



## Complete Summary

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### GUIDELINE TITLE

Gastrointestinal complications of HIV.

### BIBLIOGRAPHIC SOURCE(S)

New York State Department of Health. Gastrointestinal complications of HIV. New York (NY): New York State Department of Health; 2006 Oct. 17 p. [39 references]

### GUIDELINE STATUS

This is the current release of the guideline.

## COMPLETE SUMMARY CONTENT

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## SCOPE

### DISEASE/CONDITION(S)

- Human immunodeficiency virus (HIV) infection
- Gastrointestinal complications of HIV:
  - Esophageal disease (esophagitis including cytomegalovirus and herpes simplex esophagitis, gastroesophageal reflux disease [GERD], aphthous ulcers)
  - Gastric disease
  - Liver disease
  - Diarrhea
  - Biliary disease
  - Pancreatic disease

### GUIDELINE CATEGORY

Diagnosis  
Evaluation  
Management  
Treatment

### **CLINICAL SPECIALTY**

Allergy and Immunology  
Family Practice  
Gastroenterology  
Infectious Diseases  
Internal Medicine

### **INTENDED USERS**

Advanced Practice Nurses  
Clinical Laboratory Personnel  
Health Care Providers  
Nurses  
Physician Assistants  
Physicians

### **GUIDELINE OBJECTIVE(S)**

To provide recommendations for diagnosis and management of gastrointestinal complications of human immunodeficiency virus (HIV) infection

### **TARGET POPULATION**

Human immunodeficiency virus (HIV)-infected patients with HIV-related gastrointestinal complications

### **INTERVENTIONS AND PRACTICES CONSIDERED**

1. Evaluating patients for non-human immunodeficiency virus (HIV)-related and non-gastrointestinal (GI)-related illness, adverse effects of medications, opportunistic infections, and neoplasms
2. Management of esophageal disease
  - Oral azole antifungal
  - Diagnostic endoscopy
  - Assessing the cause of antifungal therapy failure, if indicated
  - Oral valganciclovir or intravenous ganciclovir or foscarnet for cytomegalovirus (CMV) treatment and ophthalmologic examination to assess for CMV retinal disease
  - Acyclovir, valacyclovir, or famciclovir for herpes simplex virus
  - Proton pump inhibitors for gastroesophageal reflux disease
  - Topical corticosteroids for aphthous ulcers
3. Management of gastric disease
  - Endoscopy
  - Patient education regarding GI side effects of antiretroviral (ARV) medications

- Aluminum- or bismuth-based antacids
- Antiemetic medication
- 4. Liver disease management
  - Assessment for use of any hepatotoxic medications, herbal therapies, alcohol abuse, and viral hepatitis
  - Using alternative ARV agent or discontinuing all ARV medications
  - Standard treatment for pathogens found in liver
- 5. Management of diarrhea
  - Assessment of dietary and medication history, travel history, alcohol use, sexual activity, and weight loss
  - Bacterial stool cultures
  - Biopsies from both abnormal and normal-appearing bowel segments
  - Colonoscopy, if indicated
  - Electron microscopy or polymerase chain reaction, if indicated
  - Symptomatic treatment
  - Ganciclovir, valganciclovir, or foscarnet for CMV and ophthalmologic examination
- 6. Biliary disease management
  - Abdominal ultrasound
  - Hepatoiminodiacetic acid (HIDA) scan
  - Endoscopy with or without biopsy
  - Ursodeoxycholic acid, doxepin
  - Pain treatment
  - Antimicrobial therapy with or without cholecystectomy
- 7. Management of pancreatic disease
  - Serum lipase and lactate levels
  - Abdominal ultrasound or computed tomography (CT)
  - Endoscopic retrograde cholangiopancreatography (ERCP) if indicated
  - Intravenous hydration and pain control
  - Discontinuing known or suspected pancreatotoxic agents
  - Antimicrobial therapy

## **MAJOR OUTCOMES CONSIDERED**

Efficacy and safety of treatment of gastrointestinal complications of human immunodeficiency virus (HIV) infection

## **METHODOLOGY**

### **METHODS USED TO COLLECT/SELECT EVIDENCE**

Hand-searches of Published Literature (Primary Sources)  
 Hand-searches of Published Literature (Secondary Sources)  
 Searches of Electronic Databases

### **DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE**

Not stated

### **NUMBER OF SOURCE DOCUMENTS**

Not stated

## **METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE**

Expert Consensus (Committee)

## **RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE**

Not applicable

## **METHODS USED TO ANALYZE THE EVIDENCE**

Review

## **DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE**

Not stated

## **METHODS USED TO FORMULATE THE RECOMMENDATIONS**

Expert Consensus

## **DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS**

AIDS Institute clinical guidelines are developed by distinguished committees of clinicians and others with extensive experience providing care to people with HIV infection. Committees\* meet regularly to assess current recommendations and to write and update guidelines in accordance with newly emerging clinical and research developments.

The Committees\* rely on evidence to the extent possible in formulating recommendations. When data from randomized clinical trials are not available, Committees rely on developing guidelines based on consensus, balancing the use of new information with sound clinical judgment that results in recommendations that are in the best interest of patients.

\* Current committees include:

- Medical Care Criteria Committee
- Committee for the Care of Children and Adolescents with HIV Infection
- Dental Standards of Care Committee
- Mental Health Committee
- Women's Health Committee
- Substance Use Committee
- Physician's Prevention Advisory Committee
- Pharmacy Committee

## **RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS**

Not applicable

## **COST ANALYSIS**

A formal cost analysis was not performed and published cost analyses were not reviewed.

## **METHOD OF GUIDELINE VALIDATION**

External Peer Review

## **DESCRIPTION OF METHOD OF GUIDELINE VALIDATION**

All guidelines developed by the Committee are externally peer reviewed by at least two experts in that particular area of patient care, which ensures depth and quality of the guidelines.

# **RECOMMENDATIONS**

## **MAJOR RECOMMENDATIONS**

Clinicians should evaluate patients with gastrointestinal (GI) complaints for non-human immunodeficiency virus (HIV)-related illness, non-GI-related illness, adverse effects of medications, possible opportunistic infections (OIs), and HIV-associated neoplasms.

Clinicians should not routinely dismiss GI complaints in HIV-infected pregnant women.

### **Gastrointestinal Diseases and Syndromes**

#### **Esophageal Disease**

##### *Treatment*

##### Initial Empiric Therapy

Clinicians should prescribe an oral azole antifungal (fluconazole loading dose of 200 mg, followed by 100 to 200 mg/day) as initial empiric treatment for patients with suspected esophagitis. If no improvement is seen after 7 to 10 days, diagnostic endoscopy should be performed.

##### Esophagitis in Patients Receiving Antifungal Therapy

When a patient receiving antifungal therapy presents with esophagitis, clinicians should assess for the following:

- A defect in drug absorption (common with itraconazole and ketoconazole)
- The development of resistance to the drug by the initial infecting fungus
- Development of a fungal superinfection with a resistant strain

- Development of a non-fungal etiology

#### Cytomegalovirus (CMV) Esophagitis

Clinicians should treat CMV esophagitis with oral valganciclovir or intravenously administered ganciclovir or foscarnet at induction doses for 3 to 6 weeks.

An ophthalmologic examination should be performed at the time of diagnosis to assess for the presence of concurrent CMV retinal disease.

#### Herpes Simplex Virus (HSV) Esophagitis

Clinicians should treat mild or moderate HSV esophagitis orally for 2 weeks (if absorption is not an issue) with standard treatment doses of acyclovir, valacyclovir, or famciclovir.

Clinicians should treat severe HSV esophagitis with intravenously administered acyclovir for 2 weeks. Foscarnet should be used when acyclovir-resistant HSV is suspected.

#### Gastroesophageal Reflux Disease (GERD)

Clinicians should treat GERD primarily with proton pump inhibitors (omeprazole, lansoprazole), possibly in combination with pro-motility agents (metoclopramide).

#### Aphthous Ulcers

Clinicians should use topical corticosteroids to manage aphthous ulcers; however, caution should be taken because steroid use may result in candidal overgrowth.

### **Gastric Disease**

#### *Diagnosis*

Clinicians should perform endoscopy in patients with recalcitrant symptoms or disease and/or acute events, such as hematemesis.

Clinicians should discuss with HIV-infected patients who are initiating antiretroviral (ARV) therapy the possible GI side effects associated with ARV medications. The patient should be informed that the duration of symptoms is generally limited to 2 weeks and that symptomatic treatment can be prescribed.

#### *Treatment*

Because of the high incidence of diarrhea in HIV-infected patients, magnesium-containing antacids should be avoided, and aluminum- or bismuth-based antacids should be used.

Clinicians should prescribe short courses of the oral or suppository form of prochlorperazine or promethazine with or without metoclopramide for symptomatic relief of medication-associated nausea and vomiting.

## **Liver Disease**

### *Diagnosis*

When a patient has elevated serum transaminase, the clinician should assess for use of any possible hepatotoxic medications or alternative therapies (herbal therapies), alcohol abuse, and viral hepatitis. Refer to Table 2 in the original guideline document for information on hepatotoxicity of ARV drugs. For recommendations regarding hepatitis A, B, and C management, see the New York State Department of Health (NYSDoH) guideline on [Viral Hepatitis](#).

### *Treatment*

The clinician should avoid using any potentially hepatotoxic non-essential drugs in the setting of new or worsening abnormal serum liver enzyme levels.

When one of the highly active antiretroviral therapy (HAART) agents is suspected as the cause for the hepatotoxicity, the clinician should substitute an equally potent agent. If the clinical situation does not permit the initiation of an alternative agent, the discontinuation of *all* the components of the HAART regimen is recommended. Therapy with the alternative HAART regimen should be initiated after the abnormal laboratory values have returned to the patient's baseline values.

Clinicians should initiate standard treatment for pathogens found in the liver, such as fungi and mycobacteria.

## **Diarrhea**

### *Diagnosis*

Clinicians should assess the following in HIV-infected patients with diarrhea:

- A careful dietary history, including lactose and fat intake
- Medication history to assess whether diarrhea is medication-induced
- Travel history
- Alcohol use
- Sexual activity
- Weight loss

Clinicians should perform endoscopy in the setting of moderate to severe diarrhea if stool studies for pathogens are negative and medication is not a suspected etiology.

Clinicians should perform colonoscopy in patients with bloody diarrhea or diarrhea with tenesmus when bacterial stool cultures are negative, obtaining multiple biopsies from both abnormal and normal-appearing segments of bowel.

Pathologists should be specifically instructed to seek specific organisms. Refer to Table 3 of the original guideline document for information on evaluation of diarrhea based on CD4 count.

Clinicians should perform distal duodenal biopsy in patients with large volume diarrhea (>2L/24hr) of suspected small bowel origin. If microsporidia is suspected, electron microscopy or polymerase chain reaction (PCR) should be used to confirm and identify the microsporidia.

Clinicians should include invasive enteric disease (bacterial, viral) or disseminated mycobacterial infection in the differential diagnosis in patients who present with fever and diarrhea.

### *Treatment*

Clinicians should provide symptomatic treatment for all patients with diarrhea to prevent volume depletion and wasting and to maximize comfort and functional status (see the table below).

Clinicians should counsel patients with diarrhea about the effects of diet, advocating a low-fat, lactose-free diet if these are found to be etiologic.

Clinicians should treat parasitic and bacterial pathogens with standard regimens.

Clinicians should treat CMV colitis with intravenous ganciclovir, valganciclovir, or foscarnet for 3 to 6 weeks with induction doses. Maintenance therapy remains controversial but should be used in the setting of a low CD4 count (<100 cells/mm<sup>3</sup>). An ophthalmologic examination should be performed at the time of diagnosis to assess for the presence of concurrent CMV retinal disease.

**Table: Symptomatic Treatment for Patients with Diarrhea**

<b>Agent</b>	<b>Indications</b>
Loperamide	Moderate to severe antiretroviral (ARV)-related diarrhea; should only be used after bacterial or amoebic etiology has been excluded
Diphenoxylate	Moderate to severe ARV-related diarrhea; should only be used after bacterial or amoebic etiology has been excluded
Paregoric	Moderate to severe ARV-related diarrhea; should only be used

<b>Agent</b>	<b>Indications</b>
	after bacterial or amoebic etiology has been excluded
Deodorized tincture of opium	Moderate to severe ARV-related diarrhea; should only be used after bacterial or amoebic etiology has been excluded
Bismuth subsalicylate	Mild, non-infectious diarrhea
Aluminum antacids	Mild, non-infectious diarrhea
Cholestyramine	Mild, non-infectious diarrhea
Fiber supplement	Mild, non-infectious diarrhea
Calcium carbonate pills*	ARV-related diarrhea
Glutamine supplementation*	ARV-related diarrhea

\*Anecdotally noted to be useful for ARV-related diarrhea.

## **Biliary Disease**

### *Diagnosis*

Clinicians should perform an abdominal ultrasound to establish a diagnosis of biliary disease.

Clinicians should confirm acalculous cholecystitis by hepatoiminodiacetic acid (HIDA) scan.

If stool tests and radiologic studies are unrevealing, clinicians should perform an endoscopic evaluation of the biliary tree and small bowel with or without biopsies to identify the pathogen.

### *Treatment*

Clinicians should treat the underlying pathogen(s) isolated from the biliary tract or stool.

Clinicians should treat jaundice and pruritus with ursodeoxycholic acid and symptomatic treatments such as doxepin. Pain should be treated when indicated.

Clinicians should use appropriate antimicrobial therapy with or without cholecystectomy to treat acalculous cholecystitis.

## **Pancreatic Disease**

### *Diagnosis*

Clinicians should obtain serum lipase levels in patients suspected of having acute pancreatitis; serum lactate levels should also be obtained to exclude lactic acidosis.

Clinicians should obtain abdominal ultrasound or computed tomography (CT) scans both to delineate possible non-infectious etiologies or complications of pancreatitis, such as perforating gastric ulcers or pancreatic pseudocyst, as well as to follow the degree of inflammation and response to treatment over time. Endoscopic retrograde cholangiopancreatography (ERCP) should be reserved for the evaluation of ductal lesions.

### *Treatment*

Clinicians should provide vigorous intravenous hydration and pain control for patients with severe pancreatitis. These patients should be kept "nothing by mouth" (NPO).

The clinician should discontinue the use of all known or suspected pancreatotoxic agents. If one ARV agent is to be discontinued and another ARV agent cannot be expediently substituted to maintain effective HAART, then all ARV agents should be withheld to circumvent the development of resistance.

If an infectious etiology is present or suspected, the clinician should initiate appropriate antimicrobial therapy.

## **CLINICAL ALGORITHM(S)**

None provided

## **EVIDENCE SUPPORTING THE RECOMMENDATIONS**

### **TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS**

The type of evidence supporting the recommendations is not specifically stated.

## **BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS**

### **POTENTIAL BENEFITS**

Appropriate diagnosis and management of gastrointestinal complications of human immunodeficiency virus (HIV) infection

## POTENTIAL HARMS

- There are serious documented teratogenic effects associated with *thalidomide* in pregnant women. Central nervous system toxicity and peripheral neuropathy may occur as well. Because of these potential side effects, thalidomide should only be used as second-line therapy. In adolescent and adult women capable of bearing children, thalidomide should only be used when the woman is known not to be pregnant and is using effective methods of birth control.
- *Topical corticosteroid* use may result in candidal overgrowth

## CONTRAINDICATIONS

### CONTRAINDICATIONS

The routine use of *loperamide* for symptomatic treatment should be avoided in human immunodeficiency virus (HIV)-infected patients until *Clostridium difficile* is excluded by obtaining stool *C difficile* toxin assay.

## IMPLEMENTATION OF THE GUIDELINE

### DESCRIPTION OF IMPLEMENTATION STRATEGY

The AIDS Institute's Office of the Medical Director directly oversees the development, publication, dissemination and implementation of clinical practice guidelines, in collaboration with The Johns Hopkins University, Division of Infectious Diseases. These guidelines address the medical management of adults, adolescents and children with HIV infection; primary and secondary prevention in medical settings; and include informational brochures for care providers and the public.

#### Guidelines Dissemination

Guidelines are disseminated to clinicians, support service providers and consumers through mass mailings and numerous AIDS Institute-sponsored educational programs. Distribution methods include the HIV Clinical Resource website, the Clinical Education Initiative, the AIDS Educational Training Centers (AETC) and the HIV/AIDS Materials Initiative. Printed copies of clinical guidelines are available for order from the New York State Department of Health (NYSDOH) Distribution Center for providers who lack internet access.

#### Guidelines Implementation

The HIV Clinical Guidelines Program works with other programs in the AIDS Institute to promote adoption of guidelines. Clinicians, for example, are targeted through the Clinical Education Initiative (CEI) and the AETC. The CEI provides tailored educational programming on site for health care providers on important topics in HIV care, including those addressed by the HIV Clinical Guidelines Program. The AETC provides conferences, grand rounds and other programs that cover topics contained in AIDS Institute guidelines.

Support service providers are targeted through the HIV Education and Training initiative which provides training on important HIV topics to non-physician health and human services providers. Education is carried out across the State as well as through video conferencing and audio conferencing.

The HIV Clinical Guidelines Program also works in a coordinated manner with the HIV Quality of Care Program to promote implementation of HIV guidelines in New York State. By developing quality indicators based on the guidelines, the AIDS Institute has created a mechanism for measurement of performance that allows providers and consumers to know to what extent specific guidelines have been implemented.

Finally, best practices booklets are developed through the HIV Clinical Guidelines Program. These contain practical solutions to common problems related to access, delivery or coordination of care, in an effort to ensure that HIV guidelines are implemented and that patients receive the highest level of HIV care possible.

## **IMPLEMENTATION TOOLS**

Personal Digital Assistant (PDA) Downloads

For information about [availability](#), see the "Availability of Companion Documents" and "Patient Resources" fields below.

## **INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES**

### **IOM CARE NEED**

Getting Better  
Living with Illness

### **IOM DOMAIN**

Effectiveness  
Patient-centeredness

## **IDENTIFYING INFORMATION AND AVAILABILITY**

### **BIBLIOGRAPHIC SOURCE(S)**

New York State Department of Health. Gastrointestinal complications of HIV. New York (NY): New York State Department of Health; 2006 Oct. 17 p. [39 references]

### **ADAPTATION**

Not applicable: The guideline was not adapted from another source.

### **DATE RELEASED**

2006 Oct

**GUIDELINE DEVELOPER(S)**

New York State Department of Health - State/Local Government Agency [U.S.]

**SOURCE(S) OF FUNDING**

New York State Department of Health

**GUIDELINE COMMITTEE**

Medical Care Criteria Committee

**COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE**

*Committee Chair:* Jessica E Justman, MD, Columbia University, New York, New York

*Vice-chair:* Barry S Zingman, MD, Montefiore Medical Center, Bronx, New York

*Members:* Judith A Aberg, MD, New York University School of Medicine, New York, New York; Bruce D Agins, MD, MPH, New York State Department of Health AIDS Institute, New York, New York; Barbara H Chaffee, MD, MPH, Binghamton Family Care Center, Binghamton, New York; Steven M Fine, MD, PhD, University of Rochester Medical Center, Rochester, New York; Barbara E Johnston, MD, Saint Vincent's-Manhattan Comprehensive HIV Center, New York, New York; Jason M Leider, MD, PhD, North Bronx Healthcare Network of Jacobi and North Central Bronx Hospitals, Bronx, New York; Joseph P McGowan, MD, FACP, Center for AIDS Research & Treatment, North Shore University Hospital, Manhasset, New York; Samuel T Merrick, MD, NewYork-Presbyterian Hospital/Weill Cornell Medical Center, New York, New York; Rona M Vail, MD, Callen-Lorde Community Health Center, New York, New York

*Liaisons:* Sheldon T Brown, MD, Liaison to the Department of Veterans Affairs Medical Center, Bronx Veteran Affairs Medical Center, Bronx, New York; Douglas G Fish, MD, Liaison to the New York State Department of Corrections, Albany Medical College, Albany, New York; Peter G Gordon, MD, Liaison to the HIV Quality of Care Advisory Committee, Columbia University College of Physicians and Surgeons, New York, New York; Fabienne Laraque, MD, MPH, Liaison to the New York City Department of Health and Mental Hygiene, Treatment and Housing Bureau of HIV/AIDS Prevention and Control, New York, New York; Joseph R Masci, MD, Liaison to New York City Health and Hospitals Corporation, Elmhurst Hospital Center, Elmhurst, New York

*AIDS Institute Staff Physician:* Charles J Gonzalez, MD, New York State Department of Health AIDS Institute, New York, New York

*Principal Investigator:* John G Bartlett, MD, the Johns Hopkins University, Baltimore, Maryland

*Principal Contributor:* Charles J. Gonzalez, MD, New York State Department of Health AIDS Institute

## **FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST**

Not stated

## **GUIDELINE STATUS**

This is the current release of the guideline.

## **GUIDELINE AVAILABILITY**

Electronic copies: Available from the [New York State Department of Health AIDS Institute Web site](#).

## **AVAILABILITY OF COMPANION DOCUMENTS**

This guideline is available as a Personal Digital Assistant (PDA) download from the [New York State Department of Health AIDS Institute Web site](#).

## **PATIENT RESOURCES**

None available

## **NGC STATUS**

This NGC summary was completed by ECRI Institute on July 2, 2008.

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