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Development and pilot test of a new set of good practice indicators for chronic cancer pain management

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Abstract

Background: Pain is among the most important symptoms in terms of prevalence and cause of distress for cancer patients and their families. However, there is a lack of clearly defined measures of quality pain management to identify problems and monitor changes in improvement initiatives.
Methods: We built a comprehensive set of evidence-based indicators following a four-step model: (1) review and systematization of existing guidelines to list evidence-based recommendations; (2) review and systematization of existing indicators matching the recommendations; (3) development of new indicators to complete a set of measures for the identified recommendations; and (4) pilot test (in hospital and primary care settings) for feasibility, reliability (*kappa*), and usefulness for the identification of quality problems using the lot quality acceptance sampling (LQAS) method and estimates of compliance.
Results: Twenty-two indicators were eventually pilot tested. Seventeen were feasible in hospitals and 12 in all settings. Feasibility barriers included difficulties in identifying target patients, deficient clinical records and low prevalence of cases for some indicators. Reliability was mostly very good or excellent ($k > 0.8$). Four indicators, all of them related to medication and prevention of side effects, had acceptable compliance at 75%/40% LQAS level. Other important medication-related indicators (i.e., adjustment to pain intensity, prescription for breakthrough pain) and indicators concerning patient-centred care (i.e., attention to psychological distress and educational needs) had very low compliance, highlighting specific quality gaps.
Conclusions: A set of good practice indicators has been built and pilot tested as a feasible, reliable and useful quality monitoring tool, and underscoring particular and important areas for improvement.

1. Introduction

Pain is among the most important symptoms in terms of prevalence and cause of distress for cancer patients and their families. More than one-third of cancer patients rate their pain as moderate or severe (van den Beuken-van Everdingen et al., 2007), and it has been estimated that more than 80% of the patients around the world with moderate or severe pain are inadequately treated even though science has the capacity to mitigate this situation (World Health Organization, 2007a). In the case of cancer patients, a review suggested that an average of 43% receive inappropriate care for pain (Deandrea et al., 2008).

Several efforts have been developed in recent decades to change this deficient situation in relation to

What's already known about this topic?

- The paucity of clearly defined measures has been identified as one of the barriers to improve pain care.
- Existing cancer pain management indicators are a small part of sets focusing on limited population groups.

What does this study add?

- Construction process and pilot test results of a rather comprehensive set of evidence-based indicators for cancer pain management.
- Pilot test data illustrate a baseline situation which could be used for focused quality improvement initiatives.

pain management in general and in cancer patients in particular. Proposed strategies include interventions against identified barriers (Sun et al., 2008; Borneman et al., 2010, 2011; Kravitz et al., 2011), the promotion of a clear policy shift (Gilson et al., 2007), the development of new guidelines (World Health Organization, 2007b), and some attempts to overcome the challenges of quality improvement (QI), one of which is the lack of clearly defined measures of quality pain management (Gordon and Dahl, 2004).

Initiatives using the QI approach have included (Gordon and Dahl, 2004) the pain assessment and accreditation standards used by the Joint Commission on Accreditation of Healthcare Organizations, the national nursing home QI initiative launched by the United States Centers for Medicare and Medicaid Services, which included improvement activities on pain management, and some multi-centre initiatives particularly on post-operative pain. More recently, some quality indicators on pain management have been included in a set of indicators for palliative care in general (Claessen et al., 2011), for cancer pain in older adults in hospice care (Fine et al., 2010) and for advanced cancer patients (Malafa et al., 2009; Dy et al., 2010). However, a specific and yet comprehensive set of measures to define cancer pain management is still lacking.

At the same time, research has shown that QI initiatives are more successful in significant reductions of pain intensity when they include treatment-focused strategies (Gordon and Dahl, 2004), and that evidence-based practice is more cost-effective than usual care (American Pain Society, 2008). It seems essential then to complement the usual focus on improving pain assessment and documentation with efforts to increase implementation of effective evidence-based treatment approaches in a field where much of conventionally accepted practice seems to remain supported by only clinical observation (Portenoy, 2011). All these factors underscore the need to develop, test and eventually use comprehensive, valid and reliable indicators of quality cancer pain management in order to improve, measure changes and assure the best practice for these patients.

The objective of the work reported here is the construction and pilot testing of a set of indicators for cancer pain management based on the available evidence and useful for focused QI initiatives. Data from the pilot test sites also illustrate a baseline situation regarding good practice in the control of cancer pain.

2. Methods

A multidisciplinary working group was assembled including experts from the disciplines of anaesthesiology, pharmacy, nursing, family medicine, physiotherapy and rehabilitation, and quality management. The mandate was to define evidence-based indicators in relation to assessment, initial treatment and follow-up of patients with cancer pain. Indicators are defined as measurement tools that can be used to monitor, evaluate and improve the quality of patient care, organization and support services that affect patient outcomes (Klazinga et al., 2001; Mainz, 2003). They can be related to structure, process or outcome (Donabedian, 1966, 1988). 'Structure' refers to the characteristics (material and human resources) of the settings in which care occurs, and how they are organized. 'Process' includes what is actually done in giving and receiving care. 'Outcomes' describe the effects of care on the health status and satisfaction of the patients. In order for a process indicator to be a valid measure of quality, it must have been previously demonstrated to increase the likelihood of a good outcome; similarly, a structure indicator will be a valid quality measure if it has been previously demonstrated its relationship to a good outcome, or to a process that has previously been shown to yield better outcomes (Palmer, 1998; Mainz, 2003). Therefore, the ability to assess the quality of health care using valid indicators is limited by the existing knowledge of clinical science. Evidence-based indicators translate into quality measures the existing knowledge.

To achieve our aim of defining a state-of-the-art evidence-based set of indicators for the management of cancer pain, we followed a four-step process, flowcharted in Fig. 1, including: (1) review and systematization of evidence-based recommendations in relation to the three main building blocks of cancer pain care (assessment, initial treatment and follow-up); (2) review, systematization and critical analysis of existing indicators, and identification of evidence-based recommendations not covered by existing indicators; (3) new indicator development to cover all evidence-based rec-

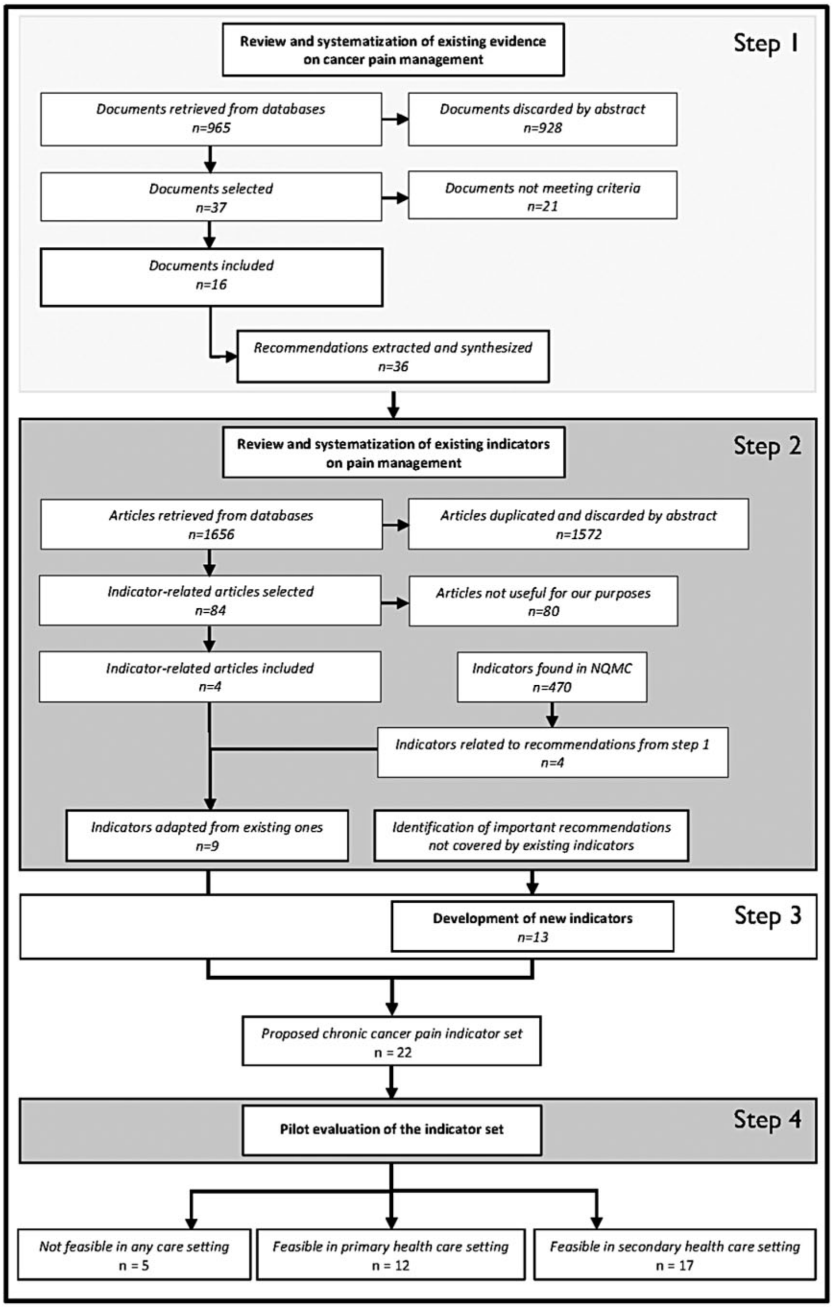

Figure 1 Detailed flow chart of the four-step process used.

ommendations found in step 1; and (4) pilot test in hospital and primary care settings of the accepted set.

2.1 Review and systematization of evidence-based recommendations

We performed a comprehensive search of literature in Medline looking mainly for systematic reviews and clinical guidelines, and in Cochrane and Ovid databases for systematic reviews in relation to cancer pain management (key words in title or abstract: 'cancer pain' and 'guidelines' or 'practice guidelines' or 'systematic review' or 'meta-analysis'), published within the last 10 years (2001–2011) in either English, French or Spanish. Additionally, a search of clinical guidelines on cancer pain was performed using the National Guideline Clearinghouse of the AHRQ, the Scottish Intercollegiate Guidelines Network (SIGN), the New Zealand Guidelines Group, the National Institute for Health and Clinical Excellence, BMJ Evidence, and GuiaSalud (a Spanish database of clinical guidelines). These searches provided a total of 965 documents, 928 of which were discarded after reviewing the abstract because either they were not guidelines or systematic reviews, or they did not contain clear recommendations for pain management. We reviewed the selected 37 documents and discarded 21 because the level of evidence and the strength of the recommendation were not stated. Occasionally, when the level of evidence of relevant recommendations was unclear, we reviewed the articles quoted for these highly recommended practices in the reference lists of the clinical guidelines. The final 16 documents meeting all criteria (they contained recommendations on cancer pain management, and the level of evidence and the strength of the recommendation were either stated or could be derived from references) provided a total of 36 evidence-based recommendations. Reviews were made by two members of the group, and the final recommendations discussed and approved by the whole group.

To harmonize the different scales used in the published literature, we had to establish our own unified scale for level of evidence and strength of recommendation (Table 1) based on the GRADE (Atkins et al., 2004; Guyatt et al., 2008), SIGN (Scottish Intercollegiate Guidelines Network, 2008) and U.S. Preventive Services Task Force proposals (http://www.uspreventiveservicestaskforce.org/uspstf/grades.htm; Guirguis-Blake et al., 2007). The group kept recommendations which had supporting evidence level A (one or more randomized controlled trials, with or without meta-analysis) or B (significant observational studies), with a strength of recommendation A (must do), B (could be done: benefit is higher than potential adverse effects) and D (must not do: adverse effects are higher than benefit), but prioritizing evidence A and strength of recommendation A or D.

Table 1 Unified system for rating evidence and strength of recommendation.

Evidence		Meaning
A	1	Several randomized controlled trials with $p < 0.01$ *with* meta-analysis
	2	Several randomized controlled trials with $p < 0.01$ *without* meta-analysis
	3	A single randomized controlled trial with $p < 0.01$
B	1	Comparative observational studies *with* statistically significant differences
	2	*Non*-comparative observational studies
	3	Case report
C	1	A meta-analysis *without* significant differences
	2	Not enough studies for a meta-analysis, or randomized controlled trials without significant differences, or randomized controlled trials with inconsistent results
D		No studies identified or available literature of no use

Strength of recommendation	Meaning
TYPE A (should be done)	Treatment of *eligible* cases is suggested. The benefit is *significantly* greater than the possible adverse effects.
TYPE B (may be done)	Treatment of cases is suggested. The benefit is greater than the possible adverse effects.
TYPE C (no recommendation)	There is no recommendation against treatment. The benefits and adverse effects are in balance. Not recommended in routine clinical practice.
TYPE D (should not be done)	The recommendation advises *against* treatment. The evidence suggests that the adverse effects outweigh the benefits.
TYPE I	Poor evidence or not enough evidence to decide for or against.

2.2 Review and systematization of existing indicators

We performed a comprehensive search for quality indicators for cancer pain management in the National Quality Measures Clearinghouse (NQMC) of the AHRQ, and in articles included in the Medline, Scopus, PsycINFO and Academic Premium databases for the last 10 years (2001–2011), containing the key words ‘Quality indicators, Health Care’ [MESH] AND ‘Pain’ [MESH] (Fig. 1). Databases provided a total of 1656 hits, but 1572 of them where discarded because of duplications and the contents described in the abstract, showing that the articles did not address the construction and validation of cancer pain indicators. Furthermore, most of the eventually selected 84 indicator-related articles were not useful because either the indicators were not fully described or they were not related to the evidence-based recommendations we had selected. An additional search for potentially non-indexed literature was done using Google, and the indicators, if any, proposed in the reviewed clinical practice guidelines were also extracted. The NQMC search yielded four valid indicators, and an additional nine were adapted from the literature search. We always tried to match the found indicators with the evidence-based recommendations we had listed, and made an assessment of the level of evidence supporting them. Those not related to any of the evidence-based recommendations found in step 1 were discarded.

2.3 New indicators development

In order to obtain a full set of tools for measuring the degree of implementation of the good practice recommendations we had found, we elaborated new clinical indicators when definite valid indicators were not found for those recommendations. The objective was to translate into measures all the evidence-based recommendations summarized after the literature search. To facilitate discussion within the group, we defined and used a standardized format for describing both the adapted and the newly constructed indicators. This format included: name (overall description) of the indicator; component of health care quality to be covered by the indicator (assessment, treatment, follow-up); data source and method for measurement (medical record review, inspection, direct observation, surveys); detailed description of the indicator, including definition of target patients to whom the quality indicator applies, and good practice to be assessed (inclusion and exclusion criteria for numerator and denominator); computation of the measurement (presence/absence, rate or proportion); indicator origin (adapted or newly built); references supporting evidence; level of evidence and strength of the recommendation or recommendations used for the indicator; and observations, remarks and further specifications to assure the reliability of the measurements (i.e., list of commercial names of recommended drugs, precise definitions of recommended procedures, valid scales).

After iterative discussion sessions, the group redefined and established indicators with the following characteristics: (1) adequate scientific evidence of the good practice measured; (2) indicator compliance under control of health professionals and facilities providing care to cancer patients; and (3) the measurement being potentially feasible on a routine basis.

2.4 Pilot testing

The set of indicators was then pilot tested in two hospitals (one medium sized: 200–500 beds, and one large sized: >500 beds) and one primary care centre (staffed by 20 physicians and 16 nurses) providing home palliative care, all of them located in the Region of Murcia (Spain). These facilities were selected because they represent the type of settings where cancer patients receive their regular care in the Spanish public health care system. The selection of settings was not at random because the primary objective was to test the indicators rather than having a statistically representative estimate of their compliance. The management and involved services in all participating facilities received written information about the study, which was approved by their research and ethics committees. Informed consent from patients was not necessary because clinical data were abstracted from medical records without any reference to patient's personal data according to a written statement from the research group to guarantee confidentiality. One of the hospitals and the primary health care centre had electronic medical records. Formats for data abstraction and guidelines for the pilot test were devised, specifying the ICD codes (to identify cases for the minimum basic data set in hospitals), and the *International Classification of Primary Care* (for the primary health care centre), sampling method, and Excel databases for calculation of reliability (*kappa*), problem identification using the lot quality assurance method (Saturno, 2000; Robertson and Valadez, 2006) and estimated compliance of indicators.

The objectives of the pilot test were threefold: (1) feasibility of the measurement in the various settings and for the different types of cancer patients in which the indicators are applicable; (2) reliability of the feasible indicators; and (3) potential usefulness for QI. *Feasibility* problems may come from difficulties in identifying target patients, deficiencies in clinical records, very low prevalence of cases, and other circumstances in which it may not be possible to measure an indicator. *Reliability* was tested calculating inter-rater *kappa* index (Landis and Koch, 1977; Cohen, 1988) for each clinical record-based indicator in samples of 15 cases, using assessment results from two independent raters not involved in designing the indicators. Reliability of inspection-based structure indicators was assessed looking at inter-rater concordance. *Usefulness for problem identification and quality improvement* was analysed using lot quality acceptance sampling (LQAS), a quality control procedure promoted by the World Health Organization (WHO) for rapid assessments, which can be used in epidemiological studies, and that we had adapted as a problem identification tool for quality management (Saturno, 2000; Robertson and Valadez, 2006). This technique allows identifying quality problems when the standard set for indicator compliance is not met. The parameters for acceptance ('good quality') were set for two situations: a standard compliance of 75% (40% threshold) and a standard compliance of 95% (70% threshold), with $\alpha \leq 0.05$ and $\beta \leq 0.01$ for both instances. These conditions require a random sample of 15 patients (15 valid medical records for each indicator) and a minimum of 12 compliance cases for accepting a 95% compliance, or eight compliance cases for accepting a 75% compliance. Centres with <12 compliance cases in the sample may be identified as problematic for a 95% standard, and centres with <8 cases are problematic for a 75% compliance standard. Additionally, actual compliance level was estimated with 95% binomial exact confidence interval for each centre individually, and using the formula for non-proportional stratified sampling for the aggregate estimate in more than one centre. The inclusion criteria for the random selection of cases for the assessment followed the concept of chronic cancer pain as described in the WHO document Normative Guidelines on Pain Management (World Health Organization, 2007b), including the usually agreed 3 months limit to include patients as chronic pain patients (Merskey and Bogduk, 1994). The pilot test study was performed in 2012.

3. Results

Fig. 1 contains detailed information about the selection process of the literature search both for the evidence-based recommendations and existing indicators (steps 1 and 2 of the construction process we followed). Eventually, we based our proposed set of 22 indicators on 36 recommendations for the management of chronic cancer pain, distributed by the aspects of care to which they apply (assessment, pharmacological, psychological and complementary treatment, education, and perceived quality/patient report), as summarized in Table 2. Nine of the 22 indicators are adapted from published ones, and 13 were developed by the work group. Some indicators include more than one recommendation. The individual description, recommendations on which they are based, level of evidence and strength of the recommendation are shown online only (Supporting Information Table S1) along with the source of data for measurement, and the

Table 2 Quality indicators for chronic cancer pain management.

A. Patient assessment: 2 indicators
  - Pain assessment: 1 indicator[a]
  - Psychological distress assessment: 1 indicator

B. Pharmacologic treatment of pain: 12 indicators
  - General: 3 indicators[a]
  - Specifics (additional) if opioid therapy: 5 indicators
  - Specific (additional) if NSAID therapy: 1 indicator
  - Complementary treatments in specific cases: 3 indicators

C. Psychological treatment: 1 indicator

D. Patient education: 3 indicators[a]

E. General complementary treatments: 2 indicators
  - Physical therapy: 1 indicator
  - Cannabinoid use: 1 indicator

F. Perceived quality/patient report: 2 indicators
  - Perceived quality of treatment: 1 indicator
  - Effectiveness of educational activities: 1 indicator

Total: 22 indicators

NSAID, non-steroidal anti-inflammatory drug.

[a] These indicators could be considered applicable for immediate implementation of CCP management due to their usual application in our environment.

ratings by local experts. For the indicators related to performance, the set was piloted using 15 valid medical records for each indicator, as indicated by the LQAS method, from several oncology-related services in hospitals, such as the oncologic outpatient unit, oncology service and radiotherapy service; general practitioner consultations and home care in the case of primary health care. Pilot test results in terms of feasibility of measurement, reliability and usefulness to identify quality problems are as follows:

3.1 Feasibility of measurement

Measurement was feasible for 17 of the 22 indicators in hospital care, and 12 of them in both hospital and primary health care. Structure indicators (five in total, including existence and content of selected protocols, and other useful pain management tools such as patient education material, perceived quality questionnaires and equianalgesic dose conversion tables) could be measured in all health care settings. The main reasons for non-feasible measurement were low incidence/prevalence of cases to evaluate (i.e., patients with pancreatic cancer and uncontrolled chronic cancer pain), indicators subsequent or dependent on compliance of other indicators which resulted to very low or non-compliance (i.e., opioid rotation using an equianalgesic dose chart, where there is no such chart available, or adequate treatment of severe chronic cancer pain, which requires that pain severity be measured first), and, particularly in primary and home care, difficulties in locating either the cases or the information needed for measurement with the current information system (i.e., patients with chronic neuropathic cancer-related pain). Detailed feasibility and reliability results are described online (Supporting Information Table S2).

3.2 Indicators reliability

Reliability results (last two columns of Supporting Information Table S2) were obtained from feasible chart reviewing-based indicators, and measured separately in the hospital and primary care settings. In hospitals, *kappa* ranged from 0.65 (in one indicator) to 1 (in seven indicators); most of them had a *kappa* index >0.8. Similar results were obtained in primary care, with only one indicator with moderate agreement ($k = 0.53$), which was discussed and found to be due to the ambiguity and confusing structure of the clinical records. Agreement was at 100% for the five inspection-based structure indicators in both primary care and hospital settings.

3.3 Usefulness for problem identification and QI

Although some variability was found, quality was low in the majority of indicators, pointing out specific issues and areas for QI (Table 3). Four indicators had acceptable quality compliance at the LQAS 75/40 standard/threshold level in at least one centre. Two of them also had acceptable quality at the LQAS 95/70 LQAS standard. All of these are medication-related indicators. Prevention of gastric side effects in patients treated with non-steroidal anti-inflammatory drugs (NSAIDs) was the least problematic [estimated overall compliance: 91.7 (77.9–97.9) in hospitals, 53.3 (26.6–73.4) in primary care], followed by the use of treatment with bisphosphonates in patients with bone metastasis (overall compliance: 51.4, 34.3–68.7, in hospitals). The only one with acceptable LQAS 95/70 compliance in all centres (no use of cannabinoids as initial treatment) could be removed from the set considering that there was no variability, with 100% compliance in all centres, and that it is unlikely that it will be problematic in the future. Other important medication-related indicators such as the use of pain intensity scales and the consequent adjustment of medication, and the prescription for breakthrough pain had very low compliance levels, underscoring the existence of relevant quality gaps. However, the worse compliance and extreme quality problems were found in relation to indicators concerning patient-centred

Table 3 Quality problem identification with LQAS and compliance estimates of feasible percentage-based indicators.

Indicator	Centres with acceptable quality (LQAS 75/40)	Centres with acceptable quality (LQAS 95/70)[a]	Compliance estimate in hospital care[b]	Compliance estimate in primary care[b]
A. Patient assessment				
A.1.1. Percentage of patients with CCP and pain assessment through validated scales	0 of 3	0 of 3	0.0 (0.0–11.6)	6.7 (1.7–32.0)
A.2.1. Percentage of patients with CCP and explicit psychological distress assessment through validated scales	0 of 3	0 of 3	0.0 (0.0–11.6)	0.0 (0.0–21.8)
B. Pharmacologic treatment of pain				
B.1.1. Percentage of patients with CCP and treated with NSAIDs in which gastric protection is prescribed	3 of 3	2 of 3	91.7 (77.9–97.9)	53.3 (26.6–73.4)
B.2.4. Percentage of patients with CCP and strong opioid treatment in which constipation prophylaxis is prescribed	0 of 2	0 of 2	33.3 (17.3–49.4)	Not feasible
B.2.5. Percentage of patients with CCP and opioid treatment in which emetic side effect prophylaxis is prescribed	0 of 2	0 of 2	38.6 (22.7–56.1)	Not feasible
B.3.1. Percentage of patients with CCP and pain assessment in which adequate treatment is prescribed according to WHO analgesic ladder	1 of 3	0 of 3	1.6 (0.0–11.6)	73.3 (44.9–88.1)
B.3.2. Percentage of patients with CCP and opioid treatment in which adequate breakthrough pain treatment is prescribed [composite indicator including: (1) treatment plan including anticipated prescription for breakthrough pain; and (2) adequate drug and dosage]	0 of 2	0 of 2	11.9 (3.8–26.5)	Not feasible
B.4.1. Percentage of patients with metastatic bone CCP in which bisphosphonate treatment is prescribed [composite indicator including: (1) bisphosphonate prescription; and (2) adequate dosage]	1 of 2	0 of 2	51.4 (34.3–68.7)	Not feasible
C. Psychological treatment				
C.1.1. Percentage of patients with CCP in which psychological distress treatment is established	0 of 3	0 of 3	0.0 (0.0–11.6)	6.7 (1.7–32.0)
D. Patient education				
D.1.3. Percentage of patients with CCP in which pharmacological treatment educational activities are carried out	0 of 2	0 of 2	0.0 (0.0–11.6)	Not feasible
E. General complementary treatments				
E.1.1. Percentage of patients with CCP in which complementary physical therapy programs are established	0 of 3	0 of 3	3.2 (0.0–11.6)	0.0 (0.0–21.8)
E.2.1. Percentage of patients with CCP in which cannabinoid treatment is not prescribed as initial treatment	3 of 3	3 of 3	100.0 (90.0–100.0)	100.0 (78.2–100.0)

CCP, chronic cancer pain; LQAS, lot quality acceptance sampling; NSAID, non-steroidal anti-inflammatory drug; WHO, World Health Organization.

[a] Centres with LQAS 95/70 accomplishment also take into account LQAS 70/45 accomplishment.

[b] Percentage estimation (binomial exact 95% confidence interval).

care, including attention to psychological distress, educational needs and the use of tools to measure patient experience/perceived quality. Structure indicators in relation to the existence of tools to support and help good practice (dose conversion tables for opioids, educational material or protocols about patient education, instruments to measure patients' experiences and perceived quality) were not present in any centre.

4. Discussion

We have constructed and pilot tested a rather comprehensive set of good practice indicators for detecting problems and monitoring changes in cancer pain management, considering current evidence-based knowledge, and assuring feasibility of measurement and reliability of feasible indicators. Lessons learned throughout this project are manifold, including but not limited to the difficulties in summarizing existing evidence, the deficiencies of current recording and information systems to support an appropriate monitoring of good practices regarding cancer pain management, and ultimately the measurement results in the pilot sites showing that cancer pain management is a deficient, extremely problematic area of health care. This finding reinforces the need of having the type of tools we propose to support focused improvement initiatives.

4.1 Disparities in classifying evidence and the proposal of recommendations

Our literature review has found that there is increasing interest in pain management and the creation of guidelines to facilitate good practice. We may highlight the WHO initiative, *WHO Normative Guidelines on Pain Management* (World Health Organization, 2007b), as well as the initiatives of the American Pain Society (Gordon et al., 2005; Miaskowski et al., 2005; American Pain Society, 2008), and in other countries as diverse as Scotland (Scottish Intercollegiate Guidelines Network, 2008) and Malaysia (Ministry of Health Malaysia, 2010). However, the existing guidelines are not homogeneous neither regarding the particular recommendations they propose nor the scales used for grading evidence and strength of the recommendation. In some cases, such important information is lacking. Consequently, we had to find and define the common ground of all the scales for grading evidence, eventually keeping only those recommendations explicitly supported by controlled trials (preferably) or significant observational studies. In many instances, we had to complement the information contained in the guidelines by reviewing the original studies quoted in the guidelines, as well as other articles found in the literature search. In other cases, the recommendations were partial and left important aspects of the same issue or decision undefined. When this occurred, we tried to combine partial recommendations on the same issue into a single indicator, which was the case in 9 of the 22 eventually proposed indicators. Most probably, these issues may explain, at least partially, why one of the gaps and challenges identified in improving quality of pain management has been the failure to define quality pain management itself (Gordon and Dahl, 2004).

4.2 Defining quality cancer pain management is not enough: The feasibility barrier

We built a selected set of 22 evidence-based indicators, but in spite of their potential relevance for monitoring the quality of cancer pain management in the sites providing care to these types of patients, measurement of all of them was not feasible. Seventeen indicators were feasible in hospitals and 12 in the primary care centre. Feasibility differences between hospital and primary care were mainly due to the kind of care provided (i.e., bisphosphonates are not prescribed in primary care), and then to some particular characteristics of the coding system for patients in primary health care (*International Classification of Primary Care*, ICPC-2), which is less detailed than the *International Classification of Diseases* (ICD-9) used in hospitals, and makes more difficult to identify target cases for particular good practices. In addition, there are the common problems of sometimes disorganized or incomplete clinical records, and also the dependence of some indicators on the compliance of other indicators, which had low compliance (i.e., pain treatment adjusted to pain severity, which is difficult to assess when pain severity has not been assessed). The latter cause accounted for most of the measuring difficulties in hospitals. However, in different contexts where the information system and clinical records are better organized, and compliance with the more general indicators is higher, feasibility barriers may be different or even not present. QI projects may also choose to prioritize the more generally applicable indicators, which are the more feasible ones.

4.3 The proposed set of indicators as a valuable quality problem identification tool

Cancer pain management is a complex issue which needs a multidimensional approach, based on comprehensive pain assessment including not only intensity, but also drug, psychological and integrative interventions (Portenoy, 2011). At the same time, both the opioid and the non-opioid analgesic drugs (i.e., NSAID) used to control cancer pain need close management of side effects, and particular attention to their dosage, route of administration, consideration of the need of rotation to adapt them to individual differences in response to the various opioid drugs, and an anticipated plan for treating breakthrough pain (Portenoy, 2011). The set of indicators we propose includes all of these important aspects and the pilot test measurement has shown which ones may be the relevant quality problems, and to what extent. First, it is striking the low, virtually nil compliance of the indicators addressing patient-centred care, including attention to psychological suffering and treatment educational needs. The comprehensive approach to cancer pain management seems to be lacking. Second, important aspects of drug treatment such as the adjustment to measured pain intensity and planned treatment of breakthrough pain are problematic in all pilot sites (LQAS results) and have a very low level of compliance (estimated 1.6% and 11.6%, respectively), while dose conversion charts were also absent in all sites. Third, while treatment is not explicitly adjusted to patient needs, more attention is paid to the prevention of side effects such as gastric protection when NSAIDS are prescribed (the indicator with the highest level of compliance in the whole set: an estimated 91.7%), and constipation and emetic prophylaxis for opioids, even though there is still great room for improvement (estimated compliance of 33.3% and 38.6%, respectively). These results may not be similar in other settings, but the measurement of the set of indicators we propose may highlight the specific QI challenges which should be addressed in any case. The proposed set is meant to be used for internal QI (identification and understanding of the extent and nature of the quality problems, motivation for change, and comparisons after change have been made) rather than for external accountability, even though some indicators may be used for both purposes.

4.4 State of the art in indicators for cancer pain control and the contribution of the set we propose

Despite the increasing interest in pain management, our literature search found only a few indicators which could be useful for our purposes. Most of the existing qualities of cancer care indicators focus on palliative care (Chvetzoff et al., 2006; Grunfeld et al., 2008; Lorenz et al., 2009; Pasman et al., 2009; Seow et al., 2009; Campion et al., 2011; Claessen et al., 2011; De Roo et al., 2013), on breast cancer (Del Turco et al., 2010; Stordeur et al., 2012), and other limited population groups such as older adults in hospice care (Fine et al., 2010), advanced cancer patients (Lorenz et al., 2009; Dy et al., 2010), and others (Malafa et al., 2009; Miller and Saigal, 2009; Mitera et al., 2010). In general, they provide a somewhat wider approach, not just pain management, to the particular type of patients and situations they address, but we did not find any evidence-based indicator set specifically or exclusively designed for cancer pain management in general. Additionally, some relevant aspects such as psychological assessment, a patient-centred view, adequate doses for pharmacological treatment, and opioid rotation (Fine et al., 2010), or other issues such as adequate dosage and drug rotation (Lorenz et al., 2009; Dy et al., 2010) are left out. Therefore, most of the indicators we propose were purposely built for our project on the basis of the good practice recommendations we could locate and summarize.

Finally, in other indicator validation studies, results on their usefulness as quality problem identification tools are not always provided and both their level of evidence and strength of the recommendation, or the methods to assess them, are not always explicit. In general, they rely heavily on the ratings from a group of experts.

The desirable next step would be the use of the set we propose on a routine basis for QI in the settings providing health care to cancer patients. This may require an appropriation at the level of front-line health care professionals, scientific societies committed to the improvement of pain management and cancer care, and health authorities; in all cases in response to their particular share of responsibility for quality care.

4.5 Limitations

Although our set tries to be comprehensive, it has some limitations regarding palliative care, end-of-life treatment and chronic cancer pain in children. General indicators, like patient assessment indicators, prevention of side effects and most pharmacological treatment indicators can be used in all of these settings, but in general quality management for palliative care, end-of-life care and paediatric populations may need specific attention and a complementary set of indicators.

In addition, the operational classification of chronic cancer pain is ambiguous (Ferrante et al., 1996; Miaskowski et al., 2005; Institute of Medicine, 2011; Kravitz et al., 2011). We have used the concept of chronic cancer pain as described in the WHO document *Normative Guidelines on Pain Management* (World Health Organization, 2007b), and the usually agreed upon 3-month limit to include patients as chronic pain (Merskey and Bogduk, 1994), which may not be completely adequate for cancer patients, given that pain control may follow similar guidelines from its onset. However, our set covers most of recommendations established by the American Pain Society for improving the quality for both acute and cancer pain management (Gordon et al., 2005).

Finally, the validation and pilot test results are context dependent and may be different in other health care systems or institutions. However, we tried to include the most frequent type of settings where cancer patients are treated. The particular interest of a given institution or professional group may also choose to apply only part of the proposed set. In any case, constant reviews may be useful for incorporating, replacing and leaving out some indicators when new evidence and recommendations are available. Further refinements may now come from their actual use by committed professionals and institutions.

Author contributions

P.J.S. contributed to the design of the study, data analysis, and drafted and revised the paper. He is guarantor. I.M-N. designed data collection tools, participated in the field work, cleaned and analysed the data, and drafted the paper. I.S.R-G. contributed to the design of the study, data collection, and data analysis, and revised the paper. F.L-S. contributed to the design of the study, monitored field work and revised the paper. D.A-G. designed data collection tools, participated in the field work and data analysis, and revised the draft paper. All the authors have discussed the results and commented on the manuscript.

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Supporting information

Additional Supporting Information may be found in the online version of this article at the publisher's web-site:

Table S1. indicators for chronic cancer pain management. Source, evidence, strength of recommendations and interest ratings.

Table S2. Feasibility and reliability of the good practice set of indicators for chronic cancer pain management.