



Bronllys Hospital, Bronllys, Brecon, Powys, LD3 0LU

This Patient Group Direction (PGD) must only be used by registered health 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. Health professionals should always access the PGD via the PTHB internet to ensure that they are always working to the most up to date version

Patient Group Direction
for the administration of

Lidocaine Hydrochloride 1% Solution for Injection

by registered health professionals

to facilitate insertion and/or removal of subdermal etonogestrel (e.g. Nexplanon®) implant

in Sexual Health Departments in Powys Teaching Health Board or postnatally via PTHB Maternity Services

Version number: PGD 0178A

Bwrdd Iechyd Addysgu Powys yw enw gweithredol Bwrdd Iechyd Lleol Addysgu Powys
Powys Teaching Health Board is the operational name of Powys Teaching Health Board

Change history

Version number	Change details	Date
PGD 0178	Initial issue, use of national PGD template	04/06/2021
PGD 0178A	Review in line with SPS template version 2.0: Updated template (no clinical changes to expired V1). Updated exclusions, adverse effects and references. Minor changes to some wording and formatting. Aligned content with other PGDs for same or associated medicine / group. Updated PGD development group members.	01/09/2023

This Powys Teaching Health Board (PTHB) PGD is based on a template developed on behalf of the Specialist Pharmacy Service, which had been peer reviewed by the Reproductive Health PGDs Short Life Working Group in accordance with their Terms of Reference. It had been approved by the Faculty for Sexual and Reproductive Health (FSRH) in April 2023. Acknowledgements:

Name	Designation
Dr Cindy Farmer	Vice President, General Training FSRH
Michelle Jenkins	Advanced Nurse Practitioner FSRH
Vicky Garner	Consultant Midwife British Pregnancy Advisory Service (BPAS)
Sim Sesane	CASH Nurse Consultant MSI Reproductive Choices
Kate Devonport	National Unplanned Pregnancy Association (NUPAS)
Chetna Parmar	Pharmacist adviser Umbrella
Heather Randle	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 Postgraduate Pharmacy 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	ICB pharmacist
Tracy Rogers	Director, Medicines Use and Safety, Specialist Pharmacy Service
Sandra Wolper	Associate Director Specialist Pharmacy Service
Jo Jenkins	Lead Pharmacist PGDs and Medicine Mechanisms, Medicines Use and Safety, Specialist Pharmacy Service
Rosie Furner (Working Group Co-ordinator)	Governance Pharmacist, Medicines Use and Safety, Specialist Pharmacy Service

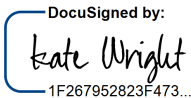
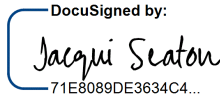


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PGD authorisation

Name	Job title and organisation	Signature	Date
Senior doctor Dr Kate Wright	Lead doctor for PTHB	 DocuSigned by: Kate Wright 1F267952823F473...	8/3/2023
Chief Pharmacist Jacqui Seaton	Chief Pharmacist for PTHB	 DocuSigned by: Jacqui Seaton 71E8089DE3634C4...	8/7/2023
Clinical Governance Lead Amanda Edwards	Clinical Governance Lead for PTHB- Assistant Director for Innovation and Improvement	 DocuSigned by: Amanda Edwards 74A4E51A42E9473...	8/15/2023
Senior representative of professional group using the PGD Claire Roche	Executive Director of Nursing and Midwifery for PTHB	 DocuSigned by: Claire Roche FC9C4C63FC374A7...	8/15/2023

[Appendix A](#) provides a staff accreditation sheet. Individual practitioners must be authorised by name to work to this PGD.

Those using this PGD must ensure that it is organisationally authorised and signed by an appropriate authorising person, relating to the class of person by whom the product is to be supplied, in accordance with Human Medicines Regulations 2012 (HMR2012)¹. **The PGD is not legal or valid without signed authorisation in accordance with [HMR2012 Schedule 16 Part 2](#).**

The final authorised copy of this PGD should be kept by PTHB for 25 years after the PGD expires.

¹ This includes any relevant amendments to legislation.

1. Characteristics of staff

<p>Qualifications and professional registration</p>	<p>Current contract of employment with PTHB.</p> <p>Practitioners must only work under this PGD where they are competent to do so. Practitioners working under this PGD must also be a registered professional with the following body:</p> <ul style="list-style-type: none"> • Nurse or midwife currently registered with the Nursing and Midwifery Council (NMC) and providing Sexual Health Services or postnatal care <p>The practitioners above must also fulfil the training and Additional requirements detailed below.</p> <p>Check Appendix A: Staff accredited to use the Patient Group Direction.</p>
<p>Initial training</p>	<p>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 individuals ensuring safe provision of the medicines listed in accordance with local policy (including Lidocaine 1% w/v injection and knowledge of its uses, contraindications and adverse effects; be alert to changes in the BNF and Summary of Product Characteristics; and be competent to assess an individual's capacity to understand the nature and purpose of the treatment and capacity to give or refuse consent to treatment).</p> <p>Recommended requirement for training would be successful completion of a relevant module/course accredited or endorsed by the FSRH (sign in with your Athens account, then search for Contraception), HEIW, or a university or as advised in the RCN training directory. In addition, completion of the FSRH Letter of competence (LOC) in Subdermal implants (LOC SDI-IR/LOC SDI-IO) or locally agreed additional training and been assessed as competent at the insertion and/or removal of the subdermal implant which should also include training and been assessed as competent in the administration of lidocaine.</p>

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	<p>Individual has undertaken appropriate training for working under PGDs for the supply and administration of medicines. Recommended training - eLfh PGD elearning programme, PTHB staff to access via ESR.</p> <p>The healthcare professional must keep up to date with current FSRH guidance relevant to the insertion/removal of the contraceptive implant including any relevant MHRA Drug Safety Updates.</p> <p>The healthcare professional has completed locally required training (including updates) in safeguarding children and vulnerable adults or a minimum of level 2 safeguarding or the equivalent.</p> <p>The healthcare professional must ensure that they have an up to date certificate for Basic Life Support (BLS) and anaphylaxis, and be competent in the administration of adrenaline.</p> <p>Additionally, practitioners:</p> <ul style="list-style-type: none"> • must be competent in the management and reporting of adverse drug reactions • must have access to the Patient Group Direction and associated online resources <p>THE PRACTITIONER MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT</p>
<p>Competency assessment</p>	<ul style="list-style-type: none"> • Individuals operating under this PGD must be assessed as competent (see Appendix A) or complete a self-declaration of competence for contraception supply, in their Personal Appraisal and Development Review (PADR). • Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions. • At least Level 2 safeguarding passport • Evidence of ongoing PGD training to be submitted to Line Manager annually. • Practitioners must be competent, recognise their own limitations and personal accountability and act accordingly. • Evidence of training in BLS and anaphylaxis.

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<p>Ongoing training and competency</p>	<ul style="list-style-type: none"> • Individuals operating under this PGD are personally responsible for ensuring 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. • Practitioners must ensure they are up to date with relevant issues and clinical skills and management of anaphylaxis, Life Support Skills, with evidence of appropriate Continued Professional Development (CPD). • Updating at least every 2 years on the use of PGD's and 1% lidocaine hydrochloride injection • Compliance with all mandatory NHS training including a minimum of safeguarding level 2. <p>It is the responsibility of the healthcare professional to maintain their own competency to practice within this PGD.</p>
<p>The decision to administer any medication rests with the individual registered health professional who must abide by the PGD and any associated organisational policies.</p>	

2. Clinical condition or situation to which this PGD applies

<p>Clinical condition or situation to which this PGD applies</p>	<p>Local anaesthetic for insertion and/or removal of subdermal etonogestrel subdermal contraceptive implant.</p> <p>It is the responsibility of the administering healthcare professional to ensure that the individual is within the inclusion criteria, and that there are no reasons for exclusion before proceeding with the treatment. If there is any reason for concern, seek medical advice.</p>
<p>Criteria for inclusion</p>	<ul style="list-style-type: none"> • Any individual requiring the insertion and/or removal of etonogestrel subdermal contraceptive implant under the etonogestrel subdermal contraceptive implant PGD. Individuals requiring lidocaine for the insertion of a subdermal contraceptive implant should also meet the inclusion criteria of the etonogestrel subdermal contraceptive implant PGD – see PGD0177. • Informed consent given. Refer to PTHB Consent to Treatment and Examination Policy. In case of

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	<p>any doubt, contact medical team or gynaecologist. The individual should be informed they are being treated using a PGD.</p> <ul style="list-style-type: none"> • Medical and drug history taken, no reason for exclusion. <p>For all clients aged 13 to 17 years, a CSERQ 4/15 questionnaire must be completed. For adults, if safe to do so, client responses to the targeted enquiry (Ask and Act) may highlight risk factors, which will indicate that the practitioner should complete the Safe Lives Risk Identification Checklist (DASH RIC). This will subsequently aid decision making regarding safeguarding and MARAC referrals. Any vulnerable adult or child protection safeguarding concerns or significant risk factors identified should be referred to the local PTHB Safeguarding team and Powys Children Services and PTHB safeguarding policies followed.</p> <p>NB. Special consideration: Consultation areas must respect an individuals' right to confidentiality and safety and provide an acceptable level of privacy.</p> <p>It is the responsibility of the administering nurse or midwife to ensure that the patient is within the inclusion criteria, and that there are no reasons for exclusion before proceeding with the treatment. If there is any reason for concern, seek medical advice.</p>
<p>Criteria for exclusion</p>	<ul style="list-style-type: none"> • Consent not given. Individuals for whom valid consent, or 'best-interests' decision, in accordance with the Mental Capacity Act 2005, has not been obtained or received. Refer to sections "Action to be taken if the individual is excluded or declines treatment". • Individuals under 16 years of age and assessed as not competent using Fraser Guidelines. • Individuals 16 years of age and over and assessed as lacking capacity to consent. • Individuals under 13 years of age. 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.

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	<p>Any individual under 13 years of age, known to have engaged in sexual activity must be referred to Powys Children Service or CEOP Safety Centre. See Action to be taken if individual is excluded for further information.</p> <ul style="list-style-type: none"> • Known hypersensitivity to the active ingredient or to any constituent of the product - see Summary of Product Characteristics, or other amide type anaesthetics. • Individual who had received a previous maximum infiltration of local anaesthetic within 4 hours. <p>Cardiovascular Disease</p> <ul style="list-style-type: none"> • Complete heart block • Hypovolaemia <p>Other conditions</p> <ul style="list-style-type: none"> • Porphyria <p>Interacting medications Interacting medicines – see current British National Formulary (BNF) www.bnf.org or individual product SPC http://www.medicines.org.uk</p>
<p>Cautions including any relevant action to be taken</p>	<ul style="list-style-type: none"> • 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. • Individuals who are breastfeeding. The individual should be informed that small amounts of lidocaine may be excreted into the breast milk. The possibility of an allergic reaction in the infant, albeit remote, should be borne in mind when receiving lidocaine when breastfeeding. • The SmPC recommends use with caution in the following patient groups. Given the dose and route used, they are not excluded under this PGD. No additional monitoring is required. This is in line with FSRH feedback. <ul style="list-style-type: none"> ○ Bradycardia ○ Congestive heart failure ○ Known acute porphyria ○ Known epilepsy

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	<ul style="list-style-type: none"> ○ Known myasthenia gravis ○ Impaired respiratory function ○ Severe renal impairment (eGFR <10ml/min/Stage 5) ● Discuss with appropriate medical/independent non-medical prescriber any medical condition or medication of which the healthcare professional is unsure or uncertain. ● Any vulnerable adult or child at risk should be referred to Safeguarding and local guidelines followed, along with PTHB Safeguarding Policies.
<p>Arrangements for referral for medical advice</p>	<p>Contact GP via the surgery or the emergency on-call service, document advice given.</p> <p>Where required, refer the individual to gynaecologist/ GUM consultant /level 3 Sexual Health services for advice, if applicable.</p> <p>Call medical cover for advice and document advice given.</p>
<p>Action to be taken if the individual is excluded or declines treatment</p>	<ul style="list-style-type: none"> ● Explain the reasons for exclusion to the individual and document in the consultation record. ● Record reason for decline in the consultation record. ● Where required refer the individual to a suitable health service provider if appropriate and/or provide them with information about further options. ● The child protection team must be contacted for children under 13 years who present having had sexual intercourse. <p>Under Section 128 and 130 of the Social Services and Wellbeing (Wales) Act 2014, staff have a duty to inform the Local Authority if they have reasonable cause to suspect that an adult or child is at risk.</p> <p>Any vulnerable adult or child protection concerns should be referred to Safeguarding and PTHB safeguarding policies followed. Consider discussing with GP. Where there are safeguarding concerns (Child Protection or Protection of Vulnerable Adults, POVA) advice from the local Safeguarding team should be sought from the Safeguarding Hub:</p> <ul style="list-style-type: none"> ● To generic email address:

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	<p>PowysTHB.Safeguarding@wales.nhs.uk</p> <p>And</p> <ul style="list-style-type: none"> • Central Safeguarding number: 01686 252806 • Out of hours: 0345 0544847 <p>Advice can also be sought from local Safeguarding leads</p>
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3. Description of treatment

Name, strength & formulation of drug	Lidocaine 1% w/v (10 mg in 1 mL) solution for injection in 2mL, 5 mL or 10 mL ampoules
Legal category	POM
Route of administration	Subcutaneous or intradermal surface infiltration only
Off label use	<p>Medicines should be stored according to the conditions detailed in the Storage section below. 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 PGD. The responsibility for the decision to release the affected medicines for use lies with pharmacy/ Medicines Management.</p> <p>Where a medicine is recommended off-label consider, as part of the consent process, informing the individual that the drug is being offered in accordance with national guidance but that this is outside the product licence.</p>
Dose and frequency of administration	<p>Insertion: Initially 5-20mg (0.5-2ml). A further dose of up to 10mg (1ml) may be used if required to a total maximum dose of 30mg (3ml).</p> <p>Removal: 5-10mg (0.5-1ml).</p> <p>Total maximum dose for concurrent removal and insertion is 40mg (4ml).</p>

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Duration of treatment	Single episode of care permitted under this PGD (i.e. insertion or removal only or concurrent removal and insertion).
Storage	Medicines must be stored securely according to national guidelines and in accordance with the product SPC .
Drug interactions	<p>All concurrent medications, including those purchased should be considered for interactions.</p> <p>A detailed list of drug interactions is available in the individual product SPC, which is available from the electronic Medicines Compendium website https://www.medicines.org.uk/emc the BNF https://bnf.nice.org.uk/ and, as this PGD supports the administration of hormonal contraception, FSRH CEU Guidance: Drug Interactions with Hormonal Contraception https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/</p> <p>Refer to a prescriber if any concern of a clinically significant drug interaction.</p>
Identification & management of adverse reactions	<p>A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk and BNF https://bnf.nice.org.uk/</p> <p>Note when used for surface anaesthesia rapid and extensive absorption may result in systemic side effects.</p> <p>Hypersensitivity reactions (allergic or anaphylactoid reactions, anaphylactic shock). In case of an acute anaphylactic reaction occurring, adequate treatment provision must be available for immediate use: Anaphylaxis and resuscitation equipment including adrenaline (1 in 1000) injection and a working telephone.</p> <p>In the case of anaphylaxis:</p> <ul style="list-style-type: none"> • Refer to adrenaline (epinephrine) PGD and anaphylaxis policy

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	<ul style="list-style-type: none"> • Request medical assistance urgently. If the GP is not immediately available dial 999 to transfer to A&E • Ensure reaction is fully documented in individual's notes • Ensure all individual's records are marked ALLERGIC TO Lidocaine 1% w/v injection • The individual may be advised to wear a MedicAlert or similar device to alert other healthcare providers <p>Report via Datix Once for Wales Reporting system</p> <p>Adverse effects are rare and usually a sign of accidental intravascular injection, excessive dosage or rapid absorption from highly vascular areas, or may result from a hypersensitivity, idiosyncrasy or diminished tolerance on the part of the patient. Systemic toxicity mainly involves the central nervous system and/or the cardiovascular system. Monitor individual for signs of:</p> <ul style="list-style-type: none"> • Confusion • Respiratory depression • Convulsions • Hypotension • Bradycardia • Dizziness <p>If overdose or severe adverse reaction suspected immediately contact doctor or refer to A&E.</p>
<p>Additional facilities and supplies</p>	<ul style="list-style-type: none"> • Access to working telephone • Suitable waste disposal facilities • Immediate access to in-date anaphylaxis kit (IM adrenaline 1:1000)
<p>Management of and reporting procedure for adverse reactions</p>	<ul style="list-style-type: none"> • 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 or search for MHRA Yellow Card in the Google Play or Apple App Store. For established medicines, serious adverse events in adults or all suspected adverse reactions in children that may be attributable to the medication should be reported. Guidance on

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	<p>the yellow card system is available at the back of the BNF or using the above link.</p> <ul style="list-style-type: none"> Record all adverse drug reactions (ADRs) in the individual's medical record and inform the individual's GP. All significant adverse drug reactions and any administration errors must be recorded. Report via Datix Once for Wales Reporting system.
Written information and further advice to be given to individual	<ul style="list-style-type: none"> Offer Manufacturer's Patient Information Leaflet (PIL). Explain mode of action, side effects, and benefits of the medicine.
Advice / follow up treatment	<p>Advise individual:</p> <ul style="list-style-type: none"> How to care for the injection site and advise to return if concerns about the injection site. Give information on who to contact in the event of an adverse reaction or concerns.
Records	<p>Record consultation details as required by local procedures. In addition, record:</p> <ul style="list-style-type: none"> The consent of the individual and: <ul style="list-style-type: none"> 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 Individual's name, address and date of birth GP contact details where appropriate Attendance date Reason for attendance Relevant past and present medical and family history, including drug history Any known allergies and previous adverse events Relevant examination findings Inclusion or exclusion from PGD A statement that administration is for insertion of subdermal implant and is by using a PGD (include version number) Advice given about the medication including side effects, benefits, and when and what to do if any concerns Details of any adverse drug reactions and what action taken Any referral arrangements

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	<ul style="list-style-type: none">• Any administration outside the marketing authorisation• Record the name/brand, dose of the medication, site of injection• Record batch number and expiry date according to local policy or national guidelines• Record follow up and/or signposting arrangements• Any other relevant information that was provided to the individual• Name and signature (which may be an electronic signature) of the clinician administering the medicine. <p>Records should be signed and dated (or a password-controlled e-records) and securely kept for a defined period in line with local policy.</p> <p>All records should be clear, legible and contemporaneous.</p> <p>A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.</p>
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4. Key references

Key references (accessed January 2023)	<ul style="list-style-type: none">• 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• Resuscitation Council (UK) Emergency Treatment of anaphylactic reactions: Guidelines for health care providers Resuscitation Council, 2021 www.resus.org.uk• FSRH Clinical Guideline: Progestogen-only Implant (February 2021) https://www.fsrh.org/standards-and-guidance/documents/cec-ceu-guidance-implants-feb-2014/
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Appendix A: Staff accredited to use this Patient Group Direction

Authorising Manager: I confirm that the practitioners named below have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of Powys Teaching Health Board for the named healthcare professionals below who have signed the PGD to work under it.

The authorising manager may wish to use the competency checklist (below).

Practitioner: By signing this PGD you are indicating that you agree to its contents and that you will work within it. PGDs 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.

Printed name of health professional	Signature of health professional	Printed name of senior representative authorising health professional	Signature of senior representative authorising health professional	Date

The authorising manager should retain a copy of the list and a copy must be sent to the Medicines Management Team, PTHB, Bronllys Hospital, Powys LD3 0LU for audit purposes.

The healthcare professional should retain a copy of the document after signing.

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Competency check list for manager or senior team lead to use as part of the authorising process for health professionals to work to a Patient Group Direction (PGD). Review of authorisation will take place on each PGD update and at the individual's annual PADR.

Name: Role:		Sign / Initial	Further training identified (Y/N)	Comments
1	The PGD sign off is for the following PGD:(document the exact title and PGD number) _____			
2	We have discussed the expiry of the PGD and are using a version accessed electronically			
3	The member of staff has the appropriate qualifications and professional registration as outlined in the PGD			
4	The Patient Group Direction has been read in full by the staff member			
5	The identified training has been completed as specified in the PGD and is in date			
6	We have discussed some examples of inclusion criteria and exclusion criteria			
7	The staff member is confident in the administration method and doses			

Staff member print & sign name		Date
Manager or senior team lead to print & sign name		Date

Please send a copy of this completed form to individual's line manager, to the staff member, and to medicines management department (info.medicinesmanagement.powys@wales.nhs.uk), in conjunction with the PGD Appendix A authorisation sheet. A copy of this form should also be kept by service lead in the training file.