Introduction:

This document summarizes evidence from available Indian and International guidelines/ published reviews in clinical journals and medical books. It aids physicians and other caregivers in making appropriate diagnostic and therapeutic decisions in an outpatient setting. It provides a framework for managing patients with particular symptom or condition. It covers diagnosis, clinical assessment, alarm features, clinical management, and investigations at outpatient level and referral management to inpatient facility/ hospital.

Scope and objective:

- To provide evidence backed recommendations for the identification and care of people with dyspepsia at outpatient clinic.
- To give physicians a practical approach and guide to the care of patients with dyspepsia
- To develop a tool that can be used with medical documentation and therefore promote compliance with best practice to standardize clinical care for patients with dyspepsia in an outpatient setting.

Target population:

Adult population with new onset of symptoms of dyspepsia.

Target Users:

- General Physicians
- Nurses
- Other health care professional
- Outpatient Clinics

The clinical protocol cover critical elements of patient care from patient's first visit to a physician, outpatient management, through to follow up and referral to inpatient facility/ hospital. The Clinical team can refer to these protocols and bibliography for detailed information.

Exclusions:

Person suffering from known underlying pathology have been excluded from the scope of this tool.

Disclaimer:

The clinical protocol are designed to be used by medical professionals licensed to practice in India as a guide and are not intended to substitute for informed medical decisions or judgment by a licensed medical professional.

Milliman

Dyspepsia: Outpatient Care Protocol

1. Introduction/definition *J1, J3, J4,B1,B2*

Dyspepsia often called indigestion is a chronic or recurrent pain or an uncomfortable feeling in the upper middle part of the abdomen. It refers to a group of upper gastrointestinal symptoms such as belching, bloating, nausea or heartburn that may be intermittent or persistent.

2. General presentation *J1,J2, J4, J5, B1,B2*

Symptoms of dyspepsia are commonly present in patients with Gastro intestinal reflux disease (GERD), peptic ulcer disease (PUD) and gastric or esophageal dysmotility disorders. A person with dyspepsia may present at the outpatient clinic with the following:

- Pain or discomfort in the upper middle part of the abdomen
- Feeling of uncomfortable fullness soon after eating, nausea, vomiting, bloating, belching, flatulence and symptoms that are worsened by food.
- Reflux-like symptoms which consist of heartburn or acid regurgitation

3. Alarm features *J1,J2, J3,J4, J5, J6,B1*

Uncomplicated dyspepsia can be managed at outpatient clinic by providing symptomatic treatment. However, dyspepsia associated with alarm features should be immediately referred to hospital for prompt treatment. The alarm features are:

- Age >55 or children under 10 years with new onset symptoms
- Gastrointestinal bleeding(blood in vomiting and stools)
- Unexplained weight loss (>3kg)
- Progressive dysphagia or persistent painful swallowing
- Persistent vomiting
- Signs of anemia (Pallor)
- Palpable mass or lymphadenopathy
- Jaundice

4. Clinical diagnosis:

The evaluation of dyspepsia at an outpatient clinic requires a careful review of medical history, a physical examination and diagnostic testing to determine the underlying cause of the disease which is beneficial for further management.

4.1. History *J4, J5,J6,B1*

Physician should include history of following parameters in clinical diagnosis to determine underlying pathology and rule out other causes.

Note: *Premorbid conditions should be considered in assessing the status of person*

- **Ask for:**

- Time of onset and duration of symptoms
- Timing and frequency of recurrence if any
- GI symptoms such as anorexia, nausea, vomiting, weight loss, and blood in vomitus and stool
- Relationship of symptoms to eating or taking medications
- Any difficulty swallowing
- Any weight loss (>3kgs)
- Any loss of appetite
- History of medications as they may be the cause of dyspepsia, for example calcium antagonists, nitrates, theophyllines, bisphosphonates, corticosteroids and NSAIDS
- Factors that worsen symptoms (particularly exertion, certain foods or alcohol) or relieve them (particularly eating or taking antacids)
- Any changes in bowel movement
- Any addiction to smoking or alcohol
- Personal history of known GI and cardiac diseases, diabetes, thyroid disorders, cardiac risk factors (e.g., hypertension, hypercholesterolemia), and any surgery performed.
- Family history of psychiatric or psychosocial disorders, upper-GI malignancy.
- Any anxiety, depression, or stress

Note:

- *A patient presenting with a single, acute episode of dyspepsia is of concern, particularly if symptoms are accompanied by dyspnea, diaphoresis, or tachycardia; such patients may have acute coronary ischemia. Chronic symptoms that occur with exertion and are relieved by rest may represent angina.*
- *Obesity, smoking, alcohol, coffee and chocolate may cause transient lower esophageal sphincter relaxations, while fatty foods may delay gastric emptying. Lying flat may increase reflux episodes.*

4.2. Physical examination *J2,J3,J4,J5, B1*

A careful physical examination should be performed by the physician and observe the person for any warning signs. It is helpful in establishing diagnosis and management thereon.

- **Check for:**

  - Vital Signs such as temperature, pulse, respiratory rate and blood pressure
  - Signs of anemia (brittle nails, cheilosis and pallor of the palpebral mucosa or nail beds)
  - Lymphadenopathy
  - Diaphoresis, cachexia
  - Gall bladder disease as suggested by positive murphy's sign
  - Abdomen is palpated for tenderness, masses, and organomegaly.
  - Gross or occult blood by doing a rectal examination in those with complaints of rectal bleeding.

5. Investigations *J2,J3, J4,J5,J6, B1*

Investigations are not routinely done but may be required to help determine the underlying pathology/cause of dyspepsia for appropriate treatment.

5.1. Routine investigations

- Complete Blood Count (CBC)
- ECG
- Serum electrolytes
- Liver function tests
- Serum lipase and amylase levels

5.1.1. Indications for routine investigations

- CBC is done to rule out anemia
- ECG is done to rule out cardiac causes
- Serum electrolytes is done to rule out electrolyte imbalances in cases exhibiting nausea, vomiting and epigastric fullness
- Liver function tests and ultrasound upper GI is done to rule out the presence of gallstones or any other hepatobiliary condition
- Serum lipase and amylase levels is done to rule out suspected pancreatitis

Note: *In presence of alarm features or associated conditions, additional investigations may be done.*

5.2. Additional investigations

- Upper GI endoscopy
- Serology test
- Upper GI Ultrasound / CT abdomen

5.2.1. Indications for additional investigations

- Upper GI endoscopy to rule out other possible causes for dyspepsia such as a peptic ulcer, reflux esophagitis, or cancer (rare). It is warranted in those with alarm features or in those older than 55years.
- Serology test to identify presence of H. Pylori
  Note: *Serology test can be done to rule out presence of H. pylori but is not recommended as it does not provide accurate results at times.*
- Upper GI Ultrasound / CT abdomen are indicated only if pancreatic or biliary disease is suspected.

6. Differential Diagnosis *J1,J2,J3 J4, J5,B1*

Physician should rule out other causes /conditions which are responsible for dyspepsia:

- Peptic ulcer disease (ulcer like dyspepsia, family history of ulcers, a history of nonsteroidal anti-inflammatory drug (NSAID) use and current cigarette smoking)
- Gastroesophageal reflux disease (reflux like dyspepsia exhibited by heartburn and regurgitation, sharp, stabbing substernal pain)
- Hiatus hernia (acid reflux, complaints of chest pain, upper endoscopy is confirmatory)
- Biliary tract disease (often asymptomatic but if pain occurs, it is episodic and severe, and may last for hours. Unlike the pain associated with peptic ulcers, the pain in gall bladder disease tends

to occur after eating, especially after the consumption of a large fatty meal. Dark urine may be present)

- Gastro paresis (dysmotility-like dyspepsia, or gastro paresis, is associated with symptoms of bloating, abdominal distention, flatulence and prominent nausea, person feels hungry but have premature satiety with resultant epigastric heaviness or fullness even after the consumption of small meals, common in diabetic cases)
- Irritable bowel disease (generally associated with abnormal bowel habits, fever, loss of appetite)
- Pancreatitis (pain, nausea ,vomiting, abdominal tenderness)
- Malabsorption disorders (nausea, vomiting, diarrhea, bloating, excessive flatus, and abdominal cramps)
- Metabolic disturbances (chest pain, palpitations, headache, altered mental status, muscle weakness)
- Intestinal parasites (diarrhea, bloating, teeth grinding, anemia, joint and muscle aches, allergies)
- Malignancy (symptoms of gastric cancer are similar to those of other causes of epigastric pain. However, the presence of "alarm symptoms," such as dysphagia, unexplained weight loss (greater than 3 kg, history of gastrointestinal bleeding or clinical signs of anemia, may help to identify patients with more serious disease. Patients with gastric cancer also tend to be older and to have a shorter presenting history; they complain of continuous pain exacerbated by food and usually have associated anorexia)
- Medication induced dyspepsia(calcium antagonists, nitrates, theophyllines, bisphosphonates, steroids and NSAIDs)

7. Management of dyspepsia *J1,J2,J3, J4,J5,J6,B1*

7.1. Principles of management

- Drug therapy
- Lifestyle modifications
- Behavioral therapy
- Referral management if condition worsens or in presence of alarm features.

7.1.1. Drug therapy

Antacids, H_2 blockers and proton pump inhibitors may be used as first line of treatment for symptomatic relief of pain due to dyspepsia in patients below 55years of age and without any alarm features.

Note:

- *The current treatment of choice for patients with ulcer like and reflux like symptoms is a combination of PPI with amoxicillin and clarithromycin administered for 7–10 days.*
- *Metronidazole may be substituted for amoxicillin in this regimen if the patient is allergic to penicillin. An alternative strategy is the combination of Bismuth, metronidazole, and tetracycline combined with a PPI for 14 days.*
- *Propkinetics are used for dyspepsia with dysmotility like symptoms.*

- Histamine-2 Receptor Antagonists (Acid Blockers): Drugs such as ranitidine, cimetidine, and famotidine suppress acid production.
- Proton Pump Inhibitors (PPIs): These drugs are used to block acid secretion, include omeprazole and lansoprazole.

- Mucosal-protecting agents: Drugs such as sucralfate and bismuth subsalicyclate help protect the lining of the stomach and small intestine. Bismuth subsalicyclate is generally only used in combination with H. pylori eradication therapy.
- Antibiotics to treat Helicobacter pylori (H. pylori) infection: Patients who do not have peptic ulcers may still test positive for H. pylori. Eradicating the bacteria appears to help reduce dyspepsia symptoms in some patients and usually involves a combination of Proton pump inhibitors with antibiotics such as metronidazole (400mg) and clarithromycin (250mg) or amoxicillin (1gm) and clarithromycin (500mg). These are usually available as a kit.
- Other medications may be prescribed for individuals with other medical problems that influence the symptoms of indigestion.

Indications, contraindications and dosage of drug therapy

Table 8. Drug Therapy				
Indication	**Therapeutic class**	**Drug name (generic)**	**Dosage**	**Contraindications**
Symptomatic relief of pain in gastro esophageal reflux disease (GERD)	Antacids	Aluminium hydroxide Or Magnesium hydroxide Or sodium bicarbonate http://www.mims.com/Page.aspx?menuid=mng&name=aluminium+hydroxide&brief=false&CTRY=IN#Dosage	10 – 15mg 2 to 3 times a day in Adults, maintenance dose is 150mg at bedtime for 4-6 weeks Administration: May be taken with or without food. Food interaction: Food decreases gastric emptying time.	Contraindicated in patients with CHF and hypertension; Hypersensitivity to aluminium salts. Caution when used during pregnancy and lactation
Deodenal ulcer, peptic ulcer, GERD	H_2 blockers	Ranitidine Or Famotidine http://www.mims.com/Page.aspx?menuid=mng&name=ranitidine&brief=false&CTRY=IN#Dosage	***Adult:*** 150 mg repeated if necessary up to 4 doses daily. Max: 2 week of continuous use at each time. For chronic episodic dyspepsia: 150 mg bid for up to 6 week. Administration: May be taken with or without food.	Contraindicated in known hypersensitivity ; porphyria Caution when used during pregnancy and lactation
Peptic ulcer disease, Zollinger Elisson syndrome, drug induced gastritis and GERD	Proton pump inhibitors	Omeprazole Or Lansoprazole http://www.mims.com/Page.aspx?menuid=mng&name=omeprazole&brief=true&CTRY=IN&searchstring=omeprazole	10 or 20 mg daily for 2-4 weeks. Administration: Tablet: May be taken with or without food. Powdered for oral suspension: Should be	Contraindicated in known hypersensitivity

			taken on an empty stomach (i.e. At least one hour before food or two hours after food). Cap: Should be taken with food. (Take immediately before a meal.)	
Helicobacter pylori (H. pylori) infection and peptic ulcer	Antibiotics	Metronidazole and clarithromycin or Amoxicillin http://www.mims.com/Page.aspx?menuid=mng&name=metronidazole&brief=false&CTRY=IN#Dosage or clarithromycin + amoxicillin + omeprazole kit or omeprazole + clarithromycin + tinidazole kit	Metronidazole 400mg and 250mg clarithromycin twice daily for 7 days or Amoxicillin 1gm and Clarithromycin 500mg twice daily for 7 days Or 1 kit daily for 14 days	History of hypersensitivity to metronidazole or other nitroimidazole derivatives. Pregnancy (1st trimester) and lactation.
Duodenal and gastric ulcers, chronic gastritis	Mucosal-protecting agents	Sucralfate http://www.mims.com/Page.aspx?menuid=mng&name=sucralfate&brief=true&CTRY=IN&searchstring=Sucralfate	1g 4 times daily before meals for 4-8 weeks upto 12 weeks if needed. Maintenance: 1 g twice daily to prevent the recurrence of duodenal ulcers. Max: 8 g/day. Administration: Should be taken on an empty stomach. (Take on an empty stomach 1 hr before or 2 hr after meals.)	Contraindicated in severe renal impairment and hypersensitivity . Caution when used during pregnancy and lactation.

7.1.1.1 Adverse reactions:

Table 3. Adverse reactions of drug therapy in Dyspepsia

Drug	Adverse reactions
Aluminium hydroxide	constipation
Ranitidine	Headache, dizziness
Omeprazole	Diarrhea, nausea, fatigue, constipation, vomiting, flatulence, acid regurgitation
Metronidazole	GI disturbances e.g. nausea, unpleasant metallic taste, vomiting, diarrhoea or constipation

Sucralfate	Constipation, diarrhea, nausea, dizziness, dry mouth.
H. Pylori drugs	Nausea, vomiting, loose stools, fatigue, abdominal cramps, headache and dizziness.

7.1.2. Lifestyle Modifications

Physician should encourage lifestyle modifications that may be required to reduce symptoms. These include:

- Improving diet (lowering intake of fats), avoiding foods that trigger symptoms of dyspepsia such as spicy or oily food, gas forming foods such as cabbage, cauliflower, raddish, chick peas, kidney beans etc
- Avoiding factors that make indigestion worse, such as eating large meals, especially heavy or greasy foods, eating late at night, eating quickly or eating before exercise
- Not lying down immediately after a meal for 2-3 hours
- Adopting measure to decrease stress and fatigue
- Stopping smoking
- Avoiding alcohol, if it produces symptoms of dyspepsia
- Maintaining a healthy weight helps to reduce symptoms of dyspepsia
- Exercising regularly (at least 30 minutes of moderate to vigorous physical activity on most days of the week) to reduce stress, control weight, and improve well-being, all of which may ease dyspepsia

7.1.3. Behavioral therapy

Some patients may need assistance from a physician and family members to respond better to psychological or social factors or to change a behavior, such as swallowing air while eating (aerophagia) that is a common cause for dyspepsia.

7.1.4. Referral management

In the presence of any one of the alarm features mentioned in the previous section referral management should be initiated. Depending on the condition of the patient supportive management should be started. Children below 10 years with sign and symptoms of dyspepsia should be immediately referred to a pediatrician.

8. Follow up:

- Educate the patient to immediately return to the physician if “Alarm signs” appear. (*Refer to patient advisory).*
- Inform about the next timely follow up visit.

9. Quality indicators

The quality indicators that are important in documenting the adherence to policy in the management of dyspepsia are:

- Referral management for alarm features

- Referral of children with signs and symptoms of dyspepsia to pediatrician
- Antibiotics started after H. Pylori detection in stool
- Lifestyle and behavioral changes advice given
- Education given

10. Patient advice:

Patient education must be reinforced about the disease, its causes, alarm features, prevention, treatment, lifestyle changes and when to seek help.

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