EVALUATION OF NAT-MPX SCREENING OF BLOOD DONORS IN A GREEK BLOOD CENTER – ITS CONTRIBUTION TO BLOOD SAFETY

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Introduction

A large number of blood transfusions are carried out every second around the world. When it is done correctly, it can lead to saving lives and improving in general a patience's healthcare. Although, a blood transfusion may also result in a series of complications starting with the risk of transmission of infective diseases. Blood safety procedures and testing of blood and blood products, reduce this risk considerably, however, with the current technology in use, the risk remains.
Nucleic acid amplification test (NAT) in blood donor screening was introduced worldwide in the last few decades evolving the diagnostic landscape. It reduces significantly the transmissions of viruses through blood, thus strengthening the blood safety system. In Greece, AHEPA Molecular blood center is running since June 2006 screening blood donations from 37 blood banks of the country. Molecular screening for the three viruses HBV, HCV and HIV is mandatory in Greece, in combination with serological testing for HBV, HCV, HIV(I,II), HTLV and syphilis.

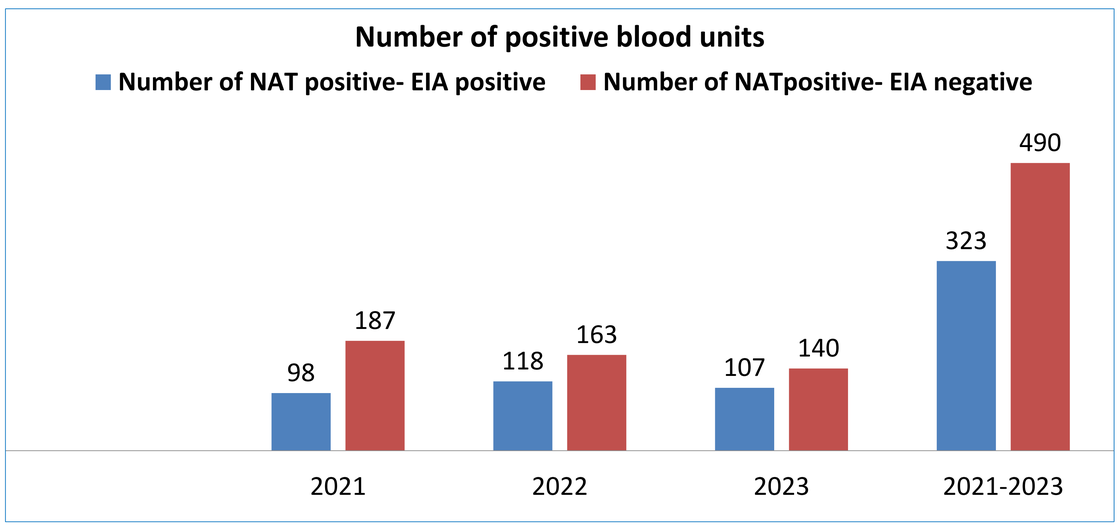

Table 1. Number of positive blood units

Year	NAT positive- EIA positive	NAT positive- EIA negative (occultHBV, initial HIV-HCV-HBV)
2021	98	187
2022	118	163
2023	107	134
2021-2023	323	490

Methods and Materials

Between 1st January, 2021 and 31st December, 2023 all blood donations at the AHEPA Molecular Blood center were screened individually using the multiplex agent (MPX- HIV, HCV, HBV) in Roche Cobas 8800 system. These donations were also tested using screening serological methods for the same three viruses based on the Abott Alinity S system.
According to the applied algorithm for all samples, a reactive result for HIV-DNA, HCV-RNA, HBV-DNA initiates a series of further testing which includes retesting of the initial sample and testing of a FFP sample from the blood unit. In addition to this, it requires a complete serological testing for HbsAg, anti-HCV, anti-HIV and HBV serological markers (Anti-HBcore, Anti-HBs, HBeAg Anti-Hbe, HBcIgM) only in case of positive HBV-DNA result. Furthermore, a follow up donor sample is requested to confirm reactivity within the first week after the original donation. A second follow up donor sample after a period of 90 days is also recommended.
For the purposes of this study, a user – friendly spreadsheet based on the MS Office Excel 2010 was developed. The file that was created is a sort of a database organized in rows and columns containing different variables such as number of blood donations per year, number of NAT positive samples, number of OBI samples. Also, it was formatted in a way that made importing, reading and analysing the data convenient.

Results

During the examined three-year period, 567948 blood donations were tested; 813/567948(0.14%) samples were found positive for at least one of the three viruses.

592/813(72.82%) were tested HBV-DNA reactive. 258/592 (43.58%) were verified with EIA as HbsAg positive. 34/592(5.74%) were found to be negative with EIA and classified as "Initial HBV reactive". 300/592(50.67%) were tested HbsAg negative but anti-HBcore positive and classified as "Occult HBV (OBI)''. Focusing on the OBI cases, 176/300 (38%) were found reactive only in the initial sample . 215/300 (45%) showed reactivity of the retesting and/or the FFP sample. 77/300 (17%) follow up samples were tested with the vast majority of them 54/300(12%) were found negative. Our testing showed, also, that 91/300 (30.33%) OBI donors had an Anti-HBs titre greater than 100IU/L.

98/813(12.05%) were tested HCV-RNA reactive. 48/98(48.98%) were verified with EIA as anti-HCV positive. 50/92(51.02%) were found to be negative with EIA and classified as "Initial HCV reactive".

123/813(15.13%) were tested HIV-DNA reactive. 22/123(17.89%) were verified with EIA as anti-HIV positive. 101/123(82.11%) were found to be negative with EIA and classified as "Initial HIV reactive".

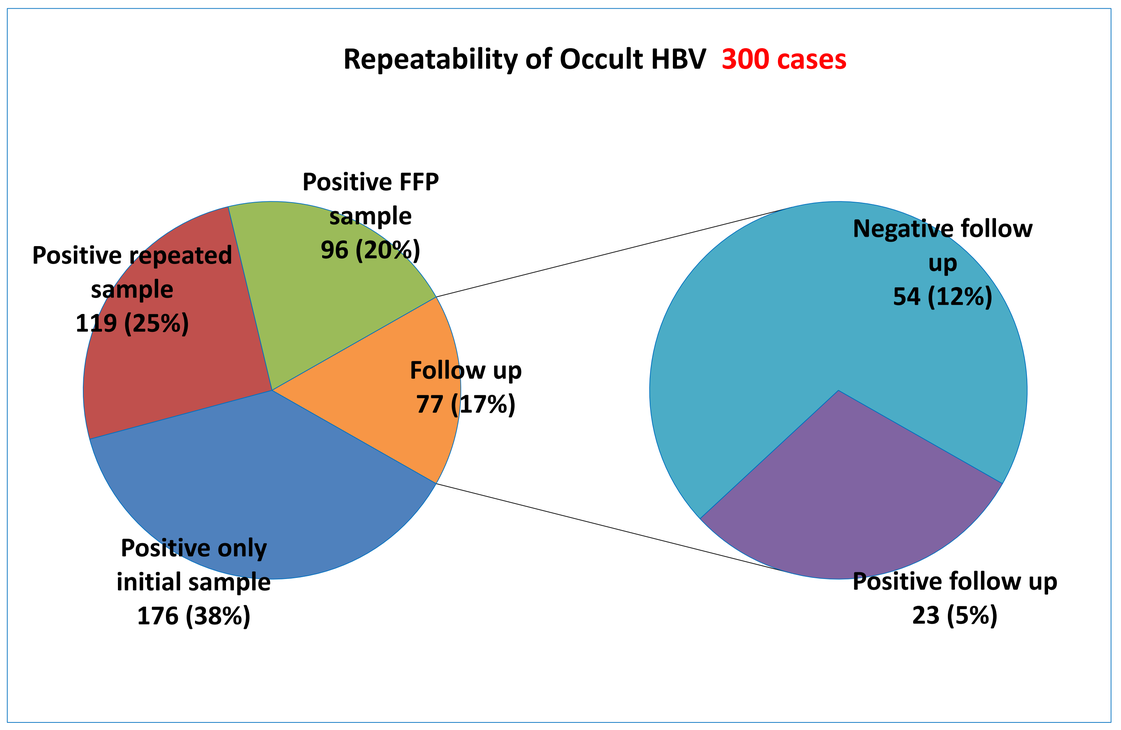

Chart 1. Repeatability of Occult HBV.

Conclusion- Discussion

The experience of the blood center's activity has proved that NAT has increased considerably the blood transfusion safety. Based on the existing literature, HBV transmission through blood components from asymptomatic apparently healthy donors later revealed as affected by occult hepatitis B is possible. In our case, 300/592(50.67%) blood units from "occult hepatitis B" (OBI) donors have been rejected and were prevented from being administrated. However, only 124/300 (41.34%) showed repeated reactivity. This represents a gap in the blood safety that suggests even more drastic measures, such as increase of NAT reagents sensitivity and testing of anti-HBcore screening for all blood donors. More over, recent studies have established that the presence of Anti-HBs confers protection against HBV infection and its transmission. Consistent with this, our data revealed that an Anti-HBs titre greater than 100IU/L was detected at a significant percentage 91/300 (30.33%) of OBI donors.

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