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PERCENTAGE OF BLOOD DONORS WITH DOUBTFUL NEGATIVE RESULTS IN AG/AB SCREENING FOR HCV, HBV AND HIV IN BLOOD BANK ,RIMS, RANCHI, JHARKHAND

Blood Bank

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ABSTRACT

Background: The serological screening tests are unable to detect the disease within their own defined window period making the recepients vulnerable to get infection.

Aim: To reduce the risk of TTI in recepients by repeating the tests with dissimilar results and increasing the grey zone range from 10 to 20 % below the cut of value.

Methods: Blood samples were screened for HIV-I and II, HBV and HCV by using chemiluminescence techanique.

Results: During January 2016 to December 2016 a total of 27790 blood units were screened which showed 282 HBSAg (1.01%) positive ,222 (0.79%) anti HCV positive and 53(0.19%) anti HIV positive. Cumulative percentage of all the blood units with OD (optical density) 0.90 RLU and above was 2.0%.

Conclusions: Doubtful negative results in Ag/ab screening for HCV, HBV and HIV should be retested. Any result showing OD 90 RLU and above should be discarded.

KEYWORDS

Transfusion Transmitted Infections, Doubtful Negative Results

INTRODUCTION

Every year millions of lives are saved through blood transfusions and many times it becomes first line of treatment. so blood transfusion should be safe for every recipient. The goal of any transfusion service must be to provide adequate and safe, blood and blood products to the recepients. In spite of advanced screening test technologies, recipients still have an increased risk of becoming infected with human immunodeficiency virus (HIV) and other transfusion transmitted infections (TTIs) such as hepatitis B virus (HBV) and hepatitis C virus (HCV) 1. Presently available all the serological screening tests are unable to detect the disease within their own defined window period making the recepients vulnerable to get infection as well as the blood donors are allowed to infect more recepients by their repeated blood donation. With close observation all the serological tests give some clue to consider the donors in their window period if the test results are different from most of the consecutive results for the particular antigen or antibody and all those samples are retested by the same procedure and if any result shows value within grey zone, their respective blood bag must be discarded to reduce the incidence of transfusion transmitted infections among the recepients. **Aim** of our study is to reduce the risk of TTI in recepients by repeating the tests with dissimilar results and increasing the grey zone range from 10 to 20 % below the cut of value. If OD **(optical density)** 1.0 is considered as cut of value then the test results from 0.80 and above (20% less than cut of value) need to be considered as grey zone results and the respective donors blood bags should be discarded.

MATERIAL AND METHODS

This retrospective study was done from January2016 to December 2016 in the department of Blood Bank, Rims,Ranchi including all the replacement and voluntary blood donors coming to that period .Donors passing the proper donor selection criteria as laid down by drug and cosmetic act were included in the study after obtaining their informed consent 6. During that period 27790 blood units were screened which showed 282 HBSAg positive blood units, 222 anti HCV positive blood units and 53 anti HIV positive blood units. All the blood samples were centrifused at 10,0000 rpm and their plasma were separated and all the samples were recentrifused which showed result in between 70 to 99 before taking the second result and all the samples which showed result in between 1.0 to 1.30 test was repeated without recentrifugation. All the test were done by chemiluminescence techanique by abbott company and strictly followed the manufacturer's guideline. For HBV and HCV third generation reagent and for HIV fourth generation reagents of abbott company were used. For all these three tests 1.0 OD was taken as cut of value and below which blood samples were considered as negative and above which blood samples were considered as positive. Every 2 to 3 days quality control were run for HBSAg, anti HCV antibody and anti HIV antibody to regulate the proper functioning of the machine. All the samples with cut off value 1.0 and more were considered as reactive and their respective blood units were discarded. Grey zone was calculated as 10% below the cut-off value. All the blood samples which showed result under grey zone were also discarded. All the grey zone samples were retested in duplicate for their respective viral marker using the same kits. On repeat testing, the grey zone samples showing value again in grey zone marked as nonreactive and the blood units were discarded and the donors were notified for repeat testing after 6 months. If on repeat testing the grey zone sample showed value above the cut-off value it was marked as reactive and blood units were discarded and donors were notified.

RESULTS

During January2016 to December 2016 a total of 27790 blood units were screened which showed **282 HBSAg(1.01%)** positive , **222(0.79%) anti HCV** positive and **53(0.19%)anti HIV** positive .Cumulative overall percentage of all the blood units with OD(**optical density**) 0.90 and above is **2.0%.**Only **1.56%** of all the blood units showed **OD 0.50 to0.89RLU** either for HBSAg,HCV or HIV and among these **0.26%** blood units showed **OD 0.70 TO 0.79RLU** and **0.14%** blood units showed **OD 0.80 to 0.89RLU** either for HBSAg, HCV or HIV respectively.**[Table 1**].Showed total no of blood units with OD 0.90 RLU and above for HBSAg, anti HCV antibody and anti HIV antibody month wise. **[Table 2].**showed average % of blood units with OD 0.90 RLU and above either for HBSAg, anti HCV antibody and anti HIV antibody month wise.**[Table 3].**showed percentage of blood units with OD less than 0.50 RLU and between 0.50 to 0.89 RLU either for HBSAg, anti HCV antibody and anti HIV antibody month wise.[Table 4]. showed no of blood units with OD 0.50 to 0.59, 0.60 to 0.69,0.70 to 0.79 and 0.80 to 0.89 RLU either for HBSAg, anti HCV antibody and anti HIV antibody month wise.

DISCUSSION

In India, screening of all blood donors is done complying with the strategy I as laid down by World Health Organization (WHO). Strategy I of WHO mentions subjecting all blood donors sample to one time ELISA for screening purposes and marking samples with OD above or equal to cut-off OD as reactive or positive and samples below cut-off OD as nonreactive or negative.[1] Literature regarding detection of grey zone sample and its application in TTI screening procedures in blood bank set up is scarce.[2] Therefore, it becomes very prudent to assess the

utility of grey zone calculation and its role in improvising the current screening methodologies.[2] Solanki et al presented their experience of testing grey zone samples as well as samples showing result 20 to 30 below the cut of value and and its role in enhancing the sensitivity of current chemiluminescence technology used for blood donor screening at their setup.[2] Presently, there are no such existing guidelines for grey zone sample testing in any regulatory authority in India and most of the blood bank in India follow the strategy I of one time ELISA testing as screening procedure as per WHO guidelines.[1] Another method to enhance the sensitivity of ELISA as screening assay is an estimation of the sample lying in a grey zone and its repeat testing. It has been very well-illustrated by Pereira et al.[3] that ELISA-based screening test for TTI in blood banks does involve a certain amount of uncertainty especially around the cut-off zone used for calculating the reactive samples. Grey zone sample testing might not have gained much relevance due to the issues of false positivity on repeat testing wherein a study conducted in Turkey have reported 70% false positivity on testing grey zone samples.[4] It has also been estimated that on applying the confirmatory test to grey zone samples resulted up to only 2% of true positivity.[5] Grey zone samples showing repeat reactivity, for either of the viral markers, on repeat testing as that of 4.6-75% in relevant studies.[5,6,7,2] One of shortcoming of our study is the inability of performing the confirmatory assay. However, repeat reactivity in grey zone sample testing is an alarming indication for mandatory implementation of more sensitive testing technologies like NAT in developing countries.[2] On the inclusion of grey zone sample testing, we observed the prevalence of HBV, HIV, and HCV to be 2%, 0.44%, and 0.56%, respectively.[2] which was higher then our study which showed prevalence of HBV, HIV, and HCV to be 1.01%,0.19% and 0.79% respectively. Recently Acar et al. have also reported similar findings of 1.76%, 0.17%, and 0.50% for HBV, HIV, and HCV in Turkey.[5] Finally to reduce the risk of TTI in recepients every blood sample should be screened primarily through ELISA and all those samples mandatarilly screened through NAT.

TABLE 1:- SHOWED TOTAL NO OF BLOOD UNITS WITH OD 0.90 RLU AND ABOVE FOR HBSAG, ANTI HCV ANTIBODY AND ANTI HIV ANTIBODY MONTH WISE.

S.N	Month	Total no of blood units screened	No of HBsAg positive blood units	% of HBsAg positive blood units	No of Anti HCV antibody positive blood units	% of Anti HCV antibody positive blood units	No of anti HIV antibody positive blood units	% of anti HIV antibody positive blood units
1	January-16	1846	15	0.05	08	0.02	05	0.01
2	February-16	2043	18	0.06	12	0.04	07	0.02
3	March-16	2187	17	0.06	14	0.05	04	0.01
4	April-16	2254	24	0.08	13	0,04	04	0.01
5	May-16	2445	35	0.12	14	0.05	03	0.01
6	June-16	2657	20	0.07	22	0.07	04	0.01
7	July-16	2561	26	0.09	29	0.10	04	0,01
8	August- 16	2388	19	0.06	31	0.11	08	0.02
9	September-16	2521	37	0.13	24	0.08	01	0.003
10	October-16	2058	17	0.06	12	0.04	06	0.02
11	November-16	2397	21	0.07	18	0.06	03	0.01
12	December-16	2433	33	0.11	25	0.08	04	0.01
Total		27790	282	1.01	222	0.79	53	0.19

TABLE2:- SHOWED AVERAGE % OF BLOOD UNITS WITH OD 0.90 RLU AND ABOVE EITHER FOR HBSAG, ANTI HCV ANTIBODY AND ANTI HIV ANTIBODY MONTH WISE.

S.N	Month	Total no of blood units screened	Total no of blood units positive for either HBSAg, anti HCV antibody and anti HIV antibody	% of total no of blood units positive for either HBSAg, anti HCV antibody and anti HIV antibody
1	January-16	1846	28	0.10
2	February-16	2043	37	0.13
3	March-16	2187	35	0.12
4	April-16	2254	41	0.14
5	May-16	2445	52	0.18
6	June-16	2657	46	0.16
7	July-16	2561	59	0.21
8	August- 16	2388	58	0.20
9	September-16	2521	62	0.22
10	October-16	2058	35	0.12
11	November-16	2397	42	0.15
12	December-16	2433	62	0.22
Total		27790	557	2.0

TABLE 3:-SHOWED PERCENTAGE OF BLOOD UNITS WITH OD LESS THAN 0.50 RLU AND BETWEEN 0.50 TO 0.89 RLU EITHER FOR HBSAG, ANTI HCV ANTIBODY AND ANTI HIV ANTIBODY MONTH WISE.

S.N	Month	Total no of samples showing OD less than 0.50 RLU either for HBSAg, anti HCV antibody and anti HIV antibody	Percentage of Total no of samples showing OD less than 0.50 RLU either for HBSAg, anti HCV antibody and anti HIV antibody	Total no of smples showing OD between 0.50 to 0.89 RLU either for HBSAg, anti HCV antibody and anti HIV antibody	Percentage of Total no of smples showing OD between 0.50 to 0.89 RLU either for either HBSAg, anti HCV antibody and anti HIV antibody
1	January-16	1802	6.48	16	0.05
2	February-16	1953	7.02	53	0.19
3	March-16	2104	7.57	48	0.17
4	April-16	2188	7.87	25	0.08
5	May-16	2353	8.46	40	0.14

6	June-16	2582	9.29	29	0.10
7	July-16	2474	8.90	28	0.10
8	August- 16	2298	8.26	32	0.11
9	September-16	2424	8.72	35	0.12
10	October-16	1971	7.09	52	0.18
11	November-16	2319	8.34	36	0.12
12	December-16	2330	8.38	41	0.14
Total		26798	96.43	435	1.56

TABLE 4:-SHOWED NO OF BLOOD UNITS WITH OD 0.50 TO 0.59, 0.60 TO 0.69,0.70 TO 0.79 AND 0.80 TO 0.89 RLU.

S.N	Month	Total no of smples showing OD between 0.50 to 0.59 RLU either for HBSAg, anti HCV antibody and anti HIV antibody	Total no of smples showing OD between 0.50 to 0.59 RLU either for HBSAg, anti HCV antibody and anti HIV antibody	Total no of smples showing OD between 0.60 to 0.69 RLU either for HBSAg, anti HCV antibody and anti HIV antibody	Total no of smples showing OD between 0.60 to 0.69 RLU either for HBSAg, anti HCV antibody and anti HIV antibody	Total no of smples showing OD between 0.70 to 0.79 RLU either for HBSAg, anti HCV antibody and anti HIV antibody	Total no of smples showing OD between 0.70 to 0.79 RLU either for HBSAg, anti HCV antibody and anti HIV antibody	Total no of smples showing OD between 0.80 to 0.89 RLU either for HBSAg, anti HCV antibody and anti HIV antibody	Total no of smples showing OD between 0.80 to 0.89 RLU either for HBSAg, anti HCV antibody and anti HIV antibody
1	January-16	6	0.02	4	0.01	4	0.01	2	0.007
2	February-16	24	0.08	15	0.05	10	0.03	4	0.01
3	March-16	22	0.07	14	0.05	08	0.02	4	0.01
4	April-16	12	0.04	7	0.02	4	0.01	2	0.007
5	May-16	15	0.05	12	0.04	10	0.03	3	0.01
6	June-16	12	0.04	8	0.02	5	0.01	4	0.01
7	July-16	13	0.04	7	0.02	5	0.01	3	0.01
8	August- 16	17	0.06	10	0.03	4	0.01	1	0.003
9	September-16	14	0.05	10	0.03	7	0.02	4	0.01
10	October-16	26	0,09	16	0.05	5	0.01	5	0.01
11	November-16	18	0.06	9	0.03	6	0.02	3	0.01
12	December-16	21	0.07	10	0.03	6	0.02	4	0.01
Total		197	0.70	122	0.43	74	0.26	39	0.14

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