Reviewer's report

Title: Treatment of pelvic girdle pain with acupuncture: adverse effects during pregnancy and delivery.

Version: 2 Date: 13 February 2008

Reviewer: Adrian White

Reviewer's report:

Review
This is a well presented report of the assessments of adverse events occurring in a trial of acupuncture for pregnancy girdle pain already published. It is an important addition to the literature on the safety of acupuncture.

Major compulsory revision:
The study methods are not clear in one important area:
Page 8: â##all adverse events of treatment were recordedâ#ï¾â## Does this represent just the practitionerâ##s observations? or was the patient actually asked whether she identified an side effect? If so, was she presented with a list of possible side effects, or asked a general question on whether she had experienced any adverse effects? How was the terminology expressed so that it was comprehensible to everyone? These factors may influence the successful collection of data on safety.

Discretionary revision
I believe the claims made for the value of this study are on the border of being excessive and could with benefit be toned down. Only 125 women were treated with acupuncture, compared with over 400 in Smithâ##s study Smith also collected data on congenital abnormalities, which was not done in this study. Although I accept that the cardiotocograph data are novel and reassuring, and the blood pH data are innovative, I wonder about their overall relevance.

There is a longstanding problem with the nomenclature in this area, concerning attribution of an adverse â##eventâ## to the effect of acupuncture. There is some logic in regarding the study as collecting data on adverse events not adverse effects â## for example, the incidence of induction of labour has been measured â## this is an â##adverse eventâ## in the wider meaning of the term, but not an adverse event that can be attributed to acupuncture. This discussion is rather semantic and the authors may not want to be involved. They are lucky that no event occurred which required them to evaluate whether acupuncture had a role in causing it.

Minor editorial recommendations:
Abstract Methods: Adverse effects were recorded of adverse effects â#ï
Results: â##but women rated acupuncture favourablyâ## â## even though this
result is given prominence, the methods section does not describe it.

Results: severe not servere (also in Table 4)

Page 4 bottom: have concluded (not has)

Page 5, line 3, close bracket missing

Page 5, Cardiotocography.

Page 6, line 4 should be comma not full stop.

Page 8, Patients â## rated their opinionsâ##: what options were offered to them? these should be briefly summarised here, though presented in full in the Table.

All references to Table and Figure should be capitalised.

Page 9, 2nd line: completing would be better than fulfilling.

Page 10 middle: withdrew, not withdraw.

64 minor adverse events occurred â## do the data allow the authors to state in how many patients these events were recorded? Some women may be more susceptible than others.

Page 11, middle: has resulted or may have resulted, not have resulted.

Page 12, 6 lines from bottom, missing SD.

Page 13. Should explore the power of the study a little more and give the reader some indication, even if only qualitatively. It seems probable that a very large study would be required to identify a change of premature birth rate from 5% to 6%, and that the sample size of this study could only identify a difference very much larger than that. That is not to diminish the importance of this study, but to indicate the difficulty of this area of research.

Page 14 line 1. Delete â## thatâ##.

Item 1, Data emerged from a relatively large trialâ## should be linked more closely with item 5, insufficient size. The relevant point is that an efficacy RCT is not an appropriate design to provide evidence of safety, even if it is large (in RCT terms). Studies of 30,000 or more have been used in the past.

Table 2, Use of oxytocin

Table 7. infiltration â## of what? Local anaesthetic?

Figure 1. Nickel allergy not nicel.

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, the manuscript does not need to be seen by a statistician.
Declaration of competing interests:

I receive a fee from the British Medical Acupuncture Society for editing the journal Acupuncture in Medicine