

Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults: Development and Dilemmas.

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As defined by the Institute of Medicine (IOM) in the United States, clinical practice guidelines are “systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances”. Guidelines are presumed to be evidence based, reliable and free from bias; the only interest is improving patient care.

Several resources are available to inform the development of clinical practice guidelines, including the major elements they should contain and the approach to guideline making. Ten such elements are: identity, developer, purpose, intended audience, target population, method of development, testing, revision plan, implementation plan, and knowledge components [<http://gem.med.yale.edu/Hierarchy/hierarchy.htm>]. The approach to guideline making includes the creation of a diverse panel of experts, a systematic review of the relevant evidence, and systematic procedures for evaluation of the evidence, developing a recommendation linked with the evidence and assigning a level of strength to the evidence and the recommendation.

Unfortunately, differences between the ideal and actual environment in which clinical practice guidelines are developed result in several dilemmas. Most important is that evidence is complex and our knowledge is always incomplete. This means that guidelines can never be derived solely from the published evidence and expert judgment is necessary. This also allows for conflicting guidelines. Additional challenges include peer/independent review of the guidelines, whether recommendations are unanimous or not, the unintended consequences (e.g. marketing, medico-legal) of the recommendations, and financial and intellectual conflicts of interest of the panel members.

In 1996 the Department of Health and Human Services (DHHS) in the United States convened a panel of experts in HIV research and clinical care from academia, clinical practice, governmental agencies and community representatives with a primary goal to provide guidance to HIV care practitioners on the optimal use of antiretroviral agents for the treatment of HIV infection in adults and adolescents in the United States. The Panel is composed of more than 30 voting members with broad expertise in HIV care and research. The funding source for the panel is the Office of AIDS Research of the National Institutes of Health. The primary areas of focus are baseline assessment, treatment goals, when to start antiretroviral therapy, what regimen to start in treatment-naïve patients, drugs or combinations to be avoided, management of adverse effects and drug interactions, management of treatment failure, and considerations in special patient populations. The intent of the guidelines is to present recommendations for these topics based upon evidence that is strong enough to guide medical practice. The Panel reviews new evidence on an ongoing basis and may update recommendations when needed. The DHHS Guidelines are now only available as a “living document” on the *AIDSinfo* website [<http://www.aidsinfo.nih.gov>]. Though there are limitations and room for improvement, the elements and approach used by the DHHS Panel has stood a 14 year test of time and continues to be regarded as a reliable source of guidance for health care practitioners caring for HIV-1-infected persons.

Recommended Reading

1. Gross PA. When guidelines don't guide the physician. *Clin Infect Dis* 2009;49:1530-1.
2. Furberg CD, Sniderman AD. Why guideline-making requires reform. *JAMA* 2009;301:429-431.
3. Rawlins MD. The decade of NICE. *Lancet* 2009;374:351-52.
4. Kendall T, McGoey L, Jackson E. If NICE was in the USA. *Lancet* 2009;374:272-3.
5. Hirsh J, Guyatt G. Clinical experts or methodologists to write clinical guidelines? *Lancet* 2009;374:273-5.

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