Queensland Community Pharmacy Scope of Practice Pilot

Gastro-oesophageal Reflux and Gastro-oesophageal Reflux Disease - Clinical Practice Guideline

Guideline Overview

Pilot and professional obligations

- Initial patient eligibility and suitability for management within the scope of the pilot
- · Patient informed consent
 - · Pilot participation
 - Financial
 - Pharmacist communication with other health practitioners
- · Professional standards
- Privacy
- · Documentation and record keeping
- Interprofessional communication

Gather information and assess patient's needs

- · Presenting signs and symptoms
 - · 'Alarm' signs and symptoms
- · Patient history
 - · Patient characteristics
 - · Medical history
 - · Lifestyle/ social history

Management and treatment plan

- · Non-pharmacological/ general measures
 - Dietary and lifestyle modification
- Pharmacological

Confirm management is appropriate

- · Contraindications and precautions
- · Drug interactions
- Pregnancy and lactation

Refer when

Refer to a medical practitioner if:

- The patient has 'red flag' warning signs
- A clear diagnosis of gastro-oesophageal reflux or GORD cannot be made
- The patient is aged under 18 or over 50 years
- The patient presents with chest pain as the primary symptom (immediate referral for cardiac investigations is required)
- The patient presents with 'alarm' signs and symptoms that may indicate the need for upper gastrointestinal endoscopy or other investigations (refer to table 1)
- The patient is being managed by a gastroenterologist
- There is an inadequate response to treatment/symptom control is inadequate after 8 weeks of PPI therapy at the standard dose, or if symptoms worsen

😆 🛮 Communicate agreed treatment plan

- · How to use
- Initial, maintenance and step down pharmacotherapy
- Adverse effects
- Communication with other health practitioners

Clinical review

- Adherence to pharmacotherapy and nonpharmacological management strategies
- Response to treatment (continue, modify, stop and/or refer)
- Adverse effects
- Communication with other health practitioners





'Red flag' warning signs at patient presentation that necessitate referral to a medical practitioner:

- Chest pain as the primary symptom
- New symptoms in patients over the age of 50
- Symptoms of anaemia including fatigue, shortness of breath, weakness, dizziness or an irregular heartbeat
- · Difficulty or painful swallowing
- Vomiting
- Jaundice
- Haematemesis or melaena
- Unexplained weight loss
- Severe, frequent or changing symptoms.

Key points

- The cardinal signs of gastro-oesophageal reflux are heartburn and regurgitation (1, 2).
- The Therapeutic Guidelines defines gastro-oesophageal reflux disease (GORD) as gastro-oesophageal reflux symptoms that are frequent (2 or more episodes per week) and severe enough to impair quality of life, or people who have complications of gastro-oesophageal reflux ⁽³⁾. However, the clinical definition of GORD may differ between resources used in clinical practice.
- The causes of gastro-oesophageal reflux and GORD are multifactorial and may involve dysfunctional peristalsis, delayed gastric emptying and impaired or transient relaxation of lower oesophageal sphincter resting tone (1, 4).
- The presumptive clinical diagnosis of gastro-oesophageal reflux and GORD are primarily based on patient reported symptoms ^(3, 4). However, response to a trial of proton pump inhibitors (PPI) can also be used to diagnose GORD ^(2, 3). A trial of high dose PPIs has a sensitivity of 80% as a diagnostic test for GORD ⁽¹⁾.
- The initial management of gastro-oesophageal reflux and GORD is based on the severity of symptoms; symptom control is the aim for most patients ⁽³⁾. Mild intermittent symptoms may be managed with diet and lifestyle modification only, however ondemand drug therapy may also be used ⁽³⁾.
- Approximately one third of patients with the symptoms of reflux have some form of mucosal damage, ranging from minor erosions to circumferential ulceration or metaplasia (e.g. Barrett's oesophagus) (3). GORD may lead to oesophageal strictures in a minority of patients or on rare occasions, malignancy (3).

When applying the information contained within this clinical practice guideline, pharmacists are advised to exercise professional discretion and judgement. The clinical practice guideline does not override the responsibility of the pharmacist to make decisions

appropriate to the circumstances of the individual, in consultation with the patient and/or their carer.



Refer when

- The patient has 'red flag' warning signs
- A clear diagnosis of gastro-oesophageal reflux or GORD cannot be made
- The patient is aged under 18 or over 50 years
- The patient presents with 'alarm' signs and symptoms that may indicate the need for upper gastrointestinal endoscopy or other investigations (refer to Table 1)
- The patient is being managed by a gastroenterologist
- There is an inadequate response to treatment/symptom control is inadequate after 8 weeks of PPI therapy at the standard dose, or if symptoms worsen.

Gather information and assess patient's needs

Presenting signs and symptoms

The clinical symptoms of GORD are common to multiple other conditions but can often be differentiated using the patient's history.

In addition to the cardinal signs of heartburn and regurgitation other atypical symptoms attributed to reflux include:

- belching
- epigastric pain
- dyspepsia
- acid brash (saliva mixing with stomach acid in the mouth) (1,2).

Extra-oesophageal symptoms that are associated with, but not specific to gastro-oesophageal reflux, may include:

- tooth sensitivity, enamel erosion (particularly on palatal surface of upper incisors) and halitosis
- pharyngeal and laryngeal signs and symptoms such as hoarseness and throat clearing, persistent cough, sore throat, pharyngitis and sinusitis
- chest pain
- sleep disturbance
- nausea
- asthma-like symptoms (cough, wheeze, shortness of breath) (3, 4).

Alarm symptoms

'Alarm' signs and symptoms that are suggestive of other serious conditions (and where endoscopy may be indicated) are listed in Table 1.

Table 1. Alarm signs and symptoms (3, 5)

The following signs and symptoms are suggestive of other serious conditions and must be referred to a medical practitioner (as endoscopy may be indicated):

- symptoms of anaemia
- difficulty or painful swallowing
- haematemesis
- melaena
- vomiting
- unexplained weight loss

- chest pain
- new symptoms in an older person
- changing symptoms
- severe or frequent symptoms
- jaundice
- inadequate response to treatment (up to 8 weeks of PPI at the standard dose).

Patient history

Sufficient information should be obtained from the patient to assess the safety and appropriateness of any recommendations and medicines.

The patient history should consider:

- age
- weight
- pregnancy and lactation status (if applicable)
- nature, severity and frequency of symptoms (typical, atypical and extraoesophageal), including 'alarm' signs and symptoms that may indicate the need for upper gastrointestinal endoscopy (refer Table 1)
- · onset and duration of symptoms
- precipitating and relieving factors
- underlying medical conditions and conditions that may complicate diagnosis e.g., coronary heart disease and asthma
- dietary patterns
- current medication (including prescribed medicines, vitamins, herbs, other supplements and over-the-counter medicines)
 - consider medications that may exacerbate or cause gastro-oesophageal reflux symptoms.
- allergies/adverse drug reactions
- pharmacological and non-pharmacological (dietary and lifestyle) strategies tried to treat current symptoms and response
- alcohol and drug history
- smoking status.

Assessment

where appropriate, conduct assessment of vital signs.

Management and treatment plan

The initial management of gastro-oesophageal reflux and GORD is based on the severity of symptoms; symptom control is the aim for most patients (3).

Pharmacist management of gastro-oesophageal reflux and GORD involves:

non-pharmacological / general measures

 Advice regarding dietary and lifestyle modification as per the <u>Therapeutic</u> <u>Guidelines: Diet and lifestyle modification for the management of gastro-oesophageal reflux in adults</u> ⁽³⁾.

pharmacotherapy

 As per the <u>Therapeutic Guidelines: Management of mild intermittent</u> symptoms of gastro-oesophageal reflux in adults, <u>Management of frequent or</u> severe symptoms of gastro-oesophageal reflux disease (GORD) in adults^{1,2} and <u>Gastro-oesophageal reflux during pregnancy</u> (3).

NB1: The efficacy and availability of PPIs has led to overuse; long-term regular PPI therapy is only recommended for a limited number of indications and should be reviewed regularly ^(3, 5).

NB2: Where regular drug therapy is required, consider referral to a medical practitioner for collaborative care and onward referral to a gastroenterologist ⁽³⁾.

Confirm management is appropriate

Pharmacists must consult the Therapeutic Guidelines, Australian Medicines Handbook and other relevant references to confirm the treatment recommendation is appropriate, including for:

- contraindications and precautions
- drug interactions
- pregnancy and lactation.

Communicate agreed management plan

Comprehensive advice and counselling (including supporting written information when required) as per the Australian Medicines Handbook and other relevant references should be provided to the patient regarding:

- individual medicine use e.g., initial dosing, maintenance and step down therapy
- how to manage adverse effects
- when to seek further care and/or treatment (if 'alarm' signs and symptoms develop or condition significantly worsens)
- when to return to the pharmacist for clinical review.

It is the pharmacist's responsibility to ensure the suitability and accuracy of any resources and information provided to patients (and parents/caregivers if applicable), and to ensure compliance with all copyright conditions.

The agreed management plan should be shared with members of the patient's multidisciplinary healthcare team, with the patient's consent.

Clinical Practice Guideline - GORD. Printed copies uncontrolled.

Patient resources/information

- Pharmaceutical Society of Australia <u>Heartburn and indigestion</u> patient information card.
- Gastroenterological Society of Australia (GESA) Patient Resources <u>Information</u> <u>about Reflux</u>.

Clinical review

Clinical review with the pharmacist should occur in line with recommendations in the Therapeutic Guidelines and other relevant guidelines. Clinical review is recommended **4-8** weeks after initiation of new treatment to assess:

- adherence to non-pharmacological management strategies and pharmacotherapy
- response to treatment and if changes to the treatment plan are required (continue, modify, stop and/or refer)
- adverse effects.

Frequency of further follow up appointments for maintenance and step-down therapy should be based on recommendations in the Therapeutic Guidelines.

Pharmacists should generally only prescribe (including repeats) a sufficient quantity of medicine for the period until the patient's next review.

Pharmacotherapy for GORD may be required longer-term; patients should be advised to return to their usual medical practitioner for collaborative care if regular pharmacotherapy is required.



Pharmacist resources

- Therapeutic Guidelines: Gastrointestinal
 - Oesophageal disorders
 - o Functional gastrointestinal disorders
- Australian Medicines Handbook:
 - o Drugs for dyspepsia, reflux and peptic ulcers
- Australian Prescriber The management of gastro-oesophageal reflux disease
- Best Practice Advisory Centre New Zealand <u>Managing Gastro-oesophageal Reflux</u>
 Disease (GORD) in adults: an update

References

- 1. Bloom S, McCartney S, Langmead L, Banks M. The modern investigation and management of gastro-oesophageal reflux disease (GORD). Clin Med (Lond). 2009;9(6):600-4.
- 2. Badillo R, Francis D. Diagnosis and treatment of gastroesophageal reflux disease. World J Gastrointest Pharmacol Ther. 2014;5(3):105-12.
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- 5. Australian Medicines Handbook: Drugs for dyspepsia, reflux and peptic ulcers. Adelaide: Australian Medicines Handbook Pty Ltd; 2022 [cited 2022 September 20]. Available from: https://amhonline.amh.net.au/chapters/gastrointestinal-drugs/drugs-dyspepsia-reflux-peptic-ulcers?menu=vertical.
- 6. Keung C, Hebbard G. The management of gastro-oesophageal reflux disease. Australian Prescriber. 2016;39:36-9.