SPHERE
NHMRC Centre of Research Excellence in Sexual and Reproductive Health for Women in Primary Care

Women's Sexual and Reproductive Health COVID-19 Coalition

Evidence-based practice and policy recommendations regarding early medical abortion: a consensus statement

Early medical abortion (EMA) is a time critical and essential healthcare service. Restrictions on travel and healthcare service provision currently in place in multiple areas of Australia may create barriers to accessing EMA for women* and compound barriers to EMA for vulnerable groups, such as women residing in regional and remote areas. Depending on the progress of the COVID-19 pandemic in Australia, these barriers to EMA may continue, worsen or be alleviated.

In order to improve the accessibility of EMA in Australia, the Coalition proposes the following evidence-based practice and policy recommendations for EMA provision throughout the COVID-19 pandemic and beyond:

1. In relation to the mandatory requirement for an ultrasound prior to a medical abortion

Ultrasound prior to early medical abortion (EMA) is considered mandatory by the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) guidance in order to confirm gestation and exclude ectopic pregnancy (1). Ultrasound is recommended in the TGA-approved mifepristone and misoprostol (sold in the composite pack MS 2 Step) product information, although this is not mandated (2).

Many international guidelines recommend that ultrasound is not an essential pre-requisite to EMA (3-7). Furthermore, in response to the COVID-19 pandemic, the Royal College of Obstetricians and Gynaecologists (RCOG) UK has issued new guidance for healthcare professionals to minimise exposure to COVID-19 infection and ensure safe and effective provision of abortion care (8). This guidance recommends that provision of abortion can proceed without routine pre-procedure ultrasound.

Although ultrasonography services in Australia are generally accessible and Medicare rebatable to patients, out of pocket costs can be high and there can be delays with accessing this service, particularly for women living in remote and regional areas (9). These delays and cost considerations may be exacerbated during the COVID-19 pandemic and its associated constraints. Additionally, due to

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restricted international travel, there is an increased number of temporary visa holder residents in Australia, and for those who do not have reciprocal health care arrangements, the cost of accessing this service can be prohibitive. However, if remote location is the barrier to ultrasound access, consideration should be given as to whether the woman can access emergency services in a timely manner if the pregnancy is indeed extrauterine or there are complications of the EMA necessitating emergency care.

The Coalition therefore recommends that:

1. *Ultrasound prior to EMA remains the best approach during COVID-19 and beyond.*
2. *In situations where obtaining an ultrasound is a significant barrier or poses a significant risk during the COVID-19 pandemic, EMA can proceed without the necessity of ultrasound assessment. However:*
    a. *the woman should be carefully screened for risk factors for ectopic pregnancy and*
    b. *an assessment made of whether an accurate gestational age can be estimated from the woman's history*
    c. *a discussion regarding the risks of foregoing a pre-procedure ultrasound should be included as part of the consent process and supported by written information and*
    d. *a robust follow-up pathway should be followed (4,8).*

If the gestation is unable to be accurately identified or there are red flags for ectopic pregnancy, then an ultrasound assessment must be arranged.

3. *RANZCOG reviews their current guidance in light of recent evidence and international guideline recommendations in relation to the mandatory requirement for an ultrasound prior to early medical abortion*

2. In relation to the gestational limit of 63 days for the use of MS-2 Step (mifepristone, misoprostol)

Abortion is a time critical intervention. The COVID-19 pandemic and other barriers to access may mean that women are unable to access a medical abortion prior to the current gestational limit of less than or equal to 63 days for EMA provision, which is the TGA-approved indication and the gestation under which the Pharmaceutical Benefit Scheme subsidy can be obtained (10). However, many countries internationally have approved mifepristone and misoprostol use for EMA for up to 70 days' gestation,

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including the US and UK (4,5). **The safety and efficacy of EMA up to 70 days' gestation is known** (11-13). There is also evidence to support the use of EMA in women up to 77 days' gestation with limited risk of adverse effects (7, 12). **Multiple guidelines support providing EMA up to 77 days' gestation** during the COVID-19 pandemic, with or without additional doses of misoprostol (8, 14).

Mifepristone and misoprostol can be used 'off-label' (non-PBS) for EMA, beyond 63 days' gestation; however, such use does not attract a PBS subsidy, thus increasing the cost significantly and potentially creating an additional barrier to women accessing EMA.

The Coalition:

1. *Supports extended use of mifepristone and misoprostol for medical abortion in women up to 70 days' gestation and*
2. *Is supportive of an application being made to the TGA to extend the approved indication for MS-2 Step for use in medical abortion up to 70 days' gestation, recognising that were TGA approval of the extended indication be successful, a subsequent application to the PBAC for subsidy of the extended indication would be required.*

3. In relation to Anti-D administration

Current guidelines recommend that Rhesus status be determined and Rhesus negative women should be offered Anti-D following an EMA in Australia (15). Prior to COVID-19, sourcing Anti-D for EMA was perceived to be difficult for some GPs (16, 17). Sourcing difficulties for clinicians may be exacerbated during the COVID-19 pandemic. Furthermore, travel restrictions may create additional difficulties in reaching health services for women requiring Rhesus antibody testing and Anti-D administration.

Following an EMA (<70 days' gestation), the risk of Rhesus sensitisation is minimal (18,19). Prior to COVID-19, countries such as the United Kingdom did not require Anti-D provision after EMA < 70 days' gestation (5). RCOG abortion guidelines during COVID-19 do not recommend blood testing prior to EMA, unless there are clinical concerns (8). Likewise, Canadian updated induced abortion guidance for during pandemics do not recommend Anti-D provision for EMA < 70 days' gestation as it requires additional patient visits (14).

In the COVID-19 situation, RANZCOG has advised that a clinician may appropriately decide not to administer Anti-D prior to 10 weeks for medical management of abortion, particularly when an additional visit may increase exposure of women and staff. For surgical management of abortion prior to 10 weeks, checking Rhesus status and administration of Anti-D is discretionary, based on the individual woman's risk benefit profile and her preferences (20).

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The Coalition recommends:

1. *The removal of requirements for Rhesus determination and administration of Anti-D in known Rhesus negative women undergoing EMA prior to 70 days' gestation.*
2. *RANZCOG and the National Blood Authority review their current guidance in light of recent evidence and international guideline recommendations in relation to the mandatory requirement of Anti-D regardless of COVID-19.*

4. In relation to MS-2 Step as an unrestricted prescription

To provide EMA in Australia, clinicians must be certified and/or registered to prescribe MS-2 Step (the composite pack of mifepristone and misoprostol) via www.ms2step.com.au. Additionally, MS-2 Step is an authority required PBS prescription, requiring clinicians to call up to receive an authority to issue the prescription. There appears to be no valid reason to require an "authority" for MS-2 Step.

The Coalition therefore:

1. *Recommends that the requirement that MS-2 Step be prescribed as an authority prescription be removed.*
2. *Is supportive of an application being made to the PBAC to remove the requirement for an authority.*

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