

Service Specification for the Community Pharmacy Sexual Health Enhanced Service 2011-2013

1. Aims and Objectives

NHS City and Hackney (hereinafter referred to as the PCT) has a number of targets in relation to sexual health:

- By 2014, reduce under 18 conception rates by 60% compared to the 1998 baseline;
- Maintain a downward trend in the conception rate in girls under 16 years of age;
- Increase use of condoms and other regular contraceptive methods in people under 26 years of age;
- 15.0% of 15 to 24 year-olds to be screened or tested for *Chlamydia*;
- Increasing screening rates for other sexually transmitted infections (STIs)

The principal aims and objectives of this enhanced service are:

- To increase access to EHC for all women who need it, in particular to improve access to EHC for young women under 26 years of age*;
- To signpost the availability of other services, thereby increasing numbers of young women accessing regular sexual health and family planning services;
- To refer 'hard to reach' patients, especially young people, into mainstream contraceptive services;
- To increase awareness of the connection between unprotected sex and STIs, and thereby to decrease the incidence of STIs among young people;
- To increase screening rates for *Chlamydia* and *Gonorrhoea* in sexually active young people from 15 to 24 years of age;
- To improve access to treatment of *Chlamydia* and other STIs for sexually active young people from 15 to 24 years of age;
- For pharmacy to act as a first port-of-call for information and education about sexual health for young people;
- To increase use of condoms by young people (25 years of age and under);
- To increase partnership working and improve communication between pharmacists and other healthcare professionals;
- To enhance pharmacists' professional practice;
- To allow a faster response to clients' needs, without the need to wait to see a doctor

*NB: the risks of undergoing an unintended pregnancy and/or termination generally outweigh those of using emergency hormonal contraception.

2. Supplier

EHC and azithromycin to treat *Chlamydia* may **only** be supplied by an accredited pharmacist, who has been trained and authorised to operate under the approved patient group directions (PGDs).

Medicines counter staff must be trained to refer each request for supply of EHC under the scheme to the accredited pharmacist.

The pharmacist must have completed the training detailed in section 6. The accredited pharmacist should normally be available 4 days a week, one of which is preferably a Saturday (if the pharmacy is open on Saturdays).

3. Service outline

Clients:

Emergency Contraception:

The EHC service is available to all pre-menopausal women of any age who need EHC following an episode of unprotected sexual intercourse (UPSI). Clients will either self-refer or may be referred by other healthcare professionals, including pharmacists not providing the service.

Free-Dom Condom Distribution

The target group is young men and women of 25 years of age and under in Hackney. Pharmacies will act as registration points where young people can receive information about contraception and STIs and be issued with the Free-Dom Card and condoms. Young people producing a card obtained at another EAP will also be able to access condoms.

Chlamydia Screening/Treatment

The Chlamydia Screening service should be offered to all sexually active young people from 15 to 24 years of age whenever they access any service from the pharmacy, including the EHC service, Pharmacy First, purchasing products, etc. Kits may be offered for the woman to test themselves and for their partners.

Chlamydia treatment is available for all sexually active young people from 15 to 24 years of age who have been notified by the Chlamydia Screening Office that they have tested positive for *Chlamydia* and have been referred to the pharmacy for treatment.

Clients under 16 years of age

Whilst the service is not aimed primarily at clients under 16 years of age, the pharmacist may make a judgement to provide EHC/azithromycin/condoms to a young person they believe to be under 16 years if:

- The consequences of not supplying are likely to outweigh the risks of using EHC/azithromycin;
- The client is unable or unlikely to access a GP or Family planning service if supply is refused at the pharmacy.

If the client is believed to be under 16 years, the pharmacist must apply the Fraser Rulings (previously known as Gillick competence). In this case, the relevant section of the Record Sheet should be completed.

General principles regarding the consultation:

- All requests for EHC/*Chlamydia* treatment must be dealt with sensitively and discreetly. Medicines counter staff must refer all such queries to the pharmacist without delay.
- The pharmacist must personally speak with and counsel the person requesting treatment. Advice may be given over the telephone, but EHC and azithromycin can only be supplied, in person, to the intended user.

- Friends, relatives and other third parties may not collect a supply of EHC/azithromycin on behalf of the intended user. If a person requests a supply on behalf of another, the pharmacist must ensure that they are given appropriate advice and information to pass on to the intended user.
- During the consultation, the pharmacist must obtain the information outlined in the relevant proforma before making any recommendation regarding EHC/azithromycin. It is important to collect all of the information required for monitoring purposes – please refer to the laminated card for codes to be used on the proformas.
- Chlamydia/Gonorrhoea screening kits may be supplied to the intended user for their own use, plus additional kits for partner screening.
- Requests for supply of condoms through the Free-Dom service must be dealt with sensitively and discreetly. Supply of condoms may be managed by appropriately trained members of pharmacy staff.

Supply of EHC

- A single pack of Levonelle 1500® can be supplied if:
 - The pharmacist is satisfied that EHC is appropriate;
 - The pharmacist is satisfied that the client understands the circumstances in which EHC will be effective.
- Please Note: The OTC product Levonelle One Step® must not be supplied, as the licensing and the patient information leaflets are different. Pharmacists will not be reimbursed for supply of the OTC product.
- The product may only be supplied for use at the time and should not be supplied for possible future use.
- The client should take the tablet on the premises, i.e. supervised consumption.
- In exceptional circumstances, the client may be given the tablet to take later in the day – in these cases the Levonelle 1500® pack should be labelled with the following information:
 - The pharmacy address;
 - ‘Keep out of reach of children’;
 - Directions for use;
 - Client identifier;
 - Date of supply.
 - Clients who are supplied with Levonelle 1500® to take away should be advised to take it as soon as possible, and should be given the following before they leave the pharmacy:
 - Dose, information and advice sheet on Levonelle 1500®, and
 - Guidance on how to take it, what happens next, and what to do if the tablet is lost/vomited.
- All clients should be given a verbal warning that the tablet may be associated with nausea or vomiting. If **vomiting** or severe diarrhoea occurs within 3 hours of taking the tablet, the client should seek further advice from a pharmacist, GP or Family Planning Clinic;
- Emphasise the failure rate and the need for follow up;
- Stress that this supply takes care of this episode of unprotected sex only;
- Advise the practise of abstinence or careful use of barrier methods until the onset of the next menstrual period and discuss future contraceptive needs.
- Advise a follow up appointment with the Family planning clinic or GP in 3-4 weeks to ensure that the method has worked. This is especially important if:
 - They do not have a period within 3-4 weeks of taking the tablet;

- Or the period is unusually light, short, or painful (possibility of failed method/ectopic pregnancy);
- They should be advised to take an early morning sample of urine with them to that appointment.
- They can attend the Family Planning clinic or GP earlier to discuss ongoing contraception.

Chlamydia and Gonorrhoea screening kits

- Every client from 15 to 24 years of age accessing the EHC service should be offered a Chlamydia and Gonorrhoea screening kit.
- Other, relevant young people from 15 to 24 years of age may be offered the dual screening kits for their own use, plus additional kits for their partner(s).
- Clients given a Chlamydia and Gonorrhoea screening kit should be given instructions as to how to use the kit.
- Clients should be advised to return samples in a sealed bag (provided with the kit) and completed forms to the pharmacy.
- The sealed bags should be taken to the pharmacy's nearest health centre from where they will be sent to the pathology laboratory for testing.

Chlamydia treatment

- Clients testing positive for Chlamydia will be referred to a pharmacy providing this enhanced service.
- A pack of azithromycin 4 x 250mg capsules/tablets can be supplied if:
 - The pharmacist is satisfied that treatment is appropriate;
 - The pharmacist is satisfied that the client understands the circumstances in which treatment will be effective.
- Azithromycin may only be supplied for use at the time and should not be supplied for possible future use.
- The client should take the azithromycin on the premises, i.e. supervised consumption.
- In exceptional circumstances, the client may be given the capsules to take later in the day – in these cases the pack should be labelled with the following information:
 - The pharmacy address;
 - 'Keep out of reach of children';
 - Directions for use;
 - Client identifier;
 - Date of supply.
- Clients who are supplied with azithromycin to take away should be advised to take it as soon as possible, and should be given the following before they leave the pharmacy:
 - Dose, information and advice sheet on azithromycin, and
 - Guidance on how to take it, what happens next, and what to do if the capsules are lost/vomited.

Free-Dom Condom Distribution

First Visit from Young Person

- Pharmacies will act in a similar way to other already established easy access points (EAPs). A private room or area needs to be provided which can act as the registration point.

- A trained worker will discuss Contraception and STIs with the Young Person, and do a condom demonstration. If the Young Person is under 16 special attention is needed to ensure that abuse is not occurring.
- The registration form will be completed online (if they have direct web access) or on paper if not, issue a card, and log how many condoms were given out.
- **Note:** If pharmacies do not have the capacity to do a full registration, it is still possible for them to distribute condoms using the 'virtual' system. While the worker will still need to carry out the same discussions and demonstrations, no card will be issued and the burden of data entry is therefore less.

Subsequent Visits

- If a Young Person is already registered and has a c-card from the pharmacy or another EAP they can go to the pharmacy to pick up their condoms.
- The Young Person will see a sign in the window (or have the information from publicity) and take their card to the counter.
- The counter staff member will look up the card number on the system and add the number of condoms given out. If the young person has lost their card it will be possible to trace them through the search function.
- The staff member writes the date on the appropriate box on the back of the card. If all boxes have been filled the young person should either be directed back to the EAP where they registered to get a new card, or the patient can be re-registered at the pharmacy.
- Worker asks if there is anything else they want to talk about (*Chlamydia* testing, emergency contraception etc – move to a private room if necessary).

Additional information

- All clients will receive an information pack, which includes details of local clinics, sexual health clinics and local GUM (genitourinary medicine) services.

4. Payments

Fee per consultation:

Service providers will also receive a fee per consultation for either EHC or azithromycin as follows:

- £15 per patient aged over 18 years
- £20 per patient aged under 18 years

Note: The fee per consultation will be paid irrespective of whether Levonelle1500® or azithromycin is supplied.

Free-Dom Registration Fee

Service providers will receive the following fees for the Free-Dom service:

- £2.50 for new patient registration
- £1.50 for re-registration of a patient whose C-card has expired

Reimbursements:

Service providers will receive:

- NHS price for Levonelle 1500®, i.e. £5.50;
- NHS price for Azithromycin 250mg capsules x 4, i.e. £8.95;
- A fee of £2 for each Chlamydia/Gonorrhoea screening kit supplied;

- A fee of £1.00 for supply of 3 condoms.
- A fee of £7.50 for a positive Chlamydia Screen

5. Record keeping

Pharmacists must keep a record of the consultation and its outcome:

- If the website is used to submit data, additional records will not be required;
- If the paper-based Record Sheet is used, then a copy must be kept by the accredited pharmacy for 8 years (or up to the client's 26th birthday in the case of clients under 16);
- If the client agrees to take the medication on the pharmacy premises then an entry on the pharmacy PMR system is not necessary. However, if the medication is given to the patient to be taken later in the day, then a record should be kept of the supply using the PMR system.

6. Training

- The pharmacist(s) must have successfully completed any specified training courses run by the tPCT, including initial training, child protection, refresher training, etc.
- The pharmacist will then be accredited as an approved practitioner for providing this service;
- It is the responsibility of the pharmacist to train pharmacy staff on the operation of the scheme and referral of requests for EHC/*Chlamydia* treatment;
- The pharmacist should maintain clinical knowledge appropriate to their practice by attending relevant study days, courses and to make themselves aware of appropriate literature;
- Pharmacy staff should attend one of the *Chlamydia* screening training courses run by the tPCT;
- The pharmacist(s) should consider completing the CPPE packs ;
- Staff involved in the Free-Dom condom distribution service should attend one of the training courses run by Brook London on behalf of the PCT.

Note: Pharmacists and/or staff who have received appropriate training in other PCTs, or through their own organisation can be accredited to provide this service. It is the responsibility of the contractor to ensure that staff are competent and have the necessary skills and knowledge to provide all elements of this service.

7. Premises

The service can only be provided in an approved pharmacy, which should have a suitable consultation room, with access to the internet.

The pharmacy will be required to provide dedicated window space for a window sticker to advertise the availability of the service from that pharmacy, and a poster giving information on contraception and sexual health services and how to access them locally.

8. Indemnity

The service provider will operate in accordance with all Acts of Parliament, statutory regulations or other such laws, recommendations, guidance or practices as may affect the provision of services specified under the Agreement.

Any litigation resulting from an accident or negligence on behalf of the Provider is the responsibility of the Provider who will meet the costs and any claims for compensation, at no cost to the tPCT. The pharmacist must ensure that their professional indemnity insurance provider has confirmed that this activity will be included in their policy.

9. Patient confidentiality

Medicines, Ethics and Practice - A Guide for Pharmacists. No 28. July 2004; Code of Ethics and Professional Standards: Part 2: Standards of Professional Performance, Section C: Confidentiality

“The public expects **pharmacists and their staff** to respect and protect confidentiality. This duty extends to any information relating to an individual, which pharmacists or their staff acquire in the course of their professional activities. Confidential information includes personal details and medication, both prescribed and not prescribed.”

The General Medical Council (GMC) has also issued a statement about the **duty of confidentiality**:

“Patients are entitled to expect that the information about themselves or others, which a doctor learns during the course of a medical consultation, investigation or treatment, will remain confidential.

Any explicit request by a patient that information should not be disclosed to particular people, or indeed to any third party, must be respected save in the most exceptional circumstances, for example where the health, safety or welfare of the patient or someone other than the patient would otherwise be at serious risk.”

This duty of confidentiality **applies equally** to people who are under the age of 16.

10. Child protection

When seeing people under the age of 16 years, pharmacists are also required to act according to Child Protection Guidelines. **The pharmacist should refer to the confidentiality aspect in their opening statement** informing the client that:

“the information you give is confidential unless I consider that you or some other young person is at risk of suffering emotional or physical harm. In these exceptional circumstances I have a duty to share this information with other health professionals such as ‘the children and family team at social services’. Hopefully, this can be done with your agreement, but this is not always required.”

If the pharmacist has any concerns relating to a possible need to breach confidentiality for the above reasons, please contact clinical support or social services in the presence of the young person. Do not act in isolation.

- When a young person is judged not to be competent in line with the Fraser ruling, they should be referred to the Family Planning Doctor or their GP. If the non-competent young person attends with a parent and both agree to treatment, then Levonelle 1500®/azithromycin can be given and both sign the PGD record sheet.

- If the non-competent young person attends with a parent but the young person does not agree to treatment they must be referred to the Family Planning clinic or GP.

11. Clinical support

The accredited pharmacist should not work in isolation and must feel confident to refer to other sources of information and support services such as, other participating pharmacists, and designated Family Planning staff, subject to the requirement for confidentiality.

12. Medical referral

The client should always be advised to talk to her GP or local family planning clinic, regardless of whether a supply is made. However, where the pharmacist, on the basis of the information obtained, is not certain that EHC/azithromycin can be supplied, the client should be referred to a GP or specialist clinic immediately.

A referral letter has been designed for use for clients who are excluded from the PGDs.

13. Copper IUD

Clients who choose or require referral for a copper IUD as emergency contraception can be referred to designated clinics. If possible, contact the clinic beforehand. Failing this, advise the client to telephone in advance to confirm that the clinic doctor is available and can fit an IUD. If not, the clinic can provide details of availability at other clinics.

14. Adverse drug reactions (ADRs)

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

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

15. Data returns

The service provider should use the pharmacy website to submit data.

The service will be monitored on access rates for:

- EHC for young women under the age of 18 years;
- EHC for young women over 18 and under the age of 26 years;
- EHC for women over the age of 26 years;
- *Chlamydia* screening/treatment for young women from 15 to 24 years of age;
- Condom supplies to young people under 26 years of age

16. References

- Summary of product characteristics for Levonelle 1500®
- Summary of product characteristics for azithromycin

- Faculty of Family Planning and Reproductive Health Care (Royal College of Obstetricians and Gynaecologists) (FFP RHC) British Journal of Family Planning: Emergency Contraception: Recommendations for clinical practice April 2000, 26(2): 93-96
- British National Formulary (latest edition)
- Medicines, Ethics and Practice A Guide for Pharmacists (latest edition)
- British Association for Sexual Health and HIV (BASHH) Guideline for the Management of Genital Tract Infection with *Chlamydia trachomatis* (latest edition) www.bashh.org
- National Chlamydia Screening Programme www.chlamydia-screening.nhs.uk
- The Manual for Sexual Health Advisors
- www.ssha.info/public/manual/index.asp

Any change to evidence based knowledge about this product will be discussed and any new published guidelines from the CSM (Committee on Safety of Medicines), FFPRHC or BASHH will be acted upon.

CPPE training which may support this service:

- Emergency Hormonal Contraception Open Learning Pack
- Emergency Hormonal Contraception Workshop
- Sexual Health: testing and treating Open Learning Pack
- Sexual Health: testing and treating Workshop
- Contraception Open Learning Pack
- Dealing with difficult discussions Open Learning Pack
- Child protection: a guide for the pharmacy team Open Learning Pack
- Child health: working with the NSF for Children, Young People and Maternity Services
- Safeguarding and Child Protection Assessment (Online assessment)

17. Transfer and subcontracting

The service provider will not assign the whole or any part of the Agreement or sub-contract the supply of services without the previous consent in writing of the Purchaser, unless special conditions are included elsewhere in the Agreement.

LEAD OFFICERS FOR AGREEMENT

The lead commissioning officer for this agreement is:

Name: Suman Baryaha
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The lead service provider officer for this agreement is:

Name:
Position:
Pharmacy:
Address:

Telephone:
Email:

SIGNING OF THE AGREEMENT

This document and the attached notes comprise the Agreement concluded between NHS City and Hackney and the pharmacy named above.

SIGNED:  **Date:** 2nd April 2012.....

SIGNED: **Date:**