2020 developments in the provision of early medical abortion by telemedicine in the UK

Abstract

The COVID-19 pandemic has necessitated the rapid implementation of telemedical health services. In the United Kingdom, one service that has benefitted from this response is the provision of early medical abortion. England, Wales, and Scotland have all issued approval orders to this effect. These orders allow women to terminate pregnancies up to certain gestational limits, removing the need for them to contravene social distancing measures to access care. However, they are intended only as temporary measures for the duration of the pandemic response. In this paper, we chart these developments and further demonstrate the already acknowledged politicisation of abortion care. We focus on two key elements of the orders: (1) the addition of updated clinical guidance in the Scottish order that suggests an extended gestational limit, and (2) sunset clauses in the English and Welsh orders, as well as an indication of similar intentions in Scotland. In discussing these two issues, we suggest that the refusal of UK governments to introduce telemedical provision of early medical abortion previously has not been based on health concerns. Further, we question whether it would be appropriate for the approval orders to be lifted following the pandemic, suggesting that to do so would represent regressive and harmful policy.

1.0 Introduction

As a result of the COVID-19 pandemic, the use of telemedicine throughout the United Kingdom's (UK) National Health Service (NHS) has quickly increased as a means of allowing patients to continue to access care without having to contravene social distancing measures and unnecessarily risk exposure to COVID-19. One area where telemedicine has been introduced is in the provision of early medical abortion (EMA).

In the past few years, the UK has seen long overdue moves to permit home use of the second drug required for an EMA [1]. The governments of Scotland [2], Wales [3], and England [4] – in that order – issued approval orders between 2017 and 2018 to permit women to take the second drug required for an EMA at home provided that the first was taken under clinical supervision. At the time, and indeed long before, there had been calls to allow women to take both drugs at home after having them prescribed remotely [1, 5]. So-called telemedical EMA (TEMA) is a means of removing barriers to abortion care and has therefore been argued for in order to ensure equality in access to care [5, 6]. Notably, the National Institute for Health and Care Excellence (NICE) in England and Wales recommends the use of telemedicine in abortion care in its 2019 guidelines [7].

In response to the COVID-19 pandemic, telemedicine has seen increased implementation throughout the NHS [8]. Whilst behind others, as of late March 2020 abortion was added to the list of services to benefit from telemedicine during the pandemic, starting with a TEMA approval order in England.

TEMA is now formally provided for in England, Wales, and Scotland. In Northern Ireland, however, provision is informal, and potentially problematic given that it remains unlawful in most circumstances.

In this paper, we outline the development of these policy changes. We first describe both EMA and TEMA, before providing a chronological overview of changes. Beginning with the twice reversed decision in England, we discuss the nature of the introduction of TEMA in both Wales and Scotland; the former mirroring England whilst the latter departs from Westminster on two important points. The far more complicated situation in Northern Ireland is then considered, followed by a look at the statistics thus far and a brief comparative discussion in which we look to the response of the United States (US). Finally, the implications – both short- and long-term – for questions of access to abortion care are discussed, demonstrating how this apparently progressive change is merely a supporting measure in the wider fight against COVID-19 which will in fact further undermine the reproductive rights of women in future.

2.0 TEMA explained

2.1 Early medical abortion

EMA requires the use of mifepristone followed, 24-48 hours later, by misoprostol. The result is an induced miscarriage followed by the expulsion of the products of conception. The World Health Organization (WHO) makes a 'strong' recommendation for this procedure to be used up to nine weeks' gestation [9]. The WHO also notes that the same drugs may be used to terminate a pregnancy at a later gestational stage, though with the caution that there are limited data for EMAs performed between nine- and 12-weeks' gestation [9]. NICE recommends a slightly higher limit of 10 weeks' gestation [7], but both fall within the bracket of what has been indicated as likely safe and effective in the absence of randomised clinical trials [10].

2.2 The introduction of telemedicine

Whilst only a recent development in the UK, various forms of TEMA has been practiced in some parts of the world for more than a decade. Planned Parenthood of the Heartlands set up such a service in Iowa in 2008 which allowed women to attend a collaborating clinic with no on-site physician, undergo a videoconference consultation with an off-site physician, and have the necessary medications dispensed by the collaborating clinic if prescribed [11]. This did require women to physically attend a clinic, but it improved access by enabling clinics that previously could not provide EMAs to do so. Another example from the US is the TelAbortion Project which has, since 2016, enabled women in several states to be posted abortion medications after obtaining screening tests locally [12]. Similarly to what was offered by Planned Parenthood of the Heartlands, access is improved even though those using the services of the TelAbortion Project are still required to attend some form of medical facility.

A different model – closer to what is often envisioned when TEMA is mentioned – is that of Women on Web. This service has been operating internationally since 2004, though is available only to those in

countries where safe access to abortion is not possible [13]. Unlike the previous two services outlined, Women on Web operates entirely online. An online question-based consultation is completed and, if the responses indicate that EMA is appropriate, the medications are sent to the woman by post. This system, then, has greater potential to improve access to abortion care as there is no need to attend a facility in person.

The safety, effectiveness, and acceptability of TEMA have previously been demonstrated. Endler and colleagues have highlighted, through a systematic review, that there are similar rates of 'complete abortion, continuing pregnancy, hospitalization, and blood transfusion' following both TEMA and in-clinic EMA [10]. They also found that both women and providers found TEMA highly acceptable. It should be noted, however, that Endler and colleagues' review does rate the quality of evidence as low, so must be taken as more indicative than conclusive. In addition to the evidence supporting the abortion itself during TEMA, it has also been demonstrated that women can reliably date their pregnancies according to their menstrual history, thereby minimising the risk of them undergoing an EMA at a later gestational stage. A study between the US and India found that only 9.8-10% (woman's estimate based on last menstrual period) and 3.4-7.7% (woman's estimate based on date of last unprotected intercourse) of women fell within the 'caution zone', which was defined as the woman dating her pregnancy at <9 weeks but her healthcare provider dating it at ≥9 weeks [14].

3.0 TEMA developments in the UK

3.1 England

The first country in the UK to instigate TEMA in response to the COVID-19 threat was England (*see Table 1*). In contrast, England did not permit home use of misoprostol until *after* Scotland and Wales [1]. However, the process resulting in the policy was unclear and initially caused widespread criticism and confusion.

On the 23rd March 2020, the UK Department for Health and Social Care issued an approval order allowing women seeking an EMA in England to self-administer both necessary medications at home. The order specified that following a consultation with an appropriate provider via electronic means, a woman may be prescribed both mifepristone and misoprostol. However, the order was revoked later that same day, replaced online by a statement that it had been published in error [15]. This led to a great deal of uncertainty, which was especially troubling for women seeking abortions at the time. As a result, an open letter was sent to Matt Hancock, the Secretary of State for Health and Social Care, on the 28th March 2020 by a group of public health specialists [16]. This letter noted the scientific evidence and advice of professionals which had been ignored and called for the order to be reinstated.

Following this letter, a second order relaxing abortion regulations in England was issued on the 30th March 2020. This second order was similar in allowing women to be prescribed both medications following remote consultation, with a gestational limit of nine weeks and six days [17]. However, it differed in its inclusion of a sunset clause; the order will expire automatically on the 30th March 2022, or with the expiration of the *Coronavirus Act 2020* if that comes first. That the order is temporary might be perceived as problematic, as will be explored shortly.

On the 6th July 2020, it was announced in the House of Commons that a public consultation will take place on whether to make the temporary provisions permanent. In response to a question posed, the Minister for Safeguarding, Victoria Atkins, confirmed that the temporary provisions would at least stay in place 'until the public consultation concludes and a decision has been made' [18].

3.2 Wales

Just one day later – on the 31st March 2020 – both Wales and Scotland followed suit. Scotland will be discussed shortly, so for now we will focus on Wales.

The Welsh approval order was issued by Vaughan Gething, the Welsh Minister for Health and Social Services, to supersede the previous order of the 27th June 2018 [3] which permitted home use of misoprostol. In almost entirely replicating the earlier English order, the Welsh approval expires either with the expiration of the *Coronavirus Act 2020* or two years after the date of the approval (in this case the 31st March 2022) [19]. Again, following the English example, the gestational limit remains at nine weeks and six days in Wales.

3.3 Scotland

As noted above, Scotland also permitted TEMA on the 31st March 2020 [20]. The approval was similar to those of England and Wales in permitting home use of mifepristone (in addition to misoprostol as previously allowed) following remote consultation. However, it differs in two important respects: guidance on gestational limit and expiration.

First, unlike the orders of England and Wales, the Scottish order does not contain an explicit gestational limit for TEMA. It is, however, accompanied by an annex containing guidance from Scottish Abortion Care Providers (the Scottish branch of the British Society of Abortion Care Providers) that includes gestational limits. This annexed document does not form a part of the approval order. Nonetheless, the Scottish Court of Session confirmed that whilst similar guidance in relation to the Scottish 2017 approval order of home use of misoprostol was advisory only, practitioners should take the guidance into account [21]. In the annexed guidance to the Scottish 2020 approval order, providers are advised that a woman should be eligible for TEMA provided she has not exceeded 11 weeks and six days' gestation [20]. This is a two week increase on the limit stipulated in the approval orders of England and Wales. It is also a two week increase on Scotland's own previous limit as per the 2017 order regarding the home use of misoprostol [2].

Second, there is no included expiration of the order. Whereas the approvals in England and Wales will automatically expire unless further action is taken, the explanatory note attached to the Scottish order merely states: 'we intend that it will have effect for a limited period so would revoke it and replace it

with the terms of the previous approval (dated October 2017) at an appropriate time when it is judged that it is no longer necessary in relation to the pandemic response' [20]. It is, then, *possible* that Scotland will maintain TEMA provisions permanently following the pandemic. At the very least, TEMA will not *automatically* become unlawful once the pandemic is over. Like England, Scotland is conducting a public consultation on the matter [22].

3.4 Northern Ireland

Northern Ireland has consistently fallen behind the rest of the UK in increasing abortion access, with EMA only becoming lawful in the country on the 21st October 2019 following the failure of the Northern Ireland Assembly to reform; this failure resulted in the enactment of the *Northern Ireland (Executive Formation etc) Act 2019*, which decriminalised abortion in Northern Ireland. The purpose of this legislation was to bring Northern Ireland in line with the rest of the UK in allowing access to abortion [23]. It is important to note that the changed law in Northern Ireland remains very different to the rest of the UK. In England, Wales, and Scotland abortion remains a criminal offence and is lawful only when performed in compliance with the requirements of the Abortion Act 1967. Abortion is not a criminal offence in Northern Ireland, and the Abortion Act 1967 does not apply. On the 31st March 2020, the *Abortion (Northern Ireland) Regulations 2020*, issued by the UK government, came into force to regulate the provision of care in Northern Ireland. The regulations were then revoked on the 14th May 2020, when they were replaced by the *Abortion (Northern Ireland) (No. 2) Regulations 2020*. On the points of relevance to our discussion, both sets of regulations are the same.

In listing the places where care may be provided in Northern Ireland the 2020 regulations are explicit that it must be provided in a hospital, clinic provided by a health and social care trust, premises used to provide primary medical services, or at home where referring to the second abortion medication in EMA [24]. The order also specifies that the Department of Health in Northern Ireland 'may, for the purposes of these Regulations, approve a place for the carrying out of terminations' [24]. Therefore, the same powers for approval orders relating to abortion provision are devolved to Northern Ireland as is the case for both Wales and Scotland. Despite calls from campaigning groups in Northern Ireland Robin Swann, the current Health Minister in Northern Ireland, has consistently resisted the call to issue approval for TEMA in Northern Ireland. However, organisations providing TEMA elsewhere in the UK are making their services available to women in Northern Ireland at this time [25].

4.0 Implications for access to abortion care

For those who have long called for the introduction of TEMA in the UK, you might expect the changes we have discussed to be welcomed. Indeed, it is acknowledged as a step in the right direction [26]. However, the presence of a sunset clause in both the English and Welsh orders, as well as an indication of similar intentions in Scotland, limits the extent to which campaigners might view them as successes.

That UK governments would permit TEMA at all suggests that it satisfies their standards of safety and effectiveness, as per guidelines from NICE that recommend considering providing abortion assessments

by phone or video call (these guidelines do only apply in England and Wales) [7]. Of course, the changes will have largely been guided by a shift in the balance of risks and benefits; delivering abortion care remotely minimises the risk of COVID-19 infection in those concerned. Whilst there have been several studies demonstrating the safety, effectiveness, and acceptability of TEMA, as already noted the quality of evidence is not high [10]. A such, even though there is sufficient evidence to indicate that TEMA should at least be tried, it is not surprising that there has been no rush by politicians to permit it. However, now that TEMA is permitted, it is feasible that health concerns will soon no longer constitute a valid reason for caution. Provided there is no notable increase in adverse outcomes, the health concern argument will be weakened by the experience of TEMA. That being the case, the risks associated with removing the approval for TEMA – notably barriers to access resulting in treatment being delayed/prevented – may be avoided.

It is also worth considering Scotland's departure from both England and Wales in providing guidance that recommends an extension of the gestational limit for EMA with its TEMA approval order. As already noted, it is generally understood that TEMA within these additional two weeks raises no major cause for concern [10]. However, Scotland did depart from the status quo at the time. It can reasonably be assumed that the justification for the raised gestational limit was to increase the number of women eligible for TEMA during the pandemic, thereby further reducing the number of individuals at risk of infection by physically attending abortion clinics. However, similarly to the issue of sunset clauses, it may be difficult to return to the lower limit again after the pandemic as, provided TEMAs that take place during this two week window prove to be safe, effective, and acceptable, the health concerns argument will be weakened. Indeed, pressure is likely to mount on both England and Wales (perhaps even Northern Ireland) to also raise their gestational limits for (T)EMA.

Finally, a possible concern with TEMA is that counselling may be inadequate, and proper disclosure of risks may not take place. If this were the case, there would be a justified concern. However, it is not the case – or at least it is not *necessarily* the case. Adequate counselling and proper disclosure of risks are possible in the context of telemedicine, and there need only be appropriate protocols in place (as there are with in-person delivery of abortion care) to ensure them.

5.0 Early data on TEMA in England and Wales

The Department of Health and Social Care released statistics in September 2020 that provide an overview of the initial months of TEMA in England and Wales [27]. It is necessary to highlight that these statistics cover England and Wales only and cover the period up to and including June 2020. Further, when breaking the data down into methods of abortion there is no explicit TEMA category. There are data on the number of medical abortions where both medications were taken at home, which it is reasonable to assume are largely the result of remote consultation and prescription. It is, however, possible that some of the abortions included in this categorisation were the result of both medications being taken home from an in-person consultation.

There are two key points to be drawn from these statistics. First, we can infer that uptake of TEMA in England and Wales has been significant. The percentage of total abortions carried out medically in the

period January to June 2020 was 82%, an increase from 72% in the same period in 2019 [27]. In the period April to June 2020, 43% of medical abortions involved both medications being self-administered at home, with this figure gradually increasing within this period. As noted above, some of those included in this 43% might not have been TEMA, but it is likely that the majority were, in part because of temporary clinic closures [28].

Second, there was a significant shift to abortions being carried out at earlier gestational ages. Abortions performed at under 10 weeks accounted for 86% of total abortions in the period of January to June 2020, compared with 81% in the same period in 2019 [27]. A more notable change is in the percentage of abortions performed before 7 weeks, rising from 40% in the period January to June 2019 to 50% in the same period in 2020 [27]. A plausible explanation for these changes is the introduction of TEMA; not having to make arrangements to attend a clinic in person allows women to access abortion services earlier. Assuming this is true, the case for TEMA is strengthened.

These statistics cover only the first three months in which TEMA was permitted in England and Wales, so conclusions cannot yet be reliably drawn. That we are still within pandemic circumstances also limits the feasibility of an accurate assessment. Nonetheless, these early figures at least suggest that the temporary approvals have been a success and have the potential to improve access in the long term. The experience of TEMA throughout the UK will also likely provide useful data for evaluating the safety, effectiveness, and acceptability of the specific model of delivery that has been implemented, but such data has not yet been published.

6.0 A note on the United States

Whilst our focus in this paper has been the UK, it is worth drawing a brief comparison to the US. Like the UK, several US states have responded to the COVID-19 pandemic by reassessing abortion provision. However, unlike the UK, where there have been changes these have been in the opposite direction with access to abortion being denied.

Abortion is legal in the US [29], however individual states are empowered to introduce whatever regulatory framework surrounding abortion that they see fit provided it does not constitute an 'undue burden' on women's access to care before foetal viability [30]. Following this a number of states, before the pandemic, introduced bans on TEMA; or effectively banned TEMA by the introduction of requirements such as examination before treatment provision or that a practitioner must supervise care. The Ohio Senate, however, only moved to ban TEMA on the 4th March 2020, as it was becoming increasingly evident that TEMA might be important as a measure to respond to the current crisis.

Moreover, in response to the crisis state governors across the US introduced executive orders mandating the cessation of non-essential medical care. In some states, notably where TEMA was already unlawful, including Texas [31] and Ohio [32], state administration was clear that they did not believe abortion to be an essential medical service and, therefore, service provision must stop. Similar orders were issued in Alabama, Alaska, Arkansas, Indiana, Iowa, Louisiana, Mississippi, Oklahoma, Tennessee and West

Virginia. Many of these orders have been successfully challenged in state courts. In Texas, after legal proceedings issued by Planned Parenthood and the Center for Reproductive Rights [33], the order has been lifted and clinics are now able to continue to operate provided they do not claim personal protective equipment assistance from authorities [34]. In many states, even where there has not yet been a successful legal challenge, clinics have vowed to remain open and continue to provide care [35]. The clear and deliberate attempt to effectively ban abortion that can be seen across the US illustrates how state governments have attempted to use the pandemic to interfere with abortion rights. In the UK, it is fortunate that the government has sought to act to ensure access in the circumstances – even if the measures introduced are also political in nature. The differing political responses can be accounted for by the differing socio-political contexts and legal traditions regarding abortion in the UK and the US [6]. In the US, abortion has become a prominent political issue because it is recognised as part of a woman's constitutional right to privacy [36]. Whereas in the UK (except Northern Ireland), the Abortion Act 1967 has succeeded to some extent in 'depoliticising' abortion by entrenching a medical framework for provision in the law [37]. That there was a medical case, based on a shift in perceptions about the risks of TEMA in the COVID context, may be why the UK government were willing to make changes that improved access for women.

7.0 Conclusion

The introduction of TEMA in the UK will save thousands of women from coming to harm both during social distancing measures and after [6]. However, the extent to which it can be considered a success for women's reproductive and sexual health and rights is limited by the fact that: in England and Wales these measures are only temporary; in Scotland the measures are intended to be temporary; and in Northern Ireland TEMA, strictly speaking, remains unlawful in most circumstances and is only accessible because providers have chosen to risk any potential legal consequences of providing care.

That is not to detract from the fact that allowing TEMA in these circumstances is a move in the right direction in terms of evidence-based medicine. With temporary measures in place, further pressure on the governments of the UK may result in further approval orders which add permanence to TEMA provision. Indeed, the public consultations in England and Scotland may do just this. It would, we suggest, be appropriate for these temporary measures to be made permanent, and we call on UK governments to do so.

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