

**PROTOCOL FOR THE SUPPLY AND ADMINISTRATION
OF EMERGENCY HORMONAL CONTRACEPTION (EHC)
BY A TRAINED PHARMACIST**

December 2000

**ALL DOCUMENTS ENCLOSED MUST BE COMPLETED WHERE
APPROPRIATE**

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GROUP PROTOCOL for the Supply and Administration of Emergency Hormonal Contraception (PC4 or Levonelle-2)

To: Pharmacists
West HAZ/PCG, Brownhills, Walsall Health Authority

By: Dr MR Antani, Family Planning Physician, Hatherton Centre
Mrs. M. Pillinger, Family Planning Nurse, Hatherton Centre
N. Barnes, Pharmaceutical Adviser, Walsall Health Authority

1. Clinical condition / situation to which this protocol applies (Reference: Crown Report, Appendix A)

This is a new specialist clinic, which will be available from community pharmacies in the Walsall West Primary Care Group/Health Action Zone area, within Walsall Health Authority as part of a Health Action Zone initiative. This additional service is provided by an accredited pharmacist, at participating pharmacies, on completion of additional training and within this group protocol.

Clients can attend pharmacies in the West Walsall area who are either unable or do not wish to attend other local agencies (i.e. family planning clinics, GP) that offer comprehensive family planning services including a choice of Emergency Contraception methods and where.

- The client (for personal reasons) chooses to accept the limited service available through a Pharmacist.
- However, if for medical reasons the client is excluded from treatment within the criteria of this protocol they will be provided with information to enable them to access other family planning services.

1. Premises

The service can only be provided in an approved pharmacy, which must have a suitable area for consultation with clients. This may be a quiet area within the shop or a separate room.

The pharmacy will be required to designate window space for a display board or poster giving information on emergency contraception and how to obtain it locally.

2. Criteria for inclusion: Client history

- A relevant medical history should be taken from all clients in accordance with the protocol
- Emergency hormonal contraception is appropriate when the client presents within 72 hours of unprotected sexual intercourse (no contraception, condom breakage/ leakage, and missed contraceptive pills).
- If more than 72 hours but less than 120 hours has elapsed, the IUD is the appropriate method and should be discussed with the client before referral to a Family Planning Clinic or the client's GP. A current FPA leaflet should be given.

If any further advice about the client's suitability for inclusion is required please contact:

Name of Centre
Hatherton Centre
WALDOC (out of hours)

Contact telephone number
01922 775042/3
01922 711777

3. Criteria for referral

Having established that the interval between the first episode of unprotected sexual intercourse and having been seen in the pharmacy is less than 72 hours, if it is then identified that the client has a history of any of the following then the client must be referred to a doctor.

- Actual or possible pregnancy, i.e. previous risk in cycle
- Previous supply of emergency contraception within the cycle in question. (If Levonelle 2 or PC4 have been taken and vomited [either 1st or 2nd dose] refer to guidance notes).
- Current breast cancer
- Severe liver disease
- Interacting drugs (refer to BNF, paper on herbal remedies, St John's Wort)
- Has experienced any severe clinical problems with hormonal contraception previously, apart from nausea.

4. Characteristics of staff

ONLY an accredited registered pharmacist will undertake this role. **Medicine counter staff must be trained to refer each request for emergency contraception to the pharmacist.**

- The pharmacist must have completed the specific training and assessment by Dr Antani and be deemed competent for this delegated duty. The accredited pharmacist will retain all training documentation.
- All accredited pharmacists will be required to attend further training every two years.
- The pharmacist will train the pharmacy staff on referral of requests for Emergency Contraception.
- All requests for emergency contraception should be handled in a sensitive and non-judgemental manner.

Guidelines for Clinical Practice

Reference – Recommendations for clinical practice: Emergency Contraception
Prepared on behalf of the Faculty of Family Planning and Reproductive Health Care of the RCOG by Dr Ali Kubba MFFP FRCOG and Dr Chris Wilkinson MFFP CSC 10/99 valid until 01/2001. (October 1999 Update)

Guidelines for the Supply and Administration of Medicines under Group Protocols.

Reference 1 – Review of Prescribing, Supply and Administration of Medicines.
A report on the Supply and Administration of medicines under Group Protocols – Appendix A
The Review Team, Chairman Dr June Crown April 1998.
Reference 2 – Review of Prescribing, Supply and Administration of Medicines. Final Report
Annex C. the Review Team Dr June Crown March 1999.

5. Description of treatment

5.1 **SCHERING PC4** (ethinylloestradiol 50 micrograms + progestogen norgestrel 500 micrograms)

Product Licence number	0053/0162
POM / P / GSL:	POM
Dose / frequency:	2 tablets as soon as possible after coitus (up to 72 hours), then 2 further tablets 12 hours later
Administration:	The earlier in the 72-hour period the first dose is given the greater the efficacy. It maybe useful if the client takes the first two tablets whilst in the pharmacy. Negotiate with the client the timing of the second dose 12 hours later. Nausea/vomiting is less likely if the tablets are taken after a light meal.
Side Effects	Nausea and vomiting, breast tenderness, headaches, dizziness and fatigue. Bleeding patterns may be temporarily disturbed.
Route / method:	Orally

Further product information is also available in the ‘summary of product characteristics’ and in the British National Formulary.

Counselling: For clients who present having missed their contraceptive pill give advice as on page 11 – Missed Pills, including lengthening the pill free interval’.

Discuss:

Mode of action -Uncertain but thought to inhibit ovum transport, ovulation and implantation.

Failure rate - 1-5 women out of 100 women will become pregnant despite taking the treatment i.e. up to 5%

Foetal effects - No evidence that this method of contraception has any teratogenic effects but every pregnancy has a 1/50 overall chance of foetal abnormality.

Other side effects - Nausea in half the women treated, vomiting is reported in up to 20%. There is no evidence of an increased risk of ectopic pregnancy.

Clients under 16 years of age – Assess Fraser criteria as covered on accredited training.

Emphasise that these tablets are for emergency use only and not as a regular method of contraception because it is not as effective for regular contraception. Inform clients that the next period may be early, on time or late. Delay is possible if Yuzpe regimen is given before ovulation is due.

Supply:	Where applicable, open one packet of Schering PC4 and observe client taking the first two tablets. The pack should be labelled with the following information: the client's name, date of issue, directions for use, the pharmacy address and 'Keep out of the reach of children'. Pack in a paper bag and issue an emergency supply of six condoms.
Information on follow-up:	Advise clients to go to a Family Planning Clinic, their GP or return to the pharmacy, with a sample of early morning urine, if they have not had a period within four weeks of taking the emergency contraceptive pills, or if the period is exceptionally light (? failed method) or painful (? ectopic pregnancy).
Written / Verbal advice:	<p>All clients should be given the following before they leave the pharmacy:</p> <ul style="list-style-type: none"> ➤ Dose, information and advice sheet on the product with their supply ➤ A leaflet on method of contraception or if desired a leaflet on all methods. ➤ A leaflet about Family Planning Services available in Walsall ➤ A leaflet about sexually transmitted diseases (STDs) and Genito-Urinary Services (GUM), if appropriate.
Method of recording:	In discussion with the client complete the protocol proforma. The completed patient proforma for the supply and administration of Emergency Contraception is completed and signed by the patient and the pharmacist. As you are counselling the client (see above) ensure you are satisfied the client understands the information given.

5.2

LEVONELLE 2

Name of medicine	:	Levonelle 2 (Two tablets, each containing 750 micrograms levonorgestrel)
Product Licence number	:	05276/0016
POM / P / GSL	:	POM 'Black Triangle drug' - all ADRs must be reported to CSM
Dose /frequency	:	One tablet as soon as possible after unprotected intercourse (up to 72 hours afterwards), followed by the remaining tablet 12 hours after the first dose
Administration	:	The earlier in the 72 hour period the first dose is given the greater the efficacy. It is therefore useful if the client takes the first tablet whilst in the pharmacy. Negotiate with the client the timing of the second dose 12 hours later.
Side Effects	:	Nausea and vomiting, breast tenderness, headaches, dizziness and fatigue. Bleeding patterns may be temporarily disturbed.

Route / method : Orally

Further product information is also available in the ‘summary of product characteristics’ and in the British National Formulary.

Counselling: For clients who present having missed their contraceptive pill give advice as on page 13 – Missed Pills, including lengthening the pill free interval’. Future contraception should be discussed in accordance with Faculty / FPA Guidelines and the necessary action taken.

Discuss: **Mode of action** -Uncertain but thought to inhibit ovum transport, ovulation and implantation.
Failure rate - 1-5 women out of 100 women will become pregnant despite taking the treatment i.e. up to 5%
Foetal effects - No evidence that this method of contraception has any teratogenic effects but every pregnancy has a 1/50 overall chance of foetal abnormality.
Other side-effects - Nausea in half the women treated, vomiting is reported in up to 20%. There is no evidence of an increased risk of ectopic pregnancy.
Clients under 16 years of age – Assess Fraser criteria as covered on accredited training.

Supply : Where applicable, open one packet of Levonelle 2 and observe client taking the first tablet. The pack should be labelled with the following information: the client’s name, date of issue, directions for use, the pharmacy address and ‘Keep out of the reach of children’. Pack in a paper bag and issue an emergency supply of six condoms.

Information on follow-up: Advise clients to go to a Family Planning Clinic, their GP or return to the pharmacy with a sample of early morning urine if they have not had a period with 28 days of taking the emergency contraceptive pills, or if the period is exceptionally light (?failed method) or painful (?ectopic pregnancy).

Written advice: **All client’s should be given the following before they leave the pharmacy:**

- Dose, information and advice sheet on the product with their supply
- A leaflet on method of contraception or if desired a leaflet on all methods.
- A leaflet about Family Planning Services available in Walsall
- A leaflet about sexually transmitted diseases (STDs) and Genito-Urinary Services (GUM), if appropriate.

Verbal advice: A verbal warning should be given that the tablets may be associated with nausea and vomiting. If this or severe diarrhoea occurs within about two hours of taking the tablets, further advice must be sought immediately from a pharmacist, GP or staff from a Family Planning Clinic.

Emphasise that emergency contraceptives are not suitable for repeated use as they have a higher failure rate than regular oral contraception. It may be advisable for the client to seek advice about ongoing contraception.

Method of recording: In discussion with the client complete the protocol proforma
The completed patient proforma for the supply and administration of Emergency Contraception is completed and signed by both the client and the pharmacist.

6. Additional Guidance Notes

6.1 Lost / Vomited Tablets

If either dose has been lost, or vomited within 2 hours of ingestion, the course may be repeated provided that the new first dose is still within 72 hours of the first unprotected intercourse of that cycle. Nausea and/or vomiting is most likely after the second dose. If a client returns having vomited, then a further course of EHC may be supplied, providing the first dose is taken within the first 72 hours. Two doses of domperidone 10mg should also be supplied and labelled to be taken with the doses of EHC. If the first new dose would be later than 72 hours after the first unprotected intercourse that cycle, referral for an IUD may be indicated and the tablets should not be issued.

6.2 Adverse Drug Reporting (ADRs)

Whilst rare, all serious ADRs should be reported, even if the effect is well recognised. For supporting information see British National Formulary (BNF). ADRs should be reported to the Committee on Safety of Medicines, using the yellow ADR card system. Cards are available in the BNF.

A client presenting with a suspected ADR should also be referred to a doctor for further investigation.

The progestogen-only emergency contraception pill, Levonelle 2 is a newly licensed product in the UK. The product is currently under surveillance by the Committee for the Safety of Medicines (Black Triangle). For this product, all adverse reactions must be reported to the CSM.

6.3 Consent

All clients should consent to receive advice and treatment from a pharmacist. For clients under sixteen, the Fraser criteria should be assessed. Where the client does not demonstrate an understanding of the service required, or the pharmacist is in anyway unsure that providing the service is in the clients best interest then the client should be referred urgently to their GP or the family planning service. The clients signature on the protocol questionnaire acts as a record of the clients consent.

6.4 Fraser Criteria

If a client is believed to be under 16 years of age, the pharmacist must assess the client's 'Fraser criteria'. A separate section to the protocol will be completed. Discussion with the young person should explore the following issues at each consultation. This should be fully documented and should include an assessment of the young person's maturity.

1. Understanding of advice given.
2. Encouraged to involve parents
3. Is likely to be sexually active, with or without contraceptive advice/treatment
4. The effect on the physical or mental health of young person if advice / treatment withheld
5. Action in the best interest of the young person

The client's signature will act as a record that the patient understands the nature of the treatment and does not want the involvement of parents. The pharmacist should sign to confirm that according to his/her assessment, the patient is able to understand and receive the advice and treatment sought.

Where the pharmacist suspects child abuse of any nature, they are advised to contact the local child protection team for guidance and if necessary to report their suspicion. Suspicion can be reported to Social Services, the Police or the NSPCC. Referrals to Social Services should be made to the duty officer where the child is usually resident. Out of hours referrals should be made to the Emergency Duty Team.

Further advice can be obtained from

Elaine Hurry Designated Nurse for Child protection 01922-858970

Dr. V. Rao Designated doctor for Child protection 01922-858973

Social Services Area Offices

Darlaston	0121-568-6611
Bloxwich	01922-710001
Willenhall	01922-710533
Walsall South	01922-658900
Shelfield	01922-743337

Out of hours emergency team 01922-626237

6.5 Choice of Emergency Hormonal Contraception

The choice of emergency hormonal contraception product will be agreed between the pharmacist and client. The following points should however be considered in agreeing that choice:

- a) Within the first 24 hours of unprotected sex, Schering PC4 or Levonelle 2 are highly effective in reducing the risk of pregnancy
- b) After 24 hours has elapsed following unprotected sex then Levonelle 2 is significantly more effective and should be the product of choice

- c) In older women (age over 35 years), Levonelle 2 should be the product of choice.
- d) Levonelle 2 should be used in women at risk of oestrogen induced adverse effects such as thrombo-embolism, focal migraine.
- e) For women with a history of vomiting induced by Schering PC4, give Levonelle-2

6.6 Important Potential Drug Interactions

Interacting Drug	Effect	EHC Product Affected
Rifampicin	Increases metabolism of hormones thus reducing efficacy	Schering PC4 and Levonelle 2
Anticoagulants	Reduction/enhancement of anticoagulant effects	Schering PC4 and possibly Levonelle 2
carbamazepine, primidone, phenobarbitone, phenytoin, topiramate	Increases metabolism of hormones thus reducing efficacy	Schering PC4 and Levonelle 2
Oral retinoids	Reduced efficacy of EHC	Schering PC4 and Levonelle 2
St. Johns Wort	Reduced efficacy of EHC	Schering PC4 and Levonelle 2

7. Audit Information

The pharmacist must keep a record of the consultation and outcome on the client proformas provided for a period of 3 years. Computerised patients medication records are recommended to be kept. Each month the pharmacist will complete an audit form provided and return it to the project manager before the 10th of each month.

The following data will be recorded and sent to the project manager:

- Date of request
- Age of client
- Reason for request
- How client heard of the scheme
- Time taken to complete consultation
- Number of clients who received EHC
- Number and reason for not supplying EHC
- Number of clients given pregnancy tests before supply
- Number of clients who returned for follow-up pregnancy tests
- Number of consultations where the pharmacist requested information from one of the external centres.

8. Management of Group Protocols

Group protocol developed by : Dr M R Antani
N. Barnes
M. Pillinger

Authorising Doctor :

Signed :

Date applicable : December 2000

Next review date : July 2001

Plan a review to enable completion prior to the above date and date the new protocol to follow on immediately, also retain a copy of each version of the protocol for ten years

Produced by:

	Name	Signature
Authorising doctor	Dr M R Antani	
Peer Review doctor	Dr. S. Ramaiah	
Family Planning Nurse	Maureen Pillinger	
Pharmaceutical Adviser	Nigel Barnes	

Signatories:

	Name	Signature
Public Health Walsall Health Authority		
Medical Walsall Health Authority		
Pharmaceutical Walsall Health Authority		

I have read the group protocol and agreed to use it in accordance with the criteria described.

Name : _____

Signature : _____

Business Address : _____

Date

:

Review date

:

previous periods)			
Did unprotected sexual intercourse occur more than 72 hours ago?			If 'yes' – refer
Does the client have breast cancer?			If 'yes' – refer
Does the client have severe liver disease?			If 'yes' – refer
COUNSELLING			YES NO
Effectiveness including failure rate discussed			
Side effects discussed			
Possible effects on foetus discussed			
First dose taken on the premises?			
If first dose not taken on premises, was a time for the first dose agreed?			
Time of second dose agreed			
Follow-up discussed			
Future contraception discussed			

Other relevant notes:

Please record:

Where the client heard about the scheme?

The reason for the request?

Action taken:

Supply: PC4/Levonelle 2 supplied

Batch number / expiry date

Referral:

Advice given:

The above information is correct to the best of my knowledge. I have been counselled on the use of emergency contraception and understand the advice given to me by the pharmacist

Client's Signature:

Date:

The action specified was based on the information given to me by the client, which, to the best of my knowledge, is correct.

Pharmacist's Signature:

Date:

Time taken to complete consultation..... minutes

Fraser Competence

For clients who are believed to be under 16 years of age. Discussion with the young person should explore the following issues at each consultation. This should be fully documented and should include an assessment of the young person’s maturity.

Assessment of Fraser Competency	YES	NO
The girl (under 16) will understand the advice given.		
The pharmacist cannot persuade her to inform her parents or to allow the pharmacist to inform them that she is seeking emergency contraception and contraceptive advice.		
The girl has or is likely to have had sexual intercourse with or without contraceptive advice/treatment		
That unless emergency contraception and/or contraceptive advice is given, her physical or mental health or both are likely to suffer.		
That her best interests require the pharmacist to give emergency contraception and/or contraceptive advice without parental consent		

Pharmacist signature _____ date _____

Clients signature: _____ Date: _____

GUIDELINES FOR MISSED PILLS AND USE OF EHC

Hatherton Centre, Walsall

NOT to be given to patients

1. Missed COC pill(s) by more than 12 hours

Pill number in packet	Tablets missed	Action
1 2 3 4 5 6 7	Missing one or more tablets from first seven in any combination and had intercourse	Condom for seven days. Give emergency contraception** if UPSI within a prolonged pill free interval plus condoms for seven days
8 9 10 11	Missed up to three of these pills and had intercourse	Emergency contraception <i>not</i> needed
12 13 14	Missed four or more of these pills and had intercourse	Condoms for seven days. Emergency contraception needed if UPSI plus condoms for seven days
15 16 17 18 19 20 21	Missed any one or more of these pills and had intercourse	Start next packed of pills immediately with no break plus condoms for seven days If so, emergency contraception <i>not</i> needed If not seen until after PFI following missed pill(s) consider emergency contraception as above

** Yuzpe Method or POEC up to day 13 of a lengthened PFI even if UPSI >72 hours previously (no efficacy data)

2. Missed POP pill(s) by more than 3 hours

Consider Emergency Contraception if UPSI occurs any time from three hours after the time of the first missed pill to seven days after restarting pill-taking (plus condoms for 7 days)

Reference: Recommendations for clinical practice: Emergency Contraception Prepared on behalf of the faculty of Family Planning and Reproductive Health Care of the RCOG by Dr Ali Kubba MFFP FRCOG and Dr Chris Wilkinson MFFP (2nd Version) CSC 1/98 valid until 01/2001 page 5 Box 2.

CLIENT LEAFLET –PROGESTOGEN-ONLY EMERGENCY CONTRACEPTION (LEVONELLE 2)

Please read this information carefully and don't hesitate to speak to the pharmacist if you have any questions. If you have any serious medical problems please discuss them with the pharmacist, to ensure emergency contraception is safe for you.

EMERGENCY PILLS & HOW THEY WORK

Emergency pills must be started within 72 hours (3 days) of unprotected sex. They contain the hormone progestogen. They work by making the lining of the womb (endometrium) unsuitable for a pregnancy to develop and sometimes by delaying the release of an egg from your ovary. This is NOT the same as an abortion.

HOW TO TAKE THE PILLS

Date:

You have been given 2 pills (Levonelle 2)

➤ Take one pill **NOW or at agreed time:**.....

➤ Wait 12 hours then take one pill at

WHAT HAPPENS NEXT

Your next period may arrive earlier, on time or later than usual. It can also be lighter or heavier than normal. If your period is shorter or lighter than usual, or has not occurred four weeks after taking emergency contraception, request a pregnancy test from one of the pharmacists in the scheme, GP or Family Planning centres.

Emergency contraception is very successful. However, if you become pregnant after taking it there is no evidence that it will harm the pregnancy.

CONTRACEPTION

Remember to use condoms in addition to your usual method

If you are taking the pill, continue to take it, but also use condoms for the next 7 days

If you are planning to start the pill you may start it on the third day of your next period / withdrawal bleed subsequent to Levonelle.

WARNING

Emergency contraception does not protect against sexually transmitted infections, however condoms reduce the risk.

WHAT TO DO IF YOU FEEL SICK

If you feel sick- ask the pharmacist to recommend an anti-emetic, that can be bought.

If you are sick (vomit) within 2 hours of taking the first tablet you should take the other tablet in the pack at once and contact your GP or any Family Planning Clinic or a pharmacist immediately for more tablets.

If you are sick (vomit) within 2 hours of taking the second dose you should contact your GP, pharmacist in the scheme or any Family Planning Clinic immediately.

CLIENT LEAFLET –COMBINED HORMONAL EMERGENCY CONTRACEPTION (SCHERING PC4)

Please read this information carefully and don't hesitate to speak to the pharmacist if you have any questions. If you have any serious medical problems please discuss them with the pharmacist, to ensure emergency contraception is safe for you.

EMERGENCY PILLS & HOW THEY WORK

Emergency pills must be started within 72 hours (3 days) of unprotected sex. They contain the same two hormones as the 'combined' pill (oestrogen & progestogen). They work by making the lining of the womb (endometrium) unsuitable for a pregnancy to develop and sometimes by delaying the release of an egg from your ovary. This is NOT the same as an abortion.

HOW TO TAKE THE PILLS

Date:

You have been given 4 pills (Schering PC4)

➤ Take 2 pills **NOW or at agreed time:**

➤ Wait 12 hours then take 2 pills at:

WHAT HAPPENS NEXT

Your next period may arrive earlier, on time or later than usual. It can also be lighter or heavier than normal. If your period is shorter or lighter than usual, or has not occurred four weeks after taking emergency contraception, request a pregnancy test from one of the pharmacists in the scheme, GP or Family Planning centres.

Emergency contraception is very successful. However, if you become pregnant after taking it there is no evidence that it will harm the pregnancy.

CONTRACEPTION

Remember to use condoms in addition to your usual method.

If you are taking the pill, continue to take it, but also use condoms for the next 7 days.

If you are planning to start the pill you may start it on the third day of your next period/ withdrawal bleed subsequent to Schering PC4.

WHAT TO DO IF YOU FEEL SICK

If you feel sick- try travel sickness pills, such as Kwells, that can be bought from Chemists and Pharmacists.

If you are sick (vomit) within 2 hours of taking the first 2 tablets you should take the other two tablets in the pack at once and contact your GP or any Family Planning Clinic immediately for more tablets.

If you are sick (vomit) within 2 hours of taking the second dose you should contact your GP or any Family Planning Clinic immediately.