, CMS began to include more extensive analysis that monitors utilization and potential provider behaviors that may signal concerns regarding adherence to payment policy and care deliver concerns. The Abt team reviewed the data analysis in these rules and considered whether these findings indicate potential areas to develop quality metrics based on available administrative data.

Federal manuals and guidance: The Medicare Benefits Policy Manual (Chapter 9), Medicare Claims Processing Manual (Chapter 11), and the State Operations Manual (Section 2080 – 2089) provide operational and oversight direction in order to administer the Medicare hospice benefit. The manuals and guidance articulate administrative requirements with which hospice providers must comply in order to participate in the Medicare program. These include payment policy, program integrity and oversight actions, and requirements to deliver care to terminally ill beneficiaries who elect the hospice benefit. The Abt team reviewed the manuals and guidance to identify opportunities to align data collection with the hospice workflow.

Federal contractor guidance: Local Coverage Determinations (LCD)
Primary agency responsible: CMS and Medicare Administrative Contractors (MAC)
Year effective: Continually updated as needed.
Summary of major implications: The Social Security Act authorizes CMS to delegate authority to the MACs, which adjudicate Medicare claims. The MACs may develop LCDs to determine whether or not an item or service is covered. A few MACs have issued LCDs to provide guidance to hospices when determining whether a beneficiary is eligible for the Medicare hospice benefit. Several LCDs offer functional and clinical markers or guidelines as well as assessment tools that could be helpful in determining hospice eligibility. The assessment tools cited in the LCD are the Palliative Performance Scale (PPS), Karnofsky Performance Status (KPS), and the Functional Assessment Staging (FAST) for dementia patients. The Abt team considered the LCDs to understand functional and clinical factors as well as the types of assessments many hospices are likely using, to reduce data collection burden associated with a patient assessment tool.

Federal guidance: CMS Measures Management System Blueprint (v15.0)
Primary agency responsible: CMS
Year of version used: September 2019
Summary of major implications: The CMS Measures Management System Blueprint (hereafter referred to as the Blueprint) is a guide for quality measure developers that describes the measure life cycle and helps prepare for CMS and National Quality Forum (NQF) quality measure evaluation. The Abt team's decision making criteria for quality measures and business processes are informed by Blueprint requirements.

Federal guidance: CMS Meaningful Measures Framework
Primary agency responsible: CMS
Year of version used: September 2019
Summary of major implications: The CMS Meaningful Measures Framework identifies high priority areas for quality measurement and improvement and is intended to increase measure alignment across programs (including public and private initiatives). The Meaningful Measures Framework also serves as a guide in developing and implementing quality measures to fill potential gaps in high priority areas. We considered the priorities identified in the Meaningful Measures Framework in the development of the draft patient assessment instrument tool, so that it would support quality measures aligned with these priorities.

6. LITERATURE REVIEW

To complement review of related guidelines, regulations and legislation, the Abt team also reviewed existing scans of hospice and palliative care literature, including searching for updated references. This included review of seminal and foundational research, such as that described in Stewart et al.'s *Framework of Quality of Life of Dying Persons in the Context of Health Care*, which helped articulate how hospice care is conceptualized and informed future research and publication.[2]

In addition, the team conducted a high-level scan and gap analysis of extant tools and items that could be included or modified for use in the assessment. Gaps in extant items also helped identify where *de novo* item development would be required. Table 4, below, summarizes the evidence emerging from these activities. More information about the literature review and environmental scan methodology, along with detailed findings, is presented in this and the following sections.

Table 4: Summary of Evidence Basis by Recommended Domain

Domain	Regulatory/CPG Sources	Literature Sources
Actively Dying	Hospice COP CPG for Palliative Care (4th edition)	Hui et al., 2015[7]
Caregiver Well-Being	Hospice COP CAHPS Hospice CPG for Palliative Care (4th edition)	Fan et al., 2019[8] Reblin et al., 2019[9] Teno, 2009[10] Stewart, 1999[2]
Psychological Well-Being	Hospice COP CAHPS Hospice CPG for Palliative Care (4th edition)	Zimmermann et al., 2018[11] Wang et al., 2017[12] Martinez et al., 2017[13] Chen et al., 2017[14] Teno, 2009[10] Stewart, 1999[2]
Social Well-Being	Hospice COP CAHPS Hospice CPG for Palliative Care (4th edition)	Bradley et al., 2018[15] Teno, 2009[10] Stewart, 1999[2]
Physical Symptoms	Hospice COP CAHPS Hospice CPG for Palliative Care (4th edition)	Kassianos et al., 2018[16] Teno, 2009[10] Stewart, 1999[2]
Physical Function	Hospice COP CPG for Palliative Care (4th edition)	Putt et al., 2017[17] Stewart, 1999[2]
Prognosis and Performance Status	Hospice COP CPG for Palliative Care (4th edition)	Carpenter, 2017[18]
Spirituality	Hospice COP CAHPS Hospice CPG for Palliative Care (4th edition)	Guerrero-Torrelles, 2017[19] Catania et al., 2016[20] Teno, 2009[10] Stewart, 1999[2]
Shared Decision Making and Advanced Care Planning	Hospice COPs CAHPS Hospice CPG for Palliative Care (4th edition)	Cardona-Morrell et al., 2017[21] Austin et al., 2015[22] Teno, 2009[10] Stewart, 1999[2]

6.1. Methods

A key goal for the literature reviews was to validate the domains in the conceptual model and to codify their support to instrument and measure development. The Abt team conducted literature reviews for each domain of validated, reliable, and applicable measures, instruments, and/or tools currently used in a post-acute care (PAC) setting (see *Section VIII. Review of Existing Items, Instruments, Scales, and Tools*, below). We used the research questions in Table 5 to help guide the literature reviews on those domains.

For candidate domains with an evidence basis in the current Hospice Item Set (HIS), we did not conduct in-depth literature reviews. These domains included psychological well-being, social well-being, physical symptoms, and shared decision-making/advance care planning.

Table 5 below shows hospice domains selected for literature review and the research questions that guided these reviews.

Table 5: Research questions guiding literature reviews by domain

Domain	Research Questions Guiding Literature Review
Actively Dying	What are the signs and symptoms of actively dying? Is there a decision rule that would accurately identify persons who are actively dying?
Caregiver well-being	What existing tools assess family/caregiver emotional needs, burden, stress, and capacity to care for a patient? What are measureable processes or outcomes to indicate quality of hospice care specific to caregiver well-being?
Physical Function	What are existing instruments, tools, or scales for assessing the presence and impact of pain and dyspnea of patients in a hospice setting?
Prognosis and Performance Status	What is the validity, reliability, and predictive ability for mortality, and applicability of, performance status instruments, tools, or scales that might be appropriate for hospice? What performance scales are currently being used in hospice and palliative care?
Spirituality	What are available instruments, tools, or scales that measure care preferences for spiritual counseling in the hospice or palliative care setting?
Grief	Are there risk factors that correlate to complicated grief disorder? Which extant assessments predict complicated grief or screen effectively for grief?

CMS specifically requested that the patient assessment instrument take into account the requirements of the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014[23] (described above in *Section VI. Review of Legislation and Regulations)*, which seeks to increase harmonization of data elements among CMS-mandated assessments in the post-acute care settings of inpatient rehabilitation facilities (IRF), long-term care hospitals (LTCH), skilled nursing facilities (SNF), and home health (HH), and quality measures derived from those instruments, to the extent feasible and appropriate. In addition to the literature review, the Abt team compiled all existing data elements from the CMS-mandated assessments in post-acute care settings for comparison and applicability to a hospice assessment instrument by candidate domain (see *Section VIII. Review of Existing Items, Instruments, Scales, and Tools*, below). After a thorough review of existing data elements in post-acute care settings for harmonization, domains for assessing quality hospice care were further refined.

We employed various methods to review current literature, focusing on extant summaries. Our methods reflected differences in the topics and associated instruments, tools, and scales. All domains underwent a basic review for potential item abstraction from the Agency for Healthcare Research and Quality (AHRQ's) technical brief "Assessment Tools for Palliative Care".[24] This brief is a systematic literature review of validated tools for palliative care, which reviews tools for many hospice domains of care. For candidate domains undergoing in-depth review, the following methods were employed: grey and peer-reviewed literature review, updates to existing structured literature reviews, and snowball (convenience sampling) method literature reviews that identified resources of interest from key seed documents and then mined papers associated with these references.

6.2. Domain: Actively Dying

Online publication directories: PubMed	*Keywords:* predictors, prognostic model, variables, signs, symptoms, factors, predicting, imminently dying, terminal phase, death, dying, mortality , survival, active death, actively dying, imminent death, last week, last 2 days, last 3 days, last week, final week, final two days, final three days, 48 hours

Grey and peer-reviewed literature:

- Agency for Healthcare Research and Quality's "Assessment Tools for Palliative Care"[24]
- American Journal of Hospice and Palliative Medicine

6.2.1 Methods

This literature review/update was conducted to address the following research questions: What are the signs and symptoms of actively dying? Is there a decision rule that can be supported by accurately identifying persons who are actively dying? This literature review was an update of a Kehl et al.[25] systematic literature review focused on the published signs and symptoms of actively dying persons, with stricter parameters that focused more closely on the last week of life. Additionally, the review searched for published research that attempted to determine the prognostic significance of signs or symptoms with expected survival of one-week or less. See Appendices for a summary of methods for the original search and the updated search.

6.2.2 Results

The review identified 12,274 articles of with 81 articles were selected for review, yielding 34 papers reflected here. From these, we identified prevalent signs and symptoms of actively dying. Only one paper presented a two-item model that was based on observed signs or reported symptoms. This model had a diagnostic accuracy of 82%[3] and furthermore only examined persons with cancer. Eight other papers presented univariate associations or multivariate associations that included laboratory data, usually because the model was developed in an acute care hospital among persons with cancer. None of these studies were generalizable to a broad hospice population dying in various settings of care. However, a list of significant prevalent signs and symptoms was compiled and reviewed by the Abt team, and presented for review. We also recently updated this review and found information that supported this list of significant prevalent signs and symptoms.[7]

6.3. Domain: Caregiver Well-Being

Online publication directories: PsycINFO, Web of Science, Google Scholar	*Keywords:* caregiver, caregiving, emotional support, burden, stress, well-being

Grey and peer-reviewed literature:

- Family Caregiver Alliance (National Center on Caregiving) Selected caregiver assessment measures: A resource inventory for practitioners (2nd ed.). 2012.[26]
- Roach et al., Center for Gerontology and Health Care Research. 2000. TIME: Toolkit of instruments to measure end of life care.[27]
- National Coalition for Hospice and Palliative Care, National Consensus Project for Quality Palliative Care.[5]
- Agency for Healthcare Research and Quality's "Assessment Tools for Palliative Care."[24]
- Journal of Gerontological Social Work
- The Gerontologist
- Journal of Clinical Epidemiology

6.3.1 Methods

The Abt team conducted a review of existing assessments and surveys on caregiver well-being to answer the following guiding question: "What existing tools assess family/caregiver emotional needs, burden, stress, and capacity to care for a patient?" Methods included a snowball (convenience sampling) literature review, which first mined key seed documents and gray literature for resources, which were reviewed and mined for relevant information.

6.3.2 Results

We abstracted 87 questionnaires, tools, or screening instruments focused on family/caregiver emotional needs, burden, stress, and capacity to care for a sick patient. Questionnaires ranged from specific, short, and unidimensional tools (e.g., 3 items) to extensive, multifactor/multidimensional long questionnaires (e.g. 25+ items). Multiple facets of family/caregiver capacity were assessed in these questionnaires and surveys, including caregiver well-being, caregiver distress, stressful experiences, need for emotional and/or spiritual support, life changes and role changes attributed to caregiving obligations, positive experiences of caregiving, caregiving competence and mastery, coping skills, relationship strain with care recipient, and family conflict. We also recently updated this review and found information that supported the potential significance of this domain.[8, 9]

6.4. Domain: Physical Symptoms

Online publication directories: PubMed; Cochrane Library	*Keywords:* See Appendices: Keywords for update to systematic review of pain and dyspnea assessments)
Grey and peer-reviewed literature: • 2017 AHRQ technical brief "Assessment Tools for Palliative Care"[24]	

6.4.1 Methods

This review attempted to answer the question: "What are the existing tools and measures for assessing the presence and impact of pain and dyspnea of patients in a hospice setting?" This literature review was performed as a systematic update to the 2017 AHRQ technical brief "Assessment Tools for Palliative Care."[24] Therefore, the same search methods were utilized to identify systematic reviews characterizing different palliative care assessments and their properties. For the purposes of this project, an extra exclusion criterion was added at the review stage to only include reviews assessing tools related to pain and dyspnea assessment.

6.4.2 Results

Of the 70 PubMed results, 20 were selected for in-depth abstract review. Nine systematic review articles were retrieved. While many of the reviews noted a number of multi-dimensional assessments to be used during palliative care or at the end of life, many of which had pain- or dyspnea-specific items, there were no new pain- or dyspnea- specific assessment tools to be reported. No new items were identified to inform review of existing relevant measures and instrument and quality measures development. Guided by a 2018 systematic review by Ahluwalia and colleagues[28], we identified additional recent information that supports the importance of this domain.[16]

6.5. Domain: Prognosis and Performance Status

Online publication directories: PubMed, Google Scholar	*Keywords:* performance status, performance assessment, performance scale, hospice, prognosis, predictive mortality, validity, reliability, licensing, end of life, palliative
Grey and peer-reviewed literature: • National Palliative Care Research Center' Measurement and Evaluation Tools[29] • Agency for Healthcare Research and Quality's "Assessment Tools for Palliative Care"[24] • Journal of Oncology Practice • Clinical Journal of Oncology Nursing • Journal of Clinical Oncology • Journal of Pain Symptom Management • Journal of Palliative Medicine	

6.5.1 Methods

Literature review was conducted for the domain of Prognosis and Performance Status to answer the following question: “What is the validity, reliability, predictive ability for mortality, and applicability of performance status scales that might be appropriate for hospice?” First, performance-status tools listed in CMS’s related Pilot A tool development documentation were obtained and reviewed. Second, we reviewed recommended tools from the National Palliative Care Research Center.[30] Third, we performed a review of the literature to ensure that we were not missing key performance status tools used in hospice using keyword searches in PubMed and Google Scholar.

6.5.2 Results

All relevant tools and measures were gathered and reviewed for possible inclusion in the patient assessment instrument and associated measures; see the following *Review of Existing Items, Instruments, Scales, and Tools* section. Guided by a 2018 systematic review by Ahluwalia and colleagues,[28] we identified additional recent information that supports the importance of this domain.[18]

6.6. Domain: Spirituality

<table>
<tr><td><i>Online publication directories:</i>
PsycINFO, Web of Science, Google Scholar</td><td><i>Keywords:</i>
spirituality, spiritual, history, screening, assessment, needs, inventory, hospice</td></tr>
<tr><td colspan="2"><i>Grey and peer-reviewed literature:</i>
• Palliative Care Research Cooperative Group (PCRC) Instrument Library, version 2.0[31]
• Agency for Healthcare Research and Quality. Assessment Tools for Palliative Care. 2016[24]
• NCI Grid-Enabled Measures (GEM) Database[32]
• The National Palliative Care Research Center (NPCRC) – Measurement and evaluation tools database[29]
• Family Caregiver Alliance (National Center on Caregiving) et al., Selected caregiver assessment measures: A resource inventory for practitioners (2nd ed.). 2012.[26]
• Roach et al., Center for Gerontology and Health Care Research. 2000. TIME: Toolkit of instruments to measure end of life care.[27]</td></tr>
</table>

6.6.1 Methods

This literature review was conducted to answer the following question about the spirituality domain: “What are the available instruments that measure care preferences for spiritual counseling in the hospice or palliative care setting?” Methods included a snowball convenience sampling literature review that pulled sources from key seed documents mentioned above. Papers thereby retrieved were scanned and mined.

6.6.2 Results

Twenty-eight assessment tools were abstracted and considered for possible use in the patient assessment instrument.[33-60] Guided by a 2018 systematic review by Ahluwalia and colleagues,[28] we identified additional recent information that supports the importance of this domain.[19, 20]

6.7. Domain: Grief

Online publication directories: PsycINFO, Web of Science, Google Scholar	*Keywords:* Risk factors for complicated grief hospice, risk factors for complicated M palliative care, risk for complicated grief palliative care, risk for complicated grief hospice, bereavement assessment, complicated grief risk assessment, "complicated grief" risk assessment hospice
Grey and peer-reviewed literature: • Palliative Care Research Cooperative Group (PCRC) Instrument Library, version 2.0[31] • Agency for Healthcare Research and Quality. Assessment Tools for Palliative Care. 2016[24] • NCI Grid-Enabled Measures (GEM) Database[32] • The National Palliative Care Research Center (NPCRC) – Measurement and evaluation tools database[29] • Family Caregiver Alliance (National Center on Caregiving) Selected caregiver assessment measures: A resource inventory for practitioners (2nd ed.). 2012.[26] • Roach et al., Center for Gerontology and Health Care Research. 2000. TIME: Toolkit of instruments to measure end of life care.[27]	

6.7.1 Methods

This literature review was conducted to answer the following question about the spirituality domain: “What are the risk factors for complicated grief?” Methods included a snowball-strategy literature review that pulled sources from seed documents mentioned above. Papers thereby retrieved were scanned and mined.

6.7.2 Results

The Abt team identified 19 screening instruments, questionnaires, or tools used to assess risk of complicated grief prior to bereavement, which were presented for potential use in a patient assessment instrument. Guided by a 2018 systematic review by Ahluwalia and colleagues,[28] we identified additional recent information that supports the importance of this domain.[61]

7. REVIEW OF EXISTING ITEMS, INSTRUMENTS, SCALES, AND TOOLS

7.1. Methods

We used two concurrent steps to identify and review potentially relevant existing items, instruments, scales, and tools. First, to promote alignment with the IMPACT Act, potentially relevant standardized patient assessment data elements (SPADE) items were compiled from a number of sources. The following pre-existing standardized assessments were reviewed for candidate items in the CMS Data Element Library (DEL), the centralized resource for CMS assessment instrument data elements (questions and responses), and their associated health information technology (HIT) standards. Lastly, the team reviewed potentially relevant, existing quality measures and the items used to calculate them.[62]

Table 6: Post-Acute Care (PAC) and palliative care assessment instrument sources

Setting	Name
Home Health	Outcome and Assessment Information Set (OASIS)
Skilled Nursing Facility (SNF)	Minimum Data Set (MDS)
Inpatient Rehab Facility (IRF)	Patient assessment instruments (PAIs) for inpatient rehab facilities (IRF-PAI)
Long-Term Care Hospital (LTCH)	Continuity Assessment Record and Evaluation (CARE) Data Set
Hospice Care	Hospice Item Set (HIS)
Hospice Survey	Hospice Consumer Assessment of Healthcare Providers and Systems CAHPS® Survey

Our review considered the following: 1) the applicability and feasibility of the current candidate items for hospice and 2) any additional candidate items for hospice not identified in step one. This involved meeting with subject matter experts and/or consulting the published literature. Our methods and research questions driving literature reviews are outlined in *Section VII. Literature Review*. All domains were reviewed for potentially relevant measure items in the Agency for Healthcare Research and Quality's (AHRQ) extensive 2017 systematic literature review on assessment tools for palliative care,[24] which provides an exhaustive list of the highest quality validated measure items for all domains of palliative care. Table 7 shows, for each domain, the source of candidate assessment items: abstracted from literature review and/or derived from existing instruments, scales, and tools.

Table 7: Candidate assessment item sources

Domain	Measure Items Derived from PAC tools/SPADE	Measure Items Abstracted from Literature Reviews
Actively Dying	X	X
Caregiver Well-Being	X	X
Psychological Well-Being	X	
Social Well-Being	X	
Physical Symptoms	X	X
Physical Function (ADLs, skin integrity, falls, and nutrition)	X	
Prognosis and Performance Status	X	X
Spirituality	X	X
Grief	X	X
Shared Decision Making and Advance Care Planning	X	

After compiling potentially relevant assessment items, they were streamlined for inclusion in in-depth review based on a number of exclusion and inclusion criteria:

Inclusion criteria:

1. Staff-administered item, instrument, scale, or tool
2. Item, instrument, scale, or tool was tested and validated in a palliative care or hospice setting

Exclusion criteria:

1. Instruments, scales, or tools greater than 6 items
2. Survey tools.

Items remaining after applying inclusion and exclusion criteria underwent a review of psychometric properties, including validity, and reliability. For this review, the team referenced AHRQ's Assessment Tools for Palliative Care[24] (widely cited as the most comprehensive toolkit on palliative care) and Brown University's Toolkit of Instruments to Measure End-of-Life Care.[27] The most promising items, instruments, scales, or tools were then summarized in memos for CMS review and consideration. In some cases, promising items were those drawn from foundational research that has been cited and updated in more recent years. Regardless, we have included citations that show original descriptions of the specific item, instrument, scale or tool. These memos were also used to guide the instrument-development and quality-measures development efforts, which helped inform a measures gap analysis. Results of assessment (and related quality measures) items review are summarized by domain below.

7.2. Results

7.2.1 Actively Dying

Following our update to a systematic review of the signs and symptoms of actively dying, hospice clinicians on the team reviewed all consistently reported signs and symptoms (described in *Appendix 1)* and created a list of these factors for focus group feedback and consideration for cognitive testing. While the list of factors does not represent an outcome, a process, or a quality measure, the goal of the list is to provide hospice clinicians signs and symptoms that could assistant in identifying a patient who is actively dying. This information could be further used to develop assessment skip patterns for patients who are actively dying.

Table 8: Assessment items reviewed: caregiver well-being

Tool	Source	# Items	Item Responses	Reliability	Validity	Description
Social Conflict	Goodman, 1991 (abstract only)[63]	3	5-point scale, responses range from: "never" to "nearly always"	0.72	NA	Measures negative aspects of supportive relationships with three items: "The stresses of caregiving have caused quarrels with people I love," "I've been in conflict with others I know about how to manage the problems of [disease]," "People don't approve of some things I've done to care for my relative with [disease]."

Tool	Source	# Items	Item Responses	Reliability	Validity	Description
Role Overload (from Caregivers' Stress Scales)	Pearlin et al., 1990[64]; Zarit & Whitlatch, 1992[65]; Aneshensel et al., 1995 (abstract only)[66]	3	4-point scale: responses range from: "not at all" to "completely"	0.78	Construct	3 items from the original 4-item scale are used to measure feelings of exhaustion and fatigue related to caregiving responsibilities. Includes the following items: "How much does each statement describe you?: you are exhausted when you go to bed at night, you have more things to do than you can handle, [and] you don't have time just for yourself?"
Role Captivity (from Caregivers' Stress Scales	Pearlin et al., 1990[64]; Zarit & Whitlatch, 1992[65]; Aneshensel et al., 1995 (abstract only)[66]	3	4-point scale, responses range from: "not at all" to "very much"	0.83	Construct	Measures feelings of being "trapped" in the caregiving role. Items ask caregivers how well these statements describe their feelings and thoughts about being a caregiver: "wish you were free to lead a life of your own, feel trapped by your (relative's) illness, [and] wish you could just run away."
Negative Consequences of Caregiving	Bass & Bowman, 1990[67]; Bass et al., 1991[68]	3	2-point scale: yes or no	0.66	NA	Measures individual consequences of caregiving with the following items: "Because of my relative's impairments and care, I have difficulty with: too many demands being made of me; getting enough rest; my physical or emotional health changing for the worse".
Appraised difficulty of caregiving	Bass & Bowman, 1990[67]; Bass et al., 1991[68]	3	4-point scale, responses range from: "strongly disagree" to "strongly agree"	0.67	NA	Measures the degree to which caregiving is perceived as threatening to the family's well-being with items like, "Caring for my impaired relative is the most difficult problem I have ever faced" and "It is easy to feel overwhelmed in a situation like this".
Zarit Burden Interview (short form)	Higginson et al 2010[69]	1	5-point scale, responses range from "never" to "nearly always:	NA	rho 0.63-0.78	Gold standard is the ZBI-22. Screens for the level of subjective burden among carers with a single item which asks: "Overall, how burdened do you feel in caring for your relative?"
Preparedness for Caregiving Scale	Archbold et al, 1990[70], 1992[71]	5	4-pont scale, responses range from: "not at all prepared" to "very well prepared	0.71	NA	Measures the degree to which caregivers feel prepared to manage the caregiving situation, including physical and emotional needs, services and caregiver stress. Gold standard was 6 week predictors and 9 month outcomes.

7.2.2 Physical Symptoms, Psychological Well-Being, and Social Well-Being

We performed a literature review to abstract items to assess physical symptoms, psychological well-being, and social well-being, as well as reviewed pre-existing, validated post-acute care assessments. We ultimate identified the items in Table 9 from pre-existing validated post-acute assessments. While hospice care differs from other post-acute care settings, there is a need to align where possible with this setting to promote interoperability of information to support care transitions and the continuum of care.

Table 9: Assessment items reviewed: physical Symptoms, psychological well-being, and social well-being

Item Name	Brief Description	Data Source
D0150. Patient Mood Interview (PHQ-2)	Screening for symptoms of depression.	SPADE (Standardized Patient Assessment Data Elements)
J0930. Preferences for pain, dyspnea and anxiety	Assesses whether the patient was asked about their preferences for pain management.	CMS Pilot A
M1100 Living Situation	Assesses patient's residential circumstance and availability of assistance.	OASIS (Outcome and Assessment Information Set)
M2102 Types and sources of assistance	Assesses ability and willingness of non-agency caregivers (such as family members, friends, or privately paid caregivers) to provide assistance for the following activities, if assistance is needed.	OASIS
AA0300. Caregiver issues, actual and/or potential risks	Assesses physical, psychological, social issues.	CMS Pilot A
AA0400. Patient or caregiver needs	Assesses physical, psychological and communication needs.	CMS Pilot A
XXXX. General Symptoms – Symptom Severity	Assesses physical, psychological symptoms.	IPOS (Integrated Palliative Outcome Scale)
J0900 Pain Screening	Multi-part item screening for and assessing pain.	HIS (Hospice Item Set)
J0905 Pain Active Problems	Assesses whether or not pain is an active problem for the patient.	HIS
J0910 Comprehensive Pain Assessment	Assesses whether or not a comprehensive pain assessment was done.	HIS
J2030 Screening for Shortness of breath	Assesses whether or not the patient was screened for shortness of breath.	HIS
J2040. Treatment for Shortness of Breath	Assesses whether or not treatment for shortness of breath was indicated.	HIS
M1400. Respiratory	Assesses if the patient dyspneic or noticeably Short of Breath.	OASIS
Observed Dyspnea Scale	Proposed by subject matter expert	External
II0200. Signs of Imminent Death at Admission	Checklist of physical signs of imminent death including: minimally responsive; Cheyne-Stokes respirations; mottled skin; low blood pressure; dark urine; decreased urine output; increased respiratory congestion; and increased agitation.	CMS Pilot A

7.2.3 Physical Function

We performed a literature review to abstract items that assess physical function, in addition to reviewing pre-existing, validated post-acute care assessments. We drew candidate items from these assessments for further consideration. These are shown in Table 10.

Table 10: Assessment Items Reviewed: Physical Function

Item Name	Brief Description	Data Source
GG0130 Self-care	Assesses patient's ability to perform activities including toileting and dressing	SPADE
GG0170 Mobility	Assesses patient's ability to perform activities including bed mobility, transfers and ambulation	SPADE

7.2.4 Prognosis and Performance Status

The team reviewed relevant items, instruments, scales, and tools to identify candidates for this domain. Table 11 below presents primary findings. Tools included for final review are the Eastern Cooperative Oncology Group (ECOG) performance status scale, the Karnofsky Performance Scale (KPS) tool, the Palliative Performance Scale Version 2 (PPSv2), and the Palliative Performance Index (PPI). In the table, a brief description of each tool is included, with cited reports of validity and reliability, ability to predict mortality, and licensing, which includes whether or not the tool is in the public domain and, if not, requirements for use or modification.

Table 11: Assessment Items Reviewed: Performance Status

Scale	Brief Description	Validity & Reliability	Predictive mortality	Licensing
ECOG (ECOG) Performance Score	6 item scale. A tool for doctors and researchers to assess how a patient's disease is progressing, how the disease affects the daily living abilities of the patient, and how to determine appropriate treatment and prognosis.	• Interrater reliability (weighted kappa) for 457 oncology patients was 0.67 [72] • Physician/nurse agreement was 71% (k=0.0486, P<0.001); nurse scoring had stronger tablORs for 6 month mortality (n-311 cancer pts receiving chemo)[73]	• In a lung cancer population, ECOG accurately predict prognosis HR 2.12 (p=0.27) (N=63)[74] • Significant trend for in-hospital mortality and ECOG grade increase (<0.001) (n=3,868 critically ill patients)[29] • Trend of increasing AOR for in-hospital mortality and ECOG grade: grade 1 of PS 1.4 (95% CI, 1.0-1.8), grade 2 of PS 2.0 (95% CIs, 1.5-2.7), grade 3 of PS 2.9 (95% CIs, 2.1-4.1), and grade 4 of PS 2.5 (95% CIs, 1.6-3.9) (n=3,868 critically ill patients)[29] • 30-day mortality study; mortality significantly increased with ECOG score (p<0.001); multivariable analysis, ECOG ≥3 was strongly associated with 30-day mortality (AOR: 5.70; 95% CI: 3.82-8.50) (n=1526 pts hospitalized with pneumonia) [75] • In log rank test for trend, ECOG delineated survival well (p<0.001) with a c statistic of 0.64 (n=1653 oncology patients receiving palliative care)[76] • Log-rank test of survival relationship between ECOG and time to death significant p=0.00000 (n=536 lung cancer patients)[77]	Public domain
Karnofsky Performance Scale (KPS)	Commonly used for assessing terminally ill patients, often used to determine appropriateness of hospice referral.	• Inter-rater agreement was 0.74 for 457 oncology patients was 0.67 [72] • Inter-rater reliability = 0.97 among 47 NHS interviewers. Construct validity of the KPS strongly related (p<0.001) to two other independent measures of patient functioning. Relationship to longevity (r = 0.30) in a population of terminal cancer patients documents its predictive validity. [78] • “Acceptable reliability and validity have been established in research and clinical practice, especially when standardized	• “Because it correlates closely with levels of symptom distress, the KPS often is used as a proxy measure for a global evaluation of a patient’s status and most appropriately as a prognostication tool to predict life expectancy” [79] • In log rank test for trend, KPS delineated survival well (p<0.001) with a c statistic of 0.63 (n=1633 oncology patients receiving palliative care) [76] • Log-rank test of survival relationship between KPS and time to death significant p=0.00000 (n=536 lung cancer patients)[77]	Public domain

Scale	Brief Description	Validity & Reliability	Predictive mortality	Licensing
		scoring guidelines are used and opportunities to interview patients are possible”[79] - Interrater reliability correlation 0.89, construct validity significant in all 18 variables (n=293 cancer pts) [80]		
Palliative Performance Scale Version 2 (PPSv2)	Measures the functional status of a patient and assigns a Palliative Performance Value; serves as a communication tool for quickly describing a patient's current functional level.	- Inter-rater agreement was 0.74 for 457 oncology patients was 0.67[72] - 2 groups with intraclass correlation coefficients for absolute agreement of 0.959 and 0.964 for group 1 at times 1 and 2, 0.951 and 0.931 for group 2 at times 1 and 2, respectively. Additionally, validity was established based on content validation through interviews of palliative care experts [81]	- In Cox proportional hazards model, including age, gender, location, diagnosis category, and initial PPS as covariates, HRs for PPS >10% were all lower and statistically significant. [82] - “Six-month mortality rates for 3 PPS categories were 96% (for PPS scores 10–20), 89% (for PPS scores 30–40), and 81% (for PPS scores ≥ 50). Evaluation of interaction terms in Cox proportional hazards models demonstrated a stronger association between PPS score and mortality among nursing home residents and patients with non-cancer diagnoses. Analysis of the area under receiver operating characteristic curves demonstrated strong predictive value overall, with somewhat greater accuracy for nursing home residents and patients with noncancer diagnoses.”[83] - “Lower PPSv2 scores on admission to hospice were associated with decreased median (interquartile range, IQR) survival time [PPSv2 10 = 2 IQR: 1–5 days; PPSv2 20 = 3 IQR: 2–8 days] IQR: 55–207. The discrimination of the PPSv2 at baseline for predicting death was highest at 7 days [area under the curve (AUC) = 0.802], followed by an AUC of 0.774 at 14 days, an AUC of 0.736 at 30 days, and an AUC of 0.705 at 90 days.” (patients in hospice with heart failure) [84] - PPS at every category was significant associated with risk ratio for death (<0.0001) among n=396 pts admitted to home hospice program [85] - In log rank test for trend, PPS delineated	PPSv2 is free but requires letter of agreement.

Scale	Brief Description	Validity & Reliability	Predictive mortality	Licensing
			survival well ($p<0.001$) with a c statistic of 0.63 (n=1631 oncology patients receiving palliative care) [76] - PPS provided distinct survival groups for patients in three palliative care settings, with log rank ($p<0.001$) and c statistics of >0.75 (n=2361 palliative care pts)[86]	
Palliative Prognostic Index (PPI)	The Palliative Prognostic Index (PPI) utilizes the PPS, oral intake, edema, dyspnea at rest, and delirium to provide snapshot of patients' current state of functioning.	- "The Palliative Prognostic Index (PPI) utilizes the PPS, oral intake, edema, dyspnea at rest, and delirium to predict 3-week and 6-week survival."[76]	- "In the testing sample (233 assessments on 95 patients) the predictive values of this scoring system were examined. In the testing set, patients were classified into three groups: group A (PPI< or =2.0), group B (2.0<PPI< or =4.0), and group C (PPI>4.0). Group B survived significantly longer than group C, and group A survived significantly longer than either of the others. Also, when a PPI of more than 6 was adopted as a cut-off point, 3 weeks' survival was predicted with a sensitivity of 80% and a specificity of 85%."[87] - PPI provided distinct survival groups for patients in three palliative care settings, with log rank ($p<0.001$) and c statistics of >0.75 (n=2361 palliative care pts) [86]	*Unknown at this time, contacting developer*

7.2.5 Spirituality

To identify candidate items in this domain, we abstracted items from the literature, in addition to reviewing pre-existing, validated post-acute care assessments.

Table 12: Assessment items reviewed: spirituality

Item Name	Brief Description	Data Source
F3000 Spiritual/Existential concerns	Assesses whether the patient has been asked if they have any spiritual or existential concerns.	HIS
XXX. Do you think s/he has felt at peace?	Assesses whether the patient feels at peace. Response categories based on 6 point scale ranging from "not at all" to "sometimes" to "cannot access".	IPOS
XXX. How much of a concern is the patient's sense of making progress on personal goals?	Assesses whether there should be concern about patient's perception of making progress on personal goals. The item is based on 7 point range of response categories ranging from "no, not at all" to "yes, patient seems preoccupied with worry" to "patient unwilling to discuss at the time".	InterRAI PC-H (Palliative Care Hospice), Section I, with POS response categories
XXX. How much of a concern is the patient's finding guidance in their religion or spirituality?	Assesses whether there should be concern about the patient finding guidance in their religion or spirituality. The item is based on 7 point range of response categories ranging from "no, not at all" to "yes, patient seems preoccupied with worry" to "patient unwilling to discuss at the time".	InterRAI PC-H, Section I, with POS response categories
XXX. How much of a concern is the patient's struggling with finding meaning of life?	Assesses whether there should be concern about the patient struggling with meaning of life issues. The item is based on 7 point range of response categories ranging from "no, not at all" to "yes, patient seems preoccupied with worry" to "patient unwilling to discuss at the time".	InterRAI PC-H, Section I, with POS response categories
XXX. How much of a concern is the patient's being at peace with their life?	Assesses whether there should be concern about the patient struggling with being at peace with their life. The item is based on 7 point range of response categories ranging from "no, not at all" to "yes, patient seems preoccupied with worry" to "patient unwilling to discuss at the time".	InterRAI PC-H, Section I, with POS response categories

7.2.6 Grief

After applying our inclusion and exclusion criteria to items abstracted from the literature, we identified four scales and indices for further review. These are presented in Table 13. As with the caregiver domain, we have included the seminal references that describe these indices and scales that have informed subsequent research. Our review considered length, validity, reliability, and applicability to hospice. None were ultimately selected for inclusion in the patient assessment instrument after team review and additional subject matter expert/clinician input. The Bereavement Risk Index (BRI) and the Pre-Death Grief Scale (PG-12) are both well validated and considered reliable.

Table 13: Assessment items reviewed: scales and indices targeting assessment of grief in family/caregivers

Item, instrument, scale, or tool	Description	Validity	Citation
Bereavement Risk Index – BRI	Multidimensional/Multifactor; Short; Can be used before or at time of death . 8 risk factors assessed: Children <14 years old at home; Occupation of principal wage earner; Anticipated employment of bereaved person; Clinging or pining; Anger; Self-reproach; Current relationships with family/others; Estimate of how survivor will cope	Content and predictive validity. Convergent and discriminant validity not reported.	Parkes CM (1993) Bereavement. In: Doyle D, Hanks GCW, MacDonald N, eds. Oxford Textbook of Palliative Medicine. Oxford University Press, Oxford: 663–78[88]
Modified Bereavement Risk Index	Specific; short. Helps providers tailor services to identified needs based on combination of self-assessment and professional assessment information. Qualitative and quantitative approaches blended. From larger BRI, keeps "Clinging or pining"; "Anger"; "Self-reproach"; and "How will key person cope?" items only. Used as a screening tool.	Validated; more consistent than original tool. Chronbach alpha of 0.80 for internal validity, and significantly predicted higher grief scores at 3 months post loss.	Kristjanson, L. J., Cousins, K., Smith, J., & Lewin, G. (2005). Evaluation of the Bereavement Risk Index (BRI): a community hospice care protocol. International Journal of Palliative Nursing, 11(12), 610-618.[89]
Pre-Death Grief Scale, derived from Prolonged Grief–12	Specific; short. From the PG-12, used a 10 item pre-death grief scale, "related to yearning, bitterness, interpersonal disengagement, and a sense of meaninglessness" E.g., "You feel yourself longing and yearning for the[resident] as she or he used to be before becoming ill"	Validity not tested; items were significantly associated with predeath grief	Kiely, D. K., Prigerson, H., & Mitchell, S. L. (2008). Health care proxy grief symptoms before the death of nursing home residents with advanced dementia. The American Journal of Geriatric Psychiatry, 16(8), 664-673.[90]
Pre-Death Grief Scale PG-12, caregiver version	Pre-loss, 12 question survey given to caregiver. Evaluation separation distress, cognitive emotional and behavioral symptoms, and evaluates proper event and impairment criterion.	The PG–12 has been shown to be reliable, to have high internal consistency (a=0.846), to be monofactorial in structure, and to be independent TLI= 0.822, CFI= 0.919, RMSEA=0.77, pCFI= 0.674 from depression, anxiety, and burden, although predeath grief influences these symptoms.	Coelho, A., Silva, C., & Barbosa, A. (2017). Portuguese validation of the Prolonged Grief Disorder Questionnaire–Predeath (PG–12): Psychometric properties and correlates. Palliative and Supportive Care, 15(5), 544–553. https://doi.org/10.1017/s1478951516001000. [91]

Item, instrument, scale, or tool	Description	Validity	Citation
BRISQ (Roberts 2017)	Brief, clinical, self -report bereavement risk screening tool. Checklist format, with yes/no response format. Only published research is on item generation and expert panel feedback. No testing yet	No published validation;	Roberts K, Holland J, Prigerson HG, et al. Development of the Bereavement Risk Inventory and Screening Questionnaire (BRISQ): Item generation and expert panel feedback. Palliative and Supportive Care. 2017;15(1):57-66. doi:10.1017/s1478951516000626.[93]

7.2.7 Shared Decision Making and Advance Care Planning

We conducted a literature review to abstract items that assess shared decision making and advanced care planning, as well as reviewed the pre-existing, validated post-acute and palliative care assessments shown in Table 14. The current HIS yielded the most candidates; we also found one additional item indicating patient preferences.

Table 14: Assessment items reviewed: shared decision making and advance care planning

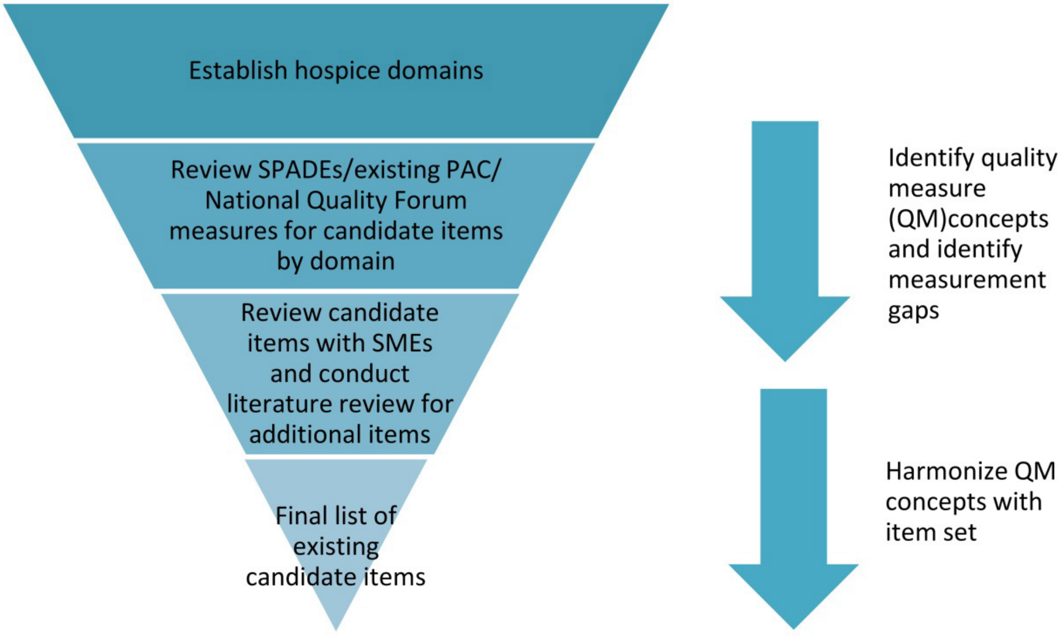
Item Name	Brief Description	Data Source
F2000. CPR preference	Assesses whether the patient/responsible party asked about preference regarding the use of cardiopulmonary resuscitation (CPR).	HIS
F2100. Other life-sustaining treatment preferences	Assesses whether the patient/responsible party asked about preferences regarding life-sustaining treatments other than CPR.	HIS
F2200. Hospitalization preference	Assesses whether the patient/responsible party asked about preference regarding hospitalization.	HIS
J0930. Preferences for maintaining alertness while dying	Assesses patient's sedation preferences and their alertness preferences while dying.	CMS Pilot A, IPOS

8. RESULTS SUMMARY AND RECOMMENDATIONS

High-quality hospice care honors patient, family, and caregiver needs by addressing physical, psychosocial, emotional, and spiritual well-being throughout the dying experience, which includes palliative care teams and hospice services. It follows that measuring high-quality hospice care must be based on the principles of addressing physical, psychosocial, emotional, and spiritual well-being for patients, their families and caregivers.

We convened a hospice quality measurement subgroup team to review gaps in current measures, including results from the existing measures review and consultation with CMS and other subject matter experts. The results of the gap analysis are informing the ongoing work to define constructs for development and the items needed to support them. Our research for the development of a patient assessment instrument to date has provided a foundation for the drafting of hospice measure concepts and draft quality measures that will be presented and discussed at the Technical Expert Panel (TEP) in November 2019.

Figure 3: Multi-step approach to reviewing existing measure constructs and concurrent quality measure development efforts



The patient assessment instrument—the Hospice Outcomes & Patient Evaluation (HOPE) tool—will have 3 primary uses: 1) development or refinement of quality measures, including potential risk adjustment; 2) care planning; and/or 3) refining the payment model, as appropriate. The initial use will be to support the collection of data for quality measures, namely outcome measures and process of care measures, and potential risk adjustment.

A key theme that has emerged in the design of the data collection instrument to support the initial quality measures concepts is that some areas or processes of care (e.g., bereaved family members) require particular types of data collection (e.g., in-person post-bereavement survey), while other domains or processes of care may be best captured through a patient assessment instrument. Still other quality constructs can be derived from administrative claims data on hospice utilization and provider and beneficiary characteristics. To measure overall quality of hospice care, the Hospice Quality Reporting Program (HQRP) can leverage three complementary sources of information to provide a comprehensive picture: 1) claims-based measurement; 2) patient assessment instrument data; and 3) post-bereavement interviews or surveys with hospice primary caregiver/s.

Based on the information-gathering activities described in this report, we recommend the following domains for CMS and TEP review for inclusion in the patient assessment instrument:

- Actively Dying
- Caregiver Well-Being
- Psychological Well-Being
- Social Well-Being
- Physical Symptoms
- Physical Function
- Prognosis and Performance Status
- Spirituality
- Shared Decision-Making and Advance Care Planning

The information-gathering activities conducted for this project thus far lend strong support to the inclusion of these domains in assessment and quality measurement. In order to expand the evidence base for a patient assessment instrument, we are pursuing additional information-gathering activities. These include recently completed focus groups with hospice personnel (summarized in the Focus Group Addendum to the present report) and cognitive testing to provide input on the candidate items. These ongoing information-gathering activities will also help identify any required modifications for alpha testing of the draft patient assessment instrument.

APPENDICES

Appendix I: Evidence table--actively dying (update to Kehl et al.)

This appendix presents an update to the information included in Kehl et al. for the “Actively Dying” domain, including those studies that are considered key or foundational in the field.

Paper/Citation	Design, data source, and symptom collection	Setting and sample	Diagnoses included	Time frame to death	Symptom and reported prevalence	Symptom and significance
CANCER ONLY STUDIES						
De La Cruz 2015[94]	Retrospective, secondary analysis of data from RCT	US; single center N=78 patients on home hospice who had symptoms assessed at least once during last week of life	• Cancer	1 week	Prevalence of moderate to severe ESAS*ratings of the following: • Appetite 92% • Fatigue 82% • Drowsiness 77% • Well-being 76% • Pain 51% • Shortness of breath 49% • Anxiety 42% • Depression 40% • Nausea 30% • Myoclonus39% • Hallucinations 28% *Edmonton Symptom Assessment Scale	
Ellershaw 2001[95]	Prospective cohort, data collection	UK; single inpatient hospice N=168 inpatients who died over one year period	• Cancer, lung and breast	2 days	• Respiratory tract secretions 13.1% • Pain 9.4% • Agitation 8.1%	
Hui 2014 “Clinical Signs of Impending Death in Cancer Patients”[96]	Prospective cohort	US; acute palliative care unit. Brazil; acute palliative care unit. N=203 patients who died in the units	• Cancer	3 days	• PPS *<20%, 93% • RASS** -2 or lower, 90% • Dysphagia of liquids, 90% • Urine output over last 12 hours <100mL, 72% • Death rattle, 66%	Positive likelihood ratios of 7 signs with high specificity (>95%), low sensitivity (<60%). LRs and Cis • Pulselessness of radial artery 15.6 (13.7-17.4)

Paper/Citation	Design, data source, and symptom collection	Setting and sample	Diagnoses included	Time frame to death	Symptom and reported prevalence	Symptom and significance
		with cancer (52 in US and 151 in Brazil)			• Apnea periods, 46% • Respiration with mandibular movement 56% • Peripheral cyanosis, 59% • Cheyne-Stokes breathing, 41% • Pulselessness of radial artery, 28% *Palliative Performance Scale **Richmond Agitation Sedation Scale	• Decreased urine output 15.2 (13.4-17.1) • Cheyne-Stokes breathing 12.4 (10.8-13.9) • Respiration with mandibular movement 10 (9.1-10.9) • Death rattle 9 (8.1-9.8) • Apnea periods 4.5 (3.7-5.2) • Peripheral cyanosis 5.7 (5.4-6.1)
Hui 2015 "Bedside clinical signs…"[97]	Prospective cohort	US; acute palliative care unit. Brazil; acute palliative care unit. N=357 enrolled, 203 patients who died in the units with cancer (52 in US and 151 in Brazil)	• Cancer	3 days	The study lists prevalence of 52 signs in the last three days of life. For reference, we only include those with highest LRs here: • Non-reactive pupils, 38% • Decreased response to verbal stimuli, 69% • Decreased repose to visual stimuli 70% • Inability to close eyelids 57% • Dropping of nasolabial fold 78% • Hyperextension of neck 46% • Grunting of vocal cords 54% • Upper GI bleed 5%	Positive likelihood ratios of symptoms to death within 3 days, (95% CI) • Non-reactive pupils, 16.7 (14.9-18.6) • Decreased response to verbal stimuli 8.3 (7.7-9) • Decreased repose to visual stimuli 6.7 (6.3-7.1) • Inability to close eyelids 13.6 (11.7-15.5) • Dropping of nasolabial fold 8.3 (7.7-8.9) • Hyperextension of neck 7.3 (6.7-8) • Grunting of vocal cords 11.8 (10.3-13.4) • Upper GI bleed 10.3 (9.5-11.1) ** only reported the high specificity symptoms

Paper/Citation	Design, data source, and symptom collection	Setting and sample	Diagnoses included	Time frame to death	Symptom and reported prevalence	Symptom and significance
Hui 2015[7]	Prospective cohort	US; acute palliative care unit. Brazil; acute palliative care unit. N=357 enrolled, 203 patients who died in the units with cancer (52 in US and 151 in Brazil)	• Cancer	7 days		Variables that significantly increased in intensity closer to death • ESAS anorexia (p=0.001) • Drowsiness (P<0.0001) • Fatigue (P<0.0001) • Poor well-being (p=0.01) • Dyspnea (p<0.0001) Variables that significant decreased in intensity closer to death • ESAS Depression • Variables that significant increased in proportion of patients closer to death • Dysphagia to solids (p=0.01) and liquids (p=0.005) • Urinary incontinence (p=0.0002)
Hui 2015[98]	Prospective cohort	US; acute palliative care unit. Brazil; acute palliative care unit. N=322 patients who died in the units with cancer (52 US/ 151 Brazil)	• Cancer	3 days		Used two items to develop & validate 3 day mortality model with four terminal leaves: • Palliative performance scale • Drooping of nasolabial scale Diagnostic accuracy was 82%
Hwang 2013[99]	Prospective observational with chart audit	South Korea, palliative care unit N=181 patients who died in the PCU with terminal	• Cancer	2 days	Symptoms developed within 48 hours of death • Pain, 23.8% • Dyspnea at rest, 21.0% • General weakness, 11.6% • Anxious or depressed mood,	Significant association between developed events and death within 48 hrs: unadjusted Odds ratio, P-value/adjusted OR Pvalue

Paper/Citation	Design, data source, and symptom collection	Setting and sample	Diagnoses included	Time frame to death	Symptom and reported prevalence	Symptom and significance
		cancer			6.1% • Nausea/vomiting, 5.5% • Poor appetite, 5.05% • Abdominal discomfort, 6.1% • Confused, 33.1% • Increased sleeping, 20.4% Signs developed within 48 hours of death • Decreased blood pressure, 90.1% • Increased pulse rate, 76.2% • Decreased urine output, 40.3% • Low oxygen saturation, 73.5% • Death rattle, 45.9% • Conscious level, 75.7% • Fever, 61.9% • Edema, 7.2%	Symptoms • Confused 0.97, 0.03/0.97, 0.03 • Signs • Decreased blood pressure 0.97, 0.01/0.96, 0.01 • Increased pulse rate 0.97, <0.01/ 0.97, 0.01 • Low oxygen saturation 0.97, 0.02/ 0.96, 0.01 • Death rattle 0.96, 0.02/ 0.96, 0.03 • Conscious level 0.95, <0.01 0.94, <0.01
Kao 2009[100]	Prospective observational cohort	Taiwan; single inpatient unit N=459 elderly patients	• Cancer	1 week		Symptoms significant to predicting death within 1 week in univariate analysis Odds ratio, p-value • Cognitive impairment 1.68, p<0.001 • ECOG 2.24 p<0.001 • Muscle power 0.57 <0.001 • Ascites 1.47 p<0.001 • Fever days 1.39 p=0.02 • Systolic BP 0.98 p=0.01 • Heart rate 1.02 p=0.002

Paper/Citation	Design, data source, and symptom collection	Setting and sample	Diagnoses included	Time frame to death	Symptom and reported prevalence	Symptom and significance
Matsunami 2018[101]	Prospective observational study	Japan; single respiratory medicine card in a hospital N=70 patients >74 diagnosed with cancer with impending death	• Cancer	1-56 hours	• Respiration with mandibular movement (78%)	
Mercandente 2009[102]	Prospective cohort	Italy; acute pain relief and palliative care unit within a cancer center N=77 patients who have terminal cancer	• Cancer	4 days-0 hours	Symptoms at 12hrs/ 24 hrs/48 hours before death • Inability to swallow 32.5/22.1/10.4 • Inability to cough 32.5/22.1/10.4 • Death Rattle 14.3/10.4/5.2 • Hydration given 33.8/20.8/9.1 • Oral nutrition given 2.6/0/0 • Pharyngeal aspiration 3.9/1.3/0	
Morita 2003[103]	Retrospective cohort	Japan; single inpatient palliative care unit N=284 patients with stay of at least 7 days or more	• Cancer	5 days, 3 days, 1 day	% of patients & communication abilities 5/3/1 days before death • Complex communication 43/28/13 • Clear simple communication 30/20/24 • Slightly incoherent 18/25/27 • Obviously incoherent 9.5/17/36	
Conill 1997 (k)[104]	Prospective observational	Spain; multicenter including hospital, home care, and hospice N=176 patients at end of life who died in one of the settings listed	• Cancer	1 week	• Anorexia 80.1% • Dry mouth 69.9% • Confusional status 68.2% • Constipation 55.1% • Dyspnea 46.6% • Dysphagia 46.0% • Anxiety 45.5% • Depression 38.6% • Paralysis 32.4%	

Paper/Citation	Design, data source, and symptom collection	Setting and sample	Diagnoses included	Time frame to death	Symptom and reported prevalence	Symptom and significance
					• Pain 30.1% • Sleep disturbances 28.4% • Cough 17.6% • Nausea 13.1% • Hemorrhage 11.9% • Vomiting 10.2% • Asthenia 8.18 • Diarrhea 6.8% • Dysuria 6.8%	
Morita 2000 (k)[105]	Prospective exploratory study	Japan; single palliative care unit with inpatient hospice N=245 hospice inpatients	• Cancer	24 hours	• Respiratory secretions 72.4%	
Mercandente 2016[106]	Retrospective cohort	Italy; home based palliative care N=412 patients ranging from less than 65 to older than 85	• Cancer as primary • Multiple comorbidities including CVD, CPD, kidney disease, liver disease	One week	% patients presented with ESAS symptom intensity greater than 4: • Pain 23.1% • Nausea 6.8% • Asthenia 99.0% • Anxiety 56.2% • Depression 85.4% • Anorexia 94.2% • Dyspnea 17.8% • Drowsiness 70.8% • Well-being 97.8%	
Bruera 2014[107]	Prospective, longitudinal, observational study	USA; acute palliative care unit. Brazil; acute palliative care unit N=203 patients who died in hospital	• Cancer, advanced	3 days	Day 3/Day 1 before death Low heart rate (<60) 0%/1% Normal heart rate (60-100) 44%/45% High heart rate (>100) 52%/54% • Low Sys BP (<100) 20%/47% • Normal Sys BP (100-140) 78%/47%	Association with change in vital signs and death within 3 days; Odds ratio, (95% CI, p-value) • Heart rate increase >10; 2.0 (1.1-3.2, 0.01) • Systolic blood pressure decrease >20 mm Hg; 2.5 (1.4-4.7, 0.0004)

Paper/Citation	Design, data source, and symptom collection	Setting and sample	Diagnoses included	Time frame to death	Symptom and reported prevalence	Symptom and significance
					• High Sys BP (>140) 2%/6% • Low dias BP (<60) 10%/27% • Normal dias BP (60-90) 90%/71% • High dias BP (>90) 1%2% • Low resp rate (<12) 0%/1% • Normal resp rate (12-20) 84%/70% • High resp rate (>20) 16%/29% • Low O^2 Sat (<85%) 14%/30% • Low normal O^2 Sat (85-90%) 31%/25% • Normal O^2 Sat(>90%) 55%/44% • Low temp (<36) 15%/13% • Normal temp (36-38.5) 83%/81% • High temp (>38.5) 2%/5%	• Diastolic blood pressure decrease >10 mm Hg; 2.3 (1.4-4.3, 0.002) • Respiratory rate decrease >5; 1.9 (0.8-5.3, 0.08) • Oxygen saturation decrease >8%; 3.7 (2.1-10.8, 0.0003) • Temperature increase >0.5° C; 2.1 (1.2-3.9, 0.002)
Bruera 2015[108]	Prospective, longitudinal, observational study	USA; acute palliative care unit. Brazil; acute palliative care unit N=193 patients who died in hospital expectedly and unexpectedly	• Cancer, advanced	3 days	Patients with expected death vs unexpected death, p value • Non-reactive pupils 40% vs 8% (p=0.03) • Death rattle 70% vs 56% (p=0.28) • Inability to close eyelids 63% vs 27% (p=0.01) • Grunting of local cords 58% vs 38% (p=0.18) • Decreased response to verbal stimuli 71% vs 43% (p=0.04) • Decreased response to visual stimuli 72% vs 50% (p=0.13)	

Paper/Citation	Design, data source, and symptom collection	Setting and sample	Diagnoses included	Time frame to death	Symptom and reported prevalence	Symptom and significance
					• Decreased urine output 64% vs 41% (p=0.11) • Peripheral cyanosis 62% vs 29% (p=0.02) • Hyperextension of neck 49% vs 31% (p=0.2) • Pulselessness of the radial artery 42% vs 8% (p=0.02) • Cheyne Stokes breathing 46% vs 19% (p=0.06) • Respiration with mandibular movement 60% vs 25% (p=0.01) • Upper gastrointestinal bleed 4% vs 14% (p=0.14)	
Sizoo 2010[109]	Retrospective cohort	Netherlands; single outpatient clinic where patients were treated; home N=55 patients with HGG	• Cancer, high grade glioma	1 week	• Drowsiness 87% • Dysphagia 71% • Seizure 28%.	
Chiang 2009[110]	Prospective observational cohort with validation, development of a prognostic model	Taiwan; single hospice ward N=727 persons; 374 in the training group and 353 in the validation group	• Cancer, terminal	7 days	Prevalence of factors significant in multivariate model by severity • Cognitive status a, 0 vs 1-3 (73% vs 27%) • Edemab, 0 vs 1-3 (50.8% vs 49.2%) • ECOG score, 1-2 vs 3-4 44.7% vs 55.3%) • Respiratory rate not included do to linearity a Cognitive status (scored as 0 = clear; 1 = lethargy; 2 = confusion; 3 = comatose)	Factors significant in multivariate analysis: Odds ratio, CI, p value • Cognitive status[a] (1-3 vs 0) 2.29 (1.18-4.43) p=0.014 • Edema[b]1.94 (1.04-3.62) p=0.038 • ECOG Score (3/4 vs 1 or 2) 3.45 (1.65-7.19) p=0.001 • Respiratory rate[c] 1.12 (1.04-1.20) =0.004 [a] Cognitive status (scored as 0 = clear; 1 = lethargy; 2 = confusion; 3 = comatose)

Paper/Citation	Design, data source, and symptom collection	Setting and sample	Diagnoses included	Time frame to death	Symptom and reported prevalence	Symptom and significance
					b Edema (scored as 0=no, 1-less than ½ finger breadth, 2=1/2-1 finger breadth,	[b] Edema (scored as 0=no, 1-less than ½ finger breadth, 2=1/2-1 finger breadth, and d 3=>1 finger breadth) [c] Scored linearly.
Chuang 2004[111]	Prospective cohort; construction of prognostic scale	Taiwan; single palliative care unity N=356 patients in training set, with 184 patients in testing set	• Cancer, terminal	1 week	• Pain • Dyspnea • Tiredness • Anorexia • Cognitive impairment • Dysphagia • Restless • Depression • Vomiting • Insomnia • Xerostomia • Edema • Ascites • Constipation • Jaundice • Weight loss • ECOG *Note that prevalence was reported by severity & testing set but for simplicity are just listed here	Model ROC for 1 week survival training set/testing set: 0.72/0.66. Significant symptom variables* included in the model: • Tiredness • Ascites • Edema • Cognitive impairment • Weight loss • ECOG *Note that the variables were ranked by severity but for simplicity are just listed here
Ethunadan 2005[112]	Retrospective cohort	UK, single hospital with multidisciplinary team N=32 patients	• Cancer	1 week	• Pain 84% • Swallowing problems 62.5% • Nausea/vomiting 9.4% • Restlessness 43.8% • Confusion 43.8%	

Paper/Citation	Design, data source, and symptom collection	Setting and sample	Diagnoses included	Time frame to death	Symptom and reported prevalence	Symptom and significance
STUDIES INCLUSIVE OF OTHER DISEASES						
Smedback 2017[113]	Retrospective cohort	Sweden; multisite study in nursing homes N=49,172 patients 60 and older who died in nursing home	• Circulatory diseases • Dementia • Cancer • Respiratory disease • Neurological disease	Last week	• Pain, 86.7% • Rattles, 42.4% • Anxiety, 33.0% • Confusion, 21.8% • Shortness of breath, 14.0% • Nausea, 11.1%	
Hall 2002 (k)[114]	Retrospective descriptive study with chart abstraction	Canada, multicenter study involving 5 long term care facilities N=185 persons who died in LTC facilities	• Cognitive impairment • Cardiac disease • Respiratory disease • Neurologic disorders • Musculoskeletal • Cancer • Others	8 hours	• Dyspnea 62% • Pain 44% • Noisy breathing (resp secretion) 39% • Delirium 29% • Dysphagia 28% • Fever 24% • Myoclonus 18% • None 8%.	
Bailey 2005 (k)[115]	Single group, before-after interventional trial with chart abstraction	USA; VA Medical center. Pre n=108, post n=95, total n=203	• Cancer • Neurologic disease • Heart disease • Lung disease • Liver disease • Other	7 days	13 Total—pre/post • Anorexia: 10.2%/44.2% • Anxiety 2.8%/13.7% • Constipation 2.8%/8.4% • Cough 10.2%/49.5% • Delirium 23.1%/37.9% • Depression 0.9%/3.2% • Dyspnea 30.6%/77.9% • Incontinence 16.7%/52.6% • Nausea/vomiting 8.3%/18.9% • Pain 28.7%/57.9% • Skin problems 15.7%/31.6% • Sleep problems 4.6%/3.2% • Weakness 13.9%/49.5%	

Paper/Citation	Design, data source, and symptom collection	Setting and sample	Diagnoses included	Time frame to death	Symptom and reported prevalence	Symptom and significance
Goodlin 1998 (k)[116]	Retrospective descriptive with chart review	USA, Patients who died in VA hospital or academic medical hospital N=104 patients (72 in academic center, 32 in VA)	• Cancer • Ischemic heart disease • COPD • Infectious processes • Stroke • CHF • Liver disease • Others	2 days	• Bed bound 68% • Dyspnea 51% • Restlessness 51% • Pain 47% • Confusion 34% • Fever 28% • Anxiety 26% • Nausea 19%, • Anorexia 19% • Incontinence 18% • Severe pain 12%	
Toscani 2005[117]	Prospective cohort & retrospective chart review & questionnaire	Italy, multicenter, 40 hospital general wards N=370 patients who died in hospital	• Cancer • Cardiovascular disease • CVAs • Respiratory dis • Acute abdominal disease • Organ failure • Trauma • Sepsis • Hematological diseases • Other	48 hours	• Fatigue 93% • Drowsiness 78% • Pain 75% • Anorexia 73% • Dyspnea 70% • Incontinence 57% • Confusion 55%, • Agitation/restlessness 50% • Difficulty swallowing 49% • Lung congestion/bronchial effusion 45% • Cough 31% • Pressure sores 27% • Constipation 26% • Fever 26% • Nausea vomiting 23% • Diarrhea 23% • Itching 3%	

Paper/Citation	Design, data source, and symptom collection	Setting and sample	Diagnoses included	Time frame to death	Symptom and reported prevalence	Symptom and significance
Steindal 2013[118]	Retrospective cross-sectional	Norway, single hospital N=190 patients 65 and older who died in hospital	• Cancer (45.8%) • Non-cancer (54.2%)	3 days	• Pain, 72.1% • Dyspnea, 75.8% • Nausea, 20.5% • Vomiting, 14.7% • Fever, 37.4% • Peripheral edema, 30.0% • Urinary incontinence, 70.0% • Fecal incontinence, 37.9% • Signs of delirium 15.3%	
Clark 2016[119]	Prospective data collection, consecutive cohort	Australia; multiple Australian 105 specialist palliative care services. N=18,975 persons identified as entering the terminal phase who died.	• Cancer (75%) • Other (25%)	Hours to days (terminal phase; 96.8% died within two days)	Symptoms that were moderately to severely distressing at beginning of terminal phase: • Fatigue 28.7% • Pain 22.2% • Breathing problem 22.1 • Appetite problem 11.6% • Bowel problems 8.9% • Difficult sleeping 6.8% • Nausea 3.9%	
Paice 2004 (k)[120]	Retrospective descriptive study with chart abstraction	US, single inpatient medical center	• Cancers • Cardiac and respiratory diseases • Bleeding • Cirrhosis • HIV • Neuromuscular • Other	48 hours	• Pulmonary congestion 92% • Confusion 86% • Fever 78% • Dyspnea 78% • Pain 77% • Fatique 46% • Sedation 36% • Agitation 32% • Constipation 32% • Decubitus ulcers 26%	

Paper/Citation	Design, data source, and symptom collection	Setting and sample	Diagnoses included	Time frame to death	Symptom and reported prevalence	Symptom and significance
Sandvik 2016[44]	Prospective longitudinal	Norway; 47 nursing home N=152 nursing home patients assessed in last days of life	• Dementia	Imminent death (median 3 days to death), day of death	Moderate to severe symptoms on day diagnosed as imminently dying/actual day of death • Pain 60.2%/45.8% • Fatigue 98.7%/89.4% • Drowsiness 97.4%/ 88.1% • Sleep quality 50%/35.2% • Nausea 24.3%/12% • Vomiting 15.3%/ 9.8% • Poor appetite 94.8%/ 78.3% • Dyspnea 43.5%/ 53.0% • Depression 33.3%/ 15.1% • Anxiety 44.2%/30.8% • Delirium 16.0%/ 3.1% • Agitation 9.2%/3.2% • Death rattle 7.7%/18.5% • Constipation 24%/8.1%	Variables significant to accurately identifying the day someone was imminently dying: Odds ratio, (95% CI, p-value) • Increased fatigue 1.8 (1.16-2.85, 0.009) • Poor appetite 1.2 (1.06-1.41, 0.005) *note that they specifically state that pain and dyspnea were NOT significant with recognizing imminently dying. Patients who in advance were identified as dying showed significantly more: • fatigue ($P < .001$) • drowsiness ($P = .006$) • loss of appetite ($P < .001$) ….compared with those who died unexpectedly
Soares 2018[121]	Retrospective cohort with chart review	Brazil; single post - acute care facility N=111 patients who died	• Dementia • Cancer	3 days	Prevalence in dementia vs cancer patients • Dyspnea, 60% vs 72% • Agitation 13% vs 25% • Pain 34% vs 57%	
Cohen 2000 (k)[122]	Prospective observational cohort with chart abstraction	US and Canada, 8 dialysis clinics N=79 persons in dialysis clinic	• ESRD	24 hours	• Agitation/delirium/restlessness 30.4% • Diarrhea 13.9% • Dysphagia 13.9% • Dyspnea 25.3% • Fever 20.3% • Myoclonus 27.8% • Nausea/vomiting 12.7% • Pain 41.7%	

Paper/Citation	Design, data source, and symptom collection	Setting and sample	Diagnoses included	Time frame to death	Symptom and reported prevalence	Symptom and significance
Zambroski 2005 (k)[123]	Retrospective descriptive study with chart review	US; single hospice agency N=90 patients who died while receiving hospice	• Heart failure	7 days	• Confusion 47.8%, • Dyspnea 63.3% • Edema 45.6% • Incontinence 38.9%	
Mazzocato 2010[124]	Retrospective chart review	Switzerland; tertiary hospital N=42 patients referred to palliative care consultant team	• Ischemic stroke • Intracerebral hemorrhage	48 hours	• Dyspnea, 81% • Pain or pain behaviors, 69% • Mouth dryness, 62% • Constipation, 38% • Anxiety, sadness, 26% • Delirium, 14% • Sleep disorders, 12% • Other symptoms, 12%	
Ljunggren 2016[125]	Retrospective cohort	Sweden; single emergency department N=96,514 adult patients who visited ED	• Cardiovascular disease • Cerebrovascular disease • Immunosuppresive disease • Cardiac failure • Kidney disease • Liver disease • Lung disease • Malignancy • Diabetes Mellitus	1 day		Multivariate ORs for 1-day mortality with CI • Oxygen saturation >90% with supplemental oxygen, 5.2 (3.1 to 9.0) • Respiratory rate >30, 4.9 (3.4, 7.3) • Respiratory rate <8, 18.1 (2.1-155.5) • Pulse rate <40 vs 50-110 4.1 (1.2-14.4) • Systolic blood pressure < 90 mmHg, 2.9 (1.8-4.9) • Unresponsive level of consciousness, 31.0 (16.9-56.8)

Appendix II: Search specifics for signs and symptoms of actively dying

Kehl et al.	Update of Kehl et al.--focus on prediction
PubMed Search Terms and parameters: (death OR terminal care OR palliative care OR end of life OR dying OR dying process OR hospice OR hospice care) AND (signs OR symptoms OR signs and symptoms OR signs and symptoms respiratory OR signs and symptoms digestive OR neurobehavioral manifestations OR neurologic manifestations OR skin manifestations OR behavioral symptoms OR affective symptoms OR depression) AND full text[sb] AND Humans[Mesh] AND English[lang] AND adult[MeSH])) year 2000 newer	PubMed Search Terms and parameters: ((predictors OR prognostic model OR variables OR signs OR symptoms OR factors OR signs symptoms OR predicting)) AND (imminently dying OR terminal phase OR death OR dying OR mortality OR survival OR active death OR actively dying OR imminent death)) AND (last week OR last 2 days OR last 3 days OR last week OR final week OR final two days OR final three days OR 48 hours)) AND full text[sb] AND Humans[Mesh] AND English[lang] AND adult[MeSH])) NOT fetal) NOT infant) NOT pregnant) NOT suicide , year 2000 newer
Over 17K total hits, 10K reviewed due to software limitations (sorted by Best Match)	2274 total hits, all reviewed (sorted by Best Match)
53 studies selected for in-depth abstract review	28 studies selected for in-depth abstract review
20 studies ordered for full review	11 studies ordered for full review
23 total papers included in review + 3 papers from citation tracking + 8 papers from original Kehl review= 34 total papers	

Appendix III: Keywords for update to systematic review of pain and dyspnea assessments

Method:	PubMed	Cochrane Library	
Search Terms and Parameters	(("palliative care"[mh] OR "palliative care"[tiab] OR "end of life"[tiab] OR "hospice care"[mh] OR "terminally ill"[tiab] OR "terminal care"[tiab] OR "terminal illness"[tiab] OR Hospice[tiab]) AND ("assessment tool"[tiab] OR "assessment tools"[tiab] OR "Surveys and questionnaires"[Mesh] OR "Questionnaires"[tiab] OR "Questionnaire"[tiab] OR "self-report"[tiab] OR instrument[tiab] OR instruments[tiab] OR scale[tiab] OR scales[tiab] OR instrumentation[tiab] OR "Psychometrics"[Mesh] OR "Psychometrics"[tiab] OR "Psychometric"[tiab]))	#1	MeSH descriptor: [Palliative Care] explode all trees
		#2	MeSH descriptor: [Hospice Care] explode all trees
		#3	"palliative care":ti,ab,kw (Word variations have been searched)
		#4	"terminally ill":ti,ab,kw (Word variations have been searched)
		#5	"terminal care":ti,ab,kw (Word variations have been searched)
		#6	"terminal illness":ti,ab,kw (Word variations have been searched)
		#7	hospice:ti,ab,kw (Word variations have been searched)
		#8	MeSH descriptor: [Terminal Care] explode all trees
		#9	#1 or #2 or #3 or #4 or #5 or #6 or #8or #9
		#10	MeSH descriptor: [Surveys and Questionnaires] explode all trees
		#11	MeSH descriptor: [Psychometrics] explode all trees
		#12	MeSH descriptor: [Palliative Care] explode all trees
		#13	"assessment tool":ti,ab,kw (Word variations have been searched)
		#14	"assessment tools":ti,ab,kw (Word variations have been searched)
		#15	Questionnaires:ti,ab,kw (Word variations have been searched)
		#16	Questionnaire:ti,ab,kw (Word variations have been searched)
		#17	"self report":ti,ab,kw (Word variations have been searched)
		#18	instrument:ti,ab,kw (Word variations have been searched)
		#19	instruments:ti,ab,kw (Word variations have been searched)
		#20	scale:ti,ab,kw (Word variations have been searched)
		#21	scales:ti,ab,kw (Word variations have been searched)
		#22	instrumentation:ti,ab,kw (Word variations have been searched)
		#23	Psychometrics:ti,ab,kw (Word variations have been searched)
		#24	Psychometric:ti,ab,kw (Word variations have been searched)
		#25	#10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20 or #21 or #22 or #23 or #24
		#26	#10 and #25
Total hits	70	0	
Selection for Abstract Review	20	0	
Selection for Full Review	9	0	
Final Selection	0	0	

Appendix IV: Significance of signs and symptoms of actively dying

	Cancer Only									Other Diseases	
	Hui clin 2014[96]	Hui Bedside 2015[97]	Hui Symptom 2015[7]	Hui Diag 2015[98]	Hwang 2013[99]	Kao 2009[100]	Bruera 2014[107]	Chiang 2009[110]	Chuang 2004[111]	Sandvik 2016[44]	Ljunggren 2016[125]
Measure of significance	Positive Likelihood ratio (CI)	Positive Likelihood ratio (CI)	P-value only**	Diagnostic accuracy of best model 82%-80%	Adj OR (p) Unadj OR (p)	OR (p)	OR (CI) p	OR (CI) p	ROC of training/testing set (0.72/0.66)	OR (CI) p/ p value only	OR (CI)
Timing to death	3 days	3 days	7 days	3 day	2 days	1 week	3 days	7 days	1 week	Death within 24-48 hrs	1 day
Symptom											
Abdominal swelling/ascites											
Anorexia			P=0.001								
Appetite problem										1.2 (1.06-1.41) 0.005 / <0.001	
Blood pressure (s=systolic, d=diastolic)					0.97 (0.01) 0.96 (0.01)	(S) 0.98 (0.01)	(S) 2.5 (1.4-4.7) 0.0002; (D) 2.3 (1.4-4.3) 0.002				
Body temperature/fever						1.39*** (0.02)	2.1 (1.2-3.9) 0.002				
Cheyne Stokes breathing	12.4 (10.8-13.9)										
Cognitive status						1.68 (<0.001)		2.29 (1.18-4.43) 0.014	included		
Confusion					0.97 (0.03) 0.97 (0.03)						
Consciousness/ coherence					0.95 (<.01) 0.94 (<.01)						31.0 (16.9-56.8)
Decreased response to verbal stimuli		8.3 (7.7-9.0)									
Decreased response to visual stimuli		6.7 (6.3-7.1)									
Depression			P=0.008								

	Cancer Only									Other Diseases	
Drooping of nasolabial fold		8.3 (7.7-8.9)		included							
Dysphagia											
Dyspnea			P<0.0001								
Eastern Cooperative Oncology Group						2.24 (<0.001)		3.45 (1.65-7.19) 0.001	included		
Edema								1.94 (1.04-3.62) 0.038	included		
Edmonton Symptom Assessment Scale measure of well being			P=0.01								
Fatigue			P<0.0001							1.8 (1.16-2.85) 0.009/ <0.001	
Grunting of vocal cords		11.8 (10.3-13.4)									
Heart rate/pulse rate					0.97 (<.01) 0.97 (0.01)	1.02 (0.002)	2.0 (1.1-3.2) 0.01				
Hyperextension of neck		7.3 (6.7-8.0)									
Inability to close eyelids		13.6 (11.7-15.5)									
Incontinence (fecal or urine)											
Level of urine output	15.2 (13.4-17.1)										
Muscle power					0.57 (<0.001)						
Non-reactive pupils		16.7 (14.9-18.6)									
Oxygen saturation					0.97 (0.02) 0.96 (0.01)	3.7 (2.1-10.8) 0.0003)					5.2 (3.1-9.0)
Peripheral cyanosis	5.7 (5.4-6.1)										
Palliative Performance Scale				Included							
Pulselessness of radial artery	15.6 (13.7-17.4)										

	Cancer Only									Other Diseases	
Respiration with mandibular movement	10.0 (9.1-10.9)										
Respiratory rate						1.9 (0.8-5.3) 0.08		1.12 (1.04-1.20) 0.004			18.1 (2.1-155.5) & 4.1 (1.2-14.4)
Respiratory secretions /death rattle	9.0 (8.1-9.8)				0.96 (0.02) 0.96 (0.03)						
Sleep problems/apnea/sleep quality	4.5* (3.7-5.2)										
Tiredness/drowsiness/increased sleeping			P<0.0001						included	0.006	
Upper gastrointestinal bleed		10.3 (9.5-11.1)									
Weight loss									included		

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