

**Service Level Agreement
Specification for Access to Sexual Health Services within Community
Pharmacies in Leeds
Scheme Number: 4**

1st June 2012 – 31st May 2013

Contents:

1. Service Outcomes and Aim	p.2
2. Service Objectives	p.3
3. Service Model	p.4
4. Provider Criteria and Accreditation	p.5
5. Record keeping	p.10
6. Financial Arrangements	p.11
7. Responsibilities	p.12
8. Monitoring Arrangements, Indicators and Performance Measures	p.15
9. Service Management	p.16
10. Period for the Agreement	p.16
11. Health and Safety	p.16
12. Training and Development	p.16
13. Confidentiality	p.16
14. Professional Indemnity	p.17
15. Complaints	p.17
16. Incidents and Near Misses	p.17
17. Signatories	p.18
18. Appendices (including PGD, Claim Form, Consultation form, Order Forms & Referral)	

1. SERVICE OUTCOMES

The overall outcome for all sexual health services in Leeds is:

All people in Leeds experience improved sexual health

Every service we commission is must contribute towards this outcome and each service has specific population target groups and specific indicators for success.

The five sexual health indicators for the city are;

- 1. Unintended Pregnancies**
- 2. New cases of STI's (inc HIV)**
- 3. Service Quality**
4. Sexual health testing and treatment (indicator not selected for this service)
- 5. People supported to live healthier lives**

For the Enhanced Pharmacy Scheme it has been decided that it will be measured using indicators 1,2,3 and 5 (see section 8 for performance measures)

The defined population for this service is;

13–24 year old young people (men and women)

The overall outcome for this age group is that;

13-24 year olds in Leeds experience improved sexual health

2. SERVICE OBJECTIVES

This service will be delivered by improved patient access and choice of sexual health services; enabling community pharmacists to provide a range of sexual health services.

The core objectives of this service will be to deliver the following;

FOR WOMEN AGED 13-24

- Provision of Emergency Hormonal Contraception (EHC) via a Patient Group Direction (PGD)
- Provision of Chlamydia and Gonorrhoea dual tests
- Pregnancy testing service
- Provision of condoms

FOR MEN AGED 15-24

- Provision of Chlamydia and Gonorrhoea dual tests
- Provision of condoms

By delivering the above services you **will**:

- Impact upon the reduction of health inequalities
- Improve services, providing fast and convenient access and plurality of provision improving patient choice
- Impact upon the reduction of unintended teenage pregnancy
- Impact upon the reduction of undiagnosed cases of Chlamydia and Gonorrhoea
- Increase knowledge of emergency contraception, especially amongst young people
- Provide knowledge of appropriate use of emergency contraception
- Increase referrals of hard-to-reach young people into mainstream contraception services (CaSH services)
- Provide advice on sexual health as appropriate, including onward signposting/referrals

- Engage a range of primary care professionals and ensure appropriate use of clinical skills and experience
- Integrate community pharmacists as members of the primary care team in providing a sexual health service for young people.
- Increase awareness and access to emergency contraception for young women.
- Increase awareness of sexual transmitted infections (STIs) and access to screening for Chlamydia and Gonorrhoea for all young people in the identified cohort (15-24yrs).
- Increase access to pregnancy testing
- Provide information and advice on contraception, safer sex and available services
- Provide referrals into CaSH clinics for young women not on a regular form of contraception
- Provide consistent opening times with trained staff offering a walk in service for young people and, where opening hours permit, an out of hours service.

3. SERVICE MODEL

The service is not intended to replace the purchase of EHC or pregnancy tests from pharmacies by women outside of this target group who would normally do this.

Supply of EHC for free on this scheme is only for women aged 13-24.

Women presenting in the pharmacy who wish to purchase OTC EHC **should not be offered** this service as an option unless they do not meet the criteria for OTC sale. In this instance guidance on the sale of OTC EHC should be followed.

The service will deliver the following based on age and gender:

FOR WOMEN AGED 13-24

- Provision of Emergency Hormonal Contraception (EHC) via a Patient Group Direction (PGD)
- Provision of Chlamydia and Gonorrhoea dual tests
- Pregnancy testing service
- Provision of condoms

FOR MEN AGED 15-24

- Provision of Chlamydia and Gonorrhoea dual tests
- Provision of condoms

In line with Patient Group Direction (PGD) 036-08 - supply of Emergency progestogen - only contraception by Community Pharmacists, the service must provide:

- Counselling with the client/patient (including issue of referral card even if EHC no issued)
- Supply of EHC (as appropriate) (including issue of referral card even if EHC is issued)
- Pregnancy testing (if appropriate) (including issue of referral card irrespective of result)
- Chlamydia and Gonorrhoea dual testing (if appropriate) (including issue of referral card)

- Supply of Health Promotion advice e.g. suggestion of screening for sexually transmitted infections, regular contraceptive use and healthy lifestyles, supply of condoms.
- Clients presenting for emergency contraception but who are excluded from the EHC PGD criteria will be referred to another local service that will be able to assist them, as soon as possible, e.g. GP, community contraception service, or will be invited to purchase the Pharmacy Medicine product if the exclusion from supply via the PGD is only due to an administrative matter, e.g. age range determined by NHS Leeds
- Referral on to other services for screening or contraceptive and sexual health advice. This includes the completion of a leedssexualhealth.com referral card for all users (see appendix for example)

4. CRITERIA

This section establishes the minimum requirements for service providers commissioned by NHS Leeds for provision of the services including;

- Training and accreditation
- On-site requirements

Prior to the commencement of enhanced services community pharmacies must be delivering all essential services

Practitioner Accreditation

For Emergency Hormonal Contraception (EHC)

In addition to the quality standards outlined in the EHC PGD (036-08); the following standards also apply:

- The accredited pharmacist must work within the agreed Patient Group Direction as defined by NHS Leeds
- All accredited pharmacists must also have accreditation via the ***Harmonised Accreditation Group (HAG)*** scheme. To achieve this status the following training should be undertaken:

Prior to attending NHS Leeds led workshop

As a **minimum** all pharmacists must have completed the following distance learning packages:

- CPPE Emergency Contraception Open Learning Programme (8 Hours)
- CPPE Safeguarding Children Open Learning Programme (1.5 Hours)
- CPPE Contraception Open Learning Programme (12 Hours)

The above training must be re-visited if CPPE publish any revisions. It is the usual practice of CPPE to notify those who have accessed their training packages of any updates.

NHS Leeds led workshop

All pharmacists must have completed the NHS Leeds led local workshop around sexual health issues (or a course recommended by NHS Leeds) and be familiar with the paperwork. Update training sessions will be run as and when needed.

Details of successful completion, in the form of certificates (preferably an electronic version), should be sent to Leeds Sexual Health Team

Pharmacists not completing the final contraception pack within 3 months of attending the NHS Leeds Led Workshop **will** be required to re-visit the workshop training.

Maintaining your HAG Accreditation

All pharmacists must ensure they maintain a minimum of 12 relevant EHC consultations (as part of this scheme) per 12 months. This is to ensure competency and ensures pharmacists meet the criteria of the HAG accreditation. If pharmacists do not meet this they will have to re-attend locally provided training. This will all be monitored by indicators and performance measures in section 8 of this document.

Optional Additional Accreditation

In addition to the HAG accreditation detailed above NHS Leeds advise pharmacists offering this scheme to also complete a further two CPPE packs;

- CPPE Dealing with difficult discussions Open Learning Programme (8 hrs)
- CPPE Sexual Health in Pharmacies (8 hrs)

These packs are only advised and not compulsory for service delivery. We do however recommend you complete these in the first year of offering the service as part of your CPD. If you do complete them please provide evidence to the Leeds Sexual Health Team so we can add it to your record.

The above training will need to be re-visited if CPPE publish any revisions. It is the usual practice of CPPE to notify those who have accessed their training packages of any updates.

For Chlamydia and Gonorrhoea Testing

These tests should only be issued to men and women under 25

Chlamydia and Gonorrhoea dual testing should be offered to every young women accessing the pharmacy for EHC and/or pregnancy testing.

A private consultation should be undertaken with those clients presenting only for a Chlamydia and Gonorrhoea test to ascertain the

appropriateness of the test and to give advice on future sexual health needs.

If possible the test should be completed onsite using the kits provided. At a bare minimum it is expected that all paperwork (Chlamydia form) is completed in the pharmacy. Once this is complete the young person may complete and return the test themselves via the postal kit provided.

If a young person falls outside of this age group they will need to be tested at their local sexual health service or GP. Please advise them to visit www.chlamydia Screening.nhs.uk or call NHS Direct on 0845 46 47

Criminal Records Check (CRB)

For All Services offered via this Enhanced Scheme

All pharmacists must have undertaken an **enhanced CRB check** and supplied details to NHS Leeds.

NHS Leeds will fund CRB checks for **two pharmacists** at each site. After your initial two CRB's you will have to fund further pharmacist checks at £44 per pharmacist (NHS Leeds will still organise and co-ordinate the CRB checking process but will recharge your organisation for the fee.

To find out about Criminal Records Checking please visit http://www.direct.gov.uk/en/Employment/Startinganewjob/index.htm?CID=EMP&PLA=url_mon&CRE=crb

Certification

As NHS Leeds is using the HAG methodology all pharmacists accredited with other local PCT's also implementing the HAG will be recognised as accredited to provide the scheme in Leeds subject to checks with the relevant accrediting PCT.

Once a pharmacist has returned all CPPE training certificates, a valid CRB and attended local PCT training they will be awarded a certificate of local accreditation.

All pharmacists participating staffing the scheme must undertake Level 2 Safeguarding training updates every three years.

All pharmacy support staff participating in the scheme must undertake Level 1 Safeguarding training updates every three years

On-site Requirements

All pharmacy counter staff should be aware of the nearest alternative sites offering free access to EHC and Chlamydia & Gonorrhoea dual testing

While participating in the service the pharmacy will designate space for posters advertising the service and will also make available leaflets signposting other Sexual Health and Contraception Services available to patients within the local health economy.

The pharmacy must have and will advertise the availability of a private consultation with the pharmacist

Pharmacists must also offer a supply of condoms free of charge to the patient (recommend 2 condoms per consultation)

The service must be provided in compliance with Fraser guidance¹ and Department of Health guidance on confidential sexual health advice and treatment for young people aged under 16².

Verbal and written advice on the avoidance of STIs and the use of regular contraceptive methods, including advice on the use of condoms, will be provided to the client. If appropriate this should be supplemented by a referral to a service that can provide treatment and further advice and care.

Pharmacists may need to share relevant information with other health care professionals and agencies, in line with recognized confidentiality arrangements, including, where appropriate, the need for the permission of the client to share the information.

¹ Fraser Guidelines – based on a House of Lords Ruling; A health professional can give advice or treatment to a person under 16 without parental consent providing they are satisfied that;

- The young person will understand the advice;
- The young person cannot be persuaded to tell his or her parents or allow the doctor to tell them that they are seeking contraceptive advice;
- The young person is likely to begin or continue having unprotected sex with or without contraceptive treatment; and
- The young person's physical or mental health is likely to suffer unless he or she receives contraceptive advice or treatment.

² Guidance available at www.dh.gov.uk/sexualhealth.

5. RECORD KEEPING

Client monitoring forms (appendix) must be completed for each individual who seeks the use of the service. These should be retained by the pharmacy and stored in an appropriate manner as detailed below.

The accredited pharmacist and, where appropriate, the pharmacy support staff lead must complete all necessary paperwork and collect data as specified to enable monitoring and evaluation of the service

The pharmacy must maintain appropriate records to ensure effective ongoing service delivery and audit. Records will be confidential and should be stored securely and for a length of time in line with the Department of Health 'Records Management: NHS Code of Practice'

6. FINANCIAL ARRANGEMENTS

Payment to pharmacists will be on the basis of one consultation per client, regardless of whether or not EHC is supplied or a test conducted. If a supply of EHC is made or a test provided, the cost of this will be reimbursed in addition to the consultation fee.

A summary of fees payable is shown below:

Service Provided	Fee
EHC Consultation Fee (including a pregnancy test if needed)	£10.00
Supply of Levonelle 1500	£6.24 incl. VAT (£5.20 excl)
Pregnancy Test	£3.00
Chlamydia & Gonorrhoea dual Test	£3.00 (only if testing kit is returned by patient will payment be made)

Payment claim forms are provided (appendix) and should be completed on a monthly basis. They should be sent to:

Noshaba Abbas
WYCSA
2-8 Brunswick Court
Bridge St
Leeds
LS2 7RJ
0113 2952572

by the 15th day of the month following the one to which the claim form relates.

Claims do not need to be made for Chlamydia and Gonorrhoea dual testing as this will be supplied by the laboratory directly to the NHS programme lead every month following the return of eligible testing kits (on your behalf).

Payment will still come through WYCSA but may appear later than other payments.

7. RESPONSIBILITIES

PCT Responsibilities

The local workshop will review the underpinning clinical knowledge required to provide a sexual health service and will ensure that the accredited pharmacist:

- Understands the aims of the service and its place in Contraception and Sexual Health services overall
- Understands confidentiality issues and has an awareness of Safeguarding issues
- Understands and is able to apply the medico-legal aspects of the service provision
- Understands and is able to use the PGD and associated paperwork
- Understands how and when to refer clients and when to ask for support and advice from the local Contraception and Sexual Health Services.
- Is able to counsel and advise clients appropriately and sensitively and refer for further contraceptive care
- Experiences problematic situations through role play and gains confidence in dealing with them
- Knows what sources of support are available to pharmacists and their staff in the provision of these services
- Has knowledge of STIs and symptoms associated with STIs

NHS Leeds will arrange contractor meetings as appropriate to promote the service development and update pharmacy staff with new developments, knowledge and evidence

NHS Leeds will provide a framework for recording relevant service information for the purposes of audit and the claiming of payment

NHS Leeds will provide up to date details of other services which pharmacy staff can use to refer service users who require further assistance

NHS Leeds is responsible for the promotion of the service locally including where appropriate the development of publicity materials which pharmacies can use to promote the service

NHS Leeds is responsible for the provision of health promotion material including leaflets on EHC, long term contraception and STIs to pharmacies.

These can be obtained from the Public Health Resource Centre by calling 0113 2953081. These must be collected by the Pharmacy.

Information/Condom packs will be supplied free of charge by NHS Leeds Sexual Health Team.

NHS Leeds will also monitor;

Pharmacy Opening hours

NHS Leeds reserves the right to withdraw service provision should the pharmacy reduce their hours of opening from those stated when the service commenced.

Pharmacy usage

NHS Leeds reserves the right to withdraw the service from pharmacies if there is no user demand for the service. This is identified as more than two calendar months per year with no activity.

Pharmacist Competency

As with the HAG accreditation guidelines pharmacists must be performing at least 12 relevant consultations as part of this enhanced service every 12 months. Failure to complete this re-requirement will involve re-training and/or the removal of the pharmacist/pharmacy from the scheme.

Stock Orders

Stock of Chlamydia & Gonorrhoea dual Testing kits, Pregnancy Tests and Condoms will be provided at the initial training session for a pharmacy. Subsequent supplies must be ordered by following the instructions below;

Stock of Pregnancy tests and Condoms will be delivered to pharmacies via Royal Mail post. To order stock contact NHS Leeds on 0113 3058448. Delivery will normally take 7 working days. It is the pharmacies responsibility to ensure that stock levels are maintained. In extreme circumstances pick up by pharmacies from our suppliers can be arranged.

External suppliers provide our Chlamydia and Gonorrhoea testing kits. The order form can be found in the bottom of your initial testing kit order. Order forms can also be requested from NHS Leeds Sexual Health Team. There is also a sample order form in the appendix of this document.

If you have any problems or queries with supplies you need to contact the service co-ordinator on 0113 3058448 asking for the pharmacy scheme lead.

Contractor responsibilities

Contractors must ensure that:

- The consultation room meets the requirements as set out for the service specification for Advanced Services and must be accredited with the PCT
- The identified pharmacies deliver the scheme for all of their contracted hours.
- A HAG accredited pharmacist is always available for **all the contracted opening hours**. If this is not possible the pharmacy will not meet the criteria and will not be admitted to the scheme.
- The scheme co-ordinator or the Pharmacy and Optometry Contracts Lead is informed immediately of any mitigating circumstances that will prevent the delivery of the service in accordance with this specification. Examples may include:
 - o Inclement weather
 - o Short term sickness of the EHC accredited pharmacist
 - o Unexpected closure of the pharmacy
- If lack of service provision due to circumstances outlined above occurs on a regular basis NHS Leeds will remove the pharmacy from the scheme, unless actions are taken to ensure full service provision is maintained.
- If the accredited pharmacist is unavailable due to the circumstances outlined above patients should be signposted to the nearest alternative provider whether that be another pharmacy or another mainstream provider e.g CaSH clinic.
- Should the accredited pharmacist leave the employment of the contractor NHS Leeds must be informed.
- In the above situation; should the accredited pharmacist be replaced by a non accredited pharmacist accreditation should be gained as soon as possible to ensure continuity of the service. Notification of this fact must be conveyed to NHS Leeds to enable timely provision of workshops.
- That the contractor's company (pharmacy owners) will allow you to provide sexual health services (including EHC, condoms and other services) to under 16's (13-24 yrs of age) following the guidelines issued with this SLA. If this is not possible the pharmacy will not meet the criteria and will not be admitted to the scheme.

- The contractor should have a Safeguarding Children and Vulnerable Adults protocol and all protocols should reflect national and local safeguarding guidelines³. (www.leedsscb.org.uk).
- If providers suspect that a service user is misusing the scheme they should alert the service co-ordinator on 0113 3058448 asking for the pharmacy scheme lead
- Pregnancy test's and condoms provided by NHS Leeds must only be used as part of this service

³ The cross government guidance on child protection, Working Together to Safeguard Children, should be referred to and is available at www.everychildmatters.gov.uk/workingtogether

8. **MONITORING & EVALUATION ARRANGEMENTS**

Service Monitoring

Activity data, in the form of quarterly monitoring forms (see appendix) must be provided to NHS Leeds when requested for purposes of monitoring, evaluation and performance review in accordance with this enhanced service specification.

Activity data forms must be submitted to:

Sexual Health Pharmacy Scheme
Public Health Directorate
NHS Leeds,
North West House,
West Park Ring Road,
Leeds,
LS16 6QG

Post payment verification checks will be made periodically by NHS Leeds. As a **minimum** this will include triangulation of data relating to the financial claims made, quarterly reports submitted and any complaints made in relation to the service.

In addition Exception Reporting (see appendix) must also be undertaken when appropriate and in a timely manner.

Evidence of appropriate completion of client monitoring forms will be sought at routine Community Pharmacy Contractual Framework Monitoring Visits.

Evaluation

Performance Measures:

The following performance measures will provide evidence for the selected indicators. These have been selected to clearly indicate *how much activity was delivered, how well it was completed and who is better off as a result.*

1. Unintended pregnancy

- Number of EHC consultations completed
- Amount of EHC issued (dispensed)
- Percentage of people accessing EHC from priority wards
- Number of pregnancy tests completed
- Number of positive pregnancy tests

2. New cases of STI's (inc HIV)

- Chlamydia prevalence rate for pharmacy scheme
- Number of Chlamydia tests completed per pharmacy
- Decline rate for Chlamydia testing per pharmacy

3. Quality sexual health services

- Number of Enhanced Sexual Health trained pharmacists (HAG accredited) currently employed at each pharmacy site.
- Number of hours a trained Enhanced Sexual Health Pharmacist is on site (monthly)
- Number of EHC consultations completed per pharmacist per financial year (required for HAG accreditation)
- Service user rating from Mystery Shop (twice yearly)
- Service user feedback via PALS and Leedssexualhealth.com

4. Sexual health testing and treatment (Indicator not selected for this service)

5. People supported to live healthier lives

- Number of referral cards completed (reported on monitoring)
- Number of users accessing services with referral from pharmacy (reported from services)

Future commissioning intentions will be based on the overall evaluation of this scheme.

An annual audit will be provided by NHS Leeds and subsequent evaluation of audit results undertaken.

9. SERVICE MANAGEMENT

Pharmacists involved in the service are invited to contact the Pharmacy & Optometry Contract Lead with any comments or concerns.

In line with the Patient Group Direction, concerns of a clinical nature should be directed for advice to the Contraception and Sexual Health Service 0113 3057884 / 2954820 or if out of hours NHS Direct on 0845 46 47

10. PERIOD OF THE AGREEMENT

This agreement will run from 1st June 2012 until 31st May 2013. At least 3 months notice must be given by either party to terminate or amend this SLA, within the 12 month contract duration. However, if there is evidence of consistent failure to maintain minimum service levels NHS Leeds reserves the right to terminate participation in the scheme immediately.

11. HEALTH AND SAFETY

The pharmacy will be responsible for the provision and maintenance of a safe and suitable environment for clients and will comply with all relevant statutory requirements, legislation, Department of Health Guidance and professional Codes of Practice and all health and safety regulations.

12. TRAINING AND DEVELOPMENT

The pharmacy contractor has a duty to ensure that pharmacists and staff involved in the provision of the service have relevant knowledge and are appropriately trained in the operation of the service, including sensitive, client centered communication skills.

Training will also be provided by NHS Leeds at set intervals for all providers.

13. CONFIDENTIALITY

All parties agree that access to records and documents containing information relating to individual clients treated under the terms of this SLA will be restricted to authorised personnel and that information will not be disclosed to a third party. The parties will comply with the Data Protection Act, Caldicott and other legislation covering access to confidential client information.

Providers must ensure that they have suitable arrangements to store documentation in a safe and secure manner.

14. PROFESSIONAL INDEMNITY

This agreement does not abrogate the pharmacy or pharmacist from any of their professional duties or obligations and NHS Leeds cannot be held liable for any action or inaction by a pharmacy or pharmacist under the auspices of this agreement that may lead to client harm.

15. COMPLAINTS

The pharmacy will effectively manage any complaints or incidents, keeping a record for audit purposes. These complaints must be incorporated into the annual complaints report as required by legislation.

16. INCIDENTS AND NEAR MISSES

Incidents and near misses related to this scheme should be reported directly to NHS Leeds using the appropriate incident report form. (Copy available from PCT).

17. SIGNATORIES

LEEDS PCT

This service spec will run from the 1st June 2012 until the 31st May 2013.

Signed: Print Name.....

Designation

Date:

(On behalf of Leeds Primary Care Trust)

SERVICE PROVIDER: PHARMACY

Please sign the appropriate sections and complete the pharmacy site information on page 22.

Service Provider:

Signed: Print Name

Designation

Date.....

(On behalf of the Pharmacy)

MULTIPLE/AREA MANAGER (if applicable)

FOR MULTIPLE Pharmacies you will also require Area Manager or Head office Sign off

Signed: Print Name

Designation

Date.....

(On behalf of the Multiple)

PHARMACY INFORMATION SHEET

Please ensure you complete this information correctly as this will be used for promotional materials and to advertise your service on the Leeds Sexual Health website.

Address:

Postcode:

Telephone Number:

Fax Number:

Pharmacy e-mail:

Pharmacy Opening Times:

Monday:

Tuesday:

Wednesday:

Thursday:

Friday:

Saturday:

Sunday:

Number of Pharmacy staff accredited to provide these services and their names:

-

-

-

Area manager name and contact details (if appropriate):

APPENDIX

- 1. Patient Group Directive**
- 2. Consultation Details Form (EHC)**
- 3. Consultation Claim Form**
- 4. Summary Claim Form (Monthly)**
- 5. Dual Test Ordering Form**
- 6 LSH.com Referral Card**

APPENDIX

1. Patient Group Directive

**Patient Group Direction for the supply of
Emergency progestogen - only contraception by
Community Pharmacists**

Author	Nazia Mohammed
Corporate Lead	Damian Riley
Approved at	NHS Leeds PGD Approval Panel
Date Approved	8th Feb 2011
Status	Approved
Ratified by	Damian Riley, Director of Primary Care
Date Ratified	8th Feb 2011
Review Date	1st Aug 2012
Expiry Date	31st Jan 2013
Identified lead for monitoring/review and contact details	Gazala Khan, Lead for Community Pharmacy Services
Patient Group Direction Number	036/08

Leeds Primary Care Trust is the registered name of NHS Leeds

Consultation Process adopted in developing the Patient Group Direction (PGD)

Title of Document	Patient Group Direction for the supply of Emergency progestogen - only contraception By Community Pharmacists
Document Type	PGD
New document	NO
Revised document	YES
If the PGD is revised what revisions were required and for what reasons e.g. change in medical procedures or change in legislation?	
Director Lead (name and job title)	Damian Riley
Author (name and job title)	Nazia Mohammed (Primary Care Pharmacist)
List of persons/groups involved in developing PGD (including job title)	Gazala Khan Manisha Singh
List of persons involved in consultation process (including job title)	Christina Adkins, Pharmacist Manager Neville Fox, Pharmacist Manager

Patient Group Direction for the supply of Emergency progestogen - only contraception By Community Pharmacists

Applies to:	<p>All practicing pharmacists with valid registration with the General Pharmaceutical Council, working to the Code of Ethics, Standards and Practice as part of the Leeds PCT commissioned enhanced service.</p> <p>YOU MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE YOU ATTEMPT TO WORK ACCORDING TO IT</p>
Clinical Condition	
Situation/ Condition	Provision of emergency contraception for the prevention of pregnancy from unprotected sexual intercourse.
Inclusion criteria	<p>Women who are 13 years or over and who present within 72 hours of exposure to the risk of pregnancy following unprotected sexual intercourse. (If the female is under 16 years of age, they must be Fraser Competent, child protection issues should be considered and the policy on safeguarding children followed).</p> <p>Verbal consent needs to be obtained from patient prior to treatment.</p>
Exclusion criteria	<ul style="list-style-type: none"> • Age less than 13 years • Pregnancy or possible pregnancy, including presentation more than 72 hours from unprotected intercourse in this cycle (consider previous issue of EHC in current cycle) • Any patient having taken EllaOne® previously within the current cycle • Hypersensitivity to levonorgestrel or any components of the tablet • Severe hepatic dysfunction • Severe malabsorption syndromes (such as Crohn's disease or severe diarrhoea) • Rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption • Acute porphyria • Trophoblastic disease • Taking or having taken in the last 4 weeks any interacting drug, including herbal remedies (as listed in the current BNF). Note especially the risk of interaction with herbal remedies containing St John's Wort (<i>Hypericum perforatum, millepertuis</i>) • Presence of any contraindication as detailed in the current Summary of Product Characteristics • Lack of valid consent (refer to Fraser Guidelines as basis of best practices for under 16's) • Patients who are not able to attend the pharmacy • History of ectopic pregnancy. • Emergency contraception is not required before day 21 postpartum

Action if excluded	Immediate referral to GP or Contraception and Sexual Health Service as appropriate.
Action if patient does not consent	Immediate referral to GP or Contraception and Sexual Health Service as appropriate. Document patients' refusal to consent and action taken.

Description of treatment

Name of medicine	Levonelle 1500® POM
Legal Classification	Prescription only medicine
License Status	Licensed in the UK for this indication in this patient group
Form	Tablet
Strength	Levonorgestrel 1.5mg
Dose	Levonelle 1500® POM product - One tablet taken as soon as possible, preferably within 12 hours, and no later than 72 hours after unprotected intercourse. If the patient vomits within three hours of taking the tablet a repeat course of treatment should be taken immediately
Dose schedule	1.5 mg per course. (Repeat course of 1.5mg if patient vomits within 3 hours of taking first tablet(s))
Route	Oral
Total treatment quantity	A maximum of two tablets (total of 3mg) can be given per treatment if patient vomits within 3 hours of taking first 1.5mg dose
Adverse reactions	<ul style="list-style-type: none"> • nausea occurs in at least 1 in 10 women and vomiting occurs in at least 1 in 100 • the menstrual cycle may be temporarily disturbed but most women will have their next menstrual period within 7 days of the expected time. • Bleeding or spotting before their next menstrual period occurs in about 16% of women in the 7 days following treatment • other side effects include breast tenderness, headache, low abdominal pain, diarrhoea, dizziness and fatigue <p>For full details of side-effects, the product literature should always be consulted.</p> <p>Report all serious suspected adverse reactions in adults; report all serious and minor adverse reactions in children (under 18 years) to the Medicines and Healthcare products Regulatory Agency (MHRA), Commission on Human Medicines using a Yellow Card or on-line via www.yellowcard.gov.uk. Report serious suspected reactions even if they are listed above, in the BNF or in the Summary of Product Characteristics (product data sheet). Yellow cards may be completed by a nurse, pharmacist, the patient or a doctor.</p> <p>Serious reactions are those that are fatal, life-threatening, disabling, incapacitating or which result in or prolong hospitalisation and/or are medically significant.</p>

<p>Written and oral advice and necessary follow-up</p>	<p>Explain:</p> <ul style="list-style-type: none"> • Treatment and course of action • Efficacy – hormonal emergency contraception is not 100% effective. It will prevent about 95% (19 in 20) of expected pregnancies if taken within 24 hours of unprotected intercourse, 85% (17 in 20) if taken between 24-48 hours after intercourse and 58% (approximately 11 in 20) if taken between 48 and 72 hours after intercourse. Use of intra-uterine device should always be considered if the client does not want to take hormonal contraception or is outside the 72 hours inclusion criteria. • Adverse effects and encourage her to report these to you, her doctor, or the Contraception and Sexual Health Service • That although there is no evidence that emergency contraception carries any risk of teratogenicity, a normal outcome to any pregnancy cannot be guaranteed <p>Advise the patient:</p> <ol style="list-style-type: none"> i) if she vomits within three hours of taking the tablets she should return promptly for further advice, contact the Leeds Contraception and Sexual Health Service or her doctor; ii) that the next period may be early or late iii) that a barrier method of contraception needs to be used until the next period as emergency contraception does not protect against unprotected intercourse in the rest of the cycle; iv) to see her doctor if any lower abdominal pain occurs (can signify ectopic pregnancy); v) she should return or visit the Leeds Contraception and Sexual Health Service or her doctor if her subsequent menstrual bleed is unusual in any way (e.g. is lighter, shorter or later than usual). <p>Provide:</p> <ul style="list-style-type: none"> • the manufacturer’s leaflet and patient information leaflet • information about local services for on-going contraceptive information and supply, and infection screening as necessary
---------------------------------------------------------------	--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

<p>Record keeping</p>	<ul style="list-style-type: none"> - The pharmacist must complete and sign the protocol form 'EHC Consultation Details'. This includes: <ul style="list-style-type: none"> • An assessment of patient need in relation to the intervention including patient history, possibility of pregnancy, inclusion criteria, and criteria for referral, the appropriateness of alternative methods of contraception, patient consent and provision of explanation of method failure and follow-up, future contraceptive needs explored and advice given, medication interactions checked, name or initial and date of birth • product name, batch number and expiry date • date and time of consultation / supply / administration • an assessment of the clients understanding of the treatment and advice given if under 16 years • record answers to necessary questions to help determine if there is a child protection issue, e.g. make a note of the age of partner, where she lives and with whom. • appropriate actions taken if a child protection issue is identified • signature and printed name and designation to ensure the practitioner delivering care is clearly identifiable • time from unprotected sexual intercourse • If excluded, a record is made of referral to GP or Leeds Contraception and Sexual Health Service - The pharmacist should explain to the client that some information needs collecting and ask for consent for this information to be issued to the PCT. This information is completed on the form titled 'Consultation Details- Enhanced Sexual Health Service'. This form is returned monthly to WYCSA. The information includes: <ul style="list-style-type: none"> - Details of any medication supplied - Date and time of consultation - Sex - Age of client - Post code (first four digits) - Ethnicity. - Complete the sections: EHC, pregnancy testing, Chlamydia testing and other information supplied. - The summary claim form sheet- Enhanced Sexual Health Service should be completed and a copy taken for the Pharmacists records. This form should also be returned to WYCSA at the end of each month to summarise the consultations. - Must label any supplied medicines, as a dispensed product and ensure records are kept on the pharmacy computer
<p>Storage Requirements</p>	<ul style="list-style-type: none"> - Store securely at room temperature in a place with restricted public access

References

- British National Formulary 59 (September 2010)
London: BMA & RPSGB
- Department of Health Review of Prescribing, Supply and Administration of Medicines. A report on the Supply and Administration of Medicines under Group Protocol London 1998
- Department of Health Review of Prescribing, Supply and Administration of Medicines. Final Report London 1999
- NHS Executive HSC 2000/026. Patient Group Directions [England only] London 2000
- Royal Pharmaceutical Society of Great Britain. *Code of Ethics and Standards in Medicines, Ethics and Practice 34*. London, RPSGB July 2010
- Emergency Hormonal Contraception Information Booklet; CPPE; The University of Manchester; 2010
- Schering Health Care Ltd: Levonelle -1500[®] Summary of product characteristics.
<http://www.medicines.org.uk/EMC/medicine/17040/XPIL/Levonelle+1500+microgram+tablet/> Accessed 14/05/2010. Updated 01/12/2009.
- Royal Pharmaceutical Society of Great Britain, Child protection guidance (August 2007) Accessed 27/09/2010
- Royal Pharmaceutical Society of Great Britain, Guidance on protection of vulnerable adults (August 2007) Accessed 27/09/2010
- Department of Health. Publication of revised guidance for health professionals on the provision of contraceptive services for under 16s.
<http://www.ffprhc.org.uk/admin/uploads/under16s.pdf> Accessed 14/05/2010. Updated 30/09/2010
- Royal College of Obstetricians and Gynaecologists. Postnatal Sexual Health and Reproductive Health. Faculty of Sexual and Reproductive Healthcare, September 2009.
<http://www.ffprhc.org.uk/admin/uploads/CEUGuidancePostnatal09.pdf> Accessed 14/05/2010
- RPSGB (2008) Legal and Ethical Advisory Service Fact Sheet No 7, *Patient Group Directions: A Resource Pack for Pharmacists*. Accessed 03/09/2010. Updated 07/2008.
- RPSGB (2004) Practice Guidance on the Supply of Emergency Hormonal Contraception as a Pharmacy Medicine. Accessed 03/09/2010

- | | |
|--|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | <ul style="list-style-type: none">• Royal College of Obstetricians and Gynaecologists. Emergency Contraception. Faculty of Family Planning and Reproductive Health Care, April 2006.
http://www.cppe.ac.uk/LearningDocuments/pdfs/EmContraceptionAppendix1A.pdf Accessed 03/09/2010 |
|--|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

Patient Group Direction for the supply of Emergency progestogen - only contraception By Community Pharmacists

Name of Community Pharmacy:	
------------------------------------	--

Pharmacist(s) to whom this Patient Group Direction applies:

I (we) agree to supply emergency progestogen-only contraception in accordance with the attached PGD when working for this Community Pharmacy:

Name(s) of Pharmacist(s) CAPITALS	GPhC reg No.	Signature(s) of Pharmacist(s)	Date

Pharmacy Specific Advice
 Pharmacies may wish to add here criteria specific to their own pharmacy e.g.:

- Record keeping requirements

These are in addition to the Patient Group Direction

Authorisation (from the owner, regional manager or superintendent pharmacist)
 I hereby authorise the above named pharmacists to carry out this activity as stated in the Patient Group Direction.

Name	Signature	Date
..... Position in company		

APPENDIX

2. Consultation Details Form (EHC)

EHC CONSULTATION DETAILS

Patient name:

Pharmacist name:

DOB:

Pharmacist signature:

Date of consultation:

Chaperone (if present):

(please see PSNC guidance, www.psnc.org.uk)

PRO-FORMA FOR THE SUPPLY OF Levenogestrel 1500mgm

YES

NO

Verbal consent given for provision of care. (client must be Fraser competent)

Unprotected intercourse within last 72 hrs.

Date: _____ Number of hrs= _____

No history of previous use of emergency contraception in this cycle.

No histories of unprotected sexual intercourse since Last Menstrual Period (LMP), other than within last 72 hours.

Possibility of pregnancy excluded **LMP:** _____ **(date)**

Possibility of IUCD fit explored and agreed as inappropriate.

Method explained, failure discussed, follow up advice given.

Future contraceptive needs explored and advised appropriately.

Medication interaction checked and negative

Criteria for exclusion checked and negative

'NO' answers to the above = Seek further advice or refer as per PGD.

'YES' answers to the above = Levonelle 1500 can be given.

LEVONELLE 1500 SUPPLIED

REFERRAL MADE

YES / NO

YES / NO

IF THE CLIENT / PATIENT UNDER 16 YEARS (DH Consent) – Fraser Guidelines

YES

Understands and accepts treatment

Advised to discuss with parent or guardian

Do you feel there could be a child protection issue?

If Yes, call the Safeguarding team on 0113 3057484 for advice and support. If out of hours call Children and Young People's Social Care on 0113 2409536

Medication issued

Date:

Time:

Batch No:

Expiry Date:

ASK ABOUT CHLAMYDIA / GONORROHOEA TESTING? DISCUSS RISK

Provide testing kit – help complete the form as part of consultation

MY REFERRAL CARD completed and given to young person

APPENDIX

3. Consultation Claim Form

CONSULTATION DETAILS – ENHANCED SEXUAL HEALTH SERVICE

Date:	Sex:
Time:	Ethnicity:
Age:	Postcode: (1 st four digits)

What service has been provided

EHC

Reason for request – missed pill/unprotected sex/split condom/other		
---------------------------------------------------------------------	--	--

*Was Levonelle 1500 supplied	Yes	No
------------------------------	-----	----

Was pregnancy test carried out	Yes	No
--------------------------------	-----	----

Regular Contraception used?	Yes	No
-----------------------------	-----	----

*If not supplied, give reason

Pregnancy Testing

*Pregnancy test performed on client's request	Positive	Negative
-----------------------------------------------	----------	----------

<ul style="list-style-type: none"> ▪ Pregnancy test performed as EHC follow up 		
-----------------------------------------------------------------------------------------------	--	--

Offer to provide Chlamydia test on urine sample	YES / NO	
-------------------------------------------------	----------	--

Chlamydia Testing

Did the young person <u>take</u> or <u>complete</u> a Chlamydia test? <i>Remember to help complete the test in store. If possible complete and send off for the young person.</i>	Take / Complete (please circle)
--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	------------------------------------

Other Information Supplied

Number of Condoms		
-------------------	--	--

Signposted to service (CASH, GUM,GP) Have you completed a Priority Card?	Yes	No
------------------------------------------------------------------------------------	-----	----

Leaflet given	Yes	No
---------------	-----	----

Other information - please state

Return to WYCSA monthly attached to summary claim form

Pharmacy Stamp

APPENDIX

4. Summary Claim Form (Monthly)

**LEEDS PRIMARY CARE TRUST
SUMMARY CLAIM FORM**

Enhanced Sexual Health Service

To: **FAO Noshaba Abbas**
WYCSA 2-8 Brunswick Court, Bridge Street, Leeds LS2 7RJ

From: Pharmacy Stamp

ESHS Claims for the month of:

Please DO NOT claim for Chlamydia tests on this form – these will be reported by the C-Swap programme to WYCSA – payment will then be made.

Number of EHC Consultations @ £10.00	Number of Levonelle 1500 supplied @ £6.00 (incl VAT)	Number of Pregnancy Tests @ £3.00	DO NOT REPORT CHLAMYDIA TESTS
Total £	Total £	Total £	

Grand Total £..... Number of Forms attached:

Please attach the individual client consultation sheets.

Declaration

I declare that to the best of my knowledge this information is correct and I claim the appropriate payment.

Signed: Date:

Please photocopy this form for your own records.
Payment will be made monthly via the Prescription Pricing Division under "local payment scheme 4"

APPENDIX

5. Dual Test Ordering Form

Leeds Sexual Health Postal Chlamydia & Gonorrhoea Tests ORDER FORM

Please fax back to NHS LEEDS on 0113 8435108

All contact details below must be completed

Your Name:

Site Address:
.....
.....

Postcode:

Contact Tel N°: Date:

Please could we order the following:	Please tick required
• Chlamydia Testing Kits (box of 36)	() max 1 box per order

If your site requires more than 36 kits you will need to request a bulk order from NHS Leeds – please call 0113 2953184 and speak to Victoria Womack

• **Condoms and Pregnancy Tests - contact Barbara.wood@nhsleeds.nhs.uk or call 0113 3057485.**
These will be sent out separately from NHS Leeds

APPENDIX

6 LSH.com Referral Card

MY PRIORITY CARD



I need to talk about FREE:

Tick all appropriate

Pregnancy Testing	<input type="checkbox"/>
Emergency Contraception	<input type="checkbox"/>
Condoms and Lube	<input type="checkbox"/>
Contraception	<input type="checkbox"/>
STI Testing	<input type="checkbox"/>
Chlamydia Testing	<input type="checkbox"/>
	<input type="checkbox"/>

Visit leedssexualhealth.com to find your nearest services or call NHS Direct on 0845 46 47



where should I go?

Visit my doctor	<input type="checkbox"/>
Visit a pharmacy	<input type="checkbox"/>
City-wise (0113 3057884)	<input type="checkbox"/>
Centre for Sexual Health (0113 3926724)	<input type="checkbox"/>
Leedssexualhealth.com	<input type="checkbox"/>
	<input type="checkbox"/>

more details....

Tel:
Address:
Who do I ask for / When to go?
Who sent me?
Today's date ___ / ___ / ___

