Author's response to reviews

Title: A primary care, multi-disciplinary disease management program for opioid-treated patients with chronic non-cancer pain and a high burden of psychiatric co-morbidity

Authors:

Paul R Chelminski (chelminp@med.unc.edu)
Timothy J Ives (tjives@med.unc.edu)
Katherine M Felix (claynef@mindspring.com)
Steven D Prakken (sprakken@earthlink.net)
Thomas M Miller (thomas_miller@med.unc.edu)
J STEPHEN Perhac (john_perhac@med.unc.edu)
Robert M Malone (rmalone@med.unc.edu)
Mary E Bryant (bbryant@med.unc.edu)
Darren A DeWalt (dewaltd@med.unc.edu)
Michael P Pignone (michael_pignone@med.unc.edu)

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Author's response to reviews: see over
Major Revisions
1. The title is more reflective of the study...

We have specifically denoted that our cohort of patients was “opioid-treated” as requested in the Conclusion section of the abstract (page 3), the last paragraph of the Introduction (pages 4 and 5), and in the first paragraph of the Discussion (page 13).

2. Table 6 is useful and provides important data. It should be referenced in the 1st paragraph of the results section (p.10). Although the substance misusers are of primary concern, it would be appropriate to include data on all lost subjects (n=22)...

We have now referenced “Table 6” in the first paragraph of the results and have re-labeled it “Table 2” (page 10, paragraph 1). It includes comparative baseline data on all non-completers and non-completers who committed substance misuse. The other tables have been re-labeled in sequence.

On page 16, paragraph 2, we acknowledge the shortcomings of our program in retaining and managing patients with substance misuse and comorbid depression:

“…The difficulty in obtaining mental health and substance abuse treatment services is a pressing public health issue and a topic of national debate in the United States. In our sample there was a clear trend toward increased co-morbid depression among substance misusers who did not complete three month follow up (Table 2.). Despite the availability of on-site psychiatric consultation, our program was not successful in retaining and managing a challenging subset of patients with substance misuse and depression.”

3. The noted limitation on possible overestimation of treatment effect is important to interpretation and should be mentioned in paragraph 3 of the discussion.

We have amended paragraph 3 of the discussion to indicate possible overestimation of treatment effect as follows: “…It is important to note that there was a statistically significant trend toward greater depression among substance misusers who did not complete the trial; thus, it is possible that the trial overestimates the effect of multi-disciplinary management on depression outcomes.” However, we would also suggest that it is plausible (even likely) that the high percentage of non-completers may have underestimated the effect of the intervention because we believe that this subset of patients would have benefited greatly from intensive management of their mood disorders had we been able to retain them. This cuts to the core of the issue/question we have struggled with the most: How do you insure effective mental health care to patients with concomitant chronic pain and substance misuse? This is problem of huge dimensions as pointed out by Iglehart (Iglehart, John K. The Mental Health Maze and the Call for Transformation. N Engl J Med. 2004 Jan 29; 350(5):507-514.). We do not have an answer but suspect that it will require a
policy-driven initiative at the national level in the United States to insure parity for mental health care.

4. (a) This limitation and the authors’ response (including availability of algorithms) should be noted in the discussion.

We have amended the last paragraph of the Discussion (page 18) section to elaborate on this limitation as follows: “Another major limitation of our study is its individualized nature. We did not adhere to strict algorithms for diagnosis and treatment and did not test a single intervention. The evidence-base for managing chronic pain in the general medicine setting is limited and the multi-modal nature of our intervention was by necessity empirical and exploratory. As such, we decided to allow more latitude and individualization in treatment choice. We have used our experience and the data collected to develop more robust algorithms to guide the management of pain and depression and to make psychiatric referral when appropriate. As a corollary to our multi-modal approach, it is difficult to ascertain if the improvements derived from pain medications, intensification of depression therapy, or simply participation in an organized program. Improvements and changes in behavior that occur as a result of becoming a target of special interest in a program are often referred to as a Hawthorne effect.”

(b) Based on the authors’ response, it is unclear in the manuscript why a committee was needed to apply the “relatively unambiguous definition …which we applied prospectively and uniformly to all participants”

The committee approach was designed to democratize the process of substance misuse determination. We felt that it was important that a variety of clinicians participate in decisions to sanction patients for substance misuse. We did not want a single authority in the practice to impose a monolithic and rigid set of rules. All cases were presented to the committee members for their opinions and perspectives. In addition, the committee serves as a teaching tool for our resident physicians so that they can gain knowledge and expertise in dealing with serious infractions of clinic policies as they relate to substance misuse. In the past, the residents (and most other providers with the exception of the clinic director) had not been involved in the enforcement of clinic policies. In addition, the committee deliberates those exceptional cases where threats were communicated to providers or prescription adulteration occurred. In these cases the committee members were asked to consider the possibility of dismissing the patient from the practice. These intricacies of the committee function are not included in the manuscript because we believe that they would distract readers from “big picture” aspects of our program. We have presented our protocols for monitoring and sanctioning substance misuse to other practices and to a national meeting of internists. We have shared these materials with others and they are available to anyone who wishes to use or adapt them. We have included the practice policy that addresses substance misuse as Appendix B; this is noted in the manuscript on page 9, paragraph 1.

7. (a) The authors make valid points in their response but the important issue of how these results impact on efficacy of the program remains unanswered in the manuscript...
We have made modifications to the Conclusion of the Abstract (page 3) and the Discussion (page 15, paragraph 2) as recommended:

“…Substance misuse and depression were common, and many patients who had substance misuse identified left the program when they were no longer prescribed opioids. Effective care of patients with chronic pain should include rigorous assessment and treatment of these co-morbid disorders and intensive efforts to insure follow up.”

“…Though high rates of substance misuse are a source of concern, our program may serve as an example for how care can be organized to reduce misuse without eschewing the benefits of opioid medications.”

(b). Though clinicians typically have no direct control of this migration outside of their practices, it is an important part of the problem and of effective disease management…

We have added a discussion of migration of patient, page 17, paragraph 1: “…We are aware that some of our substance misusing patients migrated to other practices in order to obtain opioids and other controlled substances. Our program implemented policies to prevent migration of patients within our practice (Appendix B.) and the University of North Carolina Health Care System. The cornerstone of these policies was meticulous documentation in an electronic medical record that is accessible to all physicians at our medical center to physicians and hospitals affiliated with our health care system in the surrounding communities. In general, though, we have no direct control over migration that occurs outside of our practice and our health care system. In order to curtail migration and “doctor shopping,” some states have implemented centralized monitoring systems for opioids and other controlled substances. North Carolina is currently exploring the feasibility of such a system. A description of operational state monitoring programs is available online through the United States Drug Enforcement Agency Diversion Control Program website at http://www.deadiversion.usdoj.gov/pubs/program/rx_monitor/index.html.”

8. The multiple outcomes are related measures of the treatment program and are presented and evaluated as such…

On page 11, paragraph 2, we address the issue of multiple comparisons and state our rationale for not adjusting our analyses: “…We did not correct for multiple comparisons because of the exploratory nature of our analyses.”

The aims of the study are also more explicitly stated in the last sentence of the introduction, page 5.

Minor Revisions
11. How were other psychiatric conditions referenced in this paragraph diagnosed? We thought that we addressed this concern in our first response. To diagnose depression, we used a combination of clinical interview and CESD (page 7, lines 15-18): “…To address psychiatric comorbidity, patients with depression and other complex psychiatric comorbidities (e.g. psychotic depression and bipolar disorder with substance misuse)
received psychiatric evaluation. Depression was diagnosed based on clinical interview and CESD.”

**Reviewer 2:** Bill H McCarberg

**Revisions:** None requested.