





Joint statement on 'Abortion reversal': The Royal College of Obstetricians and Gynaecologists (RCOG), The Faculty of Sexual and Reproductive Healthcare (FSRH), the Royal College of Midwives (RCM) and the British Society of Abortion Care Providers (BSACP)

Key points and recommendations

- There are no reputable national or international clinical guidelines that recommend the use of progesterone to reverse the effect of mifepristone, and no evidence that it increases the likelihood of continuing pregnancy, compared to expectant management alone.
- Although evidence shows it is uncommon for women to regret their decision to have an
 abortion, on the very rare occasions where they do change their mind after receiving
 mifepristone, they should be supported and offered non-directive, neutral counselling
 with the benefits and risks of each of their options discussed. This should usually be
 through the abortion care provider, or an obstetrics and gynaecology (O&G) service.
- Where a woman or person chooses to continue with the pregnancy after having taken mifepristone, best practice is to:
 - o Offer an ultrasound scan to establish if the pregnancy has continued
 - Advise that if it is viable, there is a reasonable chance that the pregnancy will continue (this is more likely later on in a pregnancy).
 - Advise of an increased risk of pregnancy loss later in the pregnancy, possibly with some increased risk of severe bleeding.
 - Advise that mifepristone is not known to cause birth anomalies.
 - Not offer treatment with progesterone.
 - Provide reassurance that women will be given support to understand their options, including access to counselling if desired.
 - Provide assurance that the option of returning for abortion of this pregnancy remains open (and noting the latest date where pregnancy duration reaches the legal limit for the option of abortion).
 - Refer on for antenatal care at an appropriate point in pregnancy.

Background

A medical abortion uses medication to end a pregnancy. It involves taking two different medications one after the other. Mifepristone (taken first) has the effect of priming the uterus to make the second medicine quicker and more effective. Misoprostol (usually taken 24-48 hours later) causes the uterus to contract and the pregnancy tissue to pass, similar to a miscarriage. So-called abortion 'reversal' treatment involves prescribing doses of progesterone after a woman has taken the first medication (mifepristone) with the objective of reversing the effect.

The promotion of abortion 'reversal' has been observed for several years in the United States where in some States politicians are advancing legislation to require physicians to recite incorrect advice that states abortion can be 'reversed' with doses of progesterone. **The**

American College of Obstetricians and Gynecology (ACOG) does not support the use of progesterone, citing its use for this purpose as "unproven and unethical", and we strongly agree with this position.

We have observed an increase in discussions of abortion 'reversal' in the UK Parliament and media in recent months. This follows reports, dating from early 2021, from doctors and nurses working in abortion care who raised concerned reports that women and people were being offered abortion 'reversal' treatment. Investigative journalists have corroborated these accountsⁱ.

Evidence for the use of progesterone for abortion 'reversal'

There are no reputable national or international clinical guidelines that recommend the use of progesterone to reverse the effect of mifepristone, and no evidence that it increases the likelihood of continuing pregnancy, compared to expectant management aloneⁱⁱ. One European study showed that 82% of those who opted to continue with their pregnancy having taken only mifepristone (not progesterone) at a mean gestation of nine weeks proceeded to have a live birth, using a higher dose of mifepristone than is currently recommendedⁱⁱⁱ.

A randomised controlled trial to assess the effectiveness of progesterone treatment in reversing the effects of mifepristone was published in 2020^{iv}. The trial was stopped prematurely, owing to safety concerns when three of the 12 patients experienced "severe bleeding requiring ambulance transport to an emergency department". The author of the study concluded that abortion 'reversal' treatment with progesterone is "experimental and should be offered only in approved human clinical trials to ensure proper oversight". Aside from this abandoned study, we do not recognise the legitimacy of any other studies used to evidence the safety or efficacy of progesterone as an abortion 'reversal' treatment because they do not follow the usual standards of reporting and study design for observational trials, and are not published in reputable peer-reviewed journals.

Good practice guidelines for prescribing and managing medicines and medical devices^{vi} produced by the General Medical Council (GMC) state that when prescribing any "unlicensed medicine", a doctor must be satisfied that there is sufficient evidence or experience of using the medicine to demonstrate its safety and efficacy. **We strongly believe that this is fundamentally not the case for prescribing progesterone off label in these circumstances.**

Understanding the need for abortion 'reversal'

It is essential to ensure that discussion around the use of progesterone as a treatment to reverse the effect of mifepristone is put into the context of women's experiences of abortion care in the UK. The overwhelming majority of women and people requesting an abortion are clear about their decision, and want treatment as soon as possible.

There is strong evidence that, for most women, introducing delay causes distress and the NICE 2019 guideline on abortion care states that providers should ensure minimal delay in the abortion process. It also does not require women to have "compulsory counselling or a compulsory time for reflection before the abortion" – recommending that women should be provided or referred for support to make a decision if they request this^{vii}.

Research states there is no evidence of emerging regret after an abortion, with 97.5% of women believing that their decision was the right one after 8 days, increasing to 99% after

five years. There is evidence of an increase in decision certainty after proceeding with an abortion viii.

On very rare occasions, some women may regret their decision, or change their mind during the treatment process. When this is the case, women can be supported to come to the right decision for their individual circumstances. It is important they are offered non-directive, neutral counselling that provides the benefits and risks of each of their options.

The ACOG guidelines on medical abortion state that "in the very rare case that patients change their mind about having an abortion after taking mifepristone and want to continue the pregnancy, they should be monitored expectantly" There is no evidence to show that use of progesterone in this scenario would increase the chance of a pregnancy continuing as compared to monitoring a pregnancy following the use of mifepristone. The British Society of Abortion Care Providers (BSACP) recommend to its members that if this scenario arises they should offer an ultrasound scan to establish whether there is still a pregnancy, provide evidence-based advice on the future of the pregnancy, and if a woman or person decides to continue with the pregnancy, to liaise with antenatal services.

Provision of evidence-based information and support

Internationally and nationally recognised guidelines on abortion care are clear about the importance of providing evidence-based and non-biased information to support women to make informed decisions around pregnancy choices. The World Health Organisation (WHO) is clear that access to relevant, accurate and evidence-based health information is an "essential first step in improving access to and quality of abortion care"x. RCOG clinical guidelines on abortion state that written, objective, evidence-guided information should be available for women considering abortion before the procedure, and that women should have access to objective informationxi. Evidence-based guidelines are also clear that for women and people who request it, non-directive counselling should be made available.

There is a real risk that outside of the confines of regulated abortion care, where guidelines and training are very clear about the need for neutral and evidence-based advice, those offering advice and treatments around abortion or abortion 'reversal' might not be prepared to offer objective advice that enables women to make an informed choice free from bias or coercion. Abortion providers are experienced at safeguarding vulnerable women and girls, and work within multidisciplinary teams to ensure they are protected. The healthcare regulator, the Care Quality Commission (CQC), ensures that providers comply with their fundamental standards. Individuals who prescribe abortion 'reversal' act outside regulated care systems and are unlikely to have the same skills or resources. Healthcare professionals working in abortion care are experts in the provision of evidence-based information and non-directive counselling, and should be relied upon to ensure that women are able to make informed decisions regarding abortion.

Open Democracy. UK women are being 'used as guinea pigs' by 'abortion reversal' doctors (2021)

ii American College of Obstetricians and Gynecologists (ACOG). Medication Abortion Up to 70 Days of Gestation: ACOG Practice Bulletin, Number 225 (2020)

Bernard N et al, BJOG. <u>Continuation of pregnancy after first-trimester exposure to mifepristone: an observational prospective study</u>. (2013)

- ^{iv} Creinin MD, et al, Obstetrics & Gynecology. <u>Mifepristone Antagonization With</u>
 Progesterone to Prevent Medical Abortion: A Randomized Controlled Trial. (2020)
- ^v Bhatti K et al, AJOG. Medical abortion reversal: science and politics meet (2018)
- vi GMC. Good practice in prescribing and managing medicines and devices (2021)
- vii National Institute for Health and Care Excellence. Abortion Care [NG140] (2019)
- viii Lovel I et al, Obstetrics & Gynaecology. <u>Abortion Waiting Periods and Decision Certainty</u> <u>Among People Searching Online for Abortion Care</u> (2021)
- ix ACOG. Clinical Guideline: Medication Abortion up to 70 days (2014)
- * WHO. Abortion care guideline (2022)
- xi RCOG. The Care of Women Requesting Induced Abortion (2011)