

## **Early Medical Abortion (EMA) at home – evidence paper**

### **Introduction**

1. During the Covid-19 pandemic, the Welsh Government introduced a temporary approval in Wales, enabling women and girls to take both pills for Early Medical Abortion (EMA) up to 9 weeks and 6 days gestation in their own homes, following a telephone or e-consultation with a clinician, without the need to first attend a hospital or clinic. This arrangement was put in place during the pandemic to reduce the risk of transmission of Covid-19 and ensure continued access to abortion services. It is currently time limited for two years, or until the pandemic is over, whichever is earliest.

### **Early Medical Abortion (EMA)**

2. EMAs are defined as a termination of pregnancy that takes place within the first 10 weeks of the pregnancy using medical methods. EMA involves administering two different tablets: mifepristone and misoprostol.
3. The Department of Health and Social Care (DHSC) publishes abortion statistics on an annual basis for England and Wales. Since 2009, there has been an increase in the proportion of abortions that are performed under 10 weeks. In England and Wales in 2019, 82% of abortions were performed under 10 weeks, increasing from 75% in 2009. Accessing EMA services rather than abortion later in pregnancy helps to reduce the risk of complications, which increases the later the gestation.

### **Access to EMA prior to Covid-19**

4. In 2018, the Minister for Health and Social Services used powers in Section 1(3A) of the Abortion Act 1967 to approve Welsh homes as a class of place where the second stage of treatment (misoprostol) for EMA up to 10 weeks gestation can be carried out ("the 2018 approval").
5. Under this approval, women eligible for an abortion attended the clinic to take the first pill (mifepristone) and were then offered the choice of administering the second pill (misoprostol) in their own home, or returning to the clinic to take the misoprostol. Women choosing to administer the misoprostol at home were given clear instructions about its use and where to seek help if required. In England and Wales in 2019, 36% of all EMAs carried out were where the second treatment stage was administered at home.

### **Access to EMA services during the Covid-19 pandemic**

6. The temporary approval that was put in place in response to the Covid-19 pandemic enables women and girls to take both pills (mifepristone and misoprostol) for EMA up to 10 weeks gestation in their own homes, following a telephone or e-consultation with a clinician, without the need to first attend a hospital or clinic. This temporary approval superseded the 2018 approval described above.

7. Termination of pregnancy remains an essential service. We have discussed with clinicians, professional bodies and taken account the views of women's representative groups such as the previous Cross Party Group on Women's Health and introduced these temporary measures that enable women in Wales to have access to termination of pregnancy services at home.
8. Public safety is our number one priority as we tackle the COVID-19 pandemic. The protocol used to deliver EMA services via teleconference during COVID-19 was developed by clinicians and supported by guidelines issued by NICE and The Royal College of Obstetricians and Gynaecologists (RCOG). We are confident that all clinical and safeguarding risks have been considered and managed appropriately including the assessment of gestation.

#### What does the data show?

9. The number of abortions continues to increase in both England and Wales. In 2020, there were 9,834 abortions carried out for women resident in Wales.
10. There were 358 (or 3.8%) more abortions carried out to Welsh residents in 2020 compared with 2019. The increase from 2019 is not statistically significant, but the increase from 2018 is statistically significant.
11. In 2020, 95.1% of abortions were carried out before 13 weeks, including 90.3% under 10 weeks. Of those abortions, 98.1% were funded by the NHS (67.9% in NHS hospitals and 30.2% in the independent sector under NHS contract); the remaining 1.9% were privately funded.
12. Data suggests that the temporary arrangements have enabled women to access abortions much easier and this has led to abortions taking place at a much earlier gestation which is safer and provides better outcomes for women.
13. Official statistics show that in 2020 more abortions happened at earlier gestations than in 2019, with 30% happening at 5 weeks gestation or earlier, compared with 17% in 2019. The increased number of abortions is entirely a result of more medical abortions (971 or 12% more in 2020), as the number of surgical abortions decreased considerably during the pandemic (613 or 41% fewer in 2020). The percentage of medical abortion for residents of England and Wales has been consistently increasing over recent years and we cannot say this is definitely due to the temporary approval.

#### **Clinical and professional body comments and feedback**

14. In March 2020, the Royal College of Obstetricians and Gynaecologists (RCOG), the Royal College of Midwives, the Faculty of Sexual and Reproductive Healthcare, and the British Society of Abortion Care Providers produced clinical guidance for the provision of abortion care during the COVID-19 pandemic.
15. This guidance recommended provision of Early Medical Abortion via telemedicine to minimise risk and maintain provision of abortion as a time-sensitive, essential service. Specifically, it recommends:

- Providing remote consultation via video or telephone call and limiting in-clinic care.
- use ultrasound assessment only when clinically indicated – such as in case of symptoms or history of ectopic pregnancy, the presence of an Intra-uterine device, or uncertainty about the date of last menstrual period.

16. The change in practice has been welcomed by clinicians and women's groups. Officials wrote to Chief Executives of health boards at the beginning of September 2020 to ask for feedback on how the change in practice had worked in their health board. All reported improved outcomes in a number of areas including shorter waiting times, increased numbers of abortions taking place at a lower gestation and, significantly, very positive feedback from patients using this model of care. There have also been positive outcomes in terms of better use of resources and cost effectiveness.
17. We know that being required to travel to a clinic to access abortion services is difficult for many women. There may be limited access to transport, they need to take extra time off work and finding childcare can be difficult and expensive.
18. As well as making abortion services more accessible, the discreetness of a consultation in her own home has been described as positive by patients grateful not to have to attend clinic for management of an unwanted pregnancy.

### **Feedback and responses from Health Boards**

19. Telemedicine has helped to safely treat women in a way that fits in with their lives – while ensuring they are treated by trained professionals and provided with the support they need. The change has enabled services in Wales to provide safe and effective services that are more accessible than ever before.
20. Since the introduction of telemedicine the waiting times for assessment is much reduced and the average gestational age at the time of treatment lower. This may have an effect on fewer attendances in GP surgeries, early pregnancy assessment clinics and gynaecology services as common early pregnancy complications are picked up and managed by the abortion service as the first point of contact.
21. In some health boards the average wait for an appointment from first call is 1-2 days rather than 1-2 weeks. 95% women are now accessing medical rather than surgical abortion (previously this was 75%) which is much less costly for the health economy. The average gestation of treatment has fallen (now 6+5 rather than 7+2 in 2019) and the risk of complications especially retained products of conception and failed treatment has fallen. In the previous system patients would spend 1-2 hours in the clinic and now this is usually < 15 minutes.
22. Anecdotally, officials understand that women who have previously struggled to access in-clinic care, including women in abusive relationships, are no longer sourcing help outside the regulated healthcare system. Organisations such as "Women on the Web" have previously been contacted by Welsh women unable to access care as a result of their home circumstances and thus sought (illegal)

abortion care at home. Such requests have significantly reduced since women are instead seeking care via legal means.

23. Prior to the changes, health boards covering large areas and with high levels of rurality meant that for some women, accessing abortion services required lengthy travel distances and times. The changes have led to the workforce being able to work remotely, which has led to much more flexibility in the system. The service is more efficient in terms of accessibility and waiting times and the availability of EMAH that can be posted out via registered post, has dramatically reduced the differential in accessibility for those who are disadvantaged.
24. Feedback from patients using the service has shown high levels of satisfaction with their care. A significant majority of women said that they would choose telemedicine if they were to require another abortion.
25. Staff are very positive about the service they are offering. There is better continuity of care for patients and the fact that all legalities and medication are arranged before attendance mean the process is much smoother for patients.
26. The service model is much more efficient. In Aneurin Bevan University Health Board (ABUHB) for example, prior to the changes many patients seeking abortion provision were referred to private providers. The new model of service delivery has enabled 30% more patients to be treated within the service than was previously possible.
27. There is improved continuity of care for patients with all risks and potential medical complications assessed before rather than during the patient attendance. In ABUHB, since the introduction of the new model, there have been 3 ectopic pregnancies, all appropriately managed.
28. The British Pregnancy Advisory Service (BPAS) is a commissioned independent termination of pregnancy provider for all health boards in Wales. It has provided more than 40,000 telemedical abortions since the home use of mifepristone approvals in March 2020. Since telemedicine was introduced, across the BPAS service, waiting times have fallen by more than a week and the organisation argues, this simply would not be possible without telemedicine. Shorter waiting times mean that abortions can be accessed at earlier gestations, minimising the risk of complications.
29. NHS-led services have experienced large declines in waiting times. A 'Mystery shopping' exercise performed by BPAS in 2019 for the (then) Welsh Assembly Cross-Party Group on Women's Health found that many abortion services operated only a day or two a week, and that waiting times from contact to treatment averaged around 17 days. Since the change in regulation allowing telemedicine, waiting times in these services have declined to under 5 days – within NICE and medical guideline targets.

### **Key concerns raised**

30. The response from clinicians and professional bodies has been overwhelmingly positive. However, there were some concerns raised which we have considered in the following section:

#### **Safety**

31. Abortion is a low-risk medical procedure, safer than continuing a pregnancy to term. Clinical risk is an aspect of all forms of medical care which is managed by the patient's clinical team in discussion with the patient.

32. In line with the position of leading medical bodies such as the Royal College of Obstetricians and Gynaecologists and the Royal College of Midwives, abortion is best managed as medical care between a woman and her clinical team.

33. Before the approval of mifepristone at home, thousands of women in Wales were passing their pregnancies at home. Even prior to the approval for the home use of misoprostol, women were not remaining in hospital to pass their pregnancy, but instead travelling home often while suffering the early stages of miscarriage.

#### **Ectopic pregnancy**

34. The overall rate of ectopic pregnancy and complications related to ectopic pregnancy are low in the UK. According to NICE, the rate of ectopic pregnancy is 11 per 1,000 pregnancies. In line with other research, a large scale cohort study of women with unwanted pregnancies in the UK found a smaller prevalence amongst them: 2 in 1,000 clients presenting with an extra-uterine pregnancy ref: <https://obgyn.onlinelibrary.wiley.com/doi/full/10.1111/1471-0528.16668>

35. Women seeking abortions are screened for ectopic pregnancy and have historically been exposed to ultrasound scanning at an earlier stage than those who intend on continuing their pregnancies, even though the risk of ectopic pregnancy is higher in the latter group. In maternity care, ultrasound is not used for routine screening of asymptomatic women, and the first routine ultrasound scan does not take place until 12 weeks.

36. An important part of telemedical consultation and scan screening for abortion services is assessing a woman for likelihood of ectopic pregnancy. In Cardiff and Vale University Health Board, a clinical flow-chart to standardise screening of ectopic risk has been developed. Any woman who is symptomatic or who has a risk factor for an ectopic pregnancy will be invited for ultrasound scan and assessment in clinic. This good practice is something officials would ensure is delivered on an all-Wales basis should the approval to make the arrangements for EMA at Home be made permanent.

37. NICE guidelines are clear that Early Medical Abortion can be provided before there is definitive evidence of an intrauterine pregnancy, and the nature of

scanning at very early gestations makes detection of extra-uterine pregnancies more difficult and result in high rates of false positives. There is no clinical risk to patients with an ectopic pregnancy of taking abortion medication – patients are asked to confirm their understanding that a small risk of an abnormal pregnancy (ectopic or molar) remains and will require additional treatment.

38. This approach has been confirmed as safe by the already cited large cohort study (<https://obgyn.onlinelibrary.wiley.com/doi/full/10.1111/1471-0528.16668>) which reported that the telemedical model 'resulted in very low rates of undiagnosed ectopic pregnancy' (0.03%).

39. Ectopic pregnancies diagnosed after abortion treatment present a minimal risk which is present regardless of the care pathway. In summary the small possibility of an undiagnosed ectopic does not present an additional risk for telemedicine abortion because:

- the incidence of ectopic pregnancy is very low in abortion patients
- the outcome is not influenced by the care pathway,
- screening for ectopic pregnancy takes place at an earlier gestation in abortion care than for women continuing pregnancies, thus making early detection more likely
- the majority of ectopic pregnancies are detected prior to treatment in both the in-person and telemedical care pathways
- ectopic pregnancies are not complicated by Early Medical Abortion treatment.

## **Safeguarding**

### Children

40. Additional safeguarding for under-18s include questions designed to assess the likelihood of Child Sexual Exploitation, and identification of a responsible adult present while undergoing the termination. Where an under-18 has a social worker or contact with mental health services, their caseworker will be informed. If there are doubts the teenager is invited to attend clinic for a face-to-face discussion and consideration of in-patient treatment.

### Vulnerable women/domestic abuse

41. Clinicians argue that evidence from the past year, forcing clinic attendance is likely to result in reduced safeguarding disclosures and increasing numbers of vulnerable women and girls turning to illegal, unregulated sources of abortion medication online.

42. Abortion providers ask each woman whether they feel safe at home – both those treated in-person and via telemedicine. In Cardiff & Vale for example, the UHB's safeguarding team is involved and cases managed in line with relevant guidance. NHS bodies have established an excellent working relationship social services and the police, as well as local charities and organisations to help women who need support.

43. Since telemedicine started, providers have found that clients are more comfortable disclosing domestic abuse and other problems when talking from within their more familiar setting – enabling clinicians to better support them, whatever their need. Telemedicine is not a barrier to discussing safeguarding or domestic abuse concerns.
44. We also know that women who have previously struggled to access in-clinic care, including women in abusive relationships, are no longer sourcing help outside the regulated healthcare system

### **Access to abortion services – deprivation and rurality**

45. Based on BPAS data from the first quarter of providing EMA at home (April – June 2020), compared to the same quarter in 2019 (April – June 2019), the telemedical abortion service has a positive impact on abortion care for women from more deprived backgrounds and for women from more rural and remote areas who had previously experienced longer waiting times and higher gestation at treatment.
46. Women from more rural areas have historically struggled to access abortion care in an equitable way – as a result of the need to travel a greater distance, issues for disadvantaged women of accessing private transport, and the increased difficulties of spending longer away from home. The introduction of telemedicine has had a positive impact on women from more rural areas who were particularly disadvantaged by the requirement to attend a clinic.
47. Figures from within the BPAS service show:
- Waiting times have fallen 30% more for women living in ‘rural sparse’ areas than in ‘urban’ areas
  - Gestation at treatment has fallen 12% more for women in ‘rural sparse’ areas than in ‘urban’ areas
  - Women in ‘rural sparse’ areas were 5 percentage points more likely to access Pills by Post than women in urban areas, despite no difference in overall Early Medical Abortion preference

### **Development of consistent guidance**

48. There is a significant amount of evidence and feedback that demonstrates the temporary arrangements to allow women to access early medical abortion at home have had a positive impact on termination of pregnancy provision for both the women accessing the service and the service itself.
49. However, to ensure that provision is consistent and of a high standard of care and safety, officials will work with professionals to build on current guidance, taking into account the concerns raised and good practice demonstrated by some abortion services over the last 12 months and to ensure provision is consistent with the National Clinical Framework.

50. Guidance will also be provided to the wider NHS services. There has been a very small number of cases where women who have undertaken EMA at home have called for an ambulance or attended Accident & Emergency departments. Discussions with these services has highlighted a lack of clarity for professionals in these areas and officials agree there is a need to work with professional colleagues and develop appropriate guidelines.