TREATMENT PROTOCOLS IN PRIMARY CARE

GASTRO-INTESTINAL DISORDERS

This booklet was compiled by Marija Carmen Carbonaro as part of an undergraduate project entitled “Dissemination of Protocols: Gastro-intestinal Disorders” carried out in partial fulfilment of the requirement of the course leading to the Degree of Bachelor of Pharmacy (Hons).

The study was carried out under the supervision of Professor Lilian M. Azzopardi, Head of Department, Department of Pharmacy, University of Malta.

Protocols were adapted from a previous project “Treatment Protocols for disorders of the Gastro-intestinal tract” by Steven Ellul, 2009.

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Preface

Presentation of symptoms indicative of gastro-intestinal disorders in a primary care setting including community pharmacies is common. Such symptoms may vary in severity and frequency. In some cases the symptoms presented may indicate severe or acute disease states that warrant referral. In other instances symptoms appearing to be related to gastro-intestinal disorders may be arising due to conditions occurring in other systems particularly the cardiovascular system. Pharmacists practising in community pharmacies support patients in using rational and safe non-prescription medicines and in identifying symptoms warranting referral.

This booklet has been compiled by Marija Carmen Carbonaro, a pharmacy student who is carrying out her project in this area. She has drawn on material that has been compiled by Steven Ellul, a pharmacist who participated in this research project. An area of research interest of the department is evidence-based pharmacy and quality care standards. The development of practical and contemporary protocols to be used as guidelines by pharmacists enhances the practice of the pharmacy profession. This concept strengthens interprofessional relationships between pharmacists and other prescribers and sustains the profession's contribution to patient care.

Professor Lilian M. Azzopardi
Head, Department of Pharmacy

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How to use this booklet

This handbook contains guidelines which may be used by community pharmacists, when recommending and dispensing medications to treat upper gastro-intestinal disorders. It highlights important actions that the pharmacist must carry out, in order to provide the patient with the best advice and medications possible.

Step 1: Follow the Introductory protocol for gastro-intestinal disorders.

Step 2: Follow the protocol for the symptoms presented or the disorder diagnosed.

Step 3: Follow the prescription and dispensing protocol.

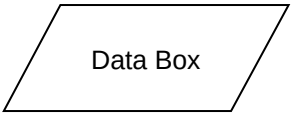
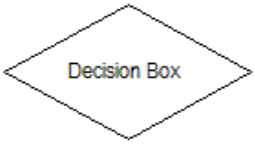
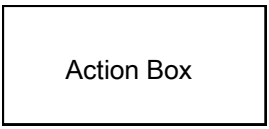
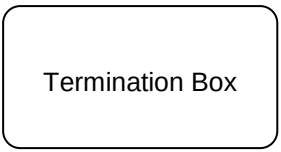
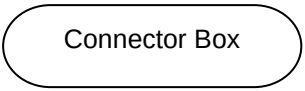
The explanatory texts contain information for pharmacists useful for the management of gastro-intestinal disorders in the primary care setting. These texts include information regarding lifestyle advice, elements of care, cautions, contraindications and referral criteria.

A list of the medicines available, with their respective active ingredients and dosage regimen is included.

Abbreviations

H_2RA: Histamine-2 Receptor Antagonist
NSAIDs: Non-steroidal anti-inflammatory drugs
PPI: Proton Pump Inhibitor
GORD: Gastro-oesophageal reflux disease
COX-2: Cyclooxygenase-2 inhibitor

Interpretation of Shapes

	Used to show known information about the patient
	Used when a decision leads to different paths along the protocol
	Used when a pharmacist is required to perform an action
	Used when it is time to exit a protocol
	Used when the protocol continues on a new page

Conditions

Dyspepsia

- Dyspepsia refers to pain or discomfort centred in the upper abdomen (around the midline). It may be characterised by feelings of upper abdominal fullness, early satiety, bloating, belching, nausea, retching and/or vomiting.

Gastro-oesophageal reflux Disease

- Gastro-oesophageal reflux disease (GORD) is caused by the reflux of stomach contents causing heartburn, which is a retrosternal burning pain of variable severity accounting for around 30% of cases of dyspepsia. Reflux may occur without producing any symptoms.
- GORD usually manifests itself as a brief acute attack of heartburn. Recurrent episodes of GORD may result in oesophageal damage, and extra-oesophageal complications include laryngopharyngeal disorders, dental erosion, sinus problems and reflux induced asthma.

Peptic ulcer Disease

- Peptic ulcer disease (PUD) occurs when the balance between peptic acid secretion and gastroduodenal mucosal defence mechanism is disrupted. This results in discontinuity in the entire thickness of the mucosa. Commonly caused by *Helicobacter pylori* infection, NSAIDs, physiologic stress and hyper-secretory states.

Helicobacter pylori Infection

- *H. pylori* is implicated in chronic active gastritis, functional dyspepsia, peptic ulcer disease, and gastric cancer. It is a urease positive gram negative organism, breaking down urea to carbon dioxide and ammonia, which is the basic principle of the test to detect its presence. Eradication of *H. pylori* reduces the reappearance of gastric and duodenal ulcers, and the risk of re-bleeding.

Pharmacotherapy

Antacids and Alginates

Antacids are effective in the symptomatic relief of heartburn, especially when used in conjunction with an alginate. Liquid antacids are considered to be more effective than tablet formulations, but most patients find tablets more convenient. To obtain the best results with tablets, they should be thoroughly chewed. One may suggest the use of liquid antacids when at home, leaving the antacid tablets as treatment during work hours.

It is important to avoid preparations which have a high content of sodium, in patients who are on a sodium restricted diet (they may be replaced by preparations containing potassium instead).

Magnesium containing antacids may have a laxative effect, while those containing aluminium may result in constipation.

Alginates form a raft which floats over stomach contents, reducing reflux and protecting the oesophageal lining. These preparations have an advantage over simple antacids, when it comes to reflux-like symptoms.

Anti-foaming agents such as dimethicone and simethicone are added in order to help reduce flatulence.

Histamine-2 Receptor Antagonists

H_2 receptor antagonists work by blocking the histamine (H_2) receptors on the gastric mucosa reducing gastric acid output. As a result there is increased ulcer healing, and a relief of GORD symptoms. They are mostly used as a maintenance treatment when severe symptoms recur, and in the treatment of NSAID associated ulcers.

Proton Pump Inhibitors

Proton pump inhibitors work as acid suppressants in the stomach by inhibiting the final stage of hydrochloric acid production, by blocking the hydrogen-potassium ATPase enzymes of the parietal cells (the proton pump). They are effective in the prevention and treatment of NSAID induced ulcers, as well as part of triple therapy for *H. pylori* eradication. PPIs are considered to be the most effective medicines for the relief of heartburn, dyspepsia and GORD. It often takes a day for them to come to full effect, so patients may need to take concomitant antacid therapy for symptomatic relief.

Motility Stimulants

Metoclopromide is a prokinetic drug which may be used to improve the gastro-oesophageal sphincter function, and it may also increase the rate of gastric emptying.

Domperidone acts as an antagonist on the dopamine D_2-receptor, increasing motility and gastric emptying, whilst decreasing postprandial reflux time. It has therefore been used to treat regurgitation and vomiting.

Triple Therapy for *H. pylori* Infection

Once *H. pylori* infection is diagnosed, triple therapy should be adopted for its eradication. It involves one week of treatment using a proton pump inhibitor, clarithromycin and amoxicillin or metronidazole. If a patient was previously treated with metronidazole, amoxicillin is preferred as part of triple therapy.

Treatment fails due to poor compliance or bacterial resistance to the antibiotic. Using two weeks of triple therapy results in higher eradication rates but adverse effects are more common and poor compliance would hinder any benefits achieved.

Cautions and Contraindications

Antacids

- Antacids containing large amounts of sodium should be avoided in patients with hepatic impairment and fluid retention.
- Aluminium containing antacids may cause constipation and as a result should be avoided in hepatic impairment, since they can precipitate coma.
- In renal impairment, there is a risk of aluminium toxicity due to accumulation from aluminium containing antacids. Absorption of aluminium is increased by citrates present in many effervescent preparations.
- Aluminium containing antacids are contraindicated in neonates and infants.
- Magnesium salts should be avoided in hepatic coma, where there is a chance of renal failure; they should be avoided, or given at a reduced dose.
- Aluminium and Magnesium containing antacids are contraindicated in hypophosphataemia.

H_2-Receptor Antagonists

- H_2-Receptor Antagonists may mask symptoms of gastric cancer. Special care should be taken with patients presenting ‘alarm features’. Malignancy has to be ruled out before treatment.
- Ranitidine should be used with caution in acute porphyria.

Proton pump Inhibitors

- Proton pump inhibitors may hide signs of gastric cancer, which should be ruled out before treatment is initiated.

Advice when Dispensing

- Antacids are best administered one hour after meals since by this time the rate of gastric emptying has slowed down and allowing the antacid to act for up to 3 hours. If taken prior to a meal, the duration of action is reduced to an hour.

- Since antacids increase gastric pH, they may interfere with enteric coated tablets, leading to unpredictable release of the drug. It is advisable to tell the patient to take antacids at a separate time from any other medication.

- Treatment with H_2RAs should be limited to a maximum of two weeks. This should ensure that the patient does not self medicate continuously for long periods of time. In cases of repeat purchase, ask the patient if they have been taking the medicine continuously, or as required.

- When food is a known cause of heartburn, H_2RAs should be taken one hour before meals.

- PPIs start having an effect on the patient a day after first administration. In patients with ongoing symptoms, antacid therapy on the first day of treatment may be required to relieve symptoms.

- Patients should be advised against taking H_2RAs and PPIs at the same time.

- PPI tablets should be taken prior to a meal with plenty of liquids to ensure optimum effect. The tablets should not be crushed or chewed.

Elements of Care

- Many patients self treat using either an antacid, alginate or a combined preparation. These preparations are adequate for symptomatic relief. Additional therapy may be more appropriate in managing persistent symptoms, which have a negative impact on the patient's quality of life.

- In older patients, their comorbidities must be taken into account prior to dispensing any medication.

- Patients who have been on long term treatment for dyspepsia, should be encouraged to step down their dose of medication, if their symptoms are controlled by first reducing the dose of the prescribed medication to the lowest effective dose. Once control has been achieved, the medication should be used as required when symptoms occur. Once symptom control is achieved with dosing as required using prescription medicine, patient may return to self management, using an antacid and/or alginate preparation.

- Patients should be educated with regards to lifestyle measures, which will support the therapy that they receive. Offer patients lifestyle advice.

- Offer the patient point-of-care (POC) testing for *H. pylori* infection, if it is available at the pharmacy.

- If the patient cannot discontinue NSAID treatment, you can treat the NSAID associated ulcer with a PPI, and continue with the treatment after ulcer healing has been achieved ,to prevent recurrence of ulcer. Alternatively, you may choose to switch from a non-selective NSAID to a cyclooxygenase-2 selective inhibitor. In patients with a history of upper GI bleeding, continuing PPI treatment may provide further protection against reoccurrence.

Lifestyle Advice

- Patients who follow extreme dietary measures should be encouraged to follow a balanced diet to reduce the risk of nutritional deficiencies. Overweight patients should be advised to lose weight, and achieve ideal body weight.

- Eating small frequent meals reduces gastric distension helping to prevent reflux. Large volume of food in the stomach slows down emptying, which worsens reflux symptoms. High fat meals delay gastric emptying. It is best to have the last evening meal a few hours (3 to 4 hours) before retiring to bed.

- Posture may affect symptoms. Bending and stooping may cause reflux; therefore it would be better for the patient to squat. Symptoms are often worse when lying down. Raising the head of the bed may increase acid clearance, thus reducing the number of episodes of reflux.

- Advise the patient to avoid tight constricting clothing since they may aggravate the condition.

- Certain foods and drinks render the oesophageal sphincter less competent by lowering pressure – these include chocolate, alcohol, peppermint and fatty foods. Spicy food, citrus and tomato extracts irritate the gastric mucosa, while Cola and Beer stimulate acid secretion in the stomach.

- Smoking lowers oesophageal sphincter competence, therefore the pharmacist should offer advice with regards to smoking cessation, since relief from heartburn might be a motivating factor in getting patients to quit smoking.

Referral Criteria

Gastro-intestinal bleeding
Patients who present with dyspepsia, along with significant signs of gastro-intestinal bleeding (malaena and haematemesis) should be referred immediately.

Patient's medication
The patient's medication should be reviewed to identify drugs which may be causing dyspepsia. These medicines include calcium antagonists, nitrates, theophyllines, corticosteroids, Selective serotonin reuptake inhibitors, bisphosphonates and NSAIDs (including aspirin). It is important to suspend NSAID therapy, if the patient requires referral.

Alarm signs
Patients, who along with dyspepsia present with chronic gastrointestinal bleeding, progressive unintended weight loss, difficulty and painful swallowing, persistent vomiting, jaundice, anaemia and an epigastric mass should be referred urgently.

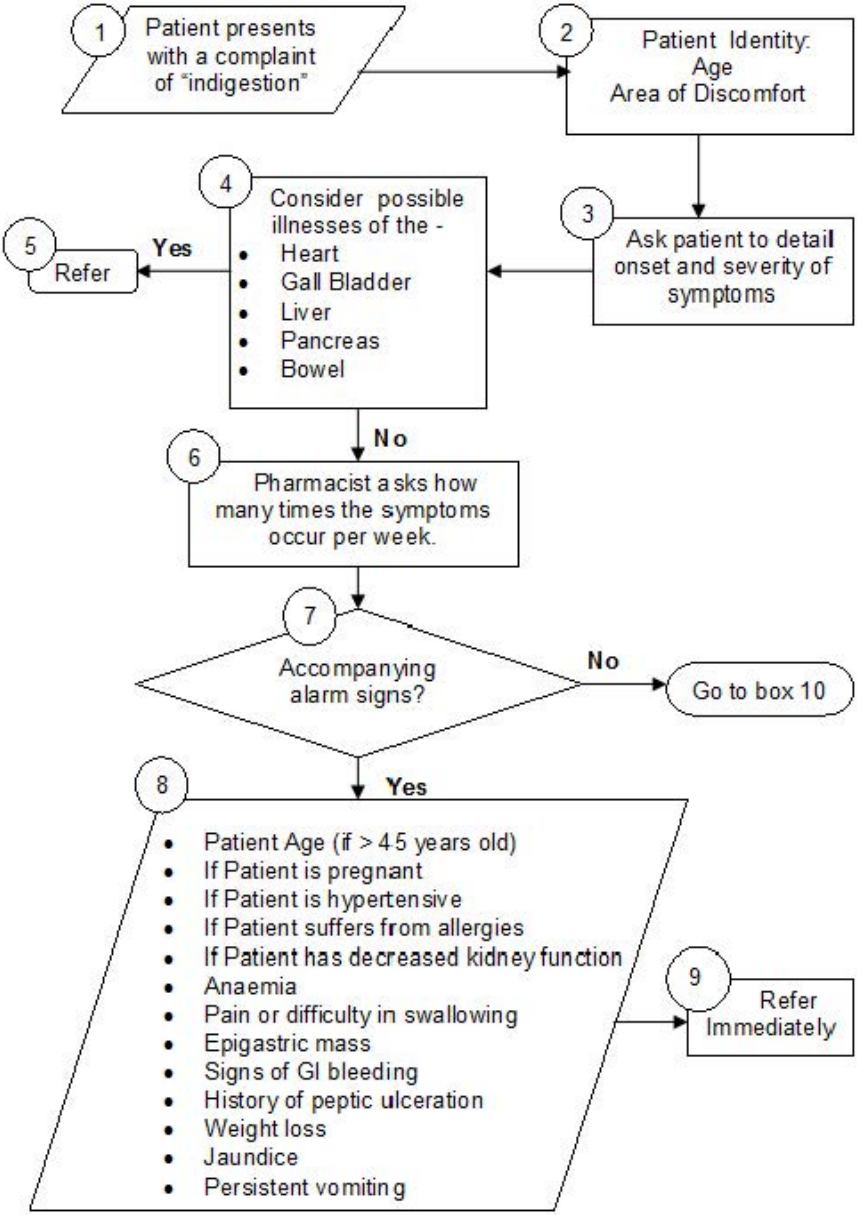
Patient age
Patients in their late 50s (>55) with persistent recent onset dyspepsia of unexplained origin, should be referred urgently.

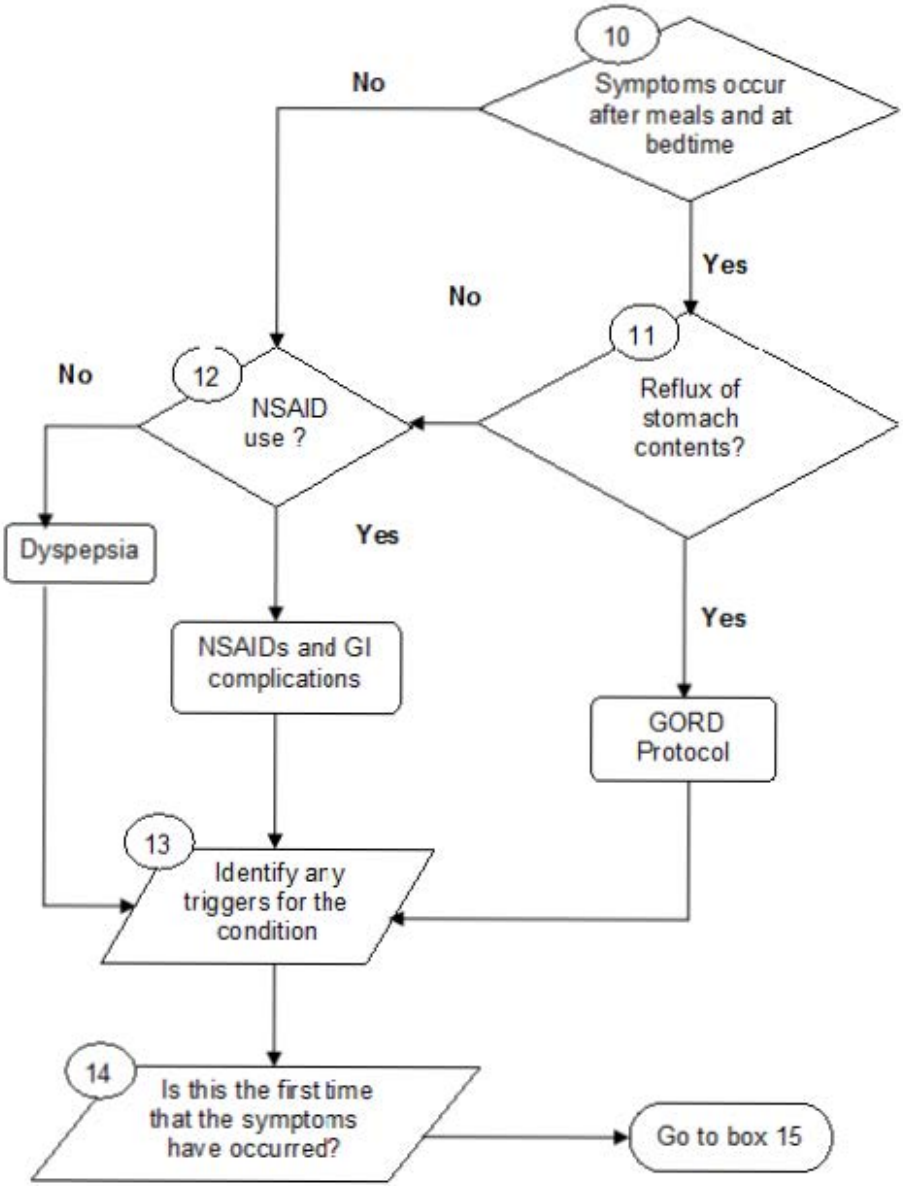
Previous history of peptic ulceration
In patients, who have previously had an endoscopy, and are suffering once again from symptoms of dyspepsia with no new alarm features, first line management should be in line with the results obtained from the patient's last endoscopy.

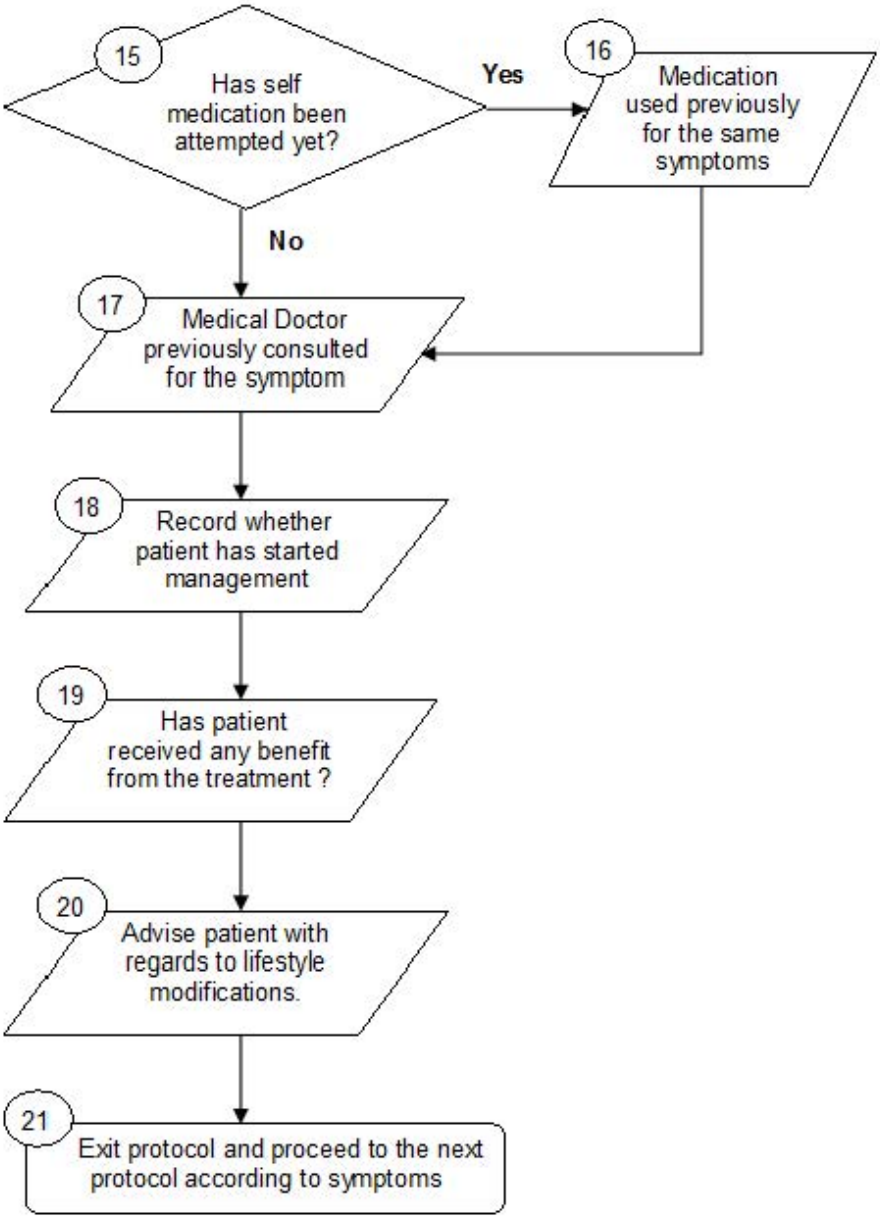
Drug therapy
Acid suppression therapy (PPI's and H_2RAs) should be stopped two weeks prior to endoscopy, since it may mask or delay the detection of malignancy.

The Protocols

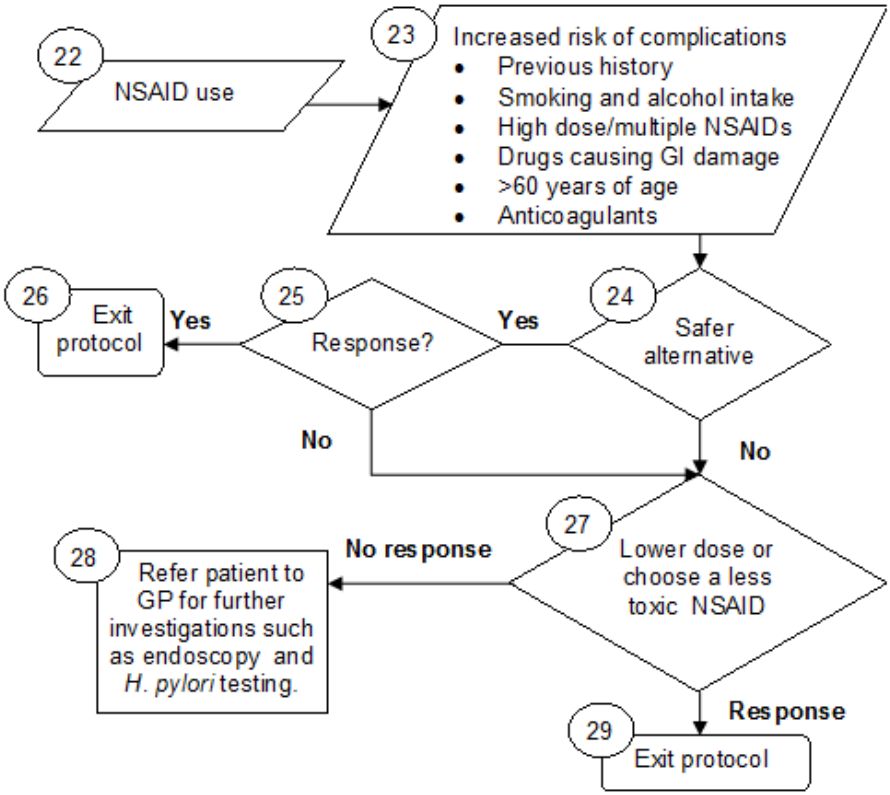
Introductory Protocol




10
Symptoms occur after meals and at bedtime
No
Yes
No
11
Reflux of stomach contents?
No
12
NSAID use ?
Yes
Yes
Dyspepsia
NSAIDs and GI complications
GORD Protocol
13
Identify ary triggers for the condition
14
Is this the first time that the symptoms have occurred?
Go to box 15


15
Has self medication been attempted yet?
Yes
16
Medication used previously for the same symptoms
No
17
Medical Doctor previously consulted for the symptom
18
Record whether patient has started management
19
Has patient received any benefit from the treatment ?
20
Advise patient with regards to lifestyle modifications.
21
Exit protocol and proceed to the next protocol according to symptoms

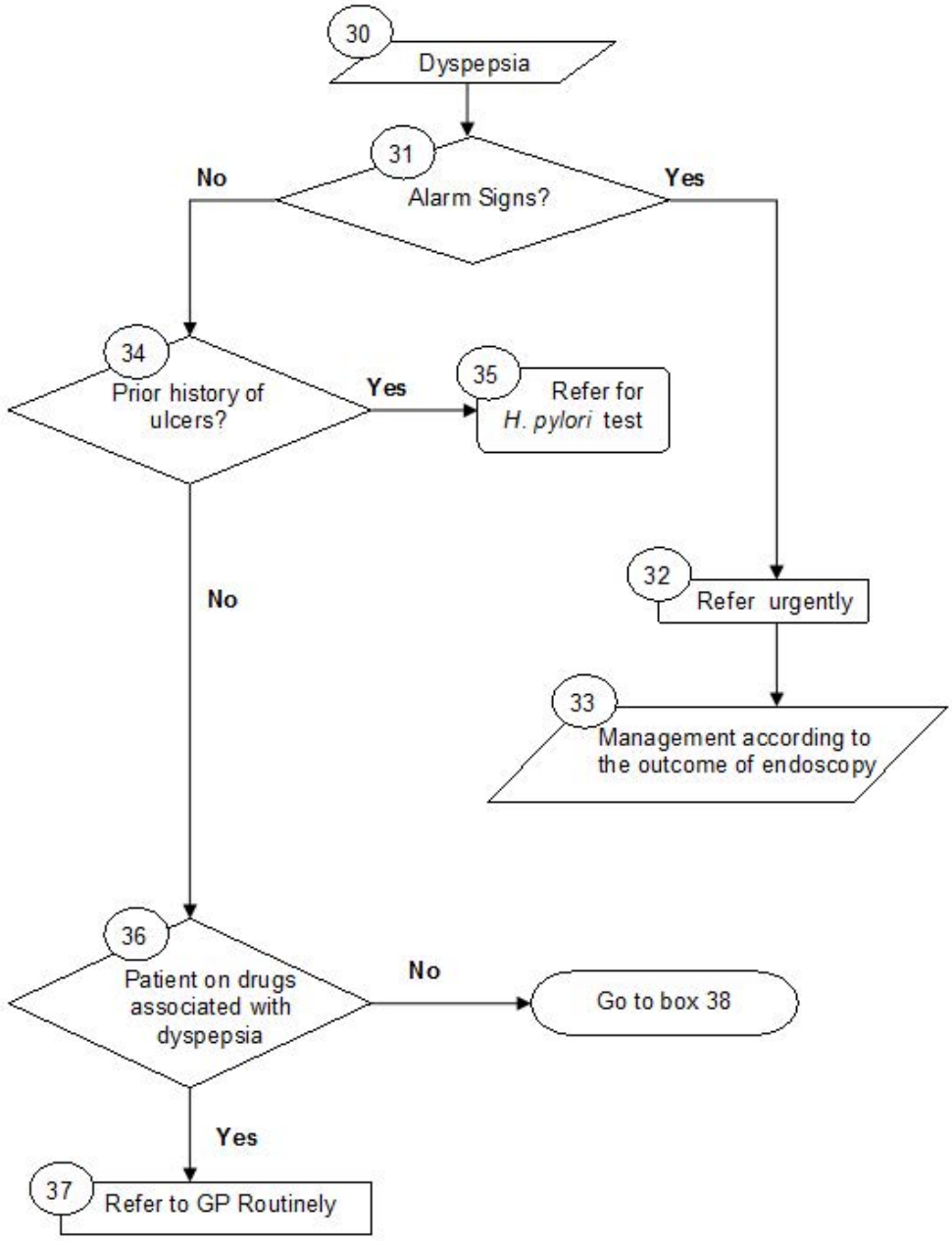
NSAID associated GI complications Protocol

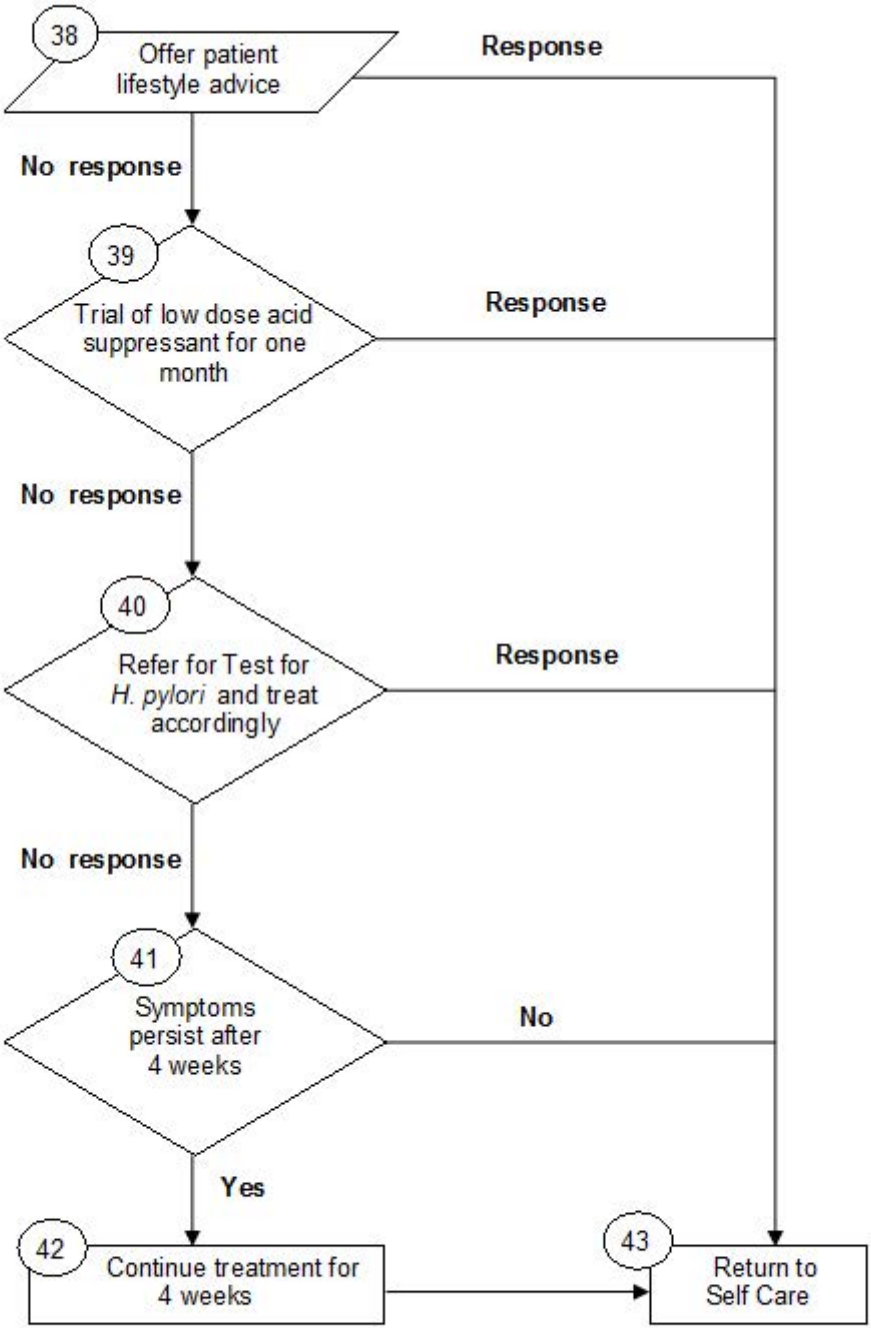


- NSAIDs are associated with serious gastro-intestinal toxicity. Elderly patients are at an increased risk.
- Safety of non-selective NSAIDs varies. **Ibuprofen** is considered the safest, whilst **Naproxen** and **Diclofenac** carry an intermediate risk of gastro-intestinal side effects. **Piroxicam** carries a higher risk of toxicity.
- **COX-2 selective inhibitors** are associated with the lowest risk of upper gastro-intestinal side effects.
- When a lesser toxic NSAID is required, **Ibuprofen** at the lowest recommended dose is preferred. The use of more than one oral NSAID is contraindicated.
- Aspirin combined with an NSAID increases the risk of side effects. This combination should only be used if absolutely necessary and patient should be closely monitored.

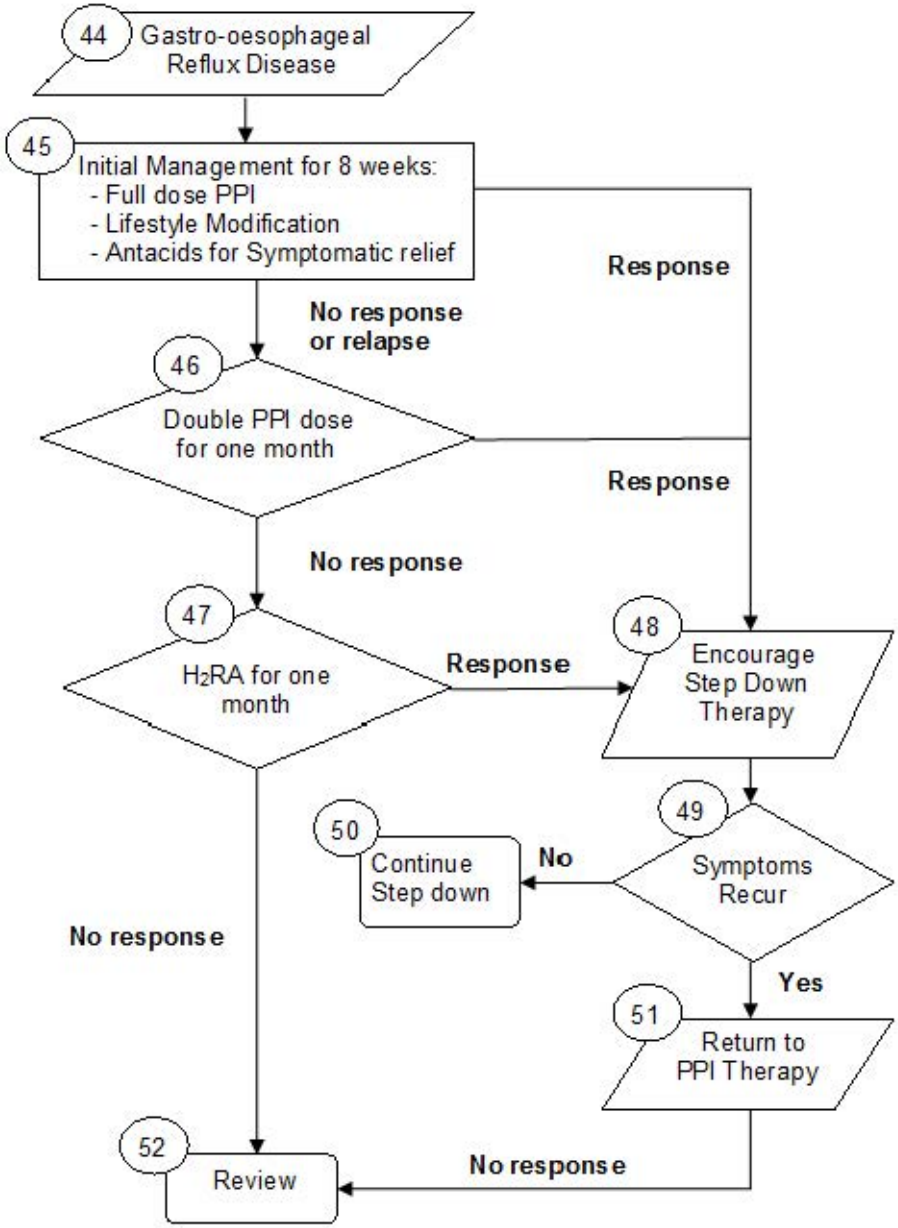
(British National Formulary, No. 61, March 2011)

Dyspepsia Protocol

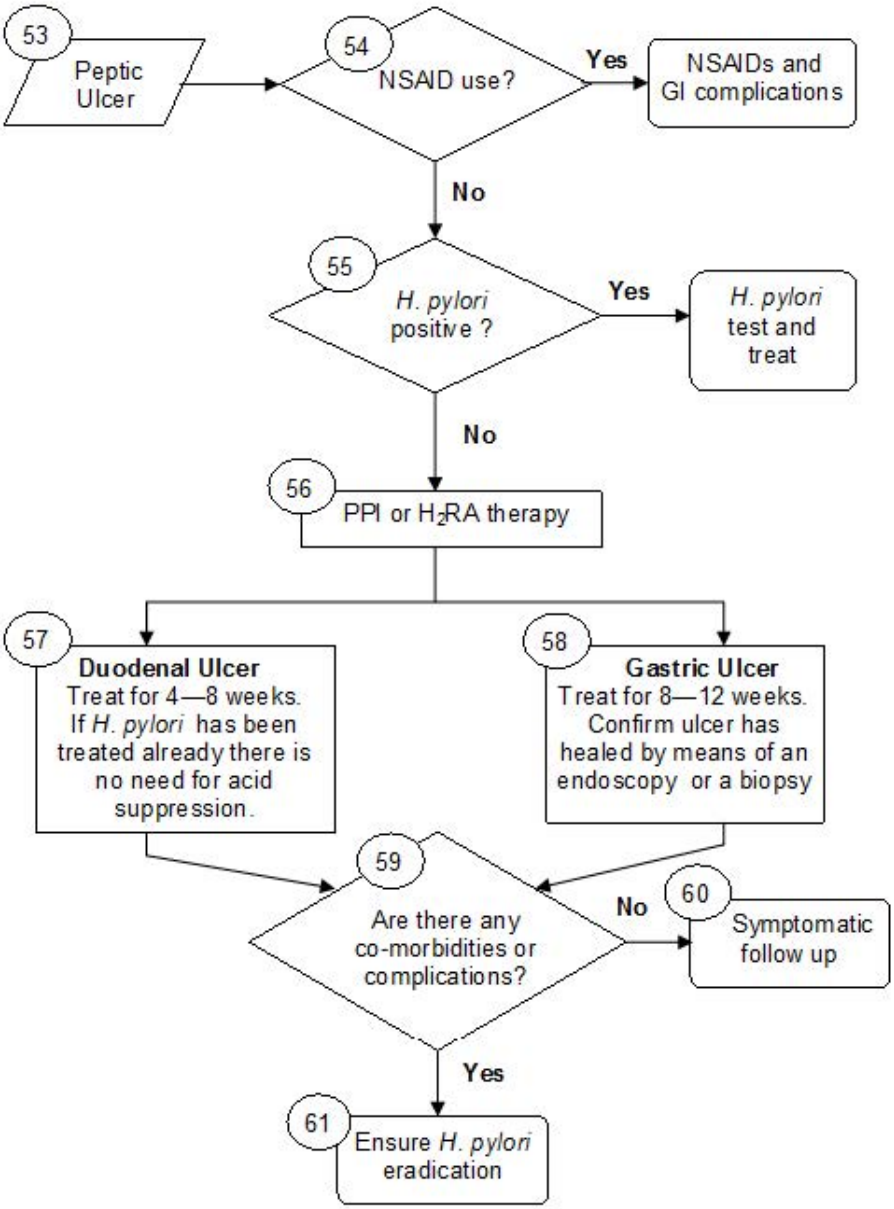



38
Offer patient lifestyle advice
Response
No response
39
Trial of low dose acid suppressant for one month
Response
No response
40
Refer for Test for H. pylori and treat accordingly
Response
No response
41
Symptoms persist after 4 weeks
No
Yes
42
Continue treatment for 4 weeks
43
Return to Self Care

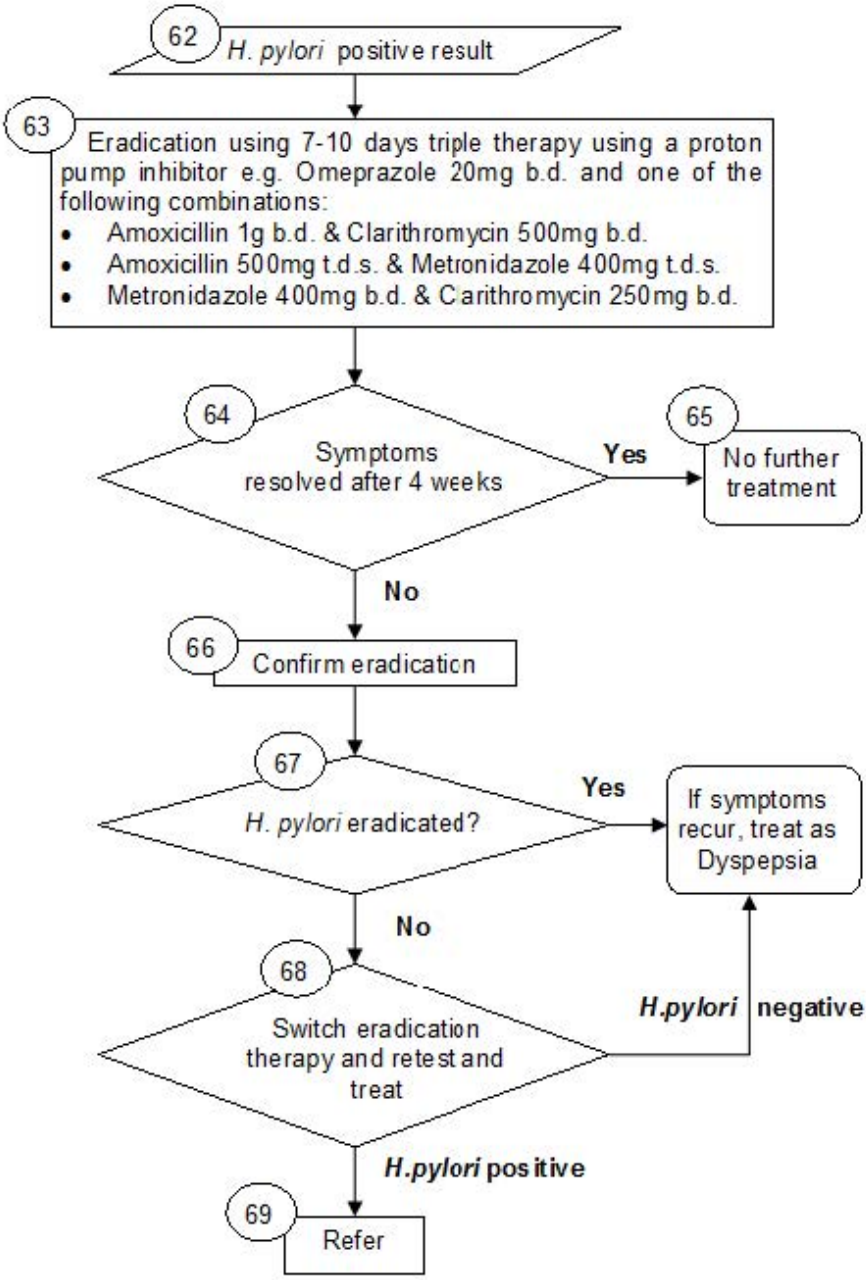
Heartburn and GORD Protocol



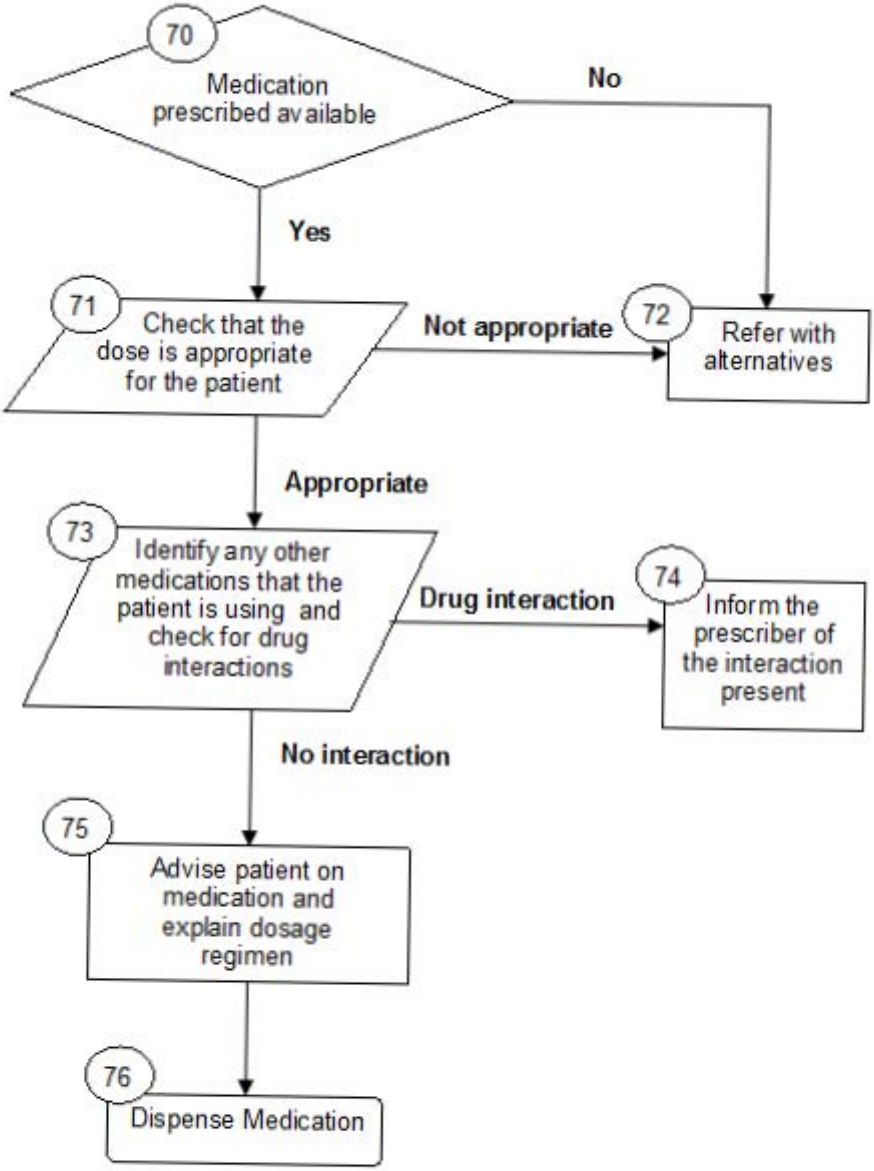
Peptic ulcer disease Protocol



H. pylori infection Protocol



Prescription and Dispensing Protocol



Appendix

Drug Interactions

Antacids	
Impair the absorption of	**ACEIs:** captopril, enalapril and fosinopril **Antibacterials:** azithromycin, cefaclor, cefpodoxime, ciprofloxacin, isoniazid, levofloxacin, moxifloxacin, norfloxacin, ofloxacin, rifampicin, tetracyclins, nalidixic acid. Magnesium salts reduce absorption of nitrofurantoin. **Antiepileptics:** gabapentin and phenytoin. **Antifungals:** itraconazole, ketoconazole. **Antihistamines:** fexofenadine. **Antimalarials:** chloroquine and hydroxychloroquine. Magnesium salts affect proguanil. **Antipsychotics:** phenothiazines and sulpiride. **Antivirals:** tipranavir **Bile Acids** **Bisphosphonates** **Cardiac glycosides:** digoxin **Corticosteroids:** deflazocort **Deferasirox:** absorption is reduced by aluminium containing antacids. **Dypiridamole** **Eltrombopag** **Iron:** oral magnesium salts reduce absorption of oral iron. **Lipid regulating Drugs:** rosuvastatin. **Mycophenolate** **Penicillamine** **Thyroid Hormones:** levothyroxine **Ulcer healing drugs:** lansoprazole **Ulipristal**
Reduce plasma concentrations of	**Antivirals:** atazanavir
Increases excretion of	**Analgesics:** alkaline urine due to some antacids increasing the excretion of aspirin. **Lithium:** increased by sodium bicarbonate

(British National Formulary, No. 61, March 2011)

Histamine H_2 - antagonists	
Inhibit metabolism and increasing plasma concentration	**Analgesics:** opioid analgesics **Anti-arrhythmics:** concentration of amiodarone, Propafenone, flecainide, and lidocaine affected by cimetidine. **Antibacterials:** erythromycin and metronidazole affected by cimetidine. **Antidepressants:** cimetidine effects citalopram, escitalopram, mirtazapine, sertraline, amitriptyline, boxepin, imipramine and nortriptyline, moclobemide (halve the dose) and tricyclics. **Antidiabetics:** cimetidine reduces excretion of metformin. **Antiepileptics:** carbamazepine, phenytoin and valproate effected by cimetidine. **Antifungals:** terbinafine concentration increased by cimetidine. **Antihistamines:** loratadine affected by cimetidine. **Antimalarials:** chloroquine, hydroxychloroquine and quinine affected by cimetidine. **Antivirals:** altegravir and saquinavir affected by cimetidine. **Anxiolytics and Hypnotics:** benzodiazepines, clomethiazole and zaleplon. Cimetidine effects concentration of melatonin. **Beta Blockers:** labetolol, metoprolol, and propranolol affected by cimetidine. **Calcium Channel Blockers:** cimetidine inhibits their metabolism. It also increases the plasma concentration if isradipine (halve the dose). **Ciclosporin:** plasma concentration increased by cimetidine. **Cilostrazol:** avoid concomitant use with cimetidine. **Cytotoxics:** cimetidine effects Fluorouracil. **$5HT_1$ angonists:** zolmitriptan inhibited by cimetidine (reduce dose) **Mebendazole** **Sildenafil:** plasma concentration increased with cimetidine. Reduce the dose. **Theopylline:** metabolism inhibited by cimetidine.

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Histamine H_2 – antagonists	
Enhance effect	**Antidiabetics:** sulphonylureas hypoglycaemic effect increased by sulphonylureas. **Antipsychotics:** chlorpromazine and clozapine affected by cimetidine. **Cytotoxics:** cimetidine affects carmustine and jomustine. **Ergot Alkaloids:** ergotamine and methysergide's ergotism increased by cimetidine.
Reduce plasma concentration	**Antifungals:** posaconazole **Antivirals:** atazanavir **Cytotoxics:** famotidine reduces plasma concentration of dasatinib. Ranitidine lower plasma concentration of Gefitinib **Ulipristal**
Accelerate metabolism	**Antibacterials:** rifampicin accelerates metabolism of cimetidine. **Anticoagulants:** coumarin metabolism inhibited by cimetidine.
Reduce absorption	**Antibacterials:** cefpodoxime **Antifungals:** itraconazole, ketoconazole **Cytotoxics:** laptinib **Hormone Antagonists:** octreotide absorption delayed. **Thyroid Hormones:** levothyroxine absorption reduced by cimetidine.
Reduce Effect	**Clopidogrel:** cimetidine reduces its antiplatelet effect.
Antagonise the effect	**Alpha-blockers:** tolazoline **Histamines**

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Proton Pump Inhibitors	
Enhance effect	**Anticoagulants:** coumarins **Antiepileptics:** phenytoin effects enhanced by esomeprazole.
Reduce plasma concentration	**Antidepressants:** omeprazole reduced by St. John's Wort. **Antifungals:** posaconazole **Antipsychotics:** clozapine concentration reduced by omeprazole. **Antivirals:** atazanavir, nelfinavir increased by omeprazole (avoid concomitant use). Tipranavir reduces concentration of omeprazole and esomeprazole. **Ulipristal** (avoid use with proton pump inhibitors)
Increased concentration	**Antibacterials:** clarithromycin and omeprazole concentration increases when both drugs given together. **Antidepressants:** escitalopram affected by omeprazole, lansoprazole concentration increased by fluvoxamine **Antifungals:** omeprazole and esomeprazole concentration increased by voriconazole (consider reducing dose) **Antivirals:** raltegravir, omeprazole increases saquinavir concentration **Anxiolytics and Hypnotics:** diazepam increased by esomeprazole and omeprazole **Cardiac Glycosides:** digoxin **Ciclosporin** **Cilostazol:** concentration increased by omeprazole and lansoprazole (avoid concomitant use) **Cytotoxics:** omeprazole reduces methotrexate excretion **Tacrolimus:** concentration increased by omeprazole
Reduce absorption	**Antacids:** absorption of lansoprazole reduced **Antifungals:** itraconazole, ketoconazole **cytotoxics:** lapatinib **Ulcer healing drugs:** lansoprazole absorption reduced by sucralfate
Reduce Effect	**Clopidogrel**

(British National Formulary, No. 61, March 2011)

Products available on the local market

Antacid and Alginate Preparations

Trade Name: Asilone Antacid liquid Oral Suspension
Manufacturer and Local Agent: Thornton and Ross Ltd., JBS Co. Limited
Active Ingredients: Light magnesium oxide 70mg/5ml, hydrated Aluminium oxide 420mg/5ml, activated dimethicone 135mg/5ml
Dosage Regimen: Adults, elderly and children over 12 years of age: 5 to 10ml after meals and at bedtime up to four times daily.

Trade Name: Asilone Antacid Tablets
Manufacturer and Local Agent: Thornton and Ross Ltd., JBS Co. Limited
Active Ingredients: Activated dimethicone 270mg, aluminium hydroxide 500mg
Dosage Regimen: One or two tablets before meals and at bedtime, or when required.

Trade Name: Gaviscon Advance Oral suspension Peppermint and Aniseed Flavour
Manufacturer and Local Agent: Reckitt Benckiser, Charles de Giorgio Ltd.
Active Ingredients: Sodium alginate 1000mg/10ml, potassium bicarbonate 200mg/10ml.
Dosage Regimen: Adults and Children over 12 years of age: 5 to 10 ml after meals and at bedtime.

Trade Name: Gaviscon Advance tablets
Manufacturer and Local Agent: Reckitt Benckiser, Charles de Giorgio Ltd.
Active Ingredients: Sodium alginate 500 mg, potassium bicarbonate 100 mg.
Dosage Regimen: Adults and children 12 years and over: One to two tablets after meals and at bedtime.

Trade Name: Gaviscon Liquid Peppermint
Manufacturer and Local Agent: Reckitt Benckiser, Charles de Giorgio Ltd.
Active Ingredients: Sodium alginate 250mg, sodium bicarbonate 133.5mg, calcium carbonate 80mg in 5ml
Dosage Regimen: Adults and children over 12 years: 10-20 ml (two to four 5 ml spoonfuls) after meals and before retiring. Children 6-12 years: 5-10 ml (one to two 5 ml spoonfuls) after meals and before retiring.

Trade Name: Maalox® Plus® Chewable tablets
Manufacturer and Local Agent: Aventis Pharma SpA, Charles de Giorgio Ltd.
Active Ingredients: Dried aluminium hydroxide 200mg, magnesium hydroxide 200mg, simethicone 25mg
Dosage Regimen: One or two tablets four times a day, 20-60 minutes before meals or at bedtime or as required.

Trade Name: Maalox® Plus® Oral suspension
Manufacturer and Local Agent: Aventis Pharma SpA, Charles de Giorgio Ltd.
Active Ingredients: Aluminium hydroxide 225mg/5ml, magnesium hydroxide 200mg/5ml, simeticone 25mg/5ml
Dosage Regimen: One or two 5ml spoonfuls (up to 16 spoonfuls) 20-60 minutes before meals or at bedtime.

Trade Name: Magnesia San Pellegrino® Powder for oral suspension (Anise Flavour)
Manufacturer and Local Agent: Actipharm S.A., Aldox Ltd.
Active Ingredient: Magnesium hydroxide 63g per 70g
Dosage Regimen: Adults: ¼ to ½ spoonfuls in half a glass of water, after meals or when symptoms occur. (Patient to use the spoon provided)

Trade Name: Magnesia San Pellegrino® Effervescent powder for oral suspension (Lemon Flavour)
Manufacturer and Local Agent: Actipharm S.A., Aldox Ltd.
Active Ingredients: Magnesium hydroxide 56.25g per 125g
Dosage Regimen: Adults: ½ to 1 spoonful in half a glass of water or when the symptoms occur. (Patient to use the spoon provided).

Trade Name: Phillips Milk of Magnesia Oral suspension
Manufacturer and Local Agent: GlaxoSmithKline, Alfred Gera & Sons Ltd.
Active Ingredients: Magnesium hydroxide 415mg per 5ml
Dosage Regimen: Adults: one to two 5ml spoonfuls, repeat as necessary to a maximum of twelve 5ml doses a day.
Children: one 5ml spoonful up to 6 times a day

Trade Name: Rennie® Fruit Tablets
Manufacturer and Local Agent: Bayer HealthCare, Alfred Gera & Sons Ltd.
Active Ingredients: Calcium carbonate 500mg
Dosage Regimen: Adults and children over 12: one or two tablets to be sucked or chewed as required up to a maximum of 16 tablets a day.

Trade Name: Rennie® Peppermint Chewable tablets
Manufacturer and Local Agent: Bayer HealthCare, Alfred Gera & Sons Ltd.
Active Ingredients: Calcium carbonate 680mg; heavy magnesium carbonate 80mg
Dosage Regimen: Adults: 2 tablets to be sucked or chewed up to a maximum of 16 tablets a day. Children from 6 to 12 years: 1 tablet as required, up to 8 tablets a day.

Trade Name: Rennie® Dual Action Liquid Oral suspension
Manufacturer and Local Agent: Bayer HealthCare, Alfred Gera & Sons Ltd.
Active Ingredients: Calcium carbonate 600mg, magnesium carbonate 70mg, sodium alginate 150mg
Dosage Regimen: Adults and children over 12: two 5ml spoonfuls, preferably 1 hour after meals and before bedtime. Not more than 8 doses per day.

Trade Name: Rennie® Dual Action Chewable Tablets
Manufacturer and Local Agent: Bayer HealthCare, Alfred Gera & Sons Ltd.
Active Ingredients: Alginic acid 150mg, calcium carbonate 625mg, heavy magnesium carbonate 73.50mg.
Dosage Regimen: Adults and children over 12: two tablets after meals and before bedtime. Not exceeding 12 tablets a day.

Trade Name: Rennie® Deflatine® Chewable tablets
Manufacturer and Local Agent: Bayer HealthCare, Alfred Gera & Sons Ltd.
Active Ingredients: Calcium carbonate 680mg; heavy magnesium carbonate 80mg; simethicone 25mg
Dosage Regimen: Adults and children over 12: one or two tablets to be sucked or chewed as required up to a maximum of 16 tablets a day.

H_2-receptor Antagonists

Active Ingredient: Cimetidine
Dosage Regimen: 400mg twice daily (at breakfast and at night) or 800mg at night for at least 4 weeks. For 6 weeks in gastric ulceration and 8 weeks in NSAID associated ulceration. This may be increased to 400 mg, four times daily. For reflux oesophagitis: 400mg four times daily for 4 to 8 weeks.
Prophylaxis of stress ulceration 200-400mg every 4 to 6 hours
Trade Names (Manufacturer and Local Agent): Timet 200, Timet 400 tablets. (Aegis Ltd. Charles de Giorgio Ltd.)

Active Ingredient: Ranitidine
Dosage Regimen: Adults and children over 12 years of age:
In ulceration: 150 mg twice daily or 300mg at night for 4 to 8 weeks.
In chronic dyspepsia: 150 mg twice daily or 300mg at night for up to 6 weeks, and 8 weeks in NSAID associated ulcer.
For NSAID ulcer prophylaxis: 300mg twice daily.
In GORD: 150mg twice daily or 300 mg at night for up to 8 weeks, 12 weeks in severe cases.
Trade Names (Manufacturer and Local Agent**):**
Asyran film coated tablets (150mg, 300mg) (Actavis, VJ Salomone Pharma Ltd.)
Zantac™ film coated tablets (75mg)
Zantac® Tablet (150mg, 300mg)
Zantac® Syrup (15 mg per ml) (GlaxoSmithKline, Alfred Gera & Sons Ltd.)

Proton Pump Inhibitors

Active Ingredient: Esomeprazole
Dosage Regimen: NSAID associated ulcer: adults over 18: 20mg once daily for 4 to 8 weeks, for prophylaxis in continued NSAID treatment: 20mg daily.
GORD in adults and children over 12: 40mg once daily for 4 weeks, for a further 4 weeks if not healed. Symptomatic treatment: 20mg once daily for 4 weeks, then 20mg daily when required.
Trade Names (Manufacturer and Local Agent):
Nexium® Gastro-resistant tablets (20mg, 40mg)
Nexium® Gastro-resistant granules for oral suspension (10mg)
(AstraZeneca, Associated Drug Co. Ltd)

Active Ingredient: Lansoprazole
Dosage Regimen: Gastric ulcer: 30mg daily in the morning. for 8 weeks
Duodenal ulcer: 30 mg in the morning for 4 weeks, maintenance dose 15 mg daily.
NSAID associated ulcer: 30mg once daily for 4 weeks, for a further 4 weeks if not fully healed. Prophylaxis: 15-30 mg once daily.
GORD: 30mg daily in the morning for 4 weeks, continued for a further 4 weeks if not healed. Maintenance dose: 15-30 mg daily.
Dyspepsia: 15-30mg daily for 2 to 4 weeks.
Trade Names (Manufacturer and Local Agent):
Lasoprol capsules (15mg, 30mg) (Aegis Ltd, Charles de Giorgio Ltd.)

Active Ingredient: Omeprazole
Dosage Regimen: For Peptic ulcers: 20mg once daily for 4 weeks in duodenal ulcer, and 8 weeks in gastric ulcers. In severe recurrent cases may be increased to 40 mg, with a maintenance dose of 20mg once daily.

In NSAID associated ulcers 20mg once daily for 4 weeks, continued for another 4 weeks if not fully healed. For prophylaxis: 20mg once daily.
For GORD: 20mg once daily for 4 weeks, continued for a further 4-8 weeks if not fully healed. Maintenance dose 20 mg once daily.
For dyspepsia: 10-20mg once daily for 2-4 weeks.

Trade Names (Manufacturer and Local Agent):
Gasec ™ capsules 20mg (Mepha LDA, Pharma.MT)
Medoprazole® capsules 20mg (Medochemie Ltd, Europharma Ltd.)
Lomex T Gastro-resistant tablets 20mg (Actavis, VJ Salomone Pharma Ltd.)
Losec® MUPS® 10mg, 20mg (AstraZeneca, Associated Drug Co. Ltd)
Ulcesep capsules 20mg (Especialidades Farmaceuticas Centrium SA, Ultra pharma Ltd.)

Active Ingredient: Pantoprazole
Dosage Regimen: Gastric ulcer: adults over 18: 40mg daily in the morning for 4 weeks.
Duodenal ulcer: adults over 18: 40mg daily in the morning for 2 weeks, for a further 2 weeks if not fully healed.
NSAID associated ulcer prophylaxis: Adults over 18: 20 mg daily.
GORD: Adults and children over 12: 20-40mg am for 4 weeks, further 4 weeks if not healed. Maintenance dose: 20-40mg.
Trade Names (Manufacturer and Local Agent):
Panrazol Gastro-resistant tablets (20mg, 40mg) (Actavis, VJ Salomone Pharma Ltd.)

Active Ingredient: Rabeprazole
Dosage Regimen: Gastric ulcer: 20mg daily in the morning for 6 weeks. For a further 6 weeks if ulcer is not fully healed.
Duodenal ulcer: 20mg daily in the morning for 4 weeks, continued for a further 4 weeks if not fully healed.
GORD: 20 mg once daily for 4-8 weeks, maintenance dose of 10-20mg daily. Symptomatic treatment in the absence of oesophagitis: 10mg daily
Trade Names (Manufacturer and Local Agent):
Pariet Gastro-resistant tablets (Janssen-Cilag, A.M Mangion Ltd.)

References

Azzopardi LM. Lecture notes in Pharmacy Practice. London: Pharmaceutical Press; 2010: 86-91.

Blenkinsopp A, Blenkinsopp J, Paxton P. Symptoms in the Pharmacy. A Guide to the Management of Common Illness. Oxford: Blackwell Science Ltd; 2005: 72 - 90

British Medical Association. The Royal Pharmaceutical Society of Great Britain. British National Formulary, Number 61. 2011.

Dzieniszewski J, Jarosz M. Guidelines in the Medical Treatment of *Helicobacter Pylori* Infection. J Physiol Pharmacol 2006; 57(3), 143-153.

Ellul S. Treatment Protocols for Disorders of the Gastro-Intestinal Tract [dissertation]. Msida (Malta): University of Malta.; 2009.

Greene RJ, Harris ND. Pathology and Therapeutics for Pharmacists. A Basis for clinical Pharmacy Practice. London: Pharmaceutical Press; 2008: 82-107.

Institute for Clinical Systems Improvement. Health Care Guideline: Initial Management of Dyspepsia and GERD. 2006.
URL: **http://www.icsi.org/dyspepsia_gerd/dyspepsia__9.html**

Medicines Authority Marketing Authorisations Issued – Revision 45 – 24/03/2010. Available at: URL: **http://medicinesauthority.gov.mt/pub/MA%20List.pdf** Accessed 4th November 2010.

National Institute for Clinical Excellence. Dyspepsia Management of dyspepsia in adults in primary care. Available from:
URL: **www.nice.org.uk/CG017NICEguideline**

New Zealand Guidelines Group. Management of Dyspepsia and Heartburn. Evidence-based Best Practice Guideline Summary June 2004. Available from:
URL: **http://www.nzgg.org.nz/guidelines/0077/Dyspepsia_Summary.pdf**

Scottish Intercollegiate Guidelines Network. Dyspepsia Guideline No. 68 Available from:
URL: **http://www.sign.ac.uk/pdf/sign68.pdf**

Veldhuyzen Van Zenten S.J.O., Flook N, Chiba N, Armstrong D, Barkun A, Bradette M *et al.* An evidence-based approach to the management of uninvestigated dyspepsia in the era of *Helicobacter pylori.* CMAJ 2000; 162 (12 Suppl)

Maalox Plus®

- Heartburn
- Indigestion
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- Dyspepsia

Maalox Plus® is used in the treatment of heartburn and eases the discomfort caused by trapped wind. It is a balanced mixture of two antacids and an antiflatulent/antifoaming agent simethicone.
The two antacids are magnesium hydroxide which is fast acting and aluminium hydroxide which is a slow acting antacid. Simethicone reduces gastroesophageal reflux.[1]

For further information please contact your doctor or pharmacist

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