A review of the impact of cost and quality of HIV kits on HIV testing in a Nigerian Teaching Hospital

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Abstract

***Background**: When HIV antibodies testing was introduced in Aminu Kano Teaching Hospital, Kano a couple of years ago, Double ELISA was used to test blood samples before a particular specimen was diagnosed as reactive or non-reactive. A time came when immunoconfirmatory test was introduced into HIV antibodies testing for confirmations of the presence of HIV.*
***Objectives**: This present retospective study is to review the impact of cost and quality of HIV reagent kits in the two periods A and B on the patients and confidence on the health care provider.*
***Methods**: We collated and compared laboratory records for both periods of HIV antibodies testing at Aminu Kano Teaching Hospital Kano consisting of period A from November 1997 to May 1998 (7 months) and period B from November 1998 to May 1999 (7months). In period A, double ELISA was used (Genie II and Immunocomb Bispot) while in period B, Immunocomb Bispot and Immunoconfirm II were used*
***Results**: The results show that the cost per test increased from two hundred and fifty Naira($2) to five hundred Naira($4). There was a reduction on the number of patients from 289 to 258 within the two periods. But the prevalence of reactive HIV antibodies decreased from 43.6% to 36.8%.*
***Conclusion**: The period when Immunoconfirmatory technique was introduced brought assurance, reliability and confidence to HIV diagnosis test in the centre.*

Introduction

Laboratory testing of patients for Human Immunodeficiency Virus (HIV) infection is an important tool in health for both patients and healthy individuals1. As the knowledge of HIV infection is increasing so also the complexity of laboratory tests for its detection is increasing2. Over 22 million people were estimated by the WHO to be infected with HIV in developing counties and most of which are in Sub-Sahara Africa as at year 1999-20003,4. The first HIV antibodies detection technique was licensed in 1985 by the Food and Drug Administration (FDA) in America2,4. Since then several test kits have been produced and introduced into the world markets. When HIV antibodies testing was introduced many years ago, the World Health Organization (WHO) recommended that Double ELISA (techniques) be adopted by developing countries5,6 before a patient can be said to be positive for HIV infection. This was to avoid false results often associated with these technologies (first and second generation ELISA kits). As time went on, the government of Nigeria introduced a confirmatory test technique for more reliability of results. This present study therefore presents two periods A and B when the different techniques were introduced in our center and the effects on the patients and health care providers

Methods

We collated and compared both periods of HIV antibodies testing at Aminu Kano Teaching Hospital Kano, Nigeria consisting of period A from November 1997 to May 1998 (7 months) and period B from November 1998 to May 1999 (7months). In period A, Double ELISA was used comprising Genie II and Capillus kit while in period B, Immunocomb Bispot and Immunoconfirm II were used.

	No of Tests	Total Positive
Males	172	75
Females	117	51
Total	289	126
	$\chi^2 = 10.2$	

Table 1: Results obtained using ELISA in Period A (November 1997 – May 1998)

	No of Tests	Total Positive
Males	172	63
Females	86	32
Total	258	95
	$\chi^2 = 4.6$	

Table 2: Results obtained in second period B (November 1998 – May 1999)

Double ELISA costed #250 naira ($2) while Immunocomb II and Immunoconfirm costed #500 naira ($4). A total of 280 sera were tested with 126 reactive while 258 sera were tested with 95 reactive in periods A and B respectively. Positive and negative controls from both the manufacturers kits and known positive hospital laboratory samples were used.

We collated and compared HIV antibodies tests results at the teaching hospital between period A and period B. A total of 547 sera, aseptical collected,separated, stored were then processed. Results obtained were analyzed using Chi square statistical method (analysis) and are presented below.

Results

The results obtained in periods A and B are presented below in tables I, II and III.

Table I shows results obtained using Double ELISA. A total of 289 sera were tested and 126 sera were reactive with a total prevalence rate of the 43.1%. Of the 289 sera, 172 were from men while 117 were from women. 75 men and 51 women were reactive respectively.

Table II shows that out of the 258 sera examined in Period B, 172 were from men with a total of 63 positive sera while 86 were women with a total of 32 positive sera. A total of 95 sera were positive giving a prevalence rate of 36.8%.

Table III shows the AKTH charges during the two periods of study. Before the introduction of Immunoconfirmatory kit, N 250 ($2) were charged. After the introduction, N500 or $4 were charged patients. X2 at 1 df P = 0.05 is highly significant.

Table IV shows that a total number of patients tested within the two periods to be 547. The overall prevalence rate was 40.4% from 221 positive cases. The finding was significant. X2 at 1 df at P = 0.05 is significant.

	Cost (₦)	Test Kit
Period A	250	Double ELISA
Period B	500	ELISA +Immuno confirm

Table 3:Cost Distribution according to kits in the two Periods A and B

	No of Tests	Total Positive (%)
Period A	289	126 (43.6)
Period B	258	95 (36.8)
Total	457	221 (40.4)

Table 4: Prevalence rates among hospital patients.

Discussion

Our results show that from the introduction of Immunconfirmatory test kits, there was a doubling of the cost of HIV testing at the teaching hospital from two dollars or N250 naira to four dollars or N500 naira. This may have accounted for the drop in the number of patients who came for HIV antibody testing from 289 in period A to 258 in period B. A difference of 41 patients in two comparable periods. The second period also witnessed a reduction in the number of positive samples from a prevalence of 43.6% in period A to 36.8% in period B. HIV antibodies testing generally will either be reactive or non-reactive depending on the presence or absence of antibodies to HIV Protein (P) or glyco protein (gp) which include the group specific or core antigens (gag) P24 and P12, the envelope proteins, gp 120/160 and gp 41, the polymerase (pol) proteins P31 and P66/51. There was a reduction in the number of positive cases when Immunoconfirmatory test was introduced. False positive results may have been recorded initially when there was absence of confirmatory tests. The causes of false positive ELISA may be due to the presence of Human leukocyte antigen (HLA) haplotypes, DR antigen in multiparous women, antoimmune disorders, multiple transfusion recipients, multiple myeloma, alcoholic hepatitis and recently influenza vaccination. Others include haemodialysis, mislabeled specimens and positive rapid plasma reagin (RPR) 2. These false positive reactions occur as a result of cross reacting antibodies. False negative are rarely observed but may occur if the patient recently acquired the HIV antigen and seroconversion has not taken place. Also in advanced HIV disease in which case the patient may have lost the ability to make HIV antibodies especially P24. The introduction of Immunoconfrimatory technique into HIV antibodies testing in this center brought about reliability of laboratory test results. Although the patients may have paid more for the investigation, as far as health care providers are concerned, the period brought both assurance and more confidence to HIV diagnosis.

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