bpas
British Pregnancy Advisory Service

Levonorgestrel 1.5mg as a GSL medication

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Introduction

The British Pregnancy Advisory Service (bpas) is a nationwide reproductive healthcare charity which cares for 90,000 women every year experiencing an unplanned pregnancy or a pregnancy they are not able to carry to term. Many women we see had not used or tried to use using emergency hormonal contraception (EHC) after an episode of unprotected sex. While the reasons for this are complex, it is bpas' belief that EHC remains a significantly underutilised resource in this country because of the restrictions on the way in which women can access it.

Progestogen-based EHC, levonorgestrel 1.5mg, has been available from behind the counter as a Pharmacy (P) medication since 2003, but it can only be obtained at a pharmacy following a consultation with a pharmacist, and often at a high price. Our work with women illustrates clearly that this acts as a barrier to access, and prevents women using this safe medication when they need it. bpas believes that progestogen-based EC clearly meets the criteria set out by the medicines watchdog the MHRA for wider sale without supervision and believes a reclassification of EC as a General Sales List (GSL) product would improve women's access and opportunity to avoid an unwanted pregnancy which risks their health and wellbeing after an episode of unprotected sex. The following briefing sets out our position.

Background

Emergency contraception is an effective way to prevent pregnancy when a woman has had unprotected sex or the chosen method of contraception has failed. In the UK, there are three methods of emergency contraception available: the copper IUD (Cu-IUD), oral ulipristal acetate 30 mg (single dose) and oral levonorgestrel 1.5 mg (single dose). Levonorgestrel is 95% effective if taken in the first 24 hours, yet it is not being utilised to its full potential. Research suggests that only one third of UK women who had an episode of unprotected sex in the last year used emergency contraception (Nappi et al., 2014).

Levonorgestrel 1.5 mg tablets are available free-of-charge on prescription from a GP, from a sexual health clinic or through a commissioned service from a pharmacy. Alternatively, it is available to purchase from pharmacies. Since 2010, there has been a 62% decline in the provision of EHC items on behalf of the NHS and sexual health clinics, which is not explained by an uptake in more effective methods which may reduce need for EHC. Most women still rely on daily pills or condoms as their main form of contraception and need swift access to EHC when that method fails or is forgotten. The decline in NHS funded provision may reflect commissioners' belief that women can access EHC from a pharmacy at their own expense if they need it and that it may be more convenient for them to access it in this way. Nevertheless, many women report barriers to access when it comes to purchasing EC from a pharmacy, namely the cost of the product and the fact that it can only be sold by a pharmacist, following a consultation, which many women find embarrassing. Cases have also gained national attention in which women were refused EHC by a pharmacist with a conscientious objection to the product.

Women are generally aware that there are times of the month when they are less likely to conceive after an episode of unprotected sex. Women therefore frequently make a personal risk assessment as to whether the risk of an unwanted pregnancy warrants the cost and embarrassment of seeking emergency contraception, and when they perceive the risk to be low may decide against obtaining it.

Switching levonorgestrel EC to GSL will improve the probability that women will take it even when they perceive themselves to be at lower risk of pregnancy, thereby reducing the number of unwanted pregnancies and the associated consequences.

Safety

Levonorgestrel has been used as an emergency contraceptive for approximately 20 years, and its efficacy and safety profile are well-established. A study published in the Lancet in 1998 that compared the efficacy of levonorgestrel to the Yupze regimen estimates that levonorgestrel, taken as two doses of 750 mcg 12 hrs apart, is 85% effective in preventing pregnancy. It also reports that efficacy declines with time of treatment after an episode of unprotected sexual intercourse: 95% effective if started within 24 hrs, 85% effective if started 24 – 48 hrs after and 58% effective if started 48 – 72 hrs after. A subsequent Lancet paper found no difference in efficacy, and fewer side effects, when a single 1.5mg dose was taken.

The new form of EHC, ulipristal acetate (EllaOne) may be slightly more effective than levonorgestrel, possibly because levonorgestrel appears not to be effective after levels of the luteinising hormone that triggers ovulation start to rise, which increases the need for rapid access. A Lancet study published in 2010 combined the results of two clinical trials, and showed that:

- of 1,714 women who received ulipristal acetate, 22 (1.3%) became pregnant
- of 1,731 women who received levonorgestrel, 38 (2.2%) became pregnant

But it is clear that both offer an effective opportunity to avoid pregnancy, and with a long history of usage, levonorgestrel EHC is currently the most appropriate candidate for a reclassification.

The World Health Organisation's Medical Eligibility Criteria for Contraceptive Use reports very few restrictions on the use of levonorgestrel emergency contraception. Levonorgestrel EC as being safe for use in breastfeeding women, women with history of ectopic pregnancy, women with history of cardiovascular disease, women with history of migraines and women with liver disease. There is no known harm to the woman, her pregnancy or the foetus, if emergency contraception fails or is taken when she is already pregnant. There is the possibility that strong liver enzyme inducers such as those in epilepsy medications may reduce the efficacy of levonorgestrel (WHO, 2015) but levonorgestrel does not compromise those medications. The advice to women using these medications is simply to take two doses, which is made clear in the package insert.

Levonorgestrel EC is a low risk medicine that prevents the much greater risks posed by pregnancy. The UK Medical Eligibility Criteria for Contraceptive Use (UKMEC) classifies levonorgestrel EC 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 (UKMEC, 2016). It can and should be used as often as need, including during the same cycle. Levonorgestrel EC is a medicine where efficacy reduces with time, so any measures that improve accessibility and availability should improve the efficacy of the product and reduce women's chances of an unwanted pregnancy.

A comparison can be made between the classification of levonorgestrel EC and Nicotine Replacement Therapy (NRT), and to apply the same harm reduction model to EC as that applied when the decision was made to remove almost all restrictions on the use of NRT products. The first NRT products (gums) were available as Prescription Only Medicines. In the early 1990s, they were reclassified to Pharmacy medicines and in the late 1990s, they were reclassified to the General Sales List, because it was considered that they could safely be sold without the supervision of a pharmacist. In the mid-2000s, restrictions on use were minimised for pregnant and breastfeeding women, children under 18 year and patients with heart disease, kidney or liver problems or diabetes, because any risks that may be associated with use by these groups, were far outweighed by the harm of continuing to smoke (MHRA Nicotine Replacement Therapy and Harm Reduction; MHRA, 2005.). There are very few risks to women posed by levonorgestrel EC, but there is significant potential harm caused by the current barriers to access. If the same harm reduction model were applied to EC as that applied to NRT, it would clearly fit the criteria of a GSL medication. Restrictions on the use of NRTs were minimised because it had become widely accepted that there were no circumstances in which it is safer to smoke than to use NRT. Similarly, there are no circumstances where it is safer to be pregnant than to take levonorgestrel EC.

Issues with current access arrangements

Although the safety profile of levonorgestrel is clear, and one reason why it is available to buy directly from the shelf in North America and several European countries, the preservation of the consultation is justified on the basis it enables the pharmacist to check the pill is being taken within the correct time frame, talk to a woman about STIs, other contraceptive options and address any safeguarding concerns. (Royal Pharmaceutical Society 2017) The consultation is also the reason why the current price, between £15 and £28, remains high, as it is not reflective of the underlying cost of the actual product.

In 2018, bpas conducted a mystery shopper study of 30 pharmacies in England to better understand the pathway to purchase. In around 10% of visits the consultation was poor and unprofessional. This included one case where the pharmacist did not want to sell it until she had shown him a negative pregnancy test, another where she was asked to show ID with a date of birth (she was 22) before sale was agreed, and a further incident where she was sold an inappropriate product. In a further 7% of cases the shopper was turned away without further help or told to come back later, even though we had established we were visiting a pharmacy where EHC was provided before visiting. Effectively this means nearly one in five visits placed a woman at risk of an unwanted pregnancy.

Generally pharmacists provided a kind, swift and non-judgmental service, once they were dealing directly with the client, however in most cases the shopper had needed to ask at least 2 people before help could be offered (15/29), and in one example four separate people were involved in the sale.

No pharmacy offered information about ongoing methods of contraception or STI testing, and where such help could be obtained. No pharmacy informed women that the IUD was the most effective method of emergency contraception and no pharmacy provided information on where that could be found. Less than 50% of pharmacies visited offered a private room for the consultation, and so it

was often held in proximity to other pharmacy users which made the experience itself more awkward for the shopper, and constrained the likelihood of asking further questions. This is particularly relevant in light of the suggestion that the consultation provides an important opportunity to address safeguarding concerns.

In our mystery shop, the client was presenting within 24 hours of an episode of unprotected sex. Research suggests that this is the experience of the majority of women: nearly 90% of women present with in the first 24 hours after an episode of unprotected sex, and the majority of the remainder within 48 hours. Presentations after 72 hours are negligible. Therefore it is unclear what benefit is served when timing of presentation is policed by the pharmacy, particularly when there is no harm caused to the woman – or effect on an implanted ovum – by use outside of the timescale, the product merely ceases to have any impact. It is possible that a pharmacist could advise against use at a time when the woman is unlikely to conceive, but given levonorgestrel poses no harm and that it is up to the woman herself to decide what level of risk she is prepared to take, it is hard to see the purpose this serves. In our mystery shop, very pharmacies inquired about a woman's cycle in any event.

Bpas' finding that pharmacists do not provide information about other methods of contraception or where they can be accessed echoes the results of a mystery shop of 40 pharmacies in 2010, published in the journal Contraception and is also reflected in a report compiled for the east Sussex National Health Service and County Council in 2013, which found during a mystery shop of 24 pharmacies that the majority did not provide advice about ongoing contraception. The reasons for this have not been explored, however pharmacists likely recognise that this is not the time or space for a comprehensive discussion about other options, and that is not what the woman needs in that moment.

In line with the bpas study, the Sussex research similarly highlighted the lack of privacy for the consultation, with the majority of requests taking place on the shop floor.

> ***"The consultation was in public and it was embarrassing… In all I believe this was the worst pharmacy I visited as the consultation was public so you were humiliated and it was scary."***

Polling conducted by Censuswide for bpas found the majority of women (64%) thought the consultation should be optional. Women described feeling embarrassed, quizzed and "slutty" as a result of the interaction.

The current gatekeeping and mandatory consultation by the pharmacist is a barrier to access, and there is good evidence to suggest that the disadvantage posed by this barrier is not offset by the advantages to women of undergoing a consultation. Removing the consultation and enabling levonorgestrel EC to be sold from the shelf would improve access. It is useful to reflect on the experience of pharmacy provision reflects that of Canada, where levonorgestrel EC was moved out from behind the counter in 2006 in some states following recognition that it could safely be used without supervision, and that the behind the counter framework inhibited women's access.

> ***"Although pharmacists have front-line contact with patients and are equipped with professional guidelines for provision of emergency contraception, they are not ideally***

positioned for a counselling role in their typical practice settings. Few pharmacies offer the privacy necessary for such a conversation. This mundane fact, together with the professional fees attached to the consultation, represents a needless barrier to access."

(Canadian Medical Association Journal, 2005)

Further considerations

Moving levonorgestrel EC to a GSL medication would provide an important opportunity to thoroughly review the information on the box and within the patient insert, and provide women with other sources of relevant support and advice. We look forward to working with a range of stakeholders and of course women themselves to establish what information women want and need, while giving them the best possible chance of avoiding an unwanted pregnancy, at a much more affordable price.