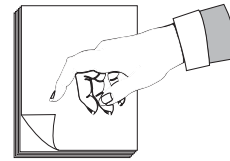


Review of proton pump inhibitor prescribing

Aims of the clinical audit

- To review the appropriate use of proton pump inhibitors (PPIs).
- To review the long-term use of PPIs.
- To identify patients who are appropriate for cessation or step-down of PPI therapy.

Please tear off each section. Registration form and clinical audit forms to be returned to NPS. Please tear off forms carefully.



How to participate

1. Select patients

Identify 20 patients who have been prescribed a PPI and are older than 16 years of age by:

- prospectively choosing patients as they present for consultation, or
- a retrospective search of electronic/paper medical records.

Exclude patients who are using a PPI as part of eradication therapy for *Helicobacter pylori*.

2. Keep patients informed

Patients must be informed that de-identified information from their medical records may be used for clinical audits. Obtain patient's verbal consent (the *Patient information and consent* leaflet may be given to the patient). Display the attached poster *Quality assurance in this practice and your privacy* in your practice.

3. Record patient data (first data collection)

Use the *Patient record form* to record the patients included. **Keep this record** to allow you to identify patients for the review phase (see 6. Completing the clinical audit cycle). DO NOT send the *Patient record form* to NPS.

Complete a clinical audit form for each patient. See notes on pages 2–5.

Please note:

- patient information must only be collected and recorded by the participating doctor.
- both full-time and part-time GPs are required to submit 20 completed clinical audit forms.

4. Submit the clinical audit forms

Return the 20 clinical audit forms and *Registration form* to:

**NPS Clinical Audit: Proton pump inhibitors 2006
Locked Bag 4888
STRAWBERRY HILLS NSW 2012**

**To be received at NPS not later than
Friday, 15 September 2006**

Note: Late submissions cannot be accepted.

5. When you receive your results

You will receive:

- your original clinical audit forms
- feedback on your individual results
- the aggregate results of all participants' management practices
- commentary on the aggregate results
- a *Review phase pack* to complete and return (see below).

6. Completing the clinical audit cycle (second data collection)

You must:

- review your individual and the aggregate results in the *Feedback report*
- identify which of your original 20 patients require follow-up
- record additional patient data
- reflect on changes in management
- submit the *Review phase pack*.

Professional development and PIP

NPS has applied for clinical audit points in the 2005–2007 triennium of the Royal Australian College of General Practitioners (RACGP) Quality Assurance & Continuing Professional Development (QA&CPD) Program (category 1 activity) and the Australian College of Rural and Remote Medicine (ACRRM) Professional Development Program (practice improvement category – includes mandatory points).

The *Review phase pack* **must** be completed and returned to NPS for RACGP and/or ACRRM clinical audit points to be allocated and for the clinical audit to qualify for the Quality Prescribing Initiative (QPI) of the Practice Incentives Program (PIP). You will then be sent a certificate of completion.

(Continued back page)

Notes for clinical audit form

Additional information to assist you to review management

The following guidelines have been used as the basis for this clinical audit:

Australian Medicines Handbook, 2006.¹

Dyspepsia: management of dyspepsia in adults in primary care, National Institute for Clinical Excellence Clinical Guideline No. 17, 2004.²

Gastro-oesophageal reflux disease in adults: guidelines for clinicians, Gastroenterological Society of Australia, 2001.³

Therapeutic Guidelines: Gastrointestinal, Version 3, 2002.⁴

Current management

(Q3 & 4) Choice and dosage of PPI

All PPIs are very effective and are clinically equivalent in most patients.¹

Some studies have shown statistically significant, but small, improvements in healing rates and symptom resolution between PPIs. The small differences indicate that very few people will gain any additional benefit from using one particular PPI over another. In addition, the doses of PPIs used in the studies have not always been comparable.

Since efficacy and adverse effects do vary among individuals, the failure of therapy with one PPI should not preclude a trial with another.

(Q5) Dosing schedule of the PPI

Intermittent, symptom-driven dosing may be used for the maintenance management of gastro-oesophageal reflux disease (GORD), peptic ulcer, non-ulcer dyspepsia and uninvestigated dyspepsia.² A single standard dose of a PPI or an H₂ antagonist, taken once on days when symptoms are troublesome, can satisfactorily control symptoms.

Patients who are satisfied with intermittent, symptom-driven therapy use PPIs or H₂ antagonists on average every 2–3 days, thus minimising medication use and saving substantially on their drug costs.³

Table 1. Standard and low doses of PPIs⁴

PPI	Standard dose*	Low dose*
omeprazole Acimax, Losec, Meprazol, Omepral, Probitor	20 mg daily	10 mg daily [†]
lansoprazole Zoton	30 mg daily	15 mg daily
pantoprazole Somac	40 mg daily	20 mg daily
rabeprazole Pariet	20 mg daily	10 mg daily
esomeprazole Nexium	20 mg daily [‡]	20 mg daily

* Standard dose refers to the dose usually recommended for initial therapy in uninvestigated dyspepsia, GORD, or oesophagitis. Low dose refers to the lower dose recommended for maintenance therapy.

[†] Losec tablets are the only brand of omeprazole available in a 10 mg strength.

[‡] 40 mg daily is indicated for erosive reflux oesophagitis.

(Q7) Lifestyle modification

Lifestyle changes are widely believed to be of some value in the treatment of reflux disease but there is inadequate research available. Given their relative simplicity, they may have some benefit and should be encouraged in anyone with reflux symptoms.

- Avoid specific foods (e.g. chocolate, fats, spices) and drinks (e.g. coffee and alcohol).
- Modify lifestyle: lose weight (if overweight or obese), quit smoking, avoid late large meals, refrain from supine positioning shortly after meals, elevate bedhead.^{1,4}

(Q8) Medication that can induce dyspepsia/ulceration

Review concurrent medications that can induce ulceration/dyspepsia.

Main drugs or drug classes that can induce dyspepsia/ulceration^{1,3,5}

- anticholinergic effect drugs
- aspirin
- bisphosphonates
- calcium-channel blockers
- clopidogrel
- conventional NSAIDs
- corticosteroids
- COX-2 selective NSAIDs
- dopaminergic drugs
- iron
- nitrates
- tetracyclines
- theophylline

NSAID-associated dyspepsia

NSAIDs should be discontinued in patients who develop dyspepsia, unless they are particularly necessary.⁴ However, low-dose aspirin for cardiovascular protection must be taken continuously. If using a conventional NSAID, use one known to have a lower gastrointestinal risk, such as diclofenac or ibuprofen, in preference to higher-risk agents such as piroxicam or ketoprofen.⁴ COX-2 selective NSAIDs may cause fewer ulcer complications than conventional NSAIDs (see *NPS RADAR, Aug 05: Elevated cardiovascular risk with NSAIDs?*). Use the lowest dose for the shortest time or use intermittent therapy.¹ Paracetamol is first line for osteoarthritis and may be used in combination with an NSAID to reduce the required NSAID dose.¹

Current management (cont'd)

Prophylaxis of dyspepsia/ulceration: for cost–benefit reasons, prophylaxis is only recommended for high-risk patients, e.g. the elderly, those with a prior ulcer, those with serious concomitant disease who would tolerate an ulcer bleed poorly, or those using high-dose NSAIDs, longer-acting NSAIDs and/or corticosteroids.⁴

(Q9) Continued need for PPI therapy

The use of PPIs for > 8 weeks should be reviewed. Once symptoms have been controlled, consider treatment withdrawal, especially in patients being treated empirically. Some patients will be able to stop PPIs altogether. Try stepping down to a lower dose or intermittent, symptom-driven therapy in those requiring ongoing therapy. Use the lowest possible dose to control symptoms and limit the number of repeat prescriptions.^{1–3}

If symptom response is inadequate after initial dosage recommendations have been maintained for 8 weeks, doubling the PPI dose may be effective in GORD; consider seeking specialist advice.³

People with a specific need for continued long-term treatment are those with endoscopically confirmed severe oesophagitis, Barrett's oesophagus, scleroderma or stricture.⁴

Adverse effects of PPIs

Despite theoretical concerns that long-term acid suppression may lead to atrophic gastritis, gastric cancer and vitamin B12 deficiency, long-term PPI therapy is not thought to have these harmful effects.⁶

However, acute interstitial nephritis is a rare but serious hypersensitivity reaction that has been reported with all PPIs. Symptoms are non-specific (e.g. weight loss, malaise, fever and nausea). Although only about 30 cases have been reported in Australia, PPIs are now the most common cause of drug-induced interstitial nephritis treated in hospital renal units. Renal function typically improves after withdrawal of the PPI, but not in all cases.⁷

Observational studies have found a 2–3-fold increase in risk of *Clostridium difficile* infection in patients using PPIs. The possibility of *C. difficile* infection may be a reason to review PPI therapy in high-risk patients (those using antibiotics, age ≥ 75 years and renal failure) before admission to hospital.^{8–10}

(Q12 & 13) *Helicobacter pylori*

H. pylori infection confers a lifetime risk of ulcer disease of 15–20% and of gastric cancer of 1.5–2%.³

H. pylori–associated ulcer disease and GORD frequently coexist.³

In the presence of *H. pylori* infection, long-term PPI therapy increases the risk of gastric mucosal atrophy and the potential risk of cancer. Eradication of *H. pylori* reduces this risk.

Consider the following patients for 'test and treat':

- uninvestigated dyspepsia
- non-ulcer dyspepsia (confirmed on endoscopy)
- peptic ulcer disease (confirmed on endoscopy)
- patients requiring long-term PPI therapy.^{2,3}

Carbon-labelled urea breath testing is only subsidised by the Medicare Benefits Schedule for:

- confirming *H. pylori* colonisation:
 - when suitable biopsy material for diagnosis cannot be obtained at endoscopy in patients with peptic ulcer disease, or where the diagnosis of peptic ulcer has been made on barium meal
 - in patients with past history of duodenal or gastric ulcer, or gastric neoplasia when endoscopy is not indicated

OR

- monitoring the success of eradication of *H. pylori* in patients with peptic ulcer disease.¹¹

Review ongoing use of proton pump inhibitors

(Q15) Duration of PPI treatment

In any patient presenting for a repeat prescription consider whether continuing treatment with a PPI is warranted.

HINT: Are your patients getting more prescriptions than they need for initial treatment?

Electronically generated prescriptions may default to the maximum number of repeats, meaning that patients may initially receive prescriptions for 6 months' supply of PPIs.

If necessary, manually choose the number of repeats when prescribing so that patients receive an initial course of 4 weeks' treatment before their return for review.

Peptic ulcer: usually only needs 4–8 weeks' treatment, especially if patients have been shown to be *H. pylori* positive and have been given eradication therapy.

Uninvestigated GORD: need for maintenance PPI treatment is difficult to predict. Determine ongoing need by a trial of withdrawal of PPI therapy after 4–8 weeks' continuous treatment.

Severe erosive or ulcerative oesophagitis, Barrett's oesophagus, scleroderma or strictures: continuous PPI therapy is indicated without withdrawal.

Prophylaxis of NSAID-induced ulcers and erosions: need for continuous therapy is governed by assessment of individual patient-related risks and endoscopic findings.¹

(Q16) Review maintenance use of PPIs

Endoscopy

The optimal role of endoscopy in patients presenting with dyspepsia is still debated.

In general:

- diagnosis will usually be symptom based
- heartburn and/or regurgitation as predominant symptoms are strongly suggestive of GORD
- routine endoscopy is not helpful because most people with reflux symptoms have no endoscopic abnormalities.³

Endoscopy is important for people with:

- alarm symptoms suggestive of malignancy, stricture or ulceration, e.g. abdominal mass, anaemia, gastrointestinal bleeding, haematemesis, pain or difficulty on swallowing, unexplained weight loss
- suspected complications
- symptoms refractory to initial PPI treatment
- unclear diagnosis (mixed, atypical or non-specific symptoms)
- need for reassurance, when verbal reassurance is inadequate.^{3,4}

Step-down approach

After a satisfactory response to an initial standard-dose PPI for 4–8 weeks, or re-treatment of relapse with a previously successful therapy, the need for ongoing treatment should be reviewed. In most patients a trial of reducing the intensity of treatment is worthwhile, with monitoring of the response according to symptoms.

The following treatment strategies should be considered:

- **Treatment withdrawal** — some patients do not experience a clinically significant relapse of symptoms after withdrawal of effective initial therapy, so a trial withdrawal may be appropriate.^{3,4} However, many patients will relapse. Exceptions to treatment withdrawal are listed below. Studies in uninvestigated dyspepsia have shown that after a short course of PPI for initial symptom control, 20–40% of patients experienced at most mild symptoms in the following 6–12 months and did not require another prescription.^{12,13}
- **Reduced dose** — continuing therapy with lower doses of the least costly but effective regimen of a PPI or a standard dose of an H₂ antagonist as appropriate.^{1,3,4} Use the minimum dose that maintains control of symptoms.^{1,2}
- **Intermittent, symptom-driven therapy** — on one or more days when symptoms occur, at the patient's discretion.^{2,3}

Exceptions to treatment withdrawal and step-down are patients diagnosed with*:

Severe oesophagitis — endoscopically confirmed	(These patients all relapse unless treated with daily PPIs)
Barrett's oesophagus	} Require ongoing full-dose or double-dose PPI therapy
Scleroderma	
Strictures	

Clinical audit: Review of proton pump inhibitor (PPI) prescribing

Please see the *Guide to clinical audit* booklet to help you complete this double-sided form.

Use a **black biro** to mark a cross (X) in the box beside your response.

If you make a mistake, use white correction fluid.



NPS office use only

Patient details

1. Your patient code: (Do not use name/s)
2. Age range: < 55 years ≥ 55 years

Current management

3. Which PPI is the patient using? drug name Brand name	4. What is the current daily dosage of PPI? e.g. omeprazole 20 mg twice a day = 40 mg/day				5. What is the dosing schedule of PPI?		
					Regularly each day	Intermittent, symptom-driven	Not known
<input type="checkbox"/> omeprazole Acimax, Losec, Meprazol, Omepral, Probitor	<input type="checkbox"/> 40 mg/day	<input type="checkbox"/> 20 mg/day	<input type="checkbox"/> 10 mg/day	<input type="checkbox"/> other	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> lansoprazole Zoton	<input type="checkbox"/> 60 mg/day	<input type="checkbox"/> 30 mg/day	<input type="checkbox"/> 15 mg/day	<input type="checkbox"/> other	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> pantoprazole Somac	<input type="checkbox"/> 80 mg/day	<input type="checkbox"/> 40 mg/day	<input type="checkbox"/> 20 mg/day	<input type="checkbox"/> other	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> rabeprazole Pariet	<input type="checkbox"/> 40 mg/day	<input type="checkbox"/> 20 mg/day	<input type="checkbox"/> 10 mg/day	<input type="checkbox"/> other	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> esomeprazole Nexium	<input type="checkbox"/> 40 mg/day	<input type="checkbox"/> 20 mg/day		<input type="checkbox"/> other	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

6. Who initiated/recommended the current PPI?
 myself after hospital stay
 another GP not known
 other medical specialist
7. Has lifestyle modification been advised?
 yes no not known
8. Is the patient using medication that can induce dyspepsia/ulceration? (See Guide page 2)
 yes no not known
9. Has the need for continued PPI treatment been reviewed?
 yes no not known
10. Has the dosage of PPI been changed during the current treatment?
 yes no not known
 increased decreased both increased and decreased
11. Has the patient tried any other treatment(s) before the current treatment?
 antacids other PPI not known
 H₂ antagonists none
12. Has this patient been tested for *H. pylori* infection?
 yes no not known
13. Has this patient had previous *H. pylori* eradication therapy?
 yes no not known

continue next column

Indication for current treatment

14. What is the clinical indication for treatment with a PPI?

14a. (Mark all that apply)

- | | |
|--|--|
| <input type="checkbox"/> uninvestigated GORD/dyspepsia | <input type="checkbox"/> confirmed peptic ulcer disease |
| <input type="checkbox"/> mild to moderate symptoms | <input type="checkbox"/> confirmed non-ulcer dyspepsia |
| <input type="checkbox"/> severe symptoms | <input type="checkbox"/> <i>H. pylori</i> -induced ulcer disease |
| <input type="checkbox"/> confirmed GORD | <input type="checkbox"/> NSAID-induced ulcer disease |
| <input type="checkbox"/> confirmed severe oesophagitis | <input type="checkbox"/> strictures/scleroderma |
| <input type="checkbox"/> Barrett's oesophagus | <input type="checkbox"/> uncertain diagnosis |
| <input type="checkbox"/> other _____ | |

If you have only marked in section 14a, turn over and complete Questions 15 and 16

14b. (Mark all that apply)

- | | |
|---|---|
| <input type="checkbox"/> prophylaxis of drug-induced dyspepsia/ulceration | Have you reviewed:
<input type="checkbox"/> risk/benefit
<input type="checkbox"/> continued need
<input type="checkbox"/> recommended dose
<input type="checkbox"/> alternative drug options |
| <input type="checkbox"/> aspirin | |
| <input type="checkbox"/> conventional NSAID | |
| <input type="checkbox"/> COX-2 selective NSAID | |
| <input type="checkbox"/> other _____ | |

If you have marked any in section 14b, STOP HERE!

Review maintenance use (> 8 weeks)

15. How long has the patient been using a PPI?

< 4 weeks

4–8 weeks

When appropriate, a step-down approach includes:

- trial of withdrawal of PPI
- switch to intermittent, symptom-driven use of PPI
- reduce dose of PPI
- switch to daily or intermittent, symptom-driven use of H₂ antagonist

8 weeks to 6 months

> 6 months

not known

16. Review maintenance use (> 8 weeks) of PPI

Does the patient have:

<input type="checkbox"/> alarm symptoms: abdominal mass, anaemia, GI bleeds, haematemesis, pain or difficulty on swallowing, unexplained weight loss	<input type="checkbox"/> persistent refractory symptoms
<input type="checkbox"/> unclear diagnosis	<input type="checkbox"/> suspected or previous complications
	<input type="checkbox"/> need for reassurance when verbal reassurance is inadequate

1 or more marked None marked
 Continue here Continue here

Has the patient had a previous endoscopy?

no yes

REFER FOR ENDOSCOPY and specialist management
STOP HERE!

Major pathology (Barrett's oesophagus, strictures, scleroderma, severe oesophagitis, malignancy)
Continue specialist management
STOP HERE!

OR

No major pathology

Has this patient achieved adequate control of symptoms?

no yes

Symptoms not resolved after 4–8 weeks with standard-dose PPI (assuming aggravating drugs were ceased/minimised and lifestyle modification was implemented) which of the following was tried?

confirmed compliance

doubled the dose of PPI

referred for endoscopy and/or specialist management

continued current management

other _____

Has this patient tried a step-down approach during this current treatment?

no yes

Plan

trial of withdrawal of PPI

switch to intermittent, symptom-driven use of PPI

reduce dose of PPI

switch to daily or intermittent, symptom-driven use of H₂ antagonist

continue current management (give details) ▼

Which approach was used? (Mark all that apply)

trialled withdrawal of PPI

switched to intermittent, symptom-driven use of PPI

reduced dose of PPI

switched to daily or intermittent, symptom-driven use of H₂ antagonist

Was it successful?

yes no ▼

Action

re-try step-down approach

maintain on current dose of PPI

refer for endoscopy



Clinical audit: Review of proton pump inhibitor prescribing

Aims of this clinical audit

- Completing this clinical audit cycle offers you the opportunity to:
- review the appropriate use of proton pump inhibitors (PPIs)
 - review the long-term use of PPIs
 - identify patients who are appropriate for cessation or step-down of PPI therapy.

Professional development and PIP

- NPS has applied for clinical audit points in the 2005–2007 triennium of the RACGP QA&CPD Program and ACRRM PD Program.
- This is the second clinical audit for the Quality Prescribing Initiative (QPI) of the Practice Incentives Program (PIP) for May 2006 to April 2007.

What this audit involves

1. Data collection phase

- Identify 20 patients.
- Complete a clinical audit form for each patient.
- Submit completed forms by 15 September 2006.

Participation in this clinical audit requires your agreement to aggregation of de-identified patient data.

2. Review phase

- Review results, record patients' progress and identify where improvement in patient management has occurred.

To see a sample audit form before enrolling, visit www.nps.org.au/healthpro

Enrol by Friday 11 August 2006.

Fax this form to: 02 9211 7579 OR Telephone: 02 8217 8700

OR Post to: PO Box 1147, Strawberry Hills NSW 2012

Your free audit pack will be forwarded by mail.

This section is for GPs to enrol in the audit/s

Please use BLOCK LETTERS

Family name	<input type="text"/>		
Given names	<input type="text"/>		
Postal address	<input type="text"/>		
Town or Suburb	<input type="text"/>		
State or Territory	<input type="text"/>	Postcode	<input type="text"/>
Phone no.	(<input type="text"/>) <input type="text"/>	Prescriber no.	<input type="text"/>
Fax no.	(<input type="text"/>) <input type="text"/>	Provider no.	<input type="text"/>

Mark here if you wish to enrol in the clinical audit on PPI prescribing

Mark here if you wish to pre-enrol in the clinical audit on analgesics

Analgesics audit, available September 2006, see over for details



National Prescribing Service Limited

Special advance notice

Clinical audit: Analgesics

- This will be the third and last clinical audit for the Quality Prescribing Initiative (QPI) of the Practice Incentives Program (PIP) for May 2006 to April 2007.

Available September 2006

Aim of the analgesics audit

- review the use of paracetamol, NSAIDs and opioids in the management of chronic non-malignant pain.

Note: Materials for this audit will not be available until September.

Why enrol now?

You can save yourself time by enrolling now and we'll send you the audit pack as soon as it is available.



**See over to enrol in the clinical audit on analgesics AND/OR
the clinical audit on proton pump inhibitor prescribing.**

NPS is an independent, non-profit organisation for Quality Use of Medicines,
funded by the Australian Government Department of Health and Ageing.