



Complete Summary

GUIDELINE TITLE

Hepatitis B virus.

BIBLIOGRAPHIC SOURCE(S)

New York State Department of Health. Hepatitis B virus. New York (NY): New York State Department of Health; 2004 Sep. 12 p.

GUIDELINE STATUS

Note: This guideline has been updated. The National Guideline Clearinghouse (NGC) is working to update this summary.

COMPLETE SUMMARY CONTENT

SCOPE
METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT
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SCOPE

DISEASE/CONDITION(S)

- Human immunodeficiency virus (HIV) infection
- Hepatitis B virus (HBV) infection

GUIDELINE CATEGORY

Diagnosis
Management
Prevention
Screening
Treatment

CLINICAL SPECIALTY

Allergy and Immunology
Family Practice
Infectious Diseases
Internal Medicine
Obstetrics and Gynecology

INTENDED USERS

Health Care Providers
Physician Assistants
Physicians
Public Health Departments

GUIDELINE OBJECTIVE(S)

To develop guidelines for the management of hepatitis B virus infection in human immunodeficiency virus (HIV)-infected patients

TARGET POPULATION

Human immunodeficiency virus (HIV)-infected patients at risk for hepatitis B virus infection

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis and Management of Clinical Syndromes (Acute and Chronic Hepatitis B)

1. Baseline hepatic function testing
2. Hepatitis B virus (HBV) serologies for all human immunodeficiency virus (HIV)-infected patients to determine their HBV infection status, including hepatitis B surface antigen (HBsAg), the antibody to hepatitis B surface antigen (HBsAb), and the immunoglobulin G antibody to hepatitis B core antigen (IgG anti-HBc) (HBcAb).
3. HBV vaccination series in HIV-infected patients with no prior HBV infection or vaccination
4. Measurement of HBV deoxyribonucleic acid (DNA) viral load in the setting of unexplained elevation of liver enzymes

Prevention and Screening

1. Patient counseling regarding transmission of HBV/HIV
2. Pre-exposure HBV prophylaxis
 - Pre-vaccination screening for HIV-infected patients to include HBsAg, HBsAb, and HbcAb IgG
 - HBV vaccination early in course of HIV disease
 - Testing for HbsAb 1 to 2 months after completion of the third vaccine dose
3. Post-exposure HBV prophylaxis
 - Administration of hepatitis B immune globulin (HBIG) and initiation of HBV vaccine series

- Determination of source patient's HBV status
4. Prophylaxis for perinatal HBV transmission
 - Administration of hepatitis B immune globulin and initiation of HBV vaccine series within 12 hours of birth

Treatment of Chronic HBV Infection

1. Hepatitis B therapy with interferon alfa-2b, lamivudine, or adefovir
2. Highly active antiretroviral therapy (HAART) in combination with lamivudine
3. Monitoring hepatic function in HIV/HBV co-infected patients who discontinue lamivudine, emtricitabine, and tenofovir
4. Choosing therapy for patients with HBV/HIV co-infection, with consideration of consequences for future treatment

MAJOR OUTCOMES CONSIDERED

Not stated

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

The Human Immunodeficiency Virus (HIV) Guidelines Program works directly with committees composed of HIV Specialists to develop clinical practice guidelines. These specialists represent different disciplines associated with HIV care, including infectious diseases, family medicine, obstetrics and gynecology, among others. Generally, committees meet in person 3 to 4 times per year, and otherwise conduct business through monthly conference calls.

Committees meet to determine priorities of content, review literature, and weigh evidence for a given topic. These discussions are followed by careful deliberation to craft recommendations that can guide HIV primary care practitioners in the delivery of HIV care. Decision making occurs by consensus. When sufficient evidence is unavailable to support a specific recommendation that addresses an important component of HIV care, the group relies on their collective best practice experience to develop the final statement. The text is then drafted by one member, reviewed and modified by the committee, edited by medical writers, and then submitted for peer review.

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

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note: This guideline has been updated. The National Guideline Clearinghouse (NGC) is working to update this summary. The recommendations that follow are based on the previous version of the guideline.

Clinical Syndromes

Clinicians should obtain baseline hepatic function tests as well as hepatitis B virus (HBV) serologies for all human immunodeficiency virus (HIV)-infected patients to determine their HBV infection status; these include hepatitis B surface antigen (HbsAg), the antibody to hepatitis B surface antigen (anti-HBs) (HBsAb), and the immunoglobulin G antibody to hepatitis B core antigen (IgG anti-HBc) (HBcAb).

Clinicians should strongly encourage all HIV-infected patients who do not have serologic evidence of prior HBV infection or who have not previously received the complete series of HBV vaccination to receive the hepatitis B vaccination series. Serologic testing for anti-HBs 1 to 2 months after the third dose should be performed. If the patient did not respond to the vaccine series, the clinician should administer a second series when the patient's CD4 count is ≥ 200 cells/mm³.

In the setting of unexplained elevations in serum liver enzymes, clinicians should consider obtaining an HBV deoxyribonucleic acid (DNA) viral load, even in the absence of serologic evidence of active hepatitis B virus replication (reactive HBsAg or hepatitis Be antigen [HBeAg]).

Prevention

Clinicians should counsel HIV/HBV co-infected patients regarding transmission.

Due to the limited efficacy of HBV vaccine in the HIV-infected population, all patients should be given counseling concerning behavior modifications to decrease the risk of acquiring HBV infection through sexual activity and injection drug use.

Pre-Exposure HBV Prophylaxis

Pre-vaccination screening for HIV-infected patients should include HBsAg, HBsAb, and HbcAb IgG.

The clinician should ideally administer the hepatitis vaccination in HIV-infected patients early in the course of HIV disease, before severe immune suppression has occurred.

The clinician should test for HbsAb 1 to 2 months after completion of the third vaccine dose.

Post-Exposure HBV Prophylaxis

Administration of prophylactic hepatitis B immune globulin (HBIG) and the initiation of the hepatitis B vaccine series (at different sites) are recommended when the non-HBV-immune patient sustains a blood or body fluid exposure to a source with acute or chronic HBV (see Table 4 in the original guideline document).

Following an HBV exposure, determination of the source patient's HBV serologic status should be sought.

Prophylaxis for Perinatal HBV Transmission

Administration of prophylactic HBIG and the initiation of the hepatitis B vaccine series (at different sites) are recommended within 12 hours of birth.

Treatment of Chronic HBV Infection

HIV-infected patients with active hepatitis B disease should be considered for therapy.

The clinician should consult with a specialist with experience in treating hepatitis B in patients with HIV infection to determine whether HBV therapy should be initiated, which therapy should be given, and how the patient should be monitored clinically once treated.

The drug regimen of choice is currently unknown because no randomized comparative trials have been conducted in this patient population. Options include interferon alfa-2b, lamivudine, or adefovir; there are insufficient data to recommend combinations of drugs at this time.

In HIV/HBV co-infected patients receiving highly active antiretroviral therapy (HAART) (with or without lamivudine) or interferon, clinicians should periodically measure hepatic transaminases during the course of treatment because of the potential for a flare of hepatitis. Clinicians should closely monitor hepatic function in HIV/HBV co-infected patients who discontinue lamivudine, emtricitabine, and tenofovir.

Lamivudine

If lamivudine is given for treatment of hepatitis B, it should never be used alone. Rather, it should be used in combination with other HIV-active antiretroviral agents as a component of HAART. The recommended dose is 150 mg twice daily or 300 mg once daily.

If lamivudine is discontinued as part of a change in the HAART regimen in patients being treated for HBV, a significant flare of alanine aminotransferase (ALT) may result; therefore, continuing lamivudine should be considered even when HIV resistance to it has developed.

Choosing Therapy for Patients With HBV/HIV Co-Infection

Before initiating therapy for HIV or HBV in co-infected persons, the clinician should consider possible consequences a specific regimen will have on future treatment options for both HIV and HBV.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is not stated.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate management of human immunodeficiency virus (HIV)-infected patients at risk for hepatitis B virus (HBV) infection

POTENTIAL HARMS

- *Hepatitis B virus vaccine*. Some data suggest that inadvertent initiation of hepatitis B vaccination during acute hepatitis B virus (HBV) infection in human immunodeficiency virus (HIV)-infected persons may actually increase the risk of chronic HBV infection. Prior to the initiation of vaccination, testing to exclude a recent HBV infection is advisable.
- *Interferon-alfa*. Interferon-alfa should not be used in patients with decompensated cirrhosis. Interferon alfa is associated with many toxicities (some life-threatening) and should only be used by clinicians who are experienced with its use. Because of its toxicity and limited efficacy, other therapies are considered preferable.
- *Highly active antiretroviral therapy (HAART)*. Several case reports have described a flare of hepatitis following initiation of HAART with subsequent clearance of hepatitis B surface antigen (HbsAg), which is postulated to reflect improved immune function. The frequency of this phenomenon is unknown, and it should be noted that following initiation of HAART, there are rare cases of fulminant hepatic failure and death. HAART is probably an important management strategy for the co-infected patient; however, it should not be relied on to clear chronic HBsAg carriage. Thus, the clinician should be aware of the potential for significant hepatitis due to immune reconstitution, direct hepatic drug toxicity, or withdrawal of lamivudine.
- *Lamivudine*. The alanine transaminase (ALT) levels will frequently rise within 1 to 2 months when lamivudine is used for HBV infection. This rise is transient and should not prompt discontinuation of therapy if the patient is otherwise well. Post-treatment ALT elevations (flares) may occur within 4 months of drug discontinuation. With rare exceptions, these flares do not seem to be clinically severe. The seroconversion from hepatitis Be antigen (HBeAg) to hepatitis Be antibody (HBeAb) may be associated with acute hepatitis that will resolve within a few months.
- *Adefovir*. As with lamivudine, severe exacerbations of hepatitis may occur when adefovir is discontinued.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Following the development and dissemination of guidelines, the next crucial steps are adoption and implementation. Once practitioners become familiar with the content of guidelines, they can then consider how to change the ways in which they take care of their patients. This may involve changing systems that are part of the office or clinic in which they practice. Changes may be implemented rapidly, especially when clear outcomes have been demonstrated to result from the new practice such as prescribing new medication regimens. In other cases, such as diagnostic screening or oral health delivery, however, barriers emerge which prevent effective implementation. Strategies to promote implementation, such as through quality of care monitoring or dissemination of best practices, are listed and illustrated in the companion document to the original guideline (*HIV clinical practice guidelines*, New York State Department of Health; 2003), which portrays New York's HIV Guidelines Program. The general implementation strategy is outlined below.

- Statement of purpose and goal to encourage adoption and implementation of guidelines into clinical practice by target audience.
- Define target audience (providers, consumers, support service providers)
 - Are there groups within this audience that need to be identified and approached with different strategies (e.g., HIV Specialists, family practitioners, minority providers, professional groups, rural-based providers)
- Define implementation methods
 - What are the best methods to reach these specific groups (e.g., performance measurement consumer materials, media, conferences)?
- Determine appropriate implementation processes
 - What steps need to be taken to make these activities happen?
 - What necessary processes are internal to the organization (e.g., coordination with colleagues, monitoring of activities)?
 - What necessary processes are external to the organization (e.g., meetings with external groups, conferences)?
 - Are there opinion leaders that can be identified from the target audience that can champion the topic and influence opinion?
- Monitor Progress
 - What is the flow of activities associated with the implementation process and which can be tracked to monitor the process?
- Evaluate
 - Did the processes and strategies work? Were the guidelines implemented?
 - What could be improved in future endeavors?

IMPLEMENTATION TOOLS

Personal Digital Assistant (PDA) Downloads
Quick Reference Guides/Physician Guides

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

Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

New York State Department of Health. Hepatitis B virus. New York (NY): New York State Department of Health; 2004 Sep. 12 p.

ADAPTATION

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

DATE RELEASED

2003 Mar (revised 2004 Sep)

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

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

Note: This guideline has been updated. The National Guideline Clearinghouse (NGC) is working to update this summary.

GUIDELINE AVAILABILITY

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

Print copies: Available from Office of the Medical Director, AIDS Institute, New York State Department of Health, 90 Church Street, New York, NY 10007-2919; Telephone: (212) 268-6108

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Hepatitis B virus. Tables and recommendations. New York (NY): New York State Department of Health; 2004 Sep. 5 p. Electronic copies: Available from the [New York State Department of Health AIDS Institute Web site](#).
- HIV clinical practice guidelines. New York (NY): New York State Department of Health; 2003. 36 p. Electronic copies: Available from the [New York State Department of Health AIDS Institute Web site](#).

Print copies: Available from Office of the Medical Director, AIDS Institute, New York State Department of Health, 90 Church Street, New York, NY 10007-2919; Telephone: (212) 268-6108

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 summary was prepared by ECRI on January 21, 2004. This NGC summary was updated by ECRI on October 19, 2005.

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