Hot News

Denial of Expert Opinion in HIV Court Cases

The transmission of HIV and cases of discrimination related to HIV-positive status has generated several court cases in the last couple of decades. In such cases, expert opinion can be very valuable and often even decisive. While in some cases an expert scientific opinion is indeed requested, in others the court makes its decision without consulting any expert.

Probably the most famous HIV court case with denial of scientific evidence and expert opinion is the recent Libyan case, in which a foreign medical staff member was charged and imprisoned for eight years for the infection of children attending that hospital. Before the announcement of the death sentence, a study had been published in Nature proving that the HIV-1 and HCV strains that infected the children were already circulating and prevalent in the hospital before the arrival of the medical staff (de Oliveira, et al. Nature. 2006;444:836-7). However, the court ignored the scientific study and released the medical staff only as a result of political negotiations. Yet, earlier court cases had already shown how valuable scientific evidence and expert opinion can be. Although the Florida dental case was the first to be thoroughly supported with scientific evidence for transmission (Ou, et al. Science. 1992; 256:1165), at that time this data was not considered in court. However, it was used by the health insurance companies to settle a claim out of court. The first case in which a scientific report was used in court was the Swedish rape case (Albert, et al. J Virol. 1994;68:5918-24), where the expert report contributed to the conviction of the accused .

Last month, a Portuguese court supported the decision of a restaurant to fire an HIV-positive cook, considering it legitimate and justified because his HIV-positive status might have represented a risk for public health. Expert opinion was requested and subsequently ignored. The scientific report included documentation from the U.S. Centers for Disease Control and Prevention (CDC), stating that "HIV-1 is found in saliva, tears, and blood", that "contact with saliva, tears, or sweat has never been shown to result in transmission of HIV", that "drying of HIV-infected human blood or other body fluids reduces the theoretical risk of environmental transmission to that which has been observed – essentially zero", and specifically that "there is no known risk of HIV transmission to co-workers, clients, or consumers from contact in industries such as food-service establishments" (CDC, 1999 #3). The court decided to use part of this report "HIV-1 is found in saliva, tears, and blood" and to add its own interpretation. The court argued that "even though the information (of the CDC) mentions that no one was ever infected with HIV due to contact with an environmental surface, this statement is not relevant for the discussion. The question at hand is not to evaluate known risks, but exclude the possibility of risks". These statements are, besides being scientifically wrong, contributing to discrimination of HIV-positive patients.

This recent case is just the top of the iceberg, since most similar cases remain uncovered because patients don't easily sue their employers. It is therefore important to have a standardized procedure on how an external expert opinion should be considered to avoid decisions based on wrong assumptions, which have a negative impact on the integration of HIV-positive patients in society.

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New trials comparing protease inhibitors and nonnucleoside analogs will assess reductions in cardiovascular risk besides antiviral efficacy in first-line therapies

Boehringer Ingelheim recently announced the initiation of a new clinical trial, called NewArT, that will compare the efficacy and safety of the NNRTI nevirapine (Viramune®) versus the ritonavir-boosted protease inhibitor atazanavir (Reyataz®, Bristol-Myers Squibb). The study will enroll 150 HIV treatment-naive patients from 18 planned sites across the USA. Both agents will be combined with the fixed-dose combination of tenofovir and emtricitabine (Truvada®, Gilead Sciences). In this phase IV, open-label, randomized trial, patients will be randomized to receive either 200 mg of Viramune twice daily or 300 mg of atazanavir boosted with 100 mg of ritonavir once daily. Patients in the Viramune arm will begin their treatment with 200 mg once daily increased to 200 mg twice daily after two weeks. The current Viramune $CD4^+$ cell criteria will be applied to both arms of the study. Patients will be treated for up to 48 weeks. The NEwArT trial results are expected to be available at the end of 2009. The primary endpoint will be virologic response at 48 weeks, defined as a viral

load < 50 copies/ml at two consecutive visits prior to week 48 and without subsequent rebound or change of antiretroviral therapy by week 48. The main secondary endpoint will be an evaluation of change in fasting lipids.

A similar trial is already ending enrollment of nearly 700 drug-naive patients outside the USA. A metabolic substudy including computerized tomography scan assessments is being performed in a subset of patients. Preliminary results are expected to be available early in 2009. The rationale to compare nevirapine and atazanavir is based on the good lipid profile of these drugs, the best within their respective families. Since the goal of complete suppression of viral replication is almost achieved with most of the approved triple-drug therapies, other issues such as metabolic abnormalities and prevention of cardiovascular risk are gaining importance in the long-term management of antiretroviral therapy. This is why the results of NewArT and ArTEN are eagerly awaited by the HIV scientific community.

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