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Protocol for the administration of lidocaine 10mg/ml spray to facilitate intrauterine contraception (IUC) insertion or removal in Integrated Sexual Health Services (ISHS) Derbyshire Community Health Services

Version Number 1.0

Change History	
Version and Date	**Change details**
Version 1 August 2023	New template

This template protocol, for local adaptation, has been peer reviewed by the Reproductive Health PGD/protocols 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 2022.

For advice on protocol use in practice/advised supporting governance please refer to When Patient Group Directions are not required and About the SPS Medicines Governance Do Once Programme

Number:	294
Implemented:	September 2023
Publication date:	January 2023
Review date	September 2025
Expiry date:	March 2026

Protocol development group

Name	Designation
Dr Cindy Farmer	Vice President, General Training Faculty of Sexual and Reproductive Healthcare (FSRH)
Michelle Jenkins	Advanced Nurse Practitioner, Clinical Standards Committee Faculty of Sexual and Reproductive Healthcare (FSRH)
Vicky Garner	Deputy Chief Midwife British Pregnancy Advisory Service (BPAS)
Gail Rowley	Quality Matron British Pregnancy Advisory Service (BPAS)
Katie Girling	British Pregnancy Advisory Service (BPAS)
Julia Hogan	CASH Nurse Consultant MSI Reproductive Choices
Kate Devonport	National Unplanned Pregnancy Advisory Service (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)
Kirsty Armstrong	National Pharmacy Integration Lead, NHS England
Dipti Patel	Local authority pharmacist
Emma Anderson	Centre for Pharmacy Postgraduate Education (CPPE)
Dr Kathy French	Specialist Nurse
Dr Sarah Pillai	Associate Specialist
Alison Crompton	Community pharmacist
Andrea Smith	Community pharmacist
Lisa Knight	Community Health Services pharmacist
Bola Sotubo	NHS North East London ICB pharmacist
Tracy Rogers	Director, Medicines Use and Safety, Specialist Pharmacy Service
Sandra Wolper	Associate Director Specialist Pharmacy Service
Jo Jenkins (Working Group Co-ordinator)	Lead Pharmacist PGDs and Medicine Mechanisms Specialist Pharmacy Service

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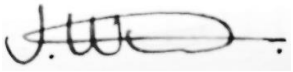
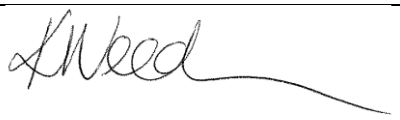
ORGANISATIONAL AUTHORISATION

This protocol has been agreed by doctors, and/or expert clinical practitioners, pharmacist and representative healthcare professionals from the trust stated below for use within Integrated Sexual Health Services (ISHS), University of Derby and Burton Teaching Hospitals Foundation Trust (UHDBFT) and Derbyshire Community Health Services Foundation Trust (DCHSFT)

This protocol is authorised for use on behalf of DCHS by the following signatories:			
Position of signatory	**Name**	**Signature**	**Date**
Deputy Chief Nurse	Jo Wain		09/08/2023
Head of Medicines Management	Kate Needham		09/08/2023
Medical Director	Dr Ben Pearson		09/08/2023
Lead Clinician ISHS	Dr Ade Apoola		09/08/2023

REVIEWED AND DEVELOPED FOR LOCAL USE BY:		
Date	**Name**	**Position**
May 2023	Lisa Walton Dr Ade Apoola Dr Amanda Smith DCHS IP&C Team	ISHS Specialist Nurse Practitioner ISHS Lead Clinician Associate Specialist ISHS

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1. Staff competencies	
Authorised staff	A registered nurse working within ISHS who is deemed competent by their clinical line manager and authorised by their professional lead to undertake the clinical assessment of patients leading to the identification of those suitable for management under this protocol.
Additional requirements	Has undertaken local training based on the use of this protocol. Has undertaken training in recognition of and treatment of anaphylaxis including basic life support in the 12 months. The nurse should be aware of any change to the recommendations for the medicines listed. • It is the responsibility of the individual to keep up-to-date with continued professional development and to work within the limitations of individual scope of practice.
2. Clinical condition or situation	
Clinical situation	Administration of lidocaine 10 mg/metered dose spray to facilitate intrauterine contraception (IUC) insertion or removal.
Individuals included	• Individual (age from menarche to 55 years) presenting for planned/emergency insertion of an intrauterine contraceptive (IUC) device. • Individual consents to treatment.
Individuals excluded	• Consent not given • Hypersensitivity to any of the ingredients of the preparation (see SPC www.medicines.org.uk) • Severe cervical ectropion • Individual concurrently receiving/using any other local anaesthetic or agents structurally related to amide-type local anaesthetic e.g. antiarrhythmic drugs such as mexiletine • Any open wounds affecting the application area or the immediate vicinity
Cautions – monitor individual closely for adverse effects	• Known epilepsy. • Known cardiovascular disease and/or heart failure. • Known impaired cardiac conduction or bradycardia. • Known severe renal impairment. • Known hepatic impairment. • Known porphyria. • Individuals currently taking antiarrhythmic drugs class III (e.g. amiodarone)
Action for individuals excluded	Refer to a doctor or ISHS non-medical prescriber to consider alternative pain relief if requested by the individual. Document advice given.
Action if individual declines treatment	Document in patient's records.

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3. Description of treatment	
Medicine to be administered	Lidocaine 10 mg/metered dose per spray. The contents of each 50ml spray bottles are sufficient to provide approximately 500 sprays with a metering spray pump. Each depression of the metered spray pump delivers 10 mg lidocaine base.
Legal status	Pharmacy Only (P) medicine
Dose schedule/administration advice:	Apply 4 metered dose sprays (total dose 40mg) to the surface of the cervix and external os and wait 3 minutes after application. As with any local anaesthetic, reactions and complications are best averted by employing the minimal effective dosage (see Overdose section below). *Note: The SPC indicates that children should be given doses commensurate with their age and weight. The maximum dose in children is up to 3 mg/kg. Therefore, up to 4 metered dose sprays is within the safety tolerance of post-menarchal young people.* It is unnecessary to dry the site prior to application. Lidocaine spray is administered using the supplied nozzles. The spray nozzle is bent to ensure correct spray function. Do not try to alter the shape as this could affect its performance. The nozzle must not be shortened, as it will affect the spray function. Nozzles are non-sterile single patient single use and standard infection control practices should be adhered to in order to prevent cross contamination – refer to the product's Risk Minimisation Materials to help reduce the risks associated with using this medicine. The bottle should be covered with a clean single use cover for each use ie small latex free glove which should be discarded immediately after use. The nozzles should be handled using gloves and the box of 50 should be kept closed between procedures. **Nozzles should not be reused and should be discarded immediately after use.** Standard infection control practices e.g. hand hygiene and waste disposal policies can be found on the DCHS Policies and Procedures section of the Intranet.
Maximum dosage to be administered under this protocol:	A maximum of 4 sprays (total 40mg) per episode of care may be administered.

Off label use	The use of lidocaine spray for the indications detailed within this protocol are outside the product licence but are supported by national guidance from the FSRH.
Storage	Do not store above 25°C. Medicines should be stored according to the conditions detailed above. However, in the event of an inadvertent or unavoidable deviation of these conditions the local pharmacy or Medicines Management team must be consulted. Where medicines 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 protocol. The responsibility for the decision to release the affected medicines for use lies with pharmacy/Medicines Management. Where a medicine is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the medicine is being offered in accordance with national guidance but that this is outside the product license.
Adverse effects	**Extremely rare:** Amide-type local anaesthetic preparations have been associated with allergic reactions (in the most severe instances anaphylactic shock). Adrenaline 1:1000/anaphylaxis kit should be readily available in areas where lidocaine spray is administered as should access to a phone to summon assistance if required. **Rare:** Systemic adverse reactions may result from high plasma levels due to excessive dosage or rapid absorption or from hypersensitivity, idiosyncrasy or reduced tolerance on the part of the individual (see cautions section above). CNS reactions are excitatory and/or depressant and may be characterised by nervousness, dizziness, convulsions, unconsciousness and possibly respiratory arrest. The excitatory reactions may be very brief or may not occur at all, in which case the first manifestations of toxicity may be drowsiness, merging into unconsciousness and respiratory arrest. Cardiovascular reactions are depressant and may be characterised by hypotension, myocardial depression, bradycardia and possibly cardiac arrest. If this occurs, then immediate assistance should be summoned and standard adult life support procedures instigated as required.

	Unknown frequency: Local irritation at the application site. Vaginal irritation.
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 via organisation incident policy.
Overdose	Toxic reactions originate mainly in the central nervous and the cardiovascular systems. Central nervous system toxicity is a graded response with symptoms and signs of escalating severity. The first symptoms are circumoral paraesthesia, numbness of the tongue, light-headedness, hyperacusis and tinnitus. Visual disturbance and muscular tremors are more serious and precede the onset of generalised convulsions. Unconsciousness and grand mal convulsions may follow, which may last from a few seconds to several minutes. Hypoxia and hypercarbia occur rapidly following convulsions due to the increased muscular activity, together with the interference with normal respiration. In severe cases, apnoea may occur. Acidosis increases the toxic effects of local anaesthetics. Cardiovascular effects are only seen in cases with high systemic concentrations. Severe hypotension, bradycardia, arrhythmia and cardiovascular collapse may be the result in such cases. If this occurs, then immediate assistance should be summoned and standard adult life support procedures instigated as required. Recovery is due to redistribution and metabolism of the local anaesthetic drug from the central nervous system. Recovery may be rapid unless large amounts of the drug have been administered.
Record keeping	The following must be recorded in the patients record:

	• Patient's name, address, date of birth, clinic number • Criteria under which the individual fits the protocol • Allergies, previous adverse events • Details of medicines including name, strength dose, route • Assessment to competency to consent (including Fraser competency) to treatment for patients at risk • Verbal consent obtained as per DCHS Consent Policy • Date and time of administration • Batch number and expiry details • A statement that administration is under a protocol • Name and signature (which may be electronic) of healthcare professional acting under the protocol to supply the medication • Relevant information that was given to the individual/carer. • Any discussion with doctor/ another professional e.g. regarding safeguarding • Advice given to patient (including side effects, contraception etc) • Any other relevant details of consultation
References	FSRH Guideline Intrauterine Contraception FSRH Clinical Guideline: Intrauterine contraception (March 2023) - Faculty of Sexual and Reproductive Healthcare Summary of Product Characteristics: www.medicines.org.uk

Appendix A – Registered health professional authorisation sheet

Protocol/Version: Protocol for the administration of lidocaine 10mg/ml spray to facilitate intrauterine contraception (IUC) insertion or removal V1.0

Valid from: 1 September 2023 **Expiry:** 31 March 2026

Before signing this protocol, check that the document has had the necessary authorisations.

Registered health professional
By signing this protocol you are indicating that you agree to its contents and that you will work within it.

The protocol does 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 protocol and that I am willing and competent to work to it within my professional code of conduct.			
Name	**Designation**	**Signature**	**Date**

Authorising manager

I confirm that the registered health professionals named above have declared themselves suitably trained and competent to work under this protocol. I give authorisation on behalf of Derbyshire Community Health Services for the above named health care professionals who have signed the protocol to work under it.			
Name	**Designation**	**Signature**	**Date**

Note to authorising manager

Score through unused rows in the list of registered health professionals to prevent additions post managerial authorisation.

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

Protocol Authorisation Forms shall be maintained and retained by the Service Manager who is responsible for the safe storage of the records.

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