IMPACT OF NONSPECIFIC REACTIVITIES IN SCREENING TESTS UPON BLOOD COLLECTION.

A. Necula[1], A. Popescu[1], M. Hoinarescu[2], I. Rachita[2]
1. National Institute of Hematology and Blood Transfusion; 2. BTS, Bucharest

BACKGROUND: Screening of blood donations relies primarily on enzyme immunoassays (EIA). Continuous refining of EIAs improved their sensitivity and specificity. As the senzitivity of the last generations of EIAs has reached almost the last limit minimizing the negative window and increasing the capacity to detect a large range of mutans and viral varians, a specificty of 100% and will probably never be achieved with current technologies. Nonspecific reactivities are frequently donor related or assay related and represent a challenge for blood services. Voluntary nonremunerated blood donors are recruited from low-risk populations and the majority of reactive results obtained in screenig turn out to be nonspecific upon confirmatory testing, determine loss of blood products and defferal of donors who require counseling, additional testing and sometimes medical evaluation. We report here the prevalence of non specific reactivities and its impact on blood collection.

METHODES: 1.655.732 blood donations collected during 2011-2014 were screened for HIV, HBV, HCV and HTLV by Blood Transfusion Centers(BTC) and repeat reactive samples sent to the Central Reference Laboratory for confirmation. A sequential algorithm is used for confirming anti-viral antibody reactivity which includes retesting in the original EIA followed by an alternative EIA and imunoblot for samples reactive in 2 EIAs or with high sample-to-cut-off ratios. An isolated rectivity in one EIA and an indeterminate or negative imunoblot result requires retesting on a follow-up sample after a time to exclude the potential serological window. HBsAg is confirmed by specific neutralization with anti-HBsAg and additional testing for anti-HBc, HBeAg/anti-HBe, Anti-HBs.

REZULTS: 15825 blood units were discarded due reactive screening tests and sent for confirmation. 12044 (76%) were actualy confirmed as positives for the suspected virus.Between 2%(HBV) and 22%(HTLV) of samples were not confirmed in the initial screening test. The yield of reactive samples by suspected virus and the rate of confirmation (HIV:801/22%; HBV:10865/91%; HCV:3608/50%; HTLV:329/34%) are concordant with the local prevalences and higher for specific antibody EIAs. The apparent specificity resulted from large scale screening ranges from 99.89% for HCV to 99.99% for HTLV with a frequency of nonpositive cases from 1/926 for HCV to 1/7630 for HTLV. Some nonspecific reactivities were only tranzient (from 2% for HBV up to 8% for HIV) and retesting the donor after several months gave negative results, but up to 74% are persistent. Donors with tranzient nonspecific reactivity or due to tests replaced by more performant ones may be eligible for future reentry.

CONCLUSIONS: The rate of nonspecific reactivity resulted from current screening of blood donations over the last four years suggests nonsignificant loss to blood collection(<1%). The donors with persistent nonspecific reactivities, though noninfected, are permanently deferred to minimize loss of resources. The challenge for the BTCs is to inform these donors of their results and to minimize donor anxiety, since it is very difficult to explain to donors that although not infected their blood is not suitable for transfusion. Additionally, misinterpretation by donors of such results, can lead to medicolegal implications.