Dyspepsia refers to a broad range of symptoms related to dysfunction of the upper gastrointestinal (GI) tract from the oesophagus to the duodenum, including retrosternal or epigastric pain, fullness, bloating, wind, heartburn, nausea and vomiting\(^1\).

Pain can vary from mild to severe, may be intermittent and may often resolve itself without medication. Large numbers of people suffer from dyspepsia, estimated to be up to 40% of the adult population in any one year\(^1\).
Of these, the main causes are:

- Gastro-oesophageal reflux disease (GORD) (15 to 25%)
- Gastric and duodenal ulcers (15 to 25%)
- Stomach cancer (2%)
- Non-ulcer dyspepsia (NUD), also called "functional" dyspepsia (60%)

Treatment of dyspepsia may involve the use of antacids, alginates, H$_2$-antagonists or Proton Pump Inhibitors (PPIs). The latter produce their therapeutic effects by suppressing acid production and there are 5 such drugs within this group; esomeprazole, lansoprazole, omeprazole, pantoprazole and rabeprazole.

In the last financial year (2006/07) NHS Dumfries and Galloway spent £1,391,224 on PPIs. Expenditure is falling due to price reductions, but usage continues to increase (see below). Note that £107k was spent on esomeprazole this year at a cost of £0.85 per DDD. This is non-formulary.

<table>
<thead>
<tr>
<th>Financial Year</th>
<th>GIC (Dispensed)</th>
<th>DDDs (Dispensed Current)</th>
<th>Cost per DDD</th>
</tr>
</thead>
<tbody>
<tr>
<td>2004/05</td>
<td>£ 2,158,918</td>
<td>2,833,723</td>
<td>£ 0.76</td>
</tr>
<tr>
<td>2005/06</td>
<td>£ 2,155,799</td>
<td>3,336,139</td>
<td>£ 0.65</td>
</tr>
<tr>
<td>2006/07</td>
<td>£ 1,391,224</td>
<td>3,650,622</td>
<td>£ 0.38</td>
</tr>
<tr>
<td>2007/08 (proj)</td>
<td>£ 1,050,639</td>
<td>3,901,915</td>
<td>£ 0.27</td>
</tr>
</tbody>
</table>

Evidence suggests that long-term treatment with a PPI is associated with complications such as rebound acid secretion, vitamin B$_{12}$ deficiency, delayed gastric emptying and bacterial overgrowth. There is also concern that prolonged PPI use may mask or delay the diagnosis of more serious GI disorders such as gastric carcinoma.

Therefore, given that PPIs currently account for around 3.4% of NHS Dumfries and Galloway’s prescribing budget and that their long-term use is associated with undesirable effects, it seems reasonable to suggest that a programme aimed at promoting and ensuring the appropriate use of PPIs be implemented.
OBJECTIVE
To ensure the appropriate prescribing of Proton Pump Inhibitors in Dumfries and Galloway.

RATIONALE
Proton pump inhibitors produce profound acid suppression via their inhibitory effect on the hydrogen-potassium adenosine triphosphate enzyme system (the proton-pump) and are therefore useful in the treatment of a number of gastric and duodenal disorders. A significant number of PPIs are prescribed for the relief of symptoms associated with Gastro-Oesophageal Reflux Disease (GORD) and as such, are only indicated for short, intermittent courses of 4 - 8 weeks duration. When used for longer periods, they are associated with undesirable effects such as rebound acid secretion, vitamin B₁₂ deficiency, delayed gastric emptying and bacterial overgrowth as well as the masking of more serious diseases such as gastric carcinoma.

The aim of this project is to gradually withdraw PPI therapy from those GORD patients who have been receiving it for longer than 8 weeks and ultimately maintaining them on alginate therapy. PPIs will still be available for acute flare-ups of the disorder but the courses will be limited to the recommended 4-8 weeks duration.
METHOD

Step 1 - Searches

Computer search to identify patients on PPIs. The following inclusion and exclusion detailed below will be applied to those patients identified by the search and a register of patients eligible to attend the dyspepsia clinics compiled. Computer records will be cross-checked with patient’s paper notes and any read codes found to be incorrectly recorded will be notified to the Practice and amended. When the patients register is completed, it will be distributed to all partners in the Practice for approval.

Inclusion criteria

- All patients who have been taking a PPI for more than 8 weeks.

Exclusion criteria

- Patients on healing doses of PPIs for treatment of duodenal ulcers for less than 4 weeks
- Patients on healing doses of PPIs for treatment of gastric ulcers for less than 8 weeks
- Patients currently on Helicobacter Pylori eradication therapy
- Patients currently under review at GI clinic or awaiting referral to one
- Patients awaiting gastroscopy or review
- Patients who have been diagnosed with Zollinger-Ellison Syndrome
- Patients who have been diagnosed with Barrett’s Oesophagus
- Patients over 90 years of age
- Patients with a terminal illness
- Patients with grade 3 or 4 oesophagitis
• Patients on high dose corticosteroids for a life-threatening or chronic illness
• Patients receiving immunosuppression therapy
• Patients undergoing chemotherapy or radiotherapy
• Patients with oesophageal strictures or oesophageal dilation
• Patients with a history of oesophageal varices
• Unstable psychiatric patients
• Known alcohol abusers
• Patients under 18 years of age
• Any other criteria as specified by the Practice

Caution

The following groups of patients may be considered for stepping down to the lowest maintenance dose of PPI but should not proceed to the stepping off stage:

• Patients with peptic ulceration associated with a negative Clo Test
• Patients diagnosed with Barrett’s Oesophagus
• Patients receiving long-term NSAID therapy

Step 2 - Patient Invitations

Letters sent out to eligible patients asking them to contact the Practice to make an appointment to attend the dyspepsia clinic. Appointments will be made via Practice reception staff. To encourage clinic attendance, Practices may choose to state in the patient letter that repeats for current medication may not be renewed, unless the patient attends the clinic.
Step 3 - The Clinic Process and Patient Management Options

The patient will be given full verbal information about the purpose of the clinic and signed consent obtained prior to any assessment being carried out. This clinical assessment will follow a structured plan. Data obtained from the clinic will be recorded on a register and will be used suggest appropriate non-drug changes in patient management and prepare the final surgery report. Part of the assessment will include evaluating the suitability for stepping the patient down to a lower PPI dose or stepping them off PPI therapy altogether and replacing it with an alginate based reflux suppressant. At the end of each clinic, the lead GP will be provided with completed patient assessment forms and patient notes. All medication changes will be approved by the GP.

Each appointment at the clinic will be scheduled to last 15 minutes and during this time the following information will be recorded:

- Patient name and identification code
- sex
- date of birth
- age
- current upper GI medication (drug name, dose, frequency, duration, concomitant NSAID use)
- diagnosis (PUD, GORD, Erosive Reflux Oesophagitis, dyspepsia, other)
- previous investigations (date, endoscopy, Barium studies, H.Pylori status, pH monitoring, other)
- current level of symptom control

If any of the following alarm features are present then the patient will be referred to a GP for an immediate consultation:
• Anaemia
• Vomiting
• Weight loss
• Dysphagia
• Epigastric mass
• Haematemesis
• Jaundice
• Progressively worsening symptoms
• Any other feature as specified by the Practice

Patients who have been prescribed a PPI healing dose for more than 8 weeks and do not meet any of the exclusion criteria will be recommended for a step down to a maintenance dose. Appendix 1 details the healing and maintenance doses of all PPIs licensed in the UK.

To improve symptom control and increase the likelihood of success of this dosage reduction, an alginate based reflux suppressant may be recommended. The alginate would be used to prevent and/or treat occasional breakthrough symptoms caused by rebound acid hypersecretion. These patients will then be reviewed in 2 - 3 months with a view to stepping them off PPI therapy completely.

Patients who have been prescribed a PPI maintenance dose for more than 8 weeks and do not meet any of the exclusion criteria will be counselled and recommended for stepping off PPI therapy. Alginate based reflux suppressant therapy will be the recommended alternative treatment. PPI therapy will still be indicated in these patients for the treatment of occasional flare-ups of GORD. In such cases, the maximum duration of PPI treatment is 8 weeks.
All patients assessed at the clinic will receive advice on lifestyle modifications that may relieve GORD symptoms:

- Weight loss
- Smoking cessation
- Reducing alcohol intake
- Head elevation in bed
- Avoidance of bending over
- Dietary advice, e.g. avoiding fatty/spicy foods.

They will also receive a patient information leaflet on Proton Pump Inhibitors.

Step 4

All patients referred to their GP for medication review will be followed up within 3 - 6 months of completion of the dyspepsia clinic. Information collected at the follow-up will be included in the end of programme final report.

An open clinic commencing 2 - 4 weeks after completion of the initial clinics will also be run. This clinic is aimed at patients experiencing problems that have arisen as a result of their medication change.

Step 5

On completion of the project, a final report providing a detailed analysis of the information collated from the register and patient reviews will be presented to the Practice. The report will show the result of all medication changes and will allow the Practice to review the success of the programme. Recommendations for continued PPI reviews will also be made and a summary of patient’s questions and concerns will be included if applicable.
CHANGES TO REPEAT PRESCRIBING

1. The audit must be checked and agreed with a GP in the practice prior to work being undertaken by the Prescribing Support Technician.

2. Agreement is made between the Practice and the Prescribing Support Technician on a suitable date for implementation.

3. It is recommended that the prescribing support technician/LHP Pharmacist notify local community pharmacies of the impending change in prescribing of PPIs and alginates.

4. The Prescribing Support Technician conducts a search of the Practice Clinical System to identify patients currently prescribed PPIs.

5. The patient list is checked to ensure that all patients are still undergoing treatment (also to avoid letters being sent to recently deceased patients).

6. No patient may be changed beyond the scope of the relevant SPC unless authorised by the prescriber.

7. All changes to prescribing must be recorded within the prescribing field and, wherever possible, an indication recorded for any medication added.

8. Each patient should be informed of any changes made in accordance with the Practice’s preferred mode of communication. The Prescribing Support Team recommends personalised written communication sent from the Practice. Additional information e.g. patient leaflets may be included wherever possible.
9. The Prescribing Support technician will communicate information about the review to relevant personnel within the practice e.g. receptionists, nurses and will, if appropriate, create on-screen reminders on the Clinical System.

10. A project file is retained by the Practice containing a list of patients involved, patient letter templates and any individual information sent, a copy of the protocol and contact details for the Prescribing Support Team.

11. The Prescribing Support Technician will record statistics of the review for report purposes and analysis of the review. No information regarding individual patients leaves the practice.

12. A follow-up audit will take place within 12 months.
REFERENCES

5. NHS D & G Management of GI Symptoms found at [www.dgprescribingmatters.co.uk](http://www.dgprescribingmatters.co.uk)
# APPENDIX 1 - HEALING AND MAINTENANCE DOSES OF PPIs

<table>
<thead>
<tr>
<th>PPI</th>
<th>Healing Dose</th>
<th>Maintenance Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Esomeprazole</td>
<td>40mg</td>
<td>20mg</td>
</tr>
<tr>
<td>Lansoprazole</td>
<td>30mg</td>
<td>15mg</td>
</tr>
<tr>
<td>Omeprazole</td>
<td>40mg</td>
<td>20mg</td>
</tr>
<tr>
<td></td>
<td>20mg</td>
<td>10mg</td>
</tr>
<tr>
<td>Pantoprazole</td>
<td>40mg</td>
<td>20mg</td>
</tr>
<tr>
<td>Rabeprazole</td>
<td>20mg</td>
<td>10mg</td>
</tr>
</tbody>
</table>
Dear

**Dyspepsia Clinic Appointment**

We are continually working to improve the healthcare offered to our patients and to ensure that you receive the most appropriate medication for your condition.

We are currently reviewing patients receiving patients repeat prescriptions for their acid related disorders (heartburn, hiatus hernia etc.) and patients on medication after ulcer healing.

We would like to invite you to attend the dyspepsia clinic where the prescribing support pharmacist will review your condition and ensure that you continue to receive the best and most appropriate treatment.

Your individual appointment is for 15 minutes, during which you will be asked to complete a simple questionnaire. It is also an ideal opportunity to ask questions that you may have.

We would be grateful if you would attend Ecclefechan surgery for your clinic appointment

**AT:**

**ON:**

Please inform the surgery if you are unable to attend and another appointment can be arranged for you.

Thank you for your co-operation.

Yours faithfully,