Response to reviewers’ comments

Reviewer 1.

Point 2: *The Indian studies [study] could have been criticised more rather than being described as minor.*

The reviewer makes relevant points about the shortcomings of the Indian study: that the population was largely illiterate and marginalised, the investigators did not do enough to ensure the participants had access to timely care for dysplasia [actually CIS or invasive cancer], and that the quality of consent was uncertain because it was not documented.

I already raised these issues in the Discussion as possible reasons why the Indian study has come in for so much criticism. Now I have made a few changes to this section to strengthen these concerns (in track changes).

But it is impossible to make definitive statements about the seriousness of these failures as the main information about them comes from the WHO case study which, though apparently based on the Delhi study, does not name the study and in fact differs from it in various details. Hence my point that a public Inquiry was needed to determine what actually happened.

I have not changed my conclusion that the ethical breaches in the Indian study appear to have been minor compared to the New Zealand study, but I have amended it to ‘relatively minor’. Once again I do not make a definitive statement because of the lack of reliable information, but say: ‘appear to be…’

Point 3. *The discussion section could be further expanded to address the issue that inquiry should be a more open process.*

I have added the important point that the records of the ‘in-house’ inquiry might be made available. I have also added a little more information about the Inquiry recommendations, and a reference to the just released article on the New Zealand study and the consequences of the Inquiry by bioethicist Carl Elliott.

Reviewer 2

I thank this reviewer for positive comments.