

WOMAN: reducing maternal deaths with tranexamic acid



Over 200 million women become pregnant each year. Despite great progress during the past three decades, deaths during pregnancy and childbirth remain a serious (and largely preventable) risk for women in around 75 countries where 98% of maternal mortality occurs. The UN estimates that 532 000 maternal deaths took place in 1990. That number had fallen to 303 000 by the end of the Millennium Development Goal (MDG) era in 2015. Haemorrhage accounts for 18% of these deaths, and is a particularly important cause of maternal mortality in Africa and Asia. Discovering new ways to prevent maternal death, especially from bleeding, therefore continues to be a high priority. The findings of the WOMAN—World Maternal Antifibrinolytic—trial, reported in *The Lancet* today, are an important milestone in that quest.

Over 20 000 women were enrolled into this trial, which took place in 21 diverse geographical settings, including countries with some of the highest rates and absolute numbers of maternal deaths. Women older than 16 years and who had a clinical diagnosis of post-partum haemorrhage were randomly assigned to receive either 1 g of intravenous tranexamic acid or a matching placebo, in addition to usual care. The original protocol for the study described a composite primary outcome of death from all causes or hysterectomy within 42 days of randomisation.

However, during the course of the trial, the decision to conduct a hysterectomy was often made at the same time as randomisation so that the administration of tranexamic acid could not influence the risk of hysterectomy. A decision was taken to add another 5000 women to the trial's recruitment target of 15 000 women in order to reach the necessary power to estimate the effect of tranexamic acid on risk of death from bleeding. This change in study protocol is crucial to understand the importance of the WOMAN trial. Deaths from bleeding, now effectively the new primary outcome for the study, were significantly reduced by 19% with the use of tranexamic acid. Moreover, there was an important time-to-treatment interaction: maternal mortality was reduced by 31% if tranexamic acid was given within 3 h of birth.

The conclusion of the WOMAN Trial Collaborators is clear: "Tranexamic acid reduces death due to bleeding in women with post-partum haemorrhage with no adverse effects. When used as a treatment for post-partum

haemorrhage, tranexamic acid should be given as soon as possible after bleeding onset." The investigators acknowledge that in many settings where most maternal deaths take place—at home or in very poorly resourced facilities—intravenous administration of tranexamic acid may not be possible. They urge further studies of tranexamic acid given by other routes.

The results of the WOMAN trial should be put in the context of overall prospects for women's and children's health in the era of the Sustainable Development Goals (SDGs). The great advantage of the MDG era was the international priority given to maternal and child health with separately identified goals. The single SDG accorded to health is broader. It includes maternal and child health, but extends its reach across infectious diseases, non-communicable diseases, substance and alcohol use, injuries, sexual and reproductive health, universal health coverage, pollution, tobacco control, research and development, financing, health workforce, and early risk detection. This new agenda for health is correct. But a risk is that the past effort on maternal and child health becomes diluted, with the danger that progress slows.

This concern is compounded by recent and ongoing changes in leadership in global health. Antonio Guterres, UN Secretary-General since January, this year, has shown little serious interest in health since his appointment. If this indifference continues it will be an important setback for women's and children's health. Ban Ki-moon's signature Every Woman Every Child initiative added energy and vigour to the global campaign for women and children. Without the personal support of the Secretary-General, women's and children's health will inevitably be downgraded on competitive international agendas. And who will be elected as Director-General of WHO, and what their priorities will be, remain open questions.

The results of the WOMAN trial show why it is so important to maintain political commitment for women's, children's, and adolescent health. New findings, such as those for tranexamic acid, offer fresh opportunities for advocacy in settings where the risks faced by women during pregnancy and childbirth are greatest. Now is a moment to accelerate, not diminish, global action for maternal, child, and adolescent health. The findings of the WOMAN trial can be an important instrument to do so.

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