


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

Nwokedi EE,* Ohonsi OA,** Alao OO,***

Departments of *Medical Microbiology and ***Haematology/ Blood Transfusion, Faculty of Basic and Allied Medical Sciences, College of Health Sciences, Benue State University, Makurdi, Nigeria.

**Department of Obstetrics and Gynaecology, Faculty of Medicine, Bayero University Kano.

Correspondence to: Dr O.O. Alao, Department of Haematology and Blood Transfusion, Faculty of Basic and Allied Medical Sciences, College of Health Sciences, Benue State University. E mail: oolaao@yahoo.com; Tel: 2348035885039

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 retrospective 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 (7 months). 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 individuals. As the knowledge of HIV infection is increasing so also the complexity of laboratory tests for its detection is increasing. 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 1999-2000. The first HIV antibodies detection technique was licensed in 1985 by the Food and Drug Administration (FDA) in America. 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 countries 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 healthcare 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 (7 months). In period A, Double ELISA was used comprising Genie II and Capillus kit while in period B, Immunocomb Bispot and Immunoconfirm II were used.
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 Immunocomb confirmatory 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.

<table>
<thead>
<tr>
<th>No of Tests</th>
<th>Total Positive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Males</td>
<td>172</td>
</tr>
<tr>
<td>Females</td>
<td>117</td>
</tr>
<tr>
<td>Total</td>
<td>289</td>
</tr>
</tbody>
</table>

$X^2 = 10.2$

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

<table>
<thead>
<tr>
<th>No of Tests</th>
<th>Total Positive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Males</td>
<td>172</td>
</tr>
<tr>
<td>Females</td>
<td>86</td>
</tr>
<tr>
<td>Total</td>
<td>258</td>
</tr>
</tbody>
</table>

$X^2 = 4.6$

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

<table>
<thead>
<tr>
<th>Cost ($)</th>
<th>Test Kit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Period A</td>
<td>250</td>
</tr>
<tr>
<td>Period B</td>
<td>500</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>No of Tests</th>
<th>Total Positive (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Period A</td>
<td>289</td>
</tr>
<tr>
<td>Period B</td>
<td>258</td>
</tr>
<tr>
<td>Total</td>
<td>457</td>
</tr>
</tbody>
</table>

Table 4: Prevalence rates among hospital patients.

**Discussion**

Our results show that from the introduction of Immunocomb confirmatory 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 glycoprotein (gp) which include the group specific or core antibodies (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 Immunocomb confirmatory 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, autoimmune disorders, multiple transfusion recipients, multiple myeloma, alcoholic hepatitis and recently influenza vaccination. Others include haemodialysis, misplaced 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 Immunocomb confirmatory 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.
Overview of management of central nervous system disease in HIV/AIDS patients with emphasis on HIV-Dementia (HIV-D).

Solomon O. Ugoya; FMCP (Neurology)

Department of Medicine, Jos University Teaching Hospital, Jos

Correspondence: Dr Solomon O. Ugoya, Department of Medicine, Jos University Teaching Hospital, PMB 2076, Jos Nigeria
E-mail: docsouls@yahoo.com

Introduction
The World Health Organization (WHO) 2001 Global Burden of disease study has reported HIV/AIDS as the leading cause of mortality in Sub-Saharan Africa, followed closely by malaria. Of persons with HIV, more than 10% have neurologic dysfunction and 30% to 70% eventually develop neurological complications. HIV may affect the nervous system directly by producing distinct neurological syndromes, or indirectly by causing immunodeficiency with a resultant susceptibility to opportunistic infections. Central nervous system involvement is one of the common manifestations of acquired immunodeficiency syndrome (AIDS). The following CNS diseases are the commonly reported: Bacterial Meningitis, tuberculous meningitis, cryptococcosis, cytomegalovirus infection, human immunodeficiency encephalopathy, Primary CNS lymphoma (PCNSL), Progressive multifocal leukoencephalopathy (PML), Vacuolar Myelopathy, Sensory Neuropathies and toxoplasmis, with low CD4 count as the regular accompaniment of these disorders in developing countries. Pathophysiology of HIV enters the nervous system early, after infection, and productive CNS infection is rarely established until systemic immunosuppression develops, probably after re-entry of HIV into CNS. Chronic immune activation with HIV disease progression leads to deregulation of macrophages, with the overproduction of various proinflammatory cytokines and chemokines within the CNS and peripheral nervous system.

Clinical Presentation
HIV-Dementia typically manifest with cognitive, behavioural, and motor dysfunction which are characteristic of sub-cortical dementia. In the early stages, short term memory loss, mental slowing, reading and comprehension difficulties appears. Gait disturbance, with stumbling and tripping, is common, and tremor and impairment of fine manual dexterity develops in most patients. Other disorders that may also be seen in other diseases include: Headache, Fever, Meningism, Coma/ altered consciousness. Focal neurological deficits (hemiplegia, visual loss etc) and seizures, Delirium (acute confusional state), Constitutional; malaise, lethargy, anorexia, nausea, vomiting, weight loss have all been reported. Dissemination to the brain and meninges is the most common clinical manifestation of cryptococcosis in about 75% to 90%; and these will manifest as meningitis, meningoencephalitis, or a cryptococcomma. HIV-1-associated myelopathies is a slowly progressive painless spastic paraparesis, with sensory ataxia and neurogenic bladder. There are prominent vacuolar changes in the ascending and descending tracts that commonly affect the thoracic spinal cord. Risk factors for VM include high number of systemic AIDS-defining illnesses (such as pneumocystis carinii). Presence of sensory neuropathy is said to be commonly associated with Vacuolar myelopathy. Disturbances in vitamin B12-dependent transmethylation pathways may be related. It is said that CSF S-adenosyl methionine concentrations are reduced in VM. HIV-Sensory Neuropathy commonly manifest as pain. These are the distal sensory polyneuropathy and antiretroviral toxic neuropathy, caused by nucleoside reverse transcriptase inhibitors. The symptoms are usually symmetrical or bilateral, of gradual onset and described as aching, painful or burning. Motor neuropathy as a result of HIV-_SN is quite rare.

Diagnostic studies
There is no definitive or diagnostic CSF profile for HIV-D. CSF analysis may be important in febrile patients and who are acutely encephalopathic mainly to exclude cryptococcal or tuberculous meningitis. CSF findings includes: high concentrations of HIV RNA and signs of immune activation. Some co-workers had reported positive correlations with increased HIV RNA and neurological complications in an untreated person with HIV/AIDS. Various CSF markers of immune activation are also elaborated in HIV-D, and these include: neopterin, α2-microglobulin, quinolinic acid, soluble Fas and protein carboxyls, they also correlate strongly with dementia severity [12, 13, 14, 15]. MRI imaging in HIV-D clearly

References

Overview of management of central nervous system disease in HIV/AIDS patients with emphasis on HIV-Dementia (HIV-D).