

# ROME IV Diagnostic Criteria FOR Disorders of Gut-Brain Interaction (DGBI)\*

*\*Formerly known as Functional GI Disorders (FGIDs)*



**ROME**  
FOUNDATION

*Improving the lives of people with Disorders of Gut-Brain Interaction*

## A. ESOPHAGEAL DISORDERS

### A1. FUNCTIONAL CHEST PAIN

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

1. Retrosternal chest pain or discomfort\*\*
2. Absence of associated esophageal symptoms, such as heartburn and dysphagia
3. Absence of evidence that gastroesophageal reflux or eosinophilic esophagitis is the cause of the symptom
4. Absence of major esophageal motor disorders†

\*Criteria fulfilled for the last 3 months with symptom onset at least 6 months prior to diagnosis with a frequency of at least once a week

\*\*Cardiac causes should be ruled out

†Achalasia/EGJ outflow obstruction, diffuse esophageal spasm, jackhammer esophagus, absent peristalsis

### A2. FUNCTIONAL HEARTBURN

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

1. Burning retrosternal discomfort or pain
2. No symptom relief despite optimal antisecretory therapy
3. Absence of evidence that gastroesophageal reflux\*\* or eosinophilic esophagitis is the cause of the symptom
4. Absence of major esophageal motor disorders†

\*Criteria fulfilled for the last 3 months with symptom onset at least 6 months prior to diagnosis with a frequency of at least twice a week

\*\*Elevated acid exposure time and/or symptom reflux association

†Achalasia/EGJ outflow obstruction, diffuse esophageal spasm, jackhammer esophagus, absent peristalsis

### A3. REFLUX HYPERSENSITIVITY

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

1. Retrosternal symptoms including heartburn and chest pain
2. Normal endoscopy and absence of evidence that eosinophilic esophagitis is the cause of the symptoms
3. Absence of major esophageal motor disorders\*\*
4. Evidence of triggering of symptoms by reflux events despite normal acid exposure on pH- or pH-impedance monitoring†

\*Criteria fulfilled for the last 3 months with symptom onset at least 6 months prior to diagnosis with a frequency of at least twice a week

\*\*Achalasia/EGJ outflow obstruction, diffuse esophageal spasm, jackhammer esophagus, absent peristalsis

†Response to antisecretory therapy does not exclude the diagnosis

### A4. GLOBUS

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

1. Persistent or intermittent, non-painful sensation of a lump or foreign body in the throat with no structural lesion identified on physical examination, laryngoscopy, or endoscopy
  - a. Occurrence of the sensation between meals
  - b. Absence of dysphagia or odynophagia
  - c. Absence of a gastric inlet patch in the proximal esophagus
2. Absence of evidence that gastroesophageal reflux or eosinophilic esophagitis is the cause of the symptom
3. Absence of major esophageal motor disorders\*\*

\*Criteria fulfilled for the last 3 months with symptom onset at least 6 months prior to diagnosis with a frequency of at least once a week.

\*\*Achalasia/EGJ outflow obstruction, diffuse esophageal spasm, jackhammer esophagus, absent peristalsis

## A5. 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 esophageal mucosal or structural abnormality is the cause of the symptom
3. Absence of evidence that gastroesophageal reflux or eosinophilic esophagitis is the cause of the symptom
4. Absence of major esophageal motor disorders\*\*

\*Criteria fulfilled for the last 3 months with symptom onset at least 6 months prior to diagnosis with a frequency of at least once a week

\*\*Achalasia/EGJ outflow obstruction, diffuse esophageal spasm, jackhammer esophagus, absent peristalsis

## B. GASTRODUODENAL DISORDERS

### B1. FUNCTIONAL DYSPEPSIA\*

*Diagnostic criteria\*\**

1. One or more of the following:
  - a. Bothersome postprandial fullness
  - b. Bothersome early satiation
  - c. Bothersome epigastric pain
  - d. Bothersome epigastric burning
- AND
2. No evidence of structural disease (including at upper endoscopy) that is likely to explain the symptoms

\*Must fulfill criteria for B1a. PDS and/or B1b. EPS

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

#### B1a. POSTPRANDIAL DISTRESS SYNDROME (PDS)

*Diagnostic criteria\* - Must include **one or both** of the following at least 3 days a week:*

1. Bothersome postprandial fullness (i.e., severe enough to impact on usual activities)
2. Bothersome early satiation (i.e., severe enough to prevent finishing a regular size meal)
3. No evidence of organic, systemic, or metabolic disease that is likely to explain the symptoms on routine investigations (including at upper endoscopy)

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

*Supportive criteria*

1. Postprandial epigastric pain or burning, epigastric bloating, excessive belching, and nausea can also be present
2. Vomiting warrants consideration of another disorder
3. Heartburn is not a dyspeptic symptom but may often co-exist
4. Symptoms that are relieved by evacuation of feces or gas should generally not be considered as part of dyspepsia
5. Other individual digestive symptoms or groups of symptoms (e.g., from GERD and IBS) may co-exist with PDS

#### B1b. EPIGASTRIC PAIN SYNDROME (EPS)

*Diagnostic criteria\* - Must include **one or both** of the following symptoms at least 1 day a week:*

1. Bothersome epigastric pain (i.e., severe enough to impact on usual activities)
2. Bothersome epigastric burning (i.e., severe enough to impact on usual activities)
3. No evidence of organic, systemic, or metabolic disease that is likely to explain the symptoms on routine investigations (including at upper endoscopy).

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

*Supportive criteria*

1. Pain may be induced by ingestion of a meal, relieved by ingestion of a meal, or may occur while fasting
2. Postprandial epigastric bloating, belching, and nausea can also be present
3. Persistent vomiting likely suggests another disorder
4. Heartburn is not a dyspeptic symptom but may often co-exist
5. The pain does not fulfill biliary pain criteria
6. Symptoms that are relieved by evacuation of feces or gas generally should not be considered as part of dyspepsia
7. Other digestive symptoms (such as from GERD and IBS) may co-exist with EPS

## B2. BELCHING DISORDERS

### *Diagnostic criteria\**

Bothersome (i.e., severe enough to impact on usual activities) belching from the esophagus or stomach more than 3 days a week

### **B2a. EXCESSIVE SUPRAGASTRIC BELCHING (FROM ESOPHAGUS)**

### **B2b. EXCESSIVE GASTRIC BELCHING (FROM STOMACH)**

### *Supportive criteria*

1. Supragastric belching is supported by observing frequent, repetitive belching
2. Gastric belching has no established clinical correlate
3. Objective intraluminal impedance measurement is required to distinguish supragastric from gastric belching

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

## B3. NAUSEA AND VOMITING DISORDERS

### **B3a. CHRONIC NAUSEA VOMITING SYNDROME (CNVS)**

### *Diagnostic criteria\** - Must include **all** of the following:

1. Bothersome (i.e., severe enough to impact on usual activities) nausea, occurring at least 1 day per week and/or one or more vomiting episodes per week
2. Self-induced vomiting, eating disorders, regurgitation, or rumination are excluded
3. No evidence of organic, systemic, or metabolic diseases likely to explain the symptoms on routine investigations (including at upper endoscopy)

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

### **B3b. CYCLIC VOMITING SYNDROME (CVS)**

### *Diagnostic criteria\** - Must include **all** of the following:

1. Stereotypical episodes of vomiting regarding onset (acute) and duration (less than 1 week)
2. At least three discrete episodes in the prior year and two episodes in the past 6 months, occurring at least 1 week apart
3. Absence of vomiting between episodes, but other milder symptoms can be present between cycles

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

### *Supportive remark*

History or family history of migraine headaches

### **B3c. CANNABINOID HYPEREMESIS SYNDROME (CHS)**

### *Diagnostic criteria\** - Must include **all** of the following:

1. Stereotypical episodic vomiting resembling cyclic vomiting syndrome (CVS) in terms of onset, duration, and frequency
2. Presentation after prolonged use of cannabis
3. Relief of vomiting episodes by sustained cessation of cannabis use

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

### *Supportive remark*

May be associated with pathologic bathing behavior (prolonged hot baths or showers)

## B4. RUMINATION SYNDROME

### *Diagnostic criteria\** - Must include **all** 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

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

### *Supportive criteria*

1. Effortless regurgitation events are usually not preceded by nausea
2. Regurgitant contains recognizable food which may have a pleasant taste
3. The process tends to cease when the regurgitated material becomes acidic

## C. BOWEL DISORDERS

### C1. IRRITABLE BOWEL SYNDROME

#### *Diagnostic criteria\**

Recurrent abdominal pain on average at least 1 day/week in the last 3 months, associated with two or more of the following criteria:

1. Related to defecation
2. Associated with a change in frequency of stool
3. Associated with a change in form (appearance) of stool

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

### DIAGNOSTIC CRITERIA FOR IBS SUBTYPES (FIGURE 11-11, FM 12)

Predominant bowel habits are based on stool form on days with at least one abnormal bowel movement.\*

**IBS with predominant constipation (IBS-C):**  $> \frac{1}{4}$  (25%) of abnormal bowel movements with Bristol stool types 1 or 2 and  $< \frac{1}{4}$  (25%) of bowel movements with Bristol stool types 6 or 7. Alternative for epidemiology or clinical practice: Patient reports that abnormal bowel movements are usually constipation (like Type 1 or 2 in the picture of BSF, see Figure 2A).

**IBS with predominant diarrhea (IBS-D):**  $> \frac{1}{4}$  (25%) of abnormal bowel movements with Bristol stool types 6 or 7 and  $< \frac{1}{4}$  (25%) of bowel movements with Bristol stool types 1 or 2. Alternative for epidemiology or clinical practice: Patient reports that abnormal bowel movements are usually diarrhea (like Type 6 or 7 in the picture of BSF, see Figure 2A).

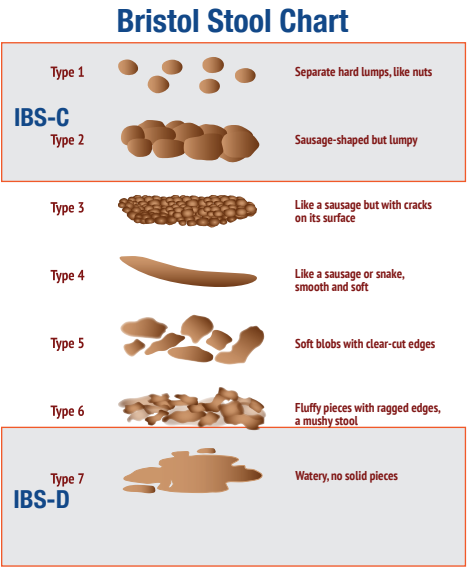
**IBS with mixed bowel habits (IBS-M):**  $> \frac{1}{4}$  (25%) of abnormal bowel movements with Bristol stool types 1 or 2 and  $> \frac{1}{4}$  (25%) of bowel movements with Bristol stool types 6 or 7. Alternative for epidemiology or clinical practice: Patient reports that abnormal bowel movements are usually both constipation and diarrhea (more than 1/4 of all the abnormal bowel movements were constipation and more than 1/4 were diarrhea, using picture of BSF, see Figure 2A).

**IBS Unclassified (IBS-U):** Patients who meet diagnostic criteria for IBS but whose bowel habits cannot be accurately categorized into 1 of the 3 groups above should be categorized as having IBS-U. Alternative for epidemiology or clinical practice: Patient reports that abnormal stools (both diarrhea and constipation) are rare.

For clinical trials, subtyping based on at least 2 weeks of daily diary data is recommended, using the “25%-rule”.

\*IBS subtypes related to bowel habit abnormalities (IBS-C, IBS-D and IBS-M) can only be confidently established when the patient is evaluated off medications used to treat bowel habit abnormalities.

# IBS SUBTYPES:



IBS Subtypes are based on >25% of abnormal BM (types 1,2 or 6,7)

- IBS-C Types 1, 2 not 6, 7 >25%
- IBS-D Types 6, 7 not 1, 2 >25%
- IBS-M Types 1, 2 and 6, 7 >25%
- IBS-U No Type >25%

Figure 11-11

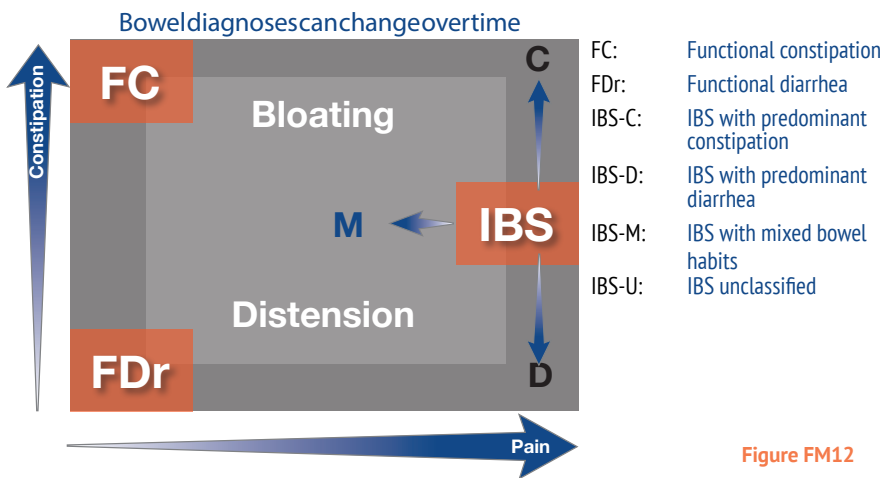


Figure FM12

## C2. FUNCTIONAL CONSTIPATION

### *Diagnostic criteria\**

1. Must include two or more of the following:\*\*
  - a. Straining during more than ¼ (25%) of defecations
  - b. Lumpy or hard stools (Bristol Stool Form Scale 1-2) more than ¼ (25%) of defecations
  - c. Sensation of incomplete evacuation more than ¼ (25%) of defecations
  - d. Sensation of anorectal obstruction/blockage more than ¼ (25%) of defecations
  - e. Manual maneuvers to facilitate more than ¼ (25%) of defecations (e.g., digital evacuation, support of the pelvic floor)
  - f. Fewer than three SBM 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

\*\*For research studies, patients meeting criteria for opioid-induced constipation (OIC) should not be given a diagnosis of FC because it is difficult to distinguish between opioid side effects and other causes of constipation. However, clinicians recognize that these two conditions may overlap.

## C3. FUNCTIONAL DIARRHEA

### *Diagnostic criterion\**

Loose or watery stools, without predominant abdominal pain or bothersome bloating, occurring in more than 25% of stools.\*\*

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

\*\*Patients meeting criteria for IBS-D (diarrhea-predominant IBS) should be excluded.

## C4. FUNCTIONAL ABDOMINAL BLOATING/DISTENSION

### *Diagnostic criteria\* - Must include both of the following:*

1. Recurrent bloating and/or distension occurring on average at least 1 day/week; abdominal bloating and/or distension predominates over other symptoms.\*\*
2. There are insufficient criteria for a diagnosis of irritable bowel syndrome, functional constipation, functional diarrhea, or post-prandial distress syndrome.

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

\*\*Mild pain related to bloating may be present as well as minor bowel movement abnormalities

## C5. UNSPECIFIED FUNCTIONAL BOWEL DISORDER

### *Diagnostic criterion\**

Bowel symptoms not attributable to an organic etiology that do not meet criteria for IBS, or functional constipation, diarrhea or abdominal bloating/distension disorders.

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

## C6. OPIOID-INDUCED CONSTIPATION

### *Diagnostic criteria*

1. New, or worsening, symptoms of constipation when initiating, changing, or increasing opioid therapy, that must include two or more of the following:
  - a. Straining during more than ¼ (25%) of defecations
  - b. Lumpy or hard stools (Bristol Stool Form Scale 1-2) more than ¼ (25%) of defecations
  - c. Sensation of incomplete evacuation more than ¼ (25%) of defecations
  - d. Sensation of anorectal obstruction/blockage more than ¼ (25%) of defecations
  - e. Manual maneuvers to facilitate more than ¼ (25%) of defecations (e.g., digital evacuation, support of the pelvic floor)
  - f. Fewer than three SBM per week
2. Loose stools are rarely present without the use of laxatives.



## D. CENTRALLY MEDIATED DISORDERS OF GI PAIN

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### D1. CENTRALLY MEDIATED ABDOMINAL PAIN SYNDROME (CAPS)\*

*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. Pain limits some aspect of daily functioning††
4. The pain is not feigned
5. Pain is not explained by another structural or functional gastrointestinal disorder or other medical condition

\*CAPS is typically associated with psychosocial comorbidity, but there is no specific profile that can be used for diagnosis

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

†Some degree of gastrointestinal dysfunction may be present

††Daily function could include impairments in work, intimacy, social/leisure, family life, and caregiving for self or others

### D2. NARCOTIC BOWEL SYNDROME/OPIOID-INDUCED GI HYPERALGESIA

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

1. Chronic or frequently recurring abdominal pain\* that is treated with acute high-dose or chronic narcotics
2. The nature and intensity of the pain is not explained by a current or previous GI diagnosis\*\*
3. Two or more of the following:
  - a. The pain worsens or incompletely resolves with continued or escalating dosages of narcotics
  - b. There is marked worsening of pain when the narcotic dose wanes and improvement when narcotics are re-instituted (soar and crash)
  - c. There is a progression of the frequency, duration, and intensity of pain episodes

\*Pain must occur most days

\*\*A patient may have a structural diagnosis (e.g., inflammatory bowel disease, chronic pancreatitis), but the character or activity of the disease process is not sufficient to explain the pain

## E. GALLBLADDER & SPHINCTER OF ODDI DISORDERS

### E1. BILIARY PAIN

#### *Diagnostic criteria*

Pain located in the epigastrium and/or right upper quadrant and all of the following:

1. Builds up to a steady level and lasts 30 minutes or longer
2. Occurring at different intervals (not daily)
3. Severe enough to interrupt daily activities or lead to an emergency department visit
4. Not significantly (<20%) related to bowel movements
5. Not significantly (<20%) relieved by postural change or acid suppression

#### *Supportive criteria*

The pain may be associated with:

1. Nausea and vomiting
2. Radiation to the back and/or right infra subscapular region
3. Waking from sleep

### E1a. FUNCTIONAL GALLBLADDER DISORDER

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

1. Criteria for biliary pain\*
2. Absence of gallstones or other structural pathology

#### *Supportive criteria*

1. Low ejection fraction on gallbladder scintigraphy
2. Normal liver enzymes, conjugated bilirubin, and amylase/lipase

\*Criteria for biliary pain: Pain located in the epigastrium and/or right upper quadrant and all of the following: 1. Builds up to a steady level and lasts 30 minutes or longer 2. Occurring at different intervals (not daily) 3. Severe enough to interrupt daily activities or lead to an emergency department visit 4. Not significantly (<20%) related to bowel movements 5. Not significantly (<20%) relieved by postural change or acid suppression

### E1b. FUNCTIONAL BILIARY SPHINCTER OF ODDI DISORDER

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

1. Criteria for biliary pain\*
2. Elevated liver enzymes or dilated bile duct, but not both
3. Absence of bile duct stones or other structural abnormalities

#### *Supportive criteria*

1. Normal amylase/lipase
2. Abnormal sphincter of Oddi manometry
3. Hepatobiliary scintigraphy

\*Criteria for biliary pain: Pain located in the epigastrium and/or right upper quadrant and all of the following: 1. Builds up to a steady level and lasts 30 minutes or longer 2. Occurring at different intervals (not daily) 3. Severe enough to interrupt daily activities or lead to an emergency department visit 4. Not significantly (<20%) related to bowel movements 5. Not significantly (<20%) relieved by postural change or acid suppression

### E2. FUNCTIONAL PANCREATIC SPHINCTER OF ODDI DISORDER

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

1. Documented recurrent episodes of pancreatitis (typical pain with amylase or lipase >3 times normal and/or imaging evidence of acute pancreatitis)
2. Other etiologies of pancreatitis excluded
3. Negative endoscopic ultrasound
4. Abnormal sphincter manometry

## F. ANORECTAL DISORDERS

### F1. FECAL INCONTINENCE

*Diagnostic criterion\**

Recurrent uncontrolled passage of fecal material in an individual with a developmental age of at least 4 years.

\*Criterion fulfilled for the last 3 months. For research studies, consider onset of symptoms of at least 6 months previously with 2-4 episodes of FI over 4 weeks.

### F2. FUNCTIONAL ANORECTAL PAIN

#### F2a. LEVATOR ANI SYNDROME

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

1. Chronic or recurrent rectal pain or aching
2. Episodes last 30 minutes or longer
3. Tenderness during traction on the puborectalis
4. Exclusion of other causes of rectal pain such as inflammatory bowel disease, intramuscular abscess, anal fissure, thrombosed hemorrhoids, prostatitis, coccygodynia and major structural alterations of the pelvic floor

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

#### F2b. UNSPECIFIED FUNCTIONAL ANORECTAL PAIN

*Diagnostic criteria\**

Symptom criteria for chronic levator ani syndrome but no tenderness during posterior traction on the puborectalis muscle.

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

#### F2c. PROCTALGIA FUGAX

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

1. Recurrent episodes of pain localized to the rectum and unrelated to defecation
2. Episodes last from seconds to minutes with a maximum duration of 30 minutes
3. There is no anorectal pain between episodes
4. Exclusion of other causes of rectal pain such as inflammatory bowel disease, intramuscular abscess, anal fissure, thrombosed hemorrhoids, prostatitis, coccygodynia and major structural alterations of the pelvic floor.

\*For research purposes, criteria must be fulfilled for 3 months with symptom onset at least 6 months prior to diagnosis.

### F3. FUNCTIONAL DEFECATION DISORDERS

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

1. The patient must satisfy diagnostic criteria for functional constipation and/or irritable bowel syndrome with constipation
2. During repeated attempts to defecate, there must be features of impaired evacuation, as demonstrated by 2 of the following 3 tests:
  - a. Abnormal balloon expulsion test
  - b. Abnormal anorectal evacuation pattern with manometry or anal surface EMG
  - c. Impaired rectal evacuation by imaging

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

~ *Subcategories F3a and F3b apply to patients who satisfy criteria for FDD* ~

#### F3a. INADEQUATE DEFECATORY PROPULSION

*Diagnostic criterion\**

Inadequate propulsive forces as measured with manometry with or without inappropriate contraction of the anal sphincter and/or pelvic floor muscles\*\*

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

\*\*This criterion is defined by age- and gender-appropriate normal values for the technique

#### F3b. DYSSYNERGIC DEFECATION

*Diagnostic criterion\**

Inappropriate contraction of the pelvic floor as measured with anal surface EMG or manometry with adequate propulsive forces during attempted defecation\*\*

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

\*\*This criterion is defined by age- and gender-appropriate normal values for the technique

## G. CHILDHOOD FUNCTIONAL GI DISORDERS: NEONATE/TODDLER

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### 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. RUMINATION SYNDROME

*Diagnostic criteria - Must include **all** of the following for at least 2 months:*

1. Repetitive contractions of the abdominal muscles, diaphragm, and tongue
2. Effortless regurgitation of gastric contents, which are either expelled from the mouth 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 GERD and regurgitation
  - c. Unaccompanied by signs of 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 **all** of the following:*

1. Two or more periods of unremitting paroxysmal vomiting with or without retching, lasting hours to days within a 6-month period
2. Episodes are stereotypical in each patient
3. Episodes are separated by weeks to months with return to baseline health between episodes of vomiting

### G4. INFANT COLIC

*Diagnostic criteria - For clinical purposes must include **all** of the following:*

1. An infant who is less than 5 months of age when the symptoms start and stop
2. Recurrent and prolonged periods of infant crying, fussing, or irritability reported by caregivers that occur without obvious cause and cannot be prevented or resolved by caregivers
3. No evidence of infant failure to thrive, fever, or illness

"Fussing" refers to intermittent distressed vocalization and has been defined as "[behavior] that is not quite crying but not awake and content either." Infants often fluctuate between crying and fussing, so that the two symptoms are difficult to distinguish in practice.

For clinical research, a diagnosis of infant colic must meet the preceding diagnostic criteria and also include both of the following:

1. Caregiver reports infant has cried or fussed for 3 or more hours/day during 3 or more days in 7 days in a telephone or face-to-face screening interview with a researcher or clinician;
2. Total 24-hour crying plus fussing in the selected group of infants is confirmed to be 3 hours or more when measured by at least one, prospectively kept, 24-hour behavior diary.

### G5. FUNCTIONAL DIARRHEA

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

1. Daily painless, recurrent passage of four or more large, unformed stools
2. Symptoms last more than 4 weeks
3. Onset between 6 and 60 months of age
4. No failure-to-thrive if caloric intake is adequate

## **G6. INFANT DYSCHESIA**

*Diagnostic criteria - Must include in an infant less than 9 months of age:*

1. At least 10 minutes of straining and crying before successful or unsuccessful 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. History of excessive stool retention
3. History of painful or hard bowel movements
4. History of large diameter stools
5. Presence of a large fecal mass in the rectum

In toilet trained children, the following additional criteria may be used:

6. At least one episode/week of incontinence after the acquisition of toileting skills
7. History of large diameter stools which may obstruct the toilet

## H. CHILDHOOD FUNCTIONAL GI DISORDERS: CHILD/ADOLESCENT

### H1. FUNCTIONAL NAUSEA AND VOMITING DISORDERS

#### H1a. CYCLIC VOMITING SYNDROME

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

1. Two or more periods of intense, unremitting nausea and paroxysmal vomiting, lasting hours to days within a 6-month period
2. Episodes are stereotypical in each patient
3. Episodes are separated by weeks to months with return to baseline health between episodes
4. After appropriate evaluation, the symptoms cannot be attributed to another medical condition

#### H1b. FUNCTIONAL NAUSEA AND FUNCTIONAL VOMITING

##### H1b1. FUNCTIONAL NAUSEA

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

1. Bothersome nausea as the predominant symptom, occurring at least twice per week, and generally not related to meals
2. Not consistently associated with vomiting
3. After appropriate evaluation, the nausea cannot be fully explained by another medical condition

\*Criteria fulfilled for at least 2 months prior to diagnosis

##### H1b2. FUNCTIONAL VOMITING

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

1. On average, one or more episodes of vomiting per week
2. Absence of self-induced vomiting or criteria for an eating disorder or rumination
3. After appropriate evaluation, the vomiting cannot be fully explained by another medical condition

\*Criteria fulfilled for at least 2 months prior to diagnosis

#### H1c. RUMINATION SYNDROME

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

1. Repeated regurgitation and rechewing or expulsion of food that:
  - a. Begins soon after ingestion of a meal
  - b. Does not occur during sleep
2. Not preceded by retching
3. After appropriate evaluation, the symptoms cannot be fully explained by another medical condition. An eating disorder must be ruled out.

\*Criteria fulfilled for at least 2 months prior to diagnosis

#### H1d. AEROPHAGIA

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

1. Excessive air swallowing
2. Abdominal distention due to intraluminal air which increases during the day
3. Repetitive belching and/or increased flatus
4. After appropriate evaluation, the symptoms cannot be fully explained by another medical condition

\*Criteria fulfilled for at least 2 months prior to diagnosis

### H2. FUNCTIONAL ABDOMINAL PAIN DISORDERS

#### H2a. FUNCTIONAL DYSPEPSIA

*Diagnostic criteria* - Must include **one or more** of the following bothersome symptoms at least 4 times a month for at least 2 months prior to diagnosis:

1. Postprandial fullness
2. Early satiation
3. Epigastric pain or burning not associated with defecation

4. After appropriate evaluation, the symptoms cannot be fully explained by another medical condition

Within FD the following subtypes are now adopted:

#### **H2a1. POSTPRANDIAL DISTRESS SYNDROME**

Includes bothersome postprandial fullness or early satiation which prevents finishing a regular meal. Supportive features include upper abdominal bloating, postprandial nausea, or excessive belching.

#### **H2a2. EPIGASTRIC PAIN SYNDROME**

Includes all of the following: bothersome (severe enough to interfere with normal activities) pain or burning localized to the epigastrium. The pain is not generalized or localized to other abdominal or chest regions and is not relieved by defecation or passage of flatus. Supportive criteria can include (a) burning quality of the pain but without a retrosternal component, (b) commonly induced or relieved by ingestion of a meal but may occur while fasting.

#### **H2b. IRRITABLE BOWEL SYNDROME**

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

1. Abdominal pain at least 4 days per month over at least 2 months associated with one or more of the following:
  - a. Related to defecation
  - b. A change in frequency of stool
  - c. A change in form (appearance) of stool
2. In children with abdominal pain and constipation, the pain does not resolve with resolution of the constipation (children in whom the pain resolves have functional constipation, not IBS)
3. After appropriate evaluation, the symptoms cannot be fully explained by another medical condition

\*Criteria fulfilled for at least 2 months prior to diagnosis

#### **H2c. ABDOMINAL MIGRAINE**

*Diagnostic criteria\* - Must include **all** of the following occurring at least twice:*

1. Paroxysmal episodes of intense, acute periumbilical, midline or diffuse abdominal pain lasting 1 hour or more (should be the most severe and distressing symptom)
2. Episodes are separated by weeks to months
3. The pain is incapacitating and interferes with normal activities
4. Stereotypical pattern and symptoms in the individual patient
5. The pain is associated with two or more of the following:
  - a. Anorexia
  - b. Nausea
  - c. Vomiting
  - d. Headache
  - e. Photophobia
  - f. Pallor
6. After appropriate evaluation, the symptoms cannot be fully explained by another medical condition

\*Criteria fulfilled for at least 6 months prior to diagnosis

#### **H2d. FUNCTIONAL ABDOMINAL PAIN – NOT OTHERWISE SPECIFIED**

*Diagnostic criteria\* - Must be fulfilled at least 4 times per month and include **all** of the following:*

1. Episodic or continuous abdominal pain that does not occur solely during physiologic events (e.g., eating, menses)
2. Insufficient criteria for irritable bowel syndrome, functional dyspepsia, or abdominal migraine
3. After appropriate evaluation, the abdominal pain cannot be fully explained by another medical condition

\*Criteria fulfilled for at least 2 months prior to diagnosis

### **H3. FUNCTIONAL DEFECATION DISORDERS**

#### **H3a. FUNCTIONAL CONSTIPATION**

*Diagnostic criteria - Must include two or more of the following occurring at least once per week for a minimum of 1 month with insufficient criteria for a diagnosis of IBS:*

1. Two or fewer defecations in the toilet per week in a child of a developmental age of at least 4 years
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 can obstruct the toilet
7. After appropriate evaluation, the symptoms cannot be fully explained by another medical condition

#### **H3b. NONRETENTIVE FECAL INCONTINENCE**

*Diagnostic criteria - Must include at least a 1-month history in a child with a developmental age older than 4 years of all of the following:*

1. Defecation in places inappropriate to the sociocultural context
2. No evidence of fecal retention
3. After appropriate evaluation, the fecal incontinence cannot be explained by another medical condition

