



James M. Anderson Center for  
Health Systems Excellence

Evidence-Based Care Guideline  
**Prevention and Management of  
Acute Gastroenteritis (AGE)**  
In children aged 2 months to 18 years<sup>a</sup>

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### Target Population

**Inclusions:** This guideline is intended primarily for use

- in children aged 2 months to 18 years of age
- with signs and symptoms of acute gastroenteritis
- with or without accompanying nausea, vomiting, fever, or abdominal pain.

**Exclusions:** This guideline does **NOT** address all considerations needed to manage those with the following:

- toxic appearance, shock, or requiring intensive care
- episodes of diarrhea lasting longer than 7 days
- previously diagnosed disorders including immunodeficiency or those affecting major organ systems
- vomiting with no accompanying diarrhea for more than 24 hours
- AGE accompanying failure to thrive
- diarrhea and/or vomiting accompanied by chronic metabolic disorders (e.g. diabetes, PKU)
- diagnosis of hyponatremic or hypernatremic dehydration
- diarrhea caused by chronic disease

Diarrhea is defined as three or more loose, watery stools a day.

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### Target Users

Include but are not limited to (in alphabetical order):

- community-based caregivers (day care, school personnel)
- patient care staff (nurses, dietitians)
- patients / families
- physicians (emergency medicine, primary care, hospitalists, residents)

### Introduction

References in parentheses ( ) Evidence strengths in [ ] (See last page for definitions)

Acute gastroenteritis (AGE) is a diarrheal disease of rapid onset, with or without accompanying symptoms and signs, such as nausea, vomiting, fever, or abdominal pain (Colletti 2010 [5], King 2003 [5b]).

Prior to the release of rotavirus vaccines in 2006 and 2008 (see [Appendix 1](#)) significant illness burden in the United States (U.S.) was attributable to AGE, including:

- 12% of hospitalizations of children less than 5 years of age and about 10% of all visits to pediatric emergency departments (ED) (Yee 2008 [3a], Fischer 2007 [4a], Charles 2006 [4a]),
- approximately 1.5 million outpatient visits, 200,000 hospitalizations and 300 deaths annually (King 2003 [5b]),
- an annual associated direct cost of \$250 million, with indirect costs of lost work and day care/school of 1 and 2 days, respectively (Coffin 2006 [3a], King 2003 [5b]), and
- approximately one-third of this burden was attributed to rotavirus, which is more likely to cause severe clinical illness and dehydration than non-rotavirus AGE, (Mast 2010 [3a], Payne 2008 [3a], Yee 2008 [3a]).

Since the introduction of rotavirus vaccine, disease burden due to AGE, as measured by healthcare utilization and costs, has decreased substantially (Payne 2011 [3a], Cortes 2011 [4a]). See [Appendix 1](#) for information on the recent and increasing impact of rotavirus vaccine.

Because most patients included in this guideline will have self-limited viral or bacterial diarrhea, dehydration caused by the disease is the focus of treatment in this guideline. A 20% drop in emergency department (ED) visits for AGE was documented for the three year period following community-wide application of the original version of this guideline (Perlstein 2002 [4a]), and adherence to published care guidelines is associated with 50% lower charges in the ED and observation

**Table 1: Etiologic Agents for Pediatric Infectious AGE in the United States**

Pathogens	Inflammatory Agents	Non-inflammatory Agents
<b>Viruses</b> 75 to 90%		<i>Rotavirus</i> enteric adenovirus <i>Calicivirus</i> (includes <i>Norovirus</i> and <i>Sappovirus</i> ) <i>Astrovirus</i>
<b>Bacteria</b> 10 to 20%	<i>Salmonella</i> <i>Shigella</i> <i>Campylobacter jejuni</i> <i>Yersinia enterocolitica</i> enterohemorrhagic <i>E. coli</i> (includes O157:H7) *other diarrheagenic <i>E. coli</i> <i>Clostridium difficile</i>	
<b>Parasites</b> 0 to 5%		<i>Giardia lamblia</i> <i>Cryptosporidium</i>

(Vernacchio 2006 [2a], Fischer 2007 [4a], Elliott 2007 [5])

\*In Cincinnati, other diarrheagenic *E. coli* are the largest percentage of bacterial pathogens (Cohen 2005 [4a]).

population (Tieder 2009 [4a]). Though there is a low prevalence of AGE in older children (compared to prevalence in children less than 5 years of age) management of the condition is similar for children of all ages, and thus older children are included in the target population for this guideline.

Challenges in the management of AGE include:

- diagnosing degree of dehydration
- effective use of oral rehydration therapy
- limiting use of intravenous (IV) fluids and laboratory studies
- determining the appropriate role of antiemetics and probiotics
- prevention of AGE.

In the target population, the objectives of this guideline are to:

- decrease use of ED services for management of mild cases
- improve the likelihood that information provided by triage and school personnel is adherent to guideline recommendations
- reduce the length of stay in the ED and inpatient setting
- reduce the rate of hospitalization.

## Etiology

Infectious agents are the most common causes of AGE. Prior to the release of rotavirus vaccines in 2006 and 2008, viruses, primarily rotavirus species, have been responsible for 75 to 90% of infectious diarrhea cases in the developed countries. Various bacterial pathogens account for another 10 to 20% of cases; parasitic

organisms such as *Giardia* species are less common (Vernacchio 2006 [2a], Fischer 2007 [4a], Elliott 2007 [5]). See [Table 1](#) for etiologic agents of infectious AGE.

Incidence of rotavirus infections is affected by climate and season, chiefly presenting January through May (Mast 2010 [3a]). Risk factors for severe rotavirus infections in children include prematurity, age less than 24 months, attendance at day care, and low maternal socioeconomic status; breastfeeding is a protective factor (Lamberti 2011 [1a], Fischer 2007 [4a], Dennehy 2006 [4a]). However, due to rotavirus vaccine, rotavirus is rapidly decreasing in significance as an etiologic agent of AGE. The impact of this change will be discerned as the AGE disease burden shifts to other known, newly discovered and currently evolving diarrheal pathogens (Payne 2008 [5]). See [Appendix 1](#) for information on the recent and increasing impact of rotavirus vaccine.

## Guideline Recommendations

### Prevention

1. It is recommended that infants be immunized against rotavirus according to the Advisory Committee on Immunization Practices (ACIP) recommendations, including during mild AGE (Soares-Weiser 2010 [1a], Staat 2011 [3a], AAP 2009b [5], Cortese 2009 [5]). See [Appendix 1](#).
2. It is recommended that families be instructed on the benefit of:
  - hand hygiene in the prevention of transmission of AGE in the home and at day care (Ejemot 2008 [1a]), and

**Table 2: Clinical Dehydration Scale (CDS) for Children**

Characteristic /	Score: --- 0 ---	--- 1 ---	--- 2 ---
<b>General appearance</b>	Normal	Thirsty, restless, or lethargic but irritable when touched*	Drowsy, limp, cold, or sweaty; comatose† or not
<b>Eyes</b>	Normal	Slightly sunken	Very sunken
<b>Mucous membranes (tongue)</b>	Moist	Sticky	Dry
<b>Tears</b>	Tears	Decreased	Absent
Score of 0 = no dehydration; Score of 1 to 4 = some dehydration; Score of 5 to 8 = severe dehydration (Bailey 2010 [2b])			

\*The scale has been validated as presented above; however, local consensus is that the wording may be subject to misinterpretation (*Local Consensus 2011 [5]*). “Lethargic but irritable when touched” does not include those who are truly lethargic, for whom there is a greater concern.  
†This guideline is **not** for the child who is comatose, in which case treat according to patient specific clinical condition

- breastfeeding as a protective practice against severe AGE in infants (*Lamberti 2011 [1a]*, *Dennehy 2006 [4a]*, *Van der Wielen 2008 [5]*).

**Note:** Overall evidence demonstrates a protective effect of probiotics against AGE in children. Due to lack of specific evidence of cause of diarrhea, organism(s), dosage, and product availability, a specific recommendation for the use of probiotics in prevention of AGE is unable to be made (*Sazawal 2006 [1a]*, *Hojsak 2010a [2a]*, *Hojsak 2010b [2a]*, *Lin 2009 [2b]*).

## Assessment

### Clinical Assessment

3. It is recommended that the history and physical examination be the primary basis for the diagnosis of AGE (*Porter 2003 [3a]*, *Local Consensus 2011 [5]*, *King 2003 [5b]*).
4. It is recommended that weight on presentation be documented as a baseline to guide rehydration therapy if needed (*Steiner 2004 [1b]*, *Snaith 2008 [4b]*).  
**Note:** Acute weight loss based on a recent, documented pre-illness weight, as might be available in the office setting, is the most reliable measure of dehydration status on presentation (*Steiner 2004 [1b]*).
5. It is recommended that clinical assessment be initially performed for the presence and degree of dehydration (none, some or severe) (*Steiner 2004 [1b]*, *Duggan 1996 [2a]*, *King 2003 [5b]*). See [Table 2](#) for a Clinical Dehydration Scale (CDS), valid for children under age 5 years (*Friedman 2004 [2a]*).  
**Note 1:** Although the CDS is the tool with the most published evidence of validity, other clinical signs and symptoms have been shown to be helpful in diagnosing degree of dehydration, and severe dehydration can exist

even in the absence of a toxic appearance (*Gorelick 1997 [3a]*). See [Appendix 2](#) and [Appendix 3](#) for additional tools and information regarding clinical assessment for dehydration.  
**Note 2:** A meta-analysis of clinical signs and symptoms of dehydration in children identified abnormal capillary refill time as the most useful individual sign for predicting some dehydration (LR, 4.1; 95% confidence interval: 1.7, 9.8) against a gold standard of rehydration weight. As capillary refill time is not included in the CDS, it is prudent to include it in the routine assessment for dehydration (*Steiner 2004 [1b]*).

### Laboratory Studies

6. It is recommended that laboratory tests **not** be routinely performed in children with signs and symptoms of AGE; e.g. serum electrolytes, tests for specific pathogens, and urinary indices (*Steiner 2004 [1b]*, *Steiner 2007 [3b]*, *Local Consensus 2011 [5]*).  
**Note 1:** Serum electrolytes are sometimes useful in assessing children with dehydration and who require IV fluids. In the absence of evidence-based criteria to direct selective electrolyte screening, clinical judgment regarding when to obtain electrolyte studies is superior to routine screening in protecting children from unnecessary testing (*Steiner 2004 [1b]*, *Wathen 2004 [3b]*, *Parkin 2010 [4b]*, *Local Consensus 2011 [5]*, *Rhee 2005 [5]*, *Steiner 2005 [5]*, *Tarini 2005 [5]*).  
**Note 2:** Consider obtaining stool testing if there is a specific pathogen community outbreak; or for children who are less than 3 months of age, have grossly bloody stools, are immunocompromised, septic, toxic, or who have a history of foreign travel (*Guarino 2008 [5a]*). A specific pathogen community outbreak may trigger health department testing requirements prior to return to day care (*Ohio Administrative Code 2009 [5]*).

**Table 3: Suggested Directions for Use of Commercial ORS** -- see [Appendix 4](#) for specific product information  
(in addition to the use of the child's preferred, usual, and age appropriate diet and fluids)

Age of Child	Try to drink at least:	How?	How much? How long?
4 years or younger	5 to 10 mL every 5 min, or 30 to 60 mL in 30 min, or 60 to 120 mL in 1 hour	Frequent small sips from a bottle, cup, spoon, or syringe	<ul style="list-style-type: none"> <li>Continue for at least 3 to 4 hours or longer to reach a total ORS intake of at least 240 mL for younger children and at least 480 mL for older children.</li> <li>If stools are still very frequent and watery, continue drinking commercial ORS.</li> <li>Otherwise, continue as desired with usual diet with or without additional commercial ORS.</li> </ul>
5 years or older	10 to 20 mL every 5 min, or 60 to 120 mL in 30 min, or 120 to 240 mL in 1 hour	If no vomiting, less frequent larger sips are fine	

(Spandorfer 2005 [2b], Atherly-John 2002 [2b], Craven 2009 [4a], Local Consensus 2011 [5])

## Management

### Rehydration: Some or No Dehydration

- It is recommended that children with some or no dehydration, including those with recurrent vomiting, be managed by frequent phone or office/urgent care follow up and, on occasion, emergency department encounters (*Local Consensus 2011 [5], Guarino 2008 [5a]*).
- It is recommended, for the child with some or no dehydration:
  - use of the child's preferred, usual, and age appropriate diet and fluids (*Brown 1994 [1b], Fayad 1993 [2a], Alarcon 1992 [2b], Margolis 1990 [2b]*), and
  - offer commercial oral rehydration solution (ORS), if tolerated and if losses exceed intake, until an adequate degree of rehydration is achieved (*Hartling 2006 [1a], Fonseca 2004 [1a]*). See [Table 3](#) for suggested directions for use. See [Appendix 4](#) for information on specific ORS options.
  - offer about 10 mL/kg of ORS for each loose stool or vomiting episode (*Armon 2001 [5a]*).
- It is recommended that the following **not** be used:
  - restrictive or progressive diets (*Alarcon 1991 [2b], Margolis 1990 [2b], Khin 1985 [2b], Placzek 1984 [2b]*)
  - a clear liquid diet (*King 2003 [5b]*) (see [Appendix 4](#))
  - diluted milk or formula (*Brown 1994 [1b]*)
  - lactose-free formula, unless previously-known lactose intolerance is present (*Brown 1994 [1b]*).

### Rehydration when IV Therapy is Chosen

- It is recommended,
  - when unable to replace the estimated fluid deficit and keep up with the on-going losses using oral feedings alone, and/or
  - for severely dehydrated children, that a bolus of IV isotonic solution (i.e. lactated Ringer's solution or normal saline) be administered until signs of dehydration have been reversed.

### Suggested initial therapy:

- 20mL/kg body weight bolus over 30 to 60 minutes with reassessment and repeat if necessary (*Hartling 2006 [1a], Fonseca 2004 [1a], Nager 2010 [2b], Neville 2006 [2b], Spandorfer 2005 [2b], King 2003 [5b], Khanna 2009 [5]*).

**Note 1:** Two small studies by a single author demonstrated that initial bolus therapy at a rate of 50 mL/kg body weight is a viable alternative (*Nager 2010 [2b], Nager 2002 [2b]*).

**Note 2:** Nasogastric (NG) as compared to IV rehydration is as efficacious, is no more labor intensive, and is associated with fewer complications (*Rouhani 2011 [1b]*). For the purposes of this guideline NG may be substituted for IV rehydration, but due to its infrequent use at Cincinnati Children's Hospital Medical Center (CCHMC), it is not otherwise mentioned in this document. It is appropriate to involve the family in the decision regarding the selection of IV versus NG for fluid replacement.

### Oral and IV Fluids after Initial Rehydration Bolus

- It is recommended that the child treated with IV fluids continue, as soon as tolerated, with:
  - a preferred, usual, and age appropriate diet and fluids, which may include commercial ORS (*Fayad 1993 [2a], Cohen 1995 [2b], Fox 1990 [2b], Hjelt 1989 [2b], Khin 1985 [2b]*), and
  - about 10 mL/kg of ORS for each loose stool or vomiting episode (*Armon 2001 [5a]*).
- It is recommended that ongoing reassessment of hydration status and tolerance of oral rehydration therapy (ORT) be used to guide the need for and choice of IV fluids after initial isotonic bolus:
  - for the hydrated child able to tolerate ORT, discontinue IV therapy
  - for the child not fully hydrated upon reassessment, give additional isotonic fluids as a bolus

- for the hydrated child unable to tolerate sufficient ORT to replace losses
  - give half-normal saline with 5% dextrose at a maintenance volume plus calculated replacement for losses
  - after child begins to urinate (or if serum electrolytes are known to be normal) add 20 mEq/L potassium chloride

(Kannan 2010 [2a], Neville 2010 [2a], Montanana 2008 [2a], Yung 2009 [2b], Drysdale 2010 [4a], Hanna 2010 [4a], Snaith 2008 [4b], Holliday 1957 [5])

**Note 1:** Patients with abnormal plasma sodium levels or abnormal kidney function are excluded from the target population for this guideline and from all of the cited studies for this recommendation. Individual consideration for these patients is particularly important regarding maintenance fluids.

**Note 2:** The grade of the body of evidence is high for not using less than 0.45% saline during the first 24 hours of IV fluid therapy for children with normal kidney function (Kannan 2010 [2a], Yung 2009 [2b], Hanna 2010 [4a]).

### Inpatient Management

13. It is recommended that a child be admitted for inpatient care when:
- the child is severely dehydrated
  - the child has intractable vomiting
  - the child is unable to maintain hydration orally due to vomiting or diarrhea losses
  - caregivers cannot provide adequate care at home and/or there are social or logistical concerns
- (Local Consensus 2011 [5], Guarino 2008 [5a]).
14. It is recommended, if the child requires IV fluids for more than 24 hours, or if reassessment reveals evidence of fluid or electrolyte imbalance, that selection and adjustment of IV fluid and rate of administration be based on sound principles and ongoing reassessment including:
- frequent clinical assessment,
  - daily weights, and
  - regular electrolyte monitoring as clinically indicated, at minimum every 2 to 3 days
- (Neville 2005 [3b], Drysdale 2010 [4a], Moritz 2010 [5], Holliday 2007 [5], Guarino 2008 [5a]).
- Note:** Strict intake and output measurements (I/O) are ideal to guide therapy. However, standardized measured daily weights are less burdensome to obtain and are sufficient to guide therapy, while inaccurate I/O are inadequate (Drysdale 2010 [4a], Snaith 2008 [4b]).

### Adjunct Therapy

There is a growing body of literature establishing the effectiveness of selected probiotics as an adjunct to rehydration therapy in simple AGE. Proven efficacy is organism- and dose-dependent and there is no evidence of efficacy for most probiotic products (see [Appendix 5](#) for product information). In developed countries, *Lactobacillus rhamnosus* GG (LGG) given in a daily dose of 10 billion colony forming units per day (CFU/day) has proven efficacy, particularly in rotavirus, to reduce the duration of diarrhea, the risk of protracted diarrhea and the duration of hospitalization (Szajewska 2007c [1a], Guarino 2008 [5a]).

15. It is recommended to talk to parents before making a decision about probiotic use. If a family chooses to use a probiotic, it is important to assure selection of an effective product (see [Appendix 5](#)).

To obtain best efficacy:

- use a dose of at least 10 billion CFU/day of LGG (see [Appendix 5](#) regarding product availability)
- start treatment as soon as possible
- treat for a total of 5 to 7 days

(Szajewska 2007b [1a], Szajewska 2007c [1a], Guandalini 2000 [2a], Local Consensus 2011 [5], Guarino 2008 [5a], Harris 2008 [5a]).

**Note:** Parameters influencing the family's decision to use probiotics may include:

- cost
- evidence of benefit
- likelihood of rotavirus origin
- transmission concerns
- safety

(Allen 2010 [1a], Szajewska 2007c [1a], Guandalini 2000 [2a]). See [Appendix 5](#) for elaboration of these parameters.

### Other Therapy

16. It is recommended that antiemetics **not** be routinely used in the management of children with AGE

(Fedorowicz 2011 [1a], Szajewska 2007a [1a]).

**Note 1:** On 9/15/2011, the U.S. Food and Drug Administration (FDA) notified the healthcare community that ondansetron may increase the risk of developing prolongation of the QT interval of the electrocardiogram. Patients at risk for adverse outcomes include those with underlying heart conditions, such as congenital long QT syndrome, those who are predisposed to low levels of potassium and magnesium in the blood, and those taking other medications that lead to QT prolongation (Mehta 2010 [2b], FDA 2011 [5], McKechnie 2010 [5]).

**Note 2:** Shared decision making may be employed in the consideration of ondansetron use in children with vomiting. Discussion points may include:

- its use may decrease vomiting during the first hours after presentation
- its use may decrease the need for IV fluids in the emergency department
- its use may reduce hospitalization rates in those patients who require IV fluids
- its use may increase diarrheal episodes
- it has a relatively high cost
- most studies of ondansetron use in children with AGE have
  - been performed only on mildly dehydrated children
  - received funding from the manufacturer of ondansetron
- its use may increase risk for long QT interval (Fedorowicz 2011 [1a], DeCamp 2008 [1a], Szajewska 2007a [1a], Yilmaz 2010 [2a], FDA 2011 [5]).

17. It is recommended that antimicrobial therapies **not** be used except for cases of culture-proven pathology (Barbara 2000 [3a], Szajewska 2010 [5]). See AAP Red Book for specifics (AAP 2009a [5]).

18. It is recommended that antidiarrheal agents **not** be routinely used in the management of children with AGE (King 2003 [5b], Khanna 2009 [5]).

### Discharge Criteria

19. It is recommended that for children receiving care in a hospital setting, prompt discharge be considered when the following levels of recovery are reached:

- sufficient rehydration achieved as indicated by weight gain and/or clinical status;
- IV fluids not required;
- oral intake equals or exceeds losses;
- medical follow up is available via telephone or office visit; and
- adequate family teaching<sup>b</sup> has occurred, including
  - hand hygiene at home, day care and elsewhere (see Recommendation #2) for prevention of AGE transmission
  - expected course of illness
  - prevention of dehydration
  - signs of dehydration

(Local Consensus 2011 [5]).

<sup>b</sup> See Health Topic at <http://www.cincinnatichildrens.org/health/g/gastroenteritis/>

### Return to Social Life

20. It is recommended that a child with diarrhea of infectious or unknown cause return to day care only when transmission can be reliably prevented, preferably after the diarrhea has ceased (Local Consensus 2011 [5], Ohio Administrative Code 2009 [5]). At minimum:
- stools are more formed
  - stools are not leaking out of the diaper
  - frequency of diaper changes are able to be handled by day care staff
  - for the toilet trained child, the child can make it to the bathroom without soiling
  - good hand hygiene is practiced by day care staff.
- Note:** Negative testing for certain pathogens may be required by law or by the day care facility (Local Consensus 2011 [5], Ohio Administrative Code 2009 [5]).

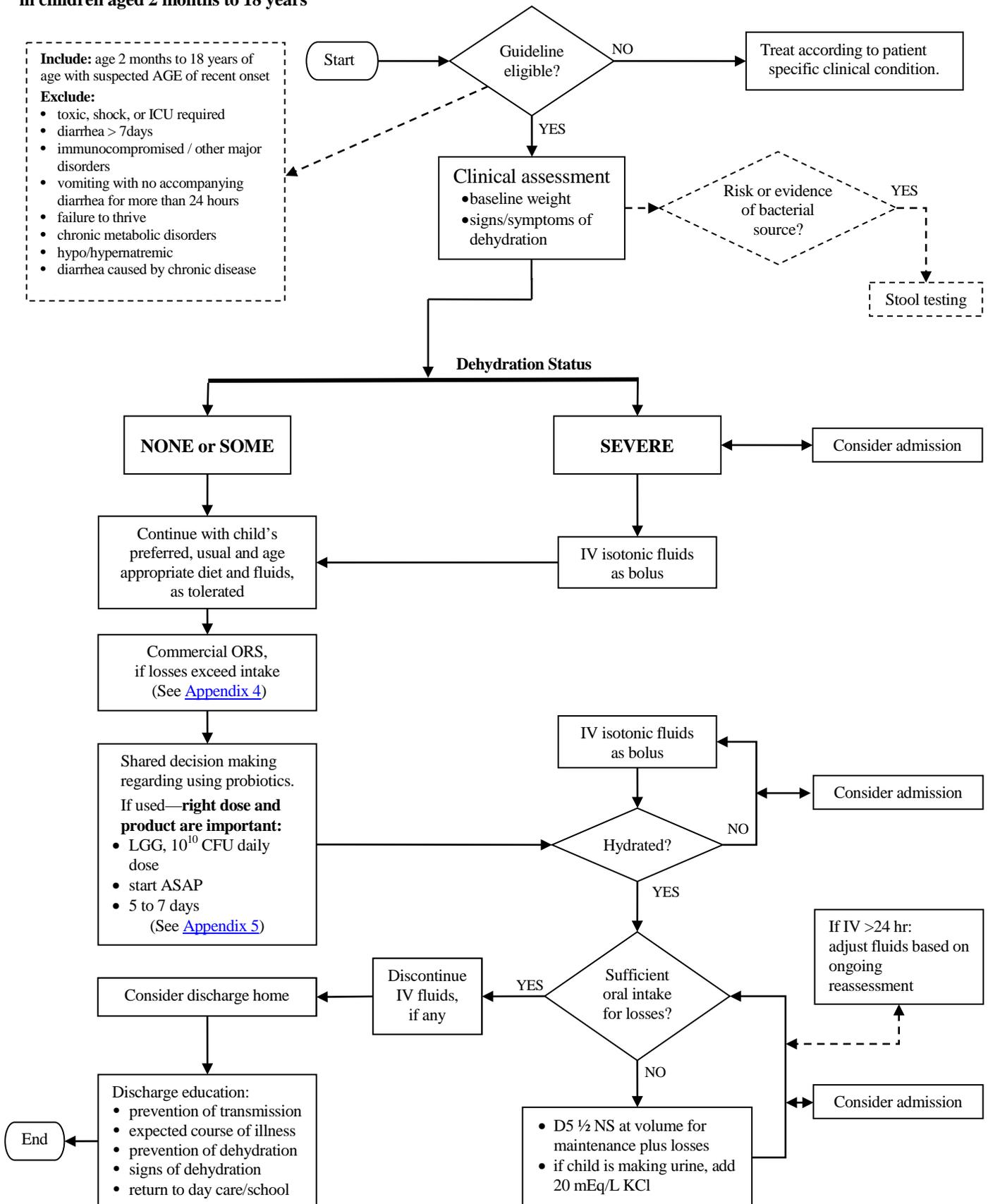
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### Research Agenda

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1. In the U.S., how will increasing rotavirus vaccine coverage change the epidemiology of diarrhea in children?
2. Among young children attending day care in the U.S., is the use of prophylactic probiotics, compared to placebo, effective in reducing incidence of AGE?
3. Among U.S. children with AGE, are there probiotic organisms (products), other than LGG (Culturelle), that are effective in improving AGE outcomes?
4. Among U.S. children at risk of poor nutritional status, does zinc supplementation, compared to placebo, reduce incidence and severity of AGE?
5. Among U.S. children at risk of poor nutritional status, does therapeutic zinc administration, compared to placebo, reduce duration of AGE?

### Algorithm for evaluation and management for Acute Gastroenteritis (AGE) in children aged 2 months to 18 years



## Appendix 1: Rotavirus and the impact in the U.S. of the new vaccine

### Burden of Rotavirus, Pre-Licensure Era

Previous to the introduction of the rotavirus vaccines in 2006 and 2008, about 22% to 54% of the AGE burden in the U.S. could be attributed to rotavirus. Rotavirus AGE is more likely to cause severe clinical illness and dehydration than non-rotavirus AGE, and generally presents in a season that peaks in February through April (*Mast 2010 [3a], Payne 2008 [3a], Yee 2008 [3a], Malek 2006 [4a]*). The case-fatality rate for ICD-9 coded rotavirus in the U.S. during 2001-2003 was 48.4 per 100,000 (*Fischer 2007 [4a]*). Rotavirus hospitalization rates in Cincinnati during the 2006 and 2007 rotavirus seasons were 30.9 and 16.8 per 10,000 population, respectively. The emergency department visit rates for rotavirus in Cincinnati during the same seasons were 401.5 and 400.9 per 10,000, respectively (*Payne 2010 [3a], Payne 2009 [3a]*).

### Vaccination Rates

Rapidly increasing coverage for children under age 5, which was still less than 50% in 2009, makes it difficult to estimate current vaccination rates for rotavirus (*Cortes 2011 [4a]*). If rotavirus coverage follows the experience of the pneumococcal conjugate vaccine uptake, rates for 2 or 3 doses may achieve over 90% coverage by 2013 (*Wooten 2010 [4a]*).

### Vaccine Effectiveness and Impact on Burden

Early analysis of monitoring and administrative data during the seasons following the release of a rotavirus vaccine in the U.S. demonstrated decreases of rotavirus infection and associated hospitalization at rates at least as good as expected (*Staat 2011 [3a], Clark 2010 [3a], Cortes 2011 [4a], Curns 2010 [4a], Wang 2010 [4a], Cortese 2009 [5]*). There was also a delay in the start and a reduction in the duration of the season (*Tate 2011 [4a], Staat 2008 [4a]*). Natural annual variation and incomplete coverage of the susceptible cohort confounded conclusive findings of the vaccine's impact which will become more clear with each rotavirus season (*Payne 2009 [3a], Cortese 2010 [4a], Flores 2010 [4a]*).

Specific surveillance and monitoring data in Cincinnati through the 2008 -2009 season demonstrated marked declines of rotavirus infection hospitalization rates among children 3 to 35 months of age, with rates well below 10 per 10,000 population (*Payne 2011 [3a]*).

A recent report on rotavirus activity in 2009-2010 confirms the sustained decline in rotavirus AGE in the U.S. Surveillance laboratories in the Midwest reported a 91% decrease in the proportion of positive rotavirus tests for the 2009-2010 season compared to the annual median for the six seasons prior to the vaccine's introduction. This is a marked change even compared to the first two post-licensure seasons. The *a priori* definition of the start of the season<sup>c</sup> was met neither nationally nor for three of the four U.S. census regions, including the Midwest, and rotavirus activity peaked during May (*Tate 2011 [4a]*).

### Cost-Effectiveness

Post-licensure studies after the first two seasons of use show decreases in costs of 55% to 75%, including medical costs (e.g. ED and hospitalization) and non-medical costs (e.g. lost earnings and family expenses to care for a child with AGE). However, these reductions are not predicted to offset the cost of the vaccine at its current price (*Widdowson 2007 [2a], Wang 2010 [4a], Plosker 2011 [5]*).

### Safety

Because the first rotavirus vaccine was withdrawn in 1999 due to an association with intussusception, attention to possible adverse events, including intussusception, was given serious attention in clinical trials during the development of the two current vaccines. A meta-analysis of safety and efficacy studies concludes that the currently licensed vaccines are not associated with increased numbers of fatal adverse events, and that there was little difference between the vaccine and placebo groups for other serious adverse events, including intussusception (*Soares-Weiser 2010 [1a]*).

### Clinical, Administrative, Public Health and Research Implications

Ambulatory clinical settings will experience the greatest impact of decreased incidence and severity of AGE during the traditional rotavirus season, with inpatient settings also receiving noticeable benefit by a reduction in both admitted and nosocomial cases (*Anderson 2011 [2a]*). Anticipation of this decrease may help 1) redirect resources ordinarily committed to care of young children with AGE, 2) direct surveillance activities and other public health initiatives, and 3) direct selection of appropriate research questions (*Flores 2010 [4a], Weinberg 2010 [5]*).

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<sup>c</sup> The National Respiratory and Enteric Virus Surveillance System (NREVSS) definition of the rotavirus season onset is the first of two consecutive weeks during which the percentage of specimens testing positive for rotavirus was  $\geq 10\%$ .

## Appendix 2: Tools for Prediction of Dehydration in Children

Clinical diagnosis of dehydration has been shown to be imprecise, and thus a general classification of a child's dehydration status such as none, some or severe is suggested by the literature as a useful starting point in the management of the child at risk for dehydration (Steiner 2004 [1b], King 2003 [5b]).

### A. Clinical Dehydration Scale (CDS): Friedman, 2004

(study populations: original development study: age 1 to 36 months; internal and external validation studies: age 1 month to 4 years; otherwise all study participants met similar inclusion/exclusion criteria as for this guideline)

Characteristics	0	1	2
<b>General appearance</b>	Normal	Thirsty, restless, or lethargic but irritable when touched	Drowsy, limp, cold, or sweaty; comatose or not
<b>Eyes</b>	Normal	Slightly sunken	Very sunken
<b>Mucous membranes (tongue)</b>	Moist	Sticky	Dry
<b>Tears</b>	Tears	Decreased	Absent

Score of 0 = no dehydration; Score of 1 to 4 = some dehydration; Score of 5 to 8 = severe dehydration (Friedman 2004 [2a], Bailey 2010 [2b], Goldman 2008 [2b], Parkin 2010 [4b])

### B. Prediction model for dehydration based on clinical findings: Gorelick, 1997

(study population: under age 5 years, and otherwise met similar inclusion/exclusion criteria as for this guideline)

- Ill general appearance
  - > 2 seconds capillary refill
  - Dry mucous membranes
  - Absent tears
- 
- Total number of positive indicators (0 to 4)**

3 to 4 = severe dehydration

2 = some dehydration

Gorelick model made no prediction for a score of 0 to 1

(Gorelick 1997 [3a])

### C. Likelihood Ratios (LR)

Likelihood ratios quantify the change in probability of dehydration when a given sign is present in a specific clinical case and depends upon a starting estimate of probability. See [Appendix 3](#) for definition and use of LR in dehydration.

Presence of clinical sign	LR+ to rule-in $\geq 5\%$ dehydration (95% CI) <sup>d</sup>	Absence of clinical sign	LR- to rule-out $\geq 5\%$ dehydration (95% CI) <sup>c</sup>
Prolonged capillary refill	4.1 (1.7 to 9.8)	Abnormally low urine output	0.27 (0.14 to 0.51)
Abnormal skin turgor	2.5 (1.5 to 4.2)	Dry mucous membranes	0.41 (0.21 to 0.79)
Absent tears	2.3 (0.9 to 5.8)	Poor overall appearance	0.46 (0.34 to 0.61)
Abnormal respiratory pattern	2.0 (1.5 to 2.7)	Sunken eyes	0.49 (0.38 to 0.63)
Poor overall appearance	1.9 (0.97 to 3.8)	Absent tears	0.54 (0.26 to 1.13)
	(Steiner 2004 [1b])	Prolonged capillary refill	0.57 (0.39 to 0.82)
At least 2 of the 4 following signs:			(Steiner 2004 [1b])
• capillary refill time	6.1 (3.8 to 9.8)		
• dry mucous membranes	(Gorelick 1997 [3a])		
• absence of tears			
• abnormal overall appearance			

### D. Acute body weight change

- Acute body weight change is the gold standard measure of dehydration in a child but is impractical for initial assessment of a child with gastroenteritis due to lack of an accurate pre-illness weight measurement (Gorelick 1997 [3a]).
- Determining weight gain following rehydration is often the only way to assess the degree of actual dehydration that existed at onset of therapies (Steiner 2004 [1b]).

<sup>d</sup> 95%CI: 95% Confidence Interval expresses the uncertainty (precision) of a measured value; it is the range of values within which we can be 95% sure that the true value lies. A study with a larger sample size will generate more precise measurements, resulting in a narrower confidence interval.

**Appendix 3: Definition of LIKELIHOOD RATIOS (LR)  
in the context of evaluating signs and symptoms for the diagnosis of dehydration**

A **likelihood ratio (LR)** is:

the likelihood of the presence of the sign or symptom in the child **WITH** dehydration, divided by the likelihood of the presence of the sign or symptom in the child **WITHOUT** dehydration.

An **LR value**:

- greater than 10 is very helpful in increasing diagnostic certainty  
the presence of sign or symptom is 10 times more likely to be present in a child with dehydration than in a child without dehydration
- of 1 is not helpful  
the presence of sign or symptom is just as likely to be present in child with dehydration as in a child without dehydration
- less than 0.2 is very helpful in ruling out the condition  
the presence of sign or symptom is one-fifth as likely to be present in a child with dehydration as in a child without dehydration

For more information on LRs see: <http://www.cebm.utoronto.ca/glossary/lrs.htm#top>

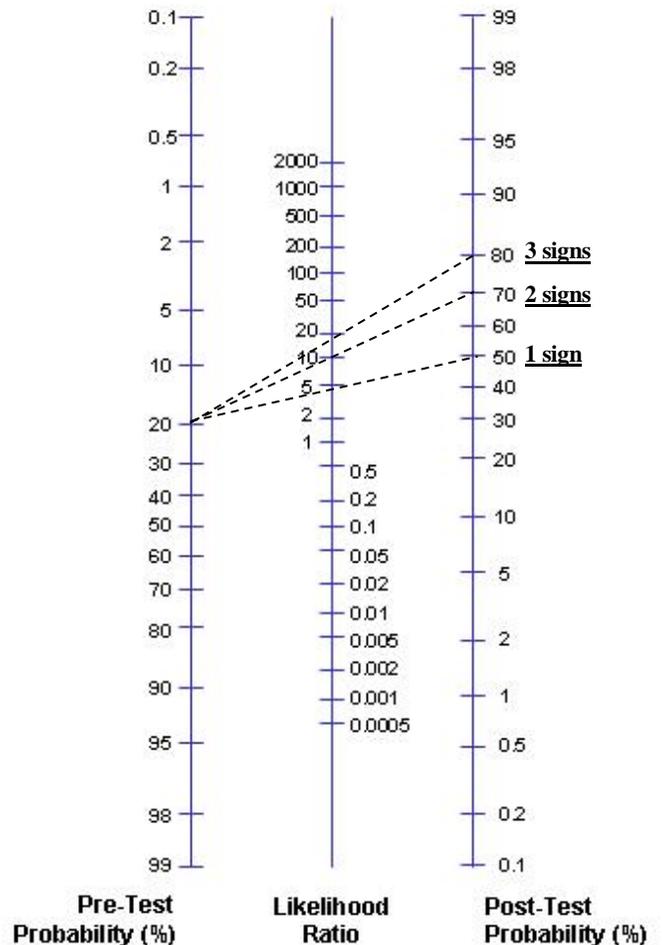
**Probability Worksheet for your own use**

1. Based on \_\_\_\_\_ (**Prior Factors Considered**), my estimate of the **pre-test probability** is \_\_\_\_\_% that this child is dehydrated.
2. The sign or symptom I found, \_\_\_\_\_, has an **LR** of \_\_\_\_\_.
3. Using the nomogram, I calculate that the **post-test probability** is \_\_\_\_\_% that this child is dehydrated.
4. Repeat steps 1 to 3, as desired, for each additional sign or symptom observed (shortcut: multiply LRs before starting).
5. The final **post-test probability** is \_\_\_\_\_% that this child is dehydrated.

**Probability Worksheet EXAMPLE**

1. Starting with this child’s chief complaint for this visit, my uncalculated, but professional estimate\* of the **pre-test probability** is **20%** that this child is dehydrated. “Pre-test” is defined as: “before I have had a chance to examine the child.”
2. The sign or symptom I found, prolonged capillary refill has an **LR of 4.1**.
3. Using the nomogram, I plot the **post-test probability at 50%** that this child is dehydrated.
4. Repeating steps 1 to 3, for each additional sign or symptom observed (**shortcut: multiply LRs before starting**), I find abnormal skin turgor (LR = 2.5), and poor overall appearance (LR = 1.9). (4.1 X 2.5 X 1.9 = **19.5 = LR for the 3 signs together**).
5. With no other significant findings, the final **post-test probability** is **80%** that this child is dehydrated.

\*Any known facts such as age, season, immunization status, etc. will affect this estimate. Numbers in the example are for example only.



**Appendix 4: Commercial Oral Rehydration Solutions**

An effective oral rehydration solution:

- is hypotonic (osmolarity <~310 mOsm/liter),
- has enough sodium to replace loss,
- adequately replaces potassium and HCO<sub>3</sub> (as bicarbonate or citrate), and
- takes advantage of equimolar Na:glucose co-transport which is 1:1 and linear until about a concentration of 100 mmol/liter.

Manufacturer/ Brand Name	Product Description	CHO gm	Na <sup>+</sup> mEq/liter	K <sup>+</sup> mEq/liter	Osmolarity mOsmol/liter	CHO:Na ratio mmol/liter: mmol/liter
<b>Solutions appropriate for oral rehydration therapy</b> (locally available products listed in order of generally increasing cost per oz.)						
Generic, e.g. Bigg's CVS Kroger Walgreen's Wal-Mart	<u>Formulations</u> <ul style="list-style-type: none"> <li>powder packets, 8 per box, mix with 8 oz. water</li> <li>1-liter liquid</li> <li>freezer pops, 2.1 oz., 16 per box*</li> <li>singles liquid, 8 oz. (4 bottles)</li> </ul> <u>Additional Information</u> <ul style="list-style-type: none"> <li>some 1-liter products may have zinc added, 7.8gm/liter</li> <li>not all formulations available at all stores</li> <li>assorted flavors, varies by product</li> <li>unflavored available in liter size only</li> </ul>	25	45	20	Flavored 270  Unflavored 250	3.1 : 1
Abbott Pedialyte	<u>Formulations</u> <ul style="list-style-type: none"> <li>powder packets, 8 per box, mix with 8 oz. water</li> <li>1-liter liquid</li> <li>freezer pops, 2.1 oz., 16 per box*</li> <li>singles liquid, 6.8 oz. (4 boxes with straws)</li> </ul> <u>Additional Information</u> <ul style="list-style-type: none"> <li>liter bottle contains 7.8 mg zinc</li> <li>not all formulations available at all stores</li> <li>assorted flavors, varies by product</li> <li>unflavored available in liter size only</li> </ul>					
WHO-ORS**	• original ORS packet [1975]	20	90	20	330	1.2 : 1
WHO-ORS**	• hypo-osmolar ORS packet [2002]	15	60	30	224	1.4 : 1
<b>Solutions NOT appropriate for severe rehydration nor as only intake at any level of dehydration--</b> These values are given for comparison only						
Coca-Cola†		112	1.6	N/A§	650	1944 : 1
Apple juice‡		120	0.4	44	730	1278 : 1
Chicken broth		0	250	8	500	0 : 1
Gatorade (Original), sports drink		59	20	3	330	62.5 : 1

\*Labeled for children 1 year of age or older.

\*\*WHO = World Health Organization; given for comparison information; generally not available in the U.S., though readily available to travelers in most developing countries

§Not applicable.

†Coca-Cola Corporation, Atlanta, GA. Figures do not include electrolytes that might be present in local water used for bottling.

‡Meeting U.S. Department of Agriculture minimum requirements.

(Gregorio 2009 [1a], Bhutta 2007 [5], Kleinman 2004 [5])

## Appendix 5: Probiotic Therapy

### A. Shared Decision Making

– parameters influencing the family's decision to use LGG may include:

<b>cost</b>	– probiotics are generally not covered by insurance
	– an effective product is currently packaged with several times the necessary number of doses
<b>evidence of benefit</b>	– CCHMC can sell capsules of an effective product by the dose, reducing the cost of a course of outpatient therapy
	– duration of diarrhea may be reduced as much as 1 to 2 days
	– there is a 75% reduction in the chance that diarrhea will last more than 7 days (to 2.7% chance from 10.7% chance)
<b>likelihood of rotavirus origin</b>	– there is evidence that 2 days of treatment (e.g. inpatient use only) confers at least some benefit
	– probiotics demonstrate a greater effect on AGE caused by rotavirus than by other viruses
	– likelihood of rotavirus source is influenced by immunization status, season, and age
<b>transmission concerns</b>	– probiotics show no benefit for invasive bacterial diarrhea
	– use may allow earlier return to day care
<b>safety</b>	– use may prevent spread of diarrhea to other family members
	– no side effects are expected in otherwise healthy children
	– check ingredient list if milk allergy is a concern
	– current laws do not require the FDA to evaluate probiotic products, therefore consumers must depend on the manufacturer for accurate labeling of product contents, and for ensuring that the product is safe <a href="http://dietarysupplements.nlm.nih.gov/dietary/faq.jsp">http://dietarysupplements.nlm.nih.gov/dietary/faq.jsp</a>

(Allen 2010 [1a], Szajewska 2007c [1a], Guandalini 2000 [2a])

### B. Product availability

– a product with the correct organism and dose are essential for families who choose to use probiotics as adjunct therapy

10 billion CFU of LGG is the criterion for efficacy of probiotics for adjunct treatment of AGE in developed countries (Szajewska 2007c [1a])

Product Brand Name	Meets efficacy criterion	Cost (# daily doses per package)	CFU	Organism(s)	Comments / References
<b>Culturelle</b> (not Culturelle for Kids, which has a lower dose--- see that entry below)	YES	\$1 (1) CCHMC outpatient pharmacy \$16 to \$20 (30) drugstore	10 billion	LGG	Available in capsules, the contents of which can be dissolved in a cool drink for oral administration (Szajewska 2007c [1a], Guandalini 2000 [2a])
<b>Florastor</b> <b>Florastor Kids</b> (powder packet)	No (see comment)	\$15-\$20 (10)	5 billion <sup>e</sup>	<i>S. boulardii</i>	A daily dose of 10 billion CFU has been shown effective in developing countries; no studies have been conducted in developed countries (Szajewska 2007b [1a], Szajewska 2009 [1b], Correa 2011 [2b], Riaz 2011 [2b])

The following products do NOT meet the criterion for effective treatment of AGE - these products are listed for comparison only, and this is not an exhaustive list of available products

<b>Align</b>	no	1 billion	<i>B. infantis</i>
<b>Colon Health</b>	no	1 billion	multiple
<b>Culturelle for Kids</b>	no	1 billion	LGG
<b>LactinexT</b>	no	2.5 billion	multiple
<b>Pearls</b>	no	1 billion	multiple
<b>Sustenex</b>	no	2 billion	<i>Bacillus coagulans</i>
<b>VSL #3-Double Strength</b>	no	900 billion	multiple
<b>Walgreens brand</b>	no	3.5 billion	multiple

Abbreviations: *B. infantis* = *Bifidobacterium infantis*; CFU = # of colony forming units; LGG = *Lactobacillus rhamnosus* GG; *S. boulardii* = *Saccharomyces boulardii*

<sup>e</sup> For comparison, mg of *S. Boulardii* product has been converted to CFU using a conversion of 5 billion CFU for 250 mg of product (Guilliams 2008 [5]).

**Appendix 6: Clinical Questions Guiding Initial Search Strategy and Article Selection\*****For introductory/background information:**

1. In US children age 2 months through 5 years and in children 6 to 18 years what is the prevalence of AGE?
2. In US children age 2 months through 3 years, how is the burden of AGE caused by rotavirus changing due to vaccination efforts?
3. In pediatric AGE in the US what are the important organisms contributing to the etiology (age stratified) since the introduction of the rotavirus vaccine?

**Prevention related questions**

4. In children in the US, is use of a rotavirus vaccination cost-effective?
5. In pediatric inpatient (and/or ED and primary care office) populations what preventive measures are effective in preventing nosocomial transmission of AGE?
6. Among young children attending daycare, is the use of prophylactic probiotics, compared to placebo, effective in reducing the incidence of AGE?

**Diagnosis related questions**

7. In children with AGE what clinical parameters best determine degree of dehydration?
8. In children with AGE, are there compelling infection control or public health/community prevention efforts and monitoring requirements to require identification of pathogen when such information is not needed for patient care?
9. In children with AGE, does determining electrolyte levels assist in management of rehydration?
10. Among children presenting by phone or in person with symptoms of AGE, what triage is effective to determine appropriate level of care?

**Treatment related questions**

11. In children with AGE what management steps prevent dehydration?
12. In children with AGE who have some or severe dehydration what rehydration management is effective?
13. In children or adolescents with AGE, is ondansetron treatment, compared to placebo, cost-effective?
14. In children with AGE, what is the ideal dosing protocol for probiotics (organism(s), dose, frequency, available products), compared to placebo, in reducing the duration of symptoms?
15. In children with AGE do other treatments (e.g. zinc, antidiarrheal agents), compared to placebo, decrease duration of symptoms or improve other outcomes?

**Other clinical questions**

16. In children with AGE what are inpatient or short stay admission criteria?
17. In children with AGE what are discharge criteria (from inpatient, short stay, emergency department [ED])?
18. In children with AGE what are criteria for return to school/daycare?
19. Among families of children with AGE what patient/family education is appropriate to prevent transmission/recurrence?
20. Among children with AGE, which management considerations are different for children age 6 to 18 from those for children age 2 months through 5 years?

\*During the course of guideline development, clinical questions in addition to these listed here were generated and subjected to the search process.

## Members of Acute Gastroenteritis Team 2011

### Community Physician

\*William DeBuys, MD, Chair

### CCHMC Physicians

Amy Guiot, MD, General Pediatrics, Hospitalist  
 \*Scott Reeves, MD, Emergency Medicine  
 Sean Moore, MS, MD, Gastroenterology  
 David Hooper, MD, Nephrology  
 Beverly Connelly, MD, MPH, Infectious Diseases  
 Paul Bunch, MD, Chief Resident Physician  
 Stephanie Clark, MD, Chief Resident Physician  
 Robert Hufnagel, MD, Resident Physician  
 Lynn Lee, MD, Resident Physician

### Other Physician

Andrea Lo Vecchio, MD, Resident in Pediatrics, Visiting Scholar from U of Naples "Federico II", Italy

### Patient Services

\*Michelle Widecan, RN, CRNP, Emergency Department  
 Rebecca Wilhelm, RD, Nutrition Services  
 Trina Hemmelgarn, PharmD, Pharmacy

### James M. Anderson Center for Health Systems Excellence

Wendy Gerhardt, Lead Guidelines Program Administrator  
 \*Eloise Clark, MPH, Guideline Developer  
 \*Danette Stanko-Lopp, MA, MPH, Epidemiologist  
 Karen Vonderhaar, RN, MSN, Methodologist

All Team Members and Anderson Center support staff listed above have signed a conflict of interest declaration and none were found

### Ad hoc Advisors

\*Richard Ruddy, MD, Emergency Medicine, Director  
 Pratip K. Nag, MD, PhD, General Pediatrics, Baylor College of Medicine, TX  
 Adam C. Levine, MD, MPH, Emergency Medicine, Brown University Alpert Medical School, RI  
 Penelope H. Dennehy, M.D., Pediatric Infectious Diseases, Hasbro Children's Hospital, Warren Alpert Medical School of Brown U, RI  
 Elizabeth Elliott, AM, General Pediatrics, Sydney Medical School, The Children's Hospital at Westmead, New South Wales, Australia  
 \*Member of previous Acute Gastroenteritis guideline development Teams

## Development Process

The process by which this guideline was developed is documented in the [Guideline Development and Update Process Manual](#); relevant development materials are kept electronically. The recommendations contained in this guideline were formulated by an interdisciplinary working group which performed systematic search and critical appraisal of the literature, using the Table of Evidence Levels described following the references, and examined current local clinical practices.

To select evidence for critical appraisal by the group for the update of this guideline, the Medline, EmBase and the Cochrane databases were searched for dates of April, 2003 to September, 2011 to generate an unrefined, "combined evidence" database using a search strategy

focused on answering clinical questions (see [Appendix 6](#)) relevant to AGE for the target population and employing a combination of Boolean searching on human-indexed thesaurus terms (MeSH headings using an OVID Medline interface) and "natural language" searching on searching on human-indexed thesaurus terms (MeSH headings using an OVID Medline interface) and "natural language" searching on words in the title, abstract, and indexing terms. The citations were reduced by: eliminating duplicates, review articles, non-English articles, and adult articles. The resulting abstracts were reviewed by a methodologist to eliminate low quality and irrelevant references. During the course of guideline development, additional clinical questions were generated and subjected to the search process, and some relevant review articles were identified.

Tools to assist in the effective dissemination and implementation of the guideline may be available online at <http://www.cincinnatichildrens.org/svc/alpha/h/health-policy/ev-based/default.htm>. Experience with the implementation of earlier publications of this guideline has provided learnings which have been incorporated into this revision (*Perlstein 2002 [4a]*).

Once the guideline has been in place for three years, the development team reconvenes to explore the continued validity of the guideline. This phase can be initiated at any point that evidence indicates a critical change is needed.

The guideline was externally appraised by four reviewers using the AGREE instrument and the results by domain are:

- Scope and Purpose 83%
- Stakeholder Involvement 72%
- Rigor of Development 86%
- Clarity and Presentation 89%
- Applicability 77%
- Editorial Independence 100%

Recommendations have been formulated by a consensus process directed by best evidence, patient and family preference and clinical expertise. During formulation of these recommendations, the team members have remained cognizant of controversies and disagreements over the management of these patients. They have tried to resolve controversial issues by consensus where possible and, when not possible, to offer optional approaches to care in the form of information that includes best supporting evidence of efficacy for alternative choices.

Proposed process and outcome measures for target population are:

- **Outcome:** Length of stay (inpatient) (*for comparison with national benchmarks (1.9 days) and to monitor a guideline objective; desired direction is sustain or decrease, current local LOS is 1.6 days during Jan-Oct, 2011*) (*Tieder 2009 [4a]*)
- **Outcome:** Gastroenteritis admission rate (area-level): rate per 100,000 population (*2008 national benchmark PDI 16 is 105/100,000; to monitor a guideline objective; desired direction sustain or decrease; current local rate is 45 per 100,000 population*) (*AHRQ 2011b [5], AHRQ 2011a [5]*)
- **Process:** Percent inpatients who were prescribed LGG within 18 hours of admission (*recent implementation of new evidence; desired direction is sustain or increase; current local rate following active implementation is 100% for Aug through Oct, 2011 [off-season]*)
- **Process:** Percent ED and inpatient patients with no dietary restrictions (child continues without delay with preferred, usual, and age-appropriate diet and fluids, as tolerated, which may include commercial ORS); documented discharge education about diet restrictions is a failure (*continuation of an ongoing measure, updated to reflect current evidence; desired direction is sustain or*

*increase; data collected for previous version of measure not applicable to this updated version)*

Upon piloting of the LGG recommendation, organizational barriers were addressed as follows:

- education of clinical staff on the evidence base for the recommendation
- on-going dissemination of information about the recommendation to incoming teams of rotating clinicians
- LGG as a default order on the electronic medical record order set
- availability of product in the organization's inpatient and outpatient pharmacies
- availability of product to discharged patients in small number of doses from the organization's outpatient pharmacy
- development of draft patient decision aid for starting or continuing LGG doses (has not been implemented at time of this publication).

The guideline has been reviewed and approved by clinical experts not involved in the development process, distributed to senior management, and other parties as appropriate to their intended purposes. The 2006 version of this guideline was included in a study of guideline quality and judged to be strongly recommended (*Lo Vecchio 2011 [4a]*).

The guideline was developed without external funding. All Team Members and Anderson Center support staff listed have declared whether they have any conflict of interest and none were identified.

Copies of this Evidence-Based Care Guideline (EBCG) are available online and may be distributed by any organization for the global purpose of improving child health outcomes. Website address: <http://www.cincinnatichildrens.org/svc/alpha/h/health-policy/ev-based/default.htm>. Examples of approved uses of the EBCG include the following:

- copies may be provided to anyone involved in the organization's process for developing and implementing evidence-based care guidelines;
- hyperlinks to the CCHMC website may be placed on the organization's website;
- the EBCG may be adopted or adapted for use within the organization, provided that CCHMC receives appropriate attribution on all written or electronic documents; and
- copies may be provided to patients and the clinicians who manage their care.

Notification of CCHMC at [EBDMInfo@cchmc.org](mailto:EBDMInfo@cchmc.org) for any EBCG, or its companion documents, adopted, adapted, implemented or hyperlinked by the organization is appreciated.

**NOTE: These recommendations result from review of literature and practices current at the time of their formulations. This guideline does not preclude using care modalities proven efficacious in studies published subsequent to the current revision of this document. This document is not intended to impose standards of care preventing selective variances from the recommendations to meet the specific and unique requirements of individual patients. Adherence to this guideline is voluntary. The clinician in light of the individual circumstances presented by the patient must make the ultimate judgment regarding the priority of any specific procedure.**

*For more information about this guideline, its supporting evidence and the guideline development process, contact the evidence group with the Anderson Center: 513-636-2501 or [EBDMInfo@cchmc.org](mailto:EBDMInfo@cchmc.org)*

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Note: Full tables of evidence grading system available in separate document:

- [Table of Evidence Levels of Individual Studies by Domain, Study Design, & Quality](#) (abbreviated table below)
- [Grading a Body of Evidence to Answer a Clinical Question](#)
- [Judging the Strength of a Recommendation](#) (abbreviated table below)

**Table of Evidence Levels** (see note above)

<i>Quality level</i>	<i>Definition</i>
1a† or 1b†	Systematic review, meta-analysis, or meta-synthesis of multiple studies
a or 2b	Best study design for domain
3a or 3b	Fair study design for domain
4a or 4b	Weak study design for domain
5	Other: General review, expert opinion, case report, consensus report, or guideline

†a = good quality study; b = lesser quality study

**Table of Recommendation Strength** (see note above)

<i>Strength</i>	<i>Definition</i>
“Strongly recommended”	There is consensus that benefits clearly outweigh risks and burdens (or visa-versa for negative recommendations).
“Recommended”	There is consensus that benefits are closely balanced with risks and burdens.
No recommendation made	There is lack of consensus to direct development of a recommendation.
<b>Dimensions:</b> In determining the strength of a recommendation, the development group makes a considered judgment in a consensus process that incorporates critically appraised evidence, clinical experience, and other dimensions as listed below.	
<ol style="list-style-type: none"> <li>Grade of the Body of Evidence (see note above)</li> <li>Safety / Harm</li> <li>Health benefit to patient (<i>direct benefit</i>)</li> <li>Burden to patient of adherence to recommendation (<i>cost, hassle, discomfort, pain, motivation, ability to adhere, time</i>)</li> <li>Cost-effectiveness to healthcare system (<i>balance of cost / savings of resources, staff time, and supplies based on published studies or onsite analysis</i>)</li> <li>Directness (<i>the extent to which the body of evidence directly answers the clinical question [population/problem, intervention, comparison, outcome]</i>)</li> <li>Impact on morbidity/mortality or quality of life</li> </ol>	

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**Note:** When using the electronic version of this document,  indicates a hyperlink to the PubMed abstract. A hyperlink following this symbol goes to the article PDF when the user is within the CCHMC network.

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