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Edmonton Classification System for Cancer Pain (ECS-CP)

Administration Manual

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1. Introduction

The Edmonton Classification System for Cancer Pain (ECS-CP) Administration Manual was developed to provide a guiding framework for the use of the ECS-CP. Through further refinement, we hope that this manual will ultimately facilitate the consistent and valid use of this instrument.

This manual consists of four key sections: (1) Background, (2) Edmonton Classification System for Cancer Pain, (3) Case Studies and (4) Frequently Asked Questions (FAQs). The first section provides foundational information for the development of the original Edmonton Staging System (Bruera, MacMillan, Hanson & MacDonald, 1989; Bruera et al., 1995). The second section describes the subsequent development of the Edmonton Classification System for Cancer Pain (ECS-CP) and process for completing the instrument. In the third section, a number of case studies are included to illustrate the practical application of this instrument in the clinical setting. The final section consists of examples of frequently asked questions to further clarify the administration and use of the ECS-CP.

2. Background

Experience in treatment of cancer pain is very complex. Approximately 70% of advanced cancer patients experience pain (Portenoy & Lesage, 1999). Although well managed in the majority of patients (Ventafridda, Tamburini, Caraceni, De Conno, & Naldi, 1987; Zech, Grond, Lynch, Hertel & Lehmann, 1995), in some cases, pain management may be more difficult. For complex pain syndromes, clinicians may need to introduce different interventions and often require more time to achieve adequate pain control. This complexity of the cancer pain experience presents unique challenges for the classification of pain. To date, there is no universally accepted pain classification measure, which can accurately predict the complexity of pain management, particularly for patients with cancer pain that is difficult to treat.

In response to this gap in clinical assessment, the Edmonton Staging System (ESS), a classification system for cancer pain, was developed (Bruera et al., 1989, 1995). Difficulties in the definitions and interpretation of some aspects of the ESS led to further refinement and development of the revised Edmonton Staging System (rESS). A preliminary validation study of the rESS suggested promising results (Fainsinger et al., 2005). We expect that ongoing validation studies will always be necessary, as our understanding of cancer pain continues to evolve.

2.1 Development of the ESS

The ESS was initially developed as a prognostic indicator for cancer pain management (Bruera et al., 1989, 1995). Using the principles of the TNM classification system[a] as a guide, Bruera and his associates hoped that the ESS could provide a common language for pain classification, similar to the TNM classification system for cancer staging.

[a] *A classification system for cancer staging that classifies a cancer's spread from primary to distant sites; this system describes three components of anatomical involvement: extent of the primary tumour (T), degree of involvement of regional lymph nodes (N) and absence or presence of distant metastasis (M) (Piccirillo & Feinstein, 1996)*

The ESS is comprised of seven features that are considered to have good clinical predictive value for difficulty in achieving adequate pain control: mechanism of pain, incidental pain, daily opioid dose on admission, cognitive function, psychological distress, tolerance, and past history of alcohol or drug addiction. Depending on the combination of these features, patients are classified as having a good, intermediate or poor prognosis for pain control. Through further modification, two features, cognitive function and opioid consumption, were excluded from the ESS, as they were not found to be independently associated with the probability of obtaining good pain control (Bruera et al., 1995).

Difficulties in definitions and interpretations of some features of the ESS, however, limited use and international acceptance. For example, some features such as incidental pain, tolerance, psychological distress and addiction history, required clearer definitions if this system was going to be used nationally and internationally. Furthermore, the accuracy of this instrument's predictive value has been questioned, when most patients classified as having difficult pain syndromes could still achieve good pain control (Obiols & Lossignol, 1995).

3. Edmonton Classification System for Cancer Pain (ECS-CP)

3.1 Development of the Revised Edmonton Staging System (rESS)

To address some of the instrument's limitations, the ESS was refined, resulting in the development of a revised version, the rESS. The major change in this revision was a reduction in the number of features from seven to five: mechanism of pain, incidental pain, psychological distress, addictive behavior and cognitive function.
Other changes were made to the number of options making up each feature, as well as definitions of terms. For example, for mechanism of pain, the number of pain mechanism options was reduced from five to four, to accurately reflect the complexity of treating neuropathic pain (over other pain mechanisms). Clearer, and in some cases, new definitions for terms were introduced [e.g. incidental pain (changed to Incident pain to reflect current language), psychological distress, addictive behavior, cognitive function]. Cognitive function was reintroduced into the rESS, despite the finding that it was not considered to be a significant predictor in one study using the ESS (Bruera et al., 1995). This feature was reintroduced to reflect the degree of cognitive impairment (rather than stating whether cognitive impairment was absent or present, as with the

ESS), which is useful for assessing the patient's ability to provide an unimpaired pain history.

The tolerance feature was not included in the rESS. Tolerance is difficult to include at initial assessment given the suggested calculation that requires time to implement. As a result, in validation study designs we have included tolerance as an outcome measure. Using the initial and final (defined as the date of stable pain control/death) opioid dose, an opioid escalation index (OEI), as originally published by Bruera et al. (1989) and applied by Mercadante (1999), can be calculated:

$$\text{OEI\%} = \frac{\text{(Final MEDD - Initial MEDD) / Initial MEDD}}{\text{Total Number of Days}} \times 100$$

Note: MEDD = morphine equivalent daily dose

An initial validation study involving 746 advanced cancer patients in acute care, a tertiary-level palliative care unit and hospice settings has been completed (Fainsinger et al., 2005). The primary focus of this study was to gather inter-rater reliability estimates, as well as predictive validity evidence, for the rESS. A subsequent validation study to assess the internal structure of the instrument, using content experts, was also completed (Nekolaichuk et al., 2005). Based on these findings, definitions were further revised. These definitions will continue to evolve with future validation studies. Given its intended use as a cancer pain classification rather than staging system, the name of the instrument was changed to the Edmonton Classification System for Cancer Pain (ECS-CP). See Appendix A for a detailed description of these validation studies.

3.2 Definitions of Terms

As mentioned previously, the ECS-CP is comprised of five discrete features:

1. Mechanism of pain
2. Incident pain
3. Psychological distress
4. Addictive behavior
5. Cognitive function

A sample of the ECS-CP and definition(s) for each of the five features appear in Table 1. Detailed guidelines for using the definitions in a clinical context are included in Appendix B.

3.3 Completion of the ECS-CP

(see Appendix C for Instructions for Use).

For each feature, there are a number of possible options, ranging from three (e.g. for incident pain) to four (e.g. mechanism of pain). For each feature, only one appropriate response is selected. The selection of responses within each feature may be based on a variety of sources, including the following:

1. Clinical interview with the patient and physical examination
2. Patient's medical record
3. Administration of objective measures, such as the CAGE (Ewing, 1984) questionnaire for screening for alcohol addiction, or the Mini-Mental Status Examination (MMSE) (Folstein, Folstein & McHugh, 1975), for the assessment of cognitive function
4. Consultation with family members and other health care team members

If the patient does not have any pain directly or indirectly related to the cancer (i.e. "No" under mechanism of pain), then no further assessment is required in relation to completion of the ECS-CP. If a patient does have a specific pain syndrome, then an in-depth assessment is warranted. Based on this assessment, a pain classification profile is assigned to each patient, using the following lettering system: **N** (mechanism of pain), **I** (incident pain), **P** (psychological distress), **A** (addictive behavior), **C** (cognitive function). An initial pain classification assessment, based on the ECS-CP, is generally conducted at the first encounter with a palliative care specialist. Subsequent assessments may be conducted if the patient's condition changes and/or as additional information regarding the five pain features is obtained.

3.4 Table 1. Sample of the Edmonton Classification System for Cancer Pain (ECS-CP)

Patient Name: _____

Patient ID No: _____

For each of the following features, circle the response that is most appropriate, based on your clinical assessment of the patient.

1. Mechanism of Pain
- No No pain syndrome
- Nc Any nociceptive combination of visceral and/or bone or soft tissue pain
- Ne Neuropathic pain syndrome with or without any combination of nociceptive pain
- Nx Insufficient information to classify

2. Incident Pain
- Io No incident pain
- Ii Incident pain present
- Ix Insufficient information to classify

3. Psychological Distress
- Po No psychological distress
- Pp Psychological distress present
- Px Insufficient information to classify

4. Addictive Behavior
- Ao No addictive behavior
- Aa Addictive behavior present
- Ax Insufficient information to classify

5. Cognitive Function
- Co No impairment. Patient able to provide accurate present and past pain history unimpaired
- Ci Partial impairment. Sufficient impairment to affect patient's ability to provide accurate present and/or past pain history
- Cu Total impairment. Patient unresponsive, delirious or demented to the stage of being unable to provide any present and past pain history
- Cx Insufficient information to classify.

ECS-CP Profile: N___I___P___A___C___ (Combination of the five responses, one for each category)

Assessed by: _____ Date: _____

4. Case Studies

There are many possible combinations for pain classification, using the ECS-CP. Some examples of pain classification profiles that patients could have include:

NcIiPoAaCo: nociceptive pain, incident pain, no psychological distress, addictive behavior present, normal cognition

NxIoPoAoCi: unknown pain mechanism, no incident pain, no psychological distress or addictive behavior, impaired cognitive function

NeIoPpAaCo: neuropathic pain, no incident pain, psychological distress and addictive behaviorpresent, normal cognition

The following case studies provide further examples of possible pain classification types. At the end of each case, indicate the patient's pain classification profile, based on the ECS-CP. The appropriate pain profile for each case is listed on page 13.

Case 1: A 65-year-old man with prostate cancer and bone metastases to the left humerus and lumbar spine, presents for further follow-up. He denies any history of pain, and reports that he has remained active, independent, and sleeps well at night.

Pain Classification Profile: **N___I___P_____A_____C_____**

Case 2: A 65-year-old woman with breast cancer with metastases to the thoracic and lumbar spine and right femur, complains of a dull almost constant pain in the right upper leg and lower back. She reports that the steady pain sometimes wakes her at night. She finds that, although initially when she stands up there may be a slight increase in the back pain, this has not limited her mobility. She has been married for 40 years, and has no history of anxiety or depression. She also has no history of drug or alcohol abuse. You note during the examination that she can move without any evidence of pain. There is some tenderness to palpation over the lower back. She is able to give a clear history, and formal cognitive assessment confirms that she has no cognitive deficits.

Pain Classification Profile: **N___I___P___A___C___**

Case 3: A 65-year-old man with lung cancer has metastases to the thoracic spine and right humerus. He reports that he has constant pain in the mid back area that does not radiate. He reports the pain as 3/10, however he states that when he attempts to stand up the pain increases to 8 to 9/10. In addition, as he walks, he has to be careful with regard to his posture to avoid precipitating a major increase in his pain. He has been married to his second wife for 20 years and has no history of anxiety or depression. He has no history of drug or alcohol abuse. You note that he is able to give a clear and concise history, and more in-depth assessment during the examination confirms that he has no cognitive deficits. However, there is tenderness to palpation over the thoracic spine, and the patient grimaces in pain as he attempts to sit or stand.

Pain Classification Profile: **N___I___P___A___C___**

Case 4: A 65-year-old woman with colon cancer has extensive intra-abdominal metastatic disease with significant retroperitoneal lymphadenopathy noted on a CT scan. She complains of deep intra-abdominal burning pain, with intermittent stabbing, shooting pain down to the right groin. She reports that the pain is 5/10 most of the time, and is making it difficult for her to sleep at night. She has not noted that movement, or attempting to have bowel movements or urinating, precipitates an increase in the pain in any way. She has been married for 35 years, and has no history of anxiety or depression. In addition she has no history of drug or alcohol abuse. You note that during the history there were some inconsistencies, and she was sometimes hesitant and had difficulty in recollecting details of the last week's events. In more formal cognitive assessment, you note that she has some difficulty with concentration and recall, and a formal mini-mental state examination confirms that she has a score of 20/30, when a score of 27 would be the expected for her age and educational level.

Pain Classification Profile: **N_____I_____P_____A_____C_____**

Case 5: You are asked to see a 65-year-old man with prostate cancer with extensive metastatic disease in the pelvis, as well as bone metastases demonstrated in the skull, thoracic and lumbar spine, and bilateral humeri and femora. You obtain a history from the chart confirmed by the family, that he has deteriorated rapidly over the last few days. He has been on rapidly escalating opioid doses, however there is poor documentation that does not provide clear information with regard to the location of the patient's pain complaint. The family reports that they remember him complaining of lower abdominal and back pain, however they are unable to clarify further the nature of the pain. Further inquiry indicates that the patient has been married for 30 years, has no history of treatment for anxiety or depression. In addition he has no history of drug or alcohol abuse. On examination you find that he is completely unresponsive and unable to cooperate with the examination in any way. Examination of the abdomen does not reveal any evidence of tenderness, guarding or rigidity. In addition the patient does not respond in any way when you apply pressure over the thoracic and lumbar spine.

Pain Classification Profile: **N_____I_____P_____A_____C_____**

Case 6: A 65-year-old woman with breast cancer presents with local metastatic disease in the area of the previous right mastectomy. In addition, she has liver metastases and bone metastases to the lower lumbar spine and left femur. She complains of an almost constant dull ache over the left femur that she rates as 4/10. This sometimes keeps her awake at night. However she finds that the pain does not increase with activity and has not limited her physical function. She has some history for management of anxiety and depression in the past, but indicates that with some counseling through her family physician and support from a psychiatrist she was able to resolve some of her difficulties and has not been on antidepressants for 5 or 6 years. She has no history of drug abuse, but indicates that she has drunk heavily in the past, particularly when she encountered stressful life experiences. When asked the CAGE questions, she answers 4/4, and states that she has had intermittent episodes of binge drinking during the course of her cancer illness. She does continue to drink 1 to 2 glasses of wine at night with dinner. You note that she is able to give a clear history, and more in-depth assessment during examination confirms that there are no cognitive deficits. There is some tenderness to palpation over the upper left leg, but you note that the patient moves comfortably from the chair to the examining bed without any difficulty.

Pain Classification Profile: **N___I___P___A___C___**

Case 7: A 65-year-old man with lung cancer with metastases to the liver has been noted to develop increasing cognitive deficits with attempts to control his pain with increasing opioid doses. He gives a history of constant pain in the right upper quadrant that he rates as 8/10. He states that the pain has been like this for the last few weeks. He finds the situation extremely distressing and has not been able to sleep at all. You note that he is tearful and emotionally labile. His family reports that he is constantly requesting extra doses of his opioid analgesic and that he has become increasingly forgetful and appears to have hallucinations particularly when he is drowsy. Paradoxically they note that he had been sleeping intermittently for hours at a time. He often falls asleep shortly after demanding an extra dose of opioid before taking the medication. He has no history of drug or alcohol abuse. However, he has a history of anxiety and depression, and has always had difficulty in coping with stressful family and work situations. He was markedly distressed when diagnosed with lung cancer, and has had difficulty accepting the news of the progression of his cancer with the development of liver metastases. On examining the patient you note that he is quite drowsy, and is only able to score 18/30 on the mini-mental state examination. There is no evidence of tenderness to palpation over the right upper quadrant where you note a 7 to 8 cm hepatomegaly.

Pain Classification Profile: **N___I___P___A___C___**

Case 8: A 65-year-old woman with colon cancer has intra-abdominal metastatic disease, as well as metastatic disease to the C4 and 5 area. She complains of constant pain in the neck area, which she rates as 3/10. In addition, there is a marked shooting, stabbing pain going down to the left shoulder and left arm, which she describes, 7 to 8/10. She notes that whenever she attempts to move her head, the pain increases in severity to 10/10 and causes her extreme distress. The patient has been married and divorced three times, and lives on her own in a second floor walk up apartment. Over the last few years she has been managed for anxiety and depression with a variety of benzodiazepines and antidepressants. She acknowledges that in her teens and twenties she did use intravenous drugs intermittently. Subsequent to that time she has continued to drink heavily, and reports her CAGE as 4/4. She acknowledges that her intermittent heavy alcohol consumption has continued up to the present. You note inconsistencies in the patient's history and that although she complains of unrelenting pain that limits her mobility, she has been noted to walk independently out of the institution on a daily basis when she has needed to smoke. During the examination you note that she is drowsy and is only able to score 15/30 on the mini-mental state examination, with a normal expected score of 24 for her age and educational level. There is certainly tenderness to palpation over the cervical spine with increased sensitivity and discomfort with light touch over the left shoulder and left arm.

Pain Classification Profile: **N___I___P___A___C___**

Pain Classification Profiles (answers):

Case 1	No	Case 5	NxIoPoAoCu
Case 2	NcIoPoAoCo	Case 6	NcIoPoAaCo
Case 3	NcIiPoAoCo	Case 7	NcIxPpAoCi
Case 4	NeIoPoAoCi	Case 8	NeIiPpAaCi

5. Frequently Asked Questions (FAQ)

Mechanism of Pain

1. **How would you classify multiple pain etiologies? For example, how would you classify someone who might present with three different pain etiologies: nociceptive (Nc), neuropathic (Ne) and unknown (Nx)?**
   The ECS-CP classification system is based on a hierarchy of *mechanism of pain* features, in which neuropathic pain represents a greater management challenge than nociceptive pain. If a patient presents with multiple pain etiologies, then the default classification would be the one with the greatest management challenge. Thus, in the example above, in which a patient presents with three pain etiologies, one of which is neuropathic pain, you would classify the mechanism of pain as neuropathic. This is also addressed in the descriptor for neuropathic pain (Ne), which refers to "neuropathic pain syndrome **with or without** any combination of nociceptive pain."

2. **Where would you classify "treatment-related" pain?**
   A variety of treatments such as surgery, radiotherapy or chemotherapy can result in pain. Based on your assessment, this pain syndrome could then be classified as either neuropathic or nociceptive.

3. **As we learn more about unique aspects of visceral pain syndromes and the role of the autonomic nervous system, will the classification system hold up?**
   It is anticipated that over time these basic mechanisms of neuropathic, nociceptive, and somatic and visceral pain syndromes may need to evolve to reflect new developments. However, as the standard teaching still relies heavily on the differentiation between neuropathic and nociceptive pain syndromes, we have continued to maintain this approach at the present time. Any future changes would need to be based on further validation studies.

4. **How would we classify a patient seen on initial consultation who has a known cancer pain syndrome, which is fully controlled at the time of assessment (pain rated as 0/10)? (e.g. if a breast cancer patient has had pain on and off for 10 years which is controlled with Acetaminophen prn but she has no current pain)**
   You appear to be describing a patient with a cancer pain syndrome so it would be wrong to classify this as **No**. It would certainly be a rare patient whose pain is always 0, but in any event even if the patient has no pain now, they are by definition on pain management for previous complaints of pain. The reason the pain is so well managed is because of the underlying characteristics which would typically be **NcIoPoAoCo**.

   However if you are describing an extreme example of a long surviving breast cancer patient who has not needed to take the Tylenol prn for months as the hormonal management & radiotherapy has resulted in no pain all this time you would classify this as **No**. However, if the patient needs to take the prn Tylenol from time to time due to the bone metastases then it is **NcIoPoAoCo**. The time interval of no pain is subjective and this is open to some interpretation - the key question would be "does the patient still feel the need to have a prn analgesic available?" If so this is <u>not</u> **No**.

Incident Pain

1. **Can patients have incident pain without background pain?**
   Some patients may indeed have incident pain without background pain, e.g. a patient with a pathological fracture may have no pain at rest but severe pain with movement.

2. **Is the trigger always predictable?**
   Pain syndromes are too diverse for an "always." The definition reflects this with the inclusion of "often a known trigger."

3. **How would you classify a patient who has lancinating pain with movement? Would this be classified as Ne or NeIi?**
   The appropriate classification would be NeIi.

4. **(a) I usually think of incident pain as having a movement trigger. Crampy bowel pain could be incident pain in your definition. Is that what you had intended?**
   The definition of incident pain has been specifically worded in order to allow inclusion of problematic episodic pain. Obviously, there always has to be some room for clinical interpretation and an occasional complaint of an episodic pain of mild intensity would have a very different significance to a patient complaining of hourly and unpredictable episodic cramping abdominal pain that has no known trigger.
   (b) It was my impression that the triggers for incident pain are limited to physical mobility. Should the definition be restricted to exclude other triggers such as swallowing, micturition or defecation?
   Given that triggers such as swallowing, micturition and defecation are predictable, they would be included under incident pain.

5. **Why must the intensity of the background pain be less than or equal to moderate intensity?**
   Background pain must be less than or equal to moderate intensity, as it would be impractical to determine if someone has significant incident pain in the presence of severe background pain. This clinical point is recognized in definitions in the literature. The Ix option can always be used if there is uncertainty or insufficient information to classify at that time.

Psychological Distress

1. **Is it conceivable that a patient may be coping appropriately, yet still experience suffering?**
   It is inevitable that patients have nuanced presentations of psychological distress. The clinical assessment could be that the patient is coping appropriately, yet still experiencing significant pain and suffering. The interpretation would then be that the patient does not have psychological distress that is exacerbating the expression of pain. We can anticipate that the assessment of this feature will sometimes be difficult. Further validation studies using the standard definition and guidelines will help to inform our success in standardizing this assessment.

Addictive Behavior

1. **Why is cigarette smoking not included in the definition for addictive behavior?**
   This is an interesting question. While there is significant literature on the impact of past history of alcohol and other substances of abuse on pain management outcomes, there is insufficient literature to suggest that cigarette smoking is associated with significant negative outcomes in terms of pain management at present. This is an important area for future research.

Cognitive Function

1. **How would you classify a patient who can describe his/her present pain, but cannot give a past pain history?**
   This patient would be classified as Ci for partial impairment as the definition states that the patient can provide a present history but not a past pain history.

2. **Why limit the ability to provide a history to pain alone?**
   The cognitive assessment was limited to a pain history since the ECS-CP is a pain classification system. Other global cognitive assessment measures, such as the Mini-Mental Status Examination (MMSE), may also be included as part of the screening process, if appropriate.

3. **Why is the Mini-Mental Status Examination (MMSE) not included in the definition for cognitive function?**
   Although the MMSE is widely used, not everyone agrees that this is the best cognitive screening tool. There is also the added complexity of cut-off scores that vary widely with education, culture and age.

General

1. **How often are the assessments done?**
   An initial pain classification assessment, based on the ECS-CP, is generally conducted prior to pain management (e.g. on admission to a palliative consultation service). Subsequent assessments may be conducted if the patient's condition changes and/or as additional information regarding the five pain features is obtained.

2. **Is this assessment purely subjective? Are there quantitative assessments that might be incorporated with the use of the ECS-CP?**
   The ECS-CP is intended to be used in conjunction with objective measures, such as a pain visual analog scale, the CAGE questionnaire as a screen for alcohol addiction (Ewing, 1984), or the Mini- Mental Status Examination (MMSE) (Folstein, Folstein & McHugh, 1975), for the assessment of cognitive function. Other quantitative measures may be used to assist in the assessment process according to local circumstances and practice.

3. **Should the staging of pain syndromes be added to one another over time, as the patient's pain profile changes? For example, a patient could initially be classified as NeIoPoCi and later be classified as NeliPpCi. How do we account for these changes?**
   It would be natural to expect that some patients' pain syndromes will evolve over time based on issues such as disease progression, or further knowledge gained from ongoing assessments. As a result, updates to account for these changes could occur at any time.

4. **How would you assess a patient if only some, but not all, of the characteristics in the guidelines for use are present?**
   The guidelines were added to help people apply the definitions, as opposed to requiring that a certain number of characteristics be present. We have deliberately maintained flexibility to accommodate clinical experience and judgment. With further research and evolution of this tool, these guidelines may become more definitive.

6. Summary

The ECS-CP offers great promise for use as a routine clinical assessment instrument for pain classification in cancer patients. A number of studies have been conducted to gather validity evidence for the ECS-CP (see Appendix A). These studies have demonstrated the credibility of the ECS-CP as a reliable and valid pain classification system. Nevertheless validation studies are ongoing with modifications to the ECS-CP and this administration manual anticipated as new evidence emerges.

At the present time, we believe the ECS-CP offers the best defined approach to predict which cancer pain patients will be more difficult or time consuming to manage. The ECS-CP enhances clinical assessment and enables physicians and the inter-disciplinary team to better manage patients' cancer pain, and better allocate resources. It also provides useful information for training palliative medicine and pain specialists in the assessment of pain staging/classification in cancer patients. Further, this system can enable researchers to compare results of outcome surveys and clinical trials in cancer pain management. It is our intention that the ECS-CP will play a significant role in prognosis, treatment planning, evaluating, and reporting research results in the assessment and management of cancer pain as we work toward the development of an international classification system for cancer pain.

7. References

Amigo P, Fainsinger RL, Nekolaichuk C, Quan H (2008). Audit of resource utilization in a regional palliative care program using the Edmonton classification system for cancer pain (ECS- CP). J of Palliative Medicine 11(6):815-818.

Bruera E, MacMillan K, Hanson J, & MacDonald RN (1989). The Edmonton Staging System for cancer pain: A preliminary report. Pain, 37, 203-09.

Bruera E, Schoeller T, Wenk R, MacEachern T, Marcellino S, Hanson J, & Suarez-Almazor M (1995). A prospective multi-center assessment of the Edmonton Staging System for cancer pain. Journal of Pain and Symptom Management, 10, 348-55.

Ewing JA (1984). Detecting alcoholism: the CAGE questionnaire. JAMA, 252(14):1905-1907

Fainsinger R, Vigano A, Neumann C (2002). Reliability and predictive value of the Revised Edmonton Staging System for cancer pain: A multi-center study. Unpublished manuscript (research proposal).

Fainsinger, R., Nekolaichuk, C., Lawlor, P., Neumann, C., Hanson, J., & Vigano, A. (2005). A multicentre validation study of the Revised Edmonton Staging System for classifying cancer pain in advanced cancer patients. Journal of Pain and Symptom Management, 29(3), 224-237.

Fainsinger RL, Fairchild A, Nekolaichuk C, Lawlor P, Lowe S, Hanson J.(2009). Is pain intensity a predictor of the complexity of cancer pain management? J Clin Oncol 27:585-590

Fainsinger RL, Nekolaichuk CL.(2008). Cancer pain assessment – Can we predict the need for specialist input? European J of Cancer , 44(8):1072-1077

Fainsinger RL, Nekolaichuk CL.(2008). A “TNM” classification system for cancer pain: The Edmonton classification system for Cancer pain (ECS-CP). Supportive Care in Cancer, 16(6):547-555

Fainsinger RL, Nekolaichuk C, Lawlor P, Hagen N, Berkovitch M. Fisch M, Galloway L, Kaye G, Landman W, Spruyt O, Zhukovsky D, Bruera E, Hanson J. (2010). An international pain classification study: What are the differences in cancer pain classification across diverse palliative care sites? [abstract]. Palliative Medicine, 24 (4, Suppl): S42.Fainsinger RL, Nekolaichuk C, Lawlor P, et al. (2010). An International Multicentre Validation Study of a Pain Classification System for Cancer Patients. Euro J of Cancer, 46(16):2896-2904.

Fainsinger RL, Nekolaichuk C, Muller V. (2014). Assessing and classifying cancer Pain: Can we develop an internationally accepted common language? Journal of Palliative Care, 30(4):279-283.

Fainsinger R, Nekolaichuk C, Fainsinger L, et al. (2017). What is stable pain control? A prospective longitudinal study to assess the clinical value of a personalized pain goal. Palliative Medicine, 31(10):913-920

Folstein MF, Folstein S, McHugh PR (1975). “Mini-mental state”: a practical method for grading the cognitive state of patients for the clinician. Journal of Psychiatric Research, 12, 89-98.

Lowe SS, Nekolaichuk CL, Fainsinger RL, Lawlor PG (2008).Should the rate of opioid dose escalation be included as a feature in a cancer pain classification system? J of Pain & Symptom Manage, 35(1):51-57.

Mercadante, S., Fulfaro, F., Casuccio, A., & Barresi, L. (1999). Investigation of an opioid response: Categorization in advanced cancer patients. Journal of Pain and Symptom Management, 18, 347-352.

Nekolaichuk, C., Fainsinger, R., & Lawlor, P. (2005). A validation study of a pain classification for advanced cancer patients using content experts: The Edmonton Classification System for Cancer Pain. Palliat Med,19(6):466-76.

Nekolaichuk C, Fainsinger RL, Lawlor P, Hagen N, Berkovitch M. Fisch M, Galloway L, Kaye G, Landman W, Spruyt O, Zhukovsky D, Bruera E, Hanson J. (2010). A predictive model for identifying complex cancer pain syndromes in patients referred to specialist palliative care services using a pain classification system [abstract]. Palliative Medicine, 24 (4, Suppl): S42

Nekolaichuk, C., Fainsinger, R., Spruyt, O., Galloway, L., Fisch, M., Kaye, G., Hanson, J., Bruera, E., Zhukovsky, D., Landman, W., Bercovitch, M. & Lawlor, P. (2011). An international pain classification system: How reliable are the assessments across different raters? [abstract]. Journal of Pain and Symptom Management, 41(1), 196-197.

Nekolaichuk, C. L., Fainsinger, R. L., Aass, N., Hjermstad, M. J., Knudsen, A. K., Klepstad, P., & Kaasa, S. (2013). The Edmonton Classification System for Cancer Pain: Comparison of pain classification features and pain intensity across diverse palliative care settings in eight countries. J of Palliative Medicine, 16(5):516-523

Nekolaichuk CL, Fainsinger RL, Lawlor P. (2013). Challenges of conducting research on cancer pain classification: How do we make sense of the outcomes? J of Palliative Medicine, 16(11): 1323-1325.

Obiols M, Lossignol D (1995). A staging system for cancer pain. Supportive Care in Cancer, 5, 357.

Piccirillo , J. F., & Feinstein, A. R. (1996). Clinical symptoms and comorbidity: Significance for the prognostic classification of cancer. Cancer, 77(5), 834-842.

Portenoy RK, Lesage P. (1999). Management of cancer pain. Lancet, 353, 1695-1700.

Ventafridda V, Tamburini M, Caraceni A, De Conno F, Naldi F (1987) A validation study of the WHO method for cancer pain relief. Cancer, 59, 850-56.

Zech DF, Grond S, Lynch J, Hertel D, & Lehmann KA (1995) Validation of the World Health Organization guidelines for cancer pain relief: A 10-year retrospective study. Pain, 63, 65-76.

Zhukovsky D, Palmer L, Bruera E, Pei B, Zhang K, Nekolaichuk C, Fainsinger R (2006) Characterization of cancer pain syndromes (PS) seen at a comprehensive cancer center (CCC) and pain response (PR) to palliative care consultation (PCC) [abstract]. Journal of Clinical Oncology, 24(18 Supp, June 20), 8551.

8. Appendices

Appendix A
Detailed Description of ECS-CP Validation Studies

Study 1: Pilot study.
An initial pilot study, involving 82 patients with advanced cancer, was designed to determine patient accrual patterns, conduct power analysis calculations and refine data collection methods for further validation studies. Based on these findings, definitions of four of the five features, as well as the research design for the subsequent regional multicentre study (i.e. Study 2), were refined. An additional category for no pain syndrome (i.e. No) was added to the mechanism of pain feature, to exclude the possibility that an absent descriptor could imply a failure to complete the assessment.

Study 2: A multicentre validation study of the Revised Edmonton Staging System for classifying cancer pain in advanced cancer patients (Fainsinger et al, 2005).
A multicentre validation study involving advanced cancer patients in tertiary palliative care, acute care and hospice settings has recently been completed within the province of Alberta. The primary focus of this validation study was to gather preliminary inter-rater reliability estimates, as well as predictive validity evidence, for the rESS. Seven hundred and forty six patients were eligible for study entry and of these, 619 (83%) had a pain syndrome. Inter-rater reliability estimates ranged from 0.67 (pain mechanism) to 0.95 (presence of addiction). In a univariate Cox regression analysis, younger patients (< 60), patients with neuropathic pain, incidental pain, psychological distress, or co-morbid psychological distress and addiction, required a significantly longer time to achieve stable pain control ($p < 0.05$). In a multivariate Cox regression analysis, only age (< 60), neuropathic pain and incidental pain were significantly associated with time to reach stable pain control ($p \leq 0.05$). In addition to these findings, patients with neuropathic or incidental pain used significantly more modalities to achieve stable pain control ($p < 0.01$). Patients with neuropathic pain, incidental pain, as well as the presence of psychological distress or addiction, required a higher final mean morphine equivalent daily dose (MEDD) ($p < 0.001$).

Study 3: A validation study of a pain classification for advanced cancer patients using content experts: The Edmonton Classification System for Cancer Pain (Nekolaichuk et al, 2005).
Although the rESS demonstrated reasonable reliability and validity in the Regional Multicentre Study (Fainsinger et al., 2005), the development of consensus definitions for the five rESS features remained a challenge. Thus, the purpose of this third study was to gather further construct validity evidence for the revised Edmonton Staging System (rESS), as well as to develop and evaluate a rESS Administration Manual to ensure

standard use. Two content expert panels, representing regional (Panel A, n=18) and national/international (Panel B, n=52) palliative medicine and pain specialists, were purposefully selected to participate in a modified Delphi survey technique. Each panel participated in two survey rounds, with response rates of 67% (Panel A, Round 1), 39% (Panel A, Round 2), 56% (Panel B, Round 1) and 64% (Panel B, Round 2). Most participants either agreed or strongly agreed with including the five existing rESS features in a pain classification system, ranging from 67% (Panel A, cognitive function) to 100% (Panel B, mechanism of pain). Most participants suggested keeping the current definitions for these features, with some revisions. Based on participant feedback, definitions for incidental pain, psychological distress, addictive behavior and cognitive function were revised, including the development of guidelines for use. The feature name for incidental pain was changed to incident pain. Participant feedback also led to inclusion of an "unable to classify" option for each of the features. As a result, the psychological distress and addictive behavior features were separated to improve clinical and analysis utility. To reflect its intended use as a classification system, the name of the instrument was changed to the Edmonton Classification System for Cancer Pain (ECS-CP).

Study 4: Should the rate of opioid dose escalation be included as a feature in a cancer pain classification system? (Lowe et al, 2008)

The purpose of this study was to assess the need for opioid dose escalation as a feature of a pain classification system for advanced cancer patients. Opioid dose escalation was included as a prognostic feature in the original Edmonton Staging System (ESS) for pain classification, but was not included among the five features of the revised ESS (rESS): pain mechanism, incident pain, psychological distress, addictive behavior and cognitive function. Mercadante's definition of opioid escalation index percentage (OEI%) has been used as a surrogate marker for opioid responsiveness. Our hypothesis was that younger age (<60), neuropathic pain, incident pain, psychological distress and addictive behavior would be associated with an OEI% > 5%. Using data from a recent multicenter validation study of the rESS, a secondary analysis of a subsample of 532 advanced cancer patients with a pain syndrome was conducted. Approximately 44% (n = 232) of the patients had an OEI% > 5%. There were no significant associations between OEI% and age, neuropathic pain, incident pain, psychological distress or addictive behavior. As originally proposed as a clinical marker, the OEI% may oversimplify the complexity of pain management in advanced cancer patients. Future studies are required to better elucidate the need for opioid dose escalation as a feature of a cancer pain classification system.

Study 5: Is Pain Intensity predictive for complexity of Cancer Pain (CP) Management? (Fainsinger et al, 2009).

The lack of a standardized cancer pain classification system prompted the development of the Edmonton Classification System for Cancer Pain (ECS-CP). Its five features have demonstrated value in predicting pain management complexity. Pain intensity (PI) on initial assessment has been proposed as having further predictive value. We hypothesized that patients with moderate to severe cancer pain will take longer to achieve stable pain control, use higher opioid doses and require more complicated analgesic regimens than patients with mild cancer pain on initial assessment. A secondary analysis of a multicentre ECS-CP validation study, involving advanced cancer patients, was conducted (n=591). Associations between pain intensity and time to stable pain control (Cox regression); final opioid dose (Kruskal Wallis one-way ANOVA); and number of adjuvant modalities (Chi Square) were calculated. Pain intensity on initial assessment was defined as mild (0-3), moderate (4-6) and severe (7-10), using a numerical scale. Patients with moderate and severe pain required a significantly longer time to achieve stable pain control ($p<0.0001$). PI was a significant predictor of time to stable pain control in the univariate regression analysis. The four significant predictors in the multivariate model were moderate and severe PI ($p<0.0001$), age ($p=0.001$), and neuropathic pain ($p=0.002$). Patients with moderate to severe pain required significantly higher final opioid doses ($p<0.0001$) and more adjuvant modalities ($p=0.015$). PI on initial assessment is a significant predictor of pain management complexity and time to stable pain control. Incorporation of this feature into the ECS-CP needs further consideration.

Study 6: Characterization of cancer pain syndromes (PS) seen at a Comprehensive Cancer Center (CCC) and pain response (PR) to palliative care consultation (PCC) (Zhukovsky et al, 2006)

Background: Comparison of cancer PS across settings is challenging due to differences in prognostic features. Data from 1 CCC participating in a multi-site international study of a pain classification system is presented to characterize cancer PS & response to PCC. Methods: The Edmonton Classification System for Cancer Pain was completed by prospective chart review to characterize PS of 100 consecutive hospitalized patients (pts) seen in PCC. Pts were followed until major PR, hospital discharge or death. Major PR was defined as <2 p.r.n. opioid doses/d & pain intensity (PI) <3/10 for 3 consecutive days (d). Results: 85% of pts had pain (n=85), with age 62.9+13.3, 47.1% male & KPS 44.5+23.1. The most common tumor diagnoses were lung (24.7%) & GU (21.2%). Pts were followed for a median of 4 d (0-27). 39% achieved a major PR. Except for steroids (49.4%) & anticonvulsants (29.4%), other adjuvant analgesic use was all <10%.

Pain-associated features:

NRS* Initial anxiety (n=72) mean ± SD	3.7+3.0
NRS Initial PI (n=77) mean ± SD	5.8±2.7
NRS Final PI (n=46) mean ± SD	2.0±2.2
Pain mechanism (n=81) %	75.3
Only nociceptive	24.7
Neuropathic ± nociceptive	
Incident pain %	50
Any psychological distress &/or addictive behavior (n=75) %	73.3
CAGE score ≥2^ (n=81) %	13.6
Cognition (n=84)) %	
Not impaired	60.7
Partial impairment	28.6
Total impairment	10.7
Final MEDD+ median (range)	60 (0-7200)
Change in MEDD median (range)	15 (-1400-1200)

*Numeric Rating Scale 0-10, 10=worst ^suggestive of alcoholism +Mean morphine equivalent daily dose

On univariate analysis, older age (p=.006), lower initial PI (p=.003), lower final PI (p=.001) & lower final MEDD (p=.002) were significantly associated with achieving major PR. On multivariate analysis, lower initial PI (p=.03) & lower final MEDD (p=.02) retained significance for achieving major PR. Conclusions: Only 39%of pts with cancer pain seen in PCC achieve a major PR by discharge or death. Despite aggressive opioid titration, 61% do not achieve a major PR & require better pain management. Potential strategies for achieving improved PR include earlier PCC, identification of more sensitive prognostic variables & critical evaluation of targeted therapies.

Study 7: Audit of Resource Utilization in a Regional Palliative Care Program Using the Edmonton Classification System for Cancer. (Amigo et al, 2008)

Introduction: The ECS-CP is a tool that has evolved from the original Edmonton Staging System for cancer pain (ESS) developed by Eduardo Bruera in 1989 and the revised Edmonton Staging System for cancer pain (rESS) further refined by Fainsinger et al. in 2005 . The ECS- CP includes five items: mechanism of pain; incident pain; psychological distress; addictive behaviour; and cognitive function. Research with the rESS has shown that patients younger than 60 years of age, patients with neuropathic pain, incident pain, and psychological distress alone or with addictive behaviour required longer time to achieve stable pain control and a higher morphine equivalent daily dose (MEDD). Also, patients with neuropathic or incident pain used significantly more modalities to achieve stable pain control. These patients will likely require admission to a tertiary center for symptom control.

Hypothesis: The hypothesis was that patients who were more challenging to manage and were admitted to a Tertiary Palliative Care Unit (TPCU) to receive the support of the

interdisciplinary team would have a higher percentage of neuropathic pain, incident pain, psychological distress, and addiction when comparing their ECS-CP profile with patients in other areas of the program (two palliative consult services in acute care hospitals and the community).
Methods: The ECS-CP scores for patients seen in the community, the TPCU and the two consult services at the Royal Alexandra (RAH) & University of Alberta (UAH) hospitals from July 2005 until October 2006 were analyzed.
Results: There was a statistically significant higher number of patients with neuropathic pain in the TPCU at 31.7% when compared to the consult services (RAH & UAH) at 8.9% and 9.8% and the community at 16.6%. Incident pain was also statistically significantly higher in patients admitted to the TPCU at 52.5% when compared with the consult services at 19.9% and 37.6%, however there was no statistically significant difference with the community at 49.1%. Psychological distress was statistically higher in the TPCU at 49.2% versus 12.9%, 30.4% and 21.1% respectively. Addictive behaviour was not very different among sites: TPCU 13.7% versus 8.9%, 11.3% and 7.2% respectively.
Discussion: Our results demonstrate that patients admitted to the TPCU had statistically significant higher percentages of neuropathic pain, psychological distress and normal cognitive function when compared with other areas of the program; and were adequately identified by the ECS-CP. The percentage of patients with incident pain, addictive behaviour and normal cognition did not differ between patients from the consult sites/RPCP and the TPCU. Challenges remain in education for use and application of the definitions of incident pain and addictive behaviour. Although the ECS-CP is primarily a clinical tool, is also useful for auditing purposes, ensuring appropriate allocation of resources.

Study 8: An International Multicentre Validation Study of a Pain Classification System for Cancer Patients (Fainsinger et al, 2010)
Purpose: The study's primary objective was to assess predictive validity of the Edmonton Classification System for Cancer Pain (ECS-CP) in a diverse international sample of advanced cancer patients. We hypothesized that patients with problematic pain syndromes would require more time to achieve stable pain control, more complicated analgesic regimens and higher opioid doses than patients with less complex pain syndromes.
Methods: Patients with advanced cancer (n = 1100) were recruited from 11 palliative care sites in Canada, USA, Ireland, Israel, Australia and New Zealand (100 per site). Palliative care specialists completed the ECS-CP for each patient. Daily patient pain ratings, number of breakthrough pain doses, types of pain adjuvants and opioid consumption were recorded until study end-point (i.e. stable pain control, discharge and death).
Results: A pain syndrome was present in 944/1100 (86%). In univariate analysis, younger age, neuropathic pain, incident pain, psychological distress, addictive behaviour

and initial pain intensity were significantly associated with more days to achieve stable pain control. In multivariate analysis, younger age, neuropathic pain, incident pain, psychological distress and pain intensity were independently associated with days to achieve stable pain control. Patients with neuropathic pain, incident pain, psychological distress or higher pain intensity required more adjuvants and higher final opioid doses; those with addictive behaviour required only higher final opioid doses. Cognitive deficit was associated with fewer days to stable pain control, lower final opioid doses and fewer pain adjuvants.
Conclusion: The replication of previous findings suggests that the ECS-CP can predict pain complexity in a range of practice settings and countries.

Study 9: An International Pain Classification Study: What are the differences in cancer pain classification across diverse palliative care sites? (Fainsinger et al, *2010)*
Aims: There is no universally accepted system to accurately predict complexity of cancer pain management. The Edmonton Classification System for Cancer Pain (ECS-CP) was developed from the original Edmonton Staging System (ESS) for Cancer Pain (1989) and the revised ESS (rESS) (2005). This study is an extension of an international multicentre validation study of the ECS-CP. The primary objective was to classify and compare cancer pain in a diverse international sample. We hypothesized that patients in settings attracting more problematic referrals would have more complex ECS-CP syndromes.
Methods: 1100 patients were recruited from 11 specialist palliative care sites (inpatient and outpatient palliative consult services, tertiary palliative care units, hospice settings) located in Canada, USA, Ireland, Israel, Australia and New Zealand (100 per site). A palliative care specialist completed the ECS-CP for each referred cancer patient. Additional information, including daily patient pain ratings, was recorded until the study endpoint (i.e. stable pain control, discharge, death). Descriptive statistics were used to describe site differences.
Results: 944/1100 pts had a pain syndrome (86%). There was substantive variability in pain features across sites (range scores): Nociceptive 42-98%, Neuropathic 2-53%; Incident pain 20- 80%; Psychological distress 7-67%; Addictive behavior 0-20%; Cognition normal 48-88%. 14- 82% achieved stable pain control, with 3-28 median days to stable pain control. Further statistical comparisons by sites will be presented.
Conclusion: Reasons for pain classification differences across sites are multifactorial, including predictable differences in referral patterns, acuity of care, lengths of stay and interpretations amongst clinicians. By providing a common language for classifying and comparing cancer pain across diverse palliative settings, the ECS-CP can help clinicians better manage cancer pain and allocate resources.

Study 10: A predictive model for identifying complex cancer pain syndromes in patients referred to specialist palliative care services using a pain classification system (Nekolaichuk et al, 2010)

Aims: There is no universally accepted system to accurately predict complexity of cancer pain management. The Edmonton Classification System for Cancer Pain (ECS-CP) was developed from the original Edmonton Staging System (ESS) for Cancer Pain (1989) and the revised ESS (rESS) (2005). This study is an extension of an international multicentre validation study of the ECS-CP. The primary objective was to develop a predictive model for identifying complex pain syndromes in patients referred to palliative care services. We hypothesized that time to stable pain control would be longer for patients with a greater number of complex pain features.

Methods: 1100 patients were recruited from 11 specialist palliative care sites (inpatient and outpatient palliative consult services, tertiary palliative care units, hospice settings) located in Canada, USA, Ireland, Israel, Australia and New Zealand (100 per site). A palliative care specialist completed the ECS-CP for each referred cancer patient. Additional information, including daily patient pain ratings, was recorded until study endpoint (i.e. stable pain control, discharge, death). Kaplan Meier, univariate and multivariate Cox regression analyses were used to develop the predictive model.

Results: 944/1100 pts had a pain syndrome (86%). Three ECS-CP features (neuropathic pain, incident pain, psychological distress), age < 60 and initial pain intensity were included as prognostic factors in the model. Median days to stable pain control increased as the number of prognostic factors increased: 0-1 (median=5), 2 (median=10), 3 (median= 11), 4+ (median=30). Detailed univariate and multivariate regression analyses will be presented.

Conclusion: This predictive model helps identify patients with more complex pain syndromes, requiring more intense interventions. The ECS-CP could play a significant future role in evaluating and treating patients, and reporting research results in cancer pain assessment and management.

Study 11: An International Pain Classification System: How reliable are the assessments across different raters? (Nekolaichuk et al, 2011)

Aims: There is no universally accepted system to accurately predict complexity of cancer pain management. The Edmonton Classification System for Cancer Pain (ECS-CP) was developed from the original Edmonton Staging System (ESS) for Cancer Pain (1989) and the revised ESS (rESS) (2005). This study is an extension of an international multicentre validation study of the ECS-CP. The primary objective was to estimate the reliability of ratings for each of the five ECS- CP features (pain mechanism, incident pain, psychological distress, addictive behaviour, cognitive function) using different raters across diverse palliative care services.

Methods: 1100 patients were recruited from 11 specialist palliative care sites (inpatient and outpatient palliative consult services, tertiary palliative care units, hospice settings) located in Canada, USA, Ireland, Israel, Australia and New Zealand (100 per site). A

palliative care specialist completed the ECS-CP for each referred cancer patient. Additional information, including daily patient pain ratings, was recorded until study endpoint (i.e. stable pain control, discharge, death). At 6 sites, two raters independently completed the pain classification system within 24 hours of each other (n=338). Intra-class correlation coefficients were used to calculate inter-rater reliability estimates across all sites.
Results: 944/1100 pts had a pain syndrome (86%); 338/944 (36%) involved two independent raters. Inter-rater reliability estimates, in descending order, were: pain mechanism 0.81 (95% CI
.77-.84), cognitive function 0.72 (95% CI .66-.77), incident pain 0.67 (95% CI .61-.72), addictive behaviour, 0.64 (95% CI .57-.70) and psychological distress 0.52 (95% CI .44-.59). Comparisons between these estimates and inter-rater reliability estimates derived from a previous ECS-CP validation study will be presented.
Conclusion: The variability across raters, particularly for incident pain, addictive behaviour and psychological distress, highlight the complexity of assessing these features. Further research is warranted to determine the need for further training and education regarding the administration of the ECS-CP.

Study 12: Comparison of pain classification features across diverse palliative care settings in eight countries (Nekolaichuk et al, 2013)
Background: Standardized approaches for assessing and classifying cancer pain are required to improve treatment of patients with complex pain profiles. The Edmonton Classification System for Cancer Pain (ECS-CP) offers a starting point for the evolution of a standardized international classification system for cancer pain and was introduced into multi-site research initiatives of the European Palliative Care Research Collaborative (EPCRC).
Objectives: The primary purpose of this study was to describe the prevalence of the five ECS-CP pain classification features – pain mechanism, incident pain, psychological distress, addictive behavior and cognition - in a diverse international sample of advanced cancer patients.
Methods: 1070 adult advanced cancer patients were recruited from 17 sites in Norway, the UK, Austria, Germany, Switzerland, Italy, Canada and Australia. 1051/1070 patients were evaluable. A clinician completed the ECS-CP for each enrolled patient. Additional information, including pain intensity, were also collected through patient self-reports, using touch-sensitive computers.
Results: 670 of 1051 evaluable patients (64%) were assessed by a clinician as having cancer pain: Nociceptive pain (n = 534; 79.7%); Neuropathic pain (n = 113, 16.9%); Incident pain (n = 408, 60.9%); Psychological distress (n = 212, 31.6%); Addictive behavior (n = 30, 4.5%); Normal Cognition (n = 616, 91.9%). The prevalence of ECSCP features and pain intensity scores (11-item scale; 0 = none, 10 = worst; rated as now) varied substantially across sites and locations of care.

Conclusion: The ECS-CP is a clinically relevant systematic framework, which is able to detect differences in salient pain classification features across diverse settings and countries. Further validation studies need to be conducted in varied advanced cancer and palliative care settings to advance the development of the ECS-CP toward an internationally recognized pain classification system.

Study 13: What is stable pain control? A prospective longitudinal study to assess the clinical value of a personalized pain goal (Fainsinger et al, 2017)
Background: A universal consensus regarding standardized pain outcomes does not exist. The personalized pain goal has been suggested as a clinically relevant outcome measure.
Aim: To assess the feasibility of obtaining a personalized pain goal and to compare a clinically based personalized pain goal definition versus a research-based study definition for stable pain.
Design: Prospective longitudinal descriptive study.
Measures: The attending physician completed routine assessments, including a personalized pain goal and the Edmonton Classification System for Cancer Pain, and followed patients daily until stable pain control, death, or discharge. Stable pain for cognitively intact patients was defined as pain intensity less than or equal to desired pain intensity goal (personalized pain goal definition) or pain intensity $\leqslant 3$ (Edmonton Classification System for Cancer Pain study definition) for three consecutive days with <3 breakthroughs per day.
Setting/participants: A total of 300 consecutive advanced cancer patients were recruited from two acute care hospitals and a tertiary palliative care unit.
Results: In all, 231/300 patients (77%) had a pain syndrome; 169/231 (73%) provided a personalized pain goal, with 113/169 (67%) reporting a personalized pain goal $\leqslant 3$ (median = 3, range = 0–10). Using the personalized pain goal definition as the gold standard, sensitivity and specificity of the Edmonton Classification System for Cancer Pain definition were 71.3% and 98.5%, respectively. For mild (0–3), moderate (4–6), and severe (7–10) pain, the highest sensitivity was for moderate pain (90.5%), with high specificity across all three categories (95%–100%).
Conclusion: The personalized pain goal is a feasible outcome measure for cognitively intact patients. The Edmonton Classification System for Cancer Pain definition closely resembles patient-reported personalized pain goals for stable pain and would be appropriate for research purposes. For clinical pain management, it would be important to include the personalized pain goal as standard practice.

Appendix B
Definition of Terms

B-1 Mechanism of Pain

No	**No** pain syndrome
Nc	Any **noc**iceptive combination of visceral and/or bone or soft tissue pain
Ne	**Ne**uropathic pain syndrome with or without any combination of nociceptive pain
Nx	Insufficient information to classify[c]

B-2 Incident Pain

Pain can be defined as incident pain when a patient has background pain of no more than moderate intensity with intermittent episodes of moderate to severe pain, usually having a rapid onset and often a known trigger (Panel B, December 2004).

Io	No incident pain
Ii	Incident pain present
Ix	Insufficient information to classify[c]

Guidelines for Use (Panel B, December 2004):

There are six key characteristics of incident pain, as defined in the ECS:

- Relationship with background pain: The intensity of incident pain is significantly greater than background pain.
- Severity: The intensity of incident pain is moderate to severe.
- Predictability: The trigger is often known, such as movement, defecation, urination, swallowing and dressing change. However, clinically significant episodic pain (i.e. no predictable trigger) can be included (e.g. bladder or bowel spasm).
- Onset: Its onset is rapid, with intensity often peaking within 5 minutes.
- Transiency: Incident pain is transient, and may return to baseline shortly after the trigger is stopped or removed.
- Recurrence: It is intermittent, recurring when the trigger is reinitiated or reapplied.

[c] Insufficient information to classify due to factors such as questionable/unknown diagnosis, patient's unwillingness to participate or physical impairments (e.g. aphasia).

B-3 Psychological Distress

Psychological distress, within the context of the pain experience, is defined as a patient's inner state of suffering resulting from physical, psychological, social, spiritual and/or practical factors that may compromise the patient's coping ability and complicate the expression of pain and/or other symptoms (Panel B, December 2004).

Po	No psychological distress present
Pp	Psychological distress present
Px	Insufficient information to classify[c]

Guidelines for Use (Panel B, December 2004):

There are five key characteristics of psychological distress, as defined in the ECS-CP:

- Relationship with pain: The definition of psychological distress is limited to patients who are experiencing psychological distress within the context of the pain experience and who appear to express their suffering through physical symptoms.
- Relationship with suffering: It is an expression of suffering, often referred to as total pain.
- Multidimensional: It is multidimensional in nature, influencing many spheres of a patient's experience, including but not necessarily limited to physical, psychological, social, and spiritual factors.
- Relationship with coping: It may impair a patient's ability to cope with his/her illness.
- Physical symptom expression: It is often expressed as an exacerbation of pain and/or other symptoms, which may be conceptualized as a form of somatization.

Assessment (Panel B, December 2004):

- Assessment of psychological distress may include, but is not necessarily limited to, the following:
- Assessment of patient's experience in multidimensional domains
- Patient's behavioral presentation and symptom reporting profile Collateral history from primary caregivers

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[c] Insufficient information to classify due to factors such as questionable/unknown diagnosis, patient's unwillingness to participate or physical impairments (e.g. aphasia).

B-4 Addictive Behavior

Addiction is a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include one or more of the following: impaired control over drug use, compulsive use, continued use despite harm, and craving. (AAPM, APS, ASAM, 2001)

Ao Addictive behavior not present

Aa Addictive behavior present

Ax Insufficient information to classify[c]

Guidelines for Use (Panel B, December 2004):

There are five key characteristics of addictive behavior, as defined in the ECS:

- Chronicity: It is a chronic disorder, which may have periods of relapse and remission. multidimensional: It is multidimensional in its development and expression, including genetic, psychosocial and environmental factors.
- Compulsivity
- Persistent use despite harm
- Craving

This definition is limited to the following:

- A remote history of prior alcohol/substance use may not be considered relevant as a complicating factor in ongoing pain assessment and management.
- Substances of abuse include alcohol, prescription/nonprescription medications, and illicit drugs.
- It does not include chronic tobacco use.

Assessment (Panel B, December 2004):

- Assessment of addictive behavior may include, but is not necessarily limited to, the following:
- Use of a screening tool, such as the CAGE (Ewing, 1984), for possible alcohol abuse
- Patient's behavioral presentation over a series of visits
- A strong clinical history of substance abuse provided by patient
- Collateral history from primary caregivers

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c Insufficient information to classify due to factors such as questionable/unknown diagnosis, patient's unwillingness to participate or physical impairments (e.g. aphasia).

B-5 Cognitive Function

The definition for cognitive function is as follows (Panel B, July 2004):

Co No impairment: Patient able to provide accurate present and past pain history unimpaired (normal cognitive function)

Ci Partial impairment: Sufficient impairment to affect patient's ability to provide accurate present and/or past pain history

Cu Total impairment: Patient unresponsive, delirious or demented to the stage of being unable to provide any present and past pain history

Cx Insufficient information to classify: Insufficient information to classify cognitive function due to factors such as questionable/unknown diagnosis, patient's unwillingness to participate or physical impairments (e.g. aphasia)

Appendix C
Instructions for Use

1. The ECS-CP should be completed by a palliative care physician (or experienced palliative care resident) or a nurse consultant/practitioner.

2. The assessment should be completed on initial assessment/admission at each site.

3. Subsequent assessments may be conducted if the patient's condition changes and/or as additional information regarding the five pain features is obtained.