Community pharmacy supply of emergency hormonal contraception: a structured literature review of international evidence

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BACKGROUND: We could find no previous published review of the evidence relating to pharmacy supply of emergency hormonal contraception (EHC). Our objectives were to review, summarize and evaluate the peer-reviewed evidence relating to community pharmacy supply of EHC both in the UK and internationally. METHODS: Systematic searches were conducted for peer-reviewed international research from January 1990 to January 2005. The UK Health Development Agency’s Evidence Base 2000 standards and the evidence categories used by the UK Department of Health were applied to each paper. RESULTS: We included 24 peer-reviewed papers. There was one randomized controlled trial (RCT); the remainder of the studies were qualitative or observational studies. Pharmacy supply of EHC enables most women to receive it within 24 h of unprotected sexual intercourse. Services were highly rated by women. One RCT showed that improving access to EHC did not reduce the use of other contraceptives, lead to an increase in risky sexual behaviour or increase the incidence of sexually transmitted infections (STIs). Users expressed some concerns about the appropriateness of receiving additional pharmacist advice regarding future contraception use and STIs. One study found pharmacy supply had led to a decrease in attendances at accident and emergency departments. CONCLUSION: There is good evidence that community pharmacy EHC services provide timely access to treatment and are highly rated by women.

Key words: community pharmacy/emergency hormonal contraception/sexually transmitted infections/systematic review

Introduction

It is generally accepted that community pharmacists have the potential to contribute to improving the public’s health and there is a history of over two decades of developmental work in this setting in the UK (Anderson et al., 2003). Supplying emergency hormonal contraception (EHC) through community pharmacies without the need for a doctor’s prescription is an important public health role for pharmacists, which has long been campaigned for in the UK as a way of reducing unwanted pregnancies (Anderson, 2001). The original EHC treatment contained a combination of estrogen and progestogen, and its side effect profile was a key reason why it remained a prescription only medicine (POM). The introduction of a progestogen-only EHC product in the UK in early 2000, with its more favourable side effect profile, changed the risk/benefit balance and led to stronger arguments that pharmacy supply should become possible.

Barriers to accessing EHC are a key issue because one study showed that the sooner it is taken after unprotected sex, the more likely it is to be effective. Research has repeatedly confirmed that many women find it difficult to obtain doctor’s appointments (or attend other service providers) within the crucial 72-hour window and that (some) women experienced judgmental attitudes from existing service providers (Ellerton et al., 2000).

In the USA in July 1997, a group of organizations in Washington State began an innovative effort to make emergency contraception more widely available to women (Wells et al., 1998) Community pharmacists worked with local prescribers to produce Collaborative Drug Therapy Agreements (CDTAs). A CDTA is a local agreement between pharmacists and physicians which allows the supply of certain medicines by pharmacists. A two-year demonstration project was initiated including education for pharmacists about emergency contraception, helping pharmacists to establish formal links with prescribers, informing women about the availability of emergency contraception and evaluating the impact of the project. The scheme involved 140 pharmacies in Washington State, with training being undertaken by 1000 pharmacists (Hayes et al., 2000). Six US states now have some form of CDTA allowing pharmacy supply: Washington, Maine, and pilot programmes in Alaska, California, New Mexico and Hawaii. However, unlike in much of Europe, Canada, Australia and New Zealand, over the counter (OTC) supply of EHC has not been approved by the Federal Drug Administration (FDA) in the USA.
In June 1999, progestogen-only EHC was made available from pharmacies in France, the first product to receive such status in a developed country. From around 2000 onwards, EHC became available from pharmacies in an increasing number of European countries, Canada, New Zealand and, more recently, Australia.

In December 1999, EHC became available in UK community pharmacies in two areas of England via Patient Group Directions (PGDs). A Patient Group Direction is ‘a written direction, signed by a doctor or dentist, and by a pharmacist, relating to supply and administration only, of a prescription only medicine (POM) or P medicine to persons generally, subject to any specific exclusions set out in the Direction’ (POM Human Use Order 1997, SI1830 Section 12). Schemes were developed in Manchester and south London to supply NHS-funded EHC (Anderson et al., 2001a,b). The PGD protocol guides the decision-making of the pharmacist and provides the legal authority for the pharmacist to supply the product (Anderson et al., 2001a,b; Savage, 2001; National Health Service Executive North West). There is no charge to the user.

These services have now been replicated in many areas of the UK. In 2001, EHC was deregulated from POM to Pharmacy (‘P’) medicine status in the UK. A P medicine is a ‘behind the counter’ product whose sale has to be supervised by a pharmacist. The NHS Centre for Pharmacy Education mounted an unprecedented national education programme for pharmacists, including workshops throughout England and a distance learning programme sent out to all pharmacists in England, which was also available via the internet. The product manufacturer also provided pharmacist education.

The contraception and sexual health survey carried out in the UK in 2003/04 showed that 27% of emergency hormonal contraception was obtained through community pharmacies (ONS, 2004).

We could find no previous published review of the evidence relating to pharmacy supply of EHC. Our objectives were through a structured literature review to: (i) evaluate the impact of pharmacy supply on service users, pharmacists and the health care system; and (ii) review the evidence on health care provider attitudes towards pharmacy supply.

Methods

Search strategies

Electronic databases (MEDLINE, EMBASE, Cochrane Library and International Pharmaceutical Abstracts) were searched for the period from 1 January 1990 to 31 January 2005 for UK and international literature. The inclusion period was from 1990 until 2004. Hand searches for the same period were conducted of the Health Education Journal, International Journal of Pharmacy Practice, Journal of Social and Administrative Pharmacy, Pharmacy World and Science, Annals of Pharmacotherapy (1992 onwards; previously Drug Intelligence and Clinical Pharmacy 1990–1991), Pharmaceutical Journal, Scanner, and abstracts of the British Pharmaceutical Conference and Health Services and Pharmacy Practice Research Conference. All searches included non-English language literature. Those studies with English abstracts were assessed for inclusion on the basis of the abstract.

Search terms were: pharmacists; community pharmacy; community pharmacy services; pharmacies; pharmaceutical services; health education; health promotion; public health; emergency hormonal contraception; emergency contraception; and contraception.

The authors separately examined the lists of titles and abstracts of papers from the searches, and then compared inclusion/exclusion lists, resolving any differences by discussion. Hard copies were obtained for all papers to be considered for inclusion.

Inclusion and exclusion criteria

Studies were included if they: (i) measured one or more outcomes of pharmacy provision of EHC; or (ii) included empirical data on perceptions or attitudes of health care providers to pharmacy supply of EHC. Papers that described service developments without supporting data were excluded.

Abstraction of data

Data from the published papers were abstracted and entered into a matrix using the following framework: authors and study; study quality; country; study design and participants; interventions (including training); outcome measures; results; and conclusions. A sub-sample of six papers was abstracted by the authors and the findings compared to identify any differences and resolve them through discussion.

Quality assessment

Quality assessment frameworks for research are generally based on a hierarchy of evidence with the randomized controlled trial (RCT) as the ‘gold standard’. The literature in the field of pharmacy practice/health promotion/public health in pharmacy contains relatively few RCTs, but a substantial number of experimental and descriptive studies.

Two approaches were used to assess the quality of the evidence. First, the UK Health Development Agency’s Evidence Base 2000 standards for transparency, systematicity and relevance were applied to each paper (see Appendix I). Secondly, each study was allocated an evidence grade using the evidence categories used by the UK Department of Health in National Service Frameworks (see Appendix II).

Results

A total of 24 studies were included (see Tables I and II). The main reason why studies were excluded in the initial sift was because they were position/discussion papers (particularly from the USA) making the case for EHC to become an OTC product. In total, 15 papers examined pharmacy supply of EHC by either OTC or by protocols (for example Patient Group Directions in the UK and Collaborative Drug Therapy Agreements in the USA). These papers came from UK (5), Europe (2), Canada (4) South Africa (1) and USA (3). The majority of papers focussed on users’ experience of EHC.

Service users’ experience

In the USA, Sommers et al. (2001) conducted a questionnaire survey of providers and users of the Washington State scheme, in which 145 CDTAs were created and 11969 supplies of EHC were made over 16 months. Pharmacists were highly rated by users for their personal interactions and for the quality of information supplied about EHC use. Ratings were lower for information about side effects, recognition and follow-up of EHC failure, and for information on regular contraceptive methods. A cross-sectional, self-administered questionnaire in 15 randomly selected pharmacies providing EHC in Washington State examined adolescent’s reasons for seeking EHC from a
Types of study and country

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<td>Use of pharmacies to raise awareness of EHC</td>
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*Two studies covered both service users’ and pharmacists’ experience.

A total of 419 questionnaires were distributed to women receiving EHC on prescription from a GP or a clinic (34%), by PGD or OTC (66%) from 112 pharmacies from one large chain in the UK (Killick and Irving, 2004). Originally, 5000 questionnaires had been distributed to 764 pharmacies; 112 had chosen to hand them out, making it impossible to measure the response rate. Sixth-four per cent of those who obtained EHC directly from the pharmacy were able to take it within 24 h of unprotected intercourse compared with 46% who obtained it on GP prescription. Around 40% were first time users. Women under 20-years-old were more likely to obtain EHC directly from a pharmacy. Women who obtained their EHC directly from a pharmacy appeared to be just as well informed, just as likely to arrange regular follow-up, and generally preferred this system, although they would prefer not to have to pay for OTC supply.

A 24-item questionnaire was sent to 800 randomly selected women in mid-Sweden one year after EHC had been deregulated (Larsson, 2004). There was a 71% response rate; 98% had heard of EHC and 65% preferred to purchase it from a pharmacy. Twenty-seven per cent (150) women had used EHC before. Regarding counselling, 39% of women favoured obtaining EHC from a clinic. Women who favoured the clinic were also more concerned about risks; 26% of women thought they would get more information from a trained professional in a clinic. Most women agreed that the service was anonymous in a pharmacy, 24% had worried about side effects and one third considered EHC to be a kind of abortion. The author therefore stated that there is still a need to improve the recruitment strategy and to get pharmacists to give more information when they supplied EHC. Regression models indicated that correct knowledge and positive attitudes were contributing factors for future use of EHC. No evidence of overuse was found.

A Canadian programme supplied EHC directly in pharmacies using trained pharmacists to supply EHC via a prescribing protocol (Dunn et al., 2003). 146 pharmacists practising in 40 Toronto pharmacies were linked with 34 physicians. A poster, a radio advertisement and a telephone hotline informed women about the service. In the first year of the project, 6931 supplies of EHC were made. A postal questionnaire was returned by 1457 (20.6%) of the women; 54% accessed EHC within 24 h
To learn about women’s experiences with EHC, explaining that pharmacy delivery facilitated rapid access to the method. Despite expressing often polarized reviews of the counselling given by the providing pharmacists, particularly regarding privacy and judgmental attitudes, participants reported that they knew how to use the method safely and properly.

Pharmacy staff in Norway exchanged EHC with very few words compared with longer consultations in other countries. Most indicated that the package insert was easy to understand and answered the majority of their questions adequately. Participants described the EHC experience as a motivating factor that, in many cases, has led to more consistent use of regular contraceptive methods. The authors conclude that, while there

Pharmacists’ and women’s views about the scheme. To examine adolescent’s reasons for seeking care from a pharmacist, need for additional medical evaluation, risk for not receiving additional medical care, and satisfaction with care provided by the pharmacist.

Part of the evaluation of a scheme in Manchester, Salford and Trafford where accredited pharmacists were permitted to supply EHC free of charge under a patient group direction, on completion of a consultation with requesting users. Twenty-four pharmacist interviews took place, drawn from a total of 55 pharmacists participating in the scheme at the time of the evaluation. Two focus groups were held with women who had used the scheme.

A series of four or five focus group discussions per country were held with 98 non-prescription EHC users from urban centres in France, Norway, Portugal and Sweden. Inclusion criteria and research instruments were common across all sites but recruitment logistics varied. Topics discussed included knowledge and attitudes about EHC before use, personal experience and post-EHC reflections and opinions. Each participant also filled out a demographic questionnaire. All participants were given a modest compensation for their time in cash or kind. A third party observer took notes throughout and the focus groups were tape recorded on audio and/or video cassettes, and later transcribed. Content analysis was conducted and comments summarised according to identified themes. 5000 self-completion, anonymous questionnaires were distributed to women requesting EHC through 764 Moss pharmacies.

Response rates were 51% (159) for pharmacists, 27 (49%) for prescribers and 470 (6.5%) for users. Most (92%) of pharmacists and prescribers were ‘satisfied’ or ‘very satisfied’ with their prescribing agreements. Pharmacists were highly rated by users for their interactions with patients and quality of information about EHC use. Ratings were lower for information about side effects, recognition and follow-up of EHC failure, and regular contraceptive methods.

126 adolescents answered the survey. The most common reasons were: convenience (44%); lack of knowledge about alternatives (38%); and privacy (31%). 58% said they would have gone to a doctor had it not been available in the pharmacy, 22% would have waited to see if they got pregnant and 20% did not know. 81% said they needed a new method of regular contraception, an evaluation for STIs or both. Adolescents were satisfied with the pharmacy service and said they would recommend it to a friend.

The authors tentatively suggest that the scheme was largely well received by pharmacists and users. Benefits included increased access at no cost to the user. Users noted a welcome absence of judgmental attitudes when accessing the service. Both users and pharmacists had a number of major concerns about the scheme centring on the potential for misuse, changes in contraceptive behaviour and the impact on sexually transmitted infections. Many pharmacists spontaneously referred to the benefits that the scheme accrued to the pharmacy profession. Participants overwhelmingly supported pharmacy access to EHC, explaining that pharmacy delivery facilitated rapid access to the method. Despite expressing often polarized reviews of the counselling given by the providing pharmacists, particularly regarding privacy and judgmental attitudes, participants reported that they knew how to use the method safely and properly. Pharmacy staff in Norway exchanged EHC with very few words compared with longer consultations in other countries. Most indicated that the package insert was easy to understand and answered the majority of their questions adequately. Participants described the EHC experience as a motivating factor that, in many cases, has led to more consistent use of regular contraceptive methods. The authors conclude that, while there


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Proportion of women receiving EHC within 24 h of unprotected intercourse.

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pharmacists practising in 40 pharmacies were linked with a designated physician who retrospectively authorized prescriptions provided by the pharmacist. Women said they wanted to receive counselling from a skilled pharmacist or another health professional. Logistic regression showed that correct knowledge of and positive attitude towards EHC contributed for 80% of women who were sufficiently positive to request EHC. In the last year, 1457 (20.6%) of women were linked to EHC. The majority of them were very satisfied with the service and almost all agreed that they understood how to take EHC. 21.1% indicated that, had they not obtained EHC in this way, they would not have obtained it.

To develop and evaluate a programme to provide EHC directly in pharmacies, a pharmacy-based study was conducted in three regions of Toronto. Women were recruited to receive a training program on EHC. The pharmacists in each pharmacy were instructed on the provision of EHC, and then they were followed up to see the number of women who requested EHC. The results showed that the programme was successful in increasing the availability of EHC in pharmacies. An estimated 195–220 abortions were prevented by the pilot project. Women's knowledge, attitudes and practices towards EHC were assessed through focus groups and a questionnaire. Most women reported positive attitudes towards EHC and were willing to purchase it. Women who had visited a contraceptive clinic in the last year had significantly better knowledge than women who had not. Women who had purchased EHC within 24 h of unprotected intercourse were more likely to understand the instructions for use. Women who had visited a contraceptive clinic were more likely to seek EHC in the future. Women who had previously purchased EHC were more likely to request it in the future. Women who had previously purchased EHC were more likely to recommend it to others. Women who had previously purchased EHC were more likely to purchase it again in the future. Women who had previously purchased EHC were more likely to use it as a method of contraception. Women who had previously purchased EHC were more likely to use it as a method of contraception. Women who had previously purchased EHC were more likely to use it as a method of contraception.

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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 the use. It is interesting to note that none of those participants with strong negative attitudes towards deregulation. The authors state that this opposition is due to clearly articulated assumptions about female sexuality, particularly that women are irresponsible, chaotic and deviant. The authors conclude that these attitudes are likely to undermine the provision of deregulated EHC.

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To explore the views of community pharmacists in the north-west of England towards the deregulation of EHC and to examine their support and training needs.

This paper describes the effectiveness of a multi-focus recruitment strategy to a pilot project allowing direct provision EHC in community pharmacy through collaborative agreements between pharmacists and physicians. The project recruited pharmacies through direct appeals to pharmacists, pharmacy managers and/or owners, and corporate pharmacy chains. 14 community pharmacists in north-west England, eight of whom were supplying EHC via patient group direction (PGD) took part in two focus groups.

The aim was to examine interviewees’ views on possible deregulation of EHC. The objective was to obtain personal and professional views on EHC and related factors and attitudes towards selling it in the future.

To explore women’s views on the deregulation of EHC prior to it becoming deregulated on 1 January 2001.

There was a 56% response rate for GPs and a 50% response rate for pharmacists, with GP respondents showing a good knowledge of EHC but a reluctance to use it. Although nearly all GPs had some reservations, usually regarding safety, privacy, pharmacy training and appropriateness and reduced use of regular contraception, 55% were in favour of OTC supply. Pharmacists had less knowledge about EHC but 75% wished to supply it OTC. Pharmacists expressed fewer reservations about OTC supply. However, a fifth expressed an ethical objection to supply. The guidelines had been read by 60% of GPs and 37% of pharmacists in Camden and Islington.

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Most women were in favour of deregulation with OTC provision perceived as quick, convenient and anonymous. Reservations regarding overuse and over-reliance upon EHC mirror those of health professionals, although it was not felt that the increased accessibility of EHC would lead to changes in sexual activity. Concerns that deregulation would promote an irresponsible attitude towards contraception were largely focused on younger women. Cost was generally regarded as a positive barrier to overuse. However, it was felt that the price should not be prohibitively high.

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A formal course with role play was a successful training method. The course also served as a team building exercise. The pharmacists had understood the concept of client confidentiality and gained confidence over time in the use of the PGD. The on-call consultants received 152 calls in the first 12 months of the scheme. Over 80% of the calls concerned clinical criteria (notably including 22% that were queries about oral contraceptives). Frequency ranged from 1–8 calls per week with 28% made at weekends. In over half (60%) of the calls, the pharmacist was subsequently able to make a supply. Queries about how clients might ‘misuse’ or ‘abuse’ the service, and this remained a concern despite the fact that it also applies to other contraceptives. Pharmacists also believed that the scheme had benefits for the profession in terms of enhanced professional standing. However, their concerns included the scope for repeated use of EHC, the possible impact on contraceptive behaviors and sexually transmitted infections and its impact on male coercive sexual behaviour. 96% of pharmacists had received requests for EHC within the last year. On average, each pharmacist received 177 requests. 69% of pharmacists were in favour of making EHC available without a prescription, and 62% were already supplying EHC without a prescription and 67% felt that it was important to increase public awareness regarding EHC. 91% of pharmacists did not have any literature regarding EHC to hand to clients, 68% had a private area in their pharmacy to counsel patients and 86% of pharmacists indicated that they discussed long-term contraception with clients. A formal course with role play was a successful training method. The course also served as a team building exercise. The pharmacists had understood the concept of client confidentiality and gained confidence over time in the use of the PGD. The on-call consultants received 152 calls in the first 12 months of the scheme. Over 80% of the calls concerned clinical criteria (notably including 22% that were queries about oral contraceptives). Frequency ranged from 1–8 calls per week with 28% made at weekends. In over half (60%) of the calls, the pharmacist was subsequently able to make a supply. Queries about how clients might ‘misuse’ or ‘abuse’ the service, and this remained a concern despite the fact that it also applies to other contraceptives. Pharmacists also believed that the scheme had benefits for the profession in terms of enhanced professional standing. However, their concerns included the scope for repeated use of EHC, the possible impact on contraceptive behaviors and sexually transmitted infections and its impact on male coercive sexual behaviour. 96% of pharmacists had received requests for EHC within the last year. On average, each pharmacist received 177 requests. 69% of pharmacists were in favour of making EHC available without a prescription, and 62% were already supplying EHC without a prescription and 67% felt that it was important to increase public awareness regarding EHC. 91% of pharmacists did not have any literature regarding EHC to hand to clients, 68% had a private area in their pharmacy to counsel patients and 86% of pharmacists indicated that they discussed long-term contraception with clients.

Table II. Continued

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<th>Publication details, evidence grading and country</th>
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<th>Outcome measures</th>
<th>Key findings</th>
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<td>Bissell P, Anderson C and Savage I (2005) A qualitative study of pharmacists’ perspectives on the supply of emergency hormonal contraception via patient group direction in the UK. Contraception, in press. B3 UK</td>
<td>Qualitative study using depth interviews with 44 community pharmacists supplying EHC in Manchester, Salford and Trafford and Lambeth Southwark and Lewisham (London).</td>
<td>To investigate pharmacists views and experiences of supplying EHC via a group prescribing protocol in community pharmacies in the UK.</td>
<td>Pharmacists were broadly very positive about their experiences supplying EHC via the group prescribing protocol. Pharmacists identified many benefits of the EHC schemes for clients and, in particular, improved access to EHC at no cost to clients. The confidential nature of the scheme was also seen as an advantage, as was the scope for signposting to other service providers. Pharmacists also believed that the scheme had benefits for the profession in terms of enhanced professional standing. However, their concerns included the scope for repeated use of EHC, the possible impact on contraceptive behaviors and sexually transmitted infections and its impact on male coercive sexual behaviour. 96% of pharmacists had received requests for EHC within the last year. On average, each pharmacist received 177 requests. 69% of pharmacists were in favour of making EHC available without a prescription, 62% were already supplying EHC without a prescription and 67% felt that it was important to increase public awareness regarding EHC. 91% of pharmacists did not have any literature regarding EHC to hand to clients, 68% had a private area in their pharmacy to counsel patients and 86% of pharmacists indicated that they discussed long-term contraception with clients.</td>
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<tr>
<th>Publication details, evidence grading and country</th>
<th>Study design, participants and setting</th>
<th>Outcome measures</th>
<th>Key findings</th>
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<tr>
<td>Anderson C and Bissell P (2004) Using semi covert research to evaluate an emergency hormonal contraception service. Pharm World Sci 26,102–106. B3 UK</td>
<td>Aimed to evaluate: whether the patient group direction protocol for supply of EHC was being adhered to; whether pharmacists were undertaking their professional duties appropriately; and how women researchers felt that the service was being delivered. Semi covert research was used; two women researchers posed as clients seeking emergency contraception in a sample of 10 participating community pharmacies at which they used two rehearsed scenarios about unsafe sexual intercourse and missed doses of the oral contraceptive pill. All transactions were tape-recorded and the recordings were used to produce the findings. The two women researchers posing as clients were also asked to record their feelings and experiences concerning the service on leaving the pharmacy.</td>
<td>Adherence to the patient group direction protocol and women’s perceptions of service provision.</td>
<td>For both scenarios, the protocol was largely adhered to and emergency contraception was supplied appropriately. The length of each consultation for both scenarios was 10–15 min. The women reported that the pharmacists had been courteous, polite and non-judgemental. The consultations were carried out in a private area or in the dispensary. The women had no concerns about confidentiality.</td>
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<td>Cohen MM, Dunn S, Cockerill R and Brown TER (2004) Using a secret shopper to evaluate pharmacist provision of emergency contraception: satisfaction levels high, with privacy a concern. Can Pharm J 137,28–33. B3 Canada</td>
<td>A pilot project in Toronto, Ontario, aimed to increase accessibility by allowing pharmacists to dispense EHC through a pharmacist–physician collaborative agreement, using a predefined protocol. Participating pharmacists received training in the pilot protocol and about EHC. Five trained ‘secret shoppers’ of varied ethnicity were trained for 2 h to use one of two predefined scripts (script 1 where EHC was clearly appropriate, and script 2 where EHC was not appropriate). They visited 34 participating pharmacies to request EHC. The pharmacists were sampled regarding size, location and hours of opening (usual business hours or open after 18.00). At the end of the visit, the secret shopper filled in a questionnaire about the encounter and provided comments. Percentages were calculated for all variables.</td>
<td>Whether participating pharmacists were following the project protocol and to determine the quality of the pharmacist-patient encounter.</td>
<td>23 small and 13 large pharmacies were visited. At two pharmacies, no pharmacist was available, leaving 34 for analyses. For script 1 encounters (n = 17), most pharmacists followed the protocol correctly to dispense EHC. For script 2 encounters (n = 17), 71.4% provided alternatives to EHC, but three pharmacists did not follow protocol and provided EHC. 52.9% of pharmacists for script 1 and 71.4% for script 2 provided a community referral for follow-up care. The majority of pharmacists (97%) treated the shopper with respect and 85% communicated clearly. Privacy was protected in 82.3% of cases but in only 22 (64.7%) of encounters was there a private consultation area. Most of the shoppers’ comments were positive and the main negative comment about the encounter was lack of privacy. There were several comments about the need for more information about STIs or the lack of an appropriate referral by the pharmacist.</td>
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<td>Kerins M, Maguire E, Fahey DK and Glucksman E (2004) Emergency contraception. Has over the counter availability reduced attendances at emergency departments? Emerg Med J 21,67–68. B3 UK</td>
<td>Retrospective search of electronic patient record systems for patients requesting emergency contraception at two emergency departments in southeast London. If reason for consultation was unclear, written case notes were reviewed. Data were collected on patient’s age, GP registration and whether or not the patient was prescribed ECH after her request. Years 2000 and 2001, after introduction of pharmacy sale and supply of EHC were compared.</td>
<td>Number of consultations for EHC at the two emergency departments</td>
<td>20 pharmacies collected data. Enquiries increased 2–4 fold. 13 collected leaflet data: there was an increase in leaflet uptake by 13–43 fold. There was a 4-fold increase in number of pregnancy tests sold and three times more prescriptions for ECP were dispensed. 160 women mainly aged from 12 to 25 years responded to the survey. The majority considered the display to be ‘good or very good’, and only 6% had not noticed it. 60% said they would use their pharmacist in the future for advice about ECP.</td>
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<tr>
<td>Sharma S and Anderson C (1998) The impact of pharmacy using window space for health promotion about emergency contraception. Health Ed J 57,42–50. B3 UK</td>
<td>A ‘before and after’ study of the effect of pharmacy window displays on enquiries about emergency contraception. 20 pharmacies participated in one London health authority. Pharmacists attended an evening seminar to introduce the scheme. Pharmacies were paid £250 for participating.</td>
<td>Number of enquires about emergency contraceptive pill (ECP); number of leaflets, ECP dispensed; pregnancy tests sold 2 weeks before, during, and 2 weeks following the campaign. Customer questionnaire to determine response to the display and how they would use pharmacies.</td>
<td>20 pharmacies collected data. Enquiries increased 2–4 fold. 13 collected leaflet data: there was an increase in leaflet uptake by 13–43 fold. There was a 4-fold increase in number of pregnancy tests sold and three times more prescriptions for ECP were dispensed. 160 women mainly aged from 12 to 25 years responded to the survey. The majority considered the display to be ‘good or very good’, and only 6% had not noticed it. 60% said they would use their pharmacist in the future for advice about ECP.</td>
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of unprotected intercourse. The majority were very satisfied with the service and almost all agreed that they knew how to take EHC. Twenty-one per cent indicated that, if EHC had not been available in the pharmacy, they would not have used it, while 10% wanted more information on contraception. Dunn et al. (2003) estimate that 195–220 abortions were prevented by their project.

Clinical and behavioural outcomes
An RCT was conducted in the USA which compared access to EHC through clinics (usual care), community pharmacies and ‘advance supply’ in which the woman received three packs of EHC (Raine et al., 2005) This study provides important new evidence and its strength is in the large number of women enrolled. A total of 2117 women aged between 15 and 24 participated, and they were followed up for 6 months. Pregnancy rates were similar in the three groups, as was the incidence of new STIs (as measured using biomarkers). There were no differences in the use of other contraceptives and no increase in risky sexual behaviour. EHC was used on more than one occasion by a small proportion of women: 6.8% of women used it twice and 4.1% used it three times. The study subjects were women attending clinics that provided family planning services and the wider applicability of the findings is not known. At 6 months, the follow-up was likely to be of too short a duration to detect any possible reduction in the pregnancy rates that might be due to enhanced access to EHC.

Attitudes of health care providers
Kumar et al. (2003) surveyed physicians, nurse practitioners, physician assistants and pharmacists in one USA state. Substantial proportions (50% of physicians and 39% of ‘mid-level’ practitioners) respondents favoured improving access to EHC through ‘behind the counter’ availability in pharmacies. Around one fifth of respondents said they would need further information about pharmacy supply before they could state whether they would support it. The authors therefore recommended a campaign to educate healthcare providers about recent scientific evidence on EHC and about CDTAs. Almost half the pharmacists said they would participate in a collaborative protocol for provision of EHC.

Attitudes of providers and users prior to deregulation
Several studies in the UK investigated the perceptions of pharmacists, doctors and potential service users prior to deregulation of EHC. A questionnaire-based study examined knowledge, use of EHC and the views of GPs and pharmacists (D’Souza and Bounds, 2001). GP respondents showed good knowledge of EHC but a reluctance to use it. Although nearly all GPs had some reservations, 55% were in favour of OTC supply. Pharmacists had less knowledge about EHC, but expressed fewer reservations about OTC supply (75% wished to supply it OTC). However, one fifth expressed an ethical objection to supply. Barrett and Harper (2000) interviewed 18 community pharmacists and six GPs to explore attitudes towards possible deregulation of EHC. Seven interviewees objected outright to the idea of deregulation and a further 14 expressed strong reservations. Folkes et al. (2001) examined the views of women about EHC prior to deregulation. Twenty-seven women, aged 18–19, were interviewed in family planning clinics. Most favoured deregulation but there were some concerns about overuse and over-reliance on EHC as a contraceptive method.

Recruitment strategies
Cockerill et al. (2004) examined recruitment strategies to increase the number of Canadian pharmacists to participate in prescribing protocols for EHC. Pharmacists were recruited through direct appeals to pharmacists, pharmacy managers and/or owners, and corporate pharmacy chains. Reference to the opportunities that participation offered to expand the pharmacist’s role in patient-focused care was the most successful strategy. Peer influence was also important.

Pharmacists’ experience
Most of the pharmacists and prescribers (92%) in the Washington State scheme were ‘satisfied’ or ‘very satisfied’ with the prescribing arrangements (Sommers et al., 2001). Seston et al. (2001) interviewed 14 UK pharmacists, eight of whom were supplying EHC under PGD took part in focus groups in northwest England. A number of them appeared to lack detailed knowledge about the mode of action of EHC and misunderstandings about this appeared to influence their attitudes to deregulation. Participants were worried about the risk of litigation. EHC was accorded a special status, which seemed to go beyond its pharmacological properties and risk–benefit profile. They were also concerned about abuse or recurrent use, although none of them could provide any examples of such abuse.

Bissell and Anderson (2003) studied the PGD scheme in Manchester. Twenty-four pharmacists participated in in-depth, semi-structured interviews. The scheme was largely well received. The authors discuss the fact that many pharmacists (and users) had anxieties about the potential for ‘inappropriate’ or ‘irresponsible’ use of EHC. One pharmacist was clearly against the scheme on the grounds that it would encourage promiscuity. Other pharmacists echoed the concerns of the GPs in Ziebland’s study (Ziebland, 1999) and the GPs and pharmacists in Barrett and Harper’s study (Barrett and Harper, 2000) in the sense that they differentiated between ‘responsible’ and ‘irresponsible’ requests for EHC. However, there were subtle differences between pharmacists’ attitudes; some thought that it was ‘better’ that women should come forward to the pharmacy to obtain EHC rather than take no action and risk pregnancy. Some referred to this as an indication of ‘responsible’ behaviour, even where the client concerned had engaged in unprotected sex. The authors suggest that the attitudes of pharmacists in this study are more nuanced in comparison with those uncovered by some other researchers in this area, and this may be a reflection of the multi-disciplinary training received by pharmacists.

Many pharmacists spontaneously referred to the benefits that the scheme accrued to the pharmacy profession. Bissell et al. (2005) combined the data from the Manchester pharmacist
interviews with that from interviews in London giving data from 44 interviews. Pharmacists were broadly positive and identified many benefits of the scheme for women. The scope for signposting to other service providers was seen as positive. Concerns were as above and there was also anxiety regarding the impact on male coercive behaviour. The authors called for further research to resolve these issues.

In a survey of 182 pharmacists in Durban, South Africa (Hariparsad, 2001), an average of 177 requests for EHC were made per pharmacy per year. Sixty-two per cent supplied EHC without prescription and 67% felt public awareness regarding EHC needed to be increased. Ninety-one per cent did not have any literature on EHC to hand to women, while 86% of pharmacists said that they discussed long-term contraceptive use with women requesting EHC. Sixty-eight per cent had a private consultation area.

Training and competency
Studies in the UK (Bacon et al., 2003) and Canada (Neubauer et al., 2004) evaluated training and the competency of pharmacists to supply EHC. Bacon et al. (2003) examined written (pharmacy records) and oral (telephone calls to clinical support) data from 20 out of 23 pharmacists before and during training, and at 5, 13–14 months after the launch of an EHC PGD service. They conclude that a formal course with role play was a successful training method. The pharmacists had understood the concept of client confidentiality and gained confidence over time in the use of the PGD. The course had also served as a team building exercise. The on-call consultants received 152 calls in the first 12 months of the scheme; 80% were clinical in nature and 20% concerned oral contraception. The training for subsequent cohorts of pharmacists was altered after analysis of the calls.

A faculty of pharmacy in Saskatchewan (Neubauer et al., 2004) developed a workshop to educate pharmacists about EHC. Of the 285 participants, 209 paid 20 Canadian dollars to be trained and completed a test consisting of 25 questions before and after a 3 h face-to-face workshop. They were required to score ≥80% to be accredited to prescribe EHC; 203 (71%) became prescribers. The average pre- and post-training scores were 58% and 85%, respectively. Canadian pharmacists can now also become accredited via an online programme from the Canadian Pharmaceutical Association.

Quality of pharmacist consultations
Covert participant research (mystery shopping) was used to evaluate the PGD scheme in Manchester, UK (Anderson and Bissell, 2004) and a pilot project in Toronto, Canada (Cohen et al., 2004). The aim of the UK study was to evaluate whether the PGD for supply of EHC was being adhered to and to evaluate how women researchers felt the service was being delivered. Two scenarios were used about unsafe intercourse and a missed dose of oral contraceptive. Two women each visited 10 pharmacies. The protocol was largely adhered to and EHC was supplied appropriately. The women reported that the pharmacists had been courteous, polite and non-judgmental, and conducted the interview privately and confidentially.

Discussion
There is a growing international body of research into pharmacy supply of EHC. We found only one RCT but the quality of the other, qualitative and descriptive studies was generally high. Most of the studies that assessed users’ experience were either focus groups or had low response rates. Women who volunteer for a focus group or reply to a questionnaire may not be representative of the rest of the population. There may also be regional variations. The evidence shows that pharmacy supply of EHC improves access and enables most women to receive it within 24 h of unprotected sexual intercourse. Women were generally satisfied with pharmacy EHC supply and the information that they received from pharmacists. There were several comments about the need for more information about STIs.

A ‘mystery shopper’ telephone survey of community pharmacists was conducted in one USA state (Bennett et al., 2003). The findings showed that many community pharmacists did not have sufficient or accurate information about EHC. Only one in three pharmacists said they would be able to fill a prescription for EHC that day. Pharmacists who knew less about EHC were less likely to say they could dispense a prescription for it. The authors concluded that increased education for pharmacists would be needed as part of interventions to increase timely access to EHC.

Effects of pharmacy EHC supply on health system usage
A retrospective study (Kerins et al., 2004) examined electronic patient records for women requesting emergency contraception at two emergency departments in south-east London hospitals in 2000 and 2001, before and after pharmacy supply became available. There was a statistically greater proportion of attendees requesting EHC in 2000 compared with 2001 (\(P = <0.001\)); this reflected a 52% decrease in requests. The authors state that there is further room for reduction in attendances at emergency departments and call for potential barriers such as high cost, pharmacy opening hours and lack of patient awareness to be addressed.

Use of pharmacies to raise awareness of emergency contraception
Sharma and Anderson (1998) studied the effect of using pharmacy window displays about EHC on raising awareness of the technology in 20 community pharmacies in one area of the UK. Enquiries about EHC increased 2–4 fold and leaflet uptake by 3–43 fold. Prescriptions for EHC rose 3-fold and pregnancy tests 4-fold.
remain some issues regarding privacy and confidentiality, and not all pharmacists conducted EHC consultations in private areas. The amount and type of information provided by pharmacists during the consultation appeared to vary considerably. There was reluctance by some women to receive information about STIs and ongoing contraceptive needs as part of the EHC consultation with the pharmacist. On the other hand, other women said they did not receive sufficient information from the pharmacist. Some pharmacists appear to be reluctant to discuss issues of regular contraception and reducing risks of sexually transmitted infections. There is also the issue of cost, in the UK; EHC can be obtained free from GPs, clinics and from some pharmacies in deprived areas under PGD. Other women have to pay £25 to obtain a pharmacy supply. In other countries, women may not only have to pay for their visit to a doctor or clinic, but also for their supply of EHC. No studies were found regarding the effect of cost.

A recurring theme from studies, particularly those prior to deregulation, was a concern amongst pharmacists, GPs and potential service users about the potential for repeated use of EHC rather than a regular method of contraception. Bissell and Anderson (2003) concluded that the pharmacists in their study had more nuanced attitudes in comparison with those uncovered by some other researchers in this area and that this may be a reflection of the multi-disciplinary training and different perspectives experienced by the pharmacists in their study. Rowlands et al. (2000) disproved the notion of widespread repeated use of EHC services in a retrospective study. Using the General Practice Research Database of 15 205 women, only 4% had used it more than twice in any year and >70% had used regular contraception within a year of using EHC. Ellertson et al. (2000) argue that women tend to overrate the health risks of emergency contraception in general, and of repeated use in particular. They state that part of the problem is undoubtedly the medical barriers that are imposed in many settings such as the requirement for pregnancy tests.

Providers also tend to overestimate the potential for misuse, although there are no studies giving any empirical basis for the fear that women abuse EHC (Ellertson et al., 2000). Indeed the European study by Gainer et al. (2003) indicates that women’s emergency contraception experience was actually a motivating factor leading to more consistent use of regular contraception. Moreover, abuse was not considered to be a problem by the women who responded to a recent Swedish questionnaire (Larsson et al., 2004).

Some commentators have argued that provision of EHC in the pharmacy might lead to changes in contraceptive behaviours that adversely affect STIs (Bissell et al., 2001; Stammers, 2001a,b). The findings from a fairly large RCT provide evidence to refute this view (Raine et al., 2005). With no changes in the use of other contraceptives, no increase in risky sexual behaviour and no increase in the incidence of STIs among the 2000 plus women in the study, the RCT provides evidence to counter negative perceptions. Moreover, a recent Scottish study (Fairhurst et al., 2004; Ziebland et al., 2005) concluded that advance supply was viewed positively by women and that concerns about repeated EHC use as well as links between easier access to EHC and risky sex or changed contraceptive behaviours appear to be unfounded. Current guidance regarding pharmacy supply of EHC in the UK (RPSGB, 2004) does not allow for advance supply; this should be reconsidered in the light of this new evidence.

Younger women are at highest risk of unprotected intercourse and unwanted pregnancy. Community pharmacies were mainly sought by women over 20-years-old and the perception of participating pharmacists was that use was mainly confined to women from higher socio-economic groups. Little is known about the reasons why younger women do not choose pharmacy supply. A recent commentary calls for more research in this area (Bissell and Anderson, 2005)

Although training provision varies in different countries, training improved pharmacists’ consultations and competency regarding EHC and enabled pharmacists to direct women to other service providers as appropriate. Mystery shopping studies have indicated that the majority of pharmacists studied supplied EHC according to protocols and in a non-judgemental manner.

There is little published research to date on the impact on other parts of the health care system. One study following deregulation of EHC in the UK showed a decrease in requests for EHC in accident and emergency departments.

Most published studies focused on obtaining feedback from service users and pharmacist service providers about their experiences. Before pharmacy supply of EHC, research from the UK and USA provided an indication of the perceptions of potential service users, pharmacists and other health professionals. In the UK, quantitative studies suggested that half of the responding GPs and three quarters of pharmacists supported pharmacy supply of EHC. Attitudes expressed by GPs and pharmacists towards potential future supply in a qualitative study were more negative. Following deregulation and the introduction of protocols for NHS supply of EHC, most pharmacists appear to be very satisfied with delivering EHC services. Pharmacists seem to see EHC supply as a way to extend and improve their role in patient-focussed care. Bissell and Anderson (2003) discuss this issue of role change and professionalization strategies in more depth.

While there was considerable support for pharmacy supply in the UK, concerns were expressed about whether improved access to EHC might affect women’s behaviour and lead to greater promiscuity. Furthermore, it was claimed that pharmacists would not provide information about avoiding risks from sexually transmitted infections (Stammers, 2001a). Evaluation of evidence relating to potentially positive and negative impacts of pharmacy supply is therefore important.

The review findings permit some observations and suggestions to be made for practice development and future research. Privacy emerged as an issue. OTC availability of EHC means that most pharmacies are likely to stock it. Market forces are then likely to apply, in that women will have a choice of pharmacies and can opt for one where they perceive the level of privacy meets their needs. In England and Wales, the new community pharmacy contract is predicted to increase the percentage of pharmacies with a consultation area and this should increase privacy.

Pharmacy consultations for EHC are an opportunity for the pharmacist to raise the issues of future contraception and
prevention of STIs. In the UK, the protocol requirements of PGDs are specific about the provision of information about STIs and evaluations of such schemes showed that such information was usually given. The extent to which this happens in OTC consultations is not fully clear. There is evidence to suggest that some pharmacists are reluctant to discuss these subjects. Furthermore, some women do not see this as part of the pharmacist’s role. Lack of privacy may be one reason for these beliefs, but pharmacists’ and women’s personal views will also play a part. Some women would like to receive more information from the pharmacist than they currently do. In considering how much and which information to give a woman, pharmacists should assess each case individually. Training may be one way to enable pharmacists to practice and develop their skills in this respect.

There is insufficient evidence to know definitively whether pharmacy availability has substituted for prescribing elsewhere (and indeed, whether it has prevented termination of pregnancies which might otherwise have resulted) or whether an increase in usage of EHC has resulted. Retrospective research analysing trends in prescribing data and pregnancy terminations in countries with and without pharmacy availability of EHC may shed further light on this aspect.

Conclusion

The evidence shows that supply of EHC from pharmacies whether by prescribing protocols or OTC sale is viewed mostly positively by both users and pharmacists. Access has improved and women are able to obtain EHC more easily—though they may have to pay more for it and take it more quickly after unprotected intercourse than if they obtain it by other routes. Evidence from a reasonably large RCT provides reassurance that EHC use is not associated with an increase in risky sexual behaviour or in the incidence of STIs. Further research is warranted on the amount and type of information that should be given at the time of the EHC consultation. Some pharmacists also need to give further consideration to using private areas for EHC consultations.

References

National Health Service Executive North West (online) Patient Group Directions (Group Protocols) http://www.groupprotocols.org.uk [accessed 25/02/05].

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Appendix I Health Development Agency standards: evidence base 2000 (UK)

Transparency—evidence must include a clear and transparent account of how it was collated, which sources of information have been consulted, who was involved in collating the evidence, how the work was funded, a full disclosure of any analysis and findings.

Systematicity—evidence identified must display clearly, regardless of the individual study, report or review methodology, the process through which the evidence was gathered and assessed.

Relevance—evidence must be judged to be relevant to health development, and in this instance to the role of community pharmacy.

See the Health Development Agency’s website (http://www.HDA-online.org.uk/evidence/eb2000): evidence base-quality standards for evidence

Appendix II Evidence categories used by the Department of Health in National Service Frameworks

Evidence from research and other professional literature

1. A1 Systematic reviews which include at least one randomized controlled trial (RCT), e.g. systematic reviews from Cochrane or NHS centre for review and dissemination.

A2 Other systematic and high quality reviews which synthesize references

2. B1 Individual RCTs


4. B3 Individual well-designed non-experimental studies, controlled statistically if appropriate. Includes: studies using case control, longitudinal, cohort, matched pairs or cross-sectional random sample methodologies, and well-designed qualitative studies; and well-designed analytical studies including secondary analysis.

5. C1 Descriptive and other research or evaluation not in B (e.g. convenience samples)

6. C2 Case studies and examples of good practice

7. D Summary review articles and discussions of relevant literature and conference proceedings not otherwise classified