Algorithm for recall of HIV reactive blood donors

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HIV testing in an important measure to protect the recipient of blood and blood products from getting the HIV infection. Hence we must use very sensitive tests to detect all the HIV infected donors. However, the flip side to an extremely sensitive test is the generation of false positivity i.e. positive test in a person who is not really infected. Hence using an extremely sensitive as well as specific test in a health population i.e. the population of voluntary blood donors is definitely going to produce false positivity in a number of donors, for example if incidence of HIV infection in general population is 1:1,00,000 and the fourth generation ELISA has a specificity of 99.9%, that means if we test all 1,00,000 people with the above mentioned ELISA then 100 people will test positive, while in reality only 1 is really infected! Hence, as the prevalence of a disease becomes rare, even the most specific and sensitive tests will produce large number of false positives. So long India was testing all blood bags anonymously except these false positives causing wastage of valuable blood by rejection it was not producing unnecessary anguish in the donors. However, with the introduction of information to the donors if they want to know their HIV ELISA status and if found positive, sending them to voluntary counselling centers (VCTC) more caution is needed because the test results could be false positives as a result of the background noise in microbiological screening assays.[1] This noise increases steeply in developing countries where various bacterial, viral and parasitic infections are common compared to developing countries.[2] An indication of the magnitude of noise in India was shown by Choudhary et al when out of 65288 voluntary donor tested 834 were positive for ELISA assay (12.8/1000 donors), when the ELISA assay was repeated this positivity fell to 1.1/1000 donors and Western blot positivity was only 0.28/1000. Still we are not certain that whether all the 0.28/1000 donors who were western blot positive were really infected or not because the absence of P31 band positivity in western blot has been shown in some studies not to be associated with HIV infection.[4]

In the paper under discussion the author wanted to see whether using a second ELISA only or a second rapid test followed by Western Blot reduces the biological false positivity of the test. The study following WHO guidelines[5] showed, this is indeed the case. The author also showed that using a rapid test following ELISA produces lesser number of biological false positives than using two ELISA tests sequentially.

Before we agree to this finding and use it universally this algorithm needs to be tested in different blood banks in our country, to give it the required robustness. The present study may be regarded as a hypothesis generating study and the hypothesis needs further retesting in our situation.

Another important finding in the present study[6] which is in line with a number of other similar studies is that high sample/cut off ratio (>2.35 in this paper) convincingly picks up true positive patients. One of the drawbacks of the present study is that the findings i.e whether those who have been reported as biological false positive are really biological false positive by antigen (P24) assay or by RNA based testing or not?

Finally we must not forget that we have the duty to protect our recipient as well as give the true picture to the donor without increasing his/her anxiety. Hence sequential ELISA positive or ELISA followed by rapid test positive blood bags no doubt are to be discarded but when the results are discordant a more pragmatic approach needs to be taken. The donor should be called for counseling only after few more investigations like unequivocal western blot positivity/antigen positivity or RNA PCR positivity.

In circumstances where it cannot be resolved immediately proper counselling and repeat studies on follow up will reveal the true picture in most of these donors.

References