

No evidence that drug used for preventing life-threatening bleeding in women during labor works

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There is insufficient evidence for the effectiveness of a drug that is being used increasingly to prevent life-threatening bleeding in women after giving birth in community settings in low income countries, according to a review of all the available research published today (Monday) in the *Journal of the Royal Society of Medicine*.

Misoprostol (brand name Cytotec) was originally developed for treating gastric ulcers, but is increasingly used in low- and middle-income countries for preventing postpartum haemorrhage (PPH). It is given to women during labour to prevent uncontrolled bleeding, and it is included on the World Health Organisation's Essential Medicines List for this use.

However, researchers led by Professor Allyson Pollock from the Centre for Primary Care and Public Health at Queen Mary, University of London (UK) identified 172 studies on the use of misoprostol during labour and found that only six had enough information to enable them to review whether or not the <u>drug</u> was effective in preventing PPH in rural and community settings in <u>low income countries</u>. The six studies failed to provide sufficient evidence that the drug worked and most had problems with study design and the fact the findings were not applicable generally.

"Current evidence to support the use of misoprostol in home or community settings in low- and middle-income countries for the



prevention of postpartum <u>haemorrhage</u> is, at best, inconclusive," said Professor Pollock.

"Yet, despite there being no proper evidence of benefit, the WHO and some countries have put it on the Essential Medicine Lists and the drug is being pushed hard by networks of global public-private partnerships and industry in low- and middle-income countries. Countries such as Nepal, India and Uganda are promoting and using it. We urge the WHO to urgently review its decision to put misoprostol on its Essential Medicines List."

According to WHO estimates, there were 342,900 deaths related to pregnancy and childbirth in 2008, most of them occurring in developing countries. A quarter of these are thought to be associated with PPH while giving birth.

The main risk factor for PPH is anaemia, which is easily treated if it is diagnosed. But without antenatal screening for the condition it is impossible to identify women who may have developed it and who are at increased risk of life-threatening bleeding during labour.

"The most effective preventive strategy for PPH is prevention of anaemia, good antenatal care including good hygiene and sanitation and good care during labour," said Professor Pollock. "Developed countries would not dream of giving women misoprostol during labour on the basis of the current evidence, yet industry and health practitioners are pushing it hard in developing countries."

One of the reasons that misoprostol is popular in developing countries is that it is a fairly stable drug that doesn't degrade if not kept in cold storage conditions, and which does not have to be given intravenously. For this reason, it is more likely to be used outside hospitals, in settings such as the home and local community when women go into labour.



"Countries should be concentrating on improving their primary care facilities, rather than thinking there is a pill to prevent every ill," said Professor Pollock. "Misoprostol is being used inappropriately at present, and the money being spent on purchasing the drug would be better spent elsewhere, for instance, in ensuring there are skilled attendants during delivery and adequate antenatal services that can detect and help to prevent complications."

More information: "Rethinking WHO guidance: review of evidence for misoprostol use in the prevention of postpartum haemorrhage", by Christina Chu, Petra Brhlikova and Allyson Pollock. *Journal of the Royal Society of Medicine* 2012: 105: 336-347. doi 10.1258/jrsm.2012.120044.

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