

Rome III
Diagnostic
Criteria for
Functional
Gastrointestinal
Disorders

A. Functional Esophageal Disorders

A1. Functional Heartburn

*Diagnostic criteria** Must include **all** of the following:

1. Burning retrosternal discomfort or pain
2. Absence of evidence that gastroesophageal acid reflux is the cause of the symptom
3. Absence of histopathology-based esophageal motility disorders

* Criteria fulfilled for the last 3 months with symptom onset at least 6 months prior to diagnosis

A2. Functional Chest Pain of Presumed Esophageal Origin

*Diagnostic criteria** Must include **all** of the following:

1. Midline chest pain or discomfort that is not of burning quality
2. Absence of evidence that gastroesophageal reflux is the cause of the symptom
3. Absence of histopathology-based esophageal motility disorders

* Criteria fulfilled for the last 3 months with symptom onset at least 6 months prior to diagnosis

A3. Functional Dysphagia

*Diagnostic criteria** Must include **all** of the following:

1. Sense of solid and/or liquid foods sticking, lodging, or passing abnormally through the esophagus
2. Absence of evidence that gastroesophageal reflux is the cause of the symptom
3. Absence of histopathology-based esophageal motility disorders

* Criteria fulfilled for the last 3 months with symptom onset at least 6 months prior to diagnosis

A4. Globus

*Diagnostic criteria** Must include **all** of the following:

1. Persistent or intermittent, nonpainful sensation of a lump or foreign body in the throat
2. Occurrence of the sensation between meals
3. Absence of dysphagia or odynophagia
4. Absence of evidence that gastroesophageal reflux is the cause of the symptom
5. Absence of histopathology-based esophageal motility disorders

* Criteria fulfilled for the last 3 months with symptom onset at least 6 months prior to diagnosis

B. Functional Gastrointestinal Disorders

BI. FUNCTIONAL DYSPEPSIA

*Diagnostic criteria** Must include:

1. One or more of the following:
 - a. Bothersome postprandial fullness
 - b. Early satiation
 - c. Epigastric pain
 - d. Epigastric burning

AND

2. No evidence of structural disease (including at upper endoscopy) that is likely to explain the symptoms

* Criteria fulfilled for the last 3 months with symptom onset at least 6 months prior to diagnosis

BIa. Postprandial Distress Syndrome

*Diagnostic criteria** Must include **one or both** of the following:

1. Bothersome postprandial fullness, occurring after ordinary-sized meals, at least several times per week
2. Early satiation that prevents finishing a regular meal, at least several times per week

* Criteria fulfilled for the last 3 months with symptom onset at least 6 months prior to diagnosis

Supportive criteria

1. Upper abdominal bloating or postprandial nausea or excessive belching can be present
2. Epigastric pain syndrome may coexist

BIb. Epigastric Pain Syndrome

*Diagnostic criteria** Must include **all** of the following:

1. Pain or burning localized to the epigastrium of at least moderate severity, at least once per week
2. The pain is intermittent
3. Not generalized or localized to other abdominal or chest regions
4. Not relieved by defecation or passage of flatus
5. Not fulfilling criteria for gallbladder and sphincter of Oddi disorders

* Criteria fulfilled for the last 3 months with symptom onset at least 6 months prior to diagnosis

Supportive criteria

1. The pain may be of a burning quality, but without a retrosternal component
2. The pain is commonly induced or relieved by ingestion of a meal, but may occur while fasting
3. Postprandial distress syndrome may coexist

B2. BELCHING DISORDERS

B2a. Aerophagia

*Diagnostic criteria** Must include **all** of the following:

1. Troublesome repetitive belching at least several times a week
2. Air swallowing that is objectively observed or measured

* Criteria fulfilled for the last 3 months with symptom onset at least 6 months prior to diagnosis

B2b. Unspecified Excessive Belching

*Diagnostic criteria** Must include **all** of the following:

1. Troublesome repetitive belching at least several times a week
2. No evidence that excessive air swallowing underlies the symptom

* Criteria fulfilled for the last 3 months with symptom onset at least 6 months prior to diagnosis

B3. NAUSEA AND VOMITING DISORDERS

B3a. Chronic Idiopathic Nausea

*Diagnostic criteria** Must include **all** of the following:

1. Bothersome nausea occurring at least several times per week
2. Not usually associated with vomiting
3. Absence of abnormalities at upper endoscopy or metabolic disease that explains the nausea

* Criteria fulfilled for the last 3 months with symptom onset at least 6 months prior to diagnosis

B3b. Functional Vomiting

*Diagnostic criteria** Must include **all** of the following:

1. On average one or more episodes of vomiting per week
2. Absence of criteria for an eating disorder, rumination, or major psychiatric disease according to DSM-IV
3. Absence of self-induced vomiting and chronic cannabinoid use and absence of abnormalities in the central nervous system or metabolic diseases to explain the recurrent vomiting

* Criteria fulfilled for the last 3 months with symptom onset at least 6 months prior to diagnosis

B3c. Cyclic Vomiting Syndrome

Diagnostic criteria Must include **all** of the following:

1. Stereotypical episodes of vomiting regarding onset (acute) and duration (less than one week)
2. Three or more discrete episodes in the prior year
3. Absence of nausea and vomiting between episodes

Supportive criterion

History or family history of migraine headaches

B4. Rumination Syndrome in Adults

Diagnostic criteria Must include **both** of the following:

1. Persistent or recurrent regurgitation of recently ingested food into the mouth with subsequent spitting or remastication and swallowing
2. Regurgitation is not preceded by retching

Supportive criteria

1. Regurgitation events are usually not preceded by nausea
2. Cessation of the process when the regurgitated material becomes acidic
3. Regurgitant contains recognizable food with a pleasant taste

C. Functional Bowel Disorders

C1. Irritable Bowel Syndrome

*Diagnostic criterion**

Recurrent abdominal pain or discomfort** at least 3 days/month in the last 3 months associated with *two or more* of the following:

1. Improvement with defecation
2. Onset associated with a change in frequency of stool
3. Onset associated with a change in form (appearance) of stool

* Criterion fulfilled for the last 3 months with symptom onset at least 6 months prior to diagnosis

** “Discomfort” means an uncomfortable sensation not described as pain.

In pathophysiology research and clinical trials, a pain/discomfort frequency of at least 2 days a week during screening evaluation is recommended for subject eligibility.

C2. Functional Bloating

*Diagnostic criteria** Must include **both** of the following:

1. Recurrent feeling of bloating or visible distension at least 3 days/month in the last 3 months
2. Insufficient criteria for a diagnosis of functional dyspepsia, irritable bowel syndrome, or other functional GI disorder

* Criteria fulfilled for the last 3 months with symptom onset at least 6 months prior to diagnosis

C3. Functional Constipation

*Diagnostic criteria**

1. Must include *two or more* of the following:
 - a. Straining during at least 25% of defecations
 - b. Lumpy or hard stools in at least 25% of defecations
 - c. Sensation of incomplete evacuation for at least 25% of defecations
 - d. Sensation of anorectal obstruction/blockage for at least 25% of defecations
 - e. Manual maneuvers to facilitate at least 25% of defecations (e.g., digital evacuation, support of the pelvic floor)
 - f. Fewer than three defecations per week
2. Loose stools are rarely present without the use of laxatives
3. Insufficient criteria for irritable bowel syndrome

* Criteria fulfilled for the last 3 months with symptom onset at least 6 months prior to diagnosis

C4. Functional Diarrhea

*Diagnostic criterion**

Loose (mushy) or watery stools without pain occurring in at least 75% of stools

* Criterion fulfilled for the last 3 months with symptom onset at least 6 months prior to diagnosis

C5. Unspecified Functional Bowel Disorder

*Diagnostic criterion**

Bowel symptoms not attributable to an organic etiology that do not meet criteria for the previously defined categories

* Criterion fulfilled for the last 3 months with symptom onset at least 6 months prior to diagnosis

D. Functional Abdominal Pain Syndrome

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*Diagnostic criteria** Must include **all** of the following:

1. Continuous or nearly continuous abdominal pain
2. No or only occasional relationship of pain with physiological events (e.g., eating, defecation, or menses)
3. Some loss of daily functioning
4. The pain is not feigned (e.g., malingering)
5. Insufficient symptoms to meet criteria for another functional gastrointestinal disorder that would explain the pain

* Criteria fulfilled for the last 3 months with symptom onset at least 6 months prior to diagnosis

E. Functional Gallbladder and Sphincter of Oddi Disorders

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Diagnostic criteria Must include episodes of pain located in the epigastrium and/or right upper quadrant and **all** of the following:

1. Episodes lasting 30 minutes or longer
2. Recurrent symptoms occurring at different intervals (not daily)
3. The pain builds up to a steady level
4. The pain is moderate to severe enough to interrupt the patient's daily activities or lead to an emergency department visit
5. The pain is not relieved by bowel movements
6. The pain is not relieved by postural change
7. The pain is not relieved by antacids
8. Exclusion of other structural disease that would explain the symptoms

Supportive criteria

The pain may present with one or more of the following:

1. Associated with nausea and vomiting
2. Radiates to the back and/or right infra subscapular region
3. Awakens from sleep in the middle of the night

E1. Functional Gallbladder Disorder

Diagnostic criteria Must include **all** of the following:

1. Criteria for functional gallbladder and sphincter of Oddi disorder
2. Gallbladder is present
3. Normal liver enzymes, conjugated bilirubin, and amylase/lipase

E2. Functional Biliary Sphincter of Oddi Disorder

Diagnostic criteria Must include **both** of the following:

1. Criteria for functional gallbladder and sphincter of Oddi disorder
2. Normal amylase/lipase

Supportive criterion

Elevated serum transaminases, alkaline phosphatase, or conjugated bilirubin temporarily related to at least two pain episodes

E3. Functional Pancreatic Sphincter of Oddi Disorder

Diagnostic criteria Must include **both** of the following:

1. Criteria for functional gallbladder and sphincter of Oddi disorder and
2. Elevated amylase/lipase

F. Functional Anorectal Disorders

FI. Functional Fecal Incontinence

*Diagnostic criteria**

1. Recurrent uncontrolled passage of fecal material in an individual with a developmental age of at least 4 years and *one or more* of the following:
 - a. Abnormal functioning of normally innervated and structurally intact muscles
 - b. Minor abnormalities of sphincter structure and/or innervation
 - c. Normal or disordered bowel habits, (i.e., fecal retention or diarrhea)
 - d. Psychological causes

AND

2. Exclusion of *all* the following:
 - a. Abnormal innervation caused by lesion(s) within the brain (e.g., dementia), spinal cord, or sacral nerve roots, or mixed lesions (e.g., multiple sclerosis), or as part of a generalized peripheral or autonomic neuropathy (e.g., due to diabetes)
 - b. Anal sphincter abnormalities associated with a multisystem disease (e.g., scleroderma)
 - c. Structural or neurogenic abnormalities believed to be the major or primary cause of fecal incontinence

* Criteria fulfilled for the last 3 months

F2. FUNCTIONAL ANORECTAL PAIN

F2a. Chronic Proctalgia

*Diagnostic criteria** *Must include all of the following:*

1. Chronic or recurrent rectal pain or aching
2. Episodes last 20 minutes or longer
3. Exclusion of other causes of rectal pain such as ischemia, inflammatory bowel disease, cryptitis, intramuscular abscess, anal fissure, hemorrhoids, prostatitis, and coccygodynia

* Criteria fulfilled for the last 3 months with symptom onset at least 6 months prior to diagnosis

Chronic proctalgia may be further characterized into levator ani syndrome or unspecified anorectal pain based on digital rectal examination.

F2a.1. Levator Ani Syndrome

Diagnostic criterion

Symptom criteria for chronic proctalgia and tenderness during posterior traction on the puborectalis

F2a.2. Unspecified Functional Anorectal Pain*Diagnostic criterion*

Symptom criteria for chronic proctalgia but no tenderness during posterior traction on the puborectalis

F2b. Proctalgia Fugax*Diagnostic criteria* Must include **all** of the following:

1. Recurrent episodes of pain localized to the anus or lower rectum
2. Episodes last from seconds to minutes
3. There is no anorectal pain between episodes

For research purposes criteria must be fulfilled for 3 months; however, clinical diagnosis and evaluation may be made prior to 3 months.

F3. Functional Defecation Disorders*Diagnostic criteria**

1. The patient must satisfy diagnostic criteria for functional constipation**
2. During repeated attempts to defecate must have *at least two* of the following:
 - a. Evidence of impaired evacuation, based on balloon expulsion test or imaging
 - b. Inappropriate contraction of the pelvic floor muscles (i.e., anal sphincter or puborectalis) or less than 20% relaxation of basal resting sphincter pressure by manometry, imaging, or EMG
 - c. Inadequate propulsive forces assessed by manometry or imaging

* Criteria fulfilled for the last 3 months with symptom onset at least 6 months prior to diagnosis

**** Diagnostic criteria for functional constipation:**

(1) **Must include two or more of the following:** (a) Straining during at least 25% of defecations, (b) Lumpy or hard stools in at least 25% of defecations, (c) Sensation of incomplete evacuation for at least 25% of defecations, (d) Sensation of anorectal obstruction/blockage for at least 25% of defecations, (e) Manual maneuvers to facilitate at least 25% of defecations (e.g., digital evacuation, support of the pelvic floor), (f) Fewer than three defecations per week.

(2) **Loose stools are rarely present without the use of laxatives.**

(3) **Insufficient criteria for irritable bowel syndrome.**

F3a. Dyssynergic Defecation*Diagnostic criterion*

Inappropriate contraction of the pelvic floor or less than 20% relaxation of basal resting sphincter pressure with adequate propulsive forces during attempted defecation

F3b. Inadequate Defecatory Propulsion*Diagnostic criterion*

Inadequate propulsive forces with or without inappropriate contraction or less than 20% relaxation of the anal sphincter during attempted defecation

G. Childhood Functional GI Disorders: Infant/Toddler

G1. Infant Regurgitation

Diagnostic criteria Must include **both** of the following in otherwise healthy infants 3 weeks to 12 months of age:

1. Regurgitation two or more times per day for 3 or more weeks
2. No retching, hematemesis, aspiration, apnea, failure to thrive, feeding or swallowing difficulties, or abnormal posturing

G2. Infant Rumination Syndrome

Diagnostic criteria Must include **all** of the following for at least 3 months:

1. Repetitive contractions of the abdominal muscles, diaphragm, and tongue
2. Regurgitation of gastric content into the mouth, which is either expectorated or rechewed and reswallowed
3. Three or more of the following:
 - a. Onset between 3 and 8 months
 - b. Does not respond to management for gastroesophageal reflux disease, or to anticholinergic drugs, hand restraints, formula changes, and gavage or gastrostomy feedings
 - c. Unaccompanied by signs of nausea or distress
 - d. Does not occur during sleep and when the infant is interacting with individuals in the environment

G3. Cyclic Vomiting Syndrome

Diagnostic criteria Must include **both** of the following:

1. Two or more periods of intense nausea and unremitting vomiting or retching lasting hours to days
2. Return to usual state of health lasting weeks to months

G4. Infant Colic

Diagnostic criteria Must include **all** of the following in infants from birth to 4 months of age:

1. Paroxysms of irritability, fussing or crying that starts and stops without obvious cause
2. Episodes lasting 3 or more hours/day and occurring at least 3 days/wk for at least 1 week
3. No failure to thrive

G5. Functional Diarrhea

Diagnostic criteria Must include **all** of the following:

1. Daily painless, recurrent passage of three or more large, unformed stools
2. Symptoms that last more than 4 weeks
3. Onset of symptoms that begins between 6 and 36 months of age
4. Passage of stools that occurs during waking hours
5. There is no failure-to-thrive if caloric intake is adequate

G6. Infant Dyschezia

Diagnostic criteria Must include **both** of the following in an infant less than 6 months of age

1. At least 10 minutes of straining and crying before successful passage of soft stools
2. No other health problems

G7. Functional Constipation

Diagnostic criteria Must include one month of **at least two** of the following in infants up to 4 years of age:

1. Two or fewer defecations per week
2. At least one episode/week of incontinence after the acquisition of toileting skills
3. History of excessive stool retention
4. History of painful or hard bowel movements
5. Presence of a large fecal mass in the rectum
6. History of large diameter stools which may obstruct the toilet

Accompanying symptoms may include irritability, decreased appetite, and/or early satiety. The accompanying symptoms disappear immediately following passage of a large stool.

H. Childhood Functional GI Disorders: Child/Adolescent

HI. VOMITING AND AEROPHAGIA**HIa. Adolescent Rumination Syndrome**

*Diagnostic criteria** Must include **all** of the following:

1. Repeated painless regurgitation and rechewing or expulsion of food that
 - a. begin soon after ingestion of a meal
 - b. do not occur during sleep
 - c. do not respond to standard treatment for gastroesophageal reflux
2. No retching
3. No evidence of an inflammatory, anatomic, metabolic, or neoplastic process that explains the subject's symptoms

* Criteria fulfilled for the last 3 months with symptom onset at least 6 months prior to diagnosis

HIb. Cyclic Vomiting Syndrome

Diagnostic criteria Must include **both** of the following:

1. Two or more periods of intense nausea and unremitting vomiting or retching lasting hours to days
2. Return to usual state of health lasting weeks to months

HIc. Aerophagia

*Diagnostic criteria** Must include **at least two** of the following:

1. Air swallowing
2. Abdominal distention due to intraluminal air
3. Repetitive belching and/or increased flatus

* Criteria fulfilled at least once per week for at least 2 months prior to diagnosis

H2. ABDOMINAL PAIN-RELATED FUNCTIONAL GI DISORDERS

H2a. Functional Dyspepsia

*Diagnostic criteria** Must include **all** of the following:

1. Persistent or recurrent pain or discomfort centered in the upper abdomen (above the umbilicus)
2. Not relieved by defecation or associated with the onset of a change in stool frequency or stool form (i.e., not irritable bowel syndrome)
3. No evidence of an inflammatory, anatomic, metabolic or neoplastic process that explains the subject's symptoms

* Criteria fulfilled at least once per week for at least 2 months prior to diagnosis

H2b. Irritable Bowel Syndrome

*Diagnostic criteria** Must include **both** of the following:

1. Abdominal discomfort** or pain associated with *two or more* of the following at least 25% of the time:
 - a. Improvement with defecation
 - b. Onset associated with a change in frequency of stool
 - c. Onset associated with a change in form (appearance) of stool
2. No evidence of an inflammatory, anatomic, metabolic, or neoplastic process that explains the subject's symptoms

* Criteria fulfilled at least once per week for at least 2 months prior to diagnosis

** "Discomfort" means an uncomfortable sensation not described as pain.

H2c. Abdominal Migraine

*Diagnostic criteria** Must include **all** of the following:

1. Paroxysmal episodes of intense, acute periumbilical pain that lasts for 1 hour or more
2. Intervening periods of usual health lasting weeks to months
3. The pain interferes with normal activities
4. The pain is associated with 2 of the following:
 - a. Anorexia
 - b. Nausea
 - c. Vomiting
 - d. Headache
 - e. Photophobia
 - f. Pallor
5. No evidence of an inflammatory, anatomic, metabolic, or neoplastic process considered that explains the subject's symptoms

* Criteria fulfilled two or more times in the preceding 12 months

H2d. Childhood Functional Abdominal Pain

*Diagnostic criteria** Must include **all** of the following:

1. Episodic or continuous abdominal pain
2. Insufficient criteria for other FGIDs
3. No evidence of an inflammatory, anatomic, metabolic, or neoplastic process that explains the subject's symptoms

* Criteria fulfilled at least once per week for at least 2 months prior to diagnosis

H2d1. Childhood Functional Abdominal Pain Syndrome

*Diagnostic criteria** Must satisfy criteria for childhood functional abdominal pain and have at least 25% of the time **one or more** of the following:

1. Some loss of daily functioning
2. Additional somatic symptoms such as headache, limb pain, or difficulty sleeping

* Criteria fulfilled at least once per week for at least 2 months prior to diagnosis

H3. CONSTIPATION AND INCONTINENCE**H3a. Functional Constipation**

*Diagnostic criteria** Must include **two or more** of the following in a child with a developmental age of at least 4 years with insufficient criteria for diagnosis of IBS:

1. Two or fewer defecations in the toilet per week
2. At least one episode of fecal incontinence per week
3. History of retentive posturing or excessive volitional stool retention
4. History of painful or hard bowel movements
5. Presence of a large fecal mass in the rectum
6. History of large diameter stools which may obstruct the toilet

* Criteria fulfilled at least once per week for at least 2 months prior to diagnosis

H3b. Nonretentive Fecal Incontinence

*Diagnostic criteria** Must include **all** of the following in a child with a developmental age at least 4 years:

1. Defecation into places inappropriate to the social context at least once per month
2. No evidence of an inflammatory, anatomic, metabolic, or neoplastic process that explains the subject's symptoms
3. No evidence of fecal retention

* Criteria fulfilled for at least 2 months prior to diagnosis

