Content and Assessment methodology
Moving on – the next step in developing an International Classification System for Cancer Pain

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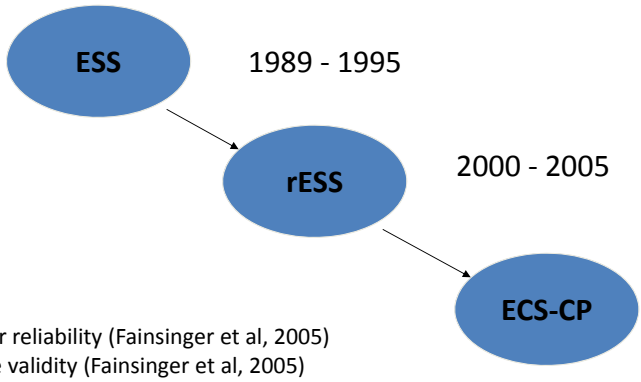
Validation journey

- One man with an idea (1987-1988)
- Single site to multicentre validation study (1989-1995)
- A group “sitting around a table” (2000-2005)
- Pilot validation study
- Multisite validation study (2005)
- Construct validation study (2005)
- International multisite validation study (2005-2010)

Development of the Edmonton Classification System for Cancer Pain (ECS-CP)



- Inter-rater reliability (Fainsinger et al, 2005)
- Predictive validity (Fainsinger et al, 2005)
- Construct validity (Nekolaichuk et al, 2005)
- Pain intensity as predictor (Fainsinger et al, 2009)
- Predictive validity in international sample (Fainsinger et al, 2010

- Bruera E, Macmillan K, Hanson J, MacDonald RN. The Edmonton staging system for cancer pain: Preliminary report. Pain 1989; 37:203-209.
- Bruera E, Schoeller T, Wenk R, et al. A prospective multicenter assessment of the Edmonton staging system for cancer pain. J Pain & Symptom Manage; 1995; 10:348-355.
- Fainsinger RL, Nekolaichuk CL, Lawlor, et al. A multicentre study of the revised Edmonton staging system for Classifying cancer pain in advanced cancer patients. J Pain & Symptom Manage 2005; 29(3):224-
- Nekolaichuk C, Fainsinger R, Lawlor P. A validation study of a pain classification system for advanced cancer patients using content experts: The Edmonton classification system for cancer pain. Palliative Medicine 2005; 19(6):466-476

- Lowe SS, Nekolaichuk CL, Fainsinger RL, Lawlor PG. Should the rate of opioid dose escalation be included as a feature in a cancer pain classification system? J Pain & Symptom Manage 2008; 35(1):51- 57
- Fainsinger RL, Fairchild A, Nekolaichuk C, Lawlor P, Lowe S, Hanson J. Is pain intensity a predictor of the complexity of cancer pain management? J of Clinical Oncology 2009; 27(4):585-590
- Amigo P, Fainsinger RL, Nekolaichuk C, Quan H. Audit of resource utilization in a regional palliative care program using the Edmonton classification system for cancer pain (ECS-CP). J of Palliative Medicine 2008; 11(6):815-818
- Fainsinger RL, Nekolaichuk C, Lawlor P, et al**.** An International Multicentre Validation Study of a Pain Classification System for Cancer Patients. Euro J of Cancer 2010;46(16):2865-2866

New perspectives

- Knudsen AK, Aass N, Fainsinger R, et al Classification of pain in cancer patients – a systematic review Palliat Med 2009;23:295–30
- Kaasa S, Apolone G, Klepstad P et al. Expert conference on cancer pain assessment and classification – the need for international consensus: Work proposals on international standards. BMJ Support Palliat Care, doi:10.1136/bmjspcare-2011-000078
- Knudsen AK, Brunelli C, Klepstad P, et al Which domains should be included in a cancer pain system? Analyses of longitudinal data. Pain 2012;153:696-703

- Complex, multidimensional nature of cancer pain continues to present unique challenges for pain classification
- The items included in the ECS-CP represent only initial efforts to define a standard core of variables
- Additional items - pain intensity, pain relief, pain localization, sleep disturbance, age, cancer diagnosis and genetic variations identified as candidates for further evaluation for inclusion in a pain classification system

Admin manual & Quick User Guide

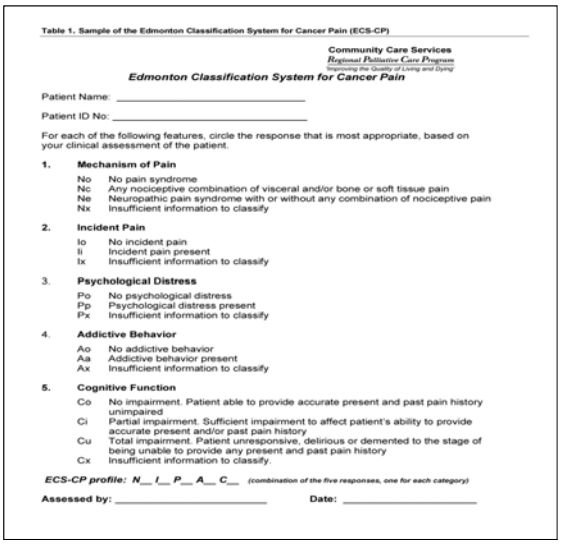


Table 1. Sample of the Edmonton Classification System for Cancer Pain (ECS-CP)

Community Care Services
Regional Palliative Care Program
"Improving the Quality of Living and Dying"

Edmonton Classification System for Cancer Pain

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:** _____

New pain terminology: A work in progress
Jensen & Gebhart Pain 2008;140;399

- "some classification is better than none and no classification is fixed for all time. As our knowledge about pain mechanisms and pain states increases and changes over time, so too will the terms change that we use to communicate. Accordingly it is to be expected that ……..the classification of chronic pain will continue to evolve and change….."

Content considerations

Patient generated	Clinician generated – ECS-CP	Outcome measures
Pain Intensity	Mechanism e.g. neuropathic	Stable pain control
Pain localization	Incident (& episodic pain)	Personalised patient pain control goal
Pain relief	Psychological distress	24 hour Opioid dose
Age	Addiction	Opioid dose escalation/Analgesic tolerance
Sleep disturbance	Cognition	Adjuvant analgesics
Cancer diagnosis		Adjuvant modalities
Genetic variation		Interdisciplinary team requirements

Research Hypothesis for future study

- *Patients with less problematic pain features, as classified by the ECS-CP, lower pain intensity and **other included variables** , will require a shorter time to achieve stable pain control, require less complicated analgesic regimens, be more responsive to opioid therapy and use lower opioid doses than patients with more complex pain syndromes.*

No problem!

Patient generated	Clinician generated – ECS-CP	Outcome measures
Pain Intensity - 1/10	Mechanism - nociceptive	Stable pain control
Pain localization – right shoulder	No Incident (& episodic pain)	Personalised patient pain control goal
Pain relief - 100%	No Psychological distress	24 hour Opioid dose
Age -70	No Addiction	Opioid dose escalation/Analgesic tolerance
Sleep disturbance - none	Normal Cognition	Adjuvant analgesics
Cancer diagnosis - Lung		Adjuvant modalities
Genetic variation - ?		Interdisciplinary team requirements

Big problem!

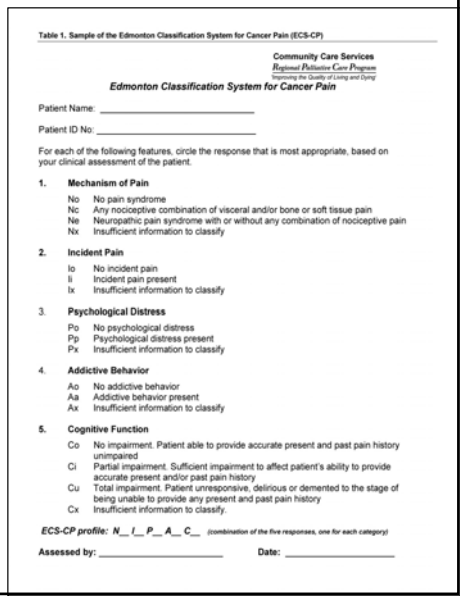
Patient generated	Clinician generated – ECS-CP	Outcome measures
Pain Intensity – 9/10	Mechanism - neuropathic	Stable pain control
Pain localization – multiple sites	Incident pain "15/10"	Personalised patient pain control goal
Pain relief – 10%	Psychological distress present	24 hour Opioid dose
Age - 45	Addiction to BZDs and alcohol	Opioid dose escalation/Analgesic tolerance
Sleep disturbance - severe	Cognition - impaired	Adjuvant analgesics
Cancer diagnosis - Lung		Adjuvant modalities
Genetic variation - ?		Interdisciplinary team requirements

Sample

- 1000 cancer patients
- Primary inclusion criteria patients with cancer, 18 years of age or older, who have been referred to a palliative care service
- Patients who do not have a cancer diagnosis or who have a nonmalignant pain syndrome will be excluded from this study
- Patients with cancer pain directly or indirectly related to the cancer will be included

Measures

- ECS-CP – use Quick User Guide
- Initial and final ECS-CP
- ? Track ECS-CP changes over time



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   - 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
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4. **Addictive Behavior**
   - Ao No addictive behavior
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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:** _____

Diagnosis of Neuropathic Pain

- The NeuPSIG criteria for defining and grading neuropathic pain (NP):-
- 1. Pain distribution is neuroanatomically plausible.
- 2. History is suggestive of a relevant lesion or disease.
- 3. Negative or positive sensory signs within innervations territory of lesion are present.
- 4. A diagnostic test confirms lesion or disease.

- First 2 criteria – possible NP
- Addition of either 3 or 4 – probable NP
- All 4 criteria present – definite NP
- ? Include painDETECT and/or LANSS

Pain Numerical Rating Scales

- Use a 10-item scale, ranging from 0 (no pain) to 10 (worst possible pain) rated for **now and average pain for the last 24 hours.**
- Patients will rate their level of pain intensity on the day of initial assessment and then daily until study termination.
- If patients are unable to rate pain now &/or for the last 24 hours due to cognitive impairment this information can be completed with assistance (e.g. clinician and/or family) and recorded as proxy data.
- As we start adding variables that are not part of standard practice we will need to consent patients and add to the burden of the study and lose generalizability with lack of inclusion of cognitively impaired populations.

Personalized Pain Goal (PPG)

- Patients with cognition sufficiently intact (as judged by the clinician) will be asked to describe on a 0 -10 scale the pain intensity level that will allow them to achieve comfort in physical, functional, and psychosocial domains (routine practice in the included sites).

Other assessment issues

- Possible additional screening for psychological distress
- Consider possible variation or addition to addiction assessment
- Other items for inclusion to be determined e.g. location of pain, sleep disturbance, anxiety, depression, wellbeing, pain relief

Information recorded until study termination

- Daily pain intensity as recorded by cognitively intact patients only using the Pain-NRS.
- Daily number of breakthrough pain doses.
- Final MEDD at study termination.
- Number and type of adjuvant analgesics and/or other treatments used during the trajectory of care from first assessment to study termination.
- Date of and reason for study termination (achievement of stable pain control, death, or discharge resulting in loss of follow-up)

Stable pain control

- Stable pain control will be defined as receiving less than three breakthrough analgesic doses per day and a patient self-reported pain score of less than or equal to 3/10 for three consecutive days
- Or achievement of the patient PPG for 3 consecutive days.
- Follow until both versions of stable pain control are achieved.
- If the patient is unable to self-report pain, then stable pain control will be defined as receiving less than three breakthrough analgesic doses per day for three consecutive days.

Stable Pain Control

For 3 Consecutive Days:	Cognitively Intact	Cognitively Impaired
< 3 PRN doses per day	√	√
Pain-NRS ≤ 3/10 Or ≤ PPG	√	

Ethical issues

- Informed consent will not be obtained from patients, as we will only be collecting clinical data routinely documented in all services
- Will need to get consent if we add data collection beyond standard practice or consider consenting a subset of patients.

Data Analysis

- *Predictive value of the Model* - Kaplan-Meier survival curves to estimate the probabilities of achieving stable pain control over time for the explanatory variables
- ? look at the number of risk factors as another predictive model
- Could also do a prediction model with cognitively intact patients only
- Associations with adjuvant treatments and opioid doses

Content considerations – still a cause of sleep disturbance!

Patient generated	Clinician generated – ECS-CP	Outcome measures
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Age	Addiction	Opioid dose escalation/Analgesic tolerance
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Cancer diagnosis		Adjuvant modalities
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