Emergency Contraception, Coronavirus, and Confidentiality: A mystery shop of pharmacy access during the pandemic

Introduction

The British Pregnancy Advisory Service (BPAS) is a charity that sees almost 100,000 clients per year for reproductive healthcare services including abortion care, pregnancy options counselling, miscarriage management, STI testing and contraception at clinics in England, Wales and Scotland. BPAS also campaigns and advocates for evidence-based, woman-centred and accessible reproductive healthcare services. BPAS is the home of the Centre for Reproductive Research and Communication (CRRC), which has a mission to emphasise women's experiences of reproductive health and pregnancy-related issues across the reproductive life course.

BPAS is the largest provider of abortion services in the UK, and in that capacity we see thousands of women every month who had not intended to conceive but also had not used emergency hormonal contraception (EHC) after an episode of unprotected sexual intercourse (UPSI). It is our observation that EHC is an under-utilised resource in the UK, despite its safety, efficacy and ease of use. The reasons for this are complex, but restrictions to how EHC can be accessed may deter some patients from using it.

Concerns have been raised about the accessibility of contraception during the current pandemic. In their recent inquiry 'Women's Lives, Women's Rights: Strengthening Access to Contraception Beyond the Pandemic', the All-Party Parliamentary Group on Sexual and Reproductive Health found that women in England are facing real difficulties in accessing contraception, and that this has been exacerbated by the pandemic due to the reduction in services offering contraception.

At a time when it is increasingly difficult for women to access their regular contraceptive methods, it is vital that there is swift access to EHC to provide women with a second chance to avoid an unwanted pregnancy. However, retail data show sales of EHC fell by 50% at the start of lockdown from March to April 2020, while NHS prescriptions for the pills declined by around 20% in the same period. Recent news reports have also cited incidents of pharmacists refusing to dispense emergency contraception due to their personal beliefs.

Mystery shopping exercise

Current government guidance states that individuals should practice social distancing of 2m or, in circumstances where 2m is not viable, 1m with risk mitigation. In May 2020, a new Standard Operating Procedure (SOP) for community pharmacies was issued by NHS England and NHS Improvement. This guidance, which was updated in August 2020, states pharmacies should "consider whatever arrangements they can to ensure social distancing in their premises is maintained" such as physical screens and barriers, and that community pharmacies should also clean work areas and equipment between uses. The Pharmacists' Defence Association (PDA) also advises members that "the use of the consultation room should be discouraged... As it is an enclosed space, any use of the consultation room raises the inherent risk to at least amber. If the consultation room must be used at all, then it is vital that either 2m social distancing can be observed or PPE is used. If PPE is used, then the rating may reduce to amber."

At BPAS, we are concerned that these requirements may make it difficult pharmacists to provide a confidential, COVID-secure, consultation, and that, as a result, women may be deterred from accessing EHC when needed.

In September 2020, BPAS undertook a mystery shopper survey with the following objectives:

- to ascertain whether and how UK pharmacies are delivering the mandatory consultation for EHC during the COVID-19 pandemic
- to assess whether and how easily women can access EHC after an episode of unprotected sex without compromising on social distancing practices.

Telephone calls were made to 34 pharmacies in England which were a mixture of high-street chains, independent shops and supermarket pharmacies, each from a different Local Authority, selected at random.

Upon answering, the caller explained that she wished to purchase the morning after pill. She did not ask for a specific product. If information about the consultation was not volunteered, she asked whether she would need to have a consultation and how this would be delivered in light of the social distancing rules. In some cases where the answer was not clear, our caller asked for more information, stating that she needed to be careful to comply with the guidelines since her partner was classified as “high risk” for COVID-19. The responses were noted in a spreadsheet immediately after the call.

Results

Our mystery shopping spoke to 34 pharmacies in total. Of these, two were out of stock of emergency contraception, and one pharmacy did not provide emergency contraception.

Of the 31 pharmacies with emergency contraception in stock and available for sale, one-third (10) did not have policies in place or the means to provide a private and COVID-secure consultation.

Within this group of pharmacies:

- In 2 pharmacies, the consultation rooms were closed due to COVID-19.
- In 5 pharmacies, the consultation room was too small to observe social distancing.
- In 2 pharmacies, the client was offered a verbal consultation using the screen at the shop floor counter.
- In 1 pharmacy, the pharmacist offered to conduct part of the consultation via a written form followed by a verbal discussion on the shop floor.

The remainder had developed different ways to try to achieve a COVID-secure, confidential consultation, with different levels of practicality. Less than half (14) pharmacies were able to use a consultation room and had developed different ways to make it safer to use. However, within this group, 4 of the pharmacies stated that they had limited capacity to provide a consultation in private because this space was heavily booked for flu vaccination appointments.

- 9 pharmacies said their consultation rooms were of a sufficient size to allow the client to observe social distancing guidance.

- 2 pharmacies had installed a protective screen in their consultation rooms.
- 3 pharmacies stated that their pharmacist would wear PPE during the consultation.

In the remaining 7 cases where a consultation within a private consultation space was not possible:

- 3 pharmacies offered to provide the consultation over the phone.
- 2 pharmacies said the consultation would be conducted using a written questionnaire.
- 1 pharmacy stated they would provide the consultation on the shop floor, pausing and restarting when other customers entered and exited the pharmacy. The pharmacist advised that they currently are not able to offer free emergency contraception under PGD during the pandemic because the length of the consultation required to prescribe EHC meant that this was unfeasible.
- 1 pharmacy offered to close the pharmacy to other customers so they could provide a confidential consultation on the shop floor.

Conclusion

A third (32.5%) of pharmacies providing EHC that we surveyed were unable to provide the mandatory consultation in a way that was both confidential and COVID-secure. Consequently, women seeking EHC in these areas may be forced to choose between risking catching or transmitting COVID-19 (by breaching social distancing rules), their privacy (by having a consultation on the shop floor), or an unwanted pregnancy. We are concerned that as a result women will not feel able to access EHC when needed.

The pharmacies we spoke to were, overall, very sympathetic to the mystery shopper, and many apologised for being unable to provide a confidential and safe consultation but were limited by the space of their store and the current licensing requirements for EHC. The physical constraints pharmacists are operating under cannot be changed – but the current regulatory framework, which places pharmacists under an obligation to undertake a consultation with every woman requesting EHC - can be amended by the Secretary for State for Health and Social Care. Reclassifying emergency hormonal contraception as a general sales list (GSL) medication would enable women to purchase this safe and effective medication directly from the shelf, without placing their health or confidentiality at risk during the pandemic.

There are 3 ways that medicines can be sold and supplied:

- on a prescription (referred to as prescription-only medicines - POM)
- in a pharmacy without prescription, under the supervision of a pharmacist (P)
- as a general sale list (GSL) medicine and sold in general retail outlets without the supervision of a pharmacist

According to the medicines regulatory body, the MHRA: “if further experience demonstrates that access to professional advice is not required for safe use of the medicine, it may then be reclassified as a General Sale List (GSL) medicine to allow sale from a wider range of retail

outlets. GSL is appropriate for medicines which can, with reasonable safety, be sold or supplied otherwise than by or under the supervision of a pharmacist."

The term "with reasonable safety" has been defined as: "where the hazard to health, the risk of misuse, or the need to take special precautions in handling is small and where wider sale would be a convenience to the purchaser."

Over the course of the 20 years that LNG EHC has been a P medication, and the 11 years in the case of UPA EHC, it is clear that these medications can be used "with reasonable safety". If EHC were reclassified as a GSL medication, it could be sold straight from the pharmacy shelf, without a consultation, as is the case in the USA, Canada and several European countries including France. Women would still be able to seek advice and assistance from a pharmacist, but the reclassification of EHC as a GSL medication would enable women to access it swiftly and safely at a time when it is essential to minimise social contact.

There is precedent for emergency contraception being reclassified by the Health Secretary. In 2000, the-then Secretary of State for Health reclassified Levonelle Emergency Contraception from a Prescription Only Medication (POM) to a Pharmacy Medication via a Statutory Instrument. One in six pregnancies is unplanned, and while we do not believe EHC is a silver bullet for these, it remains a significantly underused resource. Given the current context of a highly transmittable virus, local lockdowns, and contraceptive service closures, it is clear that there is an urgent need to reclassify EHC to prevent increasing numbers of women facing unplanned and unwanted pregnancies during the pandemic.

Further information

About EHC

Oral post-coital contraceptives have been used since the 1960s, and in 1982 the first of these methods was officially licensed for emergency post-coital use. Today, two methods of oral EHC are available in the UK: ulipristal acetate (UPA) 30 mg (single dose) and levonorgestrel (LNG) 1.5 mg (single dose). Additionally, the copper intrauterine device (Cu-IUD) is available as an emergency contraceptive, but this requires a separate appointment in primary care or SRH services for a fitting, and is unlikely to appeal to women who do not wish to change their normal method of contraception.

LNG, a progestin, has been used as an emergency contraceptive for approximately twenty years, and its efficacy is well established. A study published in the Lancet in 1998 estimated that LNG, taken as two doses of 750 mcg 12 hrs apart, is 85% effective in preventing pregnancy. It also reported that efficacy declines with time of treatment after an episode of unprotected sex: 95% effective if started within 24 hours; 85% effective if started between 24-48 hours; and 58% effective if started 48-72 hours afterwards. A subsequent Lancet paper found no difference in efficacy and fewer side effects with a single 1.5 mg dose (Grimes et al., 1998; Von Hertzen et al., 2002).

UPA, sold under the brand name EllaOne, has been provided in the UK since 2009. There is some evidence that UPA EHC it may be slightly more effective than LNG EHC which may be because LNG appears to not be effective after levels of the luteinising hormone that triggers ovulation start to rise, which increases the need for rapid access (Brache et al., 2013). A Lancet study published in 2010 combined the results of two clinical trials (Glasier et al., 2010), and showed that:

- of 1,714 women who received UPA, 22 (1.3%) became pregnant
- of 1,731 women who received LNG, 38 (2.2%) became pregnant

Both methods of oral EHC offer an effective opportunity to avoid conception, and both should be taken as soon as possible after an episode of unprotected sexual intercourse (UPSI) to minimise the risk of pregnancy. Due to the time-sensitive nature of EHC, any barriers that impede swift access may reduce women's ability to avoid an unplanned pregnancy.

Safety of EHC

Both LNG and UPA are included on the World Health Organisation's (WHO) List of Essential Medicines considered to be "the most efficacious, safe and cost-effective medicines for priority conditions" (WHO, 2019). The WHO's Medical Eligibility Criteria for Contraceptive Use (WHO, 2015) reports very few restrictions on the use of either LNG or UPA. Neither method is known to cause harm to an existing pregnancy, and both can be used by women with a history of ectopic pregnancies. Both methods can generally be used by women with a history of severe cardiovascular disease, migraines, or severe liver disease. There are no contraindications to the repeated use of either method of oral EHC.

There is some evidence that strong liver enzyme inducers such as those in epilepsy medications may reduce the efficacy of EHC, but nonetheless both methods can be used safely by women taking those medications since EHC does not compromise their effect. The advice to women using LNG is simply to take two doses, which is made clear in the package insert. Similarly, there is some evidence that EHC is less effective in women with a higher BMI, but nonetheless there are no contraindications to their use. Breastfeeding women can take UPA, but breastmilk should be discarded for 7 days afterwards. LNG is safe during breastfeeding and can be provided without restriction (WHO, 2015).

The FSRH UK Medical Eligibility Criteria for Contraceptive Use (UK MEC) classifies both LNG and UPA as either Category 1 or 2 for all listed conditions, meaning that there are either no restrictions on use or the advantages of using it generally outweigh the theoretical or proven risks. EHC can and should be used as often as needed, including during the same cycle.

UK provision of EHC

In the UK there are three avenues by which women can access oral EHC free of charge after an episode of UPSI: from their GP, from a sexual health clinic or from a commissioned service in a community pharmacy. It can also be purchased from most community pharmacies, however due to licensing restrictions all women purchasing EHC will need to undergo a mandatory yet clinically unnecessary consultation.

Despite there being several avenues available for accessing EHC, uptake is low in the UK with only one in three women using it after an episode of UPSI (Nappi et al., 2014). Compounding this, NHS-funded EHC is increasingly difficult to access due to a steep decline in funding (NHS Digital, 2019; Advisory Group on Contraception, 2018).

There remain significant barriers to EHC access in community pharmacies. Even after several major pharmacy chains agreed to reduce the price of LNG from around £30 to £15 in 2017 (BPAS, 2017), the current price is still higher than in many other European countries, and represents a significant mark-up on the drug tariff price of LNG (Chemist and Druggist, 2019; NICE, n.d.). UPA remains more expensive, at roughly £30. All women purchasing emergency contraception are required to undergo a consultation with a pharmacist due to the classification of LNG and UPA as pharmacy (P) medications. BPAS and the Royal College of Obstetricians and Gynaecologists (RCOG) have previously called for EHC to be reclassified as a general sales list (GSL) medication, so that it can be sold straight from the pharmacy shelf (BPAS, 2016; RCOG, 2019).

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