Reviewer's report

Title: High dose prolonged treatment with nitazoxanide is not effective for cryptosporidiosis in HIV positive Zambian children: a randomised controlled trial

Version: 1 Date: 8 July 2009

Reviewer: Ibrahim Abubakar

Reviewer's report:

- Major Compulsory Revisions

This is a very well conducted trial which has demonstrated the lack of efficacy of a prolonged course of high dose nitazoxanide for the treatment of cryptosporidiosis in immunocompromised children. The trial was randomised (with adequate randomisation and concealment of allocation), and appropriate analyses were undertaken. The plan to undertake modified intention to treat analysis was not specified apriori in the trial protocol (http://www.controlled-trials.com/ISRCTN41089957/ISRCTN41089957).

The sample size calculation was done to detect a fairly large effect size. Given the apriori knowledge that this intervention is only likely to be of limited effectiveness, this study may not have had the power to detect more modest but clinically relevant effects. Although the target sample of 60 participants was stated in the protocol, the effect size was not given.

It is worth noting, however, that the direction of the non significant effect based on the primary and most secondary outcome measures was in favour of placebo.

- Minor Essential Revisions

The title and abstract accurately reflect the messages in the paper. It is not clear to me whether the investigation relates to C parvum or C hominis. The abstract refers to both but the full text of the article only mentions C parvum.

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 will like to declare that I am the author of a Cochrane review on this subject. The publication of this article and one other is likely to lead to an update of the Cochrane review.

- Have you in the past five years received reimbursements, fees, funding, or salary from an organisation that may in any way gain or lose financially from the publication of this paper, either now or in the future?
  NO

- Do you hold any stocks or shares in an organisation that may in any way gain or lose financially from the publication of this paper, either now or in the future?
  NO

- Do you hold or are you currently applying for any patents relating to the content of the manuscript? Have you received reimbursements, fees, funding, or salary from an organization that holds or has applied for patents relating to the content of the manuscript?
  NO

- Do you have any other financial competing interests?
  NO

- Do you have any non-financial competing interests in relation to this paper?
  NO