

Guidelines for the use of antiretroviral agents in HIV infections in Taiwan, Revised 2002

*Infectious Diseases Society of the Republic of China;
Taiwan AIDS Society;
Medical Foundation in Memory of Dr. Deh-Lin Cheng;
Foundation of Professor Wei-Chuan Hsieh for Infectious Diseases Research and Education; and
Lee CY's Research Foundation for Pediatric Infectious Diseases and Vaccine*

Significant progress has been made in the field of antiretroviral therapy over the past year. New drugs have been approved for clinical use, and new insights gained in many aspects of therapy. In view of this, an update of the first "Guidelines for the Use of Antiretroviral Agents in human immunodeficiency virus (HIV) Infections in Taiwan," which was established in March 11, 2001, was indicated. To achieve this, the Infectious Diseases Society of the Republic of China and Taiwan AIDS Society organized a consensus meeting on November 24, 2001, gathering specialists, experts, and government officials in Taiwan, to update guidelines for current use of antiretroviral therapy in HIV-infected patients.

This updated guidelines harbored 2 major changes.

The new guidelines are more conservative in the initiation of treatment in asymptomatic patients, but at the same time, offered an option for treatment in patients with CD4⁺ T-cell counts of above 350 /mm³. A new drug, Kaletra, is now available in Taiwan, and has been included in the new guidelines.

Other important issues not addressed in the current guidelines include the side effects of antiretroviral therapy, drug resistance, patient compliance, guidelines for prevention of opportunistic infections, immunotherapy, and vaccines. An annual revision of the current guidelines will be made to update and address problems encountered in antiretroviral therapy in Taiwan, and to provide a guideline tailored for Taiwan people.

Guidelines for the use of antiretroviral agents in HIV-infected patients

A. General consideration

1. When to start

- (1) Acute HIV infection: treatment should be offered.
- (2) Symptomatic: treatment should be offered.
- (3) Asymptomatic:

Adults:

Treatment should be offered when CD4⁺ T cells <350 /mm³, or HIV RNA >30 000 copies/mL (bDNA), or HIV RNA >55 000 copies/mL (RT-PCR).

Treatment may be deferred when CD4⁺ T cells >350 /mm³, or HIV RNA <30 000 copies/mL (bDNA), or HIV RNA <55 000 copies/mL (RT-PCR).

Pediatrics:

Treatment should be offered to all newly diagnosed infected children, or if universal early treatment not feasible, treatment should be offered if there is evidence of immune suppression as follows:

Ages	CD4 ⁺ T cells	
	No./mm ³	%
1-5 yrs	<1000	<25%
6-12 yrs	<500	<25%

2. When to change

(1) Virologic failure:

- i. A reduction in plasma HIV RNA of less than 0.5 to 0.75 log₁₀ 4 weeks following initiation of therapy; or less than 1 log₁₀ by week 8.
- ii. Failure to suppress plasma HIV RNA to undetectable levels within 4 to 6 months after initiating therapy.
- iii. Repeated detection of virus in plasma after initial suppression to undetectable levels, suggesting the development of resistance.
- iv. Any reproducible significant increase, defined as 3-fold or greater, from the nadir of plasma HIV RNA not attributable to intercurrent infection, vaccination, or test methodology.

(2) Toxicity

(3) Intolerance

B. Recommended regimens^a

Diagnosis	Drug of choice		Alternative		
	Column A	Column B	Column A	Column B	
1. Acute HIV infection	Indinavir	Combivir ^b	Abacavir	AZT+3TC	
	Saquinavir-SGC	d4T+3TC		AZT+ddl	
	Ritonavir	ddl+3TC		AZT+ddC	
	Nelfinavir			d4T+ddl	
	Efavirenz				
	Nevirapine				
	Saquinavir + Ritonavir				
	Indinavir + Ritonavir				
	Kaletra ^c				
2. Asymptomatic HIV infection	Indinavir	Combivir ^b	Abacavir	AZT+3TC	
	Saquinavir-SGC	d4T+3TC		AZT+ddl	
	Ritonavir	ddl+3TC		AZT+ddC	
	Nelfinavir			d4T+ddl	
	Efavirenz				
	Nevirapine				
	Saquinavir + Ritonavir				
	Indinavir + Ritonavir				
	Kaletra ^c				
3. Advanced HIV disease	Indinavir	Combivir ^b	Abacavir Nevirapine	AZT+3TC	
	Saquinavir-SGC	d4T+3TC		AZT+ddl	
	Ritonavir	ddl+3TC		AZT+ddC	
	Nelfinavir			d4T+ddl	
	Efavirenz				
	Saquinavir + Ritonavir				
	Indinavir + Ritonavir				
	Kaletra ^c				
4. HIV-infected pediatric patients ^d	Ritonavir ^e	AZT ^g + 3TC ^e	Abacavir ^e Nevirapine ^f	AZT ^g + ddC ^e	
	Nelfinavir ^f	AZT ^g + ddl ^f		d4T ^e + 3TC ^e d4T ^e +ddl ^f	
5. HIV infection in pregnant women	Nevirapine	Combivir	Nelfinavir Indinavir	AZT + 3TC	
	Saquinavir-SGC	AZT + ddl		d4T + 3TC	
		Ritonavir			
6. Prophylaxis after occupational exposure ^h	Indinavir	Combivir	Nelfinavir Saquinavir-SGC	AZT+3TC	
				d4T+3TC	

Abbreviations: Saquinavir-SGC = Saquinavir-soft gel capsule; d4T = Stavudine; 3TC = lamivudine; AZT = zidovudine; ddl = didanosine; ddC = zalcitabine

^aAntiretroviral drug regimens are comprised of one choice each from columns A and B.

^bCombivir: AZT/3TC.

^cKaletra: lopinavir/ritonavir.

^dAll regimens used for adults are also recommended for pediatrics.

^eOral solution formulation available.

^fPowder formulation for suspension available.

^gSyrup formulation available.

^hThe previous treatment regimens of source patient should be taken into consideration; the duration of treatment is 4 weeks; the risk group should be considered, if contact with body fluid except blood, dual therapy is recommended.

*Consensus Conference Participants (in alphabetical order):

Yu-Jiun Chan, Feng-Yee Chang, Kenneths Chang, Shan-Chwen Chang, Mao-Yuan Chen, Ming-Yuan Chou, Mong-Ling Chu, Che-Yen Chuang, Chang-Phone Fung, Wei-Chuan Hsieh, Clement C.S. Hsu, Po-Ren Hsueh, Chun-Kai Huang, Fu-Yuan Huang, Kun-Yen Huang, Li-Min Huang, Chin-Ching Hung, Ko-Pin Hwang, Chi-Kin

Lan, Yeu-Jun Lau, Chin-Yun Lee, Say-Tsung Liao, Chau-Ching Lin, Hsi-Hsun Lin, Hwa-Chen Lin, Reey-Yi Lin, Sheue-Rong Lin, Cheng-Yi Liu, Ching-Chuan Liu, Yung-Ching Liu, Kwen-Tay Luh, Shiing-Jer Twu, Fu-Der Wang, Lih-Shinn Wang, Ning-Chi Wang, Wing-Wai Wong, Shiow-Ing Wu, Chin-Hui Yang, Muh-Yong Yen, Kwok-Woon Yu.