HIV screening in 'healthy' volunteers and Ethics Committees

In a recent article in the Journal, Thomson *et al.* [1] pointed out the interest of screening healthy volunteers to prevent subjects with HIV infection from entering clinical trials, and to protect research personnel in the manipulation of blood samples often taken in these studies. His paper is an excellent example of how researchers have to deal, nowadays, with ancillary aspects of the design and organization of the studies far away from the traditional methodological and ethical considerations.

The necessity to screen systematically for HIV in volunteers in our Phase I unit was considered at the early stages of its functioning. Spanish regulations and elemental ethical considerations compelled us to inform subjects wishing to participate in our studies that an HIV test would be performed, among some other clinical and analytical tests. This could preclude the participation of subjects not wishing to be aware of a possible positive result of the test (otherwise done because of a non-therapeutic intervention).

After a comprehensive discussion with the Ethics Committee supervising our unit of the pros and cons of several ways of combining the necessity of information with that of a smooth recruitment, it was decided that all subjects wishing to participate in any study ought to be informed about the performance of an HIV test. A specific HIV Consent Form (HCF) other than the consent form to participate in the trial was designed. This consent form has to be signed, both by the investigator and by the volunteer. A refusal of the volunteer precludes his or her consideration as a candidate for participation in the study. This procedure assures the healthy status of the volunteers and eliminates an important risk factor for the professionals involved in the study.

To allay misgivings about the information generated by the test, the HCF gives the volunteers the possibility of choosing whether they wish to be informed of the result of the test. Only the result, whatever his or her choosing, is considered for the volunteer's inclusion and the volunteers are duly informed about this point. We believe that this modification could reduce the impact of a frightening result on the recruitment rate.

Although early clinical studies and the social impact of Medicine and Research are often seen as distant, the lack of useful tools against an epidemic infection like AIDS, points out the necessity of re-discovering old thinking habits whilst conducting clinical research.

More recently, we have modified our HCF to include information about the social responsibility of volunteers who refuse to know the result of the test, as well as a short statement about the current therapeutic possibilities in AIDS.

This new HCF has been in use since September 1992. Since then, 208 subjects have routinely been screened. Their mean age was 21.3 ± 3.7 years and 126 were male. Most of them were upper-middle class University students, many of them in Medicine. Over this period four cases of a positive (duplicate) result for HIV by Enzimoimmunoanalysis with Ag HIV 1 CORE Y ENV derived from recombinant DNA were found, three of them in males. All cases were referred to a general hospital for confirmation of the diagnosis by Western-Blot, treatment and follow up. One case, a female, was a false positive, finally being diagnosed as lupus erythematosus. The acceptance of the updated version of HCF is excellent: in contrast to our past experience, no refusals to be tested have occurred and, except in two cases (both male, both negative), all subjects wished to know the outcome of the test.

Our experience reflects that 1) screening for HIV by objective and reliable methods should be a routine practice in clinical pharmacology studies; 2) a straightforward cooperation between the research team and the Ethics Committee is a key factor for the improvement of the scientific and ethical standards of clinical research. The Ethics Committee should be considered as an active part of the research team; 3) clear and complete information to volunteers will never preclude the success of a study. Moreover, free and conscious participation will enhance the role of the volunteer as the subject of the research and 4) clinical pharmacologists should be aware of the social impact of their work, and of the new challenges that are posed by the continuous evolution of Medicine and Science.

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