

Evidence-based Practice Center Technical Brief Protocol

Project Title: Assessment Tools for Palliative Care

I. Background and Objectives for the Technical Brief

Palliative care is care that provides relief from pain and other symptoms, supports quality of life, and is focused on patients with serious advanced illness and their families.¹ Over the last decade, a multi-professional group has published consensus guidelines that definitively and conceptually define the domains that should be addressed in palliative care (Text Box).² As many of these domains are best assessed through patient and/or caregiver reports, patient and caregiver assessment tools are essential to measuring the quality and effectiveness of palliative care. An assessment tool is an instrument completed by or with patients or families, used to collect data at the individual patient level. For example, this may include a structured tool that a provider uses in clinical care to ask about a patient’s symptoms, such as pain, or the quality of care, such as asking a patient follow-up questions about whether pain was controlled; or a questionnaire about the impact of a palliative care intervention, such as a caregiver’s assessment of how well providers communicated.³

These tools can include patient and provider reports of physical symptoms (e.g., pain and dyspnea); mental health issues (e.g., depression); caregiver outcomes (e.g., quality of life and burden); and processes of care (e.g., communication and continuity).² Moreover, measuring the effectiveness of palliative care interventions requires reliable and valid assessment tools that matter to patients and families,⁴ can evaluate the impact of interventions, and can be administered in palliative care populations and settings.⁵

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| Text Box. National Consensus Guidelines Domains for Quality Palliative Care |
| <ul style="list-style-type: none"> • Structure/Process of care (e.g., continuity, communication) • Physical Aspects of Care (e.g., pain, dyspnea) • Psychological and Psychiatric Aspects of Care • Social Aspects of Care (including caregiving) • Spiritual, Religious and Existential Aspects of Care • Cultural Aspects of Care (including cultural competence) • Care of the Patient at the End of Life • Ethical and Legal Aspects of Care (care planning) |

Over the past fifteen years, different groups have published formal compilations of palliative care assessment tools. In the mid-1990s, Teno and colleagues published the first TIME Toolkit of Instruments to Measure End-of-Life Care.⁶ In 2004, Lorenz and colleagues published a palliative care systematic review⁷ for the National Institutes of Health State of the Science Conference on Improving End-of-Life Care,⁸ which updated the TIME review and summarized the psychometrics of 99 relevant assessment tools and their use in palliative care interventions.⁹

¹⁰ The PEACE Palliative Care Quality Measures project then updated this State of the Science review through February 2007.¹¹ The PEACE project focused on tools applicable to quality indicators for palliative and hospice care and applied evaluation criteria to select and describe 39 instruments that either met the 75th percentile on the criteria or filled an important gap for measurement.

Since the PEACE project, no further reviews have comprehensively addressed the use of assessment tools in palliative care domains, although many additional tools have been developed and applied in these domains. Subsequent systematic reviews and grey literature compilations of assessment tools have addressed specific palliative care areas such as dyspnea,¹² pain,³ comprehensive assessments,¹³ both patient and caregiver satisfaction,¹⁴ instruments for caregivers of palliative care patients,¹⁵ and spiritual support in palliative care.¹⁶ Given that these tools are frequently used together or overlap in the concepts that they are measuring, a new integrated review would be valuable for the field of palliative care.

Assessment tools can be applied in several ways in palliative care, and although some tools may ideally be used for more than one application, evaluation for the specific purpose is important. First, in clinical palliative care, tools may be used by providers to directly assess symptoms or other issues with patients or families. For example, these tools may be used in interventions where the assessment tool results (i.e., reported pain scores) are provided to the patient's clinical team. Yet, data supporting the effectiveness of this use of assessment tools are mixed. A 2012 systematic review on quality improvement in palliative care¹⁷ did not find high-quality research interventions that evaluated providers' use of tools to assess patients or families. This review identified five clinical trials in ambulatory oncology populations that collected patient-reported outcome information and relayed this information to providers; only one of the five demonstrated a significant impact on patient quality of life, although some studies did find an impact on other outcomes (e.g., communication).

A second application of assessment tools includes their use as quality indicators, particularly the use of patient- or caregiver-reported data to evaluate care. Two recent systematic reviews and grey literature compilations exist of assessment tools used as quality indicators.^{18, 19}

A third application of assessment tools is in evaluating the impact of palliative care interventions in research studies. A 2015 systematic review of palliative care interventions²⁰ summarized assessment tools used in 124 clinical trials in palliative care and found that though interventions were associated with significant improvements in communication and care planning, psychosocial health, and patient and caregiver experience, only 50% of trials had statistically significantly positive findings. This review also concluded that the lack of impact on outcomes might be due to insufficient use or availability of meaningful, discriminatory, and responsive assessment tools for palliative care populations or interventions. Also of note, given the wide variety of domains evaluated and assessment tools used, the systematic review could not quantitatively synthesize results across studies. Thus, better information on what tools are tailored and responsive to palliative care interventions as well as recommendations for certain assessment tools will likely improve the quality and intervention comparability in future systematic reviews of palliative care interventions.

In order to provide a comprehensive overview of palliative care assessment tools, we will use the consensus conceptual framework on palliative care quality (Text Box), our prior reviews,^{9, 17, 20} and other recent reviews and grey literature compendia to summarize the state of current research on the use of palliative care assessment tools for three applications in palliative care: (i)

clinical practice, (ii) quality indicators, and (iii) evaluation of interventions; and identify key issues and opportunities for further research.

II. Guiding Questions

All guiding questions apply to the three applications of palliative care assessment tools (clinical practice, quality indicators, and evaluation of interventions) and discussion of results will be organized by the eight domains from the National Consensus Project Clinical Practice Guidelines for Quality Palliative Care (Text Box) as well as a ninth domain comprised of tools that cross multiple domains (i.e., patient experience/satisfaction, comprehensive assessment).

1. What assessment tools have been developed or used?
 - a. What settings, populations, and intended use were the tools developed for?
 - b. What are key features of the tools (domains addressed, types of outcomes, mode of administration)?
2. In what context have these assessment tools been used?
 - a. In what settings and populations have they been used?
 - b. How have they been applied?
3. What is the state of current research on these assessment tools?
 - a. Is there published information available on reliability, validity, responsiveness, and usability?
4. What are key issues with the use of assessment tools?
 - a. What are key strengths and weaknesses of currently available tools generally (not for specific tools) (e.g., standardization, burden on patients and caregivers, unintended consequences)?
 - b. What are key gaps for tool development and evaluation and opportunities for future research?
 - c. How have these weaknesses and gaps affected the field of palliative care?

III. Methods

1. Data Collection:

For each of the National Consensus Project Clinical Practice Guidelines for Palliative Care domains of palliative care and areas that cross domains, we will seek and compile information on palliative care assessment tools from systematic reviews. If we do not identify a systematic review for a particular domain, we will seek information on assessment tools first from a grey literature (unpublished compilations or databases of published information on tools) search, and then, where needed, through a targeted search of PubMed.

A. Systematic review search.

There is extensive recent systematic review literature in palliative care (including many published in 2015) as well as several up-to-date grey literature compendia and databases. In addition, newly-published tools that have not been widely available for use are not relevant for answering the guiding questions, and data on validity and reliability are almost always published only in the original publication about a tool. In order to

determine which National Consensus Project Clinical Practice Guidelines for Palliative Care domains are covered by recent published systematic reviews of the literature, we need to comprehensively identify, and map existing reviews. We will focus on Cochrane, PubMed and CINAHL, with targeted searches as needed of PsycINFO and PsycTESTS as used in prior reviews.¹⁴ A preliminary PubMed search is detailed in the box below. We will follow Evidence-based Practice Center guidance for use of existing systematic reviews²¹ and will assess the quality of recent relevant (last 10 years) systematic reviews for quality using the ROBIS tool.²² We selected 10 years as a timeframe because the PEACE systematic review was completed in 2007. Based on our quality assessment, and the relevance, recency, and availability of evidence tables with relevant information, we will choose systematic reviews and classify these by the domains covered (Figure 1). We will use the details about the assessment tools abstracted in these reviews.

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| ("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]) | Limit to systematic reviews and meta-analyses AND 2/2007 to present: 300 |
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B. Grey literature search.

For National Consensus Project Clinical Practice Guidelines for Palliative domains where there are not recent (last 3 years) systematic reviews, we will use targeted grey literature searching (see Figure 1 for algorithm) to identify grey literature sites that compile information about assessment tools. We will limit this grey literature search to compiled lists and databases that report on information from published studies on tool components, validity, reliability, and/or usability. These include websites that have compiled and report evaluations of tools and were created or updated recently (within the last 5 years), including the University of Washington End-of-Life Care Research Program Instruments site,²³ the City of Hope Pain & Palliative Care Resource Center,²⁴ the Measurement and Caregiver Cores of the Palliative Care Research Cooperative Group,²⁵ the National Palliative Care Research Center Measurement and Evaluation Tools²⁵ and the and the Functional Assessment of Chronic Illness Therapy (FACIT) system.²⁶ As needed, we will also search databases that abstract information on assessment tools, including the National Institutes of Health Patient Reported Outcomes Measurement Information System (PROMIS) instruments,²⁷ the Mapi Research Trust's Patient Reported Outcome and Quality of Life (PROQOLID) database of clinical outcome assessment tools, and the National Cancer Institute Grid-Enabled Measures database.²⁸ Inclusion criteria for tools are listed in Table 1.

C. Supplemental search.

After the above steps, if there are any National Consensus Project Clinical Practice Guidelines for Palliative domains that are not covered by either systematic reviews or the

grey literature, we will conduct a targeted search of PubMed to identify tools in these domains using key words for those domains added to our palliative care search in Section A above. We will use the same inclusion criteria as described for systematic reviews in Table 1 except that we would include only published articles that describe the psychometrics of assessment tools developed for or tested in palliative care populations. Given that the last comprehensive systematic review of assessment tools across domains searched through February 2007, we would begin our search in February 2006 (to provide one year of overlap with the prior review).

D. Discussions with Key Informants

We will supplement the information from the published and grey literature searches with key informant interviews, focusing on perspectives and issues not available from existing sources. In the interviews, we will address what these tools should include and do and where to look for studies. We will then compare this information to the current research that exists on tools to identify gaps and issues for future research. We will conduct interviews in one or two small groups, with a separate call for caregiver advocates to maximize their input. We will adhere to all Office of Management and Budget requirements in limiting the informants asked the same questions to no more than 9 participants. We will document interviews and submit to the Task Order Officer. Key Informants include leading palliative care researchers and quality experts applying tools in relevant populations and settings including the intensive care unit, oncology, pediatrics, heart failure, geriatrics and bereavement. The Key Informants have extensive experience in diverse aspects of tool development, application, and reviews, ranging from patient- and caregiver-reported outcomes to quality indicators and patient experience.

Discussions with key informants will address palliative care across diverse domains, settings, and populations. For researchers and providers, interviews will focus on identifying key issues and research gaps in use of assessment tools for palliative care clinical care, quality indicators, and evaluation of interventions. For the caregiver advocates, interviews will focus on their perspectives about:

- Elements of high quality palliative care.
- Use of assessment tools or surveys, such as ratings of symptoms or a questionnaire about their experience with palliative care.
- What information related to palliative care patients and caregivers need their providers to know about, which could be collected through questionnaires or other assessment tools.
- Which domains from the National Consensus project should be measured as part of palliative care.
- Experiences with questionnaires or other assessment tools, and whether or how they improved their experience of care or made things more difficult.

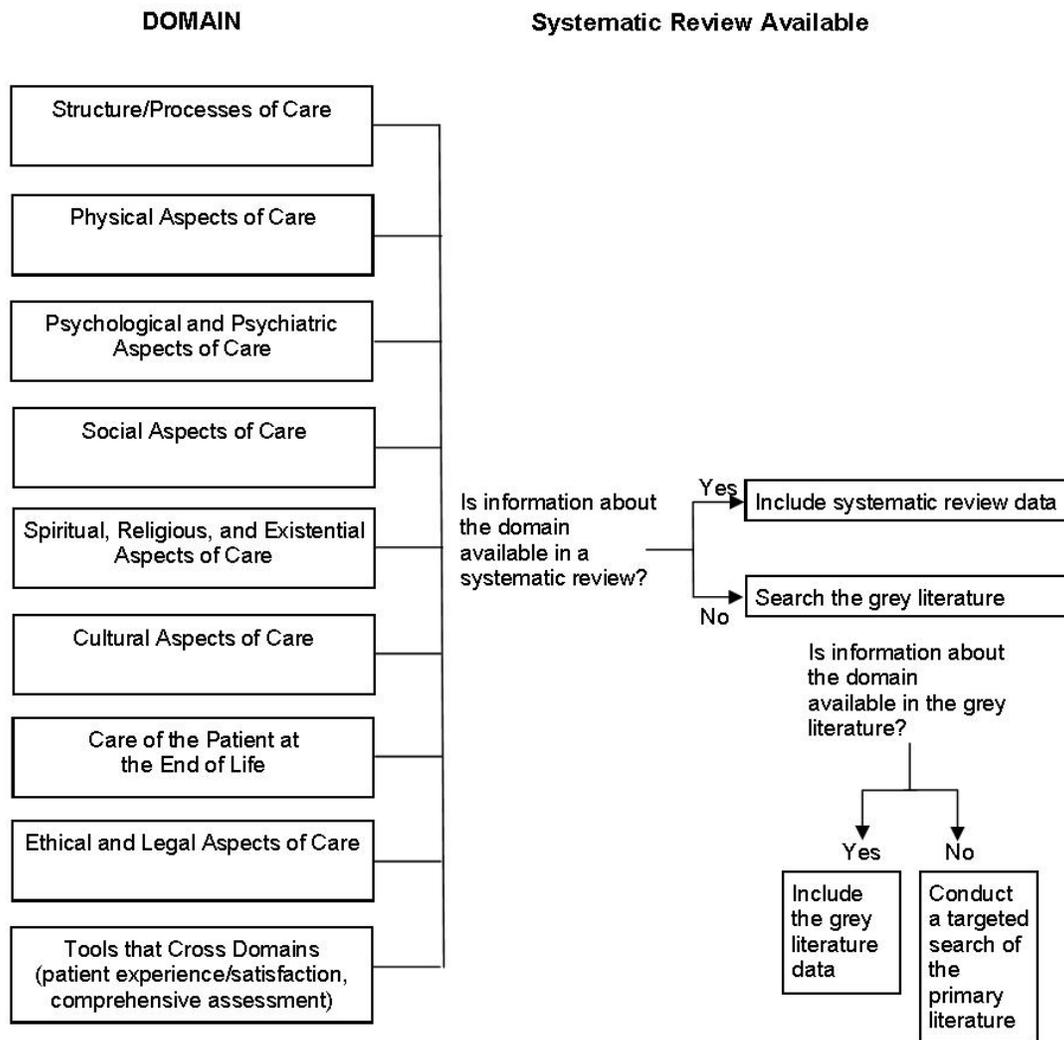


Figure 1. Search flow based on National Consensus Project Clinical Practice Guidelines for Palliative Care domains for tools .

Table 1. Inclusion Criteria

| | Criteria |
|----------------------|--|
| Content | Evaluates palliative care assessment tools used in palliative care (1) clinical practice, (2) quality indicators, (3) evaluation of interventions |
| Population | Tools developed, evaluated or implemented in populations defined as palliative care or meeting the definition of palliative care (see definition below) All diseases, age groups and settings |
| Study design | Systematic reviews For interventions, include systematic reviews of prospective, controlled trials |
| Language/ Country | English/ United States |
| Admissible evidence | Published literature only for reliability, validity, and responsiveness |

2. Data Organization and Presentation:

A. Information Management

We will abstract information on tools published since the previous comprehensive systematic reviews for the National Institutes of Health State of the Science and PEACE projects.^{9, 11, 12, 29} We will abstract information based on key elements from the National Quality Forum criteria for Patient Reported Outcomes in Performance Measurement,³⁰ which were developed by a large expert panel and are based on scientific acceptability (validity, reliability, and responsiveness to interventions) and usability (i.e., information that the tool has been used and is feasible and provides useful information for palliative care clinical practice, quality indicators, or evaluation of interventions). From the literature searches and Key Informant interviews, we will evaluate key issues and research gaps about the use of assessment tools in each of the three applications.

B. Data Presentation

Our findings will be presented as an evidence map (format to be determined) in the order of the guiding questions. We will organize the presentation into tables by the National Consensus Project Clinical Practice Guidelines for Palliative Care domains and address the three applications of tools (clinical care, quality indicators, and evaluation of interventions), settings and populations. We will catalog included tools and compile information on their characteristics (Guiding Question 1), catalog the context in which they are used (Guiding Question 2), and describe the current state of research for tools in each area (Guiding Question 3). We will provide a summation of relevant issues and gaps to answer Guiding Question 4.

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V. Definition of Terms

Palliative care: Care that provides relief from pain and other symptoms, supports quality of life, and is focused on patients with serious advanced illness and their families.¹

Assessment tool (or instrument) (or measurement tool): An instrument completed by or with patients or families, used to collect data at the individual patient level. For example, this may include a tool to evaluate a patient's symptoms, such as pain; the quality of care, such as asking a patient a follow-up question about whether pain was controlled; or the experience of care, such as a caregivers' assessment of how well providers communicated.³

Quality indicator: a population-based measure that enables users to quantify the quality of a specific aspect of care by comparing it to evidence-based criteria.³¹ Indicators require defining both those patients whose care meets the indicator criteria (the numerator) (e.g., those who are asked about their pain) and those who are eligible for the indicator, or the population of focus (the denominator) (e.g., all patients with a serious illness). When these include patient- or caregiver-reported data, they require use of assessment tools.

National Consensus Project Clinical Practice Guidelines for Quality Palliative Care domains²:

- Structure/Process of care (e.g., continuity, communication)
- Physical Aspects of Care (e.g., pain, dyspnea)
- Psychological and Psychiatric Aspects of Care
- Social Aspects of Care (including caregiving)
- Spiritual, Religious and Existential Aspects of Care
- Cultural Aspects of Care (including cultural competence)
- Care of the Patient at the End of Life
- Ethical and Legal Aspects of Care (care planning)
- Tools that cross domains: (patient experience/satisfaction, comprehensive assessment)

VI. Summary of Protocol Amendments

In the event of protocol amendments, the date of each amendment will be accompanied by a description of the change and the rationale.

VII. Key Informants

Within the Technical Brief process, Key Informants serve as a resource to offer insight into the clinical context of the technology/intervention, how it works, how it is currently used or might be used, and which features may be important from a patient or policy standpoint. They may include clinical experts, patients, manufacturers, researchers, payers, or other perspectives, depending on the technology/intervention in question. Differing viewpoints are expected, and all statements are crosschecked against available literature and statements from other Key Informants. Information gained from Key Informant interviews is identified as such in the report. Key Informants do not do analysis of any kind nor contribute to the writing of the report and have not reviewed the report, except as given the opportunity to do so through the public review mechanism

Key Informants must disclose any financial conflicts of interest greater than \$10,000 and any other relevant business or professional conflicts of interest. Because of their unique clinical or content expertise, individuals are invited to serve as Key Informants and those who present with potential conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any potential conflicts of interest identified.

VIII. Peer Reviewers

Peer reviewers are invited to provide written comments on the draft report based on their clinical, content, or methodologic expertise. Peer review comments on the preliminary draft of the report are considered by the EPC in preparation of the final draft of the report. Peer reviewers do not participate in writing or editing of the final report or other products. The synthesis of the scientific literature presented in the final report does not necessarily represent the views of individual reviewers. The dispositions of the peer review comments are documented and will be published three months after the publication of the Evidence report.

Potential Reviewers must disclose any financial conflicts of interest greater than \$10,000 and any other relevant business or professional conflicts of interest. Invited Peer Reviewers may not have any financial conflict of interest greater than \$10,000. Peer reviewers who disclose potential business or professional conflicts of interest may submit comments on draft reports through the public comment mechanism.

IX. EPC Team Disclosures

EPC core team members must disclose any financial conflicts of interest greater than \$1,000 and any other relevant business or professional conflicts of interest. Related financial conflicts of interest that cumulatively total greater than \$1,000 will usually disqualify EPC core team investigators.

X. Role of the Funder

This project was funded under Contract No. HHS 290-2015-00006-I from the Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services. The Task Order Officer reviewed contract deliverables for adherence to contract requirements and quality. The authors of this report are responsible for its content. Statements in the report should not be construed as endorsement by the Agency for Healthcare Research and Quality or the U.S. Department of Health and Human Services.