C3. ASSESSMENT OF HIV, HCV, HBV VIREMIA IN SEROPOSITIVE BLOOD DONORS; IMPACT ON DONATED BLOOD NAT SCREENING STRATEGIES.

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Background: Nucleic acid amplification techniques (NAT) has been gradually introduced worldwide, as a complement to serological testing aiming at reducing the residual risk of TTI (Transfusion Transmitted Infections), due to serological window or silent chronic infections. Triplex or duplex testing systems are comercially available and testing is performed either on ID (individual donation) or in minipools (MP) of 6 to 96 donations, according to national plolicies. Variable yields of NAT on serologically negative and serologically confirmed positives were reported for epidemiologically diverse areas, resulting in important differences in yield of window phase and occult infections. In Romania, blood donation screening for TTI relies on serological methods and previous occazional detection of viremic seronegative donations points to the need of introducing NAT. Local prevalences and levels of viremia among seropositive blood donors would contribute to establishing the pool size for NAT screenig. We report here the results of NAT testing on serologically confirmed donations.

Methods: Plasma samples from anti-HIV(201), anti-HCV(408) and HbsAg(366) confirmed donations were extracted with EZ1 DSP Virus Kit (Qiagen) and amplified with Arthus HIV, HCV and HBV kits (Qiagen) for viral load quantification.The LODs95% of the tests are 67, 34 and 3.8 IU/ml respectively. All samples were serologically confirmed by Inno-Lia Score(Innogenetics) for HIV and HCV, and by a confirmatory HbsAg assay, anti-HBc, HBeAg and anti-Hbe for HBV infection. For HCV positive samples with full developed serological profiles(316) and weak positive samples (92) with reactivities towards two different HCV antigens were tested.

Results: HIV-1: 198/201samples were had detectable RNA within a log c range of 1.7-7.4, except for one case which was repeatedly detectable under the LOD 95%. 91.9% of viral loads were over log 3.0 and 8.6% were over log 6.0, cumulating 41.2% of the recent infection cases. 3 seropositive samples were not detected by NAT, either due to the limits of the test or to originating from so called „elite controllers". HCV: Among the positive samples 71%(223/316) were detected, an yield comparable to those reported for the european countries, with 97.3% of viral loads ranging from log 3.0, and 31.4% over log 6.0. Only 4.9% were under log 3.0 and one repeatedly reactive under LOD 95%. For the weak positive samples only 8/92 were detected. HBV:90.2% of samples were detected with only 33.3% diplaying viral loads over log 3.0, and 11% repeatedly detectable under LOD 95%. 184/330(55.8%) of cases had viral loads between the LOD 95% and log 3.0, specific for the asymptomatic carriers, in contrast to 44/47 cases with viral loads over log 6.0 which were also HbeAg positive.

Conclusions: The local prevalences of blood transmitted viruses and the detection by NAT of HIV and HCV positive window-period donations during the last two years indicate that further reduction of the residual risk of TTI would occur only through introducing the NAT testing of all donations together with improving standards for donor selection. The adequate size of MPs has to be considered based on the distribution of viral loads in seropositive donors and the impact on the blood unit validation process. On the other hand,the existence of NAT negative HBV and HCV serologically positive blood donors has been reported worldwide, indicating that serological screening must be maintained evan with the most sensitive NAT performed on ID