

COST ISSUES

122. Given the cost of viral load measurements and protease inhibitors, what would you recommend for the 80% of the world who are resource poor?

Dr Saag: Serial viral load measurement should be reserved for clinical situations in which the measurement can actually have an impact on therapeutic decisions. If a clinician has very little access to medications and no drugs are available to change to when a given regimen begins to fail, it probably is not worth the expenditure of resources to routinely follow viral load. On the other hand, if therapeutic options are available, viral load measurements become quite cost effective in minimizing exposure to ineffective but expensive drugs. In rare instances, when drug supply is limited, viral load measurements may be helpful on a one-time basis to help identify individuals who would best benefit from therapy versus those in whom therapy may be deferred.

123. What strategies would you put forth to get HMOs, Medicaid, insurance companies, etc, to provide funds for viral load tests and antiretrovirals? And how would you include the pharmaceutical companies in this project?

Dr Saag: At the present time, virtually all third party payers, including HMOs, Medicaid, and Medicare, are paying for routine viral load testing. Most private insurance companies are also paying for necessary antiretroviral therapies as deemed appropriate by the treating physician. The primary difficulty in achieving access to antiretroviral therapies is within Medicaid and other government-sponsored programs. In those instances, fixed allocation of dollars has already been determined for a given population of patients. The changes in clinical treatment over the last year, which strongly advocate combination therapy with as many as three agents (some which cost \$6000 or more per year), have, in essence, bankrupted the original allocation dollars to the individual programs for those patients. The best strategy to ensure increased allocation of funds to those patient populations within the government sector would be to provide detailed evidence demonstrating a true clinical benefit, including traditional measurements of benefit (eg, mortality and morbidity) as well as quality of life, patient satisfaction, and patient productivity data.

124. As an international panel, why do you make recommendations that can only be

applied in Western Europe and the US (based on viral load measurements)? Why are alternative recommendations for poorer resource settings not given?

Dr Volberding: The field of HIV medicine does not exist independent of the harsh realities of the world in which we live. Poverty, discrimination, and limited access to medical care are more often the rule than the exception in this epidemic. Even in heavily endemic regions, other pressing societal concerns may take priority. The same, of course, can be said for almost all areas of medicine. How many patients with acute myocardial infections are treated within hours with thrombolytic drugs? This is not an excuse for the current recommendations, but there is no particular reason not to provide the best treatment guidelines when resources are available for their implementation as we work to develop easier, less expensive strategies that might be more relevant in regions with limited funds where HIV is, yet, a common disease. Some hope in this regard is possible with the NNRTIs, which may be considerably easier to synthesize, hence less expensive to manufacture, than the comparably potent protease inhibitors. In the end this is a political question and one that will be heard more and more loudly as we achieve real benefit from aggressive treatment strategies.

125. Could you distinguish between what you think is best to do and what you are capable of doing (such as initial triple therapy) taking into account the administrative limitations of social security, etc. In Belgium, for example, combination therapy is very difficult to obtain.

Dr Fischl: Optimal regimens should always be given whenever possible. However, several studies have now shown that didanosine monotherapy as well as combination therapies with zidovudine/didanosine and zidovudine/zalcitabine are superior to zidovudine monotherapy. Thus one option is to start with didanosine, if no other therapies are available.

Dr Yeni: It has not yet been validated that an initial 3-drug combination regimen is the best option for all patients. In any case, where the best recommended regimen is not available because of administrative limitations, one should try to adopt a treatment strategy validated in clinical trials. For example, 2-drug combinations and didanosine monotherapy have been demonstrated to be effective for initial therapy.

126. To what degree did cost consideration influence your decisions on antiretroviral therapy recommendations?

Dr Fischl: Cost did not influence our consideration, but only the current available data; this was essential for the recommendations of the best current therapies. Obviously, cost will present problems over the next several years. However, long-term vigorous therapy should result in prolonged and higher quality of life and potentially decrease transmission.

127. What are your views/recommendations/suggestions on access to treatment in poorer countries?

Dr Saag: Each country is limited by its available resources. There is very little that most people can do to change the economic conditions within a given country in different parts of the world. Nonetheless, strategies can be initiated that determine what resources are available and utilize those resources to the best advantage for the most number of patients. This may involve routine viral load testing and establishment of specific guidelines for the type of individuals who would receive antiretroviral therapy versus those who would not, based on available resources. These criteria would vary from country to country and are dependent on the other types of resources that are available to physicians and patients in their local communities.