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BLOOD DONOR LOSS IN THE LIGHT OF FALSE POSITIVE OUTCOMES ATTRIBUTED TO SELECTION OF SCREENING METHODS, FINANCIAL AND HUMAN CONSTRAINS

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Abstract:

Objective: *We aimed at the determination of "False Positive" testing percentage for the TTIs (Transfusion Transmitted Infections) by utilizing ICT (Immune Chromatographic Test) as first option of the test screening and we also assessed the effects on the volunteer blood donor's loss.*

Methodology: *In the timeframe of four months we screened donor's blood bag samples experiencing phlebotomy at Allied Hospital, Faisalabad for the verification of HIV (Human Immune Deficiency Virus), HBV (Hepatitis B) and HCV (Hepatitis C) with the help of immune chromatographic screening tests. We confirmed and retested all the samples those were positive in the course of initial screening process through ELISA Kit and available service of blood transfusion in the same hospital.*

Results: *Number of total volunteer donors was (62090), which was a huge number to handle. In the total sample population total 469 cases were observed as reactive at the initial stage to HBV, HIV or HCV. In the reactive cases (469); a total of 96 cases (0.15%) were observed to be tested as "False Positive" against HBV, HIV or HCV; when compared through ELISA testing Kit in the laboratory setting.*

Conclusions: *The rate of "False Positive" during sample screening was observed as 96/62090 (0.15 %). This rate is considered as very small in the loss of donors and an appropriate available resources utilization. Though, ICT is not taken as gold standard; however, at the initial screening process its importance cannot be neglected and overruled.*

Key Words: *TTIs (Transfusion Transmitted Infections), ICT (Immune Chromatographic Test), False Positive "FP" testing and Blood Donors Loss.*

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INTRODUCTION:

Blood donors screening for TTIs is considered as the corner stone to assure all the safety barriers in the course of blood transfusion process. Every service of blood transfusion needs prioritization, in the availability of resources disease can be screened out of the sample and disease prevalence can be assured. Available service of blood transfusion was screening in routine HBV, HCV and HIV; syphilis and malaria screening facility was still under procurement process. In the presence of numerous constraints, the major issue was financial and human resources. At every blood bank the implementation of gold standard was not possible because of scarcity of resources and technical expertise. Initially there was a need for the inexpensive, rapid and easy screening for the detection of any possible infectious cases among the blood donors.

Higher sensitivity degrees are a serious concern in the screening tests and False positive or negative outcomes can be reduced through maintaining reasonable specificity levels. Large volunteer deferral can be a result of the higher numbers of the donors who are False positive; whereas, blood safety can be jeopardized through False negative outcomes. Occurrence of False negative screening can also be the outcome of sophistication in the screening tests because of no sero-conversion and prolonged window period. Such occurrences can better be prevented through effective quality control and strict vigilance in the blood transfusion process to prevent possible flaws and errors [1].

Numerous other issues are created because of the false positive screening in the service of blood transfusion process. Even in the absence of psychological and social concerns in the testing process of the donor, there is a possibility of the less available blood groups shortage such as negative Rh (D) groups. Logistics issues may arise in the case of blood donor's loss which will even reduce the meager available resources. Such issues need proper handling and preventive algorithms for the screening and testing process are to be implemented in order to reduce the loss of blood donors specially in the local setups. The aroused criticism can be handled and justified in this regard. However, judicious resource utilization and safety issues can be handled expertly [2]. The blood transfusion network which is available even at tehsil level is of prime importance.

There is further increase in the false positive screening issue if the repeated screening is also false negative tested through PCR or ELISA Kits. Number of research studies have reported the scarcity of donors with transferable infectious agents in the blood transfusion process [3, 4]. False positive screening reasons include variation in the constituent reagents, testing formats, antigens and personnel misjudgments. HIV – I cross–reactivity and HBV are also reported as influenza flu vaccination incriminated as false positive screening reason [3]. False positive reactions can also be attributed to the HLA (Human Leukocyte Antigen) antibodies [4]. Increased loss of the donors is attributed to the false positive cases with wastage of the resources and energies.

Blood transfusion process also faces a dilemma of the screening kits choice by the concerned healthcare department and authorities specially in the case of rural areas. Therefore, we aimed at the determination of "False Positive" testing percentage for the TTIs (Transfusion Transmitted Infections) by utilizing ICT (Immune Chromatographic Test) as first option of the test screening and we also assessed the effects on the volunteer blood donor's loss.

METHODOLOGY:

In the timeframe of four months we screened donor's blood bag samples experiencing phlebotomy at Allied Hospital, Faisalabad for the verification of HIV (Human Immune Deficiency Virus), HBV (Hepatitis B) and HCV (Hepatitis C) with the help of immune chromatographic screening tests. We confirmed and retested all the samples those were positive in the course of initial screening process through ELISA Kit and available service of blood transfusion in the same hospital. Blood was taken from 62090 blood donors in the specified blood collection units and these units were coded in order to carry out a blind TTIs re-assessment. Hundred percent screening coverage was provided for the screening of HIV I & II, HBV & HCV in the timeframe of this particular research. Initially reactive cases were taken to the hospital.

Personnel errors were removed through re-screening of the blood samples at the hospital's screening facility. ELISA kit was used for the re-testing process to find out false positive cases which result in the shape of blood donor loss because of the ICT tools used for screening at the initial stage.

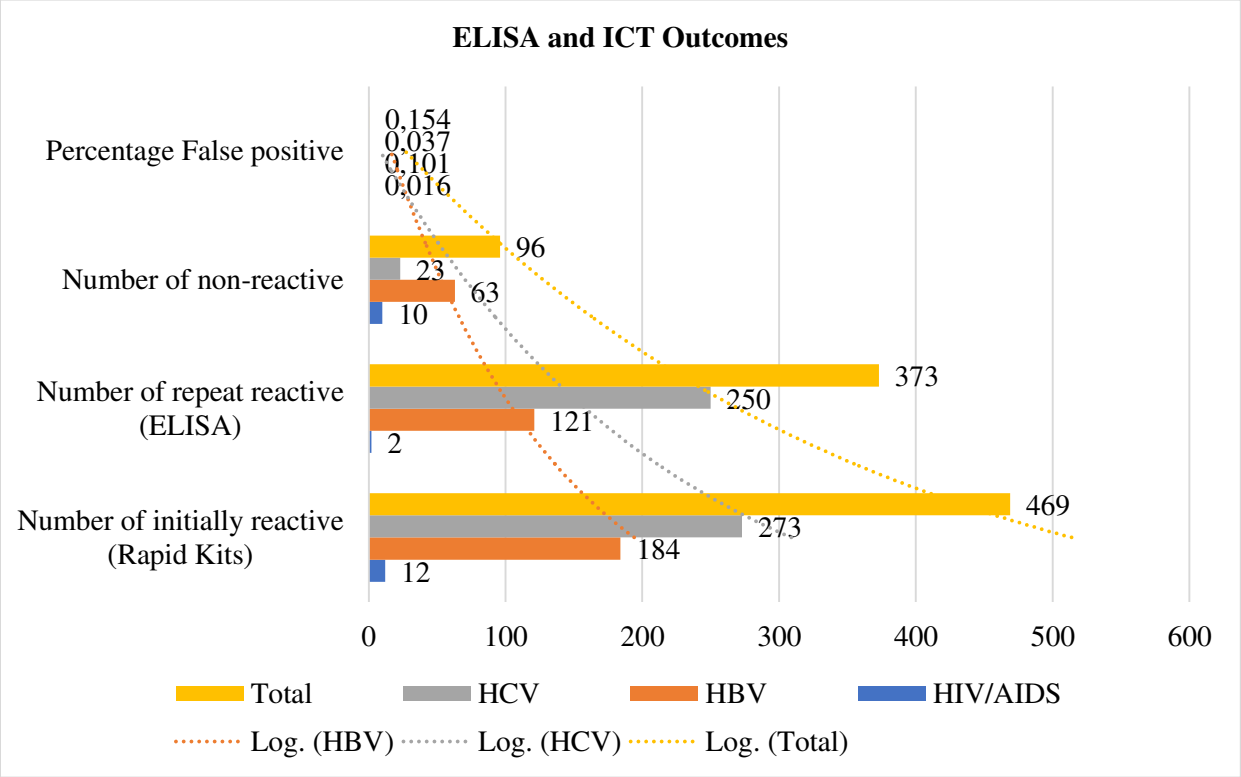
RESULTS:

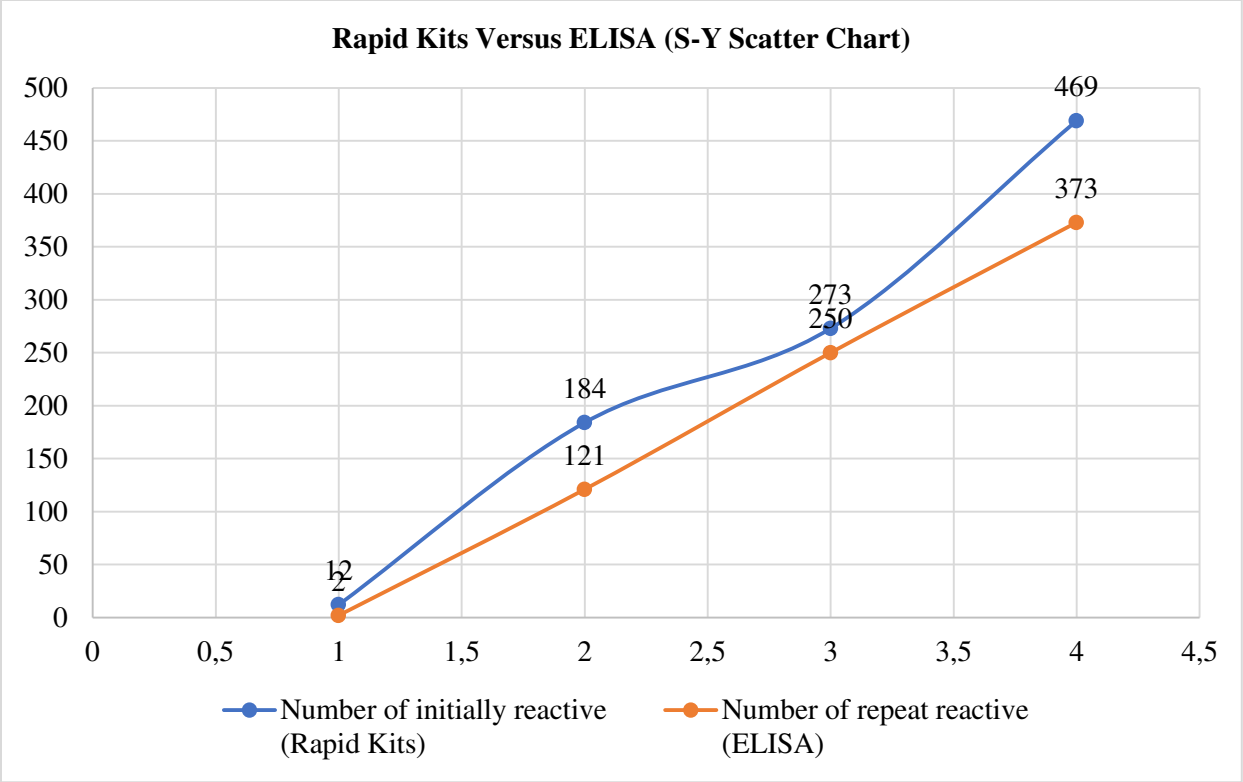
Number of total volunteer donors was (62090), which was a huge number to handle. In the total sample population total 469 cases were observed as reactive at the initial stage to HBV, HIV or HCV. In the reactive cases (469); a total of 96 cases (0.15%) were observed to be tested as "False Positive" against

HBV, HIV or HCV; when compared through ELISA testing Kit in the laboratory setting as shown in the given table.

Table: Results of HIV, HBV& HCV testing of blood donors by ICT & ELISA

Diseases	Number of initially reactive (Rapid Kits)	Number of repeat reactive (ELISA)	Number of non-reactive	Percentage False positive
HIV/AIDS	12	2	10	0.016
HBV	184	121	63	0.101
HCV	273	250	23	0.037
Total	469	373	96	0.154





DISCUSSION:

In case of implementation of novel screening strategies for the blood screening, application of the screening method is to be learnt in a better way in its mode of application and outcomes interpretations of false positive and negative cases pointed out through screening outcomes. Though, there is no doubt about the specificity and sensitivity of the licensed screening facilities and tests, at the same we cannot overrule the chances of being false positive or negative outcome. Estimates suggest that in case of ninety-five percent specificity and sensitivity, blood donor's predictive value is just two percent [4]. Resultantly, we need numerous modifications for employment in case of cut off value variation or methodology change to make donor's screening even effective [5].

Our aim was to evaluate the false positive cases with the help of ICT in comparison to the ELISA retesting for HBV, HCV & HIV/AIDS in the sample blood bags. Highest false positive cases were reported in HBVB which were observed as (0.1 %), followed by HIV & HCV. Total false positive cases in this research were observed as 0.15 % as shown in the table. Negligible loss of the donors was also estimated in this research. Our research outcomes are comparable with the outcomes of other authors [6, 7]. Numerous reasons may contribute in the false positivity of the donors such as an anti HLA antibodies cross reactivity, recent vaccination, multiparty, autoimmune diseases, alcohol use, multiple transfusions, dengue virus and malarial infections [2, 3].

False positive cases are also reported through numerous assays because of the procedural errors and constituent antigens variations. Our research reported very small values as 0.15 %. Before any permanent conclusion rechecking is to performed for the removal of prevalent doubts and misconceptions to reduce the loss of blood donors and management of the blood bank inventory.

CONCLUSIONS:

In the light of social and economic parameters initial screening through ICT is suggested in terms of rapidity, cost and safety because of meager resources and infrastructure. Better management of the pool can be secured through better methods of screening performed through licensed sensitive screening procedures and kits. The rate of "False Positive" during sample screening was observed as 96/62090 (0.15 %). This rate is considered as very small in the loss of donors and an appropriate available resources utilization. Though, ICT is not taken as gold standard; however, at the initial screening process its importance cannot be neglected and overruled.

REFERENCES:

1. Ownby HE, Korelitz JJ, Busch MP, Williams AE, Kleinman SH, Gilcher RO, et al. Loss of volunteer blood donors because of unconfirmed enzyme immunoassay screening results. Transfusion1997;37(2):199-205.
2. Choudhury LP, Tetali S. Ethical challenges in voluntary blood donation in Kerala. India J Med Ethics2007;33(3):140-2.
3. Sayers MH, Beatty PG, Haensen JA. HLA anti-bodies as a cause of false-positive reactions in screening enzyme immunoassays for antibodies to human T-lymph tropic virus type-III. Transfusion1986;26(1):113-5.
4. Kleinman SH, Busch MP. The risk of transfusion-transmitted infection: direct estimation and mathematical modeling. Baillieres Best Pract Res Clin Haematol2000;13(4):631-49.
5. Narayan S. Microbes and blood transfusion. Indian J Med Microbiol 2001;19(3):119-26.
6. Kitchen A. Hepatitis B and blood safety. Vaccine1998;16(4):34-7.
7. Wai CT, Tambyah PA. False-positive HIV-1 ELISA in patients with Hepatitis B. The Amer J Med2002;112(9):737.