Reviewer’s report

**Title:** Development and testing of a primary care disease management program for patients with chronic pain

**Version:** 1  **Date:** 28 October 2004

**Reviewer:** Bill H McCarberg

**Reviewer’s report:**

**General**

Good, well-written paper looking at a common problem in primary care, chronic noncancer pain. Most chronic conditions treated in primary care have disease management models including CHF, diabetes, COPD, asthma, hypertension, post myocardial infarction care, SDAT just to mention a few. The authors attempt to advance chronic noncancer pain management along the same disease management structure. In most other chronic conditions, following simple steps leads to improved outcomes: diabetes-home glucose monitoring, tracking the HgA1C, hypertension-keeping the blood pressure below 140/90. In this paper, the model requires multidisciplinary evaluation and intervention which is not available in primary care easily. Even with this intensive approach, the pain level decrease was not clinically significant (12-15%), pain levels did not correlate with opioid dosing, and even with intensive observation (patients sign a "contract", urine drug screens, an intensive admission interview) substance abuse during the program was high (31%). The unstated message perhaps is that pain management with opioids in a primary care practice is too risky even for the well-intentioned, careful provider.

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**Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)**

1) Page 12 line 11 mentions "neuropathic blockers". There are no such drugs. A different phrase should be used.

2) I suggest an explanation on the outcome measures BPI, CESD and PDI on what is considered mild, moderate or severe. This is taken up in a minor way in the body of the article, but the reader should be instructed that 1-3 is mild pain, 4-6 moderate and 7-10 severe such that we know that the recorded averages 6.5 represents moderate to severe pain.

3) This population is very distinct, 60% male (most chronic noncancer pain studies show a predominance of females), 87% smokers. The authors mention that the group represents patients that the primary care provider was having difficulty with. I would like an expanded explanation of this unusual group. Are males more likely to exhibit troublesome behavior? Our study found that males were much more likely to be given opioids and long-acting opioids by primary care. The inference is that providers trust the males (trust their pain complaint, trust that they will not abuse) more than the females, while this study shows that males, even when supervised closely, will abuse more. This is an important finding and worth mentioning.

4) Page 6 line 9 mentions the "Medication Contract". Some mention should be made that "contract" is not what the pain experts recommend. Medication Agreement, Informed Consent is more appropriate.

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**Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)**

1) Please use the word chronic noncancer pain, not non-malignant pain. Since John Liebeskind at UCLA proved in animals that chronic pain kills, it is misleading to think of chronic pain as
non-malignant.

2) Page 3 line 16 uses reference 16 for opioids in non-malignant pain. This reference is for the treatment of metastatic cancer, not non-malignant pain.

3) Page 4 line 11 - "fostering opioid dependence, abuse or addiction". I do not understand this statement, addiction and abuse are the same; physical dependence always happens with an opioid used long-term and is not abuse. Why are these terms used together?

4) Page 4 line 16 states that "Traditional models of office-based care focus on diagnoses and acute management of medical problems...". The authors attempt to distinguish this from disease management and give 4 examples. In standard office-based care, all 4 of the examples are used as well: 1) I use multidisciplinary teams (I refer to an oncologist for my cancer patients as I treat them in my practice) 2) I use evidence based algorithms to treat patients 3) I have interval visits to monitor response 4) I use information systems (lab follow up, appointment reminders). The authors have not made the argument that what they are doing is different. The intervention is more intensive, more structured, more coordinated, more closely tracked but this difference is not mentioned.

5) Page 6 line 15: guidelines. Only the last reference is a guideline. The others are author's opinions.

6) Page 6 line 23: less costly, generic medications. This is not a basic principle (misspelled in text) of management. It is a necessity in managed care. The principle is to be able to use as many different opioids as possible since patients respond differently to different drugs.

7) Page 7 line 1: gabapentin does not work in chronic pain; it works in a few types of neuropathic pain. Many providers have generalized the neuropathic indication to use gabapentin in fibromyalgia, chronic daily headache, myofascial pain, chronic low back pain and many other chronic pain conditions. There are very few drugs with "known efficacy in chronic pain". In neuropathic pain, Dworkin et al recently suggested there are five drugs or classes of drugs: gabapentin, Lidoderm, tramadol, opioids, tricyclics. Until the Ballantyne article in the NEJM, you could even dispute that opioids worked longer than 12 weeks which is what the clinical trials showed. The authors should state this and list the other drugs.

8) Page 10 line 21: if there was intense monitoring and psychosocial evaluation of the patients, why did the percent of patient on anti-depressants increase from 44% to only 52% after 3 months? Primary care is accused of not recognizing and treating depression adequately. In this study with the known comorbidity of depression and with psychosocial interventions, only 52% were taking a well-established treatment. Why is this?

9) The Hawthorne effect should be explained.

10) Page 13 line 22: "not lost or stolen medication" is not correctly worded. Should read: and not addiction.

Discretionary Revisions (which the author can choose to ignore)
I would like to restate a concept discussed above. Primary care is being asked to manage chronic pain patients with an increasing emphasis on the use of opioids. State medical boards encourage opioids, recent litigation against doctors for elder abuse when opioids are not used, patient Bill of Rights are just a few examples. This article attempted to follow patients using a disease management model however, I believe it did much more than that. It showed that when primary care providers are worried about patients in chronic pain, often they are right. Comorbidities are very common and difficult to treat even when screened, identified and managed by experts. In primary care, psychosocial services are often carved-out, limited, resisted by the patients with little communication back to the provider making standard, usual care a major barrier. High rates of abuse as defined conservatively in this paper are another major issue. Primary care is being squeezed between patients and organizations pushing the use of opioids, yet the substantial problem with opioid misuse cannot be ignored. In a busy primary care practice, the risk may be too high except for the infrequent, low dose patient. This paper could easily be used to argue this point if the authors chose to do so. The risk of prescribing opioids would be another conclusion from this paper and be of high importance to the field.
What next?: Accept after minor essential revisions

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: No

Declaration of competing interests:

None