A Patient Group Direction is a specific written instruction for the supply or administration of named medicines in an identified clinical situation. It is drawn up locally by Doctors, Pharmacists and other appropriate professionals, approved by the Employer and advised by the relevant professional advisory committees. In most cases, appropriate clinical care is provided on an individual basis by a specific prescriber to a specific individual patient. Patient Group Directions should only be considered where they offer a benefit to patient care without compromising patient safety in any way.
Revision History:

<table>
<thead>
<tr>
<th>Date of change</th>
<th>Approval date of PGD that is being superseded</th>
<th>Summary of Changes</th>
<th>Section heading</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>New PGD</td>
<td></td>
</tr>
</tbody>
</table>

Subject: Patient Group Direction
Identifier: NHSG/PGD_Metoclopramide_MGPG821
Replaces: N/A - New PGD
Keyword(s): PGD Patient Group Direction metoclopramide hydrochloride small bowel study GI advanced practice radiographer

Policy Statement:

It is the responsibility of individual GI Advanced Practice Radiographers and their line managers to ensure that they work within the terms laid down in this PGD and to ensure that staff are working to the most up to date PGD. By doing so, the quality of the services offered will be maintained, and the chances of staff making erroneous decisions which may affect patient, staff or visitor safety and comfort will be reduced. Supervisory staff at all levels must ensure that staff using this PGD act within their own level of competence.

The lead author is responsible for the review of this PGD as well as its dissemination. Pharmacy and Medicines Directorate is responsible for ensuring registration of this document.

Review date: At least every 2 years or sooner if current treatment recommendations change.

Document: Drafted: May 2016
Completed: July 2016
Approved: September 2016 (published November 2016)
Patient Group Direction For The Supply Of Metoclopramide Hydrochloride 5mg/5mL Oral Solution By GI Advanced Practice Radiographers Working Within NHS Grampian

Clinical indication to which this PGD applies

<table>
<thead>
<tr>
<th>Definition of situation/condition</th>
<th>This Patient Group Direction (PGD) will authorise GI Advanced Practice Radiographers as registered with the Health and Care Professions Council (HCPC) to supply Metoclopramide Hydrochloride 5mg/5mL Oral Solution to patients attending for Small Bowel Study examinations to accelerate small bowel transit, if so indicated. N.B. The use of metoclopramide to accelerate small bowel transit constitutes an 'off-label' use of the medicine and is outside the terms of the SPC. This PGD should be used in conjunction with the recommendations in the current British National Formulary (BNF) and individual Summary of Product Characteristics (SPC).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inclusion criteria</td>
<td>Patients who are over 16 years of age attending the Radiology Department at Aberdeen Royal Infirmary for Small Bowel Studies who require acceleration of small bowel transit pre-study.</td>
</tr>
<tr>
<td>Exclusion criteria</td>
<td>• Patients aged less than 16 years. • Patients with a history of gastro-intestinal obstruction, perforation or haemorrhage. • Patients 3 – 4 days after gastro-intestinal surgery. • Patients with phaeochromocytoma. • Patients with hypersensitivity to metoclopramide hydrochloride or any of the excipients. • Methaemoglobinaemia. • NADH cytochrome-b5 deficiency. • Patients who do not have a pylorus, e.g. gastrectomy, gastrojejunostomy, gastric bypass. • Parkinson’s disease. • Epilepsy. • Patients who are hypersensitive to procaine or procainamide.</td>
</tr>
</tbody>
</table>
### Precautions and special warnings
Metoclopramide Hydrochloride should be used with caution in the following patients:
- Frail and/or elderly as there is an increased risk of side effects.
- A young adult (16 – 19 years old) as there is an increased risk of extrapyramidal effects.
- Atopic allergy (including asthma).

### Referral criteria
Patients who fall into the categories detailed in the exclusion criteria.

### Action if excluded from treatment
Medical advice should be sought – refer to General Practitioner/Consultant (relevant medical practitioner).

The reason why the patient was excluded under the PGD will be documented in the Radiology Information System.

### Action if patient declines treatment
Patient should be advised of the risks and consequences of not receiving treatment. The examination can still be performed but is likely to take significantly longer.

The outcome will be recorded in the Radiology Information System if appropriate. The patient can discuss the implications with a GI Advanced Practice Radiographer or a Consultant Radiologist. If necessary the patient can be directed to the Consultant who referred them for the Small Bowel Study.

### Consent
Prior to the administration of the drug, valid consent must be obtained. Consent must be in line with current NHSG “Staff Policy for Obtaining Consent for Clinical Procedures and Healthcare Interventions”. See link below.
http://intranet.grampian.scot.nhs.uk/ccc_nhsgrampian/15692.html?pmenuID=460&
### Description of treatment available under the PGD

<table>
<thead>
<tr>
<th><strong>Name of medicine</strong></th>
<th>Metoclopramide Hydrochloride 5mg/5mL Oral Solution.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Legal status</strong></td>
<td>Metoclopramide Hydrochloride 5mg/5mL Oral Solution is a Prescription-only Medicine (PoM).</td>
</tr>
<tr>
<td><strong>Form/Strength</strong></td>
<td>Suitable for Oral administration. Each 5mL of solution contains 5mg of Metoclopramide Hydrochloride.</td>
</tr>
<tr>
<td><strong>Route/Method of administration</strong></td>
<td>10mL of Metoclopramide Hydrochloride 5mg/5mL Oral Solution is supplied to the patient for self administration prior to the ingestion of E-Z-Paque® 96% w/w powder for oral solution (N.B. E-Z-Paque® supply is not covered under this PGD).</td>
</tr>
<tr>
<td><strong>Dosage/Total Dose</strong></td>
<td>Single dose of 10mL Metoclopramide Hydrochloride 5mg/5mL Oral Solution.</td>
</tr>
<tr>
<td><strong>Duration of treatment</strong></td>
<td>Single dose.</td>
</tr>
<tr>
<td><strong>Storage requirements</strong></td>
<td>Store below 25°C and keep in the original outer carton.</td>
</tr>
<tr>
<td><strong>Follow-up (if applicable)</strong></td>
<td>If the patient feels at all unwell they should speak to a GI Advanced Practice Radiographer, a Radiographer or a Nurse. If necessary a Radiologist will be contacted for advice.</td>
</tr>
<tr>
<td><strong>Advice to patient (Verbal)</strong></td>
<td>Advice should be given on what to expect and what to do for major and minor reactions.</td>
</tr>
<tr>
<td><strong>Advice to patient (Written)</strong></td>
<td>The patient information leaflet contained in the medicine should be made accessible to the patient, parent, guardian, or person with parental responsibility. Where this is unavailable, or unsuitable, sufficient information should be given in a language the patient, parent can understand.</td>
</tr>
</tbody>
</table>
## Concurrent Medications/Drug Interactions

<table>
<thead>
<tr>
<th>Medication/Interaction</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Anticholinergics and morphine derivatives</strong></td>
<td>Anticholinergics and morphine derivatives may have both a mutual antagonism with metoclopramide on the digestive tract motility. Sedative effects of Central Nervous System depressants and metoclopramide are potentiated.</td>
</tr>
<tr>
<td><strong>Neuroleptics</strong></td>
<td>Metoclopramide may have an additive effect with other neuroleptics on the occurrence of extrapyramidal disorders.</td>
</tr>
<tr>
<td><strong>Serotonergic drugs</strong></td>
<td>The use of metoclopramide with serotonergic drugs such as SSRIs may increase the risk of serotonin syndrome.</td>
</tr>
<tr>
<td><strong>Digoxin</strong></td>
<td>Metoclopramide may decrease digoxin bioavailability. Careful monitoring of digoxin plasma concentration is required.</td>
</tr>
<tr>
<td><strong>Ciclosporin</strong></td>
<td>Metoclopramide increases ciclosporin bioavailability (Cmax by 46% and exposure by 22%). Careful monitoring of ciclosporin plasma concentration is required. The clinical consequence is uncertain.</td>
</tr>
<tr>
<td><strong>Strong CYP2D6 inhibitors</strong></td>
<td>Metoclopramide exposure levels are increased when co-administered with strong CYP2D6 inhibitors such as fluoxetine and paroxetine. Although the clinical significance is uncertain, patients should be monitored for adverse reactions.</td>
</tr>
<tr>
<td><strong>Extrapyramidal reaction causing drugs (such as phenothiazine and tetrabenazine)</strong></td>
<td>Concurrent use with metoclopramide may increase the frequency and severity of extrapyramidal side effects. Care should be exercised in the event of co-administration of these drugs.</td>
</tr>
</tbody>
</table>

Copies of PIL and SPCs for all medicines can be found at [http://www.medicines.org.uk](http://www.medicines.org.uk) or [http://www.mhra.gov.uk/spc-pil/index.htm](http://www.mhra.gov.uk/spc-pil/index.htm)
<table>
<thead>
<tr>
<th><strong>Mexiletine</strong></th>
<th>Concurrent use with metoclopramide may accelerate absorption of mexiletine.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Atovaquone</strong></td>
<td>Metoclopramide may reduce plasma concentrations of atovaquone.</td>
</tr>
<tr>
<td></td>
<td><strong>This list is not exhaustive. Refer to BNF and SPC for complete list.</strong></td>
</tr>
</tbody>
</table>

### Adverse effects and managing possible adverse reactions

<table>
<thead>
<tr>
<th>Common side effects:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Diarrhoea</td>
</tr>
<tr>
<td>• Asthenia</td>
</tr>
<tr>
<td>• Somnolence</td>
</tr>
<tr>
<td>• Extrapyramidal disorders</td>
</tr>
<tr>
<td>• Depression</td>
</tr>
<tr>
<td>• Restlessness.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Uncommon side effects:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Bradycardia</td>
</tr>
<tr>
<td>• Amenorrhoea</td>
</tr>
<tr>
<td>• Hypersensitivity</td>
</tr>
<tr>
<td>• Dystonia</td>
</tr>
<tr>
<td>• Dyskinesia</td>
</tr>
<tr>
<td>• Hallucinations.</td>
</tr>
</tbody>
</table>

| **This list is not exhaustive. Please also refer to current BNF and manufacturers SPC for details of all potential adverse reactions.** |

**BNF:**  
[https://www.medicinescomplete.com/mc/bnf/current/](https://www.medicinescomplete.com/mc/bnf/current/)  

**SPCs/PILs:**  
[https://www.medicines.org.uk/emc/](https://www.medicines.org.uk/emc/)  

If an adverse reaction does occur give immediate treatment and inform relevant medical practitioner as soon as possible.
Report the reaction to the MHRA using the Yellow Card System.
https://yellowcard.mhra.gov.uk/

**Medical advice in cases of anaphylaxis**

Injections of IM adrenaline/epinephrine 1:1000 must be available to treat an anaphylactic reaction should this occur. Medical advice must be sought as soon as possible from a doctor if any patient develops any signs of hypersensitivity. If there is a delay in medical support arriving and the condition of the patient is deteriorating then an emergency ambulance must be called on 999 or direct via ambulance control or dial 2222 (hospital internal) according to local procedure, or seek urgent medical advice. (Refer to Patient Group Direction for the administration of adrenaline (epinephrine) in cases of suspected anaphylactic reactions by qualified health professionals).

**Facilities and supplies required**

The following should be available at sites where the medication is to be supplied:

- Appropriate storage.
- An acceptable level of privacy to respect patient’s right to confidentiality and safety.
- Resuscitation equipment.
- Access to medical support (this may be via the telephone).
- Approved equipment for the disposal of used materials.
- Clean and tidy work areas, including access to hand washing facilities.
- Copies of the current PGD for the medicine specified in the PGD.
- PGD for the administration of Adrenaline (epinephrine) in cases of suspected anaphylactic reactions by qualified health professionals.

**Characteristics of staff authorised to supply medicine under PGD**

| Professional qualifications | GI Advanced Practice Radiographers as registered with the HCPC. |
| Specialist competencies | Only GI Advanced Practice Radiographers who have undertaken Specialist Postgraduate Courses in GI Advanced Practice and local training in the practice of Small Bowel Studies within Aberdeen Royal Infirmary can work to this PGD.  
Be competent to assess the patient’s capacity to understand the nature and purpose of the administration in order for the patient to give or refuse consent.  
Has undertaken appropriate training to carry out clinical assessment of patients leading to a diagnosis that requires treatment according to the indications listed in the PGD.  
The practitioner must be familiar with the SPC for all medicines supplied in accordance with this PGD.  
Be aware of current treatment recommendations and be competent to discuss issues about the drug with the patient.  
Has undertaken local training and instruction from a Consultant GI Radiologist on the safe use of Metoclopramide Hydrochloride 5mg/5mL Oral Solution during Small Bowel Study examinations. |
| Ongoing training and competency | Has attended basic life support training which is required to be updated annually.  
Has undertaken the NHS e-anaphylaxis training session (and annual updates) which covers all aspects of the identification and management of anaphylaxis. This can be accessed via eKSF, or the AT Learning® tool.  
Maintains their skills, knowledge and their own professional level of competence in this area according to their individual Code of Professional Conduct. |
| Professional managers will be responsible for | Ensuring that the current PGD is available to staff providing care under this direction.  
Ensuring that staff have received adequate training in all areas relevant to this PGD and meet the requirements above.  
Maintain up to date record of all staff authorised to supply the drug specified in PGD. |
### Authorisation of administration

GI Advanced Practice Radiographers working within the Radiology department at Aberdeen Royal Infirmary can be authorised to supply the drug specified in this PGD by their Consultant Radiologist.

All authorised staff are required to read the PGD and sign the Agreement to supply Medicines under PGD ([Appendix 1](#)).

A certificate of authorisation ([Appendix 2](#)) signed by the authorising doctor/manager should be supplied. This should be held in the individual practitioners records, or as agreed locally.

### Record of administration/supply

An electronic or paper record for recording the vetting of patients and the subsequent administration of the drug specified in this PGD must be completed in order to allow audit of practice. This should include:

- Name and address of patient
- Patient CHI and date of birth
- Details of parent/guardian, or person with parental responsibility, where applicable
- Consultant details
- Risk group, if appropriate
- Exclusion criteria, record why drug not supplied
- Reason for giving
- Consent to the administration (if not obtained elsewhere)
- Drug manufacturer, batch number and expiry date
- Dose and route of drug administration (oral)
- Signature and name in capital letters of practitioner who supplied the drug
- Date drug given
- Record of any adverse effects (advise patient’s Consultant).

These records should be retained:

**For children and young people**, retain until the patient's 25th birthday or 26th if the young person was 17 at the conclusion of treatment.

**For 17 years and over** retain for 6 years after last date of entry, for 3 years after death, or in accordance with local policy, where this is greater than above.
Audit

All records regarding the drug specified in this PGD will be filed with the normal records of medicines in the Radiology department. A designated person within the Radiology department will be responsible for auditing completion of drug forms and collation of data.

References


Metoclopramide Hydrochloride 5mg/5mL Oral solution – Date of revision of text March 2016, accessed 11/02/16.


Management and Monitoring of Patient Group Direction

PGD Consultative Group

The consultative group is legally required to include a medical practitioner, a pharmacist and a representative of the professional group who will provide care under the direction

Name: Title:

Dr Dympna McAteer Medical Professional: Consultant GI Radiologist
Mrs Gillian Cole Lead Author: GI Advanced Practice Radiographer
Mrs Grace McKerron Nurse Manager
Mrs Suzanne Nicholson Superintendent Radiographer
Mr Alan Riddoch Radiography Manager
Mr Sandy Thomson Pharmacist: Lead Pharmacist

Authorising Managers

Dr Nick Fluck
Medical Director, NHS Grampian

Mr David Pfleger
Director of Pharmacy and Medicines Management, NHS Grampian

Ms Amanda Croft
Executive Director of Nursing, Midwifery and AHPs, NHS Grampian
Health Care Professional Agreement to Supply Medicines Under Patient Group Direction

I: __________________________________________________________________________ (Insert name)

Working within: __________________________________________________________________

Agree to supply medicines under the direction contained within the following Patient Group Direction

Patient Group Direction For The Supply Of Metoclopramide Hydrochloride 5mg/5mL Oral Solution By GI Advanced Practice Radiographers Working Within NHS Grampian

I have completed the appropriate training to my professional standards enabling me to supply medicines under the above Patient Group Direction. I agree not to act beyond my professional competence nor outwith the recommendations of the Patient Group Direction.

Signed: _______________________________________________________________________

Print Name: ___________________________________________________________________

Date: _______________________________________________________________________

Professional Registration No: ___________________________________________________
Appendix 2

Certificate Of Authorisation To Supply Medicines Under Patient Group Direction

This authorises: ________________________________

Working within: ________________________________

To supply medicines under the following Patient Group Direction

Patient Group Direction For The Supply Of Metoclopramide Hydrochloride 5mg/5mL Oral Solution By GI Advanced Practice Radiographers Working Within NHS Grampian

The above named person has satisfied the training requirements and is authorised to supply medicines under the above Patient Group Direction. The above named person has agreed not to act beyond their professional competence nor outwith the recommendations of the Patient Group Direction

Signed: ________________________________ Authorising Manager/Doctor

Print Name: ________________________________

Date: ________________________________