University Hospitals of Derby and Burton NHS Foundation Trust

PATIENT GROUP DIRECTION (PGD)

Supply/Administration of Nicotine Replacement Therapy By Registered UHDB Staff in Adult UHDB services

Documentation details

Reference no:	UHDB 110
Version no:	1.1
Valid from:	06/12/2022
Review date:	06/06/2024
Expiry date:	05/12/2025

Change history

Version number	Change details	Date
1	New template – Extended for all UHDB staff on any site	May 2021
1.1	Updated to allow use of patches after assessment by a Midwife or by other staff who have undertaken pregnancy-specific VBA (Very Brief Advice) training. Updated supply section to allow up to 2 weeks' post-discharge supply to be made under PGD.	Nov 2022

Glossary

Abbreviation	Definition

1. PGD template development (PGD Working Group)

PGD Working Group Membership (minimum requirement of consultant, pharmacist and a registered professional who can work under a PGD (or manages the staff who do). If this is a review of existing PGD, replace previous names with the individuals involved for this version

Name	Designation
James Hooley	Medicines Safety Officer (Pharmacist)
Dr Gillian Lowrey	Respiratory Consultant, RDH and ImpACT+
Dr Judith Hampson	Respiratory Consultant, RDH
Dr Elspeth Spencer	Respiratory Consultant, QHB
Emma Toplis	Advanced Clinical Practitioner, Respiratory, RDH
Kate Poxon	Respiratory Nurse Specialist, QHB
Tracey Huxley	Respiratory Nurse Specialist, QHB

Where an antimicrobial is included, confirm the name, designation and date of the antimicrobial pharmacist who has reviewed this version

Name of antimicrobial pharmacist	Designation	Date Reviewed
N/A	-	-

2. Organisational authorisations

The PGD is not legally valid until it has had the relevant organisational authorisation.

University Hospitals of Derby & Burton NHS Foundation Trust authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisation and/or services
UHDB staff* providing UHDB services (includes UHDB staff/services undertaken on non-UHDB premises) This is a core PGD and can be implemented in all adult services where training and resources have been allocated by senior staff to do so (see policy and limitations below if in doubt). * Must be a profession permitted by current legislation to practice under a patient group direction.
Limitations to authorisation
It is the responsibility of the practitioner working under this PGD to ensure that this PGD is in place in the area they are practising at the time of use. In most cases, this is implicit when a senior manager requests the staff to undertake training and then authorises them in section 7 of this document. However, when working in alternative areas (e.g. internal bank or redeployment) it is important that the practitioner confirms with a departmental manager in the new department that the core PGDs are in-use in their area.

Organisational Authorisation (legal requirement).			
Role	**Name**	**Sign**	**Date**
Deputy Chief Pharmacist	Dom Moore	**Signed copy held by Pharmacy**	**06/12/2022**

Additional signatories (required as per legislation and locally agreed policy)			
Role	**Name**	**Sign**	**Date**
Medicines Safety Officer (pharmacist) *Clinical Pharmacist from PGD working group*	James Hooley	**Signed copy held by Pharmacy**	**21/11/2022**
Interim Medical Director / Deputy *Doctor*	Dr James Crampton or nominated deputy	**Signed copy held by Pharmacy**	**18/11/2022**
Chief Nurse / Deputy *Registered Professional representing users of the PGD*	Garry Marsh (exec Chief Nurse) or nominated deputy	**Signed copy held by Pharmacy**	**21/11/2022**

Local enquiries regarding the use of this PGD may be directed to UHDB.PGDgovernance@nhs.net

Section 7 provides a registered health professional authorisation sheet. Individual professionals must be authorised by name to work to this PGD.

3. Characteristics of staff

Qualifications and professional registration	All Divisions, Adult Areas, registered professional with current professional registration operating within their usual scope of practice. Must be a profession permitted by current legislation to practice under a patient group direction.
Initial training	*One of the following 2 VBA training options:* A. In-house UHDB VBA (Very Brief Advice) presentation, online video (or e-Learning when becomes available on My Learning Passport) or B. NCSCT:VBA and/or VBA in pregnant women (if routinely working in services offering NRT to pregnant ladies) - Completion of all Essential-to-role training as outlined in the UHDB PGD policy. - Individual has read and understood full content of this PGD and signed authorisation (section 7)
Competency assessment	Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines included in the PGD - if any training needs are identified these should be discussed with either the authorising manager (section 7) or the manager within the PGD working group (section 1) so that further training can be provided as required.
Ongoing training and competency	Annual Medicines Safety Training (essential to role) Review/repeat initial training above when this PGD is revised Staff regularly involved in providing stop smoking medication should consider adding the NCSCT 'Stop Smoking Medications' module to their CPD https://elearning.ncsct.co.uk/
The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisation policies.	

4. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	Nicotine Replacement Therapy for patients with tobacco dependence and to support smoking cessation
Criteria for inclusion	• Adult patients • Verbal consent • For outpatient & inpatient supplies* ONLY: Patient competent to self- administer following counselling *Note: an administration PGD is an option for 24 hours whilst pursuing prescriber review (see Duration of Treatment PGD).
Criteria for exclusion	• Haemodynamically unstable patients following recent episode of myocardial infarction or stroke • uncontrolled hyperthyroidism • phaeochromocytoma • uncontrolled cardiac arrhythmias • Patients taking Clozapine or theophylline – patients who stop smoking may require adjustments or reductions to dosages in these drugs – always refer to a prescriber for NRT as this will need to be communicated or referred as part of the discharge information • Patients with previous serious adverse reaction to NRT or any of the other ingredients contained in the products (e.g. glue in patch). • [Patches only] Patients with a generalised skin disease such as psoriasis, chronic dermatitis, patients who have had a previous reaction to transdermal patches; occasional smokers. • [Nasal spray only] Patients with chronic nasal disorders such as polyposis or rhinitis • Current use of Buproprion (Zyban) • Current use of Varenicline (Champix) • [Patches only] Pregnancy - unless the practitioner working under this PGD has completed pregnancy specific training (see cautions below)
Cautions including any relevant action to be taken	• Diabetes mellitus—blood-glucose concentration should be monitored closely when initiating treatment • **Pregnancy & breastfeeding (for TDA staff or for other staff who have undertaken pregnancy-specific VBA training):** All forms of NRT may be offered with patient's informed consent. The use of nicotine replacement therapy in pregnancy is preferable to the continuation of smoking (see off-license section of this PGD). Nicotine is present in milk; however, the amount to which the infant is exposed is small and less hazardous than second-hand smoke. • **Pregnancy & breastfeeding (for staff who have only undertaken standard VBA training):** Intermittent NRT may be initiated under this PGD if smoking cessation without nicotine replacement is considered likely to fail. The patient should make this decision themselves after being counseled and reading the product information. Intermittent therapy (e.g. gum, lozenge, inhalator) may be offered under this PGD (see exclusions – patches only to be initiated by staff with additional pregnancy specific VBA

	training. • **Severe renal disease or moderate/severe hepatic disease** – Refer to prescriber if in doubt. NRT may be issued under this PGD but increased adverse effects may be seen; counsel patients to report these and consider low dose initially **When used by inhalation** Bronchospastic disease; chronic throat disease; obstructive lung disease **With oral use** Gastritis (can be aggravated by swallowed nicotine); gum may also stick to and damage dentures; oesophagitis (can be aggravated by swallowed nicotine); peptic ulcers (can be aggravated by swallowed nicotine) **With transdermal use** patches should not be placed on broken skin; patients with skin disorders
Action to be taken if the patient is excluded	Patient excluded for medical reasons – refer to prescriber
Action to be taken if the patient or carer declines treatment	Patient declines NRT after VBA (very brief advice) given – document in patient casenotes or electronic form (eg Extramend risk assessment) Ensure patient understands the benefits of the programme Tell them NRT is available to buy if they wish to attempt to quit without involvement in the programme Provide details of community based programme or advise them to discuss with a community pharmacist if they decide to attempt to quit later
Arrangements for referral for medical advice	Refer to the medical team responsible for the inpatient or outpatient episode to consider a prescription or advice in any of the following scenarios: - Where patient is excluded due to medical diagnosis (see exclusions) - Where Varenicline (Champix) or Buproprion (Zyban) may be more appropriate - For provision of NRT on discharge including details for GP/primary care information within discharge letter.

5. Description of treatment

Name, strength & formulation of drug	Long acting transdermal nicotine preparations: • Nicotine 24 hr patch – 21mg (high strength) • Nicotine 24 hr patch – 14mg (medium strength) • Nicotine 24 hr patch – 7mg (low strength) Short acting (intermittent) nicotine preparations • Nicotine 1.5mg lozenge (Niquitin minis lozenge) • Nicotine 2mg replacement gum (Nicorette icy white) • Nicotine oral spray (quickmist spray) 1mg • Nicotine inhalator 15mg
Legal category	GSL
Route / method of administration	Transdermal - Patches Oral – gum, lozenges, spray Inhalation - inhalator
Indicate any off-label use (if relevant)	Patches in pregnant patients is outside of manufacturer recommendation. However, BTS/NCSCT support use of patches in pregnant ladies. 4-week quit success is higher with patches (36% patch+intermittent; 26% single format NRT; 16 % no medication). Therefore **all staff with pregnancy specific VBA training** (including TDAs) may initiate patches if appropriate as per cautions section of this PGD.
Dose and frequency of administration	**See cautions on **Pregnancy / Breast-feeding** above – Staff without pregnancy-specific training should only offer step one low level addiction pathway.** • **<u>Low level addiction < 10 cigarettes per day:</u>** Nicotine Gum 2mg - One required up to maximum 15 in 24 hours **OR** Nicotine 15mg inhalator – Inhale when required up to a maximum of 6 cartridges in 1 day **OR** Nicotine oral 1mg quickmist spray - If cravings are not relieved with one spray use a second one. Maximum doses: 2 sprays at a time; 4 sprays per hour; 64 sprays per day **OR** Nicotine 1.5mg mini Lozenge - Lozenges last for 10–30 minutes. Take one when there is an urge to smoke. Use is recommended 8-12 times a day but can be increased up to a maximum of 15 per day. • **Moderate level addiction 10-19 cigarettes per day:** Nicotine 14 mg patch (24 hour continuous patch but patient can be counseled to remove overnight if sleep disturbance occurs or if pregnant)

	+/- addition of short acting NRT option as per low level addiction regime • **High level addiction 20+ cigarettes per day:** Nicotine 21 mg patch (24 hour continuous patch but patient can be counseled to remove overnight if sleep disturbance occurs or if pregnant) +/- addition of short acting NRT option as per low level addiction regime
Duration of treatment	**Inpatients during hospital stay:** A) Self administration: A single pack of each treatment option may be provided to the patient (approx. 7 days). This will initially be for patient self-administration until the patient has been seen by a tobacco dependency advisor or a prescriber. Once NRT regimen confirmed by TDA / prescriber, make a supply sufficient to cover the inpatient stay plus 14 days at discharge, up to a maximum of 4 weeks supply. b) Patients **unable** to self-administer: A single patch may be applied as an administration-only PGD from ward stock. Referral should be made to prescriber to create a prescription for appropriate continuation +/- short acting NRT option. **Outpatient supplies:** Up to maximum of 14 days' supply until review with community service.
Quantity to be supplied (leave blank if PGD is administration ONLY)	As above, Up to 14 days in outpatients Up to 28 days in inpatients (sufficient to cover 14 days post-discharge) Labelling must meet the requirements outlined in Trust PGD Policy and associated training. The Pharmacy department over-label packs to meet legal requirements for supply. If you do not hold these appropriately over-labelled packs in stock, then a supply to patients is not appropriate.
Storage	Store each product as per manufacturer's information leaflet enclosed. Discuss any deviation from storage recommendations with pharmacy before use/supply.
Drug interactions	Nicotine replacement does not itself interact with medicines but smoking cessation does affect drug levels.

	Patients taking the following medicines are **excluded** (see exclusions above) from receiving NRT under a PGD: • Clozapine • Theophyliine The various manufacturers of NRT products list a further range of drugs that may theoretically be affected by smoking cessation. These do not prevent you from using this PGD but outline the importance of ensuring a referral is made and information will be available to GPs that smoking cessation is being attempted: • Drugs which are metabolised by the liver and may require dose reduction after smoking cessation: e.g. paracetamol, caffeine, imipramine, oxazepam, pentazocine, propranolol, warfarin, oestrogens, lidocaine, chlorpromazine • Drugs which may require dose reduction due to other mechanisms, e.g. insulin, beta blockers • Drugs which may theoretically require an increase in dose after smoking cessation, due to a decrease in circulating catecholamines, e.g. isoprenaline, phenylephrine A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Identification & management of adverse reactions	The following side effects are common: • Skin irritation (redness and itching) from use of patches • Hiccups, indigestion, swelling of the mouth, sore throat, change in taste, heartburn (gum, lozenges, inhalator) • Dizziness • Racing heart beat • Sleep problems or unusual dreams • Headache • Nausea • Muscle aches and stiffness A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
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: https://yellowcard.mhra.gov.uk • Record all adverse drug reactions (ADRs) in the patient's medical record. Serious adverse reactions (moderate harm or above as per NRLS definition) should be reported via trust incident management system (e.g. Datix) to ensure duty of candour and learning from harm during clinical use.
Written information to be given to patient or carer	Give marketing authorisation holder's patient information leaflet (PIL) provided with the product. Provide any leaflets or contact details for the community stop-

	smoking service the patient has been referred to.
Patient advice / follow up treatment	Advise patient that most warnings for nicotine replacement therapy also apply to continued cigarette smoking, and that the risk of continued smoking outweighs any risks of using nicotine preparations. Advise them to report adverse effects to the a nurse, doctor or pharmacist. Specific cautions for individual preparations are usually related to the local effect of nicotine. Read the leaflet. Advise on any actions the patient needs to take in relation to referral to the stock smoking service.
Records	**For inpatients**: the record of supply must be documented in the ePMA system or medicines chart used in your area. Referral: Document the products and doses in the medical notes and refer to a prescriber to create inpatient and discharge prescriptions at the earliest opportunity. Ensure a referral to the community stop-smoking service is complete if the patient consents (4 times more likely to have a successful quit attempt). **For outpatient/ambulatory areas**: an ePMA system should be used if available in your area as this will ensure all legal criteria are fulfilled and auditable. For non-ePMA areas records can be made in the medical notes or within the patient pathway (e.g. in daycase or triage where a pathway booklet is in use) but must include the legal requirements below. Ensure a referral to the community stop-smoking service is complete if the patient consents. Either the system holding the record, or the healthcare practitioner working under the PGD, must capture/document all of the following: • name of individual, address, date of birth and GP with whom the individual is registered (if relevant) • name of registered health professional • name of medication supplied/administered • date of supply/administration • dose, form and route of supply/administration • quantity supplied/administered • batch number and expiry date (if applicable e.g. injections and implants) • advice given, including advice given if excluded or declines treatment • details of any adverse drug reactions and actions taken • Confirm whether supplied and/or administered via Patient Group Direction (PGD) Records should be signed and dated (or a password controlled e-records). All records should be clear, legible and contemporaneous. If you are not recording in ePMA (or other electronic system which has ability to generate audit reports) then a record of all individuals

	receiving treatment under this PGD should also be in the clinical area for audit purposes as per UHDB PGD policy.

6. Key references

Key references	• *Electronic Medicines Compendium http://www.medicines.org.uk/ https://www.medicines.org.uk/emc/product/6628 https://www.medicines.org.uk/emc/product/6461/smpc https://www.medicines.org.uk/emc/product/5956/smpc https://www.medicines.org.uk/emc/product/4707 https://www.medicines.org.uk/emc/product/9804/pil* • *Electronic BNF https://bnf.nice.org.uk/ Accessed 06/05/2021* • *British Thoracic Society. Patient Group Direction for the Supply of Nicotine Replacement Therapy by Secondary Care Stop Smoking Services (QI Tool Appendix 5). 2017. Accessed online 06/05/2021 at https://www.brit-thoracic.org.uk/media/70101/appendix-5-pgd-for-nrt.doc* • *UHDB. PGD for Supply of Nicotine Replacement Therapy by the Lung Cancer Nurse Specialist Team at Queens Hospital Burton site. Published 28/04/2021*

7. Registered health professional authorisation sheet

PGD Name [version]: Supply of Nicotine Replacement Therapy [v1.1]
PGD ref: UHDB 110 Valid from: 06/12/2022 Expiry date: 05/12/2025

Before signing check that the document you have read is published on Koha or is an in-date hard-copy with all necessary authorisations signed in section 2. The Name/Version/Ref of the document you have read MUST match this authorisation form.

Registered health professional
By signing this patient group direction you are indicating that

a) You agree to and understand all content and commit to only work within this framework.
b) You have completed any core PGD e-Learning or training records on My Learning Passport or within your department.
c) You meet the staff characteristics and have completed any additional learning/competency outlined in Section 3 of this PGD.

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	**Designation**	**Signature**	**Date**

Authorising manager / Assessor

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 University Hospitals of Derby & Burton NHS Foundation Trust for the above named health care professionals who have signed the PGD 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 must be retained by a manager in the clinical department where the PGD is in-use to serve as a record of those registered health professionals authorised to work under this PGD.