

Functional Constipation and Soiling in Children

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Guideline Team

Team Leader

Barbara T. Felt, MD
Developmental-Behavioral Pediatrics

Team Members

Pamela I. Brown, MD
Pediatric Gastroenterology

R. Van Harrison, PhD
Medical Education

Paramjeet K. Kochhar, MD
General Pediatrics

Susana R. Patton, PhD
Pediatric Psychology

Consultants

Sheila M. Marcus, MD
Psychiatry

Daniel H. Teitelbaum, MD
Pediatric Surgery

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UMMC Guidelines Oversight Team

William E Chavey, MD
R Van Harrison, PhD
Connie J. Standiford, MD

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These guidelines should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific clinical procedure or treatment must be made by the physician in light of the circumstances presented by the patient.

Patient population: Infancy to 18 years

Objectives:

1. Present methods for early and accurate diagnosis of functional constipation and soiling in children.
2. Identify methods for education, clean out, maintenance and extended follow up.
3. Promote child and family adherence to treatment recommendations.

Key points:

For overview of diagnosis and treatment for age < 1 year see Table 1 and for age > 1 year see Table 2.

■ **Diagnosis.**

Functional constipation often begins during late infant to toddler age. [C]* Inquiring at doctor visits about stool frequency, character, and painful stool passage may aide earlier diagnosis. [IC & D]

- Symptoms and signs (Tables 3 and 4) are the best guides for accurate diagnosis. [IC & D]
- Red flags (Table 5) should be checked to exclude other disorders. [IC & D]

■ **Treatment.**

Child and family adherence to treatment recommendations is a likely predictor of success. [IC & D]

- Educate child and family (Table 6). [IC & D]
- Clean-out impaction if present – applies only to age > 1yr (Table 7), [IB]
- Diet modification to increase fiber and clear fluids (Table 8). [IC & D]
- Behavioral training initiated for age > 1 year (Table 9). [IC & D]
- Medication (Table 10) often needed to achieve stool frequency ≥ 3 times per week. [IA]
- Consider referral for additional evaluation-management if treatment failure within first month. [ID]
- Wean from medications – if used – after about 6 months if stool frequency ≥ 3 per week. [ID]
- Dietary and behavioral components should continue. [ID]

*** Strength of recommendation:**

I= generally should be performed; II = may be reasonable to perform; III = generally should not be performed.

Levels of evidence for the most significant recommendations

A = randomized controlled trials; B=controlled trials, no randomization; C=observational trials; D=opinion of expert panel

Clinical Background

Clinical Problem

Prevalence

Constipation, a common medical problem in children worldwide, affects up to 40% of infants and 30% of school-age children. Up to 8% of children have symptoms that meet criteria for functional constipation. (Table 3)

The peak occurrence of functional constipation occurs at toddler to preschool-age. About 95% of children referred for evaluation of constipation have no underlying pathologic condition and receive a diagnosis of functional constipation. A longer duration of constipation symptoms prior to diagnosis has been associated with poorer long-term outcome. Experts suggest improved outcomes with earlier diagnosis and effective management.

Rationale for Recommendations

Definitions

Children have > 4 stools per day during the first weeks of life, 2 per day by 4 months and 1 per day by 4 years of age. Stool frequency ranges from 3 per day to 3 times per week for 97% of children at 3 to 4 years of age.

The Rome III criteria for functional constipation in children/adolescents and infants/toddlers are shown in Table 3. Stool consistency and occurrence of pain at defecation are important characteristics. One month of symptoms is required for infants and toddlers to meet criteria for functional constipation and two months of symptoms are required for children.

(continued on page 9)

Table 1. Children < 1 Year: Diagnosis and Management of Functional Constipation

<p>Diagnosis</p> <ol style="list-style-type: none"> 1. <u>Symptoms / signs</u> suggestive of constipation present (Tables 3 and 4). 2. <u>No red flags</u> for other disorder (Tables 4 & 5)? If no red flags, go to step 3. If red flags present, evaluate for other disorders (Table 5) and <i>consider consultation with specialist (e.g., if Hirschsprung’s disease, cystic fibrosis, hypothyroidism considered).</i> 3. <u>Diagnosis</u> is functional constipation. Go to steps 4 and 5. <p>Treatment</p> <ol style="list-style-type: none"> 4. <u>Educate</u> caretaker(s) (Table 6). 5. <u>Change diet</u> (Table 8 and text). Is diet change effective (within 1-2 weeks)? If yes, continue diet. (Go to step 9). If no, reassess for other disorders (Go to Step 2) If no, and functional constipation remains the diagnosis, Go to step 6. 6. <u>Add medications</u> (Table 10). Monitor progress every 1-3 months. 	<p>Adjust medication to achieve ≥ 3 stools per week. If stools ≥ 3 per week, Go to Step 7. If not, review education, diet and medication adherence (Steps 3, 4, 5). If stool frequency remains suboptimal, <i>reconsider diagnosis and referral to specialist.</i> (Steps 1 & 2)</p> <ol style="list-style-type: none"> 7. <u>Are medications continuing to be effective</u> (stools ≥ 3 per week) <u>for about 6 months?</u> If yes, go to step 8. If not, review education, adherence to diet, and medication (Steps 4, 5, & 6). If stool frequency remains suboptimal, <i>reconsider diagnosis and referral to specialist</i> (Steps 1 & 2) 8. <u>Wean from medication after about 6 months</u> if stool frequency ≥ 3 per week. Monitor progress every 1-3 months. Wean is effective if stools ≥ 3 per week, If not going well, go to step 6. <p>Longer Term Follow-Up</p> <ol style="list-style-type: none"> 9. <u>Continue dietary components.</u> Follow up according to health maintenance schedules.
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Note: The management of children < 1 year differs from that for older children in the focus on dietary measures and avoidance of aggressive clean out measures.

Table 2. Children > 1 Year: Diagnosis and Management of Functional Constipation and Soiling

<p>Diagnosis</p> <ol style="list-style-type: none"> 1. <u>Symptoms / signs</u> suggestive of constipation present (Tables 3 and 4). 2. <u>No red flags</u> for other disorder (Tables 4 & 5)? If no red flags, go to Step 3. If red flags present, evaluate for other disorders (Table 5) and <i>consider consultation with specialist (e.g., if Hirschsprung’s disease, cystic fibrosis, hypothyroidism considered).</i> 3. <u>Diagnosis</u> is functional constipation / soiling. <p>Treatment</p> <ol style="list-style-type: none"> 4. <u>Educate</u> patient and caretaker(s) (Table 6). 5. <u>Is impaction present?</u> If no impaction, go to Step 6. If impaction present, prescribe clean-out (Table 7) and follow up in 1-2 weeks. If clean-out is not effective, prescribe again. If impaction persists, consider <i>consultation with specialist.</i> 6. <u>Initiate maintenance therapy: diet, behavior, and medication.</u> (Tables 8, 9, 10 and text). Adjust medication to achieve ≥ 3 stools/week. Therapy effective (≥ 3 stools/week and no soiling)? 	<p>If yes, go to Step 7 If not, and adherence problems suspected, repeat education (Step 4). If not and no adherence problems suspected, <i>reconsider diagnosis and referral to specialist</i> (Steps 1 & 2).</p> <ol style="list-style-type: none"> 7. <u>Is maintenance therapy continuing to be effective</u> (≥ 3 stools/week and no soiling) as progress monitored every 1-3 months? If yes, continue for a minimum of 4-6 months. If not and adherence problems suspected, repeat education (Step 4). If not and no adherence problems suspected, <i>reconsider diagnosis and referral to specialist</i> (steps 1 & 2). 8. <u>Wean from medications</u> after about 4-6 months if stool frequency ≥ 3 per week. Monitor progress every 1-3 months. Wean is progressing well if ≥ 3 stools/week and no soiling. If not going well, go to Step 5 to check for impaction and then resume at Step 6 for a period of 1-3 months. <p>Longer Term Follow-Up</p> <ol style="list-style-type: none"> 9. <u>Continue behavioral and dietary components</u> during and after wean from medication. After wean is completed, follow-up according to health maintenance schedules.
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Table 3. Rome III Diagnostic Criteria

Constipation Infants and Children up to age 4 years

One month of at least two of the following:

1. Two or fewer defecations per week
2. At least one episode per week of incontinence after acquiring 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 that 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.

Functional Constipation, Children age 4-18 years

At least once per week for at least two months prior to diagnosis, two or more of the following in a child with a developmental age of at least 4 years and having insufficient criteria for a diagnosis of Irritable Bowel Syndrome (see below):

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 that may obstruct the toilet.

Irritable Bowel Syndrome, Children age 4-18 years

At least once per week for at least two months prior to diagnosis, diagnosis includes *all* of the following:

1. Abdominal discomfort (an uncomfortable sensation not described as pain) or pain associated with two or more of the following at least 25% of the time
 - a. Improved 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.

Infant Dyschezia

Both criteria in an infant < 6 months

1. At least 10 minutes straining/crying before soft stool passage.
2. No other health problems

Adapted from: Rasquin 2006 and Hyman, 2006

Table 4. History and Physical Exam

History	Symptoms c/w Functional Constipation	Red Flag Symptoms (see Table 5)
Age at meconium stool passage	Within 48 hours of birth	> 48 hours
Stool characteristics		
1) Frequency / consistency	Hard and / or large caliber; Soiling accidents (encopresis)	Pencil-thin stools
2) Passage problems	Pain/discomfort, withholding; blood on stool; peri-anal fissures	Bloody diarrhea
Other symptoms	Appetite and abdominal pain wax and wane with stool passage; Enuresis.	Fatigue, fever, bilious vomiting, rash
Past / current treatment & response	Problems adhering to treatment	Poor response despite good adherence
Diet	Low fiber and fluid; high dairy	
Development	Delayed toilet training	Global developmental delay
Medication	See Table 5	
Psychosocial history	Family stressors	Suspicion of abuse
Family history	Other family members with constipation	
Physical Exam	Signs c/w Functional Constipation	Red Flag Signs (see Table 5)
General	Normal growth	Failure to thrive, Fever
Abdomen	Mild distention, palpable stool	Significant distention
Anus	Normal placement Fecal mass in rectum Stool around anus or on clothes	Anteriorly displaced Empty rectum (and no history of recent stool passage) Tight sphincter Blood in stool
Back: skin / spine	Normal	Sacral agenesis, pilonidal dimple, hair tuft.
Neurologic	Present anal wink / cremasteric	Decreased lower extremity strength / tone / reflexes; Absent anal wink / cremasteric
Pulmonary	Normal	Pneumonia

Table 5. Differential Diagnosis and/or Conditions Associated with Functional Constipation *
(**Bold** = Red Flags on Table 4)

Diagnoses	Related Symptoms and Signs
Anatomic	
<ol style="list-style-type: none"> 1. Imperforate anus or anal stenosis 2. Anteriorly displaced anus 3. Pelvic mass – sacral teratoma 4. Peri-anal abscess or fissure 	
Metabolic and gastrointestinal	
<ol style="list-style-type: none"> 1. Hypothyroidism 2. Diabetes mellitus 3. Cystic fibrosis 4. Gluten enteropathy 5. Irritable Bowel Syndrome 	<ol style="list-style-type: none"> 1. Fatigue; cold intolerance; bradycardia; poor growth 2. Polyuria; polydipsia 3. Diarrhea, rash, failure to thrive, fever, pneumonia 4. Diarrhea 5. See Table 3
Neurogenic	
<ol style="list-style-type: none"> 1. Hirschsprung’s disease 2. Pseudo-obstruction 3. Spinal cord abnormalities: (tethered cord; myelomeningocele; spinal cord tumor or trauma, Neurofibromatosis) 	<ol style="list-style-type: none"> 1. Passage of meconium >48 hours after delivery; usually presenting in infancy: small caliber stools; early onset constipation (first 3 months); failure to thrive; fever; bloody diarrhea; bilious vomiting; empty rectum; tight anal sphincter; ‘gush’ of stool on rectal. 2. Distension; bilious vomiting; ileus 3. Altered lower extremity reflexes; absent anal wink; pilonidal dimple; hair tuft; urine accidents or delayed toilet training.
Pharmacologic	
Use or exposure to: Anticholinergics, aluminum antacids, antidepressants, anti-hypertensives, chemotherapy (vincristine), cholestyramine, iron treatment, lead intoxication, opiates, vitamin D intoxication.	
Constitutional	
Genetic predisposition Cow’s milk protein allergy Infant dyschezia	Other family members with constipation Rash, rhinitis, bronchospasm See Table 3.
Dietary	
Low fiber and fluids, dehydration, malnutrition	Reduced stool volume/dry stool
Developmental / Behavioral / Social-situational	
<ol style="list-style-type: none"> 1. Mental retardation 2. Autism/Asperger’s 3. Oppositional defiant disorder 4. Depression 5. Anxiety 6. Delayed toilet training 7. Attention Deficit Hyperactivity Disorder 8. Child abuse 	<ol style="list-style-type: none"> 1. Global developmental delay 2. Delayed or atypical communication skills; restricted or atypical social interactions; atypical or repetitive behaviors; resistance to change of routine 3. Negative, argumentative, hostile 4. Persistent blunted affect, mood, energy, appetite 5. Persistent fearful or anxious behavior 6. Toileting refusals, stool with holding 7. Problems with attention, activity and impulsivity 8. Concerns raised by history or physical examination

Note: See also North American Society for Pediatric Gastroenterology, Hepatology and Nutrition Guideline 2006.

*If an associated or underlying condition is identified, the constipation should be also be treated

Table 6. General Education

1. **Incidence.** Constipation affects up to 30% of children but about 1 to 4% of all children have the more chronic problem of functional constipation with or without soiling.
2. **Begins early.** Functional constipation with or without soiling begins early in life for most children due to a combination of common factors:
 - Uncomfortable/painful stool passage.
 - Withholding to avoid discomfort at stool passage.
 - Diets higher in constipating foods and lower in fiber and fluid intake. Common features of transitioning to the toddler diet (decreased fluid intake, high dairy intake, and ‘finicky’ eating patterns) make this a high-risk time for constipation problems.
 - Use of medications that are constipating (Table 5).
 - Developmental features: increasing autonomy and perhaps toilet avoidance.
 - Family genetic factors – perhaps slower colonic transit.
3. **Physiologic changes.** Once chronic impaction of stool has occurred, physiologic changes at the rectum reduce a child’s ability to control his/her bowel movements:
 - Rectal vault is dilated resulting in reduced sensation to standard fecal volume.
 - Rehabilitation of rectal musculature and strength requires several months. Until then, the dilated rectal musculature may be less able to effectively expel stool.
 - Some children tighten the anal sphincter and pelvic floor when the urge to defecate is felt. This can lead to incomplete emptying of stool.
4. **Olfactory accommodation.** Many children do not recognize their soiling accidents due to olfactory accommodation.
5. **Psychological effects.** Children can present with low self-esteem or other behavioral concerns, although these symptoms are improved for a majority with education and management for the constipation and soiling.
6. **Commitment required.** Effective management of functional constipation requires a substantial commitment of the child and family, usually for at least 6 months but maybe up to several years.
7. **Adherence.** Degree of child and family adherence to treatment is a predictor of the child’s success.
8. **Behavioral treatment.** Formal behavioral treatment programs with at least probable efficacy:
 - Enhanced Toilet Training: individual treatment combining behavioral training (e.g., reinforcement), patient education (e.g., physiology of constipation), exercises to improve control of the external anal sphincter, and medical management.
 - Group-based Behavioral Toilet Training: group treatment combining patient education (e.g., physiology of constipation), behavior therapy (e.g., goals, contingent attention, shaping), and medical management.
 - Biofeedback: provides visual feedback of the level of tension at the sphincter muscle; some experts suggest this helps children with inappropriate contracting of the external anal sphincter

Table 7. Clean-Out and Disimpaction (Also see text)

Medication	Side Effects / Comments	Cost*
Infants (< 1 year) (Note: rarely needed)		
Glycerin suppository (1.2 grams): 1 per day x 1 day	No side effects. If more than one clean-out required, refer to pediatric gastroenterology.	25 / \$3
Children (>1 year)		
Cleanout over 2 or more days		
<u>Glycolax (Miralax or PEG 3350)</u> : 1.5-2.0 g/kg/day x 3 days (max dose 17 grams tid)	Diarrhea, bloating	16 oz/ \$5
<u>Magnesium citrate</u> : 1 oz/year of age to max of 10 oz per day for 2-3 days.	Hypermagnesemia	10 oz/ \$2
<u>Maintenance medications over time</u> (see Table 7)		
Cleanout over 1-2 days		
<u>Enemas</u> : 6 cc/kg up to 4.5 oz (135cc) every 12 – 24 hours x 1- 3	≥ 2 years of age. Invasive. Risk of mechanical trauma. For large and / or hard impaction: mineral oil enema, allow to absorb 1-3 hours, then give a phosphate enema. For small impaction: phosphate enema	
Mineral oil	Lubricates hard impaction. May not see return after administration.	16 oz / \$5
Phosphate	Abdominal cramping; Risk of hyperphosphatemia, hypokalemia and hypocalcemia especially with Hirschsprung’s or renal insufficiency or if retained. NOT recommended for children < 2 years old.	1.5 oz / \$4
Milk of molasses: 1:1 milk:molasses	For difficult to clear impaction. Because of report of cardiopulmonary decompensation, this procedure is best done in an emergency room or facility where complications can be appropriately managed.	
<u>Suppository</u> : every 12-24 hr x 1-3 days		
Glycerin: < 6 years, one infant suppository; ≥ 6 years, one adult suppository.		25 / \$3
Biscodyl: 1–<2 years, one 5 mg suppository; ≥2–<6 years, one 5 or 10 mg suppository; ≥ 6 years one 10 mg suppository.	Biscodyl: Abdominal cramping, diarrhea, hypokalemia	12 / \$4
<u>Oral/NG</u> : Polyethylene glycol electrolyte solution (Golytely or Nulytely) - 25 cc/kg per hr up to 1000 cc/hr until clear or 20 cc/kg per hr x 4 hr/day	Nausea, cramping, vomiting, bloating, aspiration, pneumonia, Mallory-Weiss tear. Large volume. Usually requires nasogastric tube and hospitalization to administer.	Golytely4L / \$18 Nulytely4L / \$25

* Approximate Retail Cost - May vary from store to store. The cost of Brand Name products is calculated as AWP -10% based upon pricing obtained from the 5/08 Amerisource Bergen product catalog. The cost of generic products is calculated as MAC plus \$3.00 based upon the Michigan Department of Community Health M. A.C. Manager, 5/08.

Table 8. Dietary Education

Infants (< 1 year)
Juices Sorbitol-based juices (e.g., prune, pear and apple) increase the water content of stools.
Children (> 1 year)
Fiber Amount of daily dietary fiber: <ul style="list-style-type: none">• Standard recommendation: 5 grams plus child age in years. Example: for child age 6 years, (5 grams + [age] 6) = 11 grams.• For children with functional constipation, some experts recommend: 10 grams plus child age in years. Example: for child age 6, (10 grams + [age] 6) = 16 grams. Sources for information on fiber: <ul style="list-style-type: none">• Parent handout for fiber content of common foods.• Additional fiber information is available at http://www.slrhc.org/healthinfo/dietaryfiber/index.html Provide education about: <ul style="list-style-type: none">• Reading food labels for fiber amount per serving (see parent handout).• How to plan meals and snacks to reach fiber goals (target \geq 3 fiber grams/meal). Fluid Target 2 ounces of non-dairy fluids for each gram of fiber intake. Examples: For a target of 11 fiber grams; 11 grams x 2 ounces = 22 ounces. For target of 16 fiber grams; 16 grams x 2 ounces= 32 ounces. Increase non-dairy fluid intake throughout the day: <ul style="list-style-type: none">• Provide extra opportunities such as a water bottle at school.• Pair water intake with fiber foods Juices Sorbitol-based juices (e.g., prune, pear and apple) increase the water content of stools. Monitor absolute and relative amounts of juice: <ul style="list-style-type: none">• Avoid juice intake volumes that are higher than AAP recommendations for children.• Encourage greater water intake over juice intake to meet daily clear fluid guidelines. Calcium Review daily calcium requirements for age and suggest alternative sources particularly if restricting dairy intake (see Parent Handout)

Table 9. Behavioral Training

1. **Documentation.** Document all stool passage on a chart or calendar. The time, amount and location of stool productions (e.g. in diaper, pants, toilet, other) and soiling/accidents provides important information about the course of the maintenance program and the likelihood of stool impaction. Medium or greater stool outputs, 1 – 2 times daily and no soiling suggest no impaction. Small stool outputs, a frequency less than every 3 days and/or an increase in soiling may suggest incomplete stool evacuation and increased risk of stool impaction. Several small outputs followed by infrequent large outputs may also suggest stool withholding. The documentation may suggest the best times for toilet sits for stool production.
2. **Routines.** Institute positive toileting routines:
 - Regular toilet sit times (e.g., after meals, at bedtime)
 - 2 to 4 times per day, about 5 minutes each
 - Most children benefit from minimizing distractions during toilet sits (e.g., handheld games, books) so they can attend to the ‘business’ of toileting.
 - Encourage children to sit on the toilet and complete their toilet sit independently.
3. **Body position.** Demonstrate proper toilet sitting position (upper body flexed forward slightly at the hips), and use of foot support. Encourage children to practice relaxing the pelvic floor (deep breathing with long, slow breaths) before tummy pushes.
4. **Praise.** Praise the child for cooperation with the various components of treatment.
 - Incentives/rewards are often useful and needed in conjunction with charts to motivate toilet sitting and stool production.
 - Immediate positive rewards work best for younger children (e.g., less than 6-7 years old). Older children (e.g., older than 7 years) can accumulate stickers over the course of the day or week to be exchanged for special activities.
 - Positive contingencies / rewards will likely be needed over time to maintain a child’s motivation during the maintenance phase. Thus, “big-ticket” items or activities are generally not recommended nor practical. Rather, use access to salient, everyday privileges that are not typically available (ie., TV, gameboy, 15 minutes later bedtime).
5. **Attitude.** Maintain a neutral to positive attitude around toileting and the child’s progress.
 - Use planned, positive and negative contingencies in a business-like manner to motivate the child’s behavior and address resistance. For example, toilet sitting at a scheduled time allows a favorite activity to follow. Refusal to sit on the toilet leads to the loss of the favorite activity until the next scheduled sitting.
 - Avoid struggles, arguments, and conflict.
 - Avoid using negative terms when describing stool/toileting (e.g., gross, yucky).
6. **Example.** Set a good example for the routines of learning, eating, exercise and toileting.
7. **Avoid negatives.** Avoid punitive approaches and embarrassment.

Table 10. Maintenance Medications

Medication	Side Effects / Comments	Cost*
Infants (< 1 year)		
Oral Medications / Other		
Juices containing sorbitol	Pear, prune, apple, grape	
Lactulose or Sorbitol: 1-3 cc/kg/day ÷ doses bid	See below	Lactulose 70% 480 ml / \$10 Sorbitol 70% 480 ml / \$7
Corn syrup (light or dark): 1-3 cc/kg/day ÷ doses bid	Not considered risk for Clostridium botulinum spores	
Glycolax 0.8 - 1.0 g/kg/day	See below	
Barley malt extract: 2-10 cc/240 cc milk or juice		
Barley water (available as Barley teabags)	Used in Asian cultures	
Children (> 1 year)		
Oral Medications		
<u>Osmotic</u>		
<u>Retains water in stool aiding bulk and softness</u>		
Glycolax (polyethylene glycol powder): 17 g/240 cc water or juice stock, 1.0 g/kg/day ÷ doses bid (approximately 15 cc/kg/day)	This is starting dose. Titrate at 2-3-day intervals to achieve 1-2 <i>mushy</i> stools per day. Reduce dose if stool consistency is liquid or diarrhea-like. May make stock solutions to administer over 1–2 days. Flatus but excellent adherence. No risk of dependence	255 gm / \$18
Lactulose: 10g/15cc, 1-3 cc/kg/day ÷ doses bid	Synthetic disaccharide; Abdominal cramping, flatus	480 ml / \$10
Sorbitol: 1-3 cc/kg/day ÷ doses bid	Less costly than lactulose	480 ml / \$7
Magnesium hydroxide (milk of magnesia): 400mg/5cc, 1–3 cc/kg/day ÷ bid 800mg/5cc, 0.5-1.5cc/kg ÷ bid	Risk of hypermagnesemia, hypophosphatemia, secondary hypocalcemia with overdose and/or renal insufficiency.	12 oz / \$3
<u>Lubricant</u>		
<u>Softens stool and eases passage.</u>		
Mineral oil: 1-3 cc/kg day as one dose or ÷ bid (Also Kondrumel – plain emulsion)	Aspiration – lipid pneumonia Chill and/or give with juice. Adherence problems. Leakage: dose too high or impaction.	16 oz / \$5
<u>Stimulants^a</u>		
<u>Improves effectiveness of colonic and rectal muscle contractions</u>		
Senna: syrup – 8.8gm sennoside/5cc 2-6yr: 2.5-7.5 cc/day ÷ doses bid 6-12yr: 5-15 cc/day ÷ doses bid (Tablets and granules available)	Idiosyncratic hepatitis, Melanosis coli, hypertrophic osteoarthropathy, analgesic nephropathy. Abdominal cramping. Melanosis coli improves after medication stopped.	8 oz / \$17 tab: 20 / \$4 grn: 6 oz / \$30
Bisacodyl: 5 mg tablets, 1-3 tablets/dose 1-2 x daily	Abdominal cramping, diarrhea, hypokalemia.	25 / \$4
Per Rectum		
Glycerin suppository: 1-2 x daily	No side effects	25 / \$3
Bisacodyl: 10 mg suppositories, 0.5 – 1 suppository, 1-2 x daily	Abdominal cramping, diarrhea, hypokalemia	12 / \$4

Note: Single agent may suffice to achieve daily, comfortable stools. * Approximate Retail Cost - May vary from store to store. The cost of Brand Name products is calculated as AWP -10% based upon pricing obtained from the 5/08 Amerisource Bergen product catalog. The cost of generic products is calculated as MAC plus \$3.00 based upon the Michigan Department of Community Health M.A.C. Manager, 5/08.

^a Stimulants should be reserved for short-term use.

Rationale for Recommendations (continued)

The term encopresis (fecal incontinence or ‘soiling’) describes voluntary or involuntary passage of formed, semi-formed or liquid stool into a place other than the toilet at regular intervals (\geq once per month) after 4 years of age. This Guideline addresses the diagnosis and management of functional constipation with or without soiling. Encopresis without constipation (non-retentive fecal incontinence) is not addressed.

Etiology

Chronic constipation often follows an acute stool problem that was not managed adequately. In one study, 63% of children with constipation and soiling had painful defecation that began before 3 years of age. Stool withholding may occur to avoid further pain. Painful defecation may be a consequence of hard stool, rash at the buttocks or fissures and lead to incomplete emptying and a build up of stool in the rectum. Stool becomes firmer as re-absorption of fluids continues. Stool retention and impaction stretch the rectum and colon and over time, several physiologic consequences occur i.e., diminished sensory threshold in the rectum for standard stool volumes and weakened rectal and sphincter musculature.

Soiling is a consequence of these physiologic alterations. This ‘soiling’ of stool reflects an overflow of liquid or formed feces from an impacted rectum for a majority of children. A minority of children may present with soiling without a history or signs/symptoms of constipation which should alert the practitioner to an underlying gastrointestinal, neuromuscular, developmental - behavioral or psychiatric disorder.

Diagnosis

Constipation may be defined according to stool frequency, character and ease of passage. (Table 3) Children less than 3 years old most often present with pain at defecation, impaction and withholding; children over 3 years of age most frequently present with soiling, impaction and withholding.

A careful history and physical exam excludes other diagnoses in the differential for the majority of patients. Table 4 lists symptoms and signs common to children with functional constipation and soiling and Red Flags for conditions in the differential diagnosis or that are associated with functional constipation. (Tables 4 & 5). Delayed meconium passage, infrequent stool passage with rare interval soiling, constipation in the first 2 to 3 months of life, abdominal distention, bloody diarrhea, and failure to thrive may indicate Hirschsprung’s disease. Hirschsprung’s disease occurs in 1:5000 children and is usually apparent in infancy (40% by 3 months, 61% by 12 months, and 82% by age 4 years). Irritable bowel syndrome affects about 0.2% of children in a primary care setting (Table 3). Infant dyschezia describes the symptoms of crying and straining in an otherwise healthy infant less than 6 months due to

problems coordinating the relaxation of the pelvic floor when straining to defecate (Table 3). Medications or environmental exposures, which may contribute to constipation, should be elicited. Developmental history may suggest concurrent developmental delay, autism or another behavioral disorder.

The abdominal exam is positive for stool impaction in about one-half of patients. Firm, packed stool in the rectum has a positive predictive value of $>84\%$ for the finding of impaction. *At least one rectal examination is indicated* for every patient with constipation to assess sphincter tone, size of the rectal vault and to determine if stool impaction is present. The rectum may be empty if the child recently evacuated stool. The rectal exam is also important to assess for anatomic abnormalities, rectal prolapse, anal stricture, anal fissures, perianal erythema and rectal mass. However, we agree with other expert panels that the digital rectal exam can be deferred to a follow up visit if the doctor-patient relationship is new or there are other concerns (e.g., history of sexual abuse, oppositional behaviors). Abdominal X-ray is not required, but may be needed to adequately assess children who are overweight or uncooperative. The neurologic exam should include the assessment of abdominal and cremasteric (males) reflexes, anal wink and lower extremity deep tendon reflexes to evaluate for underlying neurologic dysfunction (Table 4). An MRI is recommended if there are signs or symptoms of spinal abnormalities. If uncertain, consider referral to an appropriate pediatric specialist (e.g., gastroenterologist, neurologist, neurosurgeon) to decide about the need for MRI of the lumbosacral spine.

Treatment

On average, one-half to two-thirds of children with functional constipation with or without soiling recover (are able to wean medication support). The rate of recovery is improved if children begin intervention early after symptom onset. A combination of behavioral training and laxative therapy affords earlier remission for a majority of subjects.

Treatment includes child / family education, cleanout of stool impaction (if present) and a maintenance phase to allow rehabilitation of the rectal musculature. The maintenance phase includes dietary, behavioral and medication components. Successful treatment usually requires a minimum of 6 months.

General Education. (Table 6) Experts highlight the importance of explaining the physiologic basis of constipation and soiling to the child and family with two goals - to alleviate blame and to enlist cooperation. Most experts also agree that education improves family adherence to the treatment plan. Education may be aided by the use of pictures to describe the gastrointestinal tract and the changes that occur with this condition.

Clean out - Disimpaction (Table 7). An impaction is a mass of stool (often hard and large) in the rectum. A

successful maintenance phase requires that impactions are cleared. Child and family adherence to the recommended clean-out approach may be aided by discussing the options with them. Ask families about their comfort with and the ease of past oral or rectal medication administration. The provider may wish to demonstrate effective administration procedures in the office. If this is true:

- Involve the child and caretaker in the process.
- Discuss the steps.
- Allow points of choice and control for the child.
- Praise all signs of cooperation.
- Use desensitization visits if needed to accomplish parts of the procedure in a positive manner (e.g., 1st step get up on table, 2nd step - have pants down, 3rd step - accept touch on buttocks).

No randomized-controlled studies compare clean out methods. The choice of the cleanout method will depend on the child's age, and the previous experiences of the child and family. For many children, a clean out over two or more days with maintenance medications at higher doses works adequately. However, this may increase the risk of soiling for the child. One of these approaches is high-dose mineral oil; 15-30 cc per year of age per day up to 8 oz. X 3-4 days. Faster approaches (over 1-2 days) include enemas alone and combinations using enema, suppository and oral laxatives. If enemas are chosen, the guideline panel recommends that the number and type depend on the estimated size and firmness of the impaction. An adult-size enema is often needed to effectively relieve an impaction for children (preschool age and older) with chronic constipation.

If the impaction is large and hard, give a mineral oil enema first to soften and lubricate the stool. The fluid from this enema may not return. After one to three hours, give a phosphate enema. The fluid from this enema should return. Instruct the family to call your office if giving a hypertonic phosphate enema, and there is no return of stool/fluid (due to risks of hyperphosphatemia). One to three phosphate enemas given at 12 to 24-hour intervals, may be required to relieve the impaction.

If a milk of molasses enema is considered for difficult to clear impaction, *do the procedure in an emergency room or facility where complications can be managed due to report of cardiopulmonary decompensation.*

Ask the family to document the amount and character of the stool returned. Review this information along with repeat physical exam to determine the efficacy of cleanout at a visit within 1-2 weeks.

If minor re-impaction occurs, (no output within 48 hours), one enema is usually sufficient to clean out retained stool.

Maintenance Phase. (Tables 8, 9, 10) The purposes of the maintenance phase are to promote regular and adequate stool productions and prevent re-impaction so that bowel rehabilitation can occur. The maintenance phase includes dietary, behavioral, and medication components. A multi-

modal approach affords earlier remission for most children. Implement the components of the maintenance program systematically and sequentially. Learning new behaviors and modifying old ones in all areas at once can be a daunting task. Allow the child and family to work on one behavior at a time, over the course of several weeks. This will improve the likelihood of the family incorporating all the steps of the maintenance phase into a daily routine.

Dietary Education (Table 8):

Although the importance of dietary education has not been determined separately, most experts include this as a component of the maintenance phase of therapy. Dietary education includes:

- How to improve fiber and water intake
- How to read nutrition labels (see Parent Handout)
- Review daily calcium requirements and sources (see Parent Handout)

Fiber. Increasing dietary fiber may improve the frequency of bowel movements. Ongoing dietary advice is required to maintain improved fiber intake. Children may achieve greater daily fiber intake by changes in the types of foods they consume (e.g., increase in fruits and vegetables) or with the addition of fiber supplements (e.g., bran, Benefiber®, FiberSure®). A combination of changes (types of foods children eat and the addition of fiber supplements to low fiber foods) may improve the variety of the diet and help children and families maintain dietary changes over time.

High fiber intake does not adversely affect biochemical and anthropometric indicators of nutritional status. However, increasing high fiber foods (which may displace other foods) as well as recommendations to decrease the consumption of potentially constipating foods (e.g., dairy), may lead to deficits in specific nutrients. A brief 24-hour recall interview of the foods children ate prior to their medical appointment can assist careful monitoring of diet and nutrition. Target child age in years + 5 to 10 as the number of fiber grams per day.

Fluid. To maximize the benefits of a high fiber diet, at least 2 ounces of non-dairy fluids are recommended for each gram of fiber intake.

Dairy. Data are insufficient to recommend elimination of dairy products for most children with chronic constipation. However, this may be considered for children with coincident symptoms of rash, rhinitis or bronchospasm and elevated IgE antibodies to cow's milk antigens or as a time-limited trial in children unresponsive to conventional treatments.

Several studies suggest that constipation in infants may be due to cow's milk protein. In these studies, perianal irritation symptoms preceded the constipation leading to pain at stool passage and withholding. In one study, 68% of the children responded to a "prescription formula" without cow's milk protein. Since 30% of cow's-milk-protein-allergic children may be allergic to soy protein, they may

not respond if changed to a soy formula. Most allergic children will develop tolerance to cow's milk protein by 1-3 years of age. Commercially available cow's milk formulas differ from each other in the percentages and form of protein, lipids and carbohydrates which may affect tolerance.

Alternative treatments: Some commonly advocated treatments include the following:

Probiotics and prebiotics. Probiotics are nonpathogenic bacteria that modulate the gut and systemic immune system (e.g., lactobacillus, bifidobacterium). In breast fed infants, gastrointestinal flora includes such probiotics, as does yogurt and other fermented milk products. Prebiotics are non-digestible foods that stimulate the growth of bacteria that remain in the gut and act as probiotics. Recent infant formulas may include probiotics; more studies are needed to assess the relationship of these agents to the risk for constipation or the benefits for treatment.

Inulin and hydrolyzed whey protein. Infant formulas supplemented with inulin and partially hydrolyzed whey protein have been demonstrated to soften stools.

Behavioral training (Table 9 & Patient Handout): Behavioral training includes activities for child and parent. Documentation of the time, location, character and volume of stool productions helps the parent and physician evaluate the efficacy of the maintenance phase and choose sit times that will be most productive. Children are often more compliant with regular sit times if desired activities follow. Positive reinforcement for desired behaviors and neutral response for undesirable behaviors are recommended.

Medications to promote stool regularity (Table 10):

Lubricants or osmotic laxatives are often required to promote 1-2 regular soft, 'mushy' stools daily. Children treated with medications along with behavioral treatment achieved remission sooner than children who received behavioral treatment alone. Commonly used medications and recommended doses are provided in Table 10. Glycolax (Miralax®) is particularly effective, perhaps in part due to better adherence. Children tend to drink it without difficulty because the taste and consistency are usually well tolerated. This medication can be titrated by increasing or decreasing the number of ounces given (of the 17 gram per 8 oz standard solution) or by measuring the Glycolax in teaspoons (17 grams=5 teaspoons).

General medication suggestions:

- Develop a schedule (same time of day or within a daily routine) for medication administration.
- Medication should be titrated to give 1 - 2 soft, 'mushy' stools per day. 'Mushy', very easily passed stools may be important for complete evacuation, especially for children with signs of withholding.
- Some children require the use of a lubricant and an osmotic laxative together to assure complete stool passage.

- Stimulant laxatives may be required for short periods for children with severe and difficult to treat constipation.

Reduce the risk of relapse. Treatment failure occurs in about 20% of children and may occur due to adherence problems or sub-optimal treatment with re-impactions. Risks for re-impaction, (decreased stool frequency, firmer stools and withholding) may occur with changes in routine (holidays, vacations) or health (dehydration, medications). Therefore, it is important to develop specific plans for:

- Tracking stool productions and soiling episodes;
- Identifying problematic changes in stool pattern; and
- How to intervene if such problems occur.

While no studies examine adherence and outcome for pediatric constipation, the consensus of the guideline panel is that adherence to dietary, behavioral and medication strategies is important to success. The consensus is based on studies of adherence in other pediatric chronic medical conditions and the experiences of guideline panel members. Adherence may be aided by asking the family to closely track components of the maintenance phase. These records can be reviewed with the physician and problems discussed. Close tracking (especially for stool production) may be needed until medication support is weaned. The family should communicate with the medical provider if a change in stool pattern is noted. Sample stool charts are provided in the Parent Handout.

Follow-up Most experts suggest frequent follow up to assess adherence and adequacy of treatment. No studies suggest specific follow up times. However, the panel suggests follow-up every 1 to 2 weeks during clean out and early maintenance phase, then at monthly to 3-month intervals until medication is weaned.

Recovery in studies of constipation is often defined as ≥ 3 stools / week with no soiling. However, recovery in practice includes return of rectal sensation for standard stool volumes so that independent toileting occurs (for developmentally-able children) and medication is successfully weaned.

No studies suggest the most effective method to withdraw medication support. This guideline panel suggests that medication is *weaned over several months* while maintaining the progress achieved with dietary and behavioral treatments. Tracking of stool outputs is important to assure adequate frequency of stool production.

Studies have reported recovery in 50 to 70% of children by 1 to 6 years from diagnosis. In one study, 50% of children were off laxatives in 1 year and an additional 20% were weaned by 2 years. However, others suggest the rate of improvement is small after 6 to 12 months of treatment and failure to improve during the first 2 weeks predicts treatment non-responders at 3 months.

Referral to Consultants

If there are signs or symptoms of a condition in the differential diagnosis, consider referral to the appropriate subspecialty provider (see Table 5). If the constipation and soiling symptoms are not resolved by a given treatment for six months, a different or more intensive intervention should be considered. A referral to Pediatric Gastroenterology, Developmental Behavioral Pediatrics, Pediatric Psychology or Child Psychiatry may be warranted. A referral to Pediatric Gastroenterology, Neurology or Neurosurgery is recommended if the constipation problem is refractory and if an underlying spinal cord problem is suspected or an MRI evaluation is considered.

Relevant National Guidelines

This guideline is consistent with:

Evaluation and treatment of constipation in infants and children: Recommendations of the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition. *Journal of Pediatric Gastroenterology and Nutrition*, 2006; 43(3): e1-e13.

Strategy for Literature Search

The literature search for this update began with the results of the previous MEDLINE searches performed for earlier versions of this guideline. The initial search was performed from 1987 through 1996 for the original 1997 version of the guideline. A second search of literature from 1997 through May 2001 was performed for the 2003 update.

For this update, new MEDLINE searches were performed for three time periods. For all searches, the population was children (infancy to 18 years) and the results were limited to English language. The major key words were: constipation (e.g., constipation, idiopathic constipation, encopresis, fecal incontinence, soiling), clinical trials (e.g., clinical trials, cohort studies, meta-analysis), and guidelines (e.g., clinical protocols, practice guidelines, consensus development conferences).

Search 1. The North American Society for Pediatric Gastroenterology, Hepatology and Nutrition searched literature through September 2004 in preparing and reporting its 2006 guideline (see above). That search was accepted as our base for several topics, which we supplemented with a search of literature from 2004 to May 15, 2007. Topics included in this search included: symptoms (e.g., infrequent stool; painful defecation; withholding; hard stool; soiling, abdominal discomfort; impaction; palpable stool in abdomen or rectum); coexisting conditions (e.g., lead poisoning, codeine, ritalin, chemotherapy), confused conditions (e.g., Hirschprung's disease, pseudo obstruction syndrome, spinal cord abnormal, hypothyroidism, diabetes insipidus), evaluation and testing T4, TSH, calcium, lead, Celiac disease

antibodies; stool test for occult blood; rectal biopsy; abdominal radiograph; transit time), diagnosis, medications (e.g., bismocodyl, oral laxatives, rectal suppositories, magnesium salts, lactulose, glycolax), enema (e.g., mineral oil, hypertonic phosphate, milk & molasses), and other treatments.

Search 2. The search performed by the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition did not address some topics included in our guideline. For the following topics the search was from 2001 (end of our previous search) to May 15, 2007: behavioral training (e.g., positive reinforcement, toilet habits), parental intervention or education, diet (e.g., fiber, fluid, milk, milk protein, dairy products, calcium), allergy (e.g., milk, milk protein), and other behavioral and dietary interventions.

Search 3. A search of literature from 1987 to May 15, 2007, was performed for a set of terms concerning not examined specifically in our previous searches: milk-protein intolerance or allergy, breast feeding, milk-based formula, soy-based formula, protein Hydrolysate (semi-elemental or acid based).

A complete list of search terms is available upon request.

The searches were conducted in components each keyed to a specific causal link in a problem structure. The search was supplemented with recent clinical trials known to expert members of the panel. The search was single cycle. When possible, conclusions were based on prospective randomized clinical trials. In the absence of randomized controlled trials, observational studies were considered. If none were available, expert opinion was used.

Disclosures

Neither the members of the guideline team nor the consultant have a relationship with commercial companies whose products are discussed in this guideline. These individuals are listed on the front page of this guideline.

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