ESTIMATION OF RESIDUAL RISK OF TRANSFUSION TRANSMITTED HIV-1 AND HCV DURING 2011-2014.

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1. National Institute of Hematology and Blood Transfusion; 2. BTS, Bucharest BACKGROUND: The residual risk(RR) of transfusion transmitted infections(TTI) is expressed as the probability of having a potentially infectious blood unit/component validated by the current screening technologies and its estimation is a vital tool for evaluating the safety of blood supply. The RR of TTIs is mainly generated by window period (WP) infections in repeat blood donors(RBD) and depends on the characteristic length of WP for the screening tests and the incidence. Mathematical models have been developed based on these parameters, including the interval between the negative and the positive donation. The accuracy of such models is validated by measuring the observed against the predicted outcome. We had previously estimated the row potential RR based only on the observed frequencies of incident cases among RBDs. Changes in screening and confirmation technologies since 2011, inprovement in data collection, increased availability of repository samples for retrospective testing and the prevalence and incidence changes in first-time blood donors (FTBD)and RBDs after 2010, conducted to reevaluation of the RR for, that we report here. METHODS: An incidence/WP model incorporating the median interval between donations for RBDs seroconverting within 2 years (Seed et all,Internal Medicine Journal, 2005; 35:592-598) has been used. WP values published for the current screening tests are 15 and 20 days for HIV and HCV respectively. Prevalence and incidence are expressed for 100,000 donations. Data from serological screening of 1.655.732 donations (382.283 FTBD and 1.273.449 RBD) were analysed and, for HIV and HCV positive RDB the median interval between donations was determined. Where available, repository samples from previous negative donations were tested for HIV-1 p24 antigen, HIV-1 and HCV RNA respectively, to determine the infectious status.

RESULTS: The HIV-1 prevalence and incidence were 43 in FTBD and 4.3 in RBD respectively. 51/58 positive RBDs seroconverted in a median interval of 152 days the resulting theoretical RR for HIV-1 being 1/253025. For HCV a prevalence of 467 and an incidence of 2.4 were observed. 25/31 cases seroconverted within 2 years with a median interval of 95 days resulting in a theoretical RR of 1/241955. RNA testing was performed on 57%(29/51) and 20%(6/25) repository seronegative samples from seroconverting RBDs for HIV-1and HCV respectively. 3 viremic blood donations were identified for each virus corresponding to an observed frequency of infectious donations of 1/424483.

CONCLUSIONS: For HCV the estimated RR is similar to those reported in Western EU and USA prior to the introduction of NAT screening, but is well above those reported for HIV. The observed frequency of seronegative viremic donations is probably underestimated due to unavailability of all repository samples. The computed RR points to the probability of collecting at least 1 infectious blood units per year for each virus, and was restricted to incident cases among RBD, but the risk from seroconversion among FTBD should be taken into account. The local prevalences for TTIs and the detection of viremic WP-donations indicate that further reduction of the residual risk would occur only through introducing the NAT testing of all donations together with improving standards for donor selection.