University Hospitals of Derby and Burton
NHS Foundation Trust

PATIENT GROUP DIRECTION (PGD)

Supply/Administration of ORAL PARACETAMOL

By Registered Nurses, Emergency Nurse Practitioners (ENP), Emergency Care Practitioners (ECP) and Emergency Physiotherapy Practitioners (EPP) In Emergency Department and Ambulatory care at Queens Hospital, Burton and Minor Injuries departments at Samuel Johnson and Sir Robert Peel community hospitals

Documentation details

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Change history

Version number	Change details	Date
4	Use of new UHDB template	14.02.2022

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
Dr. Venkat Thungala	Emergency Department Consultant
James Kerr	Divisional Pharmacist
Divina Jose	Emergency Nurse Practitioner

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

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
In Emergency Department and Ambulatory care at Queens Hospital, Burton and Minor Injuries departments at Samuel Johnson and Sir Robert Peel community hospitals
Limitations to authorisation
Nil

Organisational Authorisation (legal requirement).			
Role	**Name**	**Sign**	**Date**
Medicines Safety Officer *Pharmacist: Medicines Safety Officer, Chief Pharmacist or assigned deputies)*	James Hooley	**Signed copy held by Pharmacy**	**04/01/2023**

Additional signatories (required as per legislation and locally agreed policy)			
Role	**Name**	**Sign**	**Date**
Divisional Pharmacist *Clinical Pharmacist from PGD working group*	**James Kerr**	**Signed copy held by Pharmacy**	**22/12/2022**
Consultant *Doctor*	**Dr Thungala**	**Signed copy held by Pharmacy**	**04/01/2023**
Interim Matron Acute Medicine QHB *Registered Professional representing users of the PGD*	**Danielle Murphy**	**Signed copy held by Pharmacy**	**04/01/2023**

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	• 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	Have undertaken the Core PGD training Individual has read and understood full content of this PGD and signed authorisation (section 7) • Completion of Medicines Management Drug Assessment • Deemed competent by their line manager to undertake the clinical assessment of a patient leading to a diagnosis that requires treatment according to the indications listed in this PGD and Trust clinical guidelines
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 the senior individual responsible for authorising individuals to act under the PGD and further training provided as required.
On-going training and competency	• Annual Medicines Safety Training (essential to role) • Review/repeat initial training above when this PGD is revised • The registered healthcare practitioner will ensure anaphylaxis and CPR training is kept updated yearly. • The registered healthcare professional must actively take part in CPD and annual individual performance reviews. • Regular training and updating in safeguarding children and vulnerable adults as per trust policy
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	• Mild to moderate pain in adults and children aged 3 months and over • Pyrexia in adults and children aged 3 months old and over • Post vaccination pyrexia for babies at 2 months
Criteria for inclusion	• Adults and children aged 2 months old and over • No history of adverse reaction to Paracetamol
Criteria for exclusion	Patients with known • alcohol dependency • Renal and hepatic impairment • Hypersensitivity to Paracetamol or to any ingredients in the product Children under 3 months old, except for post vaccination pyrexia then under 2 months old. Patients who have taken Paracetamol/Paracetamol containing products within the previous 4 hours Patients in whom the timing of the previous dose of Paracetamol cannot be confirmed. Patients who have taken four or more doses of Paracetamol within the previous 24 hours.
Cautions including any relevant action to be taken	Before administering, check the following: • When was the last time Paracetamol was taken and the cumulative Paracetamol dose over previous 24 hours.-Do not give Paracetamol more than 4grams in 24 hours. • Body weight under 50 kilograms – reduced adult dose/frequency may be required • Chronic alcohol consumption • Chronic dehydration • Chronic malnutrition • Long term use (especially those who are malnourished) • May increase toxicity when co-administration of enzyme inducing antiepileptic medication – Doses should be reduced. • Some patient may be at risk of experiencing toxicity at therapeutic doses, particularly those with a body weight under 50kg and those with risk factors for hepatotoxicity. – Use clinical judgment to adjust dose.
Action to be taken if the patient is excluded	• Discuss with ED Doctor and consider prescribing an alternative medication. • Discuss with the patient/parents/guardians and advise alternative treatment

	• Document in patients notes the reason for exclusion and actions taken.
Action to be taken if the patient or carer declines treatment	• Explain to the patient/parents/guardians the importance of treatment • Offer alternative intervention/treatment • Document in medical notes the reason for refusal, action taken, advise given • Escalate to ED doctor and consider prescribing an alternative medication/treatment if needed.
Arrangements for referral for medical advice	Seek ED Consultant advice immediately in an event of overdose even if patient feels well. Follow local emergency procedure; call 2222/3333/999 in the event of adverse reaction / anaphylaxis / cardiac arrest

5. Description of treatment

Name, strength & formulation of drug	Paracetamol • 500mg tablet • 120mg/5ml suspension • 250mg/5ml suspension
Legal category	GSL (General Sale List) / P (Pharmacy Medicine) / POM: (Prescription Only Medicine) Depending on pack size
Route / method of administration	Oral
Indicate any off-label use (if relevant)	No off-label indication
Dose and frequency of administration	**<u>Paracetamol 120mg/5ml Suspension</u>** Child 2 – 3 months (for post immunization pyrexia) • 60mg (2.5ml) single dose only Child 3 – 5 months • 60mg (2.5ml) every 4 - 6 hours up to four times in 24 hours Child 6 months – 1 year • 120mg (5ml) every 4 - 6 hours up to four times in 24 hours Child 2 – 3 years • 180 mg (7.5ml) every 4 – 6 hours up to four times in 24 hours; Child 4 – 5 years • 240 mg (10ml) every 4 – 6 hours up to four times in 24 hours;

	Paracetamol 250mg/5ml Suspension, or 500mg tablets/effervescent tablets Child 6 – 7 years • 250 mg (5ml) every 4 – 6 hours up to four times in 24 hours; Child 8 – 9 years • 375 mg (7.5ml) every 4 – 6 hours up to four times in 24 hours; Child 10-11 years • 500 mg (10ml), or 1 x 500mg tablet, every 4 – 6 hours up to four times in 24 hours; Child 12 - 15 years • 500 - 750 mg (10 – 15ml), or 1 x 500mg tablet, every 4 – 6 hours up to four times in 24 hours; 16 Years to Adult • 500mg - 1 gram (10 – 20ml), or 1 – 2 x 500mg tablets, every 4-6 hours up to four times in 24 hours; Maximum 4grams per day
Duration of treatment	STAT dose, maximum of 3-4 doses in 24 hours
Quantity to be supplied (leave blank if PGD is administration ONLY)	Triage nurse will NOT supply, only administer. If ongoing treatment is necessary and the patient has no supply at home, and a supply cannot be easily purchased the ENP/ECP/EPP can supply for adults and children over XXXXX, as appropriate to the age-related dose stated above: • TTO pack 32 x 500mg paracetamol tablets OR, • Overlabelled 100mls paracetamol 120mg/5ml liquid OR, • Overlabelled 100mls paracetamol 250mg/5ml liquid The dosing instructions of the manufacturer's packaging must reflect the dose for the individual patient according to the PGD. If not clear the additional label must include the specific dose required. The following must be added to the label before supply: • Patient's name • Date of supply • Issuing department e.g. "ED QHB"

	• The dose indicated for the patient according to dose information above (if not already clear from the manufacturer's instructions) • All packs must contain the manufacturer's leaflet
Storage	Must be stored in a lockable medicine cupboard/trolley specifically reserve for such purpose. It should be stored below 25 degrees C room temperature and monitored daily. Protect from heat, light and moisture.
Drug interactions	No clinically significant drug interactions if administered / supplied as described on this PGD. If Paracetamol is taken regularly, then the following interaction should be noted when taken with the following drugs: • Warfarin/Acenocoumarol - Paracetamol increases the anticoagulant effect. Advise to monitor INR • Atorvastatin, Flucloxacillin, Doxycycline,Rifampicin, Pravastatin, Oxytetracycline, Carbamazepine- Increased the risk of hepatotoxicity • Phenytoin, Phenobarbital - Decreased the exposure to Paracetamol
Adverse reactions	Adverse effects of Paracetamol are rare but hypersensitivity reactions including anaphylaxis and skin rash may occur. Very rare cases of serious skin reactions have been reported. Blood disorders have been reported too.
Management of and reporting procedure for adverse reactions	If adverse reactions suspected/occurs: • Assess patient using ABCDE and provide medical intervention appropriately. • Refer to ED Consultant immediately • Use the MHRA Yellow Card scheme to report any suspected adverse reactions. Go to : .https://yellowcard.mhra.gov.uk • Document on patient's medical notes • Complete incident report via organisation incident policy
Written information to be given to patient or carer	Give patient information leaflet (PIL) provided with the product. For Parents/Carer : • Medicine for Children leaflet which can be obtain on www.medicinesforchildren.org.uk/medicines/paracetamol/
Patient advice / follow up treatment	• Monitor sensitivity reaction and seek medical advice immediately • Do not take with other Paracetamol products • Children: do not exceed the dose stated for the age of the patient • 16 years and over: do not take more than 2 tablets at a time

	• 16 years and over: do not take more than 4grams or 8 tablets in 24 hours • Seek medical help immediately if taken too much even if there is no symptom. Liquid preparations: • Shake bottle for 10 seconds before use. • Use graduated medicine pot or 5 ml spoon or oral syringe provided to measure accurately. Effervescent tablet: • Dissolve the tablet in water (about 200mls) before swallowing • Stir before use To come back to ED or see GP if symptoms persist for longer than 3 days
Records	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 and that this was done 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	• *NICE Medicines practice guideline "Patient Group Directions" https://www.nice.org.uk/guidance/mpg2* • *https://medusa.wales.nhs.uk* • BNF British National Formulary - NICE ; updated 03 February 2022 • BNF for Children British National Formulary – NICE updated 03 February 2022 https://bnfc.nice.org.uk • Electronic Medicines Compedium (emc) https://www.medicines.org.uk • Medicine Management (Medicine Codes) Burton & Derby Sites

7. Registered health professional authorisation sheet

PGD Name [version]: Emergency Department, Ambulatory Care QHB and MIU SJCH and SRP - Oral Paracetamol [v1]
PGD ref: UHDB248
Valid from: 04/01/2023 **Expiry date:** 03/01/2026

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.