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THE FIRST INDIAN MULTICENTER EVALUATION OF INDIVIDUAL DONOR NUCLEIC ACID TESTING (NAT) FOR SIMULTANEOUS DETECTION OF HUMAN IMMUNODEFICIENCY VIRUS -1 AND HEPATITIS B AND C VIRUSES (HIV-1, HCV AND HBV)

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Background

Nucleic acid testing (NAT) for HIV-1 and HCV has significantly reduced transfusion transmission of these viruses in many countries where it has been implemented for blood screening. HBV NAT is currently used for blood screening in Japan and is under evaluation in other countries. India has the world's 2nd highest prevalence of HIV infection, along with a high prevalence of HCV and HBV, but has yet to adopt NAT for screening. As India has over 1850 licensed blood banks, screening methods must be adaptable to low volume settings.

Aims

The objectives of this study were: 1) to observe NAT yield for HIV-1, HCV and HBV in a representative sample of Indian blood donors, and 2) to determine the feasibility of NAT implementation in India's low volume setting.

Materials and Methods

Between June 2004 and January 2005, 12,224 unlinked samples with their serological results were obtained from 4 types of blood centers (stand alone, hospital based, government and non-government) in 7 major Indian cities. These samples were subsequently individually manually tested at the Indraprastha Apollo Hospital, New Delhi, by the PROCLEIX ULTRIO Assay (Ultrio)¹ (Chiron, Corp. Emeryville, CA U.S.) based on transcription mediated amplification for simultaneous detection of HIV-1, HCV, and HBV. Samples originally reactive by Ultrio were subsequently confirmed by the Discriminatory Assay (Chiron Corp).

Results

Of the 12,224 samples, 209 (1.7%) were reactive for at least 1 of the 3 viruses, 133 (1.1%) were confirmed reactive by NAT, and 125 (1.02%) by both serology and NAT. Of 27 samples which were Ultrio reactive but non reactive by the Discriminatory Assay, only 5 had sufficient volume for repeat Ultrio testing and were non-reactive on retest. The distribution of serology reactive and confirmed NAT reactive samples is shown in the following table:

% of 12,224 (100 x n/12,224)	HIV-1	HCV	HBV	Combined total %
% total sero-reactive	0.26 (n=32)	0.33 (n=40)	1.12 (n=137)	1.71 (n=209)
% sero-reactive/ NAT non-reactive	0.17 (n=21)	0.22 (n=27)	0.29 (n=36)	0.69 (n=84)
% total NAT reactive	0.11 (n=13)	0.12 (n=15)	0.87 (n=106)	1.09 (n=133)
% NAT reactive/ seronon-reactive (NAT yield)	0.016 (n=2)	0.008 (n=1)*	0.05 (n=6)	0.065 (n=8)

* Sample reactive to both HCV and HIV-1 also counted in HIV-1 tally

As 1 operator screened 182 samples by Ultrio in 6-7 hours, we estimated 1 operator working a single shift could perform between a few thousand to ~55,000 tests annually.

Conclusions

Our observed NAT yield for all 3 viruses in India is 1 in 1528 (0.07%) donations (1 / 6112 (0.02%), 1 / 12,224 (0.01%), and 1 / 2037 (0.05%) for HIV, HCV and HBV, respectively), approximately 29 times that observed in Japan for all 3 viruses, and possibly 515 times that observed in the U.S. or Canada for HIV alone. NAT screening was feasible in India's low volume setting. Its implementation could help intercept an estimated 3,272 infectious blood donations per year among our ~ 5 million annual donations (818, 409, and 2454 for HIV, HCV, and HBV, respectively).

¹ CE approved in Europe