Introduction

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Opportunistic infections (OIs), which in the context of HIV have been defined as infections that are more frequent or more severe because of HIV-mediated immunosuppression,[1] were the first clinical manifestations that alerted clinicians to the occurrence of AIDS. *Pneumocystis* pneumonia, toxoplasma encephalitis, cytomegalovirus retinitis, cryptococcal meningitis, tuberculosis, disseminated *Mycobacterium avium* complex (MAC) disease, and pneumococcal respiratory disease, as well as certain cancers such as Kaposi sarcoma and central nervous system lymphoma, have been hallmarks of AIDS. These OIs and many more occurred on average 7 to 10 years after infection with HIV.[2,3] Until effective antiretroviral therapy (ART) was developed, patients generally survived only 1 to 2 years after the initial manifestation of AIDS.[4]

Starting in the late 1980s, the use of chemoprophylaxis, immunization, and better strategies for managing OIs improved quality of life and lengthened survival of people with HIV.[5] Early antiretroviral drugs and treatment strategies added further benefit.[6] However, the most profound reduction in OI-related morbidity and mortality in people with HIV resulted from the introduction of highly effective combination ART in the mid-1990s.[7-13]

Despite the availability of multiple safe, effective, and simple ART regimens that, when used widely, have led to corresponding population-level declines in the incidence of OIs,[11,14,15] the Centers for Disease Control and Prevention (CDC) estimates that more than 13% of people with HIV are unaware of their HIV infection and that 34% of Americans who are aware of their HIV infection are not effectively virally suppressed.[16] As a result, OIs continue to cause preventable morbidity and mortality in the United States.

Achieving and maintaining durable viral suppression in all people with HIV, and thus preventing or substantially reducing the incidence of HIV-related OIs, remains challenging for three main reasons:

- *Not all HIV infections are diagnosed, and once diagnosed many people have already experienced substantial immunosuppression.* CDC estimates that in 2019, among those with diagnosed HIV, approximately 20% had a CD4 T lymphocyte (CD4) cell count <200 cells/mm^3 (or <14%) at the time of diagnosis.[16]
- *Not all people with diagnosed HIV receive timely, continuous HIV care or are prescribed ART.* CDC estimates that in 2019, 81% of people with newly diagnosed HIV had been linked to care within 1 month. However, only 58% of people with HIV were adequately engaged in continuous care.[16]
- *Not all people greater than 13 years old treated for HIV achieve durable viral suppression.* CDC estimates that in 2019, only 68% of people had durable viral suppression within 6 months of HIV diagnosis.[17] Causes for the suboptimal response to treatment include poor adherence, unfavorable pharmacokinetics, or unexplained biologic factors.[18,19]

Thus, some people with HIV infection will continue to present with an OI as the sentinel event leading to a diagnosis of HIV infection or present with an OI as a complication of unsuccessful viral suppression.[17]

Durable viral suppression eliminates most but not all OIs. Tuberculosis, pneumococcal disease, and dermatomal zoster are examples of infectious diseases that occur at higher incidence in people with HIV regardless of CD4 count. The likelihood of each of these OIs occurring does vary inversely with the CD4 count, however.[20-26]

Certain OIs—most notably tuberculosis and syphilis—can increase plasma viral load,[27-31] which both accelerates HIV progression and increases the risk of HIV transmission if patients are not virally suppressed by ART.

Thus, clinicians continue to need to be knowledgeable about the prevention and management of HIV-related OIs.

History of These Guidelines

In 1989, the Guidelines for Prophylaxis Against *Pneumocystis carinii* Pneumonia for Persons Infected with the Human Immunodeficiency Virus became the first HIV-related treatment guideline published by the U.S. government.[32] This guideline was published in the *Morbidity and Mortality Weekly Report (MMWR)*, which was the most rapid mode of publication at the time. It was followed by a guideline on prevention of MAC disease in 1993.[33] In 1995, these guidelines were expanded to include the treatment of 18 HIV-related OIs. In 2004, information about the prevention of HIV-related OIs was incorporated into the guidelines. The National Institutes of Health (NIH), CDC, and the HIV Medicine Association of the Infectious Diseases Society of America (HIVMA/IDSA) now jointly co-sponsor these guidelines,[1,34,35] which have been published in peer-reviewed journals and/or the MMWR in 1997, 1999, and 2002.[35-44] Since 2009, the guidelines have been managed as a living document on the web with each chapter reviewed quarterly by the guidelines committee. Updates are published as often and as promptly as deemed appropriate by the guidelines committee.

Data regarding the use of these guidelines demonstrate that the document is a valuable reference for HIV health care providers. In 2021, there were approximately 417,000 page views of the online version of the guidelines and approximately 19,600 PDF downloads.

All guideline recommendations regarding therapy and prevention are rated in terms of the quality of supporting evidence; comments about diagnosis are not rated. These ratings allow readers to assess the relative importance of each recommendation. This document focuses on adults and adolescents; recommendations for children with HIV can be found in separate documents on the Clinicalinfo website.

These guidelines are intended for clinicians, other health care providers, patients with HIV, and policymakers in the United States. Guidelines pertinent to other regions of the world, especially resource-limited countries, may differ with respect to the spectrum of relevant OIs and the diagnostic and therapeutic options that are available to clinicians.

Snapshot of Guidelines Development Process

These guidelines were prepared by the OI Working Group under the auspices of the Office of AIDS Research Advisory Council (OARAC), an authorized Federal Advisory Committee to the U.S. Department of Health and Human Services established in 1994. Co-chairs who are selected and appointed by their respective agencies or organizations (i.e., NIH, CDC, IDSA, HIVMA) convene

OI-specific working groups of clinicians and scientists with subject matter expertise in those specific OIs. The co-chairs appoint a leader for each working group.

The working groups review in real time the relevant literature published since the last review, with the help of quarterly literature searches for articles relevant to their section that are provided by guidelines support staff. The working groups propose revisions to their section as appropriate. The co-chairs, HIVMA/IDSA, and CDC review each proposed revision to recommendations and/or ratings.

The co-chairs and working group leaders have a teleconference quarterly to discuss updates to sections. The co-chairs also convene a meeting each year with members of the Panel on Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents with HIV to review guidelines content and format and set an agenda for the coming year.

The names and affiliations of all contributors, as well as their financial disclosures, are provided in Appendix B: Panel Roster and Financial Disclosures.

Guidelines Development Process	
Topic	**Comment**
Goal of the guidelines	Provide guidance to HIV care practitioners and others on the optimal prevention and management of HIV-related opportunistic infections (OIs) for adults and adolescents in the United States.
Panel members	The Panel on Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents with HIV (the Panel) is composed of co-chairs who represent the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), and the HIV Medicine Association of the Infectious Disease Society of America (HIVMA/IDSA), plus Panel members with expertise in HIV clinical care, infectious disease management, and research. Co-chairs are appointed by their respective agencies or organizations. Each working group is led by a Panel member selected by the co-chairs. Panel members are selected from government, academia, and the health care community by the co-chairs and working group leaders based on the member's area of subject matter expertise. Members serve on the Panel for a 4-year term, with an option to be reappointed for additional terms. Prospective Panel members may self-nominate at any time. When specific or unique subject matter expertise is required, the co-chairs together with working group leaders may solicit advice from individuals with such specialized knowledge. The list of the current Panel members can be found in Appendix B: Panel Roster and Financial Disclosures.
Financial disclosure and management of conflicts of interest	All members of the Panel submit a written financial disclosure annually reporting any associations with manufacturers of drugs, vaccines, medical devices, or diagnostics used to manage HIV-related OIs. A list of these disclosures and their last update is available in Appendix B: Panel Roster and Financial Disclosures. The co-chairs review each reported association for potential conflicts of interest and determine the appropriate action: disqualification from the Panel, disqualification or recusal from topic review and discussion, or no disqualification needed. A conflict of interest is defined as any direct financial interest related to a product addressed in the section of the guideline to which a Panel member contributes content. Financial interests include direct receipt by the Panel member of payments, gratuities, consultancies, honoraria, employment, grants, support for travel or accommodation, or gifts from an entity having a commercial interest in that product. Financial interests also include direct compensation for membership on an advisory board, data safety monitoring board, or speakers' bureau. Compensation and support provided to a Panel member's university or institution (e.g., grants, research funding) is not considered a financial conflict of interest. The co-chairs strive to ensure that 50% or more of the members of each working group have no conflicts of interest.
Primary users of the guidelines	HIV treatment providers
Developer	Panel on Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents with HIV—a working group of the Office of AIDS Research Advisory Council (OARAC). See Appendix B: Panel Roster and Financial Disclosures.
Funding source	Office of AIDS Research (OAR), NIH
Evidence collection	The recommendations in the guidelines are based on studies published in peer-reviewed journals. On some occasions, particularly when new information may affect patient safety, unpublished data presented at major conferences or information prepared by the U.S. Food and Drug Administration or manufacturers (e.g., warnings to the public) may be used as evidence to revise the guidelines. Members of each working group are responsible for identifying relevant literature and conducting a systematic comprehensive review of that literature that is provided to them on a quarterly basis.

Method of synthesizing data and formulating recommendations	Each section of the guidelines is assigned to a working group of Panel members with expertise in the area of interest. The members of the working group synthesize the available data. Recommendations are reviewed and updated by each working group after an assessment of the quality and impact of the existing and any new data. Aspects of evidence that are considered include but are not necessarily limited to the type of study (e.g., case series, prospective cohort, randomized controlled trial), the quality and appropriateness of the methods, and the number of participants and effect sizes observed. Finally, all proposed recommendations and supporting evidence are reviewed by the co-chairs and subject matter experts at CDC and HIVMA/IDSA before final approval and publication. OAR reviews all proposed recommendations and gives final approval.
Recommendation rating	Recommendations are rated according to the information in the table below, "Rating System for Prevention and Treatment Recommendations," and accompanied, as needed, by explanatory text that reviews the evidence and the working group's assessment. All proposed changes are discussed during teleconferences and by email and then assessed by the Panel's co-chairs and reviewed by OAR, CDC, and HIVMA/IDSA before being endorsed as official recommendations.
Other guidelines	These guidelines focus on prevention and treatment of HIV-related OIs for adults and adolescents. A separate guideline outlines similar recommendations for children who have HIV infection. These guidelines are also available on the Clinicalinfo website.
Update plan	Each working group leader and the co-chairs meet every 3 months by teleconference to review interim data that may warrant modification of the guidelines. Updates may be prompted by approvals of new drugs, vaccines, medical devices, or diagnostics; by new information regarding indications or dosing; by new safety or efficacy data; or by other information that may affect prevention and treatment of HIV-related OIs.

How to Use the Information in These Guidelines

Recommendations in this report address—

- Preventing exposure to opportunistic pathogens;
- Preventing disease;
- Discontinuing primary prophylaxis after immune reconstitution;
- Treating disease;
- When to start ART in the setting of an acute OI;
- Monitoring for adverse effects (including immune reconstitution inflammatory syndrome);
- Managing treatment failure;
- Preventing disease recurrence (secondary prophylaxis or chronic maintenance therapy);
- Discontinuing secondary prophylaxis or chronic maintenance therapy after immune reconstitution; and
- Special considerations during pregnancy.

Recommendations are rated according to the criteria in the table below and accompanied, as needed, by explanatory text that reviews the evidence and the working group's assessment. In this system, the letters A, B, or C signify the strength of the recommendation for or against a preventive or therapeutic measure, and the Roman numerals I, II, or III indicate the quality of the evidence

supporting the recommendation. In cases where there are no data for the prevention or treatment of an OI based on studies conducted in people with HIV, but there are data derived from studies in people without HIV that could plausibly guide management of patients with HIV, the recommendation is rated II or III but is assigned A, B, or C depending on the strength of the recommendation.

Rating System for Prevention and Treatment Recommendations	
Strength of Recommendation	**Quality of Evidence for the Recommendation**
A: Strong recommendation for the statement B: Moderate recommendation for the statement C: Weak recommendation for the statement	I: One or more randomized trials with clinical outcomes and/or validated laboratory endpoints II: One or more well-designed, non-randomized trials or observational cohort studies with long-term clinical outcomes III: Expert opinion

This document also includes tables in each section pertinent to the prevention and treatment of the OI(s) in that section, as well as seven summary tables at the end of the document (Tables 1–7) and a figure of the latest Advisory Committee of Immunization Practices immunization recommendations adapted to adults and adolescents with HIV.

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