London Borough of Newham

Public Health Pharmacy Services 2021-25

Service Specification

|  |  |
| --- | --- |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |

**Introduction**

This service specification forms part of the contract with the Council during the contract term.

The service specification set out London Borough of Newham’s (LBN) requirements in respect of the provision of public health smoking cessation, sexual health (condom provision and STI screening), needle exchange, naloxone provision and supervised consumption services.

Over the life of the Pseudo- Dynamic Purchasing System and in response to identified need and/or policy developments, the Council – in consultation with providers – may add services to the scope of this service specification or amend existing services therein.

Key Performance Indicators (KPIs) and tariffs will be reviewed, and potentially amended, by commissioners on an annual basis. Where appropriate and as directed by national guidance, Covid-related changes to service delivery will be permitted.

Within the service specification are sub-sections detailing the specific requirements of each service, comprising:

* Strategic context
* Population prevalence
* Service aims and outcomes
* Accessibility criteria and referral routes
* Priority populations
* Interventions
* Service quality standards and staff training competences
* Quality assurance and governance
* Tariffs.

Priority Setting

The specification has been designed to be flexible and modified based on improved intelligence and performance. In practice, there will be an annual refresh of the following:

* Priority Groups – As new intelligence emerges, the priority groups may change and evolve.
* Tariffs – The commissioner retains the right to develop new tariffs or amend existing tariffs to reflect changes in priorities.

Additional services may be included based on a contract variation.

Population Demographics

Newham is the 18th largest borough in the country and fourth largest in London with an estimated resident population of 360,000. It is the fifth youngest borough in the country with a median age of 30.8 years and is the second youngest in London.

Newham is a diverse community with 75% of the population from Black and Asian communities (BAME), which is the highest in the country. For the adult population BAME communities form 70% of the population. The rest of the population is White British (15%) and White other (14%). The estimated projections based on natural change (births and deaths) and internal and international migration suggest an increase of 15% for the adult population from 2016 to 2026[[1]](#footnote-2).

Strategic Partnerships

As part of the provision of Smoking cessation interventions, pharmacies will work closely with the specialist stop smoking service (SSSS) currently provided by Queen Mary University London (QMUL). The SSSS will process referrals from the National Referral System (NRS) and General Practice. Pharmacies will be expected to work closely with the SSSS to establish pathways for people seeking to use services who have needs that are more complex and or difficulty quitting within three attempts.

All East Integrated Sexual Health Service provided by Barts Health is the key partner for condom provision and STI screening. Pharmacies must work closely with Barts Health on the provision of these services.

Change Grow & Live (CGL) is currently the specialist provider for substance misuse services and can provide system leadership.

Furthermore, the pharmacy is expected to develop working partnerships with a range of local organisations and maintain clear referral pathways. This includes but is not limited to;

* CCGs and GPs
* Health checks programme
* Dental surgeries
* Maternity services
* Secondary care services (i.e. specialist diabetes and respiratory clinics)
* Mental Health services
* Alcohol and Substance misuse services
* Community based services offering support or other interventions to LGBT communities
* Community services
* Young people’s services
* Domestic and Sexual Violence support services
* Health watch Newham.

1. **Cross Cutting Requirements**

There are cross cutting requirements which are applicable to all service areas. The pharmacy must have an awareness and adequate understanding of these themes so they are embedded within service delivery throughout the lifetime of this contract.

Public Health Outcomes Framework

The Public Health Outcomes Framework (PHOF) sets out a vision for public health, desired outcomes and the indicators that will help to understand how well public health is being improved and protected.

Public Health England outlines and collates data on a set of indicators published through the Public Health Outcomes Framework. These are intended to help Local Authorities measure and benchmark their outcomes with other Local Authorities.

PHOF indicators relevant to specific services can be found within each subsection of the service specification.

Newham’s 50 Steps to a Healthier Borough: Health and Wellbeing Strategy 2020-2023

Newham’s Health and Wellbeing Strategy focuses on the drivers and determinants of health. It is a call to action for everyone working and living in the borough to play a role in improving the health and wellbeing of residents over the next 3 years and beyond.

With their knowledge of local communities and service delivery to hard-to-reach groups Newham pharmacies are well placed, through the provision of the public health services set out in this document, to play a vital role in supporting residents holistically and preventatively around their health and wellbeing. ln particular, pharmacies in Newham can help deliver the following priorities and their respective steps:

Priority 1: Enabling the best start through pregnancy and early years

* Step 03: Promote and support health pregnancies, childbirth and post-natal care for parents
* Step 04: Give every child in Newham the best start in life

Priority 2: Supporting our young people to be healthy and ready for adult life:

* Step 12: Enable most at risk children and young people to achieve their full potential and have access to specialist care and support services

Priority 4: Developing high quality inclusive services, ensuring equity and reducing variation

* Step 19: Improve equity in health and care service provision for all
* Step 20: Service provision reaches high standards of access and inclusivity to ensure health and wellbeing for all with a particular emphasis on BAME communities

Priority 5: Meeting the needs of most vulnerable to the worst health outcomes

* Step 24: Work to prevent communicable disease with particular focus on hepatitis C eradication, TB, sexual health and late diagnosis of HIV, as well as COVID-19

Priority 10: Workings towards smoke free Newham by 2030

* Step 41: Make Newham tobacco free by 2030
* Step 42: Provide access to high quality support to quit smoking

Priority 12: Building an inclusive economy and tackling poverty

* Step 49: Maximise the reach of the London Living Wage in the borough

Healthy Living Pharmacy

Healthy Living Pharmacies (HLP) aim to deliver a broad range of high-quality services through community pharmacies to meet local need, improving the health and wellbeing of the local population and help reduce health inequalities.

It is expected all providers will be HLP accredited or working towards level one accreditation within one year of contract commencement. All accreditation should be completed within the first 15 months of contract commencement. Accreditation requires providers to demonstrate a healthy living ethos and proactive approach to health. This includes having at least one qualified Health Champion and a track record of delivery contracted services to a high level e.g. medicines support services and health improvement services.

Further information about HLP can be found at:

<https://psnc.org.uk/services-commissioning/psnc-briefings-services-and-commissioning/psnc-briefing-033-19-how-to-become-a-healthy-living-pharmacy-level-1-august-2019/>

Making Every Contact Count

Making Every Contact Count (MECC) is an approach to behaviour change that utilises the day-to-day interactions that organisations and individuals have with other people to support them in making positive changes to their physical and mental health and wellbeing.

MECC enables the opportunistic delivery of consistent and concise healthy living information and enables individuals to engage in conversations about their health at scale across organisations and populations.

Providers delivering services are expected to:

* Promote an individual approach to behavioural change
* Link into latest advice and campaigns including but not exhaustive to: NHS Smoke free, drug and alcohol misuse campaigns, NHS 5 a day, NHS Eat Well Plate, Eat Well, Healthy Eating and Everybody Active Every Day.
* Engage conversations with customers on healthy living behaviours.
* Provide information on and referrals to local services to enable appropriate onward connection to services.
* Ensure staff are trained and confident to embed the MECC approach.

Well Newham

Well Newham is a value driven programme. Whether it is designing, developing or delivering services or programmes, the Well Newham values are central: -

* Co-produced and inclusive
* Preventative
* Resident centred
* Strength based
* Neighbourhood focused
* Evaluated

Well Newham work streams include social prescribing, health promotion, mental health and wellbeing and the social welfare alliance.

Well Newham links council, NHS, and voluntary sector partners with the aim of ensuring that every Newham resident is supported in their health and wellbeing. Pharmacies are integral to ensuring that every contact with residents counts.

You’re Welcome

You’re Welcome is a set of quality criteria for young people friendly health services. It provides a systematic framework and principles to help commissioners and service providers to improve the suitability, accessibility, quality and safety of health services for young people.

Providers delivering this service are expected to deliver the following You’re Welcome standards:

* Involve young people in their care, delivery and review of services.
* Explain confidentiality and consent
* Ensure young people feel welcomed
* Provide high quality services and integrated referrals to other lifestyle services including but not limited to stop smoking, substance misuse and healthy lifestyles services.
* Staff are trained on engaging and communicating with young people including those from marginalised groups.
* The service is part of local networks and has good links and active partnerships with a range of other projects, organisations and services working with young people.

Further information about the You’re Welcome scheme can be found at <http://www.youngpeopleshealth.org.uk/yourewelcome/wp-content/uploads/2017/02/YoureWelcome_RefreshedsStandards.pdf>

Very Brief Advice (VBA)

Customers accessing the pharmacies under this framework should be offered VBA. VBA promotes best practices to identify and signpost customers to further support from community health services like Health Practitioners, treatment providers, Pan London services. Information will be made available on appropriate services.

Providers should use the Ask, Advise and Act model to engage with customers. VBA should be used as a screening and referral method to identify customers suitable for other healthy lifestyle services provided by the provider or other locally commissioned services. Lead Pharmacists can access the following online training on conducting brief advice with customers.

Smoking cessation online training

* <https://elearning.ncsct.co.uk/>
* <https://elearning.ncsct.co.uk/vba-stage_1>
* <https://elearning.ncsct.co.uk/shs_vba-launch>

Alcohol brief Intervention online training

* <https://www.e-lfh.org.uk/programmes/alcohol/>

People can also self-assess using Drink Coach. The Drink Coach website is an anonymised online screening tool that allows individuals to assess their drinking levels and get brief advice and interventions based on their results. <https://drinkcoach.org.uk/newham-alcohol-test>

Onward referrals

Onward referrals into appropriate public health services (e.g. weight management, physical activity) should be offered to eligible customers. Commissioners may add a small tariff for onward referrals over the course of the agreement, depending on the level of time, training and/or expertise required to make the referral.

1. **Lot 1: Core service requirements and Service Standards**

All of the areas set out in this section should be applied across all areas of interventions set out in this specification. Where there is content which is specific to an intervention this will be set out in the relevant section of this document.

**Service Accessibility**

The interventions/services will be available on an open access basis. There is no requirement for customers to be referred from other agencies and respectful of customer choice. The customer will determine:

* Which delivery site they access.
* The frequency of engagement.

Services are to be available to the age groups and specific eligibility criteria listed under each subsection of the service specification.

**Services and Lead Pharmacist availability**

The pharmacy must be open for a minimum of six days per week with at least one late night opening. A qualified Lead Pharmacist(s) should be available during pharmacy opening times to ensure all services can be provided, although it is recognised that some restriction at the beginning or end of the day may be necessary.

**Premise**

The pharmacy delivering services must:

* Provide support and treatment from a pharmacy based in one of LBN’s neighbourhood wards open a minimum of six days per week, including at least one late night per week.
* Ensure there is a consultation room with four walls, a ceiling and a door that can be opened and closed.
* Ensure the consultation room provides a confidential environment where the customer and Lead Pharmacist can talk at normal speaking volumes without being overhead by staff or customers.
* Ensure pharmacy premises and consultation room is compliant with the Equality Act 2010 and accessible for customers with a physical and / or mental impairment. This may include but is not exhaustive to: a safe floor level, automatic doors, providing information in accessible formats, helping with completing forms, ground floor consultation room, auxiliary aids, ramps, handle rails and wheelchair accessibility.
* Under the Equality Act 2010, pharmacies must not treat a customer(s) unfairly because they are associated with one or more of the protected characteristics. Protected characteristics include age, disability, gender reassignment, pregnancy and maternity, race and religion, sex and sexual orientation. Pharmacies must make reasonable adjustments to provide the service/goods, support customer access and mitigate against unlawful discrimination. Reasonable adjustments may include but are not exhaustive to same sex consultation and bilingual staff.
* Maintain and comply with NHS infection control standards at all times.

**Service Standards**

The pharmacy must have in place a Standard Operating Procedure (SOP) for the delivery of each services and shall review its SOP and referral pathways for the service on an annual basis, or sooner if there are changes to the service.

The pharmacy will ensure the service is welcoming, non-judgemental, person-centred and confidential at all times.

The pharmacy has a duty to ensure the Lead Pharmacist and staff involved in the provision of the service are aware of and operate within relevant protocols. The pharmacy must also ensure that Lead Pharmacists and staff involved in the delivery of the services have relevant knowledge and are appropriately accredited in the operation of the service. This will include sensitive customer-centred communication skills. **Particular attention should be given to the requirements of the Lead Pharmacist and staff delivering specific service interventions, which can be found within each subsection of this service specification.**

The pharmacy should ensure that there are adequate support staff; including staff specifically trained in the interventions set out in the core service requirements and standards section. These staff should be present in the pharmacy at all times in order to support the Lead Pharmacist (including locum Lead Pharmacist) in the operational elements of the service and to help ensure the safe and smooth running of the service.

Where a Lead Pharmacist leaves a pharmacy, the pharmacy must assess the impact to the service delivery and ensure that LBN is informed of service issues as soon as possible. Every effort should be made to ensure service continuity.

Where a pharmacy is taken over by another provider the Local Authority must be informed three (3) months in advance of the takeover so that due diligence and contractual processes can be completed.

Use of locums

Where possible, the pharmacy should ensure that the pharmacy is staffed by a regular Lead Pharmacist/s. Should a participating pharmacy be in a position where the pharmacy will be run with different locum Lead Pharmacists for more than a month, the commissioner must be informed.

The commissioner has the right to withdraw the service from a pharmacy that is not staffed with regular Lead Pharmacists. Alternatively, the commissioner may impose additional conditions on the pharmacy in order for the pharmacy to remain providing the service.

The pharmacy will ensure that appropriate professional indemnity insurance is in place for the locum.

The pharmacy must ensure that LBN is informed immediately of any changes to personnel such that any of the services become unavailable at the pharmacy.

**Customer Confidentiality**

The pharmacy is responsible for ensuring that verbal consent to treatment and data being transferred to the commissioner is discussed with and obtained from customers using the information sheet within PharmOutcomes or any other information management system commissioned by the commissioner for this service.

All customers are entitled to confidentiality, including those under 16. There are exceptional circumstances in which confidentiality should be breached such as those concerning Child Protection and vulnerable adult issues where such concerns have been identified.

Further information about pan London child protection and adult safeguarding guidelines can be found at:

<https://londonadass.org.uk/safeguarding/review-of-the-pan-london-policy-and-procedures/>

<https://www.londoncp.co.uk/>

A clear, young people friendly version of the providers’ confidentiality policy must be displayed in all areas where young people are going to be accessing the service(s).

All staff must be fully aware of the implications and limitations of confidentiality where it relates to the best interests of young people and adults concerning sexual health, needle exchange and the laws of the UK. Where applicable, staff should be able to state the limitations and privileges of confidentiality to a young person and adult encountered in a context where no policy is in fact displayed.

Lead Pharmacists should make the following confidentiality statement at the start of the session.

“*The information you give is confidential unless I consider that you or some other young person or an adult is at risk of emotional or physical harm. In these exceptional circumstances I have a duty to share this information with other health and social care professionals”.*

Providers delivering this service must adhere to the General Pharmaceutical Council’s (GPC) confidentiality standards for pharmacies. Providers are required to:

* Respect and maintain a customer’s right to privacy and confidentiality.
* Understand the importance of managing information responsibly and securely.
* Provide a safe and secure environment to ensure discussions cannot be overheard or seen by others not involved in the customer’s care.

Further information about GPC standards for pharmacies can be found at

[*https://www.pharmacyregulation.org/sites/default/files/standards\_for\_pharmacy\_professionals\_may\_2017\_0.pdf*](https://www.pharmacyregulation.org/sites/default/files/standards_for_pharmacy_professionals_may_2017_0.pdf)

**Safeguarding – Adults and Children and Young People**

Recruitment

As a minimum the pharmacy must ensure that thorough recruitment and selection processes are in place that include, as a minimum, full tracking of previous employment history, checking of qualifications, two written references and an enhanced level Disclosure and Barring Service (DBS) check for all staff with access to customers[[2]](#footnote-3)

The pharmacy must fully comply with the LBN’s Safeguarding Adults Policy and the Newham Safeguarding Children Partnership[[3]](#footnote-4)

Children and young people

Safeguarding is the action that is taken to promote the welfare of children and protect them from harm. Child Protection is an element of safeguarding children. Working Together definition and guidance present the principles of it:

* protecting children from maltreatment
* preventing impairment of children’s mental and physical health or development
* ensuring that children grow up in circumstances consistent with the provision of safe and effective
* taking action to enable all children to have the best outcomes

All pharmacies must attend introduction to safeguarding training commissioned by the Council or alternative provider (e.g. CPPE) and be able to show evidence of appropriate accreditation as required.

Further information about child safeguarding policies, procedures and training can be found at LBN’s website <https://www.newham.gov.uk/Pages/Category/Safeguarding-children.aspx>

Staff worried about a child / young person at risk of serious harm through abuse or neglect, should contact LBN by:

*Phone:* 020 373 4600 (Monday to Thursday, 9am to 5.15pm or Friday 9am to 5pm) or 020 8430 2000 at any other time.

*Online:* <https://www.newham.gov.uk/Pages/Services/Child-protection.aspx>

Further information about child protection policies and procedures can be found at LBN’s website <https://www.newham.gov.uk/Pages/Services/Child-protection.aspx> or Newham Child Safeguarding Board <http://www.newhamlscb.org.uk/>

**Adults**

A vulnerable adult at risk is anyone aged 18 and over who: has needs for care and support, is experiencing, or at risk of abuse or neglect, and is unable to protect themselves against significant harm or exploitation. Pharmacies concerned about vulnerable adults (aged 18 and over) should complete the online Safeguarding Adults Form available at <https://adultsocialcare.newham.gov.uk/pages/what-happens-when-you-make-a-referral.aspx>   
  
Once completed the form should be returned to [Accessto.AdultsSocialCareTeam@newham.gov.uk](mailto:Accessto.AdultsSocialCareTeam@newham.gov.uk)

All pharmacies must ensure that their staff attend adult safeguarding awareness training commissioned by the Council and/or an alternative provider as agreed by the Council (e.g. CPPE). Training must be completed at the start of the contract. Staff should complete refresher training throughout the lifetime of the service contract to reflect changes in policies, procedures and legislation. Pharmacists must also ensure they have the

Level 2 core competences:

• Addresses the immediate safety of the person and ensures that a protection plan is put in place immediately when the risk of abuse is high.

• Identifies and refers to appropriate services any other associated persons including carers and children at risk.

• Practises in a manner that seeks to reduce the risk of abuse, harm or neglect.

• Uses professional and clinical knowledge and understanding of what constitutes any signs of adult abuse, harm or neglect. Including the further recognition of local safeguarding priorities, for example, financial abuse, prevent, modern slavery.

• Acts to ensure effective advocacy for the adult at risk of abuse, harm or neglect.

• Arranges advocates if required, communicating with people about safeguarding, risk and protection planning. This includes facilitating communication with use of interpreters, speech and language colleagues and aids to improve communication.

• Understands local safeguarding structures and arrangements.

• Understands mental capacity legislation as relevant to the country of practice. When DoLS are required/invoked (if appropriate), the role of mental capacity advocates, the role of lasting power of attorney and the role of the public guardian/Office of Care and Protection (OCP) and future planning arrangements such as court appointed deputies, advance decisions to refuse treatment, advanced statements and acts in best interests of the adult at risk as required.

• Documents safeguarding concerns in order to be able to inform the relevant staff and agencies as necessary, maintains appropriate records, records the wishes and views of the adult at risk and differentiates between fact and opinion. Registered professionals at level two also need to have an understanding of forensic requirements. For example, radiographers undertaking skeletal survey examinations for forensic purposes.

• Shares appropriate and relevant information with other teams within relevant information sharing protocols.

• Acts in accordance with key statutory legislation and non-statutory guidance relevant to country of practice.

• Understands how to support adults at risk who do not feel able to participate in service support, for example those experiencing coercive control, environmental health issues.

• Recognise obligations to act when they have a safeguarding concern and acting is against the expressed wishes of the person.

• Understands own and colleagues’ roles, responsibilities, and professional boundaries, including what constitutes both organisational and professional abuse. Is able to raise concerns about conduct of colleagues.

• Understands how to access local safeguarding supervision, networks and support.

Further information about adult safeguarding policies, procedures and training can be found at LBN’s website <https://adultsocialcare.newham.gov.uk/Pages/Safeguarding-adults-training-programme.aspx>

Modern Day Slavery Act 2015

Modern day slavery involves slavery, human trafficking and forced labour and domestic servitude. Traffickers and slave masters use whatever means they have at their disposal to coerce, deceive and force individuals into a life of abuse, servitude and inhumane treatment.

Pharmacies concerned about a young person and/or an adult MUST follow the safeguarding procedure set out below.

### ***Children and young people (under 18 years)***

Pharmacies concerned about a child and/or a young person at risk of or a victim of modern-day slavery **MUST:**

* Contact LBN and report child safeguarding concerns. The LBN safeguarding team can be contacted by *Phone:* 020 373 4600 (Monday to Thursday, 9am to 5.15pm or Friday 9am to 5pm) or 020 8430 2000 at any other time. Safeguarding concerns can also be reported online at <https://www.newham.gov.uk/Pages/Services/Child-protection.aspx>

### *Vulnerable adults*

Pharmacies concerned about vulnerable adults (aged 18 and over) at risk of or a victim of modern-day slavery **MUST:**

* Complete the online Safeguarding Adults Form available at <https://adultsocialcare.newham.gov.uk/pages/what-happens-when-you-make-a-referral.aspx> Once completed the form should be emailed to [Accessto.AdultsSocialCareTeam@newham.gov.uk](mailto:Accessto.AdultsSocialCareTeam@newham.gov.uk)

Further information about Modern Day Slavery can be found at: <https://adultsocialcare.newham.gov.uk/Pages/additional_SG_resources.aspx#Modern>  and <https://www.gov.uk/government/publications/identifying-and-supporting-victims-of-human-trafficking-guidance-for-health-staff/identifying-and-supporting-victims-of-modern-slavery-guidance-for-health-staff>

If a child, young person or an adult is in immediate danger, phone the police immediately on 999.

**Customer Registration**

**All customers provided with VBA and interested in receiving a service should be registered. The registration session should capture the following details:**

* Customer information (name, address, date of birth, gender, ethnicity, accessibility information)
* GP practice details
* Smoking status
* Substance misuse status
* Services required (sexual health, smoking cessation, needle exchange, referral to substance misuse service)
* Customer confidentiality and consent
* Service awareness
* Customer confidentiality and duty of care
* Provision date
* Providers must use templates on PharmaOutcomes or any other data management system commissioned by the Council over the lifetime of the contract to record and report information.

**Recording and Reporting**

The pharmacy will be expected to ensure secure systems and records to prevent misuse of service and to ensure the confidentiality for customers and to comply with GDPR requirements.

*Recording*

The pharmacy must be able to demonstrate that clear and accurate service records are kept at all times and maintain appropriate records to ensure effective ongoing service delivery and review and monitoring purposes. This will include collection of the nine protected characteristics on behalf of Newham Council as part of a Minimum Data Set (MDS) for the purposes of monitoring equity of service provision.

The pharmacy must use templates on PharmOutcomes or any other information management system requested by the commissioner in the future to record activity for Pharmacy Framework services. The pharmacy must therefore have internet access and the ability to access PharmOutcomes online.

Staff are required to have good working knowledge of and access to PharmOutcomes to record customer data, follow customer journeys and run searches, queries and service performance reports.

Providers are required to attend regular performance review meetings and quarterly provider forums facilitated by the commissioner.

*Reporting*

The pharmacy must ensure all customer activity data is uploaded correctly on the 15th of each month, in order that LBN can develop monthly and quarterly performance reports. The pharmacy must also ensure there is a lead member of staff responsible for running regular PharmOutcomes reports to monitor performance and identify areas of improvement.

**Staff performance and training**

All Lead Pharmacists and pharmacy staff delivering interventions must meet generic performance requirements. Where there are additional requirements related to a specific area of service these are set out in the relevant section of this specification. Local replacement Lead Pharmacists working in these pharmacies are expected to comply with all aspects as described above; the responsibility for this lies with the contractor.

The requirements are:

* Understanding of and ability to use the Fraser Guidelines assessment criteria.
* Understanding of local child protection procedures, and who to contact for advice.
* Understanding of local vulnerable adult procedures, and who to contact for advice.
* Knowledge of the You’re Welcome and Making Every Contact Count (MECC) criteria.
* Demonstrating effective communication with customers about healthy lifestyles.
* Demonstrating attitudes & values consistent with the provision of a young people friendly service.
* Understanding of young people’s and adult’s rights to confidential and impartial services.
* Demonstrating an understanding for discretion and need to respect privacy and confidentiality, in accordance with General Data Protection Regulations
* Demonstrating sensitivity to and understanding of coercion and domestic violence when referring people to support services.
* A clear understanding of Infection Control principles and application.
* Knowledge and understanding of the Pan-London Come Correct Condom Scheme.

The pharmacy will ensure that their staff are trained to use the appropriate electronic and web-based system that relate to the service. The Lead Pharmacist will ensure that the system is updated in line with training and local protocols.

The pharmacy should ensure that their staff are trained appropriately, particularly with regard to the risks associated with the handling of returned used injecting equipment and the correct procedures are used to minimise those risks

Training needs will be reviewed on regularly basis to monitor changing needs, improve service quality and implement clinical changes and good practice recommendations. In addition, Lead Pharmacists shall be responsible for identifying their own learning needs and recording their Continuing Professional Development (CPD) annually.

The pharmacy should also undertake CPD on a regular basis by at least one member of staff, who will if necessary, cascade the messages to other staff involved in the service.

**Awareness Raising**

Marketing and mass campaigns are effective in promoting services, prompting quit attempts and reducing smoking prevalence. All providers will:

* Participate in locally defined Public Health campaigns (e.g. Stoptober, NHS Smoke free campaign, No Smoking Day campaign, Sexual Health Awareness Week, Alcohol Awareness Week, Dry January, Overdose Awareness Day) and be active in their local community.
* Local campaigns will be defined regionally by London Directors of Public Health (DPH) in partnership with the North East London Local Pharmaceutical Committee (NELLPC) and local NHS England teams. Training and materials will be provided where required.
* Provide marketing information in a range of formats (digital and print) and languages for different groups.
* Clearly display in store and on digital platforms marketing materials provided by the Council to raise awareness and promote services.

**Performance Management**

It is required that services are delivered to the standards specified throughout this service specification and that they comply with the legal and ethical boundaries governing community pharmacy activity. Standards include:

* Children, young people and adult safe guarding policies
* Customer confidentiality
* Data recording and reporting
* Staff performance and training
* Raising awareness
* NICE service quality standards

The Commissioner will monitor the performance of services on a quarterly basis through dashboards and/or reports that will disseminate anonymised activity/performance data across all pharmacy providers.

* *Performance will be monitored through anonymised PharmOutcomes backing data analysed through MS Power BI software.*
* *Quarterly performance monitoring meetings will be held with providers, in collaboration with NEL LPC, in order to review activity and outcomes (e.g. smoking quits).*
* *Data anomalies and performance issues will be resolved through one-to-one meetings with providers as required, with improvements monitored against time-bound remedial action plans.*
* *Mystery shopping exercises will be conducted annually as a means of quality assurance.*

Should an issue be identified an action plan will be produced. The Lead Pharmacist will identify any specific service-related issues linked to under-performance and create an action plan. The timescales will be agreed according to the level of risk and LBN will send a written report to the named Lead Pharmacist within two weeks of the visit, summarising what action needs to be taken and by when. LBN will contact the pharmacy again once the agreed timescales have elapsed to confirm that the action plans have been completed.

The pace with which process progresses will be determined by the level of risk. In addition, any serious matters identified may be escalated to relevant professional bodies and Public Health England. If any further action needs to be taken, this will be documented and new timescales agreed.

If the issue remains unresolved after this, the option to use the Council’s escalation procedure and/or withdraw the service from the pharmacy may be exercised, in line with the contract Terms and Conditions.

**Quality Standards**

As a minimum, the pharmacy shall:

* Review its Standing Operating Procedures on an annual basis.
* Demonstrate that the Lead Pharmacist and all staff involved in the provision of services have completed CPD relevant to the provision of services.
* Participate in any LBN organised audit of service provision.
* Co-operate with any national or LBN led assessment of customers’ experience.
* Lead Pharmacists will record relevant service information for the purposes of monitoring using the framework provided by LBN (process checklist, appendix E & H).
* Comply with LBN’s Adult Safeguarding policies and procedures and the pan-London Local Safeguarding Board’s policies and procedures for children and young people.
* Ensure relevant recruitment and selection processes are complied with to appropriately safeguards customers.
* Demonstrate that clear and accurate records are kept and recorded appropriately on PharmOutcomes.

**Audits**

The pharmacy shall comply with any request from LBN to audit the service and provide relevant data as requested. This will include a self -audit tool that will be provided by LBN. Audits may include the use of mystery shoppers to monitor and review service provision. Mystery shopping exercises will be developed in consultation with NEL LPC and the results used for learning and development of training.

**Adverse incidents**

In the event of an adverse incident, the Lead Pharmacist must complete the incident reporting form provided as part of the contract and forward a copy to the lead service Commissioner and Newham Clinical Commissioning Group (NCCG) Medicines Management Team within 5 days. An adverse incident can be - but is not limited to - significant clinical events, dispensing errors, adverse drug reactions or near misses and breach of customer data.

Any Serious incident (SI) or critical incidents will be reported to the Commissioning Lead- Public Health and DSV, whereby the incident and learning outcomes will be discussed at contract meetings.

**London Living Wage**

In line with the London Borough of Newham’s ambition to be an accredited London Living Wage[[4]](#footnote-5) and Care Charter employer, all commissioned providers are required to offer the London Living Wage to all employees that:

1. work for two hours or more hours p/week on the services included within this service specification, and do so
2. for a period of at least eight weeks per year.

**Responsibilities of LBN:**

* Commission a comprehensive and accredited training package for advisors to access that meets service standards – including PGD training. A Training Schedule will be developed and disseminated to providers on an annual basis.
* Arrange at least two contractor meetings/training days per year to promote service development and update the knowledge of pharmacy staff.
* Commission a software platform for Providers to record service activity and outcomes.
* Develop and implement monitoring arrangements for the contract, which may include quarterly monitoring arrangements and quarterly meetings, in addition to an annual review/audit.
* To agree the specific data measurement, evaluation and review/ audit requirements of the scheme which may include quarterly monitoring arrangements and quarterly meetings, in addition to an annual review/audit.
* Evaluate the necessary evidence of compliance collated by the pharmacies in order to meet the requirements of the scheme. The evaluation will either be at the contract monitoring or annual review meetings with the pharmacies.
* Provide quarterly performance data to providers.
* To provide details of relevant referral/ inter referral points, which pharmacy staff can use to signpost customers who require further assistance.
* To provide health promotion material relevant to customers and make this available to pharmacies.
* To request the distribution of customer experience questionnaires by the pharmacies.

1. Lot 1. Core Services

Providers must demonstrate competencies in the delivery of the core service offer in tendering for all elements of the service.

Over the life of the Pseudo- Dynamic Purchasing System (PDPS) and in response to identified need and/or policy developments, the Council – in consultation with providers – may seek to add core services to the scope of the service specification or amend existing core services.

Core services currently within scope are:

**4.1 Condom provision and STI screening for Chlamydia and Gonorrhoea (CnG)**

**4.2 Stop Smoking provision**

**4.1 Sexual Health (condoms and STI screening)**

**Strategic context**

A Framework for Sexual Health Improvement in England

The Framework for Sexual Health Improvement sets out the Government’s ambitions for good sexual health for the whole population. The framework underpins key principles of best practice in sexual health commissioning. These are:

* Prioritising the prevention of sexual and reproductive health
* Strong leadership and joined-up working;
* Focusing on outcomes.

The framework offers an evidence, interventions and actions to improve sexual health outcomes, which include:

* Offering accurate, high quality and timely information that helps people to make informed decisions about relationships, sex and sexual health.
* Preventative interventions that build personal resilience, self-esteem and promote healthy lifestyle choices.
* Rapid access to confidential, open-access, integrated sexual health services in a range of settings, accessible at convenient times.
* Early, accurate and effective diagnosis and treatment of sexually transmitted infections (STIs), including HIV, combined with the notification of partners who may be at risk.
* Joined-up provision that enables seamless customer journeys across a range of sexual health and other services in primary, secondary and community settings.

Public Health Outcomes Framework

The PHOF indicators that are relevant to the pharmacy sexual health service are:

* Chlamydia and gonorrhoea detection rate per 100,000 aged 15-24 years old.
* Under 18 conception rates.
* Under 25 repeat abortions.

**Local Context[[5]](#footnote-6)**

Most adults are sexually active and good sexual health is important to individuals and communities. Poor sexual health can lead to sexually transmitted infections (STI’s) and unintended pregnancies.

The number of new sexually transmitted infections (STIs) diagnosed among residents of Newham in 2019 was 5,818. This rate of 1,648 per 100,000 residents is higher than the London average (1,663 per 100,000).

The number of new HIV diagnoses among people aged 15 years and above in Newham was 77 in 2018. The prevalence of diagnosed HIV per 1,000 people aged 15-59 years in 2018 was 6.0, worse than the rate of 2.4 in England. The rank for HIV prevalence in Newham was 15th highest (out of 147 UTLAs/UAs).

In Newham, in 2016 - 18, the percentage of HIV diagnoses made at a late stage of infection (CD4 count ≤350 cells/mm3 within 3 months of diagnosis) was 36.2%, similar to 42.5% in England.

The total rate of long-acting reversible contraception (LARC) (excluding injections) prescribed in primary care, specialist and non-specialist sexual health services per 1,000 women aged 15-44 years living in Newham was 33.5 in 2018, lower than the rate of 49.5 per 1,000 women in England. The rate prescribed in primary care was 14.2 in Newham, lower than the rate of 29.2 in England. The rate prescribed in the other settings was 19.3 in Newham, lower than the rate of 20.3 in England[[6]](#footnote-7).

**Service Aim**

The core sexual health service aims to:

* Promote a preventative approach to sexual health and healthy living through information, advice and early intervention.
* Increase the availability and provision of high quality, cost effective sexual health interventions in Newham.
* Increase the uptake of the Come Correct C-card condom distribution scheme amongst young people under 24 and increase condom use.
* Increase detection rates for STI, in particular Chlamydia and Gonorrhoea (CnG).
* Increase access to treatment of Chlamydia through referral to Bart’s Trust - All East Integrated Sexual Health Service.
* Promote Long-Acting Reversible Contraception (LARC) to all women aged 16-44 and offer referrals to All East Integrated Sexual Health Service or their GP.
* Provide high quality information & advice about safe sex and STIs.
* Provide high quality signposting to healthy living services (i.e. stop smoking and weight management), domestic violence support and mental health and addiction services.
* Work in partnership with local services (such as safeguarding and young people’s services) to promote and support sustained behaviour change interventions.

**Service Outcomes**

Sexual health services commissioned through pharmacies are part of a wider sexual health pathway and system. Services will achieve and/or contribute to the following outcomes:

* Promote a preventative approach to sexual health and healthy living through information, advice and education.
* Increased customer choice and access to sexual health services and other healthy living services.
* Improved access to services particularly among those at risk and highest of needs including:
  + Young people and vulnerable young people (such as but not limited to domestic sexual violence, exploitation and substance misuse) aged 16-24.
  + Black, Asian and minority ethnic (BAME) groups
  + Men who have sex with men (MSM).
* Increase access to and uptake of condoms.
* Increased uptake of the National Chlamydia Screening Programme (NCSP) for 15-24 year olds and achievement of coverage and diagnostic detection rate target of ≥ 2,300 chlamydia diagnoses per 100,000.
* Reduce incidence of STIs amongst young people aged 15-24 years old.
* Pharmacies should act by promoting and registering customers for all elements of the sexual health services including LARC referral (where applicable).
* Increase LARC uptake to reduce unwanted pregnancies in all ages as evidenced by conception and abortion rates.
* Reduce onward transmission of all STIs including HIV.

**Eligibility**

This service is available to:

* Newham residents only with the exception of the Come Correct Condom scheme which will be available to young people under the age of 24 from participating boroughs.
* Aged 15-24 (condom card, chlamydia and gonorrhoea screening kits)
* The following priority groups:
  + Young people
  + Black and minority ethnic groups,
  + Men who have sex with men (MSM).

*Customers under 16*

The age of consent in the UK is 16 years old. The laws protect children from abuse or exploitation, rather than to prosecute under-16s who participate in mutually consenting sexual activity[[7]](#footnote-8).

If pharmacy staff suspect a young person under the age of 16 is having non-consensual sex pharmacy, staff should identify signs of abuse and/or neglect. Signs may include but no exhaustive to forms of physical, neglect, emotional and sexual abuse. Further information can be found at

<https://www.rpharms.com/resources/quick-reference-guides/protecting-children-and-young-people#suspected>

Pharmacy staff concerned about and/or who identify a young person at risk of abuse should contact the Councils safeguarding team, and follow local and pan London protocols on <https://www.newham.gov.uk/Pages/Services/Child-protection.aspx>

**Exclusion criteria**

The service or any treatment could be withheld from a customer:

* Who has not validly consented to the services
* Who is unsuitable (or temporarily unsuitable) on clinical grounds.

**Service Referrals**

Customers can access this service through self-referral. Customers may also request a referral from their GP or any other health and social care professional working with them.

Providers are expected to develop relationships with a range of local organisations to establish and maintain clear referral pathways. For Sexual Health interventions the specific services that can refer are:

* SHINE Young People’s Sexual Health Services (Bart’s Health)
* All East Integrated Sexual Health Service, including Shine the young peoples’ service (Bart’s Health).

**Priority Populations**

N/A

**Interventions**

**Assessment**

**Pharmacies must complete a sexual health assessment with all registered customers. This is an opportunity for pharmacies to assess the needs of customers and offer interventions. Pharmacies must:**

* See customers as soon as possible. If this cannot be done immediately the customer must be offered a time to return or be directed to the nearest alternative pharmacy providing this service or nearest alternative provider.
* Undertake service activities in a private consultation area, unless advised otherwise by the customer. Consultations with customers under the age of 16 MUST take place in a private area where conversations will not be overheard by staff or other customers / customers.
* In accordance with NHS guidance, offer all customers a chaperone for the duration of their consultation.
* Inform all customers that the consultation is confidential and information will not be passed onto any third party without their consent (except in cases requiring disclosure under child protection procedures).
* Apply the Fraser competency assessment for under 16 years of age.
* For each consultation, the Lead Pharmacist should complete an assessment form template on PharmOutcomes (or any other system commissioned by the Council).
* Work within the agreed Patient Group Directive (PGD).

4.1.1 Come Correct Condom Card Scheme (C Card)

The Come Correct (or C Card) scheme provides access to free condoms in a variety of locations (called Outlets) in Newham. Once registered customers can collect condoms or get advice from any Outlet displaying the Come Correct logo.

*Issuing C Cards/Condoms*

* **The local condom card** scheme **for young people will transition to the pan-London scheme Come Correct, enabling young people to access free condoms at participating pharmacies across London. Pharmacies will be informed of the requirements for recording activity.**
* **Young people do not have to be sexually active in order** to join the C Card scheme. Pharmacies must follow the guidance provided by the local C Card scheme - on issuing condoms to young people under 16.
* Pharmacies should use the template within Therapy Audit (or any other commissioned system) and record activity and outcomes.
* Pharmacies should cover the following areas below before agreeing how many condoms are required and issuing them.
* The young person’s relationships and any sexual activity.
* Discuss the age of consent and introduce delay messages where appropriate.
* Relevant information available online and in print about sexual health and contraception.
* Condom demonstration, including what to do if a condom breaks.
* Information about sexual health services including All East Integrated Sexual Health Service, SHINE Young People’s Service and access to emergency hormonal contraception.
* How the C-Card Scheme works including all the current C-Card outlets, identifying which outlet they can use to get condoms in the future.
* Under 16’s should be given 8 condoms and over 16’s given 12 condoms on either new registrations or replenishment. This should total to a maximum of 24 condoms per month.

*Issuing emergency condoms*

Emergency condoms should only be issued when:

* A young person attends and asks for condoms but does not want to sign-up for a C-card; they can still be given up to three condoms under the scheme, provided that the young person has engaged in the “Issuing C Cards” steps outlined above.
* Issuing emergency condoms should not to be openly advertised or specifically encouraged, but those choosing to access the scheme in this manner must not be penalised or stigmatised. It is vital to ensure that they are made aware of the benefits of joining without a prejudicial attitude to their choice that could cause them to abandon condom access altogether.

*C-Card replenishments*

* Customers who already have a C-Card may attend for replenishment of their cards.
* Trained staff can give out supplies as indicated in the C-card code.
* The card number should be recorded on PharmOutcomes or any other system commissioned by the Council, and the date and supplier recorded on the back of the card.
* Under 16’s should be given 8 condoms and over 16’s given 12 condoms on either new registrations or replenishment. This should total to a maximum of 24 condoms per a month.

4.1.2 Chlamydia and Gonorrhoea (CnG) Screening Kits

* Every customer aged 13-24 will be offered a Chlamydia and Gonorrhoea screening kit plus an additional kit(s) for their partner(s).
* Pharmacies will be provided with Chlamydia and Gonorrhoea self-sampling kits free of charge through the specialist sexual health provider (currently Barts Health).
* Kits can be reordered using the form template provided in PharmOutcomes or any other system commissioned by the Council and emailed to The Doctors Laboratory (TDL).
* Customers provided with a Chlamydia and Gonorrhoea self-sampling screening kit can find instructions on how to use it inside the kit.
* Customers should be advised to return samples in the sealed bag and complete the forms provided to the laboratory as detailed in the instructions. If this this is a barrier to the customer taking the screen, the pharmacy should offer to take the sample in store where toilet facilities are available to customers. Support should be provided to complete the sample form and/or return the sample(s) on behalf of the customer.
* Customers can be signposted and obtain free of charge screening kits from the Integrated Sexual Health Service and online at <https://www.shl.uk/>.
* Pharmacies must ensure that each screening kit includes pharmacy details (name and NHS site code) to ensure payment is made.
* The mandated sections on PharmOutcomes or any future information management system commissioned by the Council must be completed prior to distributing any kits.
* Reported activity on PharmaOutcomes or any other system commissioned by LBN will be used to generate quarterly invoices.
* Payments will be made based on usable samples received by The Doctors Laboratory (TDL) and positive results identified by TDL.

Chlamydia Treatment

Initially, chlamydia treatment is not part of the contract. This may change over the life of the contract. Patients testing positive will be notified by All-East Integrated Sexual Health Service and advised where to go for treatment.

Online training to access.

**Staff competencies and training**

All Lead Pharmacists and counter staff delivering this service are required to meet the following specific sexual heath requirement and must demonstrate:

* Ability to provide sexual health information, advice and signposting to All East Integrated Sexual Health Service (Bart’s Health) and local healthy lifestyle services.
* The safe and effective use of condoms.
* Knowledge of contraception, STIs and safer sex.
* Ability to conduct a C-Card consultation and issue a card.
* Ability to facilitate customers to do a Chlamydia and gonorrhoea self-test.
* Effective communication with customers about sexuality and healthy lifestyles.
* Lead Pharmacists and counter staff are required to attend training provided by All East Integrated Sexual Health Service (Bart’s Health) or any other provider commissioned by the Council to deliver this service. Training includes but not limited to:
  + Introduction to sexual health in pharmacies
  + Condom card (c-card) training
  + CnG self-testing kit
  + Child protection and child sexual exploitation (CSE) training

Training needs will be reviewed regularly to monitor changing needs, improve service quality and implement clinical changes and good practice recommendations. In addition, Lead Pharmacists shall be responsible for identifying their own learning needs and recording their Continuing Professional Development (CPD).

Pharmacies should also undertake continuing professional development regularly by at least one member of staff, who will if necessary, cascade the messages to other staff involved in the service.

**Payment Tariffs - Core Service**

Pharmacies will be paid for outcomes delivered. Sexual Health tariffs are set out in the tables below. The Council retains the right to cap payments if required in order to stay within the available annual budget.

|  |  |
| --- | --- |
| Activity | Tariff |
| Chlamydia and gonorrhoea screening kit returned to the relevant laboratory and accurately coded on Pharmoutcomes. | £5.00 per screen |
| Chlamydia and gonorrhoea positive case found and accurately coded on Pharmoutcomes | £15.00 per case |
| C Card  New C Card customer registration  C Card re-registration (lost or expired cards only)  Replenishment  Emergency supply | £10.00  £2.50  £1.50  £1.50 |
| LARC referral to GP or All East Integrated Sexual Health service | £5.00 |

**Service Standards**

The specific national standards and guidance related to Sexual Health include, but are not limited to:

* The Manual for Sexual Health Advisers. <http://www.ssha.info/wp-content/uploads/ha_manual_2004_complete.pdf>
* Service Standards for Sexual and Reproductive Healthcare (FSRH 2016)
* UK National Guideline on Safer Sex Advice (BASHH & BHIVA 2012)
* Recommended Standards for Sexual Health Services (MEDFASH 2005)
* Progress and Priorities - Working Together for High Quality Sexual Health (MEDFASH 2008)
* National Standards for the Management of Sexually Transmitted Infections (BASHH 2019)
* Chlamydia Screening Programme Standards (7th Edition 2018)
* PH3 One to one interventions to reduce the transmission of sexually transmitted infections (STIs) including HIV, and to reduce the rate of under 18 conceptions, especially among vulnerable and at risk groups (NICE 2007)

4.2 Smoking Cessation Service

**Strategic Context**

Public Health Outcomes Framework 2016-19

The PHOF indicators that are relevant to the smoking cessation service specification are:

* Number of 4 week stop smoking quits.
* Smoking prevalence at age 15
* Smoking prevalence – adults (over 18s)
* Smoking status at time of delivery.

**Local Context**

Newham is one of the most diverse boroughs in the country with 76% of the population from Black, Asian and Minority Ethnic (BAME) groups. The borough is also affected by long-standing deprivation and inequality. Smoking remains the biggest cause of mortality and morbidity in Newham; costing local authorities, local businesses and the NHS an estimated £74.2m annually[[8]](#footnote-9).

The prevalence of smoking amongst adults in Newham is 13.8%, which is higher than the London average (12.9% respectively)[[9]](#footnote-10) From 2012-2016, smoking prevalence in Newham increased, in contrast to the decreasing trend in both London and England as a whole.[[10]](#footnote-11)￼.

Smoking prevalence amongst routine and manual workers (2018) in Newham is the same of that in England but higher than the average for London. Currently, 25.4% of manual and routine workers smoke in Newham, with the London average being 23.6%. Smoking rates amongst people with a mental health condition are higher than in the general population.

The gender split for smokers in Newham is significant – with over a quarter of men admitting to smoking (25.3%), compared to just over 9% of women. Custom House and Canning Town neighbourhood shows the highest proportion of smokers at 23.6% (on 1st April 2018). These areas are the most deprived in Newham. Other priority groups include routine and manual workers; pregnant women; children and young people; minority ethnic groups including the Gypsy, Roma and Traveller community; people with mental health issues; hospital patients and people with long term conditions.

In those households working in routine and manual job roles, nearly half will have started smoking before the age of 16. This compares to one third in managerial and professional households. Newham has a greater socioeconomic gap between current smokers compared to London (odds of being a smoker in a routine and manual occupation vs being a non-smoker in other occupations). Newham has the 4th highest deprivation score in London at 32.9 and ranks as the 21st most deprived borough in England[[11]](#footnote-12).

The health risks for babies of women who smoke are substantial. Smoking can cause complications in pregnancy and labour, including ectopic pregnancy, bleeding during pregnancy, and premature detachment of the placenta. Babies born to women who smoke during pregnancy are more likely have low birth weight. Furthermore, around 40.0% are more likely to die within the first four weeks of life than are babies born to non-smokers[[12]](#footnote-13). For pregnant women, the smoking status at time of delivery rate for Newham is 5.0%, which is the same as the London average, and better than the England average of 10.8%[[13]](#footnote-14).

Newham has a significantly lower smoking quit rate than England and London. The number of quits has declined substantially over the last 5 years from 910 in 2014/15 to just 337 in 2018/19[[14]](#footnote-15).

Young people

People who start smoking at a young age have higher prevalence rates for all types of tobacco-related cancers, and short & long-term respiratory symptoms than their non-smoking peers in their age group. Those who start smoking during childhood are more likely to continue smoking as adults, and less likely to give up than those who start smoking in later life[[15]](#footnote-16).

In England, the proportion of children aged 8 to 15 who had ever smoked has decreased from 19.0% in 1997 to 5.0% in 2017. The proportion of children who had ever tried smoking generally increased with age, being much higher among those aged 13 to 15 than among younger children[[16]](#footnote-17).

Long Term Conditions

The Department of Health & Social Care defines a long-term condition (LTC) as one that cannot, at present, be cured by medication or other therapies. Such conditions include, although are not limited to, mental health, chronic obstructive pulmonary disease (COPD), diabetes, coronary heart disease (CHD), asthma, depression and HIV/AIDS[[17]](#footnote-18).

Smoking rates amongst customers with LTCs are often higher than those of the general population and, in many cases; smoking has directly contributed to the development of an LTC. Despite this, however, only a small proportion of people with a LTC receive stop smoking interventions.

Smoking and substance misuse

The link between smoking and alcohol dependence is particularly strong, with alcohol use disorders associated with regular, more dependent smoking. Alcohol dependence, which occurs in 6% of the adult population in England, is associated with a smoking prevalence of 46%[[18]](#footnote-19).

Smoking related hospital admissions

Hospital admissions attributable to smoking (2017/18) account for 1,220 per 100,000 hospital admissions in Newham, this is lower than the London and England average at 1,370 per 100,000 and 1,530 per 100,000 respectively. However, smoking attributable mortality in Newham is 254.3 per 100,000, higher than London as a whole and ranking as the 11th worst in London[[19]](#footnote-20).

Smoking is the single biggest avoidable risk factor for cancer. Tobacco smoke is estimated to be responsible for 3 in 20 cancer cases in the UK[[20]](#footnote-21). Tobacco is estimated to have caused 43,000 cancer deaths in the UK in 2010, amounting to 27% (31% in male and 23% in female) of all cancer deaths[[21]](#footnote-22).

The main causes of preventable death in Newham are cardiovascular disease, cancers, respiratory disease, mental health and musculoskeletal diseases[[22]](#footnote-23). Premature mortality is strongly linked to the socio-economic factors associated with high levels of deprivation[[23]](#footnote-24). Newham is the fourth most deprived borough in London with a deprivation score of 32.9 and, comparing to 21.8 in England.

The rate of respiratory disease related deaths under 75 years of age (2015-2017) is high compared with the London average, particularly for males. For males, this is 51.4 per 100,000 compared to the London average of 38.1 per 100,000. For females, this is 23.8 per 100,000 compared to the London average of 22.8 per 100,000. The under 75 rate from all cardiovascular disease (2015-2017) is 100.2 per 100,000, the second highest in London and very high comparing to the London average (73.2 per 100,000). The rate was particularly high in men with 127.7 per 100,000. The under 75 mortality rate from cardiovascular disease considered preventable was 59.1 per 100,000, the 3rd highest in London, comparing to 44.9 per 100,000[[24]](#footnote-25).

Newham has the sixth highest mortality rate from COPD in London with a rate of 65.6 per 100,000 compared to 47.7 per 100,000 in London and 52.7 per 100,000 in England. The mortality rate is particularly high in men with 87.7 per 100,000 comparing to 59.4 in London and 64.1 per 100,000 in England[[25]](#footnote-26).

**Service Aim**

Pharmacy-based stop smoking services are available to patients that want to quit through a pharmacy and are not classed as a member of a ‘priority’ group. The Specialist Stop Smoking Service (SSSS) will treat priority smokers.

The specific aims of the pharmacy-based stop smoking offer include:

* Increase the availability of high quality, cost effective stop smoking interventions in Newham by working closely with the SSSS
* Deliver an evidence-based cessation service in line with the National Institute of Clinical Excellent (NICE), Department of Health and Social Care (DHSC) and National Centre for Smoking Cessation and Training (NCST) guidance.
* Increase the use of pharmacotherapy in smoking cessation to support 4 and 12 week quits.
* Provide people motivated to quit smoking tailored support through weekly one to one and/or telephone interventions, pharmacological support including NRT, and Champix for a maximum of 12 weeks.
* Provide information, very brief advice (VBA), signposting and where applicable referral to healthy living / health care services in Newham.
* Promote national and local health campaigns to raise awareness and access to pharmacy services and/or local health services.
* Promote and support sustained healthy living behaviour change interventions.
* Deliver services underpinned by the ethos, principles and practices of Making Every Contact Count (MESS), You’re Welcome and Healthy Living Pharmacies (HLP).

**Service Outcomes**

Smoking cessation services are expected to achieve the following outcomes:

* Increase the number of residents receiving stop smoking support
* Increase the number of people setting a four week stop smoking quit date and achieving it (quit conversion rate) to a minimum of 60%. The National Institute of Clinical Excellence (NICE) recommends a quit conversation rate range of 35-70% of those quitting smoking within 4 weeks.
* 85% of people who smoke, set a four-week quit date will be assessed for carbon monoxide (CO) levels 4 weeks to validate quit status and/or monitor progress.
* Increase the number of residents successfully quitting smoking at 12 weeks.
* Meet NICE guidelines for 5% of the smoking population to receive stop smoking support.
* Reduce the prevalence of smoking related illness and premature deaths in Newham – impacting on reducing smoking related socio-economic and health inequalities.
* Improve general health and wellbeing of residents
* Work in partnership with the Councils Trading Standards team to support reducing illegal tobacco trading and participate in local and national campaigns (such as tobacco control roadshows).

**Eligibility**

Smoking cessation services are available to:

* A Newham resident
* Aged 12+
* A current smoker of a tobacco product.

**Service Referrals**

Residents motivated to quit smoking can self-refer to the stop smoking service. Referrals can also be made to and from the SSS, with higher-risk ‘priority’ smokers (and smokers that have previously tried and failed to quit) to be referred by pharmacies to the SSS. Similarly, smokers that want to quit via a pharmacy and are not considered a ‘priority’ will be referred to their nearest pharmacy by the SSSS.

*See Appendices 3: Smoking cessation pathway between pharmacies and specialist service*

**Interventions**

Assessment

**Smokers who have completed the quit smoking motivation tool should be offered an assessment. The assessment session / visit should take at least 30 minutes and should cover the following:**

* **Assess**the customer’s dependence on nicotine to help predict the severity of withdrawal symptoms they may experience.
* Ask about the two most important indicators of dependence and score the customers nicotine dependence. Indicators include:  depending on their answers:
* How many cigarettes they smoke per day
* How soon after waking they smoke their first cigarette
* The higher the score, the greater the level of nicotine dependence
* Previous quit attempts, how successful were they.
* Use of pharmacotherapy treatment
* Customer’s experiences of withdrawal symptoms and cravings.
* Ask about the persons medical history, and identify people in specific groups that may be at high risk of tobacco-related harm, including:
  + People with mental health conditions
  + People who misuse substances.
  + People with a smoking-related illness (for example lung cancer).
  + People with medical conditions exacerbated by smoking: Asthma, cardiovascular disease, chronic obstructive pulmonary disease, type one diabetes mellitus.
  + Women who are pregnant.
  + Households' members of any smokers
* Ask about current medication that may be affected by stopping smoking or starting smoking cessation treatment. Lead Pharmacists must refer to the Champix PGD for a list of medications and seek further clarification using relevant reference sources such as the latest edition of the British National Formulary (BNF).
* Ensure Lead Pharmacist cross-references the customer current medication profile, when supplying any smoking cessation product.
* Confirm if the customer is not receiving smoking cessation services and treatment from another Newham smoking cessation provider.

Carbon Monoxide Monitoring

Carbon monoxide (CO) is an odourless, tasteless and poisonous gas that is present in tobacco smoke. CO in expired breath is measured in particles per million (ppm). CO monitoring is a more accurate indicator / reading of smoke intake than the number of cigarettes smoked per day. Providers must:

* Use the CO monitor loaned (free of charge) from the Council and follow instructions on how to use it.
* Ensure CO readings are routinely taken (in line with the customer quit plan) and recorded throughout the treatment period.
* Use the CO reading charter provided on PharmOutcomes to interpret and clearly communicate results to the customer.
* Ensure NICE[[26]](#footnote-27) requirements of a successful stop smoking quit is met:
* A successful 4 week quit is defined as a CO reading less than 10ppm at 4 weeks after the quit date has been set.
* A successful 12 week quit is defined as a CO reading less than 10ppp at 12 weeks after the quit date has been set.

Pharmacies are responsible for the care, storage and maintenance of the CO monitor(s). Any equipment failure or damages should be reported by the Pharmacy to the supplier Intermedical Supplies at [sales@intermedical.co.uk](mailto:sales@intermedical.co.uk) and the Commissioner to minimise any service disruption and agree an interim solution (such as a replacement monitor). Should the Pharmacy be decommissioned or no longer wish to provide the service the monitor must be returned to the Commissioner.

Pharmacies must maintain sufficient stock supplies at all times, particularly during busy periods throughout the year (such as Stoptober and New Year). Providers can request stock replenishment products (mouthpieces and alcohol free wipes) by completing the PharmaOutcomes order form and returning it to the Commissioner for authorisation and processing.

Quit Plan

All customers following an assessment should set a four week quit date supported by a quit plan. Pharmacies should use the quit plan template available in PharmOutcomes (or any other system commissioned by the Council). The quit plan should include:

* Agreed treatment option (NRT, Champix or a combination of both)
* Agreed behaviour support
* Frequency of support (weekly, fortnightly or any other option advised by the customer)
* Method of support (face to face, telephone session, texting or Skype)
* Quit smoking support network (such as peer, family support, removal of lighters and ashtrays).
* Discuss and agree coping strategies
* Progress review
* Validation of CO reading and self-reporting.

Nicotine Replacement Therapy

Nicotine Replacement Therapy (NRT) has a significant impact on helping smokers to quit smoking. NRT can help people who make a quit attempt to increase their chances of successfully stopping smoking. NRTs can reduce the rate of smoking by 50-70%[[27]](#footnote-28).

NRT should be offered in combination with additional behaviour support interventions. NRT products include but is not exhaustive to gum, patches, nasal spray, inhaler and tablets/ lozenges. Dispensation of NRT products must follow product and NRT guidance.

Varenicline

Varenicline (also known as Champix) is a prescription medication used to treat nicotine addiction. It reduces both craving for and decreases the effects of cigarettes and other tobacco products.

Providers must assess customer suitability of Champix and its dispensation in accordance with the Champix Patient Group Directions (PGD). Refer to appendix 2.

Advice on e-cigarettes

Pharmacy staff should take every opportunity to encourage smokers to stop smoking, and should assist them in their attempts to quit using evidence based treatments and behavioural support available.

NICE guidance[[28]](#footnote-29) recommends people who smoke and who are using, or are interested in using, a nicotine-containing e‑cigarette on general sale to quit smoking, must be provided with the following advice:

* E-cigarette products are not licensed medicines; they are regulated by the Tobacco and Related Products Regulations 2016.
* Many people find e-cigarette helpful to quit smoking cigarettes.
* People using e‑cigarettes should stop smoking tobacco completely, because any smoking is harmful.
* Evidence suggests that e‑cigarettes are substantially less harmful to health than smoking but are not risk free.
* Evidence in this area is still developing, including evidence on the long-term health impact.

It is expected over the contract period of this service vaping may be prescribed as an intervention to support people to quit smoking. If a smoker is assessed as motivated to quit, is seeking cessation support and it is known that they are using electronic cigarettes as part of a quit attempt, they may be eligible for treatment in line with this service specification.

Follow up visits

NCST recommend weekly follow up sessions for the first four weeks and regularly sessions (frequency agreed by the customer) for a further 8 weeks if a customer aims to quit by 12 weeks. Follow up sessions should take approximately 10-15 minutes and should cover:

* On-going review and/or newly identified issues following previous session.
* Review motivation level.
* Monitor CO reading and re-issue medication.
* Record all information on PharmOutcomes (of any other system commissioned by the Council).
* If a customer misses an appointment, three separate attempts must be made by the Pharmacy to contact the customer to offer support in person or via telephone. All face-to-face follow up visits must take place in the pharmacy.

**Staff training**

All Lead Pharmacists and counter staff delivering this service are required to meet the following specific smoking cessation related training.

All Pharmacy staff must be trained to National Centre for Smoking Cessation and Training (NCSCT) stage 2 assessment level. Pharmacies should also undertake continuing professional development on a regular basis by at least one member of staff, who will if necessary, cascade the messages to other staff involved in the service.

Lead Pharmacists should receive training on the use of PGD Champix every three years unless specified by clinical guidance or by LBN.

Lead Pharmacists shall be responsible for identifying their own learning needs and recording their Continuing Professional Development (CPD).

**Quality Assurance and Governance**

No specific items

**Payment Tariffs**

Pharmacies will be paid on a payment for outcomes delivered. Smoking cessation tariffs are set out in the tables below. The Council retains the right to cap payments if required in order to stay within the available annual budget.

Standard Payment Tariff – Maximum Available

|  |  |  |  |
| --- | --- | --- | --- |
| General Population | 4 week validated | 4 week self-reported | 12 week validated |
| Cost per customer | £60.00 | £10.00 | £80.00 |

Additional Tariffs

Additional tariffs may be introduced during the contract.

Providers will be given the option of accessing NRT through a Local Authority Framework, or providing NRT at a set cost off the Framework.

Pharmacies will be reimbursed for NRT and Champix supplies. Payment for these medications will be reimbursed according to the list price set out on the British National Formulary (BNF). Prices will be revised on a regular basis by PharmOutcomes or any other system commissioned by the Council.

Payment for these medications will only be made where the information and data has been recorded on PharmOutcomes or any other system commissioned by the Council.

**Service Standards**

Pharmacies must be able to demonstrate they meet applicable national standards and guidance. These include, but are not limited to:

* NICE Guideline 92 – Stop smoking interventions and services
* Public Health Guideline 45 – Smoking: Harm reduction
* Public Health Guideline 48 – Smoking: acute, maternity and mental health services
* Public Health Guideline 14 – Smoking: preventing uptake in children and young people
* Public Health Guideline 26 - Smoking: stopping in pregnancy and after childbirth
* Public Health Guideline 23 – Smoking prevention in schools
* Public Health Guideline 5 – Smoking: workplace interventions.

**Responsibilities of LBN:**

* Update Providers on changes to the pathway and protocols for smoking cessation,
* Submit PHE Stop Smoking Service returns quarterly.

1. Lot. 2 Specialist Requirements and Service Standards

Over the life of the PDPS and in response to identified need and/or policy developments, the Council – in consultation with providers – may seek to add core services to the scope of the service specification or amend existing core services.

Specialist services currently within scope are:

2a. Emergency Hormonal Contraception (EHC)

2b. Needle Exchange & Naloxone Service

Supervised consumption

**Lot 2a. Emergency Hormonal Contraception (EHC)**

**Aims of service**

Reduce unintended conceptions for women aged 16 to 24 by improving access to Emergency Hormonal Contraception (EHC). Over the life of the contract, the age range may be subject to change.

**Eligibility**

Women aged 16-25 for EHC

**Exclusion criteria**

The service or any treatment could be withheld from a customer:

* Who has not validly consented to the services
* Who is unsuitable (or temporarily unsuitable) on clinical grounds.

Interventions - assessment

Ensure pharmacy staff direct requests for EHC and chlamydia treatment discreetly to the Lead Pharmacist.

**Service description**

Emergency hormonal contraception (EHC) can prevent pregnancy after unprotected sex or if the contraception used has failed – for example, a condom has split or a customer has missed the oral pill.

Lead Pharmacists or any pharmacist who has done the PGD training will supply Levonorgestrel EHC to customers aged 13-24 that report an Unprotected Sexual Incident (UPSI) within the past 96 hours (4 days).

Lead Pharmacists or any pharmacist who has done the PGD training will supply Ella One EHC to customers aged 13-24 that report an Unprotected Sexual Incident (UPSI) between 72 and 120 hours (i.e. 3-5 days ago).

All provision will be in line with the requirements of a locally agreed Patient Group Direction (PGD) to females aged between 16–24 years old. Pharmacies will offer a user-friendly, non-judgmental, customer-centred and confidential service.

The essential elements of the pathway for EHC remuneration are outlined below:

* + Deliver Chlamydia and Gonorrhoea screening
  + Complete Audit C alcohol screen
  + Issue condoms
  + C-Card subscription
  + Supply EHC

Supply will be made free of charge to the customer at LBN expense. Lead Pharmacists will offer to refer EHC customers to the All East Integrated Sexual Health Service, Shine service or their GP for long acting reversible contraception (LARC) services.

The pharmacy will provide support and advice to customers accessing the service, including advice on the avoidance of pregnancy and sexually transmitted infections (STIs) through safer sex and condom use, advice on the use of regular contraceptive methods and provide onward signposting to services that provide long-term contraceptive methods and diagnosis and management of STIs.

Pharmacies should promote and offer chlamydia and gonorrhoea screening and three free condoms to all customers aged 13-24 requesting EHC.

* Customers excluded from the PGD criteria include;
  + Under 13 years of age
  + Customers aged under 16 if not Fraser competent
  + Pregnant
  + Any known hypersensitivity to EHC Levonorgestrel or Ella One or other ingredients of product used.
  + More than 72 or 120 hours (depending on EHC used) since unprotected sexual intercourse (UPSI)

Pharmacies must refer excluded customers through PharmOutcomes to another local service that will be able to assist them, as soon as possible, e.g. their GP or All East Integrated Sexual Health Services.

All customers supplied with EHC should receive information, advice and the benefits of long acting reversible contraception (LARC). Customers should be offered an electronic referral to their GP or the All East Integrated Sexual Health service to discuss LARC options.

Essential Training and PGD requirements

The registered healthcare professional authorized to operate under the EHC PGD must have undertaken appropriate education and training and successfully completed the competencies to undertake clinical assessment of patients ensuring safe provision of the medicines listed in accordance with local policy. Refer to EHC PGD in Appendices 1 for more details.

Repeat use of EHC is a marker for poor sexual reproductive health (SRH) and / or a safeguarding concern, especially for younger patients. Training provided by NHS Barts Health will outline the protocols for pharmacists when dealing with repeat EHC users and pharmacists are expected to refer these patients to the specialist SRH provider (NHS Barts Health).

EHC Pathway Alcohol screening

AUDIT (Alcohol Use Disorders Identification Test) is an alcohol screening tool that can help identify people who are hazardous drinkers or have high alcohol use disorders (including alcohol abuse or dependence).

Customers over the age of 16 accessing pharmacy sexual health services should be offered a brief alcohol screening questionnaire. The brief AUDIT C template can be found in PharmOutcomes or any Pharmacy monitoring system commissioned by the Council.

A full AUDIT 10 assessment may be required following completion of the brief AUDIT C screening questionnaire. If the customer meets or exceeds the AUDIT C threshold of five the pharmacy will conduct a full AUDIT 10, by completing the further questions.

A customer will then fit into one of the follow categories:

* + 0 – 7 Lower risk,
  + 8 – 15 Increasing risk
  + 16 – 19 Higher risk
  + 20+ possible dependence

Lead Pharmacists can also refer a customer scoring 16+ to Newham Rise CGL services (substance misuse provider) for further specialist support by completing the electronic referral available on PharmOutcomes.

**Tariffs for delivering EHC**

|  |  |  |
| --- | --- | --- |
| Emergency Hormonal Contraception Consultation (LNG) | Emergency Hormonal Contraception Consultation (UPA) | Completed AUDIT C/10 during EHC consultation |
| £24.00 | £33.00 | £5.00 |

**Lot 2b. Needle Exchange & Naloxone Service**

**Strategic Context**

Widespread provision of pharmacy needle exchange services are a vital part of harm minimisation strategies.

NICE Guidance (PH52) 2014[[29]](#footnote-30) advised that pharmacy needle exchange and syringe programmes are a cost-effective way to reduce the risks associated with transmission of blood borne viruses, infection caused by sharing equipment such as HIV, hepatitis B and C and other harms caused by drug use. Several European studies, outlined in a recent Cochrane review[[30]](#footnote-31), shows that needle exchange programmes are associated with a 50% to 60% reduction in the risk of people who inject drugs acquiring hepatitis C.

The Drug Strategy 2017 [[31]](#footnote-32)sets out the government’s approach to tackling drug use and dependence. The strategy continues the government’s approach to drug treatment, with the aspiration that all who need it should be supported to lead drug-free lives. The service will also contribute to the achievement of Newham’s 50 Steps Health and Wellbeing Strategy, specifically:

Step 24: Work to prevent communicable disease with particular focus on hepatitis C eradication, TB, sexual health and late diagnosis of HIV, as well as COVID-19The clinical guidelines on Drug Misuse and Dependence Update 2017 (orange book) state “Systematic reviews conclude that pre-provision of naloxone to heroin users can be helpful in reversing heroin overdoses. There is also evidence for the effectiveness of training family members or peers in how to administer the drug[[32]](#footnote-33).

Public Health Outcomes Framework

PHOF indicators that are relevant to needle exchange & naloxone service specification are:

* The rate of drug misuse deaths per million population over a three-year period
* Number of users of opiates that left drug treatment successfully (free of drug(s) of dependence) who do not then re-present to treatment again within 6 months as a proportion of the total number of opiate users in treatment.
* Number of users of non-opiates that left drug treatment successfully (free of drug(s) of dependence) who do not then re-present to treatment again within 6 months as a proportion of the total number of non-opiate users in treatment.

**Local Context**

**Needle Exchange**

The uptake of the service in 2021 is averaging at 565 packs being distributed per month. This is a reduction on previous years but there is still demand despite the restrictions imposed by the pandemic. In previous years the average was approximately 700 packs per month.

**Naloxone**

Naloxone supply by Newham pharmacies continues to be low. Actions will be undertaken to raise awareness of the benefits of naloxone in reducing drug related death and opiate overdose and that pharmacists are trained in engaging those patients around naloxone.

**Service Aims**

The needle exchange service aims:

* To provide advice on harm minimisation and safer injecting practices.
* For those customers accessing needle exchange services due to opiate use, engage them on the use of naloxone and distribute naloxone to them.
* Provide naloxone training to these customers, families and carers, on safer injecting and the use of the naloxone kit.
* To support access routes and referral for customers to other health and social care services and to act as a gateway to other services (e.g. specialist substance misuse services, which include substitute prescribing, hepatitis B immunisation, and screening for hepatitis C and HIV, sexual health services), as well as reinforcing harm reduction messages including safe sex advice and BBV immunisation advice.
* Ensure that those requiring needle exchange are also advised of other Pharmacy-based services included in this specification (smoking cessation and sexual health)
* Reduce the rate of sharing and other high risk injecting behaviours.
* Advice on overdose prevention (e.g. risks of poly-drug use and alcohol use).
* To reduce the amount of used injecting equipment in the community by actively encouraging more returns

**Service Outcomes**

The Needle exchange/naloxone programme is expected to contribute to the following outcomes:

* A reduction in the number of people acquiring BBVs, particularly Hep C and HIV
* An increased awareness of harm reduction and safer injecting practices amongst injecting drug users
* A reduction in the number of incidents of needle exchange waste being disposed of and an incorrect, unhygienic or risky manner.
* A reduction in overdose and drug-related deaths

**Eligibility**

Needle exchange service is available to:

* Anyone over the age of 18.

**Exclusion criteria**

People aged 17 and under are excluded from this service. However, young people aged 17 or under should be referred to the young peoples’ specialist service, which will arrange access to needle exchange. Please see below contact details for Newham YP service (CGL).

The contact details for CGL Newham (Young People & Adult substance misuse services)

Newham YP Service (CGL)

[www.newham-yp.org](http://www.newham-yp.org)

[NewhamYP@cgl.org.uk](mailto:NewhamYP@cgl.org.uk)

07741 196 424

CGL Newham Rise

newham.referrals@cgl.org.uk.

0800 652 3879

**Service Referrals**

Needle exchange and take home Naloxone provision are open access services.

**Priority populations**

N/A

**Interventions (including take home naloxone for opioid overdose prevention)**

*Needle exchange*

* 1. This service will be offered to injecting drug users, their family and friends. .
  2. The pharmacies should pro-actively raise awareness of the integrated adult and young people treatment service (CGL) on offer in Newham.

*Take home Naloxone provision*

1. The naloxone dispensing has to be delivered by a Lead Pharmacist who has completed locally arranged training (at the start of the contract), and has been deemed competent by the Lead Pharmacist in charge. The training is organised by LBN and facilitated by the Integrated adult and young people substance misuse service (CGL)
2. All users accessing the needle exchange service should be encouraged by the Pharmacy to take up offer of naloxone and should be trained on how to respond appropriately to overdose and how to administer the naloxone injection in the event of an opioid overdose.
3. The dispensing of naloxone will include training on information on harm minimisation and the benefits of naloxone. When training has been delivered to the customer, a take home naloxone kit may be issued.
4. Naloxone dispensing activity must be recorded on PharmOutcomes to trigger payments.

**Staff training**

The specific competences and training requirement for Needle Exchange and take-home naloxone are:

Lead Pharmacists participating in the scheme will be expected to have successfully completed the CPPE Substance use and misuse modules (4):

Module 1 – Substances of misuse (3 hours)

Module 2 – Harm reduction (3 hours)

Module 3 – Communication with patients and support networks (3 hours)

Module 4 – Provision of Services (3 hours)

AND

RCGP Hepatitis C: Enhancing Prevention, Testing and Care online course

Copies of CPPE and RCGP certificates must be provided to the LBN on request. Lead pharmacists should undertake these courses every two years as refreshers.

**Locally commissioned training**

Lead Pharmacists will attend one full day or 2 half days training session per year. The first attendance needs to have taken place in the first year of the contract and refresher courses attended as required. Training is provided by the Newham Rise Integrated adult and young people substance misuse service which will include awareness training and treating people in non-judgemental way.

**Mystery shopping exercises**

Mystery shoppers will be used throughout the life of the contract to ensure service users are receiving a high quality non-judgmental service. Mystery shopping exercises will be developed in consultation with the contractor body and the results used for learning and development of training.

**Locums**

Local replacement Lead Pharmacists working in these pharmacies are expected to comply with all aspects as described above; the responsibility for this lies with the contractor.

The pharmacy should ensure that their staff are trained appropriately, particularly with regard to the risks associated with the handling of returned used equipment and the correct procedures are used to minimise those risks.

It is the responsibility of the Lead Pharmacist to ensure all relevant pharmacy staff and Lead Pharmacists’ training is up-to-date at least annually.

The declaration of training and reading and signing the SOP will need to be confirmed on PharmOutcomes via enrolment. There will be a three month grace period from the start of the service: after this if not completed you will not be able to deliver the service.

**Quality Assurance and Governance**

No specific items.

**Payment Tariffs**

Pharmacies will be paid for outcomes delivered. Tariffs are set out in the table below. The Council retains the right to cap payments if required in order to stay within the available annual budget.

Standard Payment Tariff

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| General Population | Initial per pack + consultation (naloxone) | Subsequent per pack (naloxone) | Per needle pack issued | Per needle pack returned |
| Cost per customer | £15.00 | £10.00 | £2.00 | £2.00 |

**Service Standards**

Pharmacies must be able to demonstrate they meet applicable national standards and guidance. These include, but are not limited to:

* NICE Needle & Syringe Programmes (NSP’s) Guidance PH52 Guidance 2014 <http://www.nice.org.uk/guidance/ph52>
* Royal Pharmaceutical Society of Great Britain (RPSGB) Continuing Professional Development
* Community engagement: Improving health and wellbeing, and reducing health inequalities- NICE guideline NG44 (2016)
* Drug misuse prevention: Targeted Interventions. NG64 (2017)
* Take home naloxone for opioid overdose in people who use drugs

<https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/669475/phetake-homenaloxoneforopioidoverdoseaug2017.pdf>

* Drug misuse: opioid detoxification. NICE clinical guideline 52 (2007)
* Drug misuse: psychosocial interventions. NICE clinical guideline 51 (2007).
* The pharmacy will have in place an SOP dealing with needle stick injuries and rapid access to PEP (Post –Exposure Prophylaxis).

**Responsibilities of LBN:**

* Ensure the provision of exchange packs and associated materials and a clinical waste disposal service for each participating pharmacy. Waste collection will be agreed to ensure that there is not an unacceptable build-up of clinical waste on the pharmacy premises.
* To provide details of relevant referral/ inter referral points, which pharmacy staff can use to signpost customers, who require further assistance.
* To provide health promotion material relevant to the customers and make this available to pharmacies.

**Lot 2b. Supervised Consumption Service**

**Strategic Context**

The Department of Health Controlled Drugs (Supervision of Management and Use) Regulations 2013 sets out guidance to continue to promote good governance concerning safe management and dispensing of controlled drugs[[33]](#footnote-34). Supervised consumption can also reduce the availability and impact of diverted drugs on the illicit market.

Lead Pharmacists play a crucial role in building a therapeutic relationship with customers that is beneficial in promoting heath and harm reduction through regular contact. They also have a key role in the care of the adult drug users receiving opiate replacement therapy and are therefore crucial in care planning and the management of customers’ ongoing treatment.

Through the provision of supervised consumption of methadone, buprenorphine or Suboxone, the Lead Pharmacist assists in:

* Supporting customers in complying with their prescribed regime.
* Reducing incidents of accidental death through overdose.
* Keeping to a minimum the misdirection of controlled drugs, which may help to reduce drug related deaths in the community.

**Local Context**

Within Newham, there are currently 117 customers on supervised consumption (December 2020). Pre- pandemic there were 245. Supervised consumption is normally applied to a customer’s regime at the start of treatment to assist with compliance, building routine and above all else, to ensure the safe and proper use of a controlled drug. As customers become stable and comply with their medication regime and programme of structured psychosocial interventions, customers will be moved onto take away doses.

Supervised consumption is also used as part of a treatment plan for high-risk individuals to keep them safe and ensure compliance with medication regimes. The specialist treatment provider for substance misuse in Newham is expected to work closely with Lead Pharmacists operating on the Specialist Pharmacy Service Contract to provide a holistic approach to treatment, which ensures the Lead Pharmacist is part of the care planning process.

**Service Aims**

To supervise the consumption of prescribed medicines at the point of dispensing in the pharmacy, ensuring that the customer has consumed the prescribed dose currently.

To ensure customers are compliant with their agreed treatment plan by:

* Dispensing their medicines in specified instalments as instructed on the prescription.
* Supervising the consumption of the prescribed medicines at the point of dispensing to ensure that the prescribed dose has been correctly consumed by the customer.

To reduce the risk to local communities of:

* Diversion of prescribed medicines onto the illicit drugs market
* Accidental exposure to prescribed medicines
* To provide customers with regular contact with healthcare professionals and to help them access further advice or assistance.

**Service Outcomes**

The provision of supervised consumption can contribute to the following outcomes:

* A reduction of the over or under use of medicines in amongst opiate users.
* A reduction in the diversion of controlled drugs onto the illicit drugs market.
* The elimination of accidental exposure to methadone or buprenorphine and the associated harms.

**Eligibility**

The service is available to adults (aged 18 years or over) who are in receipt of prescribed substitute medication as part of an active treatment programme for substance misuse where:

* Supervised administration is specified by the prescriber.
* The customer is a Newham resident.
* Selection of the pharmacy to provide treatment will be the decision of the customers, subject to the nominated pharmacy agreeing to commence treatment.

Accessibility

The pharmacy will ensure that there are no unreasonable or strict time restrictions are imposed on the customer for picking up medication doses.

The Lead Pharmacist will take appropriate steps to ensure they are confident of the identity of the customer before supervising each dose.

**Exclusion criteria**

N/A

**Service referrals**

Referrals for supervised consumption will normally come directly from the specialist drug treatment provider – CGL

**The Service**

The service will require the Lead Pharmacist to supervise the consumption of prescribed medications when indicated by the prescriber, ensuring that the dose has been administered appropriately to the customer.

Lead Pharmacists participating in this service will be expected to take on the number of customers that they feel appropriate for their pharmacy within the parameters of good practice advised by the local treatment service, taking into account all their community responsibilities.

Terms of agreement should be set between the prescriber / specialist treatment provider, Lead Pharmacist, and customer to agree how the service will operate, what constitutes acceptable behaviour by the customer, and what action will be taken by the prescriber and Lead Pharmacist if the customer does not comply with the agreement.

Lead Pharmacists will share relevant information with other health care professionals and agencies, in line with confidentiality arrangements.

The customer’s recovery key worker will be responsible for obtaining the customer’s agreement to supervised consumption.

The prescriber should contact the customers chosen pharmacy prior to the patient attending the pharmacy, to ensure the pharmacy has capacity to take on a new customer.

The prescriber will provide the Pharmacy with the customers’ details.

The pharmacy will provide a sufficient level of privacy for the customer and safety for staff. The pharmacy will support access routes for customers to other health and social care and to act as a gateway to other services particularly those offered on the framework i.e. stop smoking.

The pharmacy will continue to provide advice and support to customers who are moving from supervised consumption to daily pick-up and beyond, this may include referral back to the prescriber where appropriate.

The pharmacy **MUST** contact the prescribing service in any of the following circumstances:

* Drug related death in pharmacy premises\*.
* Overdose\*.
* Incorrect dispensing of any controlled substance\*.
* The customer is seen to be or suspected of selling, swapping or giving away their controlled medication.
* **For a single missed dose, the pharmacy must inform the prescriber within 24 hours.**
* Where **three** consecutive doses have been missed, the Lead Pharmacist will not supply a further dose and the customer should be referred back to the prescriber. **Following three consecutive missed doses,** **it** **It is extremely important that the pharmacy contacts the prescriber as soon as possible and must be within 24 hours.**
* When a service user does not present to the pharmacy with the prescription following arrangements agreed between the prescriber and the pharmacist
* Any other occasion when the Lead Pharmacist is concerned about the customer’s wellbeing.
* Where the customer:
  + Refuses to consume their dose as prescribed.
  + Is collecting erratically (even if not breaching the 3-day rule)
  + Is under the influence of drugs/alcohol resulting in the Lead Pharmacist making a professional judgement decision not to dispense a dose.
  + Shows clear signs of deterioration of physical and/or mental health.
  + Has been violent or has threatened violence.
  + Is involved in a serious or untoward incident that affects or may affect the expected outcome of the treatment.

Lead Pharmacists will share relevant information with other health care professionals and agencies, in line with locally determined confidentiality arrangements. The customer should be informed that information is being shared (unless to do so would put another person at risk e.g. in the case of suspected child abuse).

\*These events must be reported to the Commissioner via a Serious Incident report

**Interventions**

The Lead Pharmacist will make an assessment that it is safe to supply the medication before supervising the dose.

Preparation of medication:It is important that the dose is ready for the customer’s arrival. The whole operation should be as discreet and efficient as possible, maintaining the customer’s dignity and saving the Lead Pharmacist’s time. Doses that are collected for consumption on Sundays or bank holidays must be dispensed in a container with a child resistant closure. Customers must also be advised to store their medication out of the reach of children.

Methadone: The pharmacy will present the medicine to the customer in a suitably labelled receptacle and will provide the customer with water to facilitate administration and/or reduce the risk of doses being held in the mouth. If a customer’s dose is measured out in advance of their visit then suitable containers with lids should be used. These shall be individually labelled as per normal labelling regulations. Prior to disposal of these containers, all identifying labels shall be removed / anonymised. For those service users who have to measure their dose at home, they should be provided with measuring cups so that the correct dose can be administered.

Buprenorphine and Buprenorphine/Naloxone The pharmacy will prepare the dose. The customer will be provided with water (in a disposable cup) prior to issuing the dose, this may speed up the process of the medication dissolving under the tongue. The medication should be tipped directly under the tongue without handling. The customer will need to be supervised until the tablet has dissolved. This may take between 5-10 minutes. When most of the tablet is dissolved, and only a chalky residue remains, talk to the customer to determine the dose has fully dissolved. Offer a further drink of water. Crushing of tablets is Off Licence and therefore should not be undertaken unless the prescriber requires this. If required the prescriber must write this on the prescription and both the prescriber and customer must be aware that this is Off Licence.

Espranor: TBC

Buvidal: TBC

**Missed doses** – Pharmacy must advise the prescribing agency when a customer has missed a dose within 24 hours and record the missed dose on PharmOutcomes – every missed dose **must** be recorded on PharmOutcomes.

If the customer **misses three consecutive days,** the pharmacy must stop dispensing until advised otherwise by the prescriber.

**Irregular collection**: If a customer has a pattern of non-attendance, e.g. always missing the same day or regularly missing days each week, the pharmacy should advise the prescribing agency as their prescription/dispensing arrangements may require a review.

Maintaining records

* The pharmacy will maintain records of the service provided.
* All provisions will be recorded on PharmOutcomes, including all occasions when the customer fails to attend the pharmacy to collect a prescribed dose of medication.

**Staff requirements and training**

Prior to starting service provision, the Lead Pharmacist must have successfully completed:

Lead Pharmacists participating in the scheme will be expected to have successfully completed the CPPE Substance use and misuse modules (4):

Module 1 – Substances of misuse (3 hours)

Module 2 – Harm reduction (3 hours)

Module 3 – Communication with patients and support networks (3 hours)

Module 4 – Provision of Services (3 hours)

Copies of CPPE and RCGP certificates must be provided to the LBN on request. Lead pharmacists should undertake these courses every two years as refreshers.

**Locally commissioned training**

Lead Pharmacists will attend one full day or 2 half days training session per year. The first attendance needs to have taken place in the first year of the contract and refresher courses attended as required. Training is provided by the Newham Rise Integrated adult and young people substance misuse service which will include awareness training and treating people in non-judgemental way.

**Mystery shopping exercises**

Mystery shoppers will be used throughout the life of the contract to ensure service users are receiving a high quality non-judgmental service. Mystery shopping exercises will be developed in consultation with the contractor body and the results used for learning and development of training.

**Locums**

Local replacement Lead Pharmacists working in these pharmacies are expected to comply with all aspects as described above; the responsibility for this lies with the contractor.

The pharmacy should ensure that their staff are trained appropriately, particularly with regard to the risks associated with the handling of returned used equipment and the correct procedures are used to minimise those risks.

It is the responsibility of the Lead Pharmacist to ensure all relevant pharmacy staff and Lead Pharmacists’ training is up-to-date at least annually.

The declaration of training and reading and signing the SOP will need to be confirmed on PharmOutcomes via enrolment. There will be a three month grace period from the start of the service: after this if not completed you will not be able to deliver the service.

**Quality Assurance and Governance**

No specific items

**Payment Tariffs**

Pharmacies will be paid for outcomes delivered. Tariffs are set out in the tables below. The Council retains the right to cap payments if required in order to stay within the available annual budget.

Standard Payment Tariff

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| General Population | Per supervised dose of methadone/physeptone | Per supervised dose of Espranor | Per supervised dose of buprenorphine | Per supervised dose of Suboxone |
| Cost per customer | £2.50 | £2.80 | £2.80 | £2.80 |

**Service Standards**

Pharmacies must be able to demonstrate they meet applicable national standards and guidance. These include, but are not limited to:

* Drug Misuse and Dependence: UK GuidelinesonClinical Management in September 2017 (Orange book)

Role of the Prescriber

The Newham Community Drug & Alcohol Service (CGL) or GP commissioned under the GP Shared Care arrangements will ensure that all customers undergo a comprehensive assessment.

Comprehensive assessment will include a risk assessment to establish whether the customer poses a significant risk to themselves, their children, pharmacy staff or other customers. The Treatment Provider will ensure that regular clinical reviews of every person receiving a supervised consumption service will occur. The Treatment Provider will ensure that every customer receiving treatment under supervised consumption is assigned a keyworker (as care coordinator) who may be either the prescriber or another clinical professional.

The keyworker or a nominated member of staff will normally respond to a request from the pharmacy to discuss any clinical issues or untoward incidents immediately or within 24 after the initial request.

The Treatment Provider will ensure that all new customers (including those transferring from another pharmacy) are discussed with the pharmacy prior to treatment commencing and that ideally prescriptions are received at least with 3 working days’ notice, but no less than 24 hours before the first dose is due. This is to ensure that the pharmacy is adequately prepared and has sufficient capacity to supervise an additional prescription.

Advance details to be provided to the pharmacy

The Treatment Provider must provide:

* Customer’s name and address.
* Medication details (dosage and names of all medications to be dispensed).
* Start and expiry date of prescriptions.
* Ensure the customer understands supervised consumption as part of their recovery journey before commencing treatment under supervision.
* Contact details for care co-ordinator or keyworker (name, location and telephone number, (including work mobile number if keyworker is community-based).

Changes to prescriptions

The Treatment Provider will ensure that pharmacy staff or other customers are not unnecessarily placed at risk by making changes to prescriptions, or by stopping a customer’s medication without having made reasonable attempts to discuss such changes with the person beforehand.

In instances where the Treatment Provider has been unable to discuss impending changes to medication with the customer, the Lead Pharmacist will be informed of the situation and of the intended changes so that any necessary risk management strategies can be put into place.

**Responsibilities of LBN:**

* Arrange and communicate quarterly pharmacy forum meetings
* Respond to any serious incidents reported by the pharmacies

**Appendices 1: EHC Patient Group Direction**

|  |
| --- |
| This Patient Group Direction (PGD) must only be used by registered healthcare professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used. |

**PATIENT GROUP DIRECTION (PGD)**

**Supply and/or administration of levonorgestrel 1500micrograms tablet(s) for emergency contraception**

**in Community Pharmacies in Newham, Tower Hamlets and Waltham Forest**

Version Number 1.0

|  |  |
| --- | --- |
| **Change History** | |
| **Version and Date** | **Change details** |
| Version 1  March 2020 | New template |

This Patient Group Direction (PGD) must only be used by registered professionals who have been named and authorised by their organisation to practise under it (See Appendix A). The most recent and in date final signed version of the PGD must be used.

**PGD DEVELOPMENT GROUP**

|  |  |
| --- | --- |
| Date PGD template comes into effect: | 1st March 2020 |
| Review date | September 2022 |
| Expiry date: | 28th February 2023 |

This PGD template has been peer reviewed by the Reproductive Health PGDs Short Life Working Group in accordance with their Terms of Reference. It has been approved by the Faculty for Sexual and Reproductive Health (FSRH) in November 2019.

**This section MUST REMAIN when a PGD is adopted by an organisation.**

|  |  |
| --- | --- |
| **Name** | **Designation** |
| Dr Cindy Farmer | Chair General Training Committee  Faculty of Sexual and Reproductive Healthcare (FSRH) |
| Michelle Jenkins | Advanced Nurse Practitioner, Clinical Standards Committee  Faculty of Sexual and Reproductive Healthcare (FSRH) |
| Michael Nevill | Director of Nursing  British Pregnancy Advisory Service (BPAS) |
| Katie Girling | British Pregnancy Advisory Service (BPAS) |
| Julia Hogan | CASH Nurse Consultant Marie Stopes UK |
| Kate Devonport | National Unplanned Pregnancy Association  (NUPAS) |
| Chetna Parmar | Pharmacist adviser  Umbrella |
| Helen Donovan | Royal College of Nursing (RCN) |
| Carmel Lloyd | Royal College of Midwives (RCM) |
| Clare Livingstone | Royal College of Midwives (RCM) |
| Leanne Bobb | English HIV and Sexual Health Commissioners Group (EHSHCG) |
| Deborah Redknapp | English HIV and Sexual Health Commissioners Group (EHSHCG) |
| Dipti Patel | Local authority pharmacist |
| Emma Anderson | Centre for Postgraduate Pharmacy Education (CPPE) |
| Dr Kathy French | Pan London PGD working group |
| Dr Sarah Pillai | Pan London PGD working group |
| Alison Crompton | Community pharmacist |
| Andrea Smith | Community pharmacist |
| Lisa Knight | Community Health Services pharmacist |
| Bola Sotubo | Clinical Commissioning Group pharmacist |
| Tracy Rogers | Associate Director Specialist Pharmacy Service |
| Sandra Wolper | Associate Director Specialist Pharmacy Service |
| Amanda Cooper | Specialist Pharmacy Service |
| Jo Jenkins (Woking Group Co-ordinator) | Specialist Pharmacist PGDs Specialist Pharmacy Service |
| Samrina Bhatti | Chief Pharmaceutical Officer’s Clinical Fellow Specialist Pharmacy Service |

**ORGANISATIONAL AUTHORISATIONS**

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** | **Job title and organisation** | **Signature** | **Date** |
| **Dr Jill Zelin**  **Senior doctor** | Consultant in Sexual Health, Barts Health NHS Trust |  | 27/07/20 |
| **Faisal Chowdhury**  **Senior representative of professional group using the PGD** | On behalf of NELLPC |  |  |
| **Clare Ebberson**  **Person signing on behalf of** [**authorising body**](http://publications.nice.org.uk/patient-group-directions-gpg2/appendix-a-glossary#authorising-body) | Consultant in Public Health, Families Directorate, London Borough of Waltham Forest |  | 04/08/20 |
| **Jason Strelitz**  **Person signing on behalf of** [**authorising body**](http://publications.nice.org.uk/patient-group-directions-gpg2/appendix-a-glossary#authorising-body) | Director of Public Health, London Borough of Newham | cid:image001.png@01D5B4C0.D6571750 | 17/08/20 |
| **Somen Banerjee** | Director of Public Health, London Borough of Tower Hamlets | SB's Signature | 30/11/20 |

1. **Characteristics of staff**

|  |  |
| --- | --- |
| **Qualifications and professional registration** | Current contract of employment within the Local Authority or NHS commissioned service or the NHS Trust/organisation.  Registered healthcare professional listed in the legislation as able to practice under Patient Group Directions. |
| **Initial training** | The registered healthcare professional authorised to operate under this PGD must have undertaken appropriate education and training approved by Train All East and successfully completed the competencies to undertake clinical assessment of patients ensuring safe provision of the medicines listed in accordance with local policy.   * Completion of CPPE e learning on Patient group directions <https://www.cppe.ac.uk/programmes/l/ptgpdir-e-01/> * Completion of CPPE emergency contraception module <https://www.cppe.ac.uk/programmes/l?t=EHC-E-03&evid=42031> * Successful completion of CPPE emergency contraception e assessment <https://www.cppe.ac.uk/programmes/l?t=EHC-A-12&evid=50018> * Completion of training provided by Train All East   The healthcare professional has completed locally required training (including updates) in safeguarding children and vulnerable adults to level 2.   * Completion of CPPE e learning Safeguarding children and vulnerable adults: a guide for the pharmacy team <https://www.cppe.ac.uk/programmes/l/safegrding-e-02/> * Successful completion of CPPE Safeguarding children and vulnerable adults: Level 2 e assessment <https://www.cppe.ac.uk/programmes/l?t=SAFEGRDINGL2-A-04&evid>= |
| **Competency assessment** | * Individuals operating under this PGD must be assessed as competent (see section 7) and complete a self-declaration of competence for emergency contraception. * Staff operating under this PGD are encouraged to review their competency using the [NICE Competency Framework for health professionals using patient group directions](https://www.nice.org.uk/guidance/mpg2/resources) |
| **Ongoing training and competency** | * Individuals operating under this PGD are personally responsible for ensuring that they remain up to date with the use of all medicines and guidance included in the PGD - if any training needs are identified these should be addressed and further training provided as required. |
| The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisational policies  . | |

**2. Clinical condition or situation to which this PGD applies**

|  |  |
| --- | --- |
| **Clinical condition or situation to which this PGD applies** | To reduce the risk of pregnancy after unprotected sexual intercourse  (UPSI) or regular contraception has been compromised or used incorrectly. |
| **Criteria for inclusion** | * Any individual presenting for emergency contraception (EC) between 0 and 96 hours following UPSI or when regular contraception has been compromised or used incorrectly. * No contraindications to the medication. * Informed consent given. |
| **Criteria for exclusion** | * Informed consent not given. * Individuals under 16 years old and assessed as lacking capacity to consent using the Fraser Guidelines. * Individuals 16 years of age and over and assessed as lacking capacity to consent. * This episode of UPSI occurred more than 96 hours ago. N.B. A dose may be given if there have been previous untreated or treated episodes of UPSI within the current cycle if the most recent episode of UPSI is within 96 hours. * Known or suspected pregnancy (N.B. a previous episode of UPSI in this cycle is not an exclusion. Consider pregnancy test if more than three weeks after UPSI and no normal menstrual period since UPSI). * Less than 21 days after childbirth. * Less than 5 days after miscarriage, abortion, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease (GTD). * Known hypersensitivity to the active ingredient or to any component of the product - see [Summary of Product Characteristics](https://www.medicines.org.uk/emc) * Use of ulipristal acetate emergency contraception in the previous 5 days. |
| **Cautions including any relevant action to be taken** | * All individuals should be informed that insertion of a copper intrauterine device (Cu-IUD) within five days of UPSI or within five days from earliest estimated ovulation is the most effective method of emergency contraception. If a Cu-IUD is appropriate and acceptable supply oral EC and refer to the appropriate health service provider. * Ulipristal acetate can delay ovulation until closer to the time of ovulation than levonorgestrel. Consider ulipristal if the individual presents in the five days leading up to estimated day of ovulation. * Levonorgestrel is ineffective if taken after ovulation. * If individual vomits within three hours from ingestion, a repeat dose may be given. * Individuals using enzyme-inducing drugs/herbal products or within 4 weeks of stopping them - see dose frequency section. * Body Mass Index (BMI) >26kg/m2 or weight >70kg – individuals should be advised that though oral EC methods may be safely used, a high BMI may reduce the effectiveness. A Cu-IUD should be recommended as the most effective method of EC. If levonorgestrel is to be given see dosage section. * Consideration should be given to the current disease status of those with severe malabsorption syndromes, such as acute/active inflammatory bowel disease or Crohn’s disease. Although the use of levonorgestrel is not contra-indicated it may be less effective and so these individuals should be advised that insertion of Cu-IUD would be the most effective emergency contraception for them and referred accordingly if agreed. * If the individual is less than 16 years of age an assessment based on Fraser guidelines must be made and documented. * If the individual is less than 13 years of age the healthcare professional should speak to local safeguarding lead and follow the local safeguarding policy. * If the individual has not yet reached menarche consider onward referral for further assessment or investigation. |
| **Action to be taken if the individual is excluded or declines treatment** | * Explain the reasons for exclusion to the individual and document in the consultation record. * Record reason for decline in the consultation record. * Offer suitable alternative emergency contraception or refer the individual as soon as possible to a suitable health service provider if appropriate and/or provide them with information about further options. |

1. **Description of treatment**

|  |  |
| --- | --- |
| **Name, strength & formulation of drug** | Levonorgestrel 1500 micrograms tablet (N.B. this is equivalent to 1.5mg levonorgestrel) |
| **Legal category** | P/POM |
| **Route of administration** | Oral |
| **Off label use** | Best practice advice given by Faculty of Sexual and Reproductive Healthcare (FSRH) is used for guidance in this PGD and may vary from the [Summary of Product Characteristics](https://www.medicines.org.uk/emc) (SPC).  This PGD includes off-label use in the following conditions   * + Use between 72 and 96 hours post UPSI   + Increased dose for individuals with BMI over 26kg/m2 or weight over 70kg and in individuals using liver enzyme inducing agent   + Severe hepatic impairment   + Individuals with previous salpingitis or ectopic pregnancy   + Lapp-lactase deficiency   + Hereditary problems of galactose intolerance   + Glucose-galactose malabsorption   Drugs should be stored according to the conditions detailed in the Storage section in this table. However, in the event of an inadvertent or unavoidable deviation of these conditions the local pharmacy or Medicines Management team must be consulted. Where drugs have been assessed by pharmacy/Medicines Management in accordance with national or specific product recommendations as appropriate for continued use this would constitute off-label administration under this PGD. The responsibility for the decision to release the affected drugs for use lies with pharmacy/Medicines Management.  Where a drug is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the drug is being offered in accordance with national guidance but that this is outside the product licence |
| **Dose and frequency of administration** | * Levonorgestrel 1500mcg (1 tablet) to be taken as soon as possible up to 96 hours of UPSI. * **Dose for those individuals taking enzyme inducing medicines or herbal products:** An individual who requests levonorgestrel whilst using enzyme-inducing drugs, or within 4 weeks of stopping them, should be advised to take a total of 3 mg levonorgestrel (two 1500mcg tablets) as a single dose and within 96 hours of UPSI. * **Dose for those individuals with a body mass index of more than 26kg/m2 or who weigh more than 70kg:** An individual who requests levonorgestrel with a body mass index of more than 26kg/m2 or who weighs more than 70kg, can be offered a total of 3mg levonorgestrel (two 1500mcg tablets) as a single dose and within 96 hours of UPSI. |
| **Duration of treatment** | * A single dose is permitted under this PGD. * If vomiting occurs within 3 hours of levonorgestrel being taken a repeat dose can be supplied under this PGD. * Repeated doses can be given within the same cycle. Please note:   + If within 7 days of previous levonorgestrel offer levonorgestrel again (not ulipristal)   + If within 5 days of ulipristal then offer ulipristal again (not levonorgestrel) |
| **Quantity to be supplied** | * Appropriately labelled pack of one tablet. * Two tablets should be supplied for individuals taking enzyme inducing drugs or individuals with a BMI of more than 26kg/m2 or who weigh more than 70kg. |
| **Storage** | Medicines must be stored securely according to national guidelines and in accordance with the product SPC. |
| **Drug interactions** | A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk or the BNF www.bnf.org |
| **Identification & management of adverse reactions** | A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: [www.medicines.org.uk](http://www.medicines.org.uk) and BNF [www.bnf.org](http://www.bnf.org)  The following side effects are common with levonorgestrel (but may not reflect all reported side effects):   * Nausea and vomiting are the most common side effects. * Headache, dizziness, fatigue, low abdominal pain and breast tenderness, diarrhoea. * The FSRH advises that bleeding patterns may be temporarily disturbed and spotting may occur, but most individuals will have their next menstrual period within seven days of the expected time |
| **Management of and reporting procedure for adverse reactions** | * Healthcare professionals and individuals are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk * Record all adverse drug reactions (ADRs) in the individual’s medical record. * Report any adverse reactions via organisation incident policy. |
| **Written information and further advice to be provided** | * All methods of emergency contraception should be discussed. All individuals should be informed that fitting a Cu-IUD within five days of UPSI or within five days from the earliest estimated ovulation is the most effective method of emergency contraception. * Ensure that a patient information leaflet (PIL) is provided within the original pack. * If vomiting occurs within three hours of taking the dose, the individual should return for another dose. * Explain that menstrual disturbances can occur after the use of emergency hormonal contraception. * Provide advice on ongoing contraceptive methods, including how these can be accessed. * Repeated episodes of UPSI within one menstrual cycle - the dose may be repeated more than once in the same menstrual cycle should the need occur. * Individuals using hormonal contraception should restart their regular hormonal contraception immediately. Avoidance of pregnancy risk (i.e. use of condoms or abstain from intercourse) should be advised until fully effective. * Advise a pregnancy test three weeks after treatment especially if the expected period is delayed by more than seven days or abnormal (e.g. shorter or lighter than usual), or if using hormonal contraception which may affect bleeding pattern. * Promote the use of condoms to protect against sexually transmitted infections (STIs) and advise on the possible need for screening for STIs. * There is no evidence of harm if someone becomes pregnant in a cycle when they had used emergency hormonal contraception. |
| **Advice/follow up treatment** | * The individual should be advised to seek medical advice in the event of an adverse reaction. * The individual should attend an appropriate health service provider if their period is delayed, absent or abnormal or if they are otherwise concerned. * Pregnancy test as required (see advice to individual above). * Individuals advised how to access on-going contraception and STI screening. This includes the provision of additional services per LES * Condom provision per LES |
| **Records** | Record, using PharmOutcomes or equivalent:   * The consent of the individual and * If individual is under 13 years of age record action taken * If individual is under 16 years of age document capacity using Fraser guidelines. If not competent record action taken. * If individual over 16 years of age and not competent, record action taken * Name of individual, address, date of birth * Relevant past and present medical history, including medication history. Examination finding where relevant e.g. weight * Any known drug allergies * Name of registered health professional operating under the PGD * Name of medication supplied * Date of supply * Dose supplied * Quantity supplied * Advice given, including advice given if excluded or declines treatment * Details of any adverse drug reactions and actions taken * Advice given about the medication including side effects, benefits, and when and what to do if any concerns * Any referral arrangements made * Any supply outside the terms of the product marketing authorisation * Recorded that supplied via Patient Group Direction (PGD)   Records should be signed and dated (or a password controlled e-records) and securely kept for a defined period in line with local policy.  All records should be clear, legible and contemporaneous.  A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy. |

1. **Key references**

|  |  |
| --- | --- |
| **Key references (accessed December 2019)** | * Electronic Medicines Compendium <http://www.medicines.org.uk/> * Electronic BNF <https://bnf.nice.org.uk/> * NICE Medicines practice guideline “Patient Group Directions” <https://www.nice.org.uk/guidance/mpg2> * Faculty of Sexual and Reproductive Health Clinical Guidance: Emergency Contraception - December 2017 Updated December 2018 <https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/emergency-contraception/> * Faculty of Sexual and Reproductive Health Drug Interactions with Hormonal Contraception - November 2017 <https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/drug-interactions/> * Royal Pharmaceutical Society Safe and Secure Handling of Medicines December 2018 https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines |

**Appendix A - Registered health professional authorisation sheet**

**Supply and/or administration of levonorgestrel 1500micrograms tablet(s) for emergency contraception in Community Pharmacies in Newham, Tower Hamlets and Waltham Forest**

**Version Number 1.0**

**Valid from: December 2020 Expiry: December 2023**

Before signing this PGD, check that the document has had the necessary authorisations. Without these, this PGD is not lawfully valid.

**Registered health professional**

By signing this patient group direction you are indicating that you agree to its contents and that you will work within it.

Patient group directions do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

|  |  |  |  |
| --- | --- | --- | --- |
| **I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.** | | | |
| **Name** | **Pharmacy** | **Signature** | **Date** |
|  |  |  |  |

**Authorising manager**

|  |  |  |  |
| --- | --- | --- | --- |
| **I confirm that the registered health professionals named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of Train All East (Barts Health NHS Trust) for the above named health care professionals who have signed the PGD to work under it.** | | | |
| **Name** | **Designation** | **Signature** | **Date** |
| Jill Zelin | Train All East Training Hub Director |  | [date] |

**Note to authorising manager**

This authorisation sheet should be retained to serve as a record of those registered health professionals authorised to work under this PGD.

A list of trained and competent pharmacists will be kept by Train All East and shared with the

|  |
| --- |
| This Patient Group Direction (PGD) must only be used by registered healthcare professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used. |

**PATIENT GROUP DIRECTION (PGD)**

**Supply and/or administration of ulipristal acetate 30mg tablet for emergency contraception**

**in Community Pharmacies in Newham, Tower Hamlets and Waltham Forest**

Version Number 1.0

|  |  |
| --- | --- |
| **Change History** | |
| **Version and Date** | **Change details** |
| Version 1  March 2020 | New template |

This Patient Group Direction (PGD) must only be used by registered professionals who have been named and authorised by their organisation to practise under it (See Appendix A). The most recent and in date final signed version of the PGD must be used.

**PGD DEVELOPMENT GROUP**

|  |  |
| --- | --- |
| Date PGD template comes into effect: | 1st March 2020 |
| Review date | September 2022 |
| Expiry date: | 28th February 2023 |

This PGD template has been peer reviewed by the Reproductive Health PGDs Short Life Working Group in accordance with their Terms of Reference. It has been approved by the Faculty for Sexual and Reproductive Health (FSRH) in November 2019.

**This section MUST REMAIN when a PGD is adopted by an organisation.**

|  |  |
| --- | --- |
| **Name** | **Designation** |
| Dr Cindy Farmer | Chair General Training Committee  Faculty of Sexual and Reproductive Healthcare (FSRH) |
| Michelle Jenkins | Advanced Nurse Practitioner, Clinical Standards Committee  Faculty of Sexual and Reproductive Healthcare (FSRH) |
| Michael Nevill | Director of Nursing  British Pregnancy Advisory Service (BPAS) |
| Katie Girling | British Pregnancy Advisory Service (BPAS) |
| Julia Hogan | CASH Nurse Consultant Marie Stopes UK |
| Kate Devonport | National Unplanned Pregnancy Association  (NUPAS) |
| Chetna Parmar | Pharmacist adviser  Umbrella |
| Helen Donovan | Royal College of Nursing (RCN) |
| Carmel Lloyd | Royal College of Midwives (RCM) |
| Clare Livingstone | Royal College of Midwives (RCM) |
| Leanne Bobb | English HIV and Sexual Health Commissioners Group (EHSHCG) |
| Deborah Redknapp | English HIV and Sexual Health Commissioners Group (EHSHCG) |
| Dipti Patel | Local authority pharmacist |
| Emma Anderson | Centre for Postgraduate Pharmacy Education (CPPE) |
| Dr Kathy French | Pan London PGD working group |
| Dr Sarah Pillai | Pan London PGD working group |
| Alison Crompton | Community pharmacist |
| Andrea Smith | Community pharmacist |
| Lisa Knight | Community Health Services pharmacist |
| Bola Sotubo | Clinical Commissioning Group pharmacist |
| Tracy Rogers | Associate Director Specialist Pharmacy Service |
| Sandra Wolper | Associate Director Specialist Pharmacy Service |
| Amanda Cooper | Specialist Pharmacy Service |
| Jo Jenkins (Woking Group Co-ordinator) | Specialist Pharmacist PGDs Specialist Pharmacy Service |
| Samrina Bhatti | Chief Pharmaceutical Officer’s Clinical Fellow Specialist Pharmacy Service |

**ORGANISATIONAL AUTHORISATIONS**

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** | **Job title and organisation** | **Signature** | **Date** |
| **Dr Jill Zelin**  **Senior doctor** | Consultant in Sexual Health, Barts Health NHS Trust |  | 27/07/20 |
| **Faisal Chowdhury**  **Senior representative of professional group using the PGD** | On behalf of NELLPC |  |  |
| **Jason Strelitz**  **Person signing on behalf of** [**authorising body**](http://publications.nice.org.uk/patient-group-directions-gpg2/appendix-a-glossary#authorising-body) | Director or Public Health, London Borough of Newham | cid:image001.png@01D5B4C0.D6571750 | 17/08/20 |
| **Somen Banerjee**  **Person signing on behalf of authorising body** | Director of Public Health London Borough of Tower Hamlets | SB's Signature | 30/11/20 |
| **Clare Ebberson**  **Person signing on behalf of** [**authorising body**](http://publications.nice.org.uk/patient-group-directions-gpg2/appendix-a-glossary#authorising-body) | Consultant in Public Health, London Borough of Waltham Forest |  | 05/02/2021 |

1. **Characteristics of staff**

|  |  |
| --- | --- |
| **Qualifications and professional registration** | Current contract of employment within the Local Authority or NHS commissioned service or the NHS Trust/organisation.  Registered healthcare professional listed in the legislation as able to practice under Patient Group Directions. |
| **Initial training** | The registered healthcare professional authorised to operate under this PGD must have undertaken appropriate education and training and successfully completed the competencies to undertake clinical assessment of patients ensuring safe provision of the medicines listed in accordance with local policy.   * Completion of CPPE e learning on Patient group directions <https://www.cppe.ac.uk/programmes/l/ptgpdir-e-01/> * Completion of CPPE emergency contraception module <https://www.cppe.ac.uk/programmes/l?t=EHC-E-03&evid=42031> * Successful completion of CPPE emergency contraception e assessment <https://www.cppe.ac.uk/programmes/l?t=EHC-A-12&evid=50018> * Completion of training provided by Train All East   The healthcare professional has completed locally required training (including updates) in safeguarding children and vulnerable adults to level 2.   * Completion of CPPE e learning Safeguarding children and vulnerable adults: a guide for the pharmacy team <https://www.cppe.ac.uk/programmes/l/safegrding-e-02/> * Successful completion of CPPE Safeguarding children and vulnerable adults: Level 2 e assessment <https://www.cppe.ac.uk/programmes/l?t=SAFEGRDINGL2-A-04&evid>= |
| **Competency assessment** | * Individuals operating under this PGD must be assessed as competent (see section 7) and complete a self-declaration of competence for emergency contraception. * Staff operating under this PGD are encouraged to review their competency using the [NICE Competency Framework for health professionals using patient group directions](https://www.nice.org.uk/guidance/mpg2/resources) |
| **Ongoing training and competency** | * Individuals operating under this PGD are personally responsible for ensuring that they remain up to date with the use of all medicines and guidance included in the PGD - if any training needs are identified these should be addressed and further training provided as required. * The Registered Pharmacist has the responsibility to update their own DoC every 3 years |
| The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisational policies. | |

**2. Clinical condition or situation to which this PGD applies**

|  |  |
| --- | --- |
| **Clinical condition or situation to which this PGD applies** | To reduce the risk of pregnancy after unprotected sexual intercourse  (UPSI) or regular non-hormonal contraception has been compromised or used incorrectly. |
| **Criteria for inclusion** | * Any individual presenting for emergency contraception (EC) between 0 and 120 hours following UPSI or when regular non-hormonal contraception has been compromised or used incorrectly. * No contraindications to the medication. * Informed consent given. |
| **Criteria for exclusion** | * Informed consent not given. * Individuals under 16 years old and assessed as lacking capacity to consent using the Fraser Guidelines. * Individuals 16 years of age and over and assessed as lacking capacity to consent. * This episode of UPSI occurred more than 120 hours ago. N.B. A dose may be given if there have been previous untreated or treated episodes of UPSI within the current cycle if the most recent episode of UPSI is within 120 hours. * Known or suspected pregnancy (N.B. a previous episode of UPSI in this cycle is not an exclusion. Consider pregnancy test if more than three weeks after UPSI and no normal menstrual period). * Less than 21 days after childbirth. * Less than 5 days after miscarriage, abortion, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease (GTD). * Known hypersensitivity to the active ingredient or to any component of the product - see [Summary of Product Characteristics](https://www.medicines.org.uk/emc) * Use of levonorgestrel or any other progestogen in the previous 7 days (i.e. hormonal contraception, hormone replacement therapy or use for other gynaecological indications). * Concurrent use of antacids, proton-pump inhibitors or H2-receptor antagonists. * Severe asthma controlled by oral glucocorticoids. * Individuals using enzyme-inducing drugs/herbal products or within 4 weeks of stopping. |
| **Cautions including any relevant action to be taken** | * All individuals should be informed that insertion of a copper intrauterine device (Cu-IUD) within five days of UPSI or within five days from earliest estimated ovulation is the most effective method of emergency contraception. If a Cu-IUD is appropriate and acceptable supply oral EC and refer to the appropriate health service provider. * Ulipristal is ineffective if taken after ovulation. * If individual vomits within three hours from ingestion, a repeat dose may be given. * Body Mass Index (BMI) >26kg/m2 or weight >70kg – individuals should be advised that though oral EC methods may be safely used, a high BMI may reduce the effectiveness. A Cu-IUD should be recommended as the most effective method of EC. * Consideration should be given to the current disease status of those with severe malabsorption syndromes, such as acute/active inflammatory bowel disease or Crohn’s disease. Although the use of ulipristal is not contra-indicated it may be less effective and so these individuals should be advised that insertion of Cu-IUD would be the most effective emergency contraception for them and referred accordingly if agreed. * Breast feeding – advise to express and discard breast milk for 7 days after ulipristal dose. * The effectiveness of ulipristal can be reduced by progestogen taken in the following 5 days and individuals must be advised not to take progestogen containing drugs for 5 days after ulipristal. See section ‘Written information and further advice to be given to individual’. * If the individual is less than 16 years of age an assessment based on Fraser guidelines must be made and documented. * If the individual is less than 13 years of age the healthcare professional should speak to local safeguarding lead and follow the local safeguarding policy. * If the individual has not yet reached menarche consider onward referral for further assessment or investigation. |
| **Action to be taken if the individual is excluded or declines treatment** | * Explain the reasons for exclusion to the individual and document in the consultation record. * Record reason for decline in the consultation record. * Offer suitable alternative emergency contraception or refer the individual as soon as possible to a suitable health service provider if appropriate and/or provide them with information about further options. |

1. **Description of treatment**

|  |  |
| --- | --- |
| **Name, strength & formulation of drug** | Ulipristal acetate 30mg tablet |
| **Legal category** | P |
| **Route of administration** | Oral |
| **Off label use** | Best practice advice given by Faculty of Sexual and Reproductive Healthcare (FSRH) is used for guidance in this PGD and may vary from the [Summary of Product Characteristics](https://www.medicines.org.uk/emc) (SPC).  This PGD includes off-label use in the following conditions:   * Lapp-lactase deficiency * Hereditary problems of galactose intolerance * Glucose-galactose malabsorption * Severe hepatic impairment   Drugs should be stored according to the conditions detailed in the Storage section in this table. However, in the event of an inadvertent or unavoidable deviation of these conditions the local pharmacy or Medicines Management team must be consulted. Where drugs have been assessed by pharmacy/Medicines Management in accordance with national or specific product recommendations as appropriate for continued use this would constitute off-label administration under this PGD. The responsibility for the decision to release the affected drugs for use lies with pharmacy/Medicines Management.  Where a drug is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the drug is being offered in accordance with national guidance but that this is outside the product licence. |
| **Dose and frequency of administration** | * One tablet (30mg) as a single dose taken as soon as possible up to 120 hours after UPSI. |
| **Duration of treatment** | * A single dose is permitted under this PGD. * If vomiting occurs within 3 hours of ulipristal being taken a repeat dose can be supplied under this PGD. * Repeated doses can be given within the same cycle. Please note:   + If within 7 days of previous levonorgestrel offer levonorgestrel again (not ulipristal)   + If within 5 days of ulipristal then offer ulipristal again (not levonorgestrel) |
| **Quantity to be supplied** | Appropriately labelled pack of one tablet. |
| **Storage** | Medicines must be stored securely according to national guidelines and in accordance with the product SPC. |
| **Drug interactions** | A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk or the BNF [www.bnf.org](http://www.bnf.org) |
| **Identification & management of adverse reactions** | A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: [www.medicines.org.uk](http://www.medicines.org.uk) and BNF [www.bnf.org](http://www.bnf.org)  The following side effects are common with ulipristal acetate (but may not reflect all reported side effects):   * Nausea or vomiting * Abdominal pain or discomfort * Headache * Dizziness * Muscle pain (myalgia) * Dysmenorrhea * Pelvic pain * Breast tenderness * Mood changes * Fatigue * The FSRH advises that disruption to the menstrual cycle is possible following emergency contraception. |
| **Management of and reporting procedure for adverse reactions** | * Healthcare professionals and patients/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: <http://yellowcard.mhra.gov.uk> * Record all adverse drug reactions (ADRs) in the patient’s medical record. * Report any adverse reactions via organisation incident policy. |
| **Written information and further advice to be given to individual** | * All methods of emergency contraception should be discussed. All individuals should be informed that fitting a Cu-IUD within five days of UPSI or within five days from the earliest estimated ovulation is the most effective method of emergency contraception. * Ensure that a patient information leaflet (PIL) is provided within the original pack. * If vomiting occurs within three hours of taking the dose, the individual should return for another dose. * Explain that menstrual disturbances can occur after the use of emergency hormonal contraception. * Provide advice on ongoing contraceptive methods, including how these can be accessed. * Repeated episodes of UPSI within one menstrual cycle - the dose may be repeated more than once in the same menstrual cycle should the need occur. * In line with FSRH guidance individuals using hormonal contraception should delay restarting their regular hormonal contraception for 5 days following ulipristal acetate use. Avoidance of pregnancy risk (i.e. use of condoms or abstain from intercourse) should be advised until fully effective. * Advise a pregnancy test three weeks after treatment especially if the expected period is delayed by more than seven days or abnormal (e.g. shorter or lighter than usual), or if using hormonal contraception which may affect bleeding pattern. * Promote the use of condoms to protect against sexually transmitted infections (STIs) and advise on the possible need for screening for STIs. * There is no evidence of harm if someone becomes pregnant in a cycle when they had used emergency hormonal contraception. |
| **Advice / follow up treatment** | * The individual should be advised to seek medical advice in the event of an adverse reaction. * The individual should attend an appropriate health service provider if their period is delayed, absent or abnormal or if they are otherwise concerned. * Pregnancy test as required (see advice to individual above). * Individuals advised how to access on-going contraception and STI screening as required. This includes the provision of additional services per LES * Condom provision per LES |
| **Records** | Record using PharmOutcomes or equivalent:   * The consent of the individual and * If individual is under 13 years of age record action taken * If individual is under 16 years of age document capacity using Fraser guidelines. If not competent record action taken. * If individual over 16 years of age and not competent, record action taken * Name of individual, address, date of birth * Relevant past and present medical history, including medication history. Examination finding where relevant e.g. weight * Any known medication allergies * Name of registered health professional operating under the PGD * Name of medication supplied * Date of supply * Dose supplied * Quantity supplied * Advice given, including advice given if excluded or declines treatment * Details of any adverse drug reactions and actions taken * Advice given about the medication including side effects, benefits, and when and what to do if any concerns * Any referral arrangements made * Any supply outside the terms of the product marketing authorisation * Recorded that administered/supplied via Patient Group Direction (PGD)   Records should be signed and dated (or a password controlled e-records) and securely kept for a defined period in line with local policy.  All records should be clear, legible and contemporaneous.  A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy. |

1. **Key references**

|  |  |
| --- | --- |
| **Key references (accessed December 2019)** | * Electronic Medicines Compendium <http://www.medicines.org.uk/> * Electronic BNF <https://bnf.nice.org.uk/> * NICE Medicines practice guideline “Patient Group Directions” <https://www.nice.org.uk/guidance/mpg2> * Faculty of Sexual and Reproductive Health Clinical Guidance: Emergency Contraception - December 2017 <https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/emergency-contraception/> * Faculty of Sexual and Reproductive Health Drug Interactions with Hormonal Contraception - November 2017 <https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/drug-interactions/> * Royal Pharmaceutical Society Safe and Secure Handling of Medicines December 2018 https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines |

**Appendix A - Registered health professional authorisation sheet**

**Supply and/or administration of ullipristal acetate 30mg tablet for emergency contraception in Community Pharmacies in Newham, Tower Hamlets and Waltham Forest**

**Version Number 1.0 PGD Valid from: 1st Dec 2020 Expiry: 1st Dec 2023**

Before signing this PGD, check that the document has had the necessary authorisations. Without these, this PGD is not lawfully valid.

**Registered health professional**

By signing this patient group direction you are indicating that you agree to its contents and that you will work within it.

Patient group directions do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

|  |  |  |  |
| --- | --- | --- | --- |
| **I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.** | | | |
| **Name** | **Pharmacy** | **Signature** | **Date** |
|  |  |  |  |

**Authorising manager**

|  |  |  |  |
| --- | --- | --- | --- |
| **I confirm that the registered health professionals named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of Train All East (Barts Health NHS Trust)for the above named health care professionals who have signed the PGD to work under it.** | | | |
| **Name** | **Designation** | **Signature** | **Date** |
| Jill Zelin | Train All East Training Hub Director |  |  |

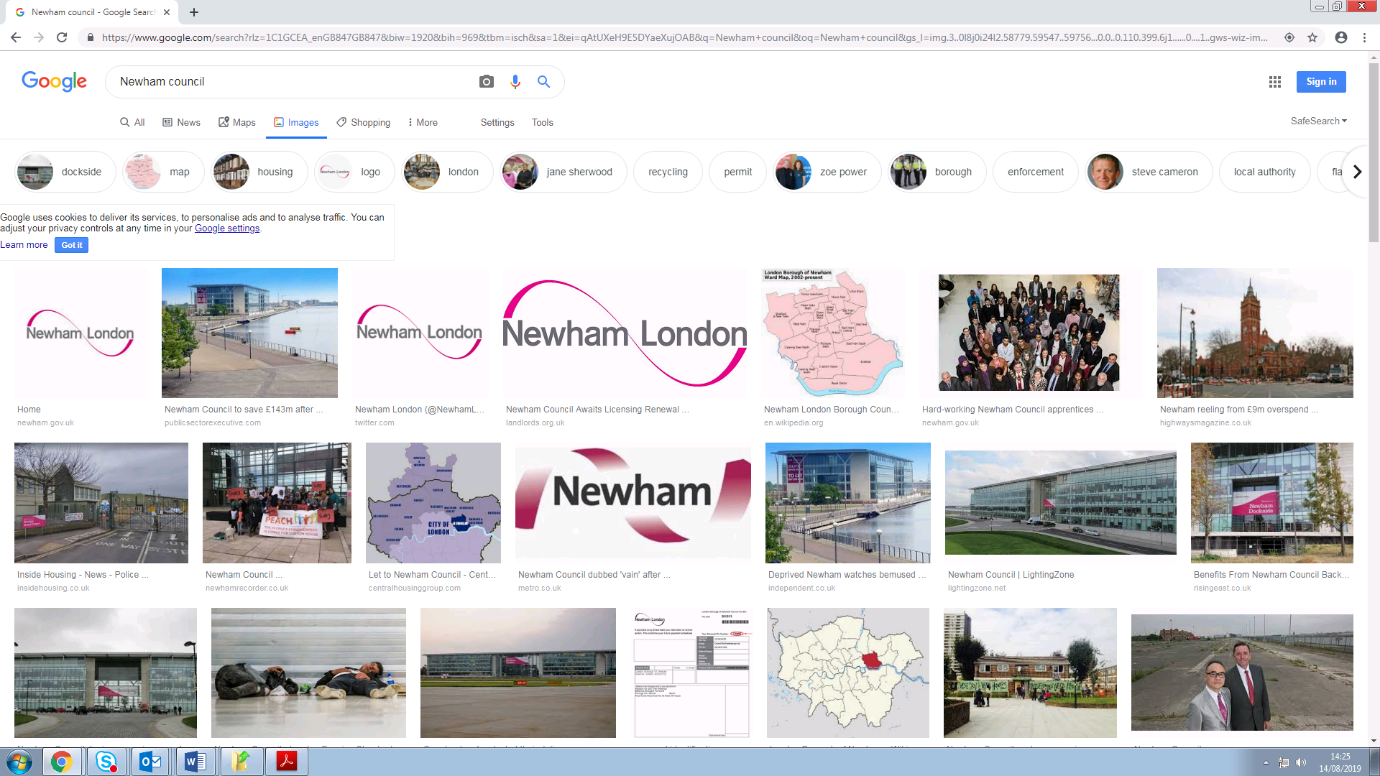
**Note to authorising manager**

This authorisation sheet should be retained to serve as a record of those registered health professionals authorised to work under this PGD.

A list of trained and competent pharmacists will be kept by Train All East and shared with the sexual health commissioners.

|  |
| --- |
| This Patient Group Direction (PGD) must only be used by registered healthcare professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used. |

**Appendices 2: Champix Patient Group Direction**

****

**PATIENT GROUP DIRECTION (PGD)**

**For the Supply of Varenicline by community Lead Pharmacists accredited to provide the Stop smoking service in Newham. This Patient Group Direction must only be used by community Lead Pharmacists who have been named and authorised by Public Health, London Borough of Newham to practice under it.**

Version Number 1.8 – FINAL

|  |  |  |
| --- | --- | --- |
| **Version** | **Change details** | **Date** |
| 0.1 | 1st draft produced by Maninder Kaur Singh  Senior Prescribing Adviser Newham Clinical Commissioning Group | 8th November 2014 |
| 0.2 | Updated by Newham Clinical Commissioning Group Medicine Management Team | 14th November 2014 |
| 0.3 | Updated by Newham Clinical Commissioning Group Medicine Management Team | 31st March2015 |
| 1.0 | Updated by Public Health London Borough of Newham | 22nd July 2015 |
| 1.5 | Updated by Public Health London Borough of Newham | 11th December 2015 |
| 1.6 | Reviewed by Consultant Lead Pharmacist  Mr Viral V Doshi FRPharmS | 7th May 2019 |
| 1.7 | Reviewed and updated by Foizul Islam, Public Health London Borough of Newham – Relative to comments made by PGD steering group on 11th June 2019 | 11th June 2019 |
| 1.8 | Reviewed by Consultant Lead Pharmacist  Mr Viral V Doshi FRPharmS. Version 1.8 - FINAL | 17th June 2019 |

**Organisations**

Each organisation using this PGD must ensure that it is formally authorised by a Lead Pharmacist, a medical lead and a governance lead on behalf of the authorising organisation to ensure that this document meets legal requirements for a PGD.

**Community Lead Pharmacists**

Each community Lead Pharmacist using this PGD must ensure that it is formally authorised i.e. signed by a Lead Pharmacist, medical lead and governance lead of the commissioning organisation which has legal authority to do so, ensuring that this document meets legal requirements for a PGD.

This PGD must only be used by registered community Lead Pharmacists who have been named and authorised to do so. This will be a locally agreed arrangement between the commissioner and the provider.

The most recent and in date final signed version of the PGD must be used. Lead Pharmacists are responsible and accountable for ensuring that they work under the relevant PGD and correct Service Specification applicable to the area, and commissioner, where they are working.

|  |  |  |  |
| --- | --- | --- | --- |
| **1. Purpose of the PGD** | | | |
| For use by accredited community Lead Pharmacists currently registered with the General Pharmaceutical Council (GPhC) and who are working in a pharmacy contracted by the London Borough of Newham to supply Varenicline under this PGD. | | | |
| **2. Clinical detail** | | | |
| 2.1 | **Indication** | | Adjunct to smoking cessation in combination with motivational support in nicotine dependent adults in accordance with the Newham Public Health Stop Smoking Service specification. |
| 2.2 | **Inclusion criteria** | | * Clients over 18 years of age. * Patients accessing the pharmacy level 2 stop smoking service in need of pharmacological treatment. * Patients identified by an accredited Newham community Lead Pharmacist as sufficiently motivated to quit smoking with Varenicline. * The patient agrees to receive behavioural supportaccording to an agreed protocol. * Varenicline has been assessed as the most appropriate treatment for the client. A full medical history is taken and documented and there are no contraindications or cautions for treatment with Varenicline (see criteria for exclusion and referral). * The patient must be registered with a Newham GP. * Informed consent has been obtained and documented. * Patients who are taking other medications that need dose adjusting on quitting or resuming smoking should agree to keep their GP informed of their smoking status. The Lead Pharmacist will share information with the GP unless a patient chooses to opt out. |
| 2.3 | **Exclusion criteria** | | * Smokers not sufficiently motivated to quit or use Varenicline. * Patient under 18 years of age. * Pregnancy (or if there is a likelihood of being pregnant). * Breastfeeding. * Patient currently using Nicotine Replacement Therapy (NRT) or Bupropion (Zyban) or already receiving Varenicline prescribed by the GP. * Hypersensitivity to varenicline or any of the listed excipients (refer to SPC): <http://www.medicines.org.uk/emc/medicine/19045> * Epilepsy or history of fits or seizures or other conditions that potentially lower the seizure threshold. * Patients with current (or a history of) serious psychiatric illness such as schizophrenia, bipolar disorder and major depressive disorder. * Moderate or severe renal impairment. * End stage renal disease. * Where there is no valid patient consent. * Patients who have received a previous course of varenicline within 6 months, unless special circumstances have hampered the person's initial attempt to stop smoking, when it may be reasonable to try again sooner. Refer to service specification for further information. * The patient is NOT registered with a Newham GP. |
| 2.4 | **Cautions / need for further advice** | | **Please note: This list is not exhaustive and further clarification using relevant reference sources such as the latest edition of the BNF** [**www.bnf.org.uk**](http://www.bnf.org.uk) **cross-referencing the patient current medication profile, should be made by the Lead Pharmacist supplying any smoking cessation product.**   * As a general protocol, further medical advice should be sought from the patient’s General practitioner (GP) if deemed appropriate. * Elderly patients: No dosage adjustment is necessary for elderly patients. Because elderly patients are more likely to have decreased renal function, prescribers should consider the renal status of an elderly patient. * End Stage Renal Disease:   Based on insufficient clinical experience with Varenicline in patients with end stage renal disease, treatment is not recommended in this patient population (see SPC for full details).   * Neuropsychiatric symptoms:   Changes in behaviour or thinking, anxiety, psychosis, mood swings, aggressive behaviour, depression, suicidal ideation and behaviour and suicide attempts have been reported in patients attempting to quit smoking with Varenicline in the post-marketing experience.  A large randomised, double-blind, active and placebo-controlled study (EAGLES) was conducted to compare the risk of serious neuropsychiatric events in patients with and without a history of psychiatric disorder treated for smoking cessation with Varenicline, Bupropion, nicotine replacement therapy patch (NRT) or placebo. The primary safety endpoint was a composite of neuropsychiatric adverse events that have been reported in post-marketing experience.  The use of Varenicline in patients with or without a history of psychiatric disorder was not associated with an increased risk of serious neuropsychiatric adverse events in the composite primary endpoint compared with placebo  Depressed mood, rarely including suicidal ideation and suicide attempt, may be a symptom of nicotine withdrawal. However, if a patient suffers from excessively depressed mood (beyond normal withdrawal symptoms from smoking cessation), **Varenicline must be stopped and patient referred to their GP.**  Clinicians should be aware of the possible emergence of serious neuropsychiatric symptoms in patients attempting to quit smoking with or without treatment. If serious neuropsychiatric symptoms occur whilst on Varenicline treatment, patients should discontinue Varenicline immediately and contact a healthcare professional for re-evaluation of treatment.  **NOTE WELL: MHRA / CHM Advice**: Varenicline should be discontinued immediately if agitation, depressed mood or changes in behaviour that are of concern for the Lead Pharmacist, patient’s family or caregiver are observed or if the patient develops suicidal thoughts or suicidal behaviour.  **Lead Pharmacists should be aware of the possible emergence of significant depressive symptomatology in patients undergoing a smoking cessation attempt, and should advise patients accordingly.**   * Patients with History of Psychiatric Disorders:   Smoking cessation, with or without pharmacotherapy, has been associated with the exacerbation of underlying psychiatric illness (e.g. depression). Care should be taken with patients with a history of psychiatric illness. If this is a consideration, community Lead Pharmacists should liaise with the clients GP or mental health team prior to smoking cessation and patient must be monitored closely while taking varenicline (BNF).   * Effect of Smoking Cessation:   Based on Varenicline characteristics and clinical experience to date, no clinical meaningful drug interactions have been reported. Since metabolism of Varenicline represents less than 10% of its clearance, active substances known to affect the Cytochrome P450 system are unlikely to alter the pharmacokinetics of Varenicline and therefore a dose adjustment of Varenicline would not be required.  However, levels of certain drugs taken by a patient once smoking has been stopped may be affected and thus, patients should be monitored for adverse effects. Examples of these drugs include:  • Caffeine  • Clozapine  • Chlorpromazine  • Theophylline  • Warfarin  • Insulin  • Olanzapine  • Dextropropoxyphene  • Flecainide  • Fluvoxamine  • Phenylbutazones e.g. Oxazepam  • Some beta blockers e.g. Propranolol  • Tricylic Antidepressants such as Imipramine   * Patients on insulin   Varenicline may be supplied. However, patients should be advised to monitor their blood glucose level closely.   * Missed dose of Varenicline:   The patient should be advised not to take a double dose to make up for the one that was missed. It is important they take the medication regularly and at the same time each day. If they have forgotten to take a dose, they should take it as soon as they remember but if it is almost time for the next dose they should not take the tablet they have missed. |
| 2.5 | **Patient consent**  **[verbal, written, implied]** | | * Patient consent must be obtained before the supply is made in line with local consent policy. This should include consent to inform the patient’s GP of the supply of varenicline. |
| 2.6 | **Recommend action if patient excluded for treatment under PGD** | | * The Lead Pharmacist should refer the patient to their GP **or** * Offer patient option for nicotine replacement therapy (NRT) * Refer to Appendix 2. |
| 2.7 | **Recommended action if patient declines treatment** | | * Offer alternative treatment / advice as appropriate. * Advise on the benefits of smoking cessation. * Provide information about other smoking cessation services such as telephone support line or where applicable, level 3 commissioned smoking cessation services. * Document all information given. * Record refusal reason in the patient medication records (PMS) system – PharmOutcomes OR any other future information management system commissioned by the Council. |
| **3. Description of treatment** | | | |
| 3.1 | | **Generic (brand) name, strengths, form and action** | Varenicline (Champix®) 0.5mg film coated tablets  http://www.mims.com/resources/drugs/HongKong/pic/Champix film-coated tab 0.5 mg110.GIF  0.5mg (white) tab  4mm x 8mm  Varenicline (Champix®) 1mg film coated tablets  http://www.mims.com/resources/drugs/HongKong/pic/Champix film-coated tab 1 mg1078.GIF  1.0mg (blue) tab  5mm x 10mm  Action:  Varenicline (Champix**®**) Tablets  ACTION: Varenicline binds with high affinity and selectively at the α4 β2 neuronal nicotinic acetylcholine receptors, where it acts as a partial agonist. It alleviates the symptoms of cravings, withdrawal and reduces the rewarding / reinforcing effects of smoking. |
| 3.2 | | **Legal status (POM/P/GSL)** | Prescription only medicine (POM) |
| **Licensed or unlicensed use** | Licensed use only |
| 3.3 | | **Route of administration** | Oral |
| 3.4 | | **Dose and frequency** | The patient should set a date to stop smoking. The target stop date should be delayed until 7 to 14 days after starting treatment for the drug to achieve its optimal effect.  **Days 1 – 3**  0.5mg (white tablets) once daily  **Days 4 – 7**  0.5mg (white tablets) twice daily  **Day 8 – 12 weeks**  1mg (light blue tablets) twice daily  Note: The quit date is often on day 8 of taking varenicline  Tablets should be swallowed completely with plenty of water and can be taken with or without food. If the client is affected by nausea or other gastric disturbances, they should be advised to take Varenicline WITH food. However, patients who cannot tolerate the adverse effects of Varenicline, but are still motivated to continue treatment, may have their dose lowered temporarily or permanently to 0.5 mg twice daily.  Maximum single dose 1mg  Maximum daily dose 2mg |
| 3.5 | | **Quantity to be supplied** | Patients should be supplied with a 14-day initiation pack at their first appointment and should set a quit date 7 to 14 days after initiation.  A 14-day maintenance pack is then supplied fortnightly (or the equivalent, if the lower dose of 0.5mg twice daily is used). |
| 3.6 | | **Treatment protocol** | Patients should be supplied a 14-day initiation pack and should set a quit date for 7 to 14 days after initiation;  Only 14-day prescription packs should be used throughout the quit attempt (or the equivalent, if the lower dose of 0.5mg twice daily is used).  Treatment lasts for a maximum of 12 weeks (6x14 day packs).  Patients should be seen weekly for at least 4 weeks after the quit date and fortnightly for the remainder of the treatment if they successfully quit.  1st supply – 2 weeks (initiation pack containing 11 x 0.5mg tablets & 14 x 1mg tablets)  2nd supply – 2 weeks (1mg tablets x 28)  3rd supply – 2 weeks (1mg tablets x 28)  4th supply – 2 weeks (1mg tablets x 28)  5th supply – 2 weeks (1mg tablets x 28)  6th supply – 2 weeks (1mg tablets x 28)  **Each supply of Varenicline must be labelled and include a patient information leaflet (PIL).** |
| 3.7 | | **Adverse effects** | Patients should be asked at every appointment about nicotine withdrawal symptoms, including mood changes. Smoking cessation with or without treatment is associated with various nicotine withdrawal symptoms. For example, dysphoric or depressed mood; insomnia, irritability, frustration or anger; anxiety; difficulty concentrating; restlessness; decreased heart rate; increased appetite or weight gain have been reported in patients attempting to stop smoking.  NB: The list below is not exhaustive. Refer to the current BNF and up-to-date SPC of Varenicline for full details of adverse effects: [www.medicines.org.uk](http://www.medicines.org.uk)  Very common side effects include:   * Nausea is the most common side effect (about 28.6% of patients). In the majority of cases, it was mild to moderate in severity and occurred early in the treatment period approximately 30 minutes after taking varenicline. However, this can be reduced by taking the tablet after food and the reaction usually diminishes gradually. * Abnormal dreams / Insomnia. * Nasopharyngitis (Inflammation of the nose and throat). * Headache.   Common side effects include:   * Weight increased, decreased appetite, increased appetite, dysgeusia. * Dyspnoea, cough * Bronchitis, sinusitis * Somnolence, dizziness, transient loss of consciousness * Gastro-intestinal disturbance, dry mouth. * Chest pain, Fatigue.   Note well:   * Abnormal thinking - Stop Varenicline and refer to GP immediately. * Suicidal Ideation - Stop Varenicline and refer to GP immediately.   Effects on ability to drive and use machines:  Varenicline may have minor or moderate influence on the ability to drive and use machines. Varenicline may cause dizziness, somnolence and transient loss of consciousness, and therefore may influence the ability to drive and use machines. Patients are advised not to drive, operate complex machinery or engage in other potentially hazardous activities until it is known whether this medicinal product affects their ability to perform these activities.  Treatment discontinuation:  At the end of treatment, discontinuation of Varenicline was associated with an increase in irritability, urge to smoke, depression, and / or insomnia in up to 3% of patients.  Hypersensitivity reactions:  There have been post-marketing reports of hypersensitivity reactions including angioedema in patients treated with Varenicline. Clinical signs included swelling of the face, mouth (tongue, lips, and gums), neck (throat and larynx) and extremities. There were rare reports of life-threatening angioedema requiring urgent medical attention due to respiratory compromise. Patients experiencing these symptoms should discontinue treatment with Varenicline and contact a health care provider immediately.  Cutaneous reactions:  There have been post-marketing reports of rare but severe cutaneous reactions, including Stevens-Johnson Syndrome and Erythema Multiforme in patients using Varenicline. As these skin reactions can be life threatening, patients should discontinue treatment at the first sign of rash or skin reaction and contact a healthcare provider immediately.  Cardiovascular events:  Patients taking Varenicline should be instructed to notify their doctor of new or worsening cardiovascular symptoms and to seek immediate medical attention if they experience signs and symptoms of myocardial infarction or stroke.  **Adverse Drug Reaction (ADR’s):**  The Medicines and Health Products Regulatory Agency (MHRA) asks that all suspected reactions (including those not considered to be serious) are reported through the Yellow Card Scheme. An adverse reaction should be reported even if it is not certain that the drug has caused it, or if the reaction is well recognised, or if other drugs have been given at the same time. If in doubt, please report!  It is possible to report ADR’s online at:[**www.yellowcard.mhra.gov.uk**](http://www.yellowcard.mhra.gov.uk) or via the yellow card found at the back of the current edition of the BNF. If reporting via the latter, please post the yellow card to:  FREEPOST YELLOW CARD (No other address details required).  Alternatively, to report a Yellow Card: Freephone: 0808 100 3352 (10am to 2pm Monday to Friday only).  **Report all ADRs to patient’s GP.** |
| 3.8 | | **Communication to the GP** | When the initial supply of varenicline is made in accordance with this PGD, the community Lead Pharmacist should inform the client’s GP via PharmOutcomes or any other commissioned software system within two working days of the supply made. Refer to Appendix 3. |
| 3.9 | | **Information to be provided to the client** | Each dispensed supply of Varenicline must be labelled. Advice to clients should include specific product advice on dosage, method of administration and side effects. A Patient Information Leaflet (PIL) with Varenicline **must always** be supplied.  Patients should be advised to set a quit date 7 to 14 days after initiation.  Patients should be seen weekly for at least 4 weeks before the quit date and fortnightly for the remainder of the treatment if they successfully quit.  The major reasons for Varenicline failure are:   * Unrealistic expectations. * Lack of preparation for the fact that tablets may cause nausea. * Insufficient or incorrect use. * Insufficient support from trained smoking cessation advisors. In the 1st 5 weeks.   It is important to make sure that the patient understands the following points:  Varenicline is not a magic cure: effort and determination are crucial. It works by acting on the parts of the brain that are affected by nicotine in cigarettes. It does not remove all temptation to smoke, but it does make abstinence easier (‘it takes the edge off the discomfort’).  Varenicline is safe, but about a third of clients may experience mild nausea usually about 30 minutes after taking it. This reaction often diminishes gradually over the first few weeks, and most patients tolerate it without problems (Refer to P7 of this PGD).  The tablet must be Swallowed whole with water and not chewed. It can be taken with / without food but patients are advised to take with food to alleviate nausea.  **NOTE WELL: Patients must inform their GP** if they are on concurrent medications as stopping smoking may affect their levels e.g. Clozapine, Warfarin, insulin, theophylline. (Refer to P5 of this PGD).  Discuss the effects of Varenicline on the ability to drive and use machines. (Refer to P9 of this PGD).  If the patient suffers from excessively depressed mood (beyond normal withdrawal symptoms from smoking cessation), advise to stop the tablets and inform the GP and Lead Pharmacist. |
| 3.10 | | **Record keeping by the Lead Pharmacist** | Patient notes (Manual, Computerised, patient Held) should provide the following details:   * Patient’s name, address, date of birth and GP details. * Date of supply * Name of the accredited community Lead Pharmacist supplying Varenicline under the current version of the PGD. * Batch number and expiry date of Varenicline provided. * Inclusion / exclusion. (Refer to Appendix 1) * Advice given to patient. * Details of any adverse drug reaction and actions taken including documentation in the patient’s medical record. * All record keeping must be documented in PharmOutcomes or any other future platform commissioned by the Council. |

|  |
| --- |
| **References**   * British National Formulary (BNF) 76th Edition, September 2018. * Summary of Product Characteristics (SPC) for Champix**®**:[www.emc.medicines.org.uk](http://www.emc.medicines.org.uk). 21st August 2018 * NICE Stop Smoking interventions and Services - March 2018. <https://www.nice.org.uk/guidance/ng92> * NCSCT update on Varenicline and the EAGLES study: <http://www.ncsct.co.uk/usr/pub/Varenicline_SPC_update.pdf> * Anthenelli RM, Benowitz NL, West R, et al. Neuropsychiatric safety and efficacy of varenicline, bupropion, and nicotine patch in smokers with and without psychiatric disorders (EAGLES): a double-blind, randomized, placebo-controlled clinical trial. Lancet. 2016 Apr 19:e1-e14. [Epub ahead of print]. * Smoking Cessation Service Research Network: Sample Varenicline PGD (2008)+NeLM (National Electronic Library for Medicines)-to PGD or Not to PGD * NHS Clinical Knowledge Summaries. www.nice.org.uk /clinical-knowledge-summaries * NHS PGD website: [www.medicinesresources.nhs.uk](http://www.medicinesresources.nhs.uk) * National Institute for Health and Clinical Excellence (NICE). Varenicline for smoking cessation. NICE technology appraisal 123, Feb 2008. * CPPE Manchester: Open learning for Lead Pharmacists: Patient Group Directions. * NICE: Patient Group Direction; 2nd August 2013 (MPG2 – updated March 2017). * NHSE Varenicline PGD template for use by Public Health. |

|  |  |  |
| --- | --- | --- |
| **4. Staff characteristics required for the provision of Varenicline under the PGD in community pharmacies.** | | |
| 4.1 | **The Lead Pharmacist authorised to supply and/or administer medications under the PGD must meet the following criteria:** | **BEFORE WORKING TO THIS PGD, THE LEAD PHARMACIST MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION.**  **Qualifications**   * A Lead Pharmacist registered with the General Pharmaceutical Council * The Lead Pharmacist must be a registered Newham Level 2 Stop Smoking Advisor * The Lead Pharmacist has successfully completed the Newham accredited training programme for the supply of varenicline under PGD. * The contractor must meet the requirements of the enhanced service agreement * Working within a Newham pharmacy accredited to provide level 2 stop smoking services.   **Resources**   * The Lead Pharmacist must have access and regularly refer to: * Current British National Formulary (BNF) [www.bnf.org.uk](http://www.bnf.org.uk); * Varenicline (Champix®) Summary of Product Characteristics: [www.medicines.org.uk](http://www.medicines.org.uk) * Information about other services involved in providing healthy lifestyles (sign posting). * The Accredited pharmacy should have a private consultation room / area available for all client consultations. |
| 4.2 | Competency assessment and maintenance | * It is the responsibility of the individual Lead Pharmacist to ensure that they and their staff are competent in all aspects of supply of Varenicline and are up-to-date on all aspects of medicines information on Varenicline and on current medicines policies. * The Lead Pharmacist should have achieved the competency levels specified in the NICE Competency Framework for Health Professionals using Patient Group Directions.   <http://www.nice.org.uk/mpc/goodpracticeguidance/GPG2.jsp>   * The Lead Pharmacist must maintain a regular Self-Assessment Declaration of Competency every two years or sooner if appropriate. * It is the responsibility of the Lead Pharmacist to undertake Continuing Professional Development and to make this information available on request. |

**PGD development group**

|  |  |
| --- | --- |
| **Name** | **Job title and organisation** |
| Lead Doctor | Dr Adeola Agbebiyi  Public Health Consultant  London Borough of Newham |
| Lead Author Reviewed by Consultant Lead Pharmacist | Mr Viral V Doshi FRPharmS  Independent Consultant Lead Pharmacist |
| Lead Pharmacist | Bola Sotubo  Assistant Director of Medicines Management  Newham Clinical Commissioning Group |
| Other members of the PGD working group | Foizul Islam  Public Health Commissioner  London Borough of Newham |

**Organisational authorisations and other legal requirements**

The PGD is not legally valid until it has had the relevant organisational authorisations. To ensure compliance with the law, organisations must add local authorisation details i.e. clinical authorisations and the authorising organisation. Complete details below or use format agreed according to local policy.

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** | **Job title and organisation** | **Signature** | **Date** |
| Lead Doctor | Dr Adeola Agbebiyi  Public Health Consultant  London Borough of Newham |  | 5th July 2019 |
| Consultant Lead Pharmacist | Mr Viral V Doshi FRPharmS  Consultant Lead Pharmacist |  | 17th June 2019 |
| Lead Pharmacist | Bola Sotubo  Assistant Director of Medicines Management  Newham Clinical Commissioning Group |  | 12th June 2019 |
| Person signing on behalf of authorising body | Jason Strelitz  Director of Public Health  London Borough of Newham |  | 3rd September 2019 |

Appendices 3: Smoking cessation pathway pharmacies and specialist service

**Successful 12 weeks quit** – CO reading

Resident choose to continue Nicotine Replacement Therapy **in pharmacy**

**Nicotine Replacement Therapy**

**Successful 4 weeks quit** – CO reading

**First Contact in pharmacy**

Non-priority groups (or priority groups that would prefer pharmacy support) are registered.

**Priority groups and patients with 2 or more failed quit attempts are referred to QMUL for specialist stop smoking support.**

**Relapse/ does not quit after 12 weeks: Refer to QMUL**

**Relapse/ does not quit after 4 weeks: Refer to QMUL**

1. Joint Strategic Needs Assessment 2017-19, London Borough of Newham and Newham Clinical Commissioning Group, <https://www.newham.gov.uk/Documents/Health%20and%20social%20care/AdultJointStrategicNeedsAssessment.pdf> [↑](#footnote-ref-2)
2. <https://www.londoncp.co.uk/safer_recruit.html> [↑](#footnote-ref-3)
3. <https://www.newhamscp.org.uk/policies-and-procedures/> [↑](#footnote-ref-4)
4. <https://www.newham.gov.uk/Pages/News/Mayor-to-call-on-businesses-to-offer-London-Living-Wage.aspx> [↑](#footnote-ref-5)
5. Newham local authority summary profile of local authority sexual health, Public Health England, 2020 [↑](#footnote-ref-6)
6. https://fingertips.phe.org.uk/static-reports/sexualhealth/E09000025.html?area-name=Newham [↑](#footnote-ref-7)
7. [↑](#footnote-ref-8)
8. Action on Smoking and Health: The Local Costs of Tobacco: ASH Ready Reckoner (2019 Edition): <http://ash.lelan.co.uk/> [↑](#footnote-ref-9)
9. <https://fingertips.phe.org.uk/static-reports/tobacco-control/at-a-glance/E09000025.html?area-name=Newham> [↑](#footnote-ref-10)
10. PHE, 2019 Finger tips tobacco control profiles, date accessed: 04/07/2019 <https://fingertips.phe.org.uk/profile/tobacco-control/data#page/0/gid/1938132885/pat/6/par/E12000007/ati/102/are/E09000002> [↑](#footnote-ref-11)
11. Healthy Lives Needs Assessment (2020) – Smoking data - Newham [↑](#footnote-ref-12)
12. <https://www.ncsct.co.uk/usr/pub/LSSS_service_delivery_guidance.pdf> [↑](#footnote-ref-13)
13. https://fingertips.phe.org.uk/search/smoking#page/0/gid/1/pat/6/par/E12000007/ati/102/are/E09000025 [↑](#footnote-ref-14)
14. Newham local authority fingertips on smoking data, Public Health England, 2020 [↑](#footnote-ref-15)
15. <https://www.ncsct.co.uk/usr/pub/LSSS_service_delivery_guidance.pdf> [↑](#footnote-ref-16)
16. <https://files.digital.nhs.uk/3E/EC36A2/HSE17-Child-Health-rep.pdf> [↑](#footnote-ref-17)
17. <https://www.ncsct.co.uk/usr/pub/LSSS_service_delivery_guidance.pdf> [↑](#footnote-ref-18)
18. PHE, 2019 Finger tips tobacco control profiles, date accessed: 04/07/2019 <https://fingertips.phe.org.uk/profile/tobacco-control/data#page/0/gid/1938132885/pat/6/par/E12000007/ati/102/are/E09000002> [↑](#footnote-ref-19)
19. The fraction of cancer attributable to modifiable risk factors in England, Wales, Scotland, Northern Ireland, and the United Kingdom in 2015. <https://www.nature.com/articles/s41416-018-0029-6> [↑](#footnote-ref-20)
20. The fraction of cancer attributable to modifiable risk factors in England, Wales, Scotland, Northern Ireland, and the United Kingdom in 2015. <https://www.nature.com/articles/s41416-018-0029-6> [↑](#footnote-ref-21)
21. Mortality from smoking in developed countries 1950−2020. <https://gas.ctsu.ox.ac.uk/tobacco/C4308.pdf> [↑](#footnote-ref-22)
22. Newham JSNA <https://www.newham.gov.uk/Documents/Health%20and%20social%20care/AdultJointStrategicNeedsAssessment.pdf> [↑](#footnote-ref-23)
23. Regional inequalities in premature mortality in Great Britain. <https://doi.org/10.1371/journal.pone.0193488> [↑](#footnote-ref-24)
24. PHE fingertips profiles, all indicators. <https://fingertips.phe.org.uk/profile/health-profiles/data#page/0/gid/1938132701/pat/6/par/E12000007/ati/102/are/E09000025/iid/108/age/163/sex/4> [↑](#footnote-ref-25)
25. Regional inequalities in premature mortality in Great Britain. <https://doi.org/10.1371/journal.pone.0193488> [↑](#footnote-ref-26)
26. Stop smoking interventions and services (NG92), NICE, 2018 [↑](#footnote-ref-27)
27. Stead LF Carroll AJ, Lancaster T. Group behaviour therapy for smoking cessation. Cochrane Database of Systematic Reviews, 2017, Issue 3. Art No: CD001007. DOI: 10.1002/14651858.C [↑](#footnote-ref-28)
28. Stop smoking interventions and services (NG92), NICE, 2019 [↑](#footnote-ref-29)
29. [↑](#footnote-ref-30)
30. <https://www.ncbi.nlm.nih.gov/pubmed/28922449> [↑](#footnote-ref-31)
31. [↑](#footnote-ref-32)
32. [↑](#footnote-ref-33)
33. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\_data/file/214915/15-02-2013-controlled-drugs-regulation-information.pdf [↑](#footnote-ref-34)