Emergency hormonal contraception: The community pharmacy perspective

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Abstract
Objective. To explore the views of community pharmacists in the North West of England towards the deregulation of emergency hormonal contraception (EHC) and to examine their support and training needs.

Design. Two focus group discussions.

Subjects. Fourteen community pharmacists, of whom eight were currently participating in a scheme to supply EHC free of charge through a patient group direction (PGD).

Results. A number of themes emerged from the discussions, which appeared to influence participants’ views towards the use of EHC and towards deregulation. A number of participants appeared to lack detailed knowledge about the mode of action of EHC and misunderstandings about this, coupled with erroneously held beliefs about the adverse effects of the drug, appeared to influence their attitudes to deregulation. Participants identified risks associated with pharmacy supply of EHC, both to women and to themselves, in the form of litigation. EHC was accorded a special status which seemed to go beyond its pharmacological properties and risk-benefit profile. A key and recurring theme was abuse, an ill-defined concept which appeared to refer to multiple or repeated use. It is interesting to note that none of those participants supplying EHC under a PGD could provide any examples of such abuse from their own experience.

Conclusions. This small-scale study provides useful insights into the attitudes of these pharmacists towards EHC, the impact of increased availability of the drug, and the type of women who they believed would use EHC.

Key message points
• Pharmacists in this study accorded EHC a special status when compared with other deregulated drugs.
• Participants had concerns regarding abuse of the drug, defined as multiple or repeated use, and held perceptions of the kind of women they felt would use EHC in pharmacies.
• None of the pharmacists supplying EHC under a PGD could provide examples of abuse to support their assertions.
• The risk of litigation from the supply of EHC in pharmacy was a clear concern for participants, although in some cases fears were based on erroneous assumptions about the mode of action of EHC.
• Some participants had limited knowledge of the mode of action of EHC and held contradictory views about its efficacy.

Introduction
In the United Kingdom (UK) the government is committed to reducing unwanted pregnancies and terminations, notably, but not exclusively, amongst teenage women. Although the teenage pregnancy rate is acknowledged as one of the highest in Europe, the termination rate is also high amongst older women, with almost half (48%) of all terminations occurring in the 20-29 age group. Effective access to emergency hormonal contraception (EHC), which can be taken within 72 hours of unprotected intercourse, is likely to be an important part of any sexual health strategy to reduce unwanted conceptions. The drug levonorgestrel (prescription-only brand name, Levonelle-2®) has recently been deregulated by the UK government, at the manufacturer’s request, from a prescription-only medicine (POM) to a pharmacy (P) status, thus allowing over-the-counter sales in pharmacies to women aged 16 years or over.

By increasing access to emergency contraception through pharmacies, it is hoped that more women will use this often-neglected form of contraception. Previous concerns about existing provision of EHC have centred on the non-uniformity of provision; difficulties obtaining an appointment with a general practitioner (GP); judgmental and sometimes hostile attitudes of health professionals, and the restricted opening hours of many family planning clinics and GP surgeries. The main professional organisations representing GPs, pharmacists and family planning professionals all supported the deregulation of EHC; indeed the British Medical Association (BMA) has criticised the government for not allowing sales of the drug to under 16s. However, few studies have sought to investigate the views of community pharmacists towards this form of contraception.

A number of drugs have been deregulated from POM to P medicine status in the UK since 1992. There have been calls for deregulation of EHC for several years, and this is seen as one aspect of the drive to reduce termination and pregnancy rates in the UK.

In 1999 the manufacturers of Levonelle-2®, Schering Healthcare, applied to the Medicines Control Agency (MCA) for a change in the product licence from POM to a P medicine. In the UK, the MCA is the organisation with the authority to licence medicines for human use and to determine their availability status. At the same time, Health Action Zones in Manchester and the London Borough of Lambeth and three primary care groups in Derbyshire established pilot schemes to provide EHC (initially PC4® then subsequently Levonelle-2®) under patient group directions (PGD). A PGD is defined as ‘a written direction, signed by a doctor or dentist and by a pharmacist, relating to the supply of medicines or pharmacy medicine to persons generally, subject to any exclusions that may be set out in the direction.’ PGDs can be authorised at Health Authority or NHS Trust level. A PGD is therefore a written document which sets out the circumstances in which the medicine can be supplied, lists those who are excluded from treatment, sets out when further advice should be sought from a doctor (this could include telephone advice or referral of the patient), details of any follow-up action and of records required to be kept. Under the PGDs currently in operation, women attending participating pharmacies have a private 10-15 minute
consultation with the pharmacist to determine whether they meet the criteria for using EHC.\textsuperscript{10} If the pharmacist is satisfied that this is the case, EHC is provided free-of-charge. This differs from over-the-counter sales of EHC, as the pharmacist is in effect a dependent prescriber, working to a group direction designed by family planning professionals. In order to supply EHC under the PGD, the pharmacist must take the patient through a series of questions to satisfy themselves that supply is appropriate. The pharmacist then signs to denote that EHC has been supplied. Therefore when following a PGD, the professional responsibility ultimately rests with the organisation which has produced the PGD, whereas in the over-the-counter route, this decision rests with the pharmacist and the patient to pay.

EHC is also available on prescription through general practices, family planning clinics (FPCs), other family planning agencies (including Brook Advisory Centres), genito-urinary clinics, some obstetric and gynaecology wards and some, but by no means all, Accident and Emergency (A and E) departments. Community pharmacies are acknowledged as one of the most accessible forms of healthcare due to their opening hours and lack of need for an appointment.\textsuperscript{12} Research has shown that most enquiries for EHC take place at weekends, when many general practices and FPCs are closed.\textsuperscript{13}

Although EHC is available from a range of sources, there appears to be little uniformity in where and when it can be accessed. A telephone consumer survey of the availability of EHC in North West England found that approximately half of A and E departments were unwilling to provide EHC, and the authors acknowledged the need to develop an accessible service which is available to women 24 hours a day, 7 days a week.\textsuperscript{14} The deregulation of Levonelle-\textsuperscript{20} from a POM to P medicine therefore represents an opportunity to expand supply through pharmacies and increase client accessibility to EHC services.

A comprehensive review of the programmatic and social science publications on EHC found a considerable body of literature from the UK on the existing provision of EHC.\textsuperscript{4} Studies have addressed non-uniformity of provision, women’s attitudes to the use of EHC, views on existing provision (particularly concerns about the judgmental attitudes of health professionals), the feasibility of increasing access to EHC and the impact of wider availability on use of other methods of contraception.\textsuperscript{4}

Surveys of women who have used EHC indicate high levels of dissatisfaction with the service that they received.\textsuperscript{15} In one study, more than half the women who had used EHC previously indicated some level of dissatisfaction with the service they received. A qualitative study of eight women from the same general practice who had used EHC in the past found that they were reluctant to contact health professionals and that GPs or family planning nurses had previously given them misleading information about side effects and contraindications.\textsuperscript{16} In this study, one of the most often quoted difficulties was getting past the ‘gatekeeper’, usually the doctors’ receptionist. One of the main concerns these women had was fear of being judged by the health professional concerned, particularly if they had used EHC before.

Several studies have addressed women’s attitudes to using this form of contraception. Findings from a study of women presenting for a termination suggest that 93% of these women would have used EHC had they been aware of its availability and how to access it.\textsuperscript{17} A New Zealand study found that 62% of women attending abortion clinics would have used EHC if they had had a supply at home and 57% stated they would have used it if it had been available over-the-counter in pharmacies.\textsuperscript{18}

Two studies have suggested that some women have concerns about taking EHC, particularly with regard to what they perceive to be the high doses of hormones contained within it.\textsuperscript{16,19} It is worth noting that both these studies took place before the introduction of Levonelle-\textsuperscript{20}, which is recognised to have fewer side effects than its predecessor as it contains no oestrogen. The authors of these studies suggest that health professionals may not be passing on to women evidence about the safety of EHC.

There has been limited research on the views of pharmacists towards possible deregulation of EHC to pharmacy status, with four published UK studies.\textsuperscript{7,8,20} Harper and Barrett (1998) found little support for recategorisation in their small-scale (n = 18), interview-based study of pharmacist and GP attitudes to EHC deregulation.\textsuperscript{6} However, it is worth noting that this study had only a small sample and was also carried out prior to the licensing of Levonelle-\textsuperscript{20}. The key concerns relating to the deregulation were expressed in terms of irresponsible use, the need to regulate supply to prevent abuse, issues of therapeutic safety and the need for adequate training for pharmacists.\textsuperscript{6}

Blackwell et al surveyed 4000 community pharmacists (response rate: 39%) on their views about possible deregulation of EHC, using a structured postal questionnaire.\textsuperscript{7} Overall, their results were more positive towards supporting recategorisation, with over 75% of their sample indicating their willingness to be involved in the deregulated supply of EHC. However, the survey indicated a perceived need for specific training before effective deregulation could take place and only 40% of respondents felt that, at present, they were individually competent to supply. Furthermore, there was a positive association between perceived competence and willingness to supply.

The key concerns in this study centred on safeguarding clients’ health and the possible adverse public health effects associated with the reduced use of barrier methods of contraception. Their specific concerns were dominated by issues of safety and fears that women might use EHC as their regular form of contraception. However, studies have shown that most women attending for EHC have previous contraceptive experience and as many as 50% of consultations are the result of failure of barrier methods. Other studies have shown that where women are provided with a supply of EHC to use at home they do not use it significantly more often than women who used it from orthodox sources.\textsuperscript{21} The key message from Blackwell et al’s work was that deregulation would need to be accompanied by comprehensive training programmes, and that many pharmacists wanted supply to be restricted to ‘specialist’ pharmacists or those working within a patient group direction environment.\textsuperscript{7}

A more recent study of over 1800 community pharmacists found broad agreement with the notion of EHC deregulation, although pharmacists did raise some practical concerns and the majority of pharmacists wished to be paid a professional fee for providing an EHC service.\textsuperscript{8} A recently published, small scale (n = 123) survey of community pharmacists also found considerable support for OTC supply of EHC, although training and pharmacy facilities were areas which were highlighted as needing to be addressed.\textsuperscript{20}

**Aim**

The aim of this study was to explore the views of community pharmacists in the North West of England towards the deregulation of emergency contraception from...
a POM to a P medicine and, in particular, to examine their support and training needs.

Method
Focus groups were the research method for this study. The rationale for this method included: to allow for discussion in groups, sharing of experiences, to challenge views and to enable participants to reflect on their own views in the light of the group discussion.

Two focus groups were convened, one (A) with community pharmacists currently providing EHC under a PGD as part of a Health Action Zone (HAZ) scheme, and one (B) with pharmacists with no experience of providing EHC. It was felt that both groups of pharmacists would bring unique and differing insights and experience to the discussion.

Prior to the roll-out of the PGD scheme, all community pharmacists in the catchment area (Manchester, Salford and Trafford) had been polled by the local HAZ on their opinions about the supply of EHC. With the permission of the HAZ scheme a letter of invitation to participate in focus groups was sent to pharmacists who had either shown a positive attitude or were not opposed to the deregulation of EHC, but who were not currently supplying it. Pharmacists who had previously stated their moral/ethical opposition to EHC deregulation were excluded from the focus group as it was considered that this may have detracted from the dynamics of the group discussion and from the specific aims of the study. Moreover, the ethical and moral concerns of pharmacists have been articulated widely in the pharmaceutical press and have been discussed elsewhere. This is not to suggest that the moral/ethical debate should not be taken seriously, merely that their inclusion in these groups would not have contributed to an exploration of pharmacists’ practical needs and concerns.

Pharmacists supplying EHC under the local protocol were approached in the same way and were invited to attend a separate group. It is important to note that both groups used pharmacists working within the Manchester area who were therefore either working within the HAZ pilot scheme or were likely to be aware how it operates. The findings from these groups should be considered in this context. However, there has been much discussion, both about the deregulation of EHC and the operation of the protocol schemes in the journal of pharmacy’s professional body, The Pharmaceutical Journal, and therefore most community pharmacists in the UK were likely to be aware of the debate.

The main themes discussed in both groups related to pharmacists concerns about the deregulation of EHC from a POM to a P medicine and participants’ perceived support and training needs should such a switch take place. In the HAZ group, participants also discussed their experiences of providing HEC under a PGD and what their concerns had been prior to starting the scheme, and whether these fears had been realised in practice.

A topic guide was formulated for both groups with key themes to discuss. However, this was not intended as a rigid schedule and participants were able to bring to the discussion topics which they felt were of relevance. The discussions were tape-recorded with the participants’ consent and were transcribed verbatim. Participants were assured that their anonymity and confidentiality would be maintained at all times and consented to their quotes being used for the purposes of research. The transcripts were analysed by repeated reading by two researchers (ES and KH) to draw out the key themes.

Results
Details of participants
Two focus group discussions took place at the University of Manchester during July 2000. Eight participants from the HAZ protocol scheme took part in the first group; their quotes are denoted in the text by the letter A. Six pharmacists from the Manchester area, who were not involved in the supply of HEC under protocol, took part in the second discussion; their quotes are denoted in the text by the letter B. Participants in both groups had a range of experience, included both employees and proprietor pharmacists, and worked in a variety of community pharmacy settings, including multiples, small chains and independents.

Main themes
In analysing the findings from the two focus groups, four key, inter-related themes emerged which influenced the participants’ views towards the use of emergency contraception and towards possible deregulation to P status. These were:
1) knowledge about the mode of action
2) risk
3) special status
4) abuse.

Knowledge about the mode of action
A number of the study participants in both groups seemed to lack detailed knowledge of the actions of EHC, or were hesitant about their knowledge base. It could be argued that misunderstandings about the way in which the drug worked and beliefs about possible adverse outcomes influenced the attitudes of these pharmacists towards the deregulation of the drug.

One participant demonstrated a confused understanding of the importance of timing in relation to the efficacy of EHC in preventing pregnancy and did not seem to be aware that the efficacy decreases with time. (Data from the WHO Task force study of levonorgestrel versus the Yuzpe regimen indicate that the pregnancy rate increased from 0.5% when treatment was given within 12 hours of intercourse to 4.1 when given between 61-72 hours after intercourse23);

“it’s 95% effective if you take it within 72 hours but if you use it as a sole means of contraception it’s something like 85%...so there is a 15% chance (of getting pregnant).” [A]

Another pharmacist seemed to believe that if a woman took EHC after the 72-hour cut-off point, this could bring about an abortion:

“If somebody was taking it after the 72 hours...and the pharmacy weren’t told that...maybe you could run into problems legally...if implantation occurred you could be on the end of an abortion case which could get you into a lot of trouble.” [B]

What was interesting was the way in which participants could hold seemingly contradictory views about the action of EHC. The above respondent, who believed that taking EHC after 72 hours could result in an abortion, made the following comment later in the same discussion, indicating an understanding of the 72-hour limit in terms of efficacy of working and contradicting a previous statement:

“It’s just the efficacy of stopping pregnancy...its best if it’s used before 48 hours but there is still quite a high
Risk
The pharmacists identified potential risks from the supply of EHC in pharmacy, both to the women and to themselves, in the form of possible litigation. Participants expressed concerns about the teratogenic effects of EHC even though there is no evidence to date to suggest that taking emergency contraception early in pregnancy causes foetal abnormalities. In some cases, participants recognised their lack of knowledge of the possible outcomes of giving EHC in pregnancy, but were clearly concerned that these could be serious:

“What happens if you gave (EHC) and forgot to ask if somebody was pregnant and then the baby was born deformed?” [B]

Although this respondent was open about a lack of knowledge regarding teratogenicity, there were clearly demonstrated concerns that taking the drug while pregnant could have adverse consequences:

“I don’t know much about the drug in all honesty…I don’t know what possible adverse effects can occur as a consequence of taking this later in pregnancy.” [B]

However, when respondents were probed to explore their understanding of the likelihood of teratogenic effects, several suggested that this was likely to be low or the same as through natural conception:

“I was under the impression that it (incidence) was very low” [B]

“It’s the same as natural (conception), isn’t it?” [B]

One participant was also concerned about the legal repercussions of supplying EHC after the 72-hour period, although this concern was based on erroneous assumptions about the way in which the drug prevents conception. EHC acts to prevent the egg embedding in the lining of the womb, but has no impact where a fertilised egg has already embedded itself and cannot be regarded as an abortifacent, despite this pharmacist’s concerns:

“We must be very careful not to supply this too late because at that point the fertilised egg could have started to embed itself…we could be talking about the criminal prosecution of a pharmacist for attempting to procure an illegal abortion.” [A]

Lack of knowledge about the effects of taking EHC led this pharmacist to be fearful of the consequences, both of prescribing and not prescribing the drug:

“I would be frightened of either over-prescribing it or under-prescribing it…what are the repercussions of me not prescribing it and the person becomes pregnant and if I do not prescribe it what happens if something goes wrong? But again, I don’t know what can go wrong.” [B]

Special status
Throughout the discussion a sense emerged of the ‘special’ status which these pharmacists accorded EHC. This appeared to be due in part to its hormonal content and some respondents believed that if taken more than a couple of times in unspecified time period it could have a damaging effect on the woman taking it:

“If you talk about PC4…you’re not supposed to be using it more than twice in 6 months because of the effects of oestrogen on the female.” [B]

The following comment suggests that this pharmacist does not see the prescribing of EHC simply in pharmacological terms, but also took into account the social context of the situation:

“This is something completely different, isn’t it? This involves a woman…she might be expecting…you’ve got a husband or a boyfriend…I mean, when you go for a cough medicine, its for you, the whole family doesn’t have to be involved when you have a cough.” [A]

Respondents highlighted ‘differences’ between EHC and other deregulated drugs, such as ranitidine (for dyspepsia) and it was clear that the perceived outcome of failing to supply EHC or prescribing for a woman who was already pregnant in terms of either an unwanted pregnancy or damage to an existing pregnancy were the factors which gave this drug its special status:

“The outcome was completely different with say, ranitidine. If the situation didn’t resolve within a week, you then automatically referred to the doctor. Now, unfortunately with (EHC) it’s too late. It’s more like falling off a cliff with this situation.” [B]

“Well, it’s different from selling a cough mixture…it’s what can go wrong that’s the problem….” [B]

Perhaps inevitably, moral and ethical issues were raised about the point at which an embryo can be considered to be a life. Opponents of abortion believe that life begins at the moment of conception, rather than at the point at which the embryo embeds in the womb and as such, regard EHC as an abortifacent, as it can prevent implantation:

“You can get into the whole ethical issue about the unborn child…and when does it become life?” [B]

This comment is interesting as it raises the notion that women might try and purchase EHC to abort a pre-existing pregnancy. There is no evidence to support this notion and a more detailed understanding of the mode of action of EHC would reassure this participant that taking the drug would have no impact on the viability of the pregnancy.

What these quotes illustrate is how underlying social views and attitudes towards pregnancy and abortion underpinned these pharmacists’ attitudes towards EHC. As such, it could be argued that it was not the chemical content of the drug per se that caused these pharmacists most concern, rather it was the perceived consequences of either supplying or not supplying the drug, in particular their perception that this would result in an unwanted pregnancy, foetal abnormalities or a termination. This inability to disentangle these social attitudes from the reality of practice and the evidence-base for this drug prevented these pharmacists from making an accurate assessment of the risk: benefit ratio of this drug.

Abuse
Another key and recurrent theme during both focus groups was that of ‘abuse’. Concerns about abuse of the drug
dominated their thinking and were used as a justification of maintaining PGDs, even where there was no evidence that abuse (as defined by these pharmacists) existed, or whether protocols would have any success in preventing abuse. The term ‘abuse’ was poorly defined and appeared to be largely based on anecdotal evidence. Despite poor definitions by the groups, it appeared that these pharmacists were using ‘abuse’ as a synonym for multiple or repeated use:

“What it does have is the potential for abuse...there are ladies out there who will start carrying these routinely, just in case...it will become their normal method of contraception.” [A]

“Abuse can be...once every 6 months or it could be once every month or once a week...ideally this should only be used as a last resort in an emergency...that's why it's called Emergency (emphasis) hormonal contraception.” [B]

Few, if any, of the pharmacists participating in the HAZ scheme (group A) had seen examples of multiple use and, contrary to expectations, many of the clients had been women in their twenties who had experienced failure of their contraceptive method:

“I haven't seen a teenager, I think the youngest I have had is 22...” [A2]

“Since I've been doing this, I've never had any individual back several times in the month...I've never had multiple (use) problems.” [A]

In addition, the perception that women using EHC would have used it many times in recent months appeared to be erroneous:

“The...patients where I've given emergency contraception...when we are taking the history...it (previous use of EHC) was all 1 year ago, over 2 years ago...” [A]

One participant, who earlier in the discussion had expressed concerns that EHC would predominantly be used by young women and women having casual sex, admitted that all of the clients seen by this pharmacist had consulted as a result of contraceptive failure of some sort:

“All either failures of condoms, forgotten pills and only one got carried away and that was post-vasectomy.” [A]

One participant argued that women might actually try and purchase EHC to procure an abortion, although the medical evidence indicates that it can have no effect on an established pregnancy:

“They could be fairly far gone in the pregnancy and not admitting to it...it could be two weeks for all we know.” [B]

Stereotyping of the type of women who might access emergency contraceptive services could also be seen as a possible barrier. The comments below, drawn from both groups of pharmacists, suggest that they felt that only women who having casual sex or not using regular methods of contraception would access EHC:

“OK, there are a proportion of people where it does happen...their condom splits...but how many people do you get where it's happened and they're not protecting themselves? They've gone out for the night and they're not taking condoms...” [B]

“(EHC) is going to be carried and used by people who are having casual sex and therefore they should be encouraged to be using barrier methods of contraception.” [A]

This is interesting because unpublished data from one of the group protocol schemes operating to provide EHC suggests that as many as half of all women were consulting as a result of contraceptive failure, for example a split condom or missed pill (Karen O’Brien, personal communication, 2000). In much of the research on the use of EHC, commentators fail to recognise that for many women using EHC is a rational and responsible act.

The stereotyping of women who would access EHC appeared to be dichotomised into two groups; the feckless, irresponsible young women, having casual sex who would use and ‘abuse’ EHC on a regular basis and would not use other methods of contraception, and the ‘ladies’ who had the financial means to afford to buy the product over the counter and would take it in replacement of their regular contraception:

“Is there going to be the situation...where there are...ladies who can afford to buy it...have no regular contraceptive...are they going to come in and use it and when they choose it?” [A]

“They can go into any pharmacy as and when they like, there will be no controls and there will be ladies who always have a pack in their bag for regular use, and if they happen to use it two or three times a month they are quite happy with that.” [A]

Discussion

With the recent deregulation of levonorgestrel from POM to P status, women aged 16 years or over in the UK can now purchase EHC over-the-counter. One of the main reasons for deregulating EHC to pharmacy status is to increase the availability and access of women to this method of contraception. Therefore it is important that pharmacists are willing and able to prescribe this drug in a non-judgmental manner. This is particularly significant as some of the criticism of existing provision of EHC has centred on hostile attitudes from reception staff and health professionals.16 Research with young women and teenagers suggests that a friendly welcome is one of the key factors which suggest that a large percentage of consultations for EHC are a result of contraceptive failure (e.g. split condom or missed pill) rather than not using any method of contraception.25 A survey of EHC use in women attending
sharred by some of the pharmacists in this study. There seems to be little acknowledgement that the decision to use EHC could be viewed as a rational act by women whose normal method of contraception may have failed, or by women who are aware they have had unprotected sex and wish to avoid the risk of an unwanted pregnancy or a termination.

Now that EHC is available as an OTC product in community pharmacies, it will be interesting to see how many women make use of this option and what impact this has on the development of PGDs. The high retail price of £20 may deter many customers and may in fact lead to the development of more PGDs for the supply of EHC in areas where women are unable to afford this.

This study is small-scale and limited to one region of the UK, so further research on a larger scale would need to be conducted to find out whether these views are shared by community pharmacists throughout the country. Nonetheless, this study provides useful insights into the attitudes of these pharmacists to EHC, to the impact of increased availability of the drug and the type of women who believed they would use EHC.

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