Complete Summary

GUIDELINE TITLE

Diagnostic, monitoring, and resistance tests for HIV.

BIBLIOGRAPHIC SOURCE(S)

New York State Department of Health. Diagnostic, monitoring, and resistance tests for HIV. New York (NY): New York State Department of Health; 2005 May. 12 p.

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: New York State Department of Health. Diagnostic, prognostic, and resistance tests for HIV. New York (NY): New York State Department of Health; 2004. 18 p.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Human immunodeficiency virus (HIV, HIV-1, HIV-2) infection

GUIDELINE CATEGORY

Counseling
Diagnosis
Evaluation
Risk Assessment
Screening
Technology Assessment

CLINICAL SPECIALTY

Allergy and Immunology
Family Practice
Infectious Diseases
Obstetrics and Gynecology
Pediatrics

INTENDED USERS

Advanced Practice Nurses
Clinical Laboratory Personnel
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To recommend the most appropriate human immunodeficiency virus (HIV) related tests including new screening methods, viral load assays, and anti-retroviral (ARV) resistance profiles

TARGET POPULATION

Adults and children older than eighteen months:

- who are at risk of acquiring human immunodeficiency virus (HIV) infection,

  or

- who have been diagnosed as being HIV infected (HIV-1 or HIV-2)

INTERVENTIONS AND PRACTICES CONSIDERED

Counseling

1. Informed consent for tests
2. Post-test counseling
3. Risk reduction counseling as indicated

Diagnostic Tests

Serologic Tests

1. Human immunodeficiency virus (HIV-1) antibody screening assays
    - Enzyme-linked immunoabsorbent assays (ELISA)
    - Home access HIV-1 test system (dried blood spot)
    - Rapid tests
        - OraQuick ADVANCE (OraSure Technologies)
        - Reveal Rapid HIV-1 Antibody Test (MedMira Laboratories)
        - Uni-Gold Recombigen HIV Test (Trinity Biotech)

2. HIV-1 confirmatory antibody assays
    - Western blot (WB)
    - Indirect immunofluorescence assay (IFA)
3. HIV-2 antibody screening assays
    - Combination ELISA

Alternative Antibody-Testing Technologies (for HIV-1 detection only)

1. Oral fluid collection (oral mucosal transudate [OMT]):OraSure
2. Detection of HIV-1 antibodies in urine (note that patients should be counseled regarding reduced sensitivity and specificity of this test)

Viral Identification Assays

1. Deoxyribonucleic acid (DNA) polymerase chain reaction (DNA-PCR)
2. Plasma HIV ribonucleic acid (RNA)
3. Viral culture

Monitoring Tests

1. Lymphocyte analysis (CD4 percentage)
2. Viral load assays
    - Reverse transcription-polymerase chain reaction (RT-PCR) (Roche Amplicor HIV-1 Monitor and Roche Amplicor HIV-1 Monitor Ultrasensitive)
    - Branched chain DNA (bDNA) (Versant HIV-1 RNA 3.0 assay)
    - Nucleic acid sequence-based assays (NucliSens HIV-1 QT assay [bioMérieux])
3. Drug resistance tests
    - Genotypic assays
        - INNO-LiPA HIV-1 RT (Innogenetic/Bayer Diagnostics)
        - Trugene HIV-1 genotyping test (Visible Genetics)
        - ViroSeq HIV-1 genotyping system (Applied Biosystems)
    - Phenotypic assays
        - Antivirogram (Tibotec-Vicro)
        - PhenoSense (ViroLogics)

MAJOR OUTCOMES CONSIDERED

- Sensitivity and specificity of diagnostic tests and screening and confirmatory assays
- Test results, including false-positive, false-negative, and indeterminate results (also known as inconclusive or nondiagnostic results)
- Absolute copy number generated (for viral load assays)
- Efficacy of tests at predicting human immunodeficiency virus (HIV) progression
- Clinical utility of resistance testing

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 three to four 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

Diagnostic Tests

- Diagnostic human immunodeficiency virus (HIV) tests must be performed in compliance with the New York State HIV Confidentiality Law, including written informed consent and full post-test counseling.
- HIV infection should be diagnosed using either the enzyme-linked immunosorbent assay (ELISA) or rapid testing; positive results are confirmed with a Western blot assay.
- Polymerase chain reaction (PCR) diagnostic testing of plasma and peripheral blood mononuclear cells for HIV ribonucleic acid (RNA) or deoxyribonucleic acid (DNA) is recommended for establishing the diagnosis of infection in infants born to HIV-1-infected mothers.
- Clinicians should maintain a high level of suspicion for acute HIV infection in all patients presenting with a compatible clinical syndrome. When acute retroviral syndrome is suspected, a plasma HIV RNA assay should be used in conjunction with HIV-1 antibody test to diagnose acute or primary HIV infection.
- If a recent high-risk exposure to HIV is suspected, a baseline antibody test should be obtained. If the baseline test result is negative, tests should be repeated at 1, 3, and 6 months.
- An individual who tests negative 3 months after exposure but continues to engage in risky behavior should receive counseling to reduce his/her personal risk and the potential transmission to others. Such an individual should be offered repeat testing no more than every 3 months as long as risky behavior continues.

Refer to the original guideline document for discussions of specific serologic tests, including HIV-1 antibody screening assays (enzyme-linked immunosorbent assay [ELISA], home access HIV-1 test system, and rapid tests) and HIV-1 confirmatory antibody assays (Western blot, indirect immunofluorescence assay).

HIV-2

- Clinicians should ask questions regarding possible HIV-2 exposure to identify patients who require HIV-2 screening tests.

Alternative Antibody-Testing Technologies

See the original guideline document for a discussion of alterative antibody-testing assays that test body fluids other than blood (e.g., oral fluid or urine). (Note: The alternative antibody-testing assays are only approved for HIV-1 antibody testing and should not be considered for persons who may be at risk for infection with HIV-2.)

Viral Identification Assays

DNA Polymerase Chain Reaction (DNA-PCR)

- All initial positive DNA PCR reactions should be confirmed with a second PCR test on a separate specimen.

Plasma HIV RNA Assays

- A plasma HIV RNA assay should be used in conjunction with HIV-1 antibody test to diagnose acute or primary HIV infection.

Viral Culture

- A single positive viral culture for HIV should be confirmed with a second specimen.

Monitoring Tests

- Clinicians should measure and follow the CD4 percentage in addition to the absolute count.
- Clinicians should repeat CD4 or viral load results that are inconsistent with the clinical presentation before management decisions are made.

Lymphocyte Analysis

- HIV clinicians should measure and follow the CD4 percentage in addition to the absolute count.

Viral Load Assays

See the original guideline document for a discussion of various viral load assays, which quantify the amount of HIV-1 RNA circulating in the infected patient's blood (e.g. Roche Amplicor HIV-1 Monitor and Roche Amplicor HIV-1 Ultrasensitive, Versant HIV-1 RNA 3.0 assay, and the NucliSens HIV-1 QT assay).

Drug Resistance Tests

- When resistance tests are obtained, expert advice in interpretation is strongly encouraged.
- Genotypic resistance testing should be performed before initiating treatment in anti-retroviral (ARV) therapy-naive patients to determine whether they were infected with drug-resistant virus.
- Resistance testing should be performed promptly in cases of virologic failure or incomplete viral suppression.
- Resistance testing should be performed while patients are still receiving therapy or have been off therapy for no more than 1 year.

See the original guideline for further discussion and description of genotype and phenotype assays for testing drug resistance.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

Recent clinical trial and epidemiological data have contributed to the current guidelines for the use of resistance tests, although long-term data are lacking.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

This guideline is intended to help clinicians make appropriate decisions about diagnostic, prognostic, and resistance testing for human immunodeficiency virus (HIV) in children and adults.

POTENTIAL HARMS

False-positive and false-negative test results

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. Diagnostic, monitoring, and resistance tests for HIV. New York (NY): New York State Department of Health; 2005 May. 12 p.

ADAPTATION

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

DATE RELEASED

2004 (revised 2005 May)

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

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This guideline updates a previous version: New York State Department of Health. Diagnostic, prognostic, and resistance tests for HIV. New York (NY): New York State Department of Health; 2004. 18 p.

GUIDELINE AVAILABILITY

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, 5 Penn Plaza, New York, NY 10001; Telephone: (212) 268-6108

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- 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, 5 Penn Plaza, New York, NY 10001; 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 NGC summary was completed by ECRI on February 1, 2005. This summary was updated by ECRI on August 4, 2005.

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Date Modified: 9/15/2008