



New ethical obligations accompany new HIV drugs, conference told

Ann Silversides

Researchers recruiting people who are newly infected with HIV for clinical trials should accept supplementary ethical obligations, a recent research conference in Victoria was told.

"Today's newly infected people are not at risk of short-term death," said Jean-Pierre Bélisle, a researcher with l'École des hautes études commerciales in Montreal. "Yet they are often pressured to enter clinical trials within days of testing positive, when they are very vulnerable because of the emotional shock."

Bélisle told the conference of Canadian Association of HIV Research that many of these newly diagnosed patients are young, with low literacy levels. Although all clinical trials undergo ethical review and require signed informed consent, said Bélisle, "many [newly infected persons] cannot read or understand long texts, so a written information sheet is not enough. Research ethic boards need to explore new ways to convey information, perhaps through videotapes or obligatory information sessions with independent counsellors."

To give truly informed consent for an aggressive early start on antiretroviral therapy, these patients need sophisticated treatment information and a lot of basic information about living with HIV. For example, "they need to know they could be well for years without treatment."

They also need to know the practical consequences of embarking on drug therapy: it may be a lifetime commitment, it's difficult to take so many pills each day and it can be costly to do so, and it is difficult to hide both the pill taking and drug side effects from acquaintances.

Several sessions at the conference concerned the difficulty that all patients have adhering to treatment that includes protease inhibitor therapy. Patients say the disadvantages include the number of pills that have to be taken and the limitations that strict drug schedules place on spontaneous activity. Side effects, which can include weight redistribution and intestinal problems, are also a problem.

In a study of 53 HIV-positive women in Ontario, only 6% reported that they weren't sure whether they had taken all their medication exactly as prescribed. However, when asked "when was the last time you missed taking any of your medication," 47% reported missing within the last week. The researchers concluded that additional time should be spent addressing potential barriers to adherence before embarking on antiretroviral drug regimens.

Dr. Joep Lange of the University of Amsterdam noted

that "only a year ago, long-term toxicity [of antiretroviral therapy] was a nonissue." However, because of the side effects that are now known to accompany protease inhibitors — these include lipodystrophy, hyperlipidemia and insulin resistance — lifelong therapy with these drugs "may not be attainable. We have to search for protease-inhibitor-sparing regimens, and alternating treatment options."

Lange thinks poor prescribing is a major contributor to drug failure. "You can't go to just any clinic — [you have to see] people who know and understand these drugs."

Lange added that despite talk of protease-inhibitor toxicity, "we should not forget" the toxicity associated with the earlier HIV-fighting drugs, such as zidovudine.

Living longer with AIDS

Researchers reported some good news about the life expectancy of Vancouver's gay and bisexual men, which improved between 1990/92 and 1995/97. However, it still lags significantly behind life expectancy in the general population.

The study of men who live in Vancouver's West End was an attempt to evaluate the impact of newer antiretroviral drugs. It was undertaken by the British Columbia Centre for Excellence in HIV/AIDS and the Department of Psychology at Simon Fraser University.

Between the 2 time periods, gay and bisexual men experienced an increase of almost 4 years in life expectancy at age 20, researcher Keith Chan told the conference. At age 20, life expectancy for the men was an additional 37 years in the 1990/92 period, and 40.8 years in the 1995/97 period.

However, "life expectancy among gay men is quite low compared with the general population," he noted. At age 20, life expectancy within the general population is roughly 55 years, for an average life span of 75 years.

Researchers say the life-expectancy gains for gay and bisexual men "are likely attributed to rapid use of more potent antiretroviral drugs" among HIV-positive men.

A separate telephone survey within the same population found that the HIV-infection rate among the men was about 15.7%, and that 83% of the members of this group were receiving antiretroviral therapy.

It found no difference in age and education between HIV-positive and HIV-negative men, but HIV-positive men were more likely to have an annual income of less than \$10 000.

Ann Silversides is a Toronto journalist.