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I.7 Mifepristone and Misoprostol for medical management of intrauterine fetal demise

MSF strongly supports the application from the WHO Department of Sexual and Reproductive Health and Research for the extension of the indication of mifepristone-misoprostol for the management of intrauterine fetal demise.

Intrauterine fetal demise is a clinical condition where the foetus is no longer alive, but the cervix remains closed and the uterus has not started to expel the foetus. This condition may be managed expectantly, treated surgically or medically. Evidence shows that medical management with mifepristone-misoprostol is effective. Several studies demonstrated that this condition can be associated with haemorrhage, with a rare complication of disseminated intravascular coagulation and with sepsis, leading to increased morbidity and mortality. Currently, there is no specific medicines included in the EML for the management of intrauterine fetal demise.

In 2005, mifepristone (200 mg tablet) and misoprostol (200 micrograms tablet) have been included in the Complementary List of the EML, as uterotonics, for medical abortion, with a specific requirement for close medical supervision. Misoprostol (200 micrograms) was included in the EML for the management of incomplete abortion and miscarriage, prevention and treatment of postpartum haemorrhage where oxytocin is not available or cannot be safely used. A vaginal formulation of misoprostol with a lower dose (25 micrograms) was also included in the EML, for use for induction of labour only, where appropriate facilities are available.
In 2019, the Expert Committee on the Selection and Use of Essential Medicines moved mifepristone-misoprostol to the Core List, removed the requirement for close medical supervision and recommended the inclusion of co-packaged mifepristone and misoprostol (combi-pack).
MSF warmly welcomed and strongly supported all these proposals.

The 2022 WHO “Abortion care guideline” recommends the use of combination mifepristone plus misoprostol, for the medical management of intrauterine fetal demise at ≥ 14 to ≤ 28 weeks. “Suggested regimen is 200 mg mifepristone administered orally, followed 1–2 days later by repeat doses of 400 µg misoprostol administered sublingually or vaginally every 4–6 hours. The minimum recommended interval between use of mifepristone and misoprostol is 24 hours. Misoprostol can be repeated at the noted interval as needed to achieve success of the abortion process. Providers should

use caution and clinical judgement to decide the maximum number of doses of misoprostol in pregnant individuals with prior uterine incision. Uterine rupture is a rare complication; clinical judgement and health system preparedness for emergency management of uterine rupture must be considered with later gestational age". Medical management of intrauterine fetal demise with mifepristone-misoprostol can be performed by a wide range of healthcare providers including non-physician healthcare providers.

MSF protocols indicate mifepristone with misoprostol for the management of intrauterine fetal demise and it is used in MSF programs.

MSF urges the 24th Expert Committee on the Selection and Use of Essential Medicines to extend the indications of mifepristone-misoprostol for the management of intrauterine fetal demise in the WHO Model List of Essential Medicines.

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