

**Locally Commissioned Service for**  
**EMERGENCY HORMONAL CONTRACEPTION (EHC)**

<b>Service Name</b>	EMERGENCY HORMONAL CONTRACEPTION
<b>Specification Number</b>	273
<b>Commissioner Lead</b>	Amy Dunne/Paul Jamieson
<b>Period of Agreement</b>	2 years extension (1 <sup>st</sup> September 2021 – 31 <sup>st</sup> August 2023)
<b>Date of Review</b>	June 2023

## 1. Executive Summary

### 1.1 Overview

- a. Wigan Council is commissioning and funding a Pharmacy Emergency Hormonal Contraception Service to ensure that residents have ease of access to oral emergency contraception. This will contribute to achieving a reduction in the number of unintended conceptions in women of all ages.
- b. The Contractor (this is the term used throughout this specification to refer to the provider signing up to provide this locally commissioned service) is required to arrange for a competent Pharmacist to offer information and advice to women **presenting** for emergency hormonal contraception and, if deemed to be appropriate, to issue and supply medication in line with this service specification.
- c. The Contractor will work with the local provider of the National Chlamydia Screening Programme to ensure residents at risk of chlamydia are supported to access testing and treatment.
- d. The Contractor must provide safer sex advice and signpost to local sexual health services.

## 2. National Context and Local Context

### 2.1 National Context

#### 2.1.1 Overview of commissioning responsibilities

- a. The Health and Social Care Act 2012 divided responsibilities for the commissioning and funding of sexual and reproductive health services between local authorities, Clinical Commissioning Groups (CCGs) and NHS England.
- b. Local authorities are responsible for commissioning and funding the provision of most but not all sexual and reproductive healthcare provision. Local authorities are mandated to commission and fund comprehensive open-access sexual and reproductive health services for the benefit of all persons present in their area. Local authorities can commission and fund other services including HIV/STI prevention and support programmes. Local authorities have the lead for improving health and for coordinating efforts to protect public health.
- c. NHS England is responsible for commissioning and funding GP practices to offer routine methods of contraception for their registered patients. GPs are also required to test for HIV/STIs, as and when required, and to offer or arrange for treatment of infection. NHS England is responsible for commissioning and funding HIV treatment and care.
- d. Clinical Commissioning Groups are responsible for commissioning and funding abortion services. CCGs are also responsible for arranging for patients to obtain permanent methods of contraception/sterilisation procedures including vasectomies and for the promotion of opportunistic STI testing and treatment within general practice.

#### 2.1.2 Public Health Outcomes Framework

- a. The [Public Health Outcomes Framework](#) sets out a vision for public health. The Framework includes three indicators relating to sexual health:
  1. [Indicator 2.04](#): Under-18 conception rate
  2. [Indicator 3.02](#): Chlamydia diagnosis rates among young adults aged 15-24s

3. [Indicator 3.04](#): % of persons diagnosed with HIV at a late stage of infection

- b. Provision of EHC (emergency hormonal contraception) as described in this specification is expected to contribute to reducing the number of under-18 conceptions as well as the number of unintended conceptions amongst women of all ages.

### 2.1.3 National Chlamydia Screening Programme (NCSP)

- a. Genital Chlamydia infection is the most commonly diagnosed bacterial sexually transmitted infection in the UK. Prevalence of the infection is highest in sexually active women aged 16-19 and men aged 20-24.
- b. Chlamydia often has no symptoms and opportunistic screening of asymptomatic young people is considered the best approach for detecting and treating this infection. Untreated infection can have serious long-term consequences including pelvic inflammatory disease, ectopic pregnancy, and tubal factor infertility.
- c. The National Chlamydia Screening Programme (NCSP) in England was established in 2003. The programme aims to prevent and control chlamydia through early detection and treatment of asymptomatic infection, so reducing onward transmission and the consequences of untreated infection.

## 2.2 Rationale

- a. Community Pharmacies can promote health and wellbeing amongst their local population which includes integrating with existing health and care pathways and other activities to encourage more people to use their services.
- b. Community Pharmacies offer accessible healthcare because:
1. Appointments are unnecessary.
  2. Opening hours are long.
  3. Many staff are from the local community and understand local culture and social norms.
  4. They are able to offer advice on healthy behaviours and, if appropriate onward referral to other services.
- c. Emergency hormonal contraception can be used if a woman has had sexual intercourse without using a regular method of contraception or if her regular method has failed to reduce her risk of having an unintended conception. Levonorgestrel 1.5mg can be used up to 96 hours and Ulipristal acetate 30mg up to 120 hours following unprotected sexual intercourse. Intrauterine devices can also be used for the purposes of emergency contraception and can be inserted up to 5 days after the first UPSI in a natural menstrual cycle, or up to 5 days after the earliest likely date of ovulation (whichever is later).
- d. The consistent and correct use of regular contraception is the best method for sexually active women and their male partners to avoid an unintended conception. There is a correlation between high uptake of reliable methods of contraception and low rates of unintended conceptions among women of all ages and low rates of under-18 conceptions.

### **3. Greater Manchester Approach**

Under the remit of the Greater Manchester Sexual Health Network's commissioners group all 10 local authorities are working collaboratively to develop a standardised specification and similar payment for services provided to ensure Greater Manchester residents receive equitable provision of sexual health services across all localities.

### **4. Local Context**

#### **4.1 Overview of Commissioning for Wigan Borough**

- a. Wigan Borough Clinical Commissioning Group and Wigan Council are working in partnership to commission selected health and care services in Wigan Borough, including sexual and reproductive health services. The current contracting responsibility for emergency hormonal contraception provision by Pharmacies is held by Wigan Council.

#### **4.2 Local Context**

- a. The Deal for the Future sets out our direction of travel to 2020, it is Wigan's strategic response to; Public Sector Reform, Greater Manchester (GM) devolution, and the needs of its communities and residents, underpinned by three key principles;
  - Confident Places - An attractive, accessible and lively borough, with a prosperous economy as the location of choice for investment.
  - Confident People - Improving life opportunities and independence, making sure people feel safe and supported in their communities; helping people to stay healthier for longer.
  - Confident Council - Your council has re-focused its reduced resources towards early intervention and prevention to achieve more for less.
- b. Sexual ill health can affect all parts of society and people's needs throughout the life course. Sexual health, reproductive health and HIV services make an important contribution to the health and wellbeing of individuals and communities. The current economic challenges and pressure on resources necessitate the need to ensure that sexual health service provision in Wigan meets the needs of the local population, delivering the best possible outcomes and best value for money.
- c. In addition to sexual health being a public health concern in its own right, there is also strong evidence linking it to other risk taking behaviours such as drug and alcohol misuse, and to other key issues affecting those in Wigan, such as domestic abuse and Child Sexual Exploitation. We know that there are connections between sexual health and physical and mental health, and that poor sexual health within the Borough can result in a range of poor individual, social and economic outcomes for residents. Our view is that a sexual health system that is focused on addressing clinical issues without investing sufficient resources in early intervention and preventative measures, including supporting positive behaviour change is unlikely to achieve a transformative impact in Wigan.
- d. A comprehensive review of sexual health services in Wigan has allowed us to work with key partners, stakeholders and residents to establish a set of principles for the transformation of sexual health services in Wigan. These principles look to deliver healthy and resilient communities by supporting residents to take greater responsibility for their sexual health.

Wigan have developed a delivery model which we believe has the capability of meeting this transformative aim and have awarded the contract for Integrated Sexual Health Services to Spectrum CIC. Spectrum will now work with Wigan Council and key partners and stakeholders to achieve this ambition.

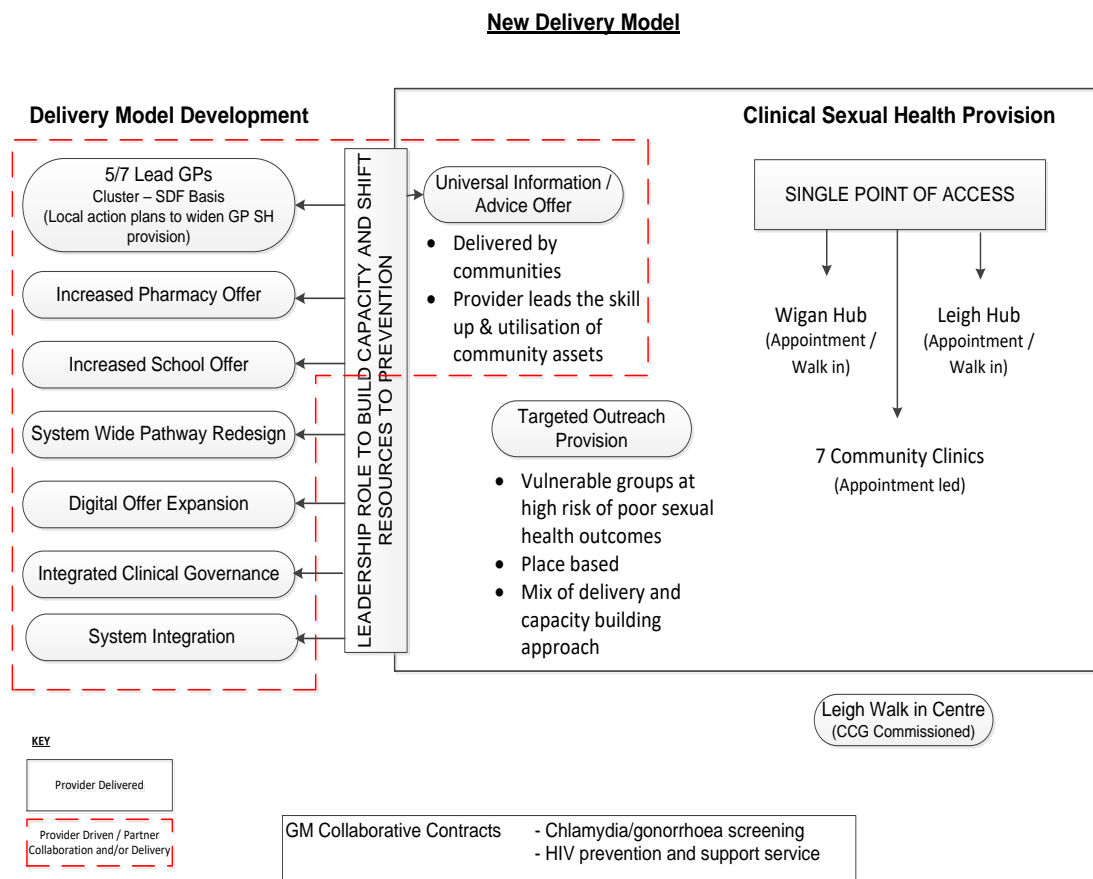
#### **4.3. Local Delivery Model**

- a. Instead of looking at residents as a collection of needs and problems, we view everyone as unique individuals who have strengths, assets, gifts and talents. Through a 'different conversation', we need to understand residents' strengths and gain insight to how we can effectively support people to live the best life they can, and connect them to what they enjoy within their local community, rather than fitting them into an inflexible range of traditional and expensive services. This is what we call an asset based approach.
- b. We also recognise that people accessing sexual health services may also require support with other needs which impact upon sexual health and wellbeing, such as; smoking, alcohol and drug use. In fact, the presentation of a sexually transmitted infection or request for Emergency Hormonal Contraception (EHC) may be the result of other challenges people may be facing, such as mental health issues, changing relationship status or domestic abuse. This is supported by the fact that phase one of the consultation highlighted that people would like to be able to access other support at the same time as sexual health services. A fully effective response that reduces recurrent sexual health needs (and therefore the demand on services) is therefore likely to require a holistic and integrated approach which builds on the users' own assets to address causal factors.
- c. We have therefore developed a set of seven key principles that we feel are necessary for the transformation of sexual health delivery in Wigan to deliver healthy and resilient communities by supporting residents to take greater responsibility for their sexual health and to improve their sexual health outcomes. The principles are:
  - One organisation will be responsible for the coordination of care; ensuring services are safe and effective and have appropriately trained and skilled staff across the workforce.
  - Staff will have different conversations, talking to people about their strengths and the things that matter to them, for example positive relationships and lifestyle factors.
  - There will be an increased opportunity to access information and advice online, book appointments and where it is safe to do so, order self-sampling kits to undertake tests at home.
  - There will be an increased outreach in communities, appropriate to need, to bring these services closer to people in their communities.
  - There will be a single point of access to services with one phone number and website, helping to get people to the right place at the right time.
  - We will take an asset based approach to support positive sexual health behaviours, this means working more closely with places like Schools and colleges, GP surgeries, Pharmacies and Community Groups.
  - Where possible one person or service can help you with the things you need support with, to reduce the number of times you have to repeat information and wait between appointments.

d. We have developed a delivery model based on the above principles that also takes into account the following considerations:

- How we can deliver the right level of service, in the right place, at the right time, according to the identified needs of the service user and in line with our ambitions to increase the breadth and depth of sexual health services available within General Practice.
- How we can effectively build on the opportunities offered by a range of local community assets, including; Schools, Community Organisations and Pharmacies and link them to our specialist provision.
- How we can work with our biggest asset – our residents - to identify innovative ways for people to access sexual health support in their communities.
- How we can support gradual shift and movement of resources within the system as we travel towards an increasingly prevention-led system.

e. The delivery model is illustrated by the following diagram:



#### 4.4. Anticipated Role of Pharmacies within the Delivery Model

- Closely linked to the development of a lead GP practice in each cluster, we are aiming for a model where an extended sexual health offer will be available from our Pharmacies in Wigan.
- We are anticipating that the following provision will be openly accessible across Community Pharmacy to increase access to a universal offer in our communities:

- Sexual health advice and information.
- Access to contraception, including oral emergency hormonal contraception.
- Access to condoms and lubricants.
- Screening, testing and treatment of STIs within clinically appropriate environments, including HIV testing.

c. We would envisage community pharmacy staff working in a different way and having a championing role in relation to sexual health;

- Actively promoting reliable and effective contraceptive methods in line with national guidance and referring on where clinically indicated.
- Promoting regular STI and HIV testing.
- Promoting condom use.
- Assessing for safeguarding and wider determinants of poor sexual health.
- Signposting elsewhere in local community networks as appropriate/connecting into local community assets.

d. We will work with Spectrum Sexual Health Service, the Greater Manchester Local Pharmaceutical Committee and Pharmacies contracted to deliver emergency hormonal contraception over the next 12-24 months to understand the opportunities there are for building this capacity within local Community Pharmacy and what support will be required to realise them.

#### **4.5. Overview of Sexual & Reproductive Health of residents in Wigan Borough**

a. Improving the sexual health and wellbeing of the population is one of the public health priorities for Wigan Borough. Sexual ill-health is a particular issue for Greater Manchester with high rates of sexually transmitted infections including HIV and high rates of unintended conceptions.

##### **4.5.1 Sexually Transmitted Infections and HIV**

a. Sexually transmitted infections can be passed from an infected person to their partner during sexual intercourse. Several infections can lead to long-term health problems if not detected and treated. Some infections such as HIV can be managed but not cured. The correct and consistent use of condoms and other prevention tools is important to control and prevent the transmission of infection.

##### **4.5.2 Conceptions / Contraception**

a. There were 3,631 births in Wigan<sup>1</sup> in 2017. There is some academic evidence that suggests around 12% of all conceptions nationally are unintended<sup>2</sup>. The correct and consistent use of a regular method of contraception is important for the purpose of avoiding an unintended conception. Residents can obtain routine methods including contraceptive pills from their GP. Sexual and reproductive health services offer the full range of contraceptive methods. There

<sup>1</sup> Office for National Statistics. *Live births in England and Wales*

<sup>2</sup> Assumed value from Montouchet, C & Trussell, J. (2013). Unintended pregnancies in England in 2010: costs to the National Health Services (NHS). *Contraception*, 87(2), 149-153.

has been a gradual rise in the proportion of women opting to use a long-acting method of contraception such as the contraceptive implant which is recognised in national guidance to reduce the number of pregnancies<sup>3</sup>

- b. The rate of abortions among female residents aged 15-44 in Wigan is 17.5 per 1,000 women (2017), lower than the Greater Manchester rate of 18.8, but higher than the national rate of 17.3%. Of this, 39.3% were repeat abortions, compared to 39.4% (Greater Manchester), and 38% (nationally)<sup>4</sup>.
- c. The 2017 under-18 conception rate in Wigan is 23.0 per 1,000, higher than both the Greater Manchester (21.9) and national (17.9) rates.

#### 4.5.3 Quick Start Contraception

Women who access emergency hormonal contraception from the Pharmacy may not be using regular contraception. Quick starting is the term used to describe immediate initiation of a contraceptive method at the time a woman requests it rather than waiting for the start of the next natural menstrual period. Quick starting and bridging contraception (using a method of contraception to provide contraceptive cover until the woman's preferred method can be commenced) is available in Wigan via Spectrum services and may be appropriate for users of the pharmacy service. Pharmacies should ensure they are aware of how to refer residents into Spectrum services for quick start contraception.

### 5. Aims, Objectives and Outcomes

#### 5.1 Aims

- a. Wigan Council is commissioning and funding a Pharmacy Emergency Hormonal Contraception Service to promote the use of and maintain ease of access to emergency hormonal in order to reduce the number of unintended conceptions amongst female residents of all ages and to encourage safer sex and the use of regular methods of contraception.

#### 5.2 Objectives

- a. In this specification, providers (pharmacies) are referred to as 'contractors'.
- b. Contractors offering oral emergency hormonal contraception as detailed in this specification will consult with clients **presenting** for emergency hormonal contraception and:
  1. Offer information and advice about all methods of emergency contraception including the emergency copper intrauterine device (Cu-IUD) and provide information on the probability of failure with advice on the course of action in the event of this occurring.
  2. Using a shared decision-making approach, will support the client to come to a decision on the best method of emergency contraception for them and where appropriate, will issue and supply free oral emergency contraception in accordance with this service specification and the Patient Group Direction (PGD) for Levonorgestrel if this is supplied. If the client is under 16 years of age, Fraser competencies will be adhered to.
  3. Offer advice, referral and signposting information about regular methods of contraception including long-acting methods and how to obtain them through patient's GP or any integrated sexual and reproductive health service (these are open access in England so

<sup>3</sup> <https://www.nice.org.uk/guidance/cg30/chapter/1-Recommendations#contraception-and-principles-of-care>

<sup>4</sup> Department of Health & Social Care (2019). National Statistics, Abortion statistics for England and Wales: 2017.



anyone can attend any provider). In Wigan Borough integrated sexual and reproductive health services are provided by Spectrum.

4. Work with the local provider of chlamydia screening to ensure that residents at risk of chlamydia are supported to access testing and treatment for chlamydia.
5. Offer information and advice about safer sex and the benefits of screening for sexually transmitted infections.
6. Offer free condoms and advise on the importance of using lubricants, signposting as necessary.

### **5.3 Expected Outcomes**

#### **5.3.1 Direct Influence on Outcomes**

- a. Provision of emergency hormonal contraception as described in this specification is expected to contribute to achieving the following outcomes:
  1. Reducing the number and rate of unintended conceptions.
  2. Reducing the number and rate of abortions.
  3. Reducing the number and rate of under-18 conceptions.
- b. Access to chlamydia screening and treatment is expected to contribute to achieving the following outcomes:
  1. Reducing the prevalence of chlamydia among young men and women through the prompt detection and treatment of asymptomatic infection.
  2. Preventing the consequences of untreated infection.

#### **5.3.2 Indirect Influence on Outcomes**

- a. Provision of emergency hormonal contraception as described in this specification is expected to contribute to achieving the following outcomes:
  1. Improving knowledge and understanding of emergency contraception.
  2. Improving knowledge and understanding the benefits of using a regular method of contraception.
  3. Improving knowledge and understanding of the importance of condoms.
  4. Increasing the uptake of regular methods of contraception (including long-acting reversible methods).
  5. Improving the uptake of screening for chlamydia and other sexually transmitted infections.
- b. Access to chlamydia screening and treatment is expected to contribute to achieving the following outcomes:
  1. Improving knowledge and understanding of chlamydia.
  2. Improving knowledge and understanding of the risks associated with unsafe sex.
  3. Improving knowledge and understanding of the benefits of regular screening for chlamydia and other sexually transmitted infections.
  4. Improving the uptake of screening for chlamydia among asymptomatic young women and men.

## 6. Overview

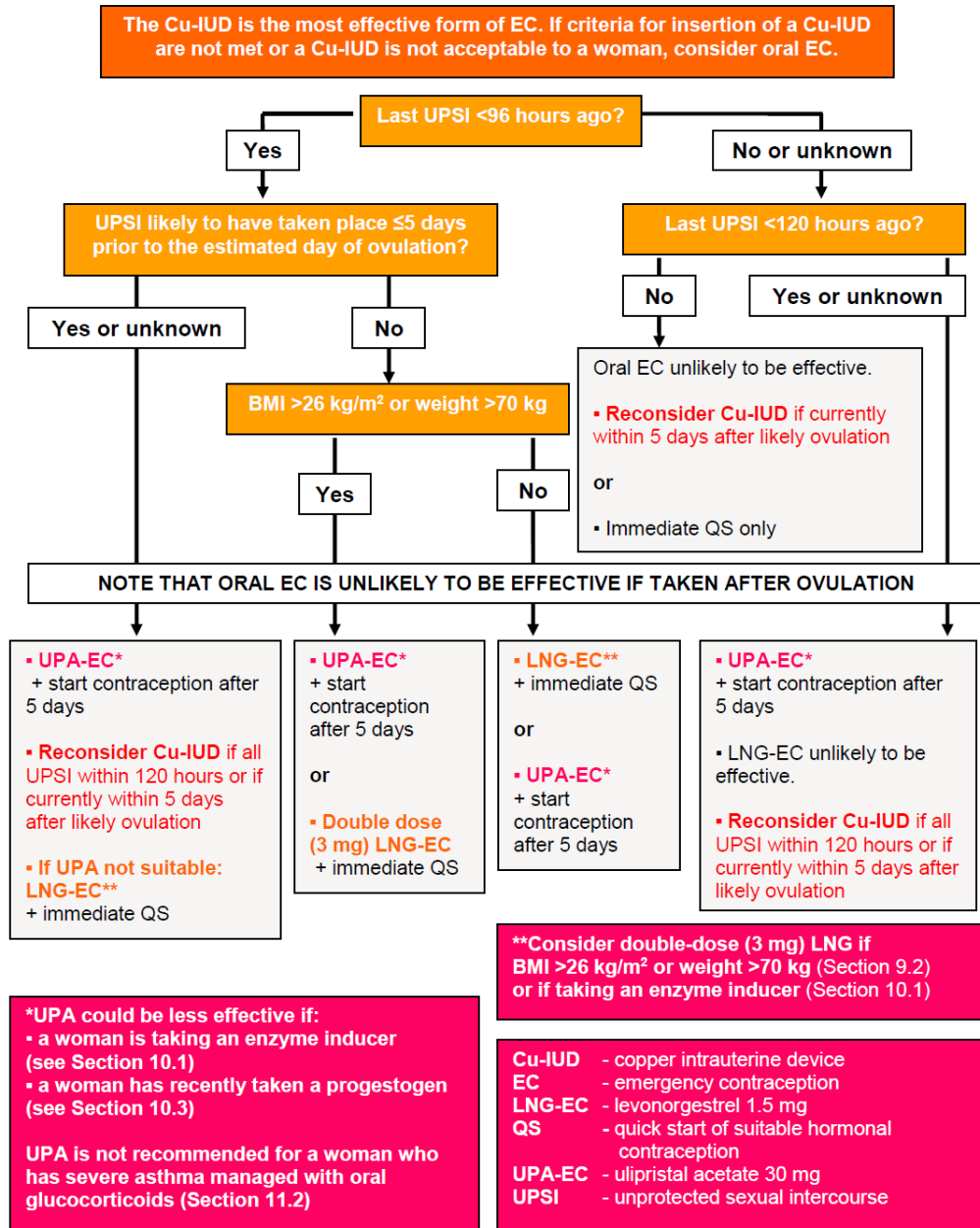
### Service Description

#### 6.1 General Requirements

- a. Wigan Council is commissioning and funding the Contractor to provide oral emergency hormonal contraception free of charge, to women **presenting** for this provision in line with requirements set out in this specification.
- b. The Contractor is required to arrange for a qualified and competent Pharmacist (see 7.2) to consult with clients **presenting** for emergency hormonal contraception. If deemed to be clinically appropriate, the Pharmacist can supply the medication to the client in accordance with the service specification and the Patient Group Direction (PGD) for Levonorgestrel issued by Wigan Council. The Pharmacist should follow the Faculty of Sexual and Reproductive Health (FSRH) algorithm to inform discussion with the client on the most appropriate choice of oral emergency hormonal contraception for the client. The current FSRH decision making algorithm for oral emergency contraception at the time of writing has been included in this service specification, however Pharmacists are required to keep up to date with subsequent recommendations from the Department of Health and FSRH in the area of Emergency Hormonal Contraception and follow the most up to date guidance at the time of the consultation with the client.



**Algorithm 2: Decision-making Algorithm for Oral Emergency Contraception (EC):  
Levonorgestrel EC (LNG-EC) vs Ulipristal Acetate EC (UPA-EC)**



- d. The contractor is required to ensure that the service is provided for at least 70% of the Pharmacies total opening hours (core and supplementary).
- e. The Pharmacy must not sell 'over the counter' (OTC) EHC products in preference to supplying products via the Pharmacy Service. If an accredited Pharmacist is not available then the client should be signposted to an alternative approved Pharmacy which provides the service. Only if this is not possible and the client agrees can an OTC product be sold.
- f. The Contractor should ensure that Pharmacists participating in the service have appropriate insurance cover.
- g. The Contractor is required to ensure that at each consultation the Pharmacist:
  1. Determines if the client is competent to consent to treatment.
  2. Ensures that UPSI occurred within the appropriate timeframe for treatment.
  3. Ensures that the client is not already pregnant – if necessary carrying out a pregnancy test.
  4. Discusses the full range of emergency contraception including:
    - Emergency intrauterine device (IUD).
    - Products containing Ulipristal acetate.
    - Products containing Levonorgestrel.
  5. Discusses the effectiveness of emergency contraception and the benefits, risks, and possible side effects of the various methods, enabling the client to make an informed decision.
  6. Refers to the Pharmacy Product Licence for Ulipristal 30mg Tablet and the Patient Group Direction issued by Wigan Council for Levonorgestrel 1.5mg Tablet to determine if it is appropriate to issue emergency hormonal contraception - including:
    - Inclusion and exclusion criteria.
    - Cautions.
    - Drug interactions.
    - Dose and quantity to be issued and supplied.
  7. Provides advice on what to do if the client vomits within 3 hours of taking the EHC.
  8. Provides advice on the clients next period and when a pregnancy test should be carried out.
  9. Refers clients to other services for assistance when supply of EHC via the Community Pharmacy is not appropriate.
  10. Discusses the benefits of using a regular method of contraception for protection from an unintended conception and signposts / refers the client to their GP or a sexual and reproductive health clinic.
  11. Discusses the benefits of the consistent use of condoms for protection from sexually transmitted infections and, if deemed appropriate, provides the client with a supply of three condoms and raise awareness of the importance of lubricants.
  12. Discusses the importance and benefits of regular screening for sexually transmitted infections and signposts / refers the client to a sexual and reproductive health clinic if symptomatic or concerned.

13. Discusses the benefits of regular screening for chlamydia (16–24 year olds) and, signposts to sexual health service if required.
14. Completes the Client Record Form for every consultation (appendix 1). Under no circumstances should this form be given to the client to complete. The Pharmacist should complete the form during the consultation and explain all areas fully to the client.
15. Completes a Client Competence Form if appropriate (appendix 2).
16. Ensures that the Client Record from and Client Competence Form (where appropriate) are stored securely for 8 years for adults, or until the 25<sup>th</sup> birthday for clients aged under 18 years.

- h. It is the expectation that consultations will take place in the pharmacy wherever possible in a designated room or area. The designated room or area should meet the relevant guidelines and should allow the conversation between the Pharmacist and the client to remain confidential (see 8.2). In the event that a face to face consultation is not appropriate, pharmacists may consider carrying out the consultation remotely if they can be satisfied that informed consent can be obtained and shared decision making principles upheld. Safeguarding considerations must be taken into account and it is recommended that the reason for remote consultation is documented on the client record form.
- i. The Contractor is required to adhere to national and local guidelines for offering sexual health advice and treatment to young people including the requirement to assess Fraser competence.
- j. The Contractor will ensure compliance with local policies and procedures for safeguarding children and vulnerable adults.
- k. The Contractor is required to promote the free emergency hormonal contraception service.
- l. The Sexual Health Commissioner in the Local Authority will ensure that the Contractor has information about local sexual and reproductive health services including website details to aid Pharmacists to make accurate and appropriate referrals.

## 6.2 Condoms

- a. Free condoms should be offered to all clients **presenting** for a consultation. The commissioner will reimburse the contractor as described in this specification.

## 6.3 Pregnancy Testing

- a. If the client is suspected to be or there is a risk that they are pregnant, a pregnancy test should be provided prior to administering oral emergency hormonal contraception. The commissioner will reimburse the contractor for this test as described in this specification.

## 6.4 Population Data Collection

- a. The Contractor is required to ensure that wherever possible, for all clients **presenting** for emergency hormonal contraception that a minimum of the first 4 digits postcode data is collected and recorded in the backing data section of Wigan's pharmacy EHC invoice/claim form, as per section 13.1. Non-provision of this information should not preclude a client from accessing emergency hormonal contraception.

## **6.5 Inclusion and exclusion criteria**

### **6.5.1 Emergency hormonal contraception**

- a. The Contractor is responsible for ensuring that emergency hormonal contraception is supplied in accordance with the Pharmacy product licence for Ulipristal or the inclusion and exclusion criteria detailed in the Patient Group Direction for Levonorgestrel.

## **6.6 Referral sources and processes**

- a. The Contractor is required to accept self-referrals and referrals from other healthcare professionals.
- b. The Contractor is required to signpost or refer clients to other relevant services, as and when required – e.g. sexual and reproductive health services, safeguarding teams.

## **7. Governance and Operation**

### **7.0 Clinical Governance**

#### **7.1 General Requirements**

- a. The Contractor is required to ensure compliance with the requirements for clinical governance set out in The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013<sup>5</sup> including to:
1. Design and implement a clinical effectiveness programme.<sup>6</sup>
  2. Design and implement a risk management programme – to include:
    - Production and use of standard operating procedures for – for instance:
      - Dispensing drugs and appliances.
      - Procurement, storage and handling of stock.
      - Maintenance of equipment.
      - Processes for reporting incidents.
      - Processes for disposing of clinical and confidential waste.
      - Processes for responding to and reporting safeguarding concerns.
  3. Design and implement a clinical audit programme.
  4. Design and implement an information governance programme – to include:
    - Ensuring that data and personal information is collected and recorded in accordance with the approved particulars for information management.
  5. Design and implement a staffing / staff management programme – to include:
    - Ensuring that all members of staff (and locums) involved in the operation of the emergency hormonal contraception service are competent and have the relevant qualifications and accreditations.

---

<sup>5</sup> See: <https://www.legislation.gov.uk/uksi/2013/349/schedule/4/made?view=plain>

- Ensuring that members of staff (and locums, if appropriate) can obtain training and undertake continuing professional development.
6. Design and implement a patient / public involvement programme – to include:
- Promotion of Emergency Hormonal Contraception service.
  - Implementation of processes to collect and respond to feedback or complaints.
7. Design and implement a premises improvement programme – to include:
- Ensuring the premises are maintained in accordance with the approved particulars for premises. (See 10.0)

b. The Contractor is required to have a clinical governance lead for the Pharmacy.

## **7.2 Clinical skills and competencies**

a. The Contractor is required to ensure that all Pharmacists involved in the provision of emergency hormonal contraception have:

1. Relevant qualifications, registrations and / or accreditations.
2. Completed relevant learning – for example:
  - CPPE emergency hormonal contraception module<sup>7</sup>
  - CPPE Chlamydia testing and treatment module<sup>8</sup>
  - CPPE safeguarding children and vulnerable adults e-learning module<sup>9</sup>
  - CPPE PGD e-learning module<sup>10</sup>
3. Have achieved the competency levels specified in the NICE competency framework for Health Professionals using Patient group Directions (PGDs).
4. Self-assessed their knowledge, understanding, skills and confidence, and have self-declared their competence to issue and supply emergency hormonal contraception and to work under a PGD:
  - Pharmacists are required to complete the CPPE declaration of competence form for emergency hormonal contraception<sup>11</sup> prior to offering this service.
  - Pharmacists are required to renew their CPPE declaration of competence at no more than three year intervals or if there is a significant update in guidance.

b. The Contractor is required to ensure that all Pharmacists (including locums) have completed and signed the relevant declaration of competence statement. Copies should be kept on file within the contractor premises and made available to the Commissioner on request.

c. The Contractor is required to ensure that all Pharmacists have signed the PGD and that copies are kept on file.

<sup>7</sup> See: <https://www.cppe.ac.uk/programmes/l/ehc-a-10>

<sup>8</sup> See: <https://www.cppe.ac.uk/programmes/l/chlamydia-k-05>

<sup>9</sup> See: <https://www.cppe.ac.uk/programmes/l/safegrding-w-05>

<sup>10</sup> See: <https://www.cppe.ac.uk/programmes/l/ptgpdire-01/>

<sup>11</sup> See: <https://www.cppe.ac.uk/services/docs/commissioners/commissioner%20-%20emergency%20contraception.pdf>

- d. The Contractor is expected to ensure that each Pharmacist has had a Disclosure and Barring Service (DBS) enhanced check as part of best practice recruitment processes. DBS checks should be renewed on a periodic basis in line with best practice guidance<sup>12</sup>.
- e. The Client Record Form for the supply and administration of Emergency Contraception must be completed at each consultation and securely kept for the minimum time period as stated in this service specification.
- f. All patient facing pharmacy support staff must be trained to refer each request for emergency hormonal contraception to the Pharmacist. If the Pharmacist present is not competent to provide the service, staff must direct clients to at least one other Pharmacy in the nearby area providing the service. Pharmacy staff should check that there is a Pharmacist available who is competent to provide the service before referring the client.

### 7.3 Care Pathway and Protocols

- a. The Contractor is required to discuss the benefits of using a regular method of contraception with all clients **presenting** for emergency contraception and signpost to other services as follows (see Section 15 for more information on local and national services):
  - Clients should be signposted to their GP for routine prescribing of contraceptive pills or the contraceptive injection. Sexual health service and some GPs may also prescribe and insert contraceptive implants, intrauterine systems (IUSs) / intrauterine devices (IUDs) – coils. Clients can be signposted to their GP or sexual and reproductive health clinic to obtain these other methods of contraception.
  - Clients can be signposted to sexual and reproductive health services in any area for sexually transmitted infection advice, testing or treatment. Information and guidance can be accessed via the Spectrum website at <https://spectrumhealth.org.uk/services/sexual-health>. Clients at risk of HIV can be signposted to order a self-sampling kit online at [www.test.hiv](http://www.test.hiv) or can receive testing at any sexual and reproductive health service clinic, some GPs and some pharmacies.
  - Clients at risk of or living with HIV in Greater Manchester should be signposted to PaSH (Passionate about Sexual Health) for advice and support for them and their families.
- b. The Contractor will signpost or refer clients who need or could benefit from an emergency intrauterine device (IUD) to a sexual and reproductive health clinic.

### 7.4 Clinical Incidents and reporting

- a. Pharmacies have a legal obligation<sup>13</sup> to use an approved incident reporting system. Contractors should record, report, and respond to incidents in a manner that complies with the requirements set out in the approved particulars<sup>14</sup> including but not limited to:
  1. Maintaining a patient safety incident log.
  2. Reporting patient safety incidents to the National Patient Safety Agency (NPSA), via the National Reporting and Learning Service (NRLS).

<sup>12</sup> <https://www.gov.uk/government/collections/dbs-checking-service-guidance--2>

<sup>13</sup> <https://www.legislation.gov.uk/ukxi/2013/349/schedule/4/made?view=plain>

<sup>14</sup> See: <https://www.gov.uk/government/publications/clinical-governance-approved-particulars>



- b. The Contractor is required, as part of this contract, to inform Wigan Council of any and all incidents relating to the provision of EHC provision which directly or indirectly involves a Service User, within THREE working days of the 'incident'.
- c. The Pharmacy is required to notify Wigan Council of any concerns or fitness to practice issues that are raised by commissioners of other services.

### **7.5 Infection Control**

- a. The Contractor will maintain their premises to a high standard of cleanliness in order to minimise the risk of healthcare acquired infection for staff and customers.

### **7.6 Disposal of Waste**

- a. The Contractor is required to dispose of clinical and other waste in a safe and lawful manner. See: [Health Technical Memorandum 07-01](#)

## **8.0 Information Governance**

### **8.1 General requirements**

- a. The Contractor must be compliant with the requirements set out in the Data Security and Protection (DSP) Toolkit<sup>15</sup>. The current version can be found on the website of NHS Digital (also known as the Health and Social Care Information Centre)<sup>16</sup>. The associated assessment should be completed on an annual basis.
- b. The Contractor is required to have an appropriate range of policies, procedures and processes, to secure and protect the personal information of clients in line with the requirements of the law.
- c. The Contractor must ensure that all members of staff (including locums) are aware of their responsibilities in relation to the protection of personal information.

### **8.2 Confidentiality**

- a. The Contractor is required to have a confidentiality code of conduct (or similar).
- b. **It is the expectation that consultations will take place in the pharmacy wherever possible in a designated room or area. The designated room or area should meet the relevant guidelines and should allow the conversation between the Pharmacist and the client to remain confidential (see 8.2). In the event that a face to face consultation is not appropriate, pharmacists may consider carrying out the consultation remotely if they can be satisfied that informed consent can be obtained and shared decision making principles upheld. Safeguarding considerations must be taken into account and it is recommended that the reason for remote consultation is documented on the client record form.**
- c. The Contractor is required to ensure that all members of staff (and locums) know and understand their responsibilities in relation to maintaining confidentiality and are able to explain the code of conduct (or similar) to clients.

### **8.3 Recording**

- a. The Contractor must keep records of which clients have accessed the service. Ideally computerised records should be kept, but paper records may be acceptable if these can be stored securely.

---

<sup>15</sup> <https://psnc.org.uk/our-news/replacement-for-ig-toolkit-now-available-to-complete/>

<sup>16</sup> See: <https://www.igt.hscic.gov.uk/>

- b. For **every consultation** the Pharmacist must complete the Client Record Form (appendix 1) **Under no circumstances should this form be given to the client to complete.** The Pharmacist should complete this form during the consultation ensuring all sections are completed and all information and advice is given to the client in a way they can understand.

## **9. Safeguarding**

### **9.1 General Requirements**

- a. The Contractor is required to develop, adopt and implement policies and procedures for safeguarding children and adults at risk. These policies and procedures should be developed in line with and reference to the policies and procedures of the Wigan Safeguarding Board.
- Wigan Safeguarding Children Board  
<http://www.wiganlscb.com/home.aspx>
  - Wigan Safeguarding Adult Board  
<http://wigansafeguardingadults.org/>
  - Greater Manchester Safeguarding Procedures  
<https://greatermanchesterscb.proceduresonline.com/>
- b. The Contractor is required to ensure that all members of staff (including locums) are aware of their safeguarding duties and responsibilities. Staff should receive safeguarding training in line with the requirements of the Safeguarding Children and Young People: Roles and Competencies for Healthcare Staff <https://www.rcn.org.uk/professional-development/publications/007-366> and Adult Safeguarding: Roles and Competencies for Health Care Staff <https://www.rcn.org.uk/professional-development/publications/pub-007069>.
- c. The Contractor is required to ensure that all members of staff (including locums) know how to record concerns and refer to Children's Social Care and Adult Social Care. They should also be aware of how to seek advice from their local Named and Designated Safeguarding Professionals.
- d. Contact Details for Safeguarding Referrals, Support and Advice
- Wigan Children's Social Care  
<https://apps.wigan.gov.uk/ChildReferral/>
  - Wigan Adult Social Care  
<https://www.wigan.gov.uk/Resident/Health-Social-Care/Adults/report-abuse-or-neglect-of-a-vulnerable-adult.aspx>
  - Wigan Borough Clinical Commissioning Group Safeguarding Team  
Telephone Number: 01942 481766

Email: [safeguarding.wbccg@nhs.net](mailto:safeguarding.wbccg@nhs.net)

- Wigan Safeguarding Children Board  
<http://www.wiganlscb.com/Contact-WSCB.aspx>
- Wigan Safeguarding Adults Board  
<http://wigansafeguardingadults.org/Board/Contact-us.aspx>

## 9.2 Child Sexual Exploitation

- a. The sexual exploitation of children and young people under 18 involves exploitative situations, contexts and relationships where young people (or a third person or persons) receive 'something' (e.g. food, accommodation, drugs, alcohol, cigarettes, affection, gifts, money) as a result of performing, and/or others performing on them, sexual activities.
- b. In all cases those exploiting the child/young person have power over them by virtue of their age, gender, intellect, physical strength and/or economic or other resources.
- c. In order to improve the effectiveness of safeguarding and protecting children and young people from this form of abuse the Contractor is expected to ensure that all staff have an awareness of CSE (Wigan Safeguarding Children Board offer training which can be accessed via their website <http://www.wiganlscb.com/Professionals/Training.aspx>) and the steps they can take to both identify concerns and refer appropriately. Pharmacists may wish to follow the Greater Manchester Sexual Health (SH) CSE checklist as a prompt to ensure a series of key questions are asked during the general consultation process with all under 18 and vulnerable clients if the Pharmacist thinks there is any risk / or suspect CSE.  
<http://www.sexualhealthnetwork.co.uk/media/documents/GMSHN%20Exploitation%20Risk%20Assessment%20Tool%20final-5aaacd809d627f82ef89f2d23bc249c8.pdf>

## 10.0 Premises

### 10.1 General Requirements

- a. The Contractor has a legal requirement to develop and implement a premises standards programme. NHS England requires contractors to ensure that their programme sets out how the approved particulars<sup>17</sup> will be implemented.
- b. The Contractor is required to have a confidential consultation room (or area) and this should be used for consultations for emergency contraception. It must:
  - Ensure that there is sufficient space for customers, clients and staff members;
  - Be kept clean and in good repair.
  - Be laid out and organised for the purpose of consulting or providing a healthcare service.
  - Be laid out and organised so that, once a consultation has commenced and is in progress, other members of staff (or customers) cannot interrupt the consultation or enter the room / area without permission.

---

<sup>17</sup> See: <https://www.england.nhs.uk/wp-content/uploads/2018/02/approved-particulars-premises.pdf>

- Not be used for storage of stock (other than stock that could be used or supplied during a consultation).

## **11.0 Partnership Working and Relationships**

### **11.1 Relationship with other services**

- a. The Contractor is required to develop and maintain links with other relevant services including:
- Spectrum community Health CIC is responsible for offering clinical advice about contraception and emergency contraception. It should be noted that residents can attend any sexual and reproductive health service in England free of charge
  - The Passionate about Sexual Health (PaSH) Partnership
  - GP practices
  - Safeguarding Teams (Wigan Safeguarding Boards for Adults and Children)
  - Other pharmacies

### **11.2 Interdependencies**

- a. The Contractor should note the following interdependencies:
1. Wigan Council is responsible for authorising and issuing Patient Group Directions.
  2. The Centre for Pharmacy Postgraduate Education (CPPE) offers e-learning for Pharmacists involved in the provision of emergency hormonal contraception and operates the Declaration of Competence scheme.
  3. The National Institute for Health and Care Excellence (NICE) provides guidance for staff working under a patient group direction (PGD).

## **12. Performance and Outcomes**

### **12.1 Outcomes Monitoring**

- a. Wigan Council anticipates that provision of the emergency hormonal contraception scheme will contribute to achieving the following outcomes which are regularly monitored:

	Outcome	Indicators	Source

1	Reduction in the number of unintended conceptions	Rate and number of abortions Rate and number of second or subsequent abortions	DH Abortion Statistics
2	Reduction in the number of under-18 conceptions	Number and rate of under-18 conceptions	ONS Conception Statistics

## 12.2 Service Monitoring

- a. Wigan Council requires the Contractor to record all consultations using the Client Record Form and Invoice/Claim Form. The Invoice/Claim Form should be submitted via the process outlined in section 13.1. The Client Record Form must be retained in the Pharmacy and under no circumstances should any patient identifiable data (PID) be submitted with the Invoice/Claim Form.
- b. Wigan Council will use the data for the purposes of monitoring provision, outcomes and for audit purposes.

	Indicator	Source	Frequency
1	Number of consultations for emergency hormonal contraception	Wigan EHC invoice/claim form	To be supplied with every invoice
2	Number of clients supplied with oral emergency hormonal contraception	Wigan EHC invoice/claim form	To be supplied with every invoice
3	Number of clients supplied with condoms	Wigan EHC invoice/claim form	To be supplied with every invoice

## 12.3 Contract monitoring and compliance

- a. NHS England is responsible for monitoring compliance with the NHS Community Pharmacy Contractual Framework.
- b. Wigan Council will monitor compliance with the terms and conditions set out in this contract and may make arrangements for visits to contractors when appropriate. As part of the conversations with pharmacies over the next 12 -24 months, Wigan Council wishes to work with the Greater Manchester Local Pharmaceutical Committee and Wigan Pharmacies to understand what opportunities for strengthening the quality assurance and monitoring framework related to this specification there are.

## 12.4 Complaints, compliments and suggestions

- a. The Contractor is required to have a process for receiving, reviewing, and responding to complaints and suggestions.
- b. The Contractor will inform the Commissioner in the event that a complaint is received about the emergency hormonal contraception service.

## 13. Remuneration

### 13.1 Fees

a. Wigan Council has set the following fees:

Emergency Hormonal Contraception		
	Element of services	Fee
A1	EHC Consultation	£10.00 per consultation whether or not EHC is supplied
A2	Drug costs <sup>18</sup>	Ulipristal acetate 30mg @ £14.05 per unit Levonorgestrel 1.5mg @ £5.20 per unit plus VAT @ 5%
A3	Pregnancy test	£5.00 plus VAT @ 20% When carrying out a test only, the Pharmacy cannot claim a consultation fee
A4	Condoms (pack of 3)	£1.30 plus VAT @ 5%

b. Wigan Council reserves the right to revise fees

c. Invoices are submitted via Wigan's EHC Invoice/Claim Form. Each pharmacy has its own personalised invoice template which can be obtained via [startwellinvoices@wigan.gov.uk](mailto:startwellinvoices@wigan.gov.uk). Guidance on using the invoice template is also available via [startwellinvoices@wigan.gov.uk](mailto:startwellinvoices@wigan.gov.uk). Please note that failure to use this template will result in non-payment.

<sup>18</sup> based on June 2019 Drug Tariff

- d. Wigan Council will only accept claim submissions for the Pharmacy Emergency Hormonal Contraception Service backdated for a period of 3 months. Any claims submitted more than 3 months in arrears will not be accepted and payment will not be made.
- f. Under no circumstances must the Client Record Forms be submitted with invoices.
- g. Wigan Council reserves the right to verify claims by, but not limited to, inspecting paper and computer records in accordance with ethical guidelines.

### **13.2 Volume**

- a. Wigan Council is not setting a minimum or maximum number of consultations. However, the Commissioner reserves the right to limit or suspend the service on a temporary basis in the event that demand for provision exceeds the available budget.

## **14. Guidelines and Resources**

### **14.1 National Guidelines**

#### **General**

[Department of Health \(2013\) 'A Framework for Sexual Health Improvement in England'](#)

[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/142592/9287-2900714-TSO-SexualHealthPolicyNW\\_ACCESSIBLE.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/142592/9287-2900714-TSO-SexualHealthPolicyNW_ACCESSIBLE.pdf)

[Department of Health \(2013\) 'Sexual Health Clinical Governance: Key principles to assist commissioners and providers to operate clinical governance systems in sexual health services'](#)

[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/252975/Sexual\\_Health\\_Clinical\\_Governance\\_final.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/252975/Sexual_Health_Clinical_Governance_final.pdf)

#### **Emergency Contraception**

[Faculty of Sexual and Reproductive Health:](#)

<https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/emergency-contraception/>

[Faculty of Sexual and Reproductive Health:](#)

<https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-emergency-contraception-march-2017/>

#### **Contraception**

[National Institute for Health and Care Excellence \(NICE\) Quality Standard \(QS129\) Published September 2016](#)

<https://www.nice.org.uk/guidance/qs129>

[National Institute for Health and Care Excellence \(NICE\) Long-acting reversible contraception overview](#)

<https://pathways.nice.org.uk/pathways/long-acting-reversible-contraception>

[Faculty of Sexual and Reproductive Health guidance on contraception:](#)

<https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/>

## Chlamydia Screening and Treatment

[Public Health England \(2014\) 'Developing integrated chlamydia screening provision'](#)

[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/373133/Developing\\_NCSP\\_services\\_locally.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/373133/Developing_NCSP_services_locally.pdf)

[Public Health England \(2014\) 'Development of specifications for the commissioning of chlamydia screening in general practice and community pharmacy'](#)

<https://www.gov.uk/government/publications/chlamydia-screening-in-general-practice-and-community-pharmacies>

NHS England (2016) 'Community Pharmacy Contractual Framework for 2016-18'

<https://www.england.nhs.uk/commissioning/primary-care/pharmacy/framework-1618/>

### 14.2 National resources

#### (a) National Sexual Health Information Line

- Members of the public can call the National Sexual Health Helpline on 0300 123 7123 between 9am and 8pm, Monday to Friday.

#### (b) Sexwise website (fpa)

- Members of the public can visit [www.sexwise.fpa.org.uk](http://www.sexwise.fpa.org.uk) for information and advice about contraception and sexual health.
- Providers of sexual and reproductive health services can register for a free account. Account holders can download patient information leaflets and other resources. See: <https://www.fpa.org.uk/resources/free-sexual-health-information-england-northern-ireland>

## 15. Local Guidelines and Services

### 15.1 Local Services

#### (a) Spectrum Sexual Health Service

<https://spectrumhealth.org.uk/services/sexual-health/>

#### (b) RUClear - Chlamydia and Gonorrhoea screening for 16-24 year olds:

[www.ruclear.co.uk](http://www.ruclear.co.uk)

#### (c) PaSH – HIV prevention, care and support in Greater Manchester:

[www.gmpash.org.uk/hiv](http://www.gmpash.org.uk/hiv)

### 15.2 Safeguarding

a. Actions to be carried out when you are worried a child is being abused can be found at

- Wigan Safeguarding Children Board  
<http://www.wiganlscb.com/home.aspx>
- Wigan Safeguarding Adult Board  
<http://wigansafeguardingadults.org/>
- <http://greatermanchesterscb.proceduresonline.com/>



- b. GM Protocol on Working with Sexually Active People under the age of 18 years  
[http://greatermanchesterscb.proceduresonline.com/chapters/p\\_work\\_sexually\\_act\\_yp.html](http://greatermanchesterscb.proceduresonline.com/chapters/p_work_sexually_act_yp.html)

**15.3 Point of contact -**

The operational contacts for the agreement at Wigan Council are:

Paul Jamieson (Start Well Public Health Commissioning, Wigan Council): [p.jamieson@wigan.gov.uk](mailto:p.jamieson@wigan.gov.uk)

Zoe Trumper (Medicines Management, Wigan Borough CCG):  
[Zoe.Trumper@WiganBoroughCCG.nhs.uk](mailto:Zoe.Trumper@WiganBoroughCCG.nhs.uk)

For queries relating to invoices, please contact [startwellinvoices@wigan.gov.uk](mailto:startwellinvoices@wigan.gov.uk).