WHO essential medicines for reproductive health

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Since 1977, the WHO's Model List of Essential Medicines has been a rigorous evidence-based document providing a list of essential and life-saving medicines. Specifically, over the course of the last few decades, a large body of scientific evidence and programmatic use has accumulated for existing medicines for reproductive health and the development of new life-saving therapies. The 21st edition of the WHO Model List of Essential Medicines issued in June 2019, added heat stable carbetocin and tranexamic acid (TXA) to the core list of medicines for reproductive health and moved mifepristone and misoprostol from the complementary to the core list. All of these medicines are important for preventing the leading causes of maternal morbidity and mortality.¹

Uterotonics and TXA are pivotal for management of postpartum haemorrhage (PPH), which continues to be the leading cause of maternal deaths in most low-income countries.² Decades of evidence have demonstrated that PPH can be prevented by the prophylactic administration of uterotonics during the third stage of labour. Typically, in settings where multiple uterotonic options are available, oxytocin (10 IU, intramuscular/intravenous (IM/IV)) is the recommended agent for the prevention of PPH for all births.³ However, oxytocin is sensitive to heat exposure and must be transported and stored at 2–8°C continuously.⁴ This represents a problem in low-resource settings where the cold chain is difficult to maintain. Following the availability of new evidence, the 2018 updated WHO recommendations on the use of uterotonics for PPH prevention recommends carbetocin in settings where oxytocin is not available or its quality cannot be guaranteed, and its cost is comparable to other effective uterotonics.³ Heat stable carbetocin does not require refrigeration and therefore eliminates the barriers associated with refrigerated storage and transport for non-heat-stable uterotonics, making this a viable and important option for prevention of PPH.

In addition to this, WHO recommends the use of TXA as part of the standard treatment package.⁵ Based on the results of a large randomised controlled trial early use of TXA reduced death due to bleeding in women with PPH, regardless of the cause, and with no adverse maternal effects.⁶ TXA is relatively cheap, easy to administer and it is often available in healthcare settings due to its use in trauma and surgery. This agent was already included in the Essential Medicine List (EML) since 2011, but for the treatment of patients with trauma. The 2019 EML now includes TXA also as a core medicine for reproductive health to treat PPH.

Unsafe abortion is the fourth leading cause of maternal mortality globally. Nearly 25 million unsafe abortions occur worldwide each year and most of these (97%) take place in low-income and middle-income countries.⁷ The combination of mifepristone followed by misoprostol used for the medical management of abortion were added to the complementary list of essential medicines in 2005 as important reproductive health medications to decrease maternal mortality and morbidity due to unsafe abortions. Since 2005, evidence has accumulated documenting the safety and effectiveness of these medications in clinical trials and programmatic use. WHO guidelines recommend that they can be provided at primary care level and by non-physician providers. Specialised investigations are not needed and the process can be managed outside of a facility and without the direct supervision of the provider.^{8–15} Service delivery with limited medical supervision can improve privacy, convenience and acceptability of the abortion process without compromising safety and effectiveness. Moving these medications to the core list and removal of the stipulation that direct supervision is required is aligned with the evidence and guidance generated through the last decade.

All three medications have been added to the core list, which means that these medications

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do not require specialised diagnostic or monitoring facilities and/or specialist care and/or training. These changes to the core list of the 21st WHO Model List of Essential Medicines provide an opportunity for ministries of health, non-governmental organisations, national and international associations and civil society organisations to advocate for their inclusion to national essential medicine lists. Aligning with the global commitments to strengthening primary healthcare and access to universal health coverage, access to these essential Sexual and Reproductive Health (SRH) medicines will contribute to these commitments to ensure that access to life-saving medicines are available for all women globally, leaving no one behind.

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