Special Article

Pain Measurement Tools and Methods in Clinical Research in Palliative Care: Recommendations of an Expert Working Group of the European Association of Palliative Care

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Abstract

An Expert Working Group was convened under the auspices of the Steering Committee of the Research Network of the European Association of Palliative Care to review the status of the use of pain measurement tools (PMTs) in palliative care research conducted in a multilingual-multicenter setting. Based on a literature review and on the experts' opinion, the present work recommends that standardized methods should be applied for the use of PMTs in research in palliative care. Visual analogue scales, numerical rating scales, and verbal rating scales are considered valid to assess pain intensity in clinical trials and in other types of studies. Among the multidimensional questionnaires designed to assess pain, the McGill Pain Questionnaire and Brief Pain Inventory are valid in many multilingual versions. Specific recommendations for PMT use and administration, depending on the study type and aim, are reviewed. Special population requirements specific of clinical situations encountered in palliative care (elderly, terminal, cognitively impaired patients, pediatric patients) are also considered. J Pain Symptom Manage 2002;23:239–255. © *U.S. Cancer Pain Relief Committee, 2002.*

Key Words

Palliative care, pain, pain measurement, clinical trials

Introduction

Pain is among the most common and distressing symptoms encountered by patients with advanced cancer and other terminal illnesses. The relief of pain is a clinical task at the very heart of the endeavor of palliation. The challenge of

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this task is to achieve effective relief with minimal side effects and to deliver this service to all patients in need of these interventions. Success in meeting this challenge requires delineation of the scope of the problem, characterization of the pain syndromes, determination of optimal therapeutic strategies, identification of barriers to implementation of effective strategies, determination of strategies to overcome these obstructions, and the monitoring of outcomes for purposes of continual quality improvement.

Evidence-based medicine requires the testing and evaluation of strategies to assure their effectiveness and to define optimal approaches for all contingent indications. Through this approach, ineffective strategies are to be discarded and effectual strategies are submitted to trials against competing options to determine the best approach to serve as the standard for future comparison. It is incumbent upon palliative care practitioners to participate in the challenge of clinical research to enhance the efficacy of palliative practices to the benefit of our patients and their families.[1] Interpretation of research data requires that the data be valid and recorded in an interpretable format. In clinical studies on pain, valid and reliable outcomes should be used. Furthermore, in order to compare data between studies, a standardization of outcomes, namely, pain measures, will increase the validity of the comparisons.

Many approaches to the measurement of pain attributes have evolved over the past four decades. Some of them have been applied to cancer pain and palliative care,[2] but the selection and application of these approaches in palliative care has often been capricious and idiosyncratic. The lack of uniformity in the approach to outcome measurement in evaluating chronic pain conditions has diminished from the ability to draw meaningful conclusions from much of the published literature.[3–5]

This article reports the results of the work of an Expert Working Group which was convened under the auspices of the European Association of Palliative Care (EAPC) Research Network to prepare recommendations for the measurement of pain in palliative care research.

Research Issues in Palliative Medicine

The patient populations that are the focus of palliative medicine are often frail, and have deteriorating health and multiple symptoms. At the end of life, cognitive impairment of variable severity is common. These factors impact both the ability to extrapolate pain management data derived from other clinical contexts with relatively healthy patient populations and the ability to conduct clinical research. They specifically influence the processes of data collection necessary for prospective studies. Research methodologies must be sensitive to these considerations. Specific recommendations will be made for approaches suitable for patients with cognitive impairment and for children.

No valid instrument is applicable at the moment for the assessment of pain in the cognitively impaired. A behavioral scale has been recently designed for pain assessment in the cognitively impaired patient and its validation is ongoing (DOLOPLUS, Bernard Wary, personal communication).

Study Types

The working group defined six types of pain studies in palliative care, three descriptive study designs and three intervention designs (Table 1).

Descriptive Studies

Descriptive studies of pain are needed to define the prevalence and severity and scope of pain in various patient populations encountered in palliative care. These studies are performed to clarify clinical variability, pain course and prognosis, quality of care, and services. Depending upon the epidemiological method used, the results of these studies give information of varied generalizability.

1. Prevalence/severity studies: Pain is evaluated in a specific patient population to define its prevalence and severity.[6–10]

Table 1
Study Types

Descriptive Studies
Prevalence/severity studies
Trajectory studies
Pain syndrome characterization
Intervention Studies
Phase I
Phase II
Phase III

2. Trajectory studies: Pain is evaluated at repeated intervals in a defined patient population over time.[11]
3. Pain syndrome characterization: The clinical characteristics of pain and its relationship to clinical and investigation findings are collated to define and to describe specific pain syndromes.[12]

Intervention Studies

Intervention studies are needed to evaluate the effect of a therapeutic strategy. Pain management interventions may include primary therapies against the underlying pathology, analgesic drug therapy, invasive interventions, and psychological or social interventions.

1. Phase I studies: This term typically refers to drug interventions with new agents. The aim of the study is to define the maximal dose range that can be administered without excessive toxicity and to determine the acute toxicity profile of the agent.
2. Phase II studies: This term refers to prospective studies aimed at evaluating the impact of a study intervention with regard to the primary outcome, pain; secondary outcomes, such as quality of life and satisfaction; and costs, such as adverse effects and treatment-related resource utilization.

In the evaluation of analgesic drugs, Phase I and II studies are often combined. In addition to essential pharmacokinetic data, pharmacodynamic effects including analgesia and adverse effects are measured. Pharmacokinetic/pharmacodynamic (PK/PD) studies correlate drug effects with measurement of plasma concentration in blood or other relevant compartments, such as cerebrospinal fluid. PK/PD studies may be performed with a single administration of a study drug or prolonged administration.

3. Phase III studies: This term refers to studies comparing the relative efficacy of two or more treatment approaches with a view to determining an optimal approach. These studies typically evaluate drugs with similar outcomes in phase II studies.

Pain evaluation approaches must be appropriate for the study type and patient population that will constitute the subjects of the study.

Covariates

A list of the covariates that are most relevant to pain studies in palliative care is provided in Table 2.

Description of Pain Measurement Tools (PMTs)

Pain is a subjective sensation which can be described according to several relevant features or attributes (quality, location, intensity, aversiveness, emotional impact, frequency, etc.). Among these attributes, intensity is recognized as one of the most relevant clinical dimension of the pain experience.[13] Being a subjective experience, there is no objective method to measure pain. However, pain intensity can be measured in patients in a reliable and valid way by recording the self-rating of the sensation on different types of scales.[14–20] When considering pain assessement limited to the intensity dimension, PMTs should have a unidimensional structure.

Since clinical pain is not only the product of a primary sensory modality, but rather, a complex human experience with functional, emotional, social, and spiritual components, multidimensional PMTs and health-related quality of life measures are also appropriate to address specific research questions related to the measurement of pain intensity.

The measurement of pain for purposes of clinical research demand that the selected tool is valid and appropriate to the patient population and the study design. The Expert Working Group reviewed unidimensional and multidimensional pain measurement tools suitable for this purpose.

Unidimensional Pain Measurement Tools

Three types of unidimensional pain measurement tools were considered, visual analogue scales (VAS), categorical verbal rating scales (VRS), and categorical numerical rating scales (NRS). All of these approaches are commonly used to measure pain intensity and are well validated in the cancer population.[21–27] VAS, VRS, and NRS are also commonly used to measure pain relief.[25,27]

When applied in the chronic nonmalignant pain or cancer pain populations, the unidimensional pain scales—VAS, NRS and VRS can be considered equivalent. The choice should

Table 2
Recommendations for Clinical and Pain-Related Covariates to be Documented in Pain-Related Studies

Basic demographic data to be collected for all studies
1. Age
2. Sex
3. Disease diagnosis
4. Predominant pain mechanism: neuropathic, nociceptive (visceral or somatic), idiopathic
5. Performance status
6. Cognitive function: normal or impaired
7. Current analgesic therapy: Drug(s), dose(s), non-drug therapies

Other covariates that may be relevant to specific study designs
1. Stage of disease at time of study
2. Sites of metastases
3. Place of care
4. Specific pain syndrome
5. Primary therapies (i.e., antitumor treatments among patients with cancer)
6. Co-existing psychological disorder (present vs. absent, specific diagnoses)
7. Measure of cognitive function (i.e., Mini Mental Status Examination Score)

be influenced by practical considerations based on available knowledge (see also Table 3).[28]

Numerous verbal rating scales exist and use different words in different languages. The verbal 15-level scale developed by Gracely et al. for rating experimental pain can be considered a ratio scale,[14,15] but this is not proven for the many scales available in the literature. After much discussion of the issues related to translational validity of verbal rating scales, the Expert Working Group recognized that a simple intensity scale of "none, mild, moderate, and severe" is the most widely used in the clinical context, but also that scales with a larger number of intervals are more desirable, both in research and in clinical practice, because of higher sensitivity to treatment effects.[15] A validated multilingual translation of the more simple VRS does not exist, but a valid multilingual six-level VRS is presented in Appendix 1.[29]

The VAS has been studied and is often considered an ideal scale, because it is continuous, approximates a ratio scale, and is more independent from language than verbal scales (although the choice of the extreme anchor words or end-phrases can be relevant).[16,19,20,30] On the other hand, its validity more strongly depends on the appropriateness of administration method and of the instructions given to the study subjects.[19,20] It is, therefore, more difficult to use than other scales.

Evidence suggests that numeric rating scales are easier to apply and are associated with better compliance than the VAS.[28,31] Based on the available evidence,[17,28,32] the use of a standard 0–10 numeric rating scale and 100-mm horizontal visual analogue scale can be recommended. Although these are typically administered with pen and paper, other valid approaches include the use of touch screens for VAS and NRS, sliding scales, and verbally administered numeric rating scales.[20]

For purposes of intervention studies, both pain intensity and pain relief can be measured.[21,22] Pain relief can be measured by asking the patients to compare pain now with previous pain experiences. Pain relief measurement validity is limited to short-term intervention studies (24 hours or less); in chronic studies, its validity has been seriously questioned[33] and the construct underlying its meaning in descriptive studies is uncertain.[5,6,34,35]

Multidimensional Pain Measuring Tools

Three multidimensional scales were considered, the McGill Pain Questionnaire, the Brief Pain Inventory, and the Memorial Pain Assessment Card. Although recognizing that other instruments exist[36] or are under study,[37,38] the Expert Working Group recommends the use of the Short form of the Brief Pain Inventory or the McGill Pain Questionnaire. Both of these tools are well validated in multiple languages and are thus suitable for application in an international setting. The Expert Working Group withheld recommendation of the Memorial Pain Assessment Card[35] because it is not validated in languages other than English.

The Brief Pain Inventory (BPI)[39] is a simple and easy to administer tool that provides information about the history, intensity, location, and quality of pain. Numeric scales (range 0 to 10)

Table 3
Evidence-Based Criteria Adopted for Recommending Pain Measurement Tools

Scale	Ease of Administration	Validity	Sensitivity to Treatment Effect	Validated in Palliative Care	Multilingual Validity
VAS	− Kremer et al. 1981[31] − Briggs et al. 1999[60]	+ Scott & Huskinsson 1976[16] + Price et al. 1994[20] + Jensen et al. 1986[28]	+ Littmann et al. 1985[27] + Joyce et al. 1975[64]	+ De Conno et al. 1994[61]	NA
NRS 0-10	+ Kremer et al. 1981[30] + Jensen et al. 1986[28]	+ Jensen et al. 1986[28] + Jensen et al. 1993[18] + Jensen et al. 1994[32]	+ Farrar et al. 2000[66]	+ De Conno et al. 1994[61]	+ Serlin et al. 1995[40]
VRS	+ Jensen et al. 1986[28]	+ Jensen et al. 1986[28] + Gracely et al. 1978[14]	+/− Littman et al. 1985[27]	+ De Conno et al. 1994[61]	+ Bullinger et al. 1998[29]
Relief	NA	+/− De Conno et al. 1994[61] + Wallenstein et al. 1980[25] − Fishman et al. 1987[35] − Feine et al. 1998[33]	+ Littman et al. 1985[27] + Farrar et al. 2000[66]	+ De Conno et al. 1994[61]	NA
BPI	+/− Twycross et al. 1996[48]	+ Serlin et al. 1995[40] +/− Twycross et al. 1996[49]	? Twycross et al. 1996[49]	+ Twycross et al. 1996[49]	+[a]
McGill	NA. The expert consensus was that this instrument is more demanding than others	+ Melzack 1975, 1985[50, 52] +/− Holroyd et al. 1992[62]	+ Melzack 1985[52] − De Conno et al. 1994[61]	+ Graham et al. 1980[51] + Dudgeon et al. 1993[53] + De Conno et al. 1994[61]	+/−

NA = not available; + Studies providing evidence for validity; − Studies not providing evidence of validity; +/− Studies offering mixed results
[a] See text for full list.

indicate the intensity of pain in general, at its worst, at its least, and right now. A percentage scale quantifies relief from current therapies. A figure representing the body is provided for the patient to shade the area corresponding to his or her pain. Seven questions determine the degree to which pain interferes with function, mood, and enjoyment of life. The BPI is self-administered and easily understood, and has been translated and validated in many different languages.[40–48] A Norwegian (S. Kaasa, personnal communication), and Spanish (J.M. Nunez-Olarte, personal communication) validation are ongoing. It is suitable for repeated evaluation of pain—that is, weekly or bi-weekly—but its use for this purpose needs further study.[49]

The McGill Pain Questionnaire (MPQ)[50] is a self-administered questionnaire that provides global scores and subscale scores that reflect the sensory, affective, and evaluative dimensions of pain. It has been validated in cancer pain.[51] A short form of the MPQ (SF-MPQ) was developed for use in research settings.[52,53] The SF-MPQ consists of 15 representative words from the sensory ($n = 11$) and affective ($n = 4$) categories of MPQ. The Present Pain Index, verbal rating scale, and a visual analogue scale (VAS) measuring pain intensity is included. The 15 words are scored using a 4-point verbal rating scale, ranging from none, mild, moderate, to severe pain. The SF-MPQ correlates highly with the MPQ. Whereas the MPQ is available in many languages, the SF-MPQ is not.

Health-Related Quality of Life Measures

Several measures of health-related quality of life (HRQL) have been developed and internationally validated during the last decade.[54] These measures are multi-dimensional and in-

clude several domains, such as physical function, psychological function, social function, and various symptoms which are prevalent in advanced medical illnesses. Pain is included as a single item or as a dimension in many of these measures. The European Organization for Research and Treatment of Cancer (EORTC) quality-of-life questionnaire has been specifically designed for the use in oncology clinical trials in a multicenter multilingual setting[55,56] and has a pain-related scale.[57]

By using a measure of HRQL, a more comprehensive picture of the patient's total symptom burden and function might be obtained. This may be favorable when compared to using one scale or one measure for pain. However, HRQL instruments are long and can be difficult to complete for patients with reduced performance status. HRQL should be included in descriptive studies and in prospective phase III studies. At the moment, research in HRQL measures and pain is still insufficient to make specific recommendations on which tool should be used in pain-related studies.[54,58,59]

Summary of Criteria Adopted for Recommendation

Table 3 summarizes some of the evidence that can be used to support the appropriateness of the PMTs considered. The use of a scale can be recommended according to several criteria. Practicality and appropriateness for palliative care studies were emphasized.

1. Ease of administration. This criterion has obvious practical implications. Between two instruments sharing all other psychometric properties the choice should favor the one that maximizes patients' compliance. In this respect, the VAS may have disadvantages when compared with other instruments, especially in the elderly,[31,60] although some have found that the percentage of incorrect responses with the VAS is higher but comparable with those obtained with other instruments.[28] The BPI is usually considered easy to complete, but in one study that employed this questionnaire for clinical purposes, the percentage of missing responses and of noncompliant patients in repeated administration was relatively high.[49]

2. Validity. This criterion is fundamental and guarantees that the instrument measures what it is meant to measure (within the limited aims of our review, pain intensity). Human sensation has no external "gold standard" with which to compare empirical measures, and indirect methods of inferring validity are necessary. These may include concurrent validity with other supposedly valid measures,[16,20,25,61] crossmodality matching,[14,15] matching of experimentally-administered pain stimuli with clinical pain,[19] and factor analysis.[28,39,61,62]

The pain intensity measures obtained with VAS, VRS, and NRS are valid; the assessment of pain relief has been demonstrated to be valid in the short-term assessment of analgesics[25] and when used over intermediate periods of time,[61] but it is problematic in longer-term evaluation.[33,35]

3. Sensitivity to treatment effect. Sensitivity to change can be considered one aspect of validity. The measure must be shown to be valid for the use for which it is recommended.[63] For the use of PMTs in clinical trials, a scale should show changes in pain intensity when a change is expected. Sensitivity to treatment effects of VAS, NRS, and VRS for pain intensity and short-term relief is well demonstrated.[27,52,61,64–66] The only study[49] that evaluated repeated administration of the BPI in a clinical context demonstrated that clinical changes can be detected by this instrument, but did not specifically address sensitivity (for this reason, this point is associated with a question mark in Table 3). Data on the McGill Pain Questionnaire are variable.[52,61]

4. Validation studies in palliative care. Data on the validity and reliability of an instrument in the specific area of interest are relevant to establish its specific value and recommended use.[51,53]

5. Multilingual validity. The availability of multilingual and multicultural validity and reliability data is particularly relevant because these recommendations are made also to allow multicenter international trials. The specific use of different words as end-phrases or anchor points for the VAS has been shown to change the distribution of patient responses.[30] No study is available that assesses how the translation of intensity describing words in another language may affect the VAS and NRS measuring properties. It is advisable that the words used are strictly intensity descriptors and repre-

sent the semantic range from minimum to maximum sensation.[19] When using verbal scales, the availability of validated translations is particularly important.[29] The popularity of the BPI in recent years has led to validation in many different languages.[40] The McGill Pain Questionnaire also is available in many languages, but its complexity can be problematic in international trials. For instance, at least two validated Italian versions are available, and they are difficult to compare with the original English version.[67,68]

Other criteria can be used for discussing the validity of psychological measures and are not considered in this article. Reliability and, for multidimensional questionnaires, internal consistency are basic requirements of any psychometric instrument, and are demonstrated for all the instruments considered and reported in Table 3.

Principles in the Application of Pain Measurement Tools

Several principles are relevant when incorporating a PMT into the methodology of a descriptive or interventional study:

1. Appropriateness: The selected tool must be appropriate to the study design and the intended study population.
2. Frequency of application: The frequency of pain measurement must be relevant to the research question to be addressed and the study population. It must be practical and not excessively burdensome.
3. Data collection: Data should be collected in a standardized format, which is applied identically to all participating patients. The procedure should be documented as part of the study protocol. Where the patient population is heterogeneous and comprises subpopulations that require different measurement approaches, contingencies for the application of differing methods of group specific data collections should be documented. However, in general, it is not recommended that different measurement approaches be applied subpopulations in the same study.
4. Documentation of demographic and pain-related covariates: The Expert Working Group recommends documentation of the demographic and clinical covariates listed in Table 2.

Recommendations of the Expert Working Group for the Selection of Pain Measurement Tools for Specific Study Types

Based on the available evidence, the Expert Working Group offered recommendations for the selection of PMTs for specific types of studies.

Prevalence/Severity Studies

1. Adult patients with no cognitive impairment: The Brief Pain Inventory-Short Form was considered the preferred tool for this purpose. Data should be analyzed with respect to pain severity and pain interference with function. These two outcomes, therefore, should be used in the sample size estimation of the study.
2. Adult patients with cognitive impairment: Where possible, pain severity should be assessed using the standard 4-point verbal rating scale for pain present at the moment of interview (none, mild, moderate, severe). Additional desired data include satisfaction with pain relief and whether or not pain level is acceptable.
3. Adult patients who are unable to communicate: Observer rating using the 4-point VRS for pain now.

Trajectory Studies

1. Adult patients with no cognitive impairment: When long-term variability is evaluated, the Brief Pain Inventory-Short Form is the preferred tool for this purpose. Data should be analyzed with respect to pain severity and pain interference with function and to changes in these parameters over time. When short-term variability is evaluated, such as in studies of breakthrough pain, this should be supplemented with measurement of pain intensity and/or pain relief using VAS or 0-10 NRS at clinically relevant intervals.[69,70]
2. Adult patients with cognitive impairment: Where possible, pain severity should be assessed using the standard 4-point verbal

rating scale (none, mild, moderate, severe). Additional desired data include satisfaction with pain relief and whether or not pain level is acceptable.

3. Adult patients who are unable to communicate: Observer rating using 4-point VRS for pain now.

Pain Syndrome Characterization

1. Adult patients with no cognitive impairment: Co-administration of both the Brief Pain Inventory-Short Form and the short form of McGill Pain Questionnaire is recommended. Together, these tools provide excellent coverage of quantitative and qualitative pain characteristics. These data should be integrated with detailed recording of the clinical narrative, pain characteristics, exacerbating and relieving factors, response to previous trials of analgesic therapies, findings of physical examination, and relevant imaging studies.
2. Adult patients with cognitive impairment or unable to communicate: The nature of the data needed for characterization of pain syndromes requires a level of detail that cannot be derived from these patient populations. The Expert Working Group recommends that adequate cognitive function should be an inclusion criteria for studies of pain syndrome characterization.

Pharmacokinetic/Pharmacodynamic (PK/PD) Studies

1. Adult patients with no cognitive impairment: The primary pain measures in these studies are pain intensity and pain relief; pain unpleasantness has also been studied.[71] Both pain intensity and relief should be measured by using a standard VAS or 0–10 NRS. In general, the working group recommends the NRS over the VAS because of data on better compliance. These measures should be applied with a frequency appropriate to the agent under investigation.[70,72–74]
2. Adult patients with cognitive impairment or unable to communicate: The nature of the data needed for PK/PD studies requires a level of compliance that can not be derived from these patient populations. Adequate cognitive function and ability to communicate should be inclusion criteria for PK/PD studies.

Phase I and II Studies

1. Adult patients with no cognitive impairment: Repeated measurement of pain at both long-term and short-term intervals is needed. Long-term changes in pain and pain-related interference with function can be measured using the Brief Pain Inventory-Short Form at intervals of 3 days to 2 weeks. Short-term changes in pain and pain relief should be measured using a standard VAS or 0–10 NRS administered at least three times daily for 4 days.[18] Although data specific to the palliative care population are lacking, this recommendation is based on the evidence that averaging multiple measures of pain intensity across time maximizes the reliability and validity of pain assessments and is preferred to assessment of average pain over last 24 hours.[18] In general, the working group recommends the NRS over the VAS because of data on better compliance. These measures should be applied more frequently depending on the study aim and on the agent under investigation.[70,74,75]
2. Multiple dose Phase II studies should incorporate measures of adverse effects and the impact of the intervention on quality of life. For Phase I and single dose studies, quality-of-life evaluation is not needed. There are inadequate data to make firm recommendations regarding the choice of measure to record data regarding adverse effects and quality of life. However, the EORTC QLQ-C30 is the only valid HRQL instrument available in a significant number of different languages.[56]
3. Adult patients with cognitive impairment: The Expert Working Group did not recommend that patients with cognitive impairment be candidates for Phase I/Phase II studies. The development of behavioral scales (Bernard Wary, personal communication), or simplified prorated scales to measure pain, satisfaction, distress, and adverse outcomes might provide valid assessments to obtain useful in-

formation from this population in intervention studies, but trial development is, at the moment, not recommended.

Phase III Analgesic Studies

1. These studies should be restricted to patients who are cognitively intact.
2. Repeated measurement of pain at both long-term and short-term intervals should be performed. Long-term changes in pain and pain-related interference with function should be measured using the Brief Pain Inventory-Short Form at intervals of 3 days to 2 weeks. Short-term changes in pain and pain relief should be measured using a standard VAS or 0–10 NRS administered at least three times daily for 4 days. In general, the Expert Working Group recommends the NRS over the VAS because of data on better compliance.
3. The Expert Working Group recommends that all Phase III studies incorporate measures of adverse effects, quality of life, and measure of satisfaction. The same observations on the instrument of choice made for Phase II studies apply.

When a crossover design is incorporated, patient preference between the treatment arms should be ascertained.[76]

Pain Measurement Tools for Children

The following recommendations concerning pain assessment in children reflect the contribution of a separate study group organized by the EuroPain group. (List of EuroPain Collaborators: P. Poulain, MD, Chair, E. Pichard-Léandri, MD, C. Wood, MD, M. Vieyra, PhD, H. H. Abu-Saad, MD, RN, G. Schaffer Vargas, MD.) Evaluation of pain in children is always delicate and notoriously difficult, because it depends on the level of cognitive development and psychological condition of the child. The reactions to prolonged pain, as seen in palliative care, may be characterized by withdrawal and are similar to depression in its manifestations. Pain measurement tools used in children must determine the presence and the severity of pain in various conditions.

Most pain scales used in adults can also be used in children, provided they can be understood. Pain should be assessed from a multidimensional perspective by combining subjective and objective measurement tools, including self-report,[77] behavioral measures, and physiologic indicators. Physiologic measures alone cannot be interpreted simply as pain, as they are also signs of stress.[78] In children under the age of 5 and in those with developmental deficits, self-assessment is limited.[79] In older children, the correlation between self-assessment and behavioral methods is variable.[77] False replies and underrating are possible. As a result, a multidimensional approach is, in general, warranted.

Unidimensional Pain Measurement Tools

The VAS is generally the "gold standard" for children, as it is for adults. The scale has been adapted for children and is usually presented vertically. Particularly in the setting of palliative care, reliability of self-assessment will depend on the care with which it is applied to obtain measurements. NRS is used in children but they have to be old enough to count up to 10, which means they have to be school-aged children. Other tools are more useful in the preschool child. A VAS score can be obtained from a 3-year-old child, but the reply can be misleading, as at that age the child does not have the same abstract capacities of older children. They have a tendency to choose the extremities of the scale, whether for the VAS or another tool (such as the "algocube"). The Bieri Face Scale can be recommended[80,81] as it is sensitive to pain intensity and less to emotions in comparison with the Smiley Analogue Scale.[82,83] Indeed, recently it has been shown[84] that scales with smiles or tears show higher rating scores than scales with "neutral" faces (as the Bieri scale). The number of faces is also important. Although some scales show up to 9 faces, the best choice may be a scale using from 5 to 6 faces, because of the child's cognitive capacities. The Bieri scale has a shorter version (Carl Von Baeyer, personal communication). The Poker Chip Tool representing four pieces of hurt has been used in acute pain.[85]

Multidimensional Pain Measurement Tools

The McGill Pain Questionnaire and the McGill Pain Questionnaire-Short Form can be proposed to children over approximately 9 years of age. Drawings and body outlines are

specific methods for communicating with children, useful for diagnosis and followup.[86] The Pediatric Pain Assessment Tool has established content, convergent, discriminant, and construct validity.[87] The tool has been validated for use in children with cancer and is being currently used to assess the effectiveness of pain management in pediatric palliative care.

Behavioral pain assessment tools. Few behavioral measurement tools have been evaluated for their response to medication, and insufficient attention has been paid to the significance of behaviors in terms of level of pain.[88] In younger children or in children with handicaps and communication problems, these are, nonetheless, the preferred tools. Various scales have been developed for postoperative pain, but pain behavior can be different in advanced disease. Scales that have been validated for use in chronic pain conditions include the DEGR scale for cancer pain[89] and San Salvadour Scales[90] for cognitively delayed children.

The San Salvadour Scales[90] has 22 items. Many of them depend on the child's response to manipulation during physical examination, basal state, and sleep. It is correlated with the level of autonomy. It has never been used in palliative care but the relevance of palliative care in neurologically disabled children can suggest its use in special populations.

The DEGR scale[89] consists of ten indicators divided into three subgroups, voluntary expression of pain, direct signs of pain and psychomotor alterations. Observation of the child is carried out at rest, on movement, and during social interaction and play. It has been validated in French for children with cancer aged 2 to 6 years. Translations in English and Spanish are available. At the moment, it is the only available measurement tool for prolonged pain in young children. It is appropriate for younger children in palliative care but lacks the benefit of self-report.

Practical Recommendations

Recommendations for children are more difficult because of the paucity of studies addressing pain in the palliative care of pediatric patients. As a result, the recommendations here below must be adapted to the study design with the same criteria used in adults, with specific attention to the more difficult and ethically demanding situation.

1. Children with no cognitive impairment and old enough to understand: VAS, Faces scale, Poker Chip tool, MPQ, drawings.
2. Children with cognitive impairment: San Salvadour is a possibility in the absence of another tool that might apply to palliative care in the neurologically disabled child. To confirm this recommendation, further validation studies are necessary.
3. Children unable to communicate because of their age and poor physical status: DEGR.
4. For the younger children (<2 years), the DEGR should be tried as no other scale is available or adapted.

Conclusions

The measurement of pain is a cardinal activity in palliative care research. The members of the Expert Working Group hope that these recommendations may assist researchers in project development. It is acknowledged that some of the recommendations address areas that have not been formally studied or validated, and are, therefore, open to study and criticism. The Expert Working Group did not attempt a systematic literature review but used a critical approach to give substantial examples for all the statements provided. All statements lacking specific references reflect the opinion of the expert consensus. When sufficient evidence existed, the recommendations underline that they should be used to implement state-of-the-art research in palliative care. The widespread application of these recommendations will facilitate greater standardization of outcomes and presentations of data, and will enhance the applicability and relevance of accumulated data to the palliative care patient population. These recommendations should also help in evaluating critically the available literature on the use of PMTs in research in palliative care.

The Expert Working Group acknowledges that other study designs and methods are feasible beyond the ones reviewed. The present recommendations will be relevant to pain measurement in most study designs. Specific study

requirements may necessitate research approaches that are not covered by our work.

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Appendix 1

Valid Translations of the Verbal Rating Scale from SF-36 (with Permission)

French: Au cours de ces 4 dernières semaines, quelle a été l'intensité de vos douleurs physiques?	entourez la réponse de votre choix
nulle	1
très faible	2
faible	3
moyenne	4
grande	5
très grande	6
English: How much bodily pain have you had during the past 4 weeks?	circle one
none	1
very mild	2
mild	3
moderate	4
severe	5
very severe	6
Italian: Quanto dolore fisico ha provato nelle ultime 4 settimane?	indichi un numero
nessuno	1
molto lieve	2
lieve	3
moderato	4
forte	5
molto forte	6
Czech: Jak velké bolesti jste mel(a) v poslednich 4 tydnech?	zakrouzkujte jedno cislo
Zadné	1
velmi mirné	2
mirné	3
stredni	4
silné	5
velmi silné	6
Danish: Hvor stærke fysike smerter har du haft i de sidste 4 uger?	soet kun én ring
ingen smerter	1
megen lette smerter	2
lette smerter	3
middelstærke smerter	4
stærke smerte	5
meget stærke smerter	6
Dutch: Hoeveel lichamelijke pijn heeft u de afgelopen 4 weken gehad?	omcirkel één cijfer
geen	1
heel licht	2
licht	3
nogal	4
ernstig	5
heel ernstig	6
Finnish: Kuinka paljon ruumiillista kipua tai särkyä olette tuntenut viimeksi kuluneiden neljän viikon aikana?	rengastakaa yksi numero
ei lainkaan	1
hyvin lievää	2
lievää	3
kohtalaista	4
vaikeaa	5
erittäin vaikeaa	6

(*continued*)

Appendix 1
Continued

German: Wie stark waren Ihre Schmerzen in den vergangenen 4 Wochen?	Bitte kreuzen Sie nur eine Zahl an
Ich hatte keine Schmerzen	1
Sehr leicht	2
Leicht	3
Mäßig	4
Stark	5
Sehr stark	6
Hungarian: Milyen erõs testi fájdalmai voltak az elmúlt 4 hébten?	csak egy számot jelöljön meg!
nem voltak	1
nagyon enyhe	2
enyhe	3
közepes	4
erõs	5
nagyon erõs	6
Norwegian: Hvor sterke kroppslige smerter har du hatt løpet av de siste 4 ukene?	sett ring rundt ett tall
ingen	1
meget svake	2
svake	3
moderate	4
sterke	5
meget sterke	6
Polish: Jak bardzo odczuwali Panstwo w ciagu ostanich 4 tygodni ból fizyczny?	zakresl jedno
Zadnego	1
bardzo lagodny	2
lagodny	3
sredni	4
silny	5
bardzo silny	6
Portuguese: Durante as ultimas 4 semanas teve dores?	circule uma
nenhumas	1
muito fracas	2
ligeiras	3
moderadas	4
fortes	5
muito fortes	6
Serbian: Da li ste osecali telesni bol, i ako jeste u kolikoj meri, tokom poslednje 4 nedelje?	zaokruziti jedan broj
bez bola	1
vro blag bol	2
blag bol	3
umeren bol	4
tezak bol	5
vrlo tezak bol	6
Slovak: Aké vel' ké telesné bolesti ste mali v piebehu poslednych 4 tyzdnov?	zakrúzkujte jednu moznost'
ziadne	1
vel' mi mierne	2
mierne	3
stredné	4
väcsie	5
t'azké	6

(*continued*)

Appendix 1
Continued

Spanish: ¿Tuvo dolor en alguna parte del curpo durante las 4 últimas semanas?	marque un solo número
no ninguno	1
sì, muy poco	2
sì, un poco	3
sì, moderado	4
sì, mucho	5
sì, muchissimo	6
Swedish: Hur mycket värk eller smärta har Du haft under de senaste fyre veckorna?	sätt en ring runt en siffra
ingen	1
mycket lätt	2
lätt	3
måttlig	4
svår	5
mycket svår	6
Turkish: Gectigimiz bir ay (4 hafta) içerisinde ne kada bedensel agrilariniz oldu?	birinin etrafina daire cizin
hiç	1
çok hafif	2
hafif	3
orta hafiflikte	4
asiri derecede	5
çok asiri derecede	6

In this questionnaire the scale is intended to evaluate pain during the previous 4 weeks. Different time frames can be chosen depending on the study requirements and aims.