BSACP
BRITISH SOCIETY OF ABORTION CARE PROVIDERS

Submission to the Welsh Government consultation on home use of both pills for early medical abortion up to 10 weeks' gestation in Wales

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Background to the organisation making this submission

The British Society of Abortion Care Providers (BSACP) is the principal, authoritative Society for health professionals working in abortion care in the UK, its Crown Dependencies and its Overseas Territories. It aims to provide a supportive community to promote best practice in abortion care. It was formed in October 2015 and is a specialist Society of the Royal College of Obstetricians and Gynaecologists (RCOG). It is separate from the RCOG but works closely with it and with its Faculty of Sexual and Reproductive Healthcare (FSRH). Representatives of all devolved nations sit on its Council. Its membership comprises mainly doctors, nurses and midwives who deliver abortion care for the National Health Service (NHS) – whether in NHS settings or the independent sector. The three main independent sector providers (ISPs) are: the British Pregnancy Advisory Service (BPAS), MSI Reproductive Choices (MSUK) and the National Unplanned Pregnancy Advisory Service (NUPAS).

Global context

BSACP regards the temporary measures put in place for Wales by the Welsh Government in response to the coronavirus pandemic as a major contribution to the public health which recognises abortion as an essential service. Sweden was already offering telemedicine and mifepristone at home within an ongoing clinical trial in Stockholm before the pandemic.[1] Ireland was the first country in the world to approve telemedicine for abortion during the pandemic; it did this by confirming on 26 March that the existing law permitted it.[2] England followed four days later and Wales and Scotland the day after that with specific regulations (https://bsacp.org.uk/resources/covid-19-advice/). The only other countries known to have taken such action, including the treatment itself, are South Africa on 3 April,[3] France on 10 April[4] and Moldova on 18 August.[5] Great Britain has come to be cited around the world as an example of healthcare excellence with respect to the introduction of these measures .[1 6-12]

An integral part of wider changes in service delivery

Remote consultations and the ability to take both medicines at home are a logical response to the pandemic, integral to other changes in the way of working. These measures help to limit the spread of infection and allow women[a] access to abortion care if they are self-isolating.[13] Even before the pandemic, NICE had recommended that the NHS should consider abortion assessments by phone or video call, and in a range of settings, to meet the needs of women.[14] In its systematic review, NICE

[a] Within this submission we use the term woman. However, it is important to acknowledge that it is not only people who identify as women for whom it is necessary to access women's health and reproductive services in order to maintain their health and wellbeing. Abortion services and delivery of care must therefore be appropriate, inclusive and sensitive to the needs of those individuals whose gender identity does not align with the sex they were assigned at birth.

found that community prescribing and telemedicine improved access to abortion services and facilitated a more patient-centred approach to care with no difference in outcomes.[15] NICE noted that telemedicine is likely to improve access, especially for vulnerable groups.[16] Moving away from a 'seen and examined' regulation is progressive and allows both patient and clinician much greater flexibility. Early medical abortion (EMA) has been subject to multiple innovative service modifications since the pandemic struck.[17] For example, the concept of 'resource stewardship' including 'no-test' medical abortion was rapidly developed.[18]

BSACP believes that these changes combined have been responsible for the ability to meet demand for the service during a pandemic and for the highly significant downward shift in gestation reflected in the England and Wales abortion statistics – 27% of medical abortions at under 6 weeks in Q1 and Q2 of 2020 cf. 16% for the same period in 2019.[19] By June 2020, more than a half of women undergoing medical abortion were taking both pills at home.

Scope of submission

As the consultation requires, the main part of the BSACP submission is about the impact of the temporary measures on the delivery of early medical abortion in Britain. Our submission draws heavily on high quality scientific evidence; these studies have all been designed, conducted and written up at an intense pace during the pandemic. The submission also draws on soundings from our members specifically with respect to the current consultations and also from two previous parliamentary consultations we have responded to (see https://bsacp.org.uk/resources/bsacp-submissions-to-formal-consultations/).

Effectiveness

In this and the following three sections of this submission, we present in detail the findings from the national cohort study by Aiken et al of data from BPAS, MSUK and NUPAS.[20] The study sample represents 85% of the total number of medical abortions performed in England and Wales during the study period. The sample includes all patients who accessed an early medical abortion (EMA) from these three providers during the two months before and two months after the service model change respectively. A comparison was made of 22,158 women having an EMA between 1 January and 1 March 2020 (the traditional cohort) with 29,984 accessing an EMA between 6 April and 30 June 2020 (the telemedicine-hybrid cohort). In the latter cohort, 61% of patients were treated entirely by telemedicine. This study is not only scientifically robust but also reports on the real-world experience of how the entire service was delivered.

Patients in the latter cohort received care using no-test telemedicine if they had a low risk of ectopic pregnancy and their self-reported last menstrual period (LMP) indicated a gestation of less than 10 weeks. Rates of successful medical abortion were found to be high under both service delivery models: 98.2% in the traditional cohort compared to 98.8% in the telemedicine-hybrid cohort. Within the telemedicine-hybrid cohort, rates of successful medical abortion were significantly higher for the telemedicine group compared to the in-person group (99.2% v 98.1%). This may be due to the ability of women to better control the timing at which they took their medicines, using regimens with more optimal intervals between the mifepristone and misoprostol.

These findings confirm the results from the previous study from Scotland about the high efficacy of taking misoprostol at home in patients who had been seen at a clinic and had a scan.[21] A recent prospective cohort study of 663 telemedicine abortions up to 12 weeks' gestation in the NHS in Scotland reports a similar high effectiveness.[22] Follow-up with completed questionnaires at both day 4 and day 14 post-abortion was achieved in 605 women (91%). Outcomes were verified by cross-linkage with hospital and community service records. 522 of the 663 women (79%) had their gestational age determined by LMP alone and 650/663 (98%) had a complete abortion.

Safety

In the national cohort study, significant adverse events in both cohorts were rare.[20] Haemorrhage requiring transfusion was reported in 0.08% of cases in the traditional cohort and 0.04% of cases in the telemedicine-hybrid cohort. No cases of significant infection resulting in hospital admission, major surgery or death were reported.

The overall incidence of ectopic pregnancy was equivalent in both cohorts: 0.2% in the traditional pathway and 0.2% in the telemedicine pathway. Thus, the very low incidence of ectopic pregnancy was no different in the modified care pathway from traditional in-person care with a routine ultrasound scan, meaning there is no evidence that the telemedicine model is missing this complication that can arise in any pregnancy.

There were 11 cases (0.04%) in the telemedicine-hybrid cohort in which the gestational age at abortion was subsequently reported as being greater than the expected 10 weeks. In all these cases, the medical abortion was completed at home without additional complications. Whilst these women would have been offered a surgical abortion had the true gestation been known, given the

restriction in the English approval order, that restriction is not supported by clinicians and has no evidence base or rationale to support it. Indeed, evidence shows that self-managed abortion up to 23 weeks is safe and effective.[23] BSACP believes that the decision about what method (surgical or medical) and location (home or clinic) is best made by informational exchange between women and their clinical team, having weighed up all the circumstances of the individual concerned. Also, it is best managed through clinical guidelines and not via rigid legal restriction which is incompatible with personalised care.[24] The cohort study from Scotland, where there is no gestational limit applied by the approval order, showed few complications, with zero cases of haemorrhage requiring transfusion and zero cases of infection requiring intravenous antibiotics.[22]

The lowered gestation at treatment brought about by increased use of the new model of care will have an overall beneficial effect on women's health as both morbidity and mortality are known to be lower the shorter the gestation.[25] It will also be less distressing for women, both because the pregnancy itself is less advanced and because any underlying symptoms of pregnancy such as nausea, which can be debilitating, will have less time to develop.

Accessibility, convenience and waiting times

A large majority of patients who had a telemedicine abortion from the independent sector providers (ISPs) opted to have the pills delivered by post.[26 27] A minority opted to travel to a clinic to collect the pills. The latter choice was made by, among others, those who did not want to incur delays in the postal service, those for whom a delivery might have been received by a member of the household the patient did not want to disclose the abortion to or those who had concern about the package being delivered to the correct address.[26] In the NHS study in Scotland, 65% of patients reported the ability to collect medication from a pharmacy to be of high importance to them.[22]

The new pathway gives women greater choice about when to start their EMA. By not being tied to a clinic appointment date, women can decide to begin the process over the weekend or at a particular time that is convenient for them.

Women identify minimal delay as a high priority in abortion services and find delays distressing.[28] The national cohort study showed improved access after introduction of the temporary measures.[20] Mean waiting time to treatment declined from 10.7 days in the traditional pathway to 6.5 days in the telemedicine-hybrid cohort. This fall in waiting time meant that gestational age at treatment also declined, resulting in 40% being at 6 weeks or less compared to 25% in the traditional pathway. This

highly significant improvement in accessibility is a major benefit of the new measures which allows treatment to run more smoothly and reduces women's distress.

Data collected by the three main ISPs and analysed by the RCOG, confirms this highly significant fall in waiting times with the temporary measures in place. The longest waiting time in 2019 was 15.34 days and the shortest waiting time in 2020 was 5.48 days. Reduction in waiting times has beneficial effects only; there is no waiting time that is too short.[29]

Another form of evidence on access comes from a study on the use of online telemedicine by British residents. A highly significant decrease in requests was seen by Women on Web following the introduction of the temporary measures.[30] This decrease points not only to the removal of access barriers posed by COVID-19 but also to pre-existing barriers. The modified model of care allows more women to access abortion care through official health sector channels.

Acceptability

Detailed acceptability studies from both BPAS[27] and MSUK[26] draw on samples of roughly 1 in 10 of all those having EMAs with these ISPs, each study containing more than 1,000 subjects. The BPAS study includes all those having the pills at home; the MSUK includes only those who had their consultation via telemedicine.

Overall satisfaction with the treatment was more than 95%. 80% or more of patients were satisfied with pain control measures. In the MSUK study, 99% felt they had had an opportunity to ask questions, 92% felt they had had enough information and 87% had no concerns about the safety of taking the medicines outside a health facility.[26] In the BPAS study, 78% would have an EMA using a telephone consultation in the future, 78% would have both pills at home and 69% would have their medicines delivered by mail.[27] The Scottish cohort study, with its 91% response rate to follow-up at two points in time, reported that 95% of women found the overall experience as somewhat/very acceptable, 87% found the remote consultation acceptable and 71% would opt for such a consultation again if it were to be needed.[22]

Privacy and confidentiality

In the MSUK study, 95% felt they were able to talk privately. BSACP supports the ability of patients to opt to have their consultation in a place of their choosing away from the clinic. Those under coercive control are best protected by being free to choose their preferred time and place to ensure

they are alone and cannot be overheard. Furthermore, protests outside clinics can be intrusive and distressing and avoiding them is one of the reasons women cite as to why they pursue telemedicine by email where remote clinician-to-woman care is not available.[31]

Providers and services

The temporary measures have had multiple effects on those involved in delivering abortion services; on balance these have been overwhelmingly positive. Some BSACP members report personal challenges in the wholesale switch from face-to-face to remote consultations but they have embraced it in order to put their patients first. Members believe that the temporary measures allow much more flexibility in running services and they improve overall service efficiency.

A particular example of benefits to providers has been the facility to prescribe from home. Our members who work for MSUK pointed out the following non-COVID related benefits of the measures:

- Greater flexibility in childcare arrangements for the 58% of doctors who have children
- Ability to continue working when suffering from a mild viral illness/injury or long-term health problems
- Obviating a commute to the workplace

There are financial savings to be made from the lower gestations associated with the modified care pathway and from the fact that more women choose not to have surgery. Extrapolating from the estimates of the NICE guideline,[14] about £6.7 million per year is being saved in England under the temporary measures.

Possible concerns

We will consider four potential concerns that might be raised about the modified management of those undergoing EMA: a) uncertain gestational age due to lack of routine ultrasound scanning, b) late diagnosis of an ectopic pregnancy, c) difficulty in perception of non-verbal cues relevant to an unstable decision about abortion and to safeguarding issues and d) committing to initiation of the abortion process and taking the medicines away from medical supervision.

With regard to a), as mentioned above in the Safety section, the 11 cases in the national cohort telemedicine-hybrid group that were at more than the expected 10 weeks all completed the abortion at home without additional complications.[20] With regard to b), although routine ultrasound

scanning is not necessary, clinical guidance for remote care excludes women who have risk factors for or symptoms/signs suggestive of an ectopic pregnancy. Routine scanning in symptom-free women without risk factors is questionable as it may aid detection of some cases but falsely reassure others that a pregnancy is intrauterine.[32] The absolute incidence of ectopic pregnancy in those undergoing abortion is known to be ten times lower than that in the general population.[33] The general population are not seen in person and scanned unless they have symptoms of an ectopic pregnancy. There is no clinical justification for maintaining an inconsistency in care between those continuing their pregnancy and those choosing EMA.[20]

Regarding c), the experience of BSACP members is the converse; their experience is that women can talk more freely and openly when consulting over the phone than in a clinic. Many people are intimidated by medical consultations and, with abortion care being so intensely personal and private, face-to-face discussions can be perceived as threatening. Many women expect to be judged, given the stigma attached to abortion care[34] – an expectation reinforced by the frequent protests that occur outside abortion clinics (https://bsacp.org.uk/wp-content/uploads/2020/10/BSACP-Position-Statement-Protests-18082020.pdf). In contrast, people are accustomed to talking over the phone and when consultations are conducted from the privacy and safety of their own home, they are more likely to be open and honest, rather than feeling obliged to offer answers they perceive to be expected of them. This impression is borne out by consultations often taking longer over the phone – as the patients simply talk more – and that rates of identification of safeguarding issues have increased.

Finally, with respect to d), it is clear from experience so far that women are well able to make the decision to swallow the mifepristone by themselves in the privacy of their homes. Taking both mifepristone and misoprostol at home has been routine practice across the world for many years and has an excellent safety record.[35] [36] The deregulation of mifepristone in Canada in 2017 has not resulted in a clinically significant increase in abortion complications, continuing pregnancy or adverse events.[37] Mifepristone is a very safe medicine. Table 1 shows numbers of spontaneous adverse drug reaction reports for mifepristone, sildenafil (Viagra) and paracetamol.

Table 1 Drug Analysis Profile data from UK Yellow Card Scheme for the years 2000 – 2019

Drug	Classification	Serious ADR reports	Fatal ADR reports
Mifepristone	POM	253	17
Sildenafil	P	892	170
Paracetamol	GSL	5598	545

Source: https://yellowcard.mhra.gov.uk/iDAP/

Note: Please read the important caveats about these data on the website. The existence of an adverse drug reaction report in the iDAP does not necessarily mean that the medicine has caused the reaction. It is not possible to exactly quantify the safety of different medicines by comparing the numbers presented in the iDAPs.

Effect on other NHS services

We have not received any hard data on this so far. BSACP considers it likely that there have been reduced referrals to Early Pregnancy Units as those previously with pregnancies too early, or where the pregnancies were non-viable, will simply be managed via telemedicine.

Information on risks given to women

Information availability has increased rapidly during the pandemic. BPAS includes the risks and complications in its information about Pills by post: https://www.bpas.org/abortion-care/abortion-treatments/the-abortion-pill/remote-treatment/. MSUK includes a series of videos in its information about At Home Abortion Pills: https://www.msichoices.org.uk/abortion-services/online-medical-abortion/ .

BSACP is satisfied that patients who opt to receive their EMA via the modified pathway are being given access to high-quality information and support. An example of NHS information for those in Lothian, Scotland, is at: https://www.lothiansexualhealth.scot/pregnancy-planning/abortion-services-during-covid-19/. There was no difference found in recall/acceptability of Lothian service users who had the information face-to-face or via video.[38] In Wales, the video made by the Beth service in Gwent has received acclaim: https://abuhb.nhs.wales/community-services/sexual-health-services/sexual-health-accordion/think-you-may-be-pregnant/.

As part of the pathway change and to improve the process of gaining informed consent, information (links and documents via e-mail) is now given at the initial presentation so the patient has a chance to read and think of questions prior to the telephone consultation. Previously, this would have been

conveyed in a face-to-face consultation, where people are often nervous, may be reticent to ask questions, and often may not be receptive to retaining information as they are in an unfamiliar environment, stressed and expecting to be judged.[39]

In the MSUK study, 92% of women undergoing telemedicine EMA reported that they 'definitely' had enough information to take the medication by themselves.[26]

Safeguarding

BSACP is familiar with the phenomenon of reproductive control[40] and with domestic violence – the two overlap and probably have similar antecedents. Survivors of domestic abuse in the UK, especially those living with their abuser, have reported worsening of the abuse during the pandemic.[41] The United Nations has termed this high prevalence of domestic violence, exacerbated by lockdown, the 'shadow pandemic'.[42] Forced sex and contraceptive sabotage are two of the behaviours that those with unintended pregnancies who present to our members are describing. The vast majority of cases of coercive control involve men controlling women and our experience is that coercive control is more commonly seen in the form of denying a woman access to healthcare and abortion than attempting to force her to have an abortion against her will. It would appear that there is a direct correlation between the imposition of social distancing measures and threats to women's wellbeing, health and safety in this respect. Remote consultation is essential for these women as, during lockdown and in higher-tier restrictions, they find it hard to leave their house without explanation. Although this situation may ease after the pandemic, allowing women to choose options of care makes it more flexible for those who are in a form of long-term lockdown.

We understand that an audit done during the first three months of their Pills by Post service showed that 1 in 10 clients at BPAS underwent an enhanced safeguarding risk assessment. This is a 12% increase compared to March 2020. Data from MSUK show a 27% increase in the detection of safeguarding issues since the start of the pandemic.

BSACP members expressed their view that anti-abortion groups are wrong to state that safeguarding can only be provided in face-to-face consultations. Providers have protocols in place to ensure that a woman is able to talk in private and is not being coerced. It seems likely that this is easier to achieve where a woman can use her own phone in private than when she has to attend a clinic where a coercive partner is aware of, or indeed even present at, her consultation. BSACP believes that some women will feel better able to talk freely when they are in their own environment than they may do

when in a clinic environment that might feel intimidating. MSUK reports that three of its major safeguarding cases from 2019 – i.e. before the pandemic – were identified during a telephone consultation. These were the rape of a 12-year old girl by her stepfather and uncle, the identification of a human trafficking ring from which three women were rescued following a multi-agency response and a 10-year old who was raped by her stepfather who could only be traced by her call.

We anticipate that abortion services will continue to offer in-person care where remote consultations raise safeguarding concerns. This gives women choice and also allows providers to give the most appropriate care to every individual.

Equality considerations

As always, the impact of an unwanted pregnancy on marginalised individuals and communities is proportionately greater. Remote consultations are beneficial for those who would otherwise need an extended period of childcare to attend an appointment; this is particularly relevant for those parenting a child with special needs. Consultations in which the patient and practitioner do not share a language always bring additional challenges. However, in many settings, use of phone interpreters has been common practice for some time. The patient and practitioner not being in the same physical space is somewhat more challenging but the use of video-consulting options will assist once these become universally available.

BSACP believes that some younger women will have difficulties travelling from the family home and that telemedical services will have been particularly beneficial for them as they are under the scrutiny of parents, who may be unaware of their sexual activity. BSACP believes that advantages for many disabled people will apply too in that journeys to health facilities and potential difficulties with access to buildings will have been avoided. These issues may have been exacerbated during COVID restrictions but are ever-present in these particular groups.

BSACP believes that the Women on Web study,[30] mentioned above, most likely shows that particular groups have had difficulty accessing EMA up to the onset of the pandemic and now feel more comfortable accessing the modified pathway. These groups will include those with mental health problems, single-parent families, those with disabilities, those living in poverty, sexual assault survivors, those living on islands or in very rural locations[43] and others particularly with intersecting issues.

Ten-week limit

The temporary measures impose a 10-week gestational limit, as did the previous regulations for misoprostol. This is an additional restriction which is not evidence-based. There has been no suggestion that clinicians have been conducting medical abortions inappropriately. In Scotland, no such restriction was brought in; rather the regulation refers to clinical guidance issued by the Scottish Abortion Care Providers Network. This currently advises an upper gestational limit of 11 weeks and 6 days and is in keeping with modern clinical practice. BSACP views the imposition of an arbitrary but fixed gestational limit as problematic as it removes choice and takes decision-making away from the woman, as advised by her clinical team. It also adversely impacts the facility-based practice of medical abortion at higher gestations by insisting that mifepristone is swallowed on the premises and/or that women have to administer misoprostol in a clinic and then get home before pain and bleeding get too intense. BSACP sees arrangements aligned with those in Scotland as preferable and hopes that the Welsh Government will follow the lead of the Scottish Government.

Making the measures permanent

In the longer term, BSACP maintains its belief that abortion should be decriminalised.[44] BSACP notes that restrictions on the storage and community prescription of mifepristone in place over the last 30 years have prevented use of the drug for emergency contraception; mifepristone has been known to be more effective than hormonal methods since 1992,[45] thus many unintended pregnancies (and abortions) could have been averted if it had been available for this use over these decades. There is a general point here too: unduly strict regulation often has harmful effects on patients.

Abortion services must be seen in the wider context of the health service response to the coronavirus pandemic. There has been widespread blue-sky thinking, innovation and introduction of new ways of working.[46] The pace of this work has been unprecedented despite the intense pressures of working in a pandemic. NHS England and Improvement has set up the national Beneficial Changes programme to identify these innovations and how they have improved delivery of healthcare.[47] The Beneficial Changes Network and Accelerated Access Collaborative are working together on this. Two emerging themes relevant to this submission are digitisation of services and person-centred care. There is much more to be done, for example in building video consultation and electronic prescribing capacities in all relevant health facilities.

The use of remote consultations has been adopted by most services and has transformed the face of healthcare. Routine scanning has been widely switched to scanning when clinically indicated.

Delivery of medicines by courier or mail or collection at service provider facilities, pharmacies or other locations has been seen in many different services. All the advantages of telemedicine and 'click and collect' are applicable generally and are not confined to the exceptional times of a pandemic. This has already led to these new ways of working becoming embedded in health service delivery even before the Beneficial Changes programme has reported its findings.

Although 'no-test' EMA has been widely adopted in abortion care, this change in routine practice does not depend on the temporary measures. Intimate examinations should be kept to a minimum; given the high degree of accuracy in estimating gestation according to date of LMP,[48] it is highly unlikely that abortion providers will revert to routine ultrasound scanning. Requiring a woman to attend a clinic merely to swallow a pill would be unreasonable.

We can understand how the emergency measures for abortion care came to have a sunset clause. However, the landscape is now completely different, with almost one year of experience of being able to work much more flexibly and especially in light of the newly published safety data. The results of the national cohort study show that there is no need for routine scanning prior to EMA and that women can be 'trusted' to use abortion pills without direct medical supervision. A telemedicine pathway for EMA facilitates a shorter wait for the procedure, with equivalent effectiveness and safety and high acceptability.

Within the current outdated legal framework of our jurisdiction, BSACP believes that remote consultations and the ability for patients to take both pills at home should remain an approved and valid way of working beyond the pandemic. This fits with a human rights imperative and is a critical step towards complying with binding international legal obligations.[6] Telemedicine demonstrably enhances people's autonomy.[49] We would go as far as to say that reversion to the previous regime would be severely retrogressive and contrary to scientific evidence and medical advice; it would also suggest underlying political motivation to restrict access to abortion care. Not to make the measures permanent would also run counter to the efforts of NHS England's Beneficial Changes programme to embrace and adopt innovations that are seen as greatly beneficial to healthcare delivery.

In sum, BSACP believes that there is overwhelming support on scientific, clinical, social, economic, legal and ethical grounds for these measures to be made permanent.

22/2/2021

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