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#### Journal of AIDS and HIV Research

#### Review

# A review on human immunodeficiency virus (HIV) strain candidate vaccine development: Prospect and challenges

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Human immunodeficiency virus (HIV) has one of the highest incidence and mortality rates of any infectious disease, with more than 33 million people infected worldwide. Specifically, HIV causes the destruction of helper T cells, ultimately resulting in the suppression of the immune system and leaving its human host susceptible to countless of other pathogenic agents. The development of an effective HIV vaccine has continued for more than 20 years. But the use of preventative vaccines using traditional vaccine technologies, which have proven successful for other diseases, has thus far failed with HIV. One vaccine, AIDSVAX, was the first HIV vaccine to reach a phase III efficacy trial, but has not yet been shown to eradicate HIV. Hope now lies in the development of therapeutic vaccines using novel technologies. One such vaccine is ALVAC-HIV, which when used in conjunction with other vaccines (AIDSVAX or Lipo-6T with IL-2 injections) has shown a great deal of promise in clinical trials suppressing viral replication and improving the immune system. Other therapeutic vaccines, such as Ad5, however, have been unsuccessful. While many believed that developing an effective HIV vaccine is impossible, efforts continue into researching its structure, transmission, immune system suppression, genetic variability, and immune system evasion. As long as research continues, hope remains that someday an effective vaccine will be developed.

**Key words:** Vaccines, human immunodeficiency virus (HIV), acquired immunodeficiency syndrome (AIDS), recombinant, lymphocytes.

#### INTRODUCTION

First documented in 1984, human immunodeficiency virus (HIV) has become one of the most notorious and evasive viruses to date. HIV causes the destruction of CD4+ lymphocytes, cells important to robust immune

system functionality (Kwong et al., 1998). HIV is a retrovirus, which typically do not kill the cells they infect. It has been observed, however, that some helper T-cells are killed when infected with HIV (Fan et al., 1998). The

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mechanism by which helper T-cells are destroyed is not yet fully understood, although research has shown that it is linked to a cell's apoptotic activity (Stocker et al., 2008; Banda et al., 1992; Groux et al., 1992). Most HIV research has focused on CD4+ T-cell depletion, but it has also been observed that CD8+ T-cell counts decrease in response to HIV infection (Brenchley et al., 2004; Roederer et al., 1995). This decrease results when infected helper T-cells are destroyed, subsequently affecting the response of B-cells and cytotoxic T-cells. Some HIV variants have also been recognized to affect cytotoxic T-cells by inactivating their T-cell receptor, disabling them from interacting with the major histocompatibility complex (MHC) class 1 molecules (Meier et al., 1995). HIV then compromises the immune system, because the destruction of lymphocytes results in the inadequate production of antibodies to fight off the infection and an inability to engulf and destroy the virus. Immune system suppression ultimately results in the development of acquired immunodeficiency syndrome (AIDS) (Kwong et al., 1998).

Approximately 33 million people are infected with HIV, with more than 7,000 new infections reported every day (Dolin, 2009). Originally, HIV infection was considered an adult health problem, but due to transmission from infected mother to newborn, it has become a major killer of children under the age of five (Adetunji, 2000). This is particularly evident in developing nations, where more than 90% of the world's HIV-related deaths occur and where 25 to 30% of children born to infected mothers die before the age of five (Adetunji, 2000). In developed countries, a great deal of funding has gone into educating, researching, and treating HIV infection. But despite these efforts, it is estimated that at least 1 million people in the United States live with HIV. That figure continues to rise, with 56,300 new infections reported each year (Centers for Disease Control and Prevention [CDC], 2010). It was also estimated that 21% (232,700 people) of those infected with HIV in the US are not even aware of their status (U.S. Department of Health and Human Services, 2010; CDC, 2010). With the prevalence of HIV infection and mortality occurring at high levels, it is critical that an effective and safe vaccine be developed. Despite more than 20 years of intense research. however, this has proven to be no easy task, leaving many to question whether an effective vaccine is even possible.

The aims of this paper were to call attention to the need for an effective vaccine and to discuss how the pathogenesis and nature of HIV makes developing a vaccine especially difficult.

#### WHAT IS A VACCINE?

A vaccine is any preparation of killed or living microorganisms introduced into the body to produce an immune response to a specific disease. Vaccines

designed to prevent individuals from contracting a disease are considered preventive (Idoko and Isa, 2005). The role of a preventative vaccine is to introduce a person's immune system to the virus, stimulating a response that will allow the body to "remember" and later recognize the disease (Idoko and Isa, 2005). In addition to preventative vaccines, scientists are developing therapeutic vaccines, which can be used to treat individuals who have already been infected (Idoko and Isa, 2005). The premise behind the development of therapeutic vaccines is to suppress HIV replication, thereby allowing the immune system to induce T-cell responses to the infection (Fauci, 1993; Lu et al., 2004). The ultimate goal of therapeutic vaccines is to reduce dependence on antiretroviral drugs and to control viral suppression (Idoko and Isa, 2005).

#### VIRUS STRUCTURE AND TRANSMISSION

HIV is a polyhedral virus with an outer double layer lipid envelope (Hutchinson, 2001). Embedded in the outer envelope membrane are spikes composed of glycoproteins (gp) 120 and 41 subunits (Hutchinson, 2001; Burton et al., 2004). The surface of each spike is made up of the outer envelope glycoprotein, gp120, which is non-covalently bound to gp41, which anchors the complex in the envelope membrane (Kwong et al., 1998). Beneath the envelope is a protein matrix that surrounds the protein capsid (Hutchinson, 2001; Johnston and Fauci, 2008). The capsid is a hollow core made of proteins where HIVs genetic material, RNA, and the enzyme reverse transcriptase are stored (Hutchinson, 2001).

HIV causes the destruction of CD4+ lymphocytes (Kwong et al., 1998). There are two kinds of lymphocytes, T-cells and B-cells, which are used to recognize and respond to substances foreign to the body (Hutchinson, 2001). Three different types of T-cells exist: helper, cytotoxic, and suppressor T-cells (Hutchinson, 2001; Wexler, 2010). Helper T-cells are used to alert and activate other cells of the immune system to respond to invaders (Hutchinson, 2001; Wexler, 2010). Helper Tcells recruit and amplify the response of B-cells and cytotoxic T-cells (Hutchinson, 2001; Wexler, 2010). Cytotoxic T-cells destroy antigen-infected cells, while suppressor T-cells suppress the immune system after the destruction of infected cells (Hutchinson, 2001; Wexler, 2010). In response to the presence of antigens, B-cells will produce and secrete antibodies (Hutchinson, 2001; Wexler, 2010). Receptors found on the surface of T-cells enable them to recognize different antigens. Helper Tcells carry a CD4+ glycoprotein receptor, while cytotoxic and suppressor T-cells have CD8+ glycoprotein receptors (Hutchinson, 2001; Kwong et al., 1998). The receptors expressed on these different T-cells will bind with complementary antigens initiating a defensive immune response (Hutchinson, 2001).

Studies in HIV transmission have shown that mucosal tissues are the primary sites for HIV entry and infection (Belyakov et al., 1998). Once HIV enters the body, it will target specific cells that contain the cell receptor CD4+ such as helper T-cells, and some macrophages and dendritic cells (Hutchinson, 2001; McDonald et al., 2003). HIV attaches itself to cells by binding its envelope alycoprotein, gp120, to the CD4+ receptor (Hutchinson, 2001; Kwong et al., 1998; Marsh, 1984). However, the binding of gp120 to CD4+ alone does not result in the entry of HIV into a cell (Kwong et al., 1998). The presence of a co-receptor, mainly CCR5 on macrophages or CXCR4 on T-cells, must also be present on the cell surface in order for HIV to enter the cell (Moore et al., 2004; Kwong et al., 1998; Murakami et al., 1997). Once HIV is brought into the cell, its RNA genome will be replicated and expressed as is usual for retroviruses (Fan et al., 1998).

#### **VACCINE STRATEGIES**

One determinant of vaccine efficacy is its ability to elicit humeral and cellular responses (Oh et al., 2003). An effective HIV vaccine will need to be able to induce both strong cytotoxic T lymphocyte (CTL) and neutralizing antibody responses (Lemckert et al., 2004; Oh et al., 2003). In doing so, viral replication could be restricted and virus particles destroyed (Oh et al., 2003). Initially, HIV vaccine designs followed traditional vaccine technologies, using live attenuated viruses, whole killed viruses, and protein subunits (Barouch, 2008). These technologies were expected to raise antibodies and MHC class II restricted CTL responses (Yang, 2009). While these approaches have historically been successful in eliciting protective immune responses against other viruses, these strategies have thus far been slow to yield any break-through results (Yang, 2009).

The first promising vaccine to be developed was AIDSVAX. AIDSVAX, a monomeric version of the HIV trimeric gp120 envelope glycoprotein, was aimed at inducing envelope-specific antibody immune responses (Barouch, 2008). Thus far, AIDSVAX is the only HIV vaccine to reach a phase III efficacy trial. However, results of two independent studies have been disappointting. The first study, known as VAX004, was conducted in the United States, Puerto Rico, Canada, and Netherlands (Singh et al., 2005). Volunteers were randomized to either the vaccine (AIDSVAX B/B) or a placebo (Flynn et al., 2005). The vaccine contained two forms of gp120 from the HIV subgroup B (Singh et al., 2005). The vaccine, AIDSVAX B/B, was chosen because it reflected the common virus subgroups found in those areas (Singh et al., 2005). Results of the study showed that the production of neutralizing antibodies and CD4+- blocking antibody responses were apparent, but the vaccine was not effective in preventing HIV infection or modifying

disease progression (Flynn et al., 2005).

Disappointing results were reinforced by conclusion of the second study, which was conducted in Thailand. The vaccine was changed to AIDSVAX B/E to reflect common virus subgroups as former one (Pitisuttithum et al., 2006). Again, the results of the study showed that the vaccine did not prevent HIV infection nor did it delay disease progression (Pitisuttithum et al., 2006).

Given the slow progress in developing effective vaccines using traditional approaches, novel vaccine technologies, which include plasmid DNA vaccines and live recombinant vectors, are also being investigated (Barouch, 2008). Live recombinant vectors are vaccines made of a non-HIV virus, which is engineered to carry genes that encode recombinant proteins, like gp120, of the HIV virus. The use of such vaccines focuses on eliciting MHC class I restricted CTL responses (Yang, 2009).

The most notable novel vaccine strategy to be clinically tested is ALVAC-HIV. ALVAC-HIV is a recombinant canarypox vector vaccine genetically engineered to express HIV gp120 (Brander and Walker, 1999). Despite initially disappointing results, AIDSVAX is being researched in clinical trials along with ALVAC-HIV. Studies that evaluated the tolerance of the combined vaccine regimen have showed promising results (Nitayaphan et al., 2004). A study conducted in Thailand using the AIDSVAX B/E and ALVAC-HIV vaccines, showed that the use of both vaccines was well tolerated and immunogenic (Nitayaphan et al., 2004). The findings of this allowed researchers to advance to a phase III trial, which evaluated the efficacy of using four priming injections of ALVAC-HIV and two booster injections of AIDSVAX B/E (Rerks-Ngarm et al., 2009). This study was designed to evaluate the prevention of HIV infection and the effects of early vaccination on viral load after infection (Rerks-Ngarm et al., 2009). Results of the study were promising. Within the "to treat" group, which at enrollment was composed of HIV-positive subjects, evidence to suggested that the vaccine regimen had the ability to prevent virus infection (Rerks-Ngarm et al., 2009).

ALVAC-HIV has also been investigated in combination with other vaccine. One such study examined a therapeutic regimen combining ALVAC-HIV and a Lipo-6T vaccine followed by subcutaneous IL-2 injections as a booster for antiviral therapy (Le'vy et al., 2005). The use of boosters in antiviral therapy is critical since antiviral drugs can sometimes induce unbearable adverse effects just as painful and malicious as HIV itself. Effects of the antiviral drugs can sometimes be so agonizing that patients will either temporarily stop usage, known as "drug holidays," or completely discontinue their use. The results of the ALVAC-HIV/Lipo-6T booster study demonstrated that the therapeutic regimen induced and sustained CD4+ T lymphocyte immune responses in chronically infected patients (Le'vy et al., 2005). While additional trials will need to be conducted, this particular

study provided evidence for the concept that a therapeutic vaccine given prior to antiviral drug holidays may contribute to the containment of viral replication (Le'vy et al., 2005).

Another novel vaccine that has been developed is Ad5, a live recombinant adenoviral vector vaccine (Cheng et al., 2007). The efficacy of adenovirus vector vaccines has shown promise in animal models and early clinical evaluations testing their immunogenicity, but their ability to elicit CTL responses in humans has thus far failed (Singh et al., 2005; Cheng et al., 2007). Ad5 was tested in two efficacy trials, but no trial was carried out to completion. Results from the first trial, the STEP study, revealed that the vaccine did not prevent HIV infection nor did it lower early viral load in vaccinated volunteers (Buchbinder et al., 2008). These results led to the immediate termination of the STEP study as well as the second efficacy trial, known as Phambili (Johnston and Fauci, 2008).

DNA-based vaccines are also of significant interest, because of their ability to elicit strong cellular responses (MacGregor et al., 1998). The first DNA based vaccine to be tested in humans was APL 400-003, which contained genes that encode the *env* and *rev* proteins of HIV (MacGregor et al., 1998). Participants of the study did not experience any local or systemic reactions to the vaccine and it was shown that the vaccine increased gp120 antibody concentrations in individual patients (MacGregor et al., 1998). Some increases in CTL activity and proliferation were also identified. While the results of the study suggested that DNA-based vaccines could be significantly immunogenic and safe, more trials must be conducted in order to better understand the potential benefits and/or downsides to this approach.

# OBSTACLES IN EFFECTIVE VACCINE DEVELOPMENT

Unique biological characteristics of HIV make effective vaccine development exceptionally difficult. HIV is quite genetically diverse, despite its small genome. Its genome is composed of nine genes, but only two, *gag* and *env*, are reliable genes for vaccine development, since they are less affected by the high mutation rate of HIV (Hutchinson, 2001).

In general, any gene has the potential to be mutated. Due to the mutation rates of reverse transcriptase, a vast number of HIV strains and subgroups have arisen (Barouch, 2008). Each strain can be classified into three groups: M (major), O (outlier), and N (non-M/non-O), from which they can be further classified into subgroups known as clades and recombinant forms (Barouch, 2008; Hutchinson, 2001; Spira et al., 2003). Accounting for over 90% of HIV infections are M-group strains (Spira et al., 2003). Within the M group are nine major subgroups that include A-D, F-H, J, and K (Spira et al., 2003). Clades are

classified by their envelope (*env*) sequences that make up the envelope proteins, gp120 and gp41, which can differ by 10% to >25% (McMichael and Hanke, 2003; Spira et al., 2003).

Despite the relatively diverse assortment of clades, the vast majority (98%) of vaccines used in preclinical trials are derived from strains from clade B, the predominant form of virus in the US and Europe (Olin et al., 2006). The majority of HIV infections, however, occur in Africa and Asia, where an array of different clades can be found (Spira et al., 2003). Sub- Saharan Africa alone is estimated to be home to >70% of the world's HIV infected adults (Cao et al., 2003). Unfortunately, due to a lack of clinical and laboratory infrastructure in these regions, the development of new vaccines rarely occurs in countries with the highest incidences of HIV infection (Cao et al., 2003). Some have the question as to whether existing and newly developed vaccines based on clade B strains will be effective in eliciting cross-clade responses (Cao et al., 2003).

Complexity is further compounded when considering the ability of different HIV subtypes to co-infect and coexist in different body fluids and organs within a host (Hutchinson, 2001; Jobes et al., 2006; Pandit and Sinha, 2010; Ball et al., 1994). The ability of more than one HIV strain to co-infect and exist within a single person has important implications in understanding HIV transmission, particularly regarding the development of an effective vaccine (Jobes et al., 2006). Most of these cases observe infection with two different sub-types. However, some have reported infection of variants from the same subtype (Jobes et al., 2006). Incidences of recombination, although less common, have also been observed (Jobes et al., 2006). A case of dual infection and recombination was documented from a participant in the phase III efficacy trial VAX004 (Jobes et al., 2006). This volunteer appeared to be infected with two strains of HIV subtype B, but was later found to have been infected by a recombinant form of clades A and B strains B (Jobes et al., 2006). The number of possible dual and recombinant forms that HIV can take suggests that the virus may possess a greater ability to defeat the immune system and defend against vaccines than previously understood, further complicating vaccine development.

Another obstacle to overcome is the extraordinary ability of HIV to shield conserved epitopes and evade neutralizing antibody responses (Lemckert et al., 2004). Neutralizing antibodies is important because they bind to proteins (e.g. gp120 and gp41) on the surface of HIV, inhibiting its ability to enter and infect cells (Lemckert et al., 2004; Koff, 2010). HIV is able to evade neutralizing antibodies for three general reasons. First, the gp120 and gp41 glycoprotein complexes have loop domains that are highly variable (Lemckert et al., 2004; Koup, 2002). Second, the envelope is heavily glycosylated, which protects the susceptible antibody regions of the gp120 and gp41 glycoprotein complex (Lemckert et al., 2004;

Koup, 2002). Finally, gp120 is very flexible which makes it more difficult to bind to than a rigid protein (Koup, 2002).

#### **FUTURE DIRECTIONS**

Since 1987, more than 10,000 individuals worldwide have received preventative HIV vaccine immunizations in clinical trials, with roughly 7,000 in the United States (Ackers et al., 2003). Despite substantial efforts to advance research in vaccine development, a truly functional and interventional therapy has yet to be established. But while research continues, HIV prevalence and mortality continue to grow. Understanding and researching HIV structure, transmission, and its mode of suppressing the immune system by destroying helper T-cells will be pivotal in developing and utilizing an effective vaccine.

As noted earlier, there are many hurdles and unsolved problems to overcome before a truly effective preventative or therapeutic vaccine can be produced. Overall, there are two main challenges that need to be addressed before an effective vaccine can be developed. First, vaccines designed for more than one subgroup must be investigated. Second, an effective mechanism or mechanisms need to be developed that can elicit strong CTL responses to HIV. If any one of these challenges can be met, vaccine development would take a significant step forward.

Despite disappointing clinical trials, there is hope for an effective vaccine. While a preventative vaccine appears to be less promising, given the genetic variability and mutation rate of the virus, considerable potential remains in developing a therapeutic vaccine regimen. Research has identified monoclonal antibodies against HIVs proteins such gp120 and gp41 that have been shown to elicit strong neutralizing antibody responses in different clade isolates, as well as vaccine regimens involving the suppression of HIV replication. While therapeutic vaccines are unable to prevent infection, the use of a truly effective therapeutic vaccine would be able to control and suppress HIV replication, thereby presenting infected individuals with tolerable symptoms and hopefully improved longevity. At present, education, public policy, and antiretroviral approaches have not prevented the rampant spread of HIV. For this reason, development of an effective vaccine may be our best hope. As to when and whether an effective HIV vaccine would be available is uncertain, but a commitment to furthering our understanding about HIV, how it is transmitted, and how it affects the immune system will be required if further advances are to be achieved.

#### **Conflict of Interests**

The author(s) have not declared any conflict of interest.

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#### Journal of AIDS and HIV Research

#### Review

# Improving United Nations Development Programme's (UNDP's) research on human immunodeficiency virus (HIV) and acquired immune deficiency syndrome (AIDS) in Africa

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This paper poses methodological and ethical questions on the measures adopted by the human development index (HDI) data in assessing development in Africa, with particular emphasis on human immunodeficiency virus and acquired immune deficiency syndrome (HIV/AIDS). It is a well-known fact that these measures are great indicators of development or otherwise. The central position of the paper is that given the difficulty in collecting data reports on Africa, how accurate and reliable are the HDI standards in measuring the spread of HIV and AIDS in Africa? The crux of the argument is giving the cultural deficit of most African societies as well as the HDI measures and standards it deserves thorough assessment.

Key words: HIV/AIDS, human, development, culture.

#### INTRODUCTION

The measures adopted by the human development index over the years have been studied by scholars. Most scholars, like Chowdhury (1991) and Noorbakhsh (1998), emphasized on the limitations of the arbitrariness of the qualitative and quantitative measures such as ranking and the assignment of weights which are used as the indices for assessment. In this paper, the emphasis is on the social, political, technological and cultural limitations of the human development index, regarding the assessment of HIV and AIDS in Africa. In particular, the study stresses the limitations and the backdrops of data collection in Africa. Divided into four different categories,

it states the problem and briefly examines the growing trend of human immunodeficiency virus (HIV) and acquired immune deficiency syndrome (AIDS) over the years in Africa as reported by the human development index, as well as the means of data collection which is used as the basis of assessment; secondly, it offers a constructive criticism of these assessment measures with specific reference to their political, social and technological limitations and finally, the study offers suggestions on what the HDI can do to improve the quality of data collection and assessment of HIV and AIDS in Africa using Badach's proposed model.

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#### Statement of the problem

This research is motivated by certain underlining problems in the area of research on HIV and AIDS in Africa. Briefly, the following common problems will be highlighted:

- 1) Generally in Africa there is a lack of an adequate demographic and socioeconomic data.
- 2) This has led to an obvious problem of access and use of valid data in policy making.
- 3) There is insufficient data or insufficient demand and use of data, its application by policy makers and key stake holders both at National and international level.
- 4) The general notion that a wrong data would ultimately lead to the application of the wrong policy.
- 5) Finally, the United Nations Development Programme (UNDP) since its inception has spent billions of dollars on HIV and AIDS, yet, we still have a lot of unreported cases of HIV and AIDS as well as increasing number of yearly infections. This is the case because inaccurate data hinders effective policy making. The UNDP spends more on research in vain with limited and often criticized results. Based on this aforementioned problem, the aim of this study would be to use Badachs guide for policy analysis to proffer solutions on how an effective method of data gathering on HIV and AIDS can be adequately implemented by the UNDP. There are eight rules when using Eugene Badachs model of policy analysis and this includes:
- 1) Define the problem: As already stated earlier.
- 2) Assemble some evidence.
- 3) Construct alternatives.
- 4) Select criteria.
- 5) Project outcomes.
- 6) Confront tradeoffs.
- 7) Decision on best alternative.
- 8) Telling the story.

To a large extent, Badachs model provides a bench mark for our analysis in this paper and the first three rules such as defining the problem, assembling evidence and constructing alternatives was judiciously followed in this paper. This is followed by projecting outcomes and confronting the possible tradeoffs or challenges. Having stated the problems, the next phase examines some evidences based on scholarly reviews on data management and collection in Africa and its constraints.

# THE HUMAN DEVELOPMENT INDEX AND HIV/AIDS IN AFRICA

The human development index has provided a benchmark for the assessment of sustainable development in Africa. One of its measures for assessing life expectancy

among countries is the degree and spread of HIV and AIDS in a country at any particular point in time (de la Escosura, 2011). In Africa, particularly Sub-Saharan Africa, the report of the HDI indicates a rapid and escalating growth of HIV infections; this in effect determines life expectancy and the level of development in the African region. According to the records, between 1990 and 2011, there was a continuous growth in the number of the carriers of HIV and AIDS infections in Africa, totaling about 39 million. By 2011, it reported that there were 34.0 million people in the world infected with this epidemic with Sub-Saharan Africa having a total of 23.5 million; and this in HDI report as indicated was due to the increasing death occurrences of 1.2 million annually, coupled with a rapid decline due to safety and enlightenment campaigns. Meanwhile, North America and Western and Central Europe had a total of 2.0 and 1.0 million people infected at rather low annual death rates of 28 000 and 7500, respectively, according to the HDI record (UNAIDS Global Fact Sheet, 2012). These reports when considered with other variables such as aross domestic product (GDP), level of poverty and income, and others, depict the life expectancy of a particular country at a given time.

# HDI METHOD OF DATA COLLECTION AND ASSESSMENT OF HIV/AIDS

The measurement of HIV and AIDS falls under the life expectancy variable of the human development index which is compiled by the United Nations Development Program and published as the Human Development Report on an annual basis. The measurement thus serves as a global benchmark on assessing sustainable development, by examining the impact of GDP, education and life expectancy to ascertain the relationship among variables. The HDI basically collects its data on HIV and AIDS in African countries using primary sources such as the Joint UN Program and updates on HIV and AIDS, the Report on the Global HIV/AIDS Epidemic, and a joint publication of UNAIDS and the World Health Organization. On an annual basis, various regional centers provide update reports based on investigations, national data findings, data findings from governments, organizations. non-governmental international organizations and private sector organizations (such as employers, insurers and hospitals) (HDR, 2004). These reports are compiled, and states are assigned numerical values based on the quantity of the HIV/AIDS causalities recorded annually.

#### **HOW EFFECTIVE IS THE HDI DATA AND METHODS**

#### The place of culture

In an attempt to solve the problem of HIV and AIDS in

Africa, cultural solutions must be taken into cognizance (Müller and Moyo, 2011; Airhihenbuwa and Webster, 2004). While scholars have noted this stated fact, they however have not examined the nexus between the effect of African culture (bad governance and poor state of infrastructure) and the assumed predominance of HIV/AIDS in Africa. Why is culture a necessity for explaining the limited assumption of the prevalence of HIV/AIDS Africa? In extant literature, the emphasis has been on the need to place culture at the praxis of any development ideas, prescriptions or generalizations (Robert, 1994; Ali, 1992); unfortunately, the researchers have largely de-emphasized this concept, in the long run. Take for instance while there are plethora of debates on the origin of HIV and AIDS, its rather popular correlation with underdevelopment is largely questionable. The popular perception among scholars is that Africa is backward and that HIV and AIDS hinder development, or they are indicators of underdevelopment. But the case of Botswana appears to question this scholarly contention. thus underscoring the need to study development and underdevelopment in relation to cultural realities, where development and underdevelopment are predetermined by HIV/AIDS.

First, with Botswana's improving GDP praised by the international community, in 2007, the country's HIV/AIDS records were still on the high side (Rosling, 2013). This displaces the whole idea of development to be facilitated by absence of HIV and AIDS predominance (Rosling, 2013). It is on this instance that to totally displacing the peculiarity of Africa's culture when it comes to the study of HIV/AIDS predominance will be intellectually incapacitating. Indeed, there are reasons one should be skeptical about the predominance of HIV/AIDS in Africa, because of certain features inherent in African culture, complicated by state shoddiness and adynamia which are asymmetrically opposed to modernization and development. Or to succinctly put it, there are certain features limiting the propensity at development, making nonsense or complicating any effort of linking Africa's underdevelopment or otherwise to HIV/AIDS. Among the features, which will be considered next, are certainly technological constraints and political corruption which are all broadly endemic features in the African society, necessitated by weak governance which complicates the process of data collection, and limits the validity of quantitative findings used as benchmark for generalizations by most international agencies particularly the UNDP's HDI.

#### **Technological constraints**

The effectiveness of any study both for academic and development purposes is hinged on the methodology of data collection (Rolfe, 2006). To a large extent, the validity

and trustworthiness of a data totally depends on the wideness of its coverage, its all-encompassing approach, and not on narrow estimates. In Africa, getting adequate and up-to-date records in hospitals and maternal homes is an increasing challenge. How can the HDI obtain adequate result in Africa when the health care sector is in shambles, lacking adequate finance, space, electricity and modern computer to save health records of patients (Malan, 2012)? In Nigeria for instance, according to a study by Idowu et al. (2003) on the use of information technology in three government-owned health care institutions, it was found out that none of the hospitals had ever been connected to the internet. So, how can it be argued that the HDI assessment and measures are not inadequate? The study by Abdulkadir et al. (2011) indicates that the update and accuracy of medical records in Nigeria is questionable. Similarly, in their study, where medical records handling and archiving were assessed by examining the unit record books of Radiology and other departments in six regional hospitals, they accounted thus:

In all centres, there were variable non-documentation of patients' age and sex, hospital number, doctors' names and date of request. The names of patients and consultants in charge were commonly indicated. Unit record books generally suffered mutilations and in 27.2 to 33.2% of the requests, clinical information was inadequate or not provided. Radiological requests information provision and handling in our tertiary hospitals were inadequate.

Again, what implication does this have for the HDI adequacy on HIV/AIDS and underdevelopment or otherwise in Africa? It simply implies that given the weakness of most African governments in the provision of essential infrastructures for the public health care system, the idea of generating adequate data used as the basis of generalization remains highly impossible. The same situation was seen in Congo, a country that has been marred with crisis for a long time, the "Medecins d'Afrique" is currently engaged in a vast programme to combat AIDS through its documentation (Pana Press, 2013). This simply implies that Congo given the instability in the social and political sphere has no definite and proper documentation program.

#### Discrimination against HIV and AIDS patients

Another important factor to be considered as a limitation to the adequacy and accuracy of the HDI data on Africa is the staggering rate of discrimination against HIV and AIDS patients in the continent. Due to the fact that most individuals with HIV and AIDS are discriminated against, the burden of health care as well as health provisions are left on the shoulders of the family members and friends

(IHAC, 2013). This to a large extent could limit hospital documentation of HIV and AIDS cases in most African societies. Given the great divide between the health care system and patients in Africa, getting adequate data from hospitals or even private clinics might be difficult, accordingly complicating the whole process of obtaining very reliable information on HIV and AIDS patients in Africa. And it is a fact that only the few rich and the well-to-do can afford hospital bills and medical care in the African continent (Mbele, 2005).

#### Unregistered hospitals and clinics

In examining the validity of an adequate HDI-generated data, furthermore, an issue that must not be left out also is the existence of many health care centers that are not approved by the governments and thus will not want to affiliate with any agency of any sort in most African states. As mentioned earlier, the adequacy of any datagathering methodology is dependent on its coverage within the involved polity (Rolfe, 2006). The issue of unregistered clinics is further aggravated by government legislations. In Kenya, while one may applaud the passage of the Health Care Record bill in 2006, which demanded that Kenyans register with governmentacknowledged and approved hospitals, the national hospital insurance funds of civil servants awarded medical insurance to unregistered clinics and health care outlets in April, 2012 (Wabala, 2012). What this simply means is that there are no existing legislations governing the modus operandi of the health care sector in Kenya (Wabala, 2012). So, how can reliable data be collected and available in the health facilities?

In September, 2012, the Lagos State government in Nigeria shut down 15 clinics and hospitals which had been operating illegally for years in the urban society. With Lagos being one of the metropolitan cities in the country, how well can it be argued that the annual HDI and UNDP surveys have been able to obtain the accurate and adequate records they need to compare HIV epidemic with that in other countries (Akinsanmi, 2012)? The implication of this is that given the dormant approach of most African government towards the adequate regulation of the health care system, accuracy in data collection is highly limited.

#### Corruption in the health sector

Corruption is an endemic phenomenon in Africa affecting every aspect and context of the society. Corruption goes beyond embezzlement of government funds or direct stealing of government monies in the areas of contract awards, budgetary allocations and during implementation of policies. Corruption comes with a lot of complexities and complications which threaten the viability of the health care industry in terms of health care accessibility, equity and outcome (Vian, 2008). In a qualitative comparative study of Armania, Bulgaria, Albania, Armenia, Azerbaijan, Republic of Georgia, Mozambique and Carpe Verde, Vian (2008) found out that the Presidents Emergency Plan for AIDS Relief (PEPFAR), the Global Fund for AIDS, TB and Malaria, and other development partners, contributing hundreds of millions of dollars per year, created pressure to increasingly spend funds and increased the risk of corruption by requiring hasty decisions with limited and falsified, and sometimes unavailable data. From the foregoing, the tendency to inflate the number of carriers of HIV and AIDS in African countries due to perceived aid benefits from external donors remains a questionable issue and deserves further studies and thorough investigation, especially given the fact that virtually all the governments in Africa are corrupt.

#### Does aid increase occurrences of HIV and AIDS?

Studies have gueried the prevalence of HIV/AIDs in Africa in donor-dependent countries. Particularly in the case of Uganda, the rationale behind the acceptance of the prevalence of HIV and AIDS in Uganda by the incumbent president has been linked to the government's total dependence on aids (Tumushabe, 2006). To a large extent, Museveni's government has been totally dependent on aid from non-governmental organizations, international donors and others. With a constant huge yearly pay by late 1999 and early 2000 to 2005, Uganda was heavily externally financed to the tune of 600 million dollars per year (Tumushabe, 2006). In reality, the early assistance was vital for the government's delivery of basic social services and amenities, reduce the prevalent high costs of basic services, goods and remuneration of its public servants, which owed to the harsh economic situation suffered in the country after the long years of despotic military leadership under the Idi Amin and Obote regimes (Tumushabe, 2006).

Accordingly, considering the economic devastation and financial apocalypse of the Museveni-led Ugandan government, as well as its corrupt tendencies, how justifiable is that the government did not embrace the prevalence of HIV and AIDS as a premise to attract financial largess? Tumushabe (2006) has argued that the Museveni government in its attempt to claim the success of HIV/AIDS eradication monopolized the press and has given the international community a positive impression; meanwhile, HIV and AIDS in Uganda remain a threatening epidemic issue till date (Tumushabe, 2006).

# CONSTRUCTING THE ALTERNATIVES: HOW CAN HDI IMPROVE DATA COLLECTION ON HIV AND AIDS IN AFRICA?

#### Solution 1: Adequate and comprehensive researches

If the HDI will tackle the perceived and unclear prevalence of HIV/AIDS in Africa, it must be certain about the number of the carriers of this disease in the continent. It is the position of this paper that the HDI under the umbrella of the UNDP must spend more on research. Adequate data-gathering techniques in Africa will not take merely a year to build but decades. UNDP must invest and develop a more adequate and sophisticated data-gathering mechanism. In doing this, if the HDI is sincere, it must work with the government agencies, adequately financing and mobilizing its activities during this period. This is because any project left in the hands of African governments is due to be "compromised", given the kakistocratic system that has ravaged the political and social spheres in Africa.

# Solution 2: Integrated electronic health record systems

The HDI must invest wisely together with the collaboration of the various national governments at the development of an adequate health data base system, which will connect various government-registered clinics and hospitals together in a database at the national level and at the continental level. The integrated electronic health record system is operational in most developed societies like the United States, Canada and United Kingdom. The information contained in this database is organized primarily to support enduring, efficient and quality health care. And the database will help in sharing information about patients within the nation or across the continent. The implication this will have on the African states is not only a radical change in the health care delivery system, but also a radical improvement in recognizing the prevalent diseases that mostly result in mortality in the continent. Malaria, tuberculosis and typhoid are even more deadly diseases that kill sporadically, more than HIV/AIDS.

Without an adequate health care system, sicknesses are further complicated by giving the wrong medications for the wrong diseases. Millions of Africans have died due to this inadequacy in health records. Thus, there must be an adequate, interconnected data system managed by the HDI; otherwise, the true position of HIV/AIDS prevalence in Africa will remain elusive. It is only when the accurate number of HIV/AIDS infection is known that the adequate approach towards prevention can be devised.

# Solution 3: Partner with existing educational institutions in the area of research

Given the institutional collapse in most developing countries particularly Africa, the UNDP cannot rely on the collaborative effort of the bureau of statistics in most of these countries, rather a collaboration with the educational sector which essentially lacks funding will be necessary not only to improve data access but as well as the culture of research in these countries. A collaboration with colleges of sciences as well as departments of public health and medicine in various educational institutions would help to eliminate such forms of biases in data collection which will be strictly projected for academic and research purposes. It is appalling that majority of ongoing research on HIV and AIDS in Africa is undertaking in developed countries. This will also enhance a joint involvement of African institutions and scholars in the search for effective preventive measures and possibly a cure for the disease.

# PROJECTING OUTCOME: POSSIBLE EFFECTS OF THE AFOREMENTIONED SOLUTIONS

There are two possible outcomes if this policy is adequately implemented. First it will not only transform the status of health care delivery on the continent but will enhance other sectors of the society such as security, transparency and public scrutiny. If an adequate interconnected health care data base system is installed this will encourage other sectors of the society to emulate same features. Secondly, and as mentioned before, partnering with educational institutions in data accumulation will make it easier for researchers to develop sound and quality findings on what the government can do to curtail the spread of HIV and AIDS in the country. What target population or area needs much more focus in terms of intense enlightenment programs and public awareness? Instead of spending unnecessarily and outrageously without a defined target population that needs such enlightenment, a quality data will define the population that needs such enlightenment.

#### TRADEOFFS: CONSTRAINTS

#### **Finance**

For the UNDP to adequately implement this policy there are tradeoffs, one which is funding. First its present spending on HIV and AIDS in the continent will have to be directed to the area of adequate and measurable/reliable data. Though much of the funding on HIV and AIDS have been directed towards finding a cure for the epidemic, the

organization will have to re-direct its focus on solving the number of problems by adequately ensuring that there is available and reliable data. This will be highly difficult as the funds necessary to implement the already stated policies can be demanding, given the technological backwardness of the continent as well as the general state of education and research.

#### **BEST ALTERNATIVE**

However, there must be a major step taken. Before partnering with educational institutions in the area of research, there is a need to partner with major stake holders in the health care industry in the continent before a major step is taken at integrating public universities.

#### **Conflict of Interests**

The author(s) have not declared any conflict of interest.

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Journal of AIDS and HIV Research

Full Length Research Paper

# External quality assessment: On-site evaluation of HIV testing and counselling sites in Nigeria

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A cross-sectional quantitative assessment was conducted to evaluate the quality of testing in 242 human immunodeficiency virus (HIV) testing and counselling (HTC) sites in 25 states including the Federal Capital Territory (FCT) in Nigeria. A checklist assessing eight different quality systems essentials (QSE) adapted from World Health Organization/African Regional Office (WHO/AFRO) laboratory strengthening checklist was used. From the total percentage score obtained, the quality status of sites were classified using a zero to five step rating, based on the WHO/AFRO quality improvement stepwise approach. The 242 sites assessed were public (81%) and private (19%) health facilities; 104(43%) were primary and 138 (57%) secondary facilities. Only one site was at Step 5. Approximately, 15% performed at Step 4, 22% at Step 3, 26.5% at Step 2, 22.5% at Step 1 and 15% at Step 0. For the QSEs, mean percentage score was highest (100%) for human resource and lowest for proficiency testing [21.54 (95% C.I; 17.33 to 25.76)]. Overall, the public facilities performed better than the private facilities so did the secondary compared to the primary. The findings suggest that the performance of HTC sites remains low despite adequate human resources. Routine assessments and more effort on mentoring for quality improvement is required.

Key words: External quality assessment, on-site evaluation, HTC sites, Nigeria.

#### INTRODUCTION

In 2011, World Health Organization (WHO) reported an estimate of 34 to 46 million persons living with human Immunodeficiency virus (HIV) infection worldwide and that acquired immune deficiency syndrome (AIDS) has become the leading cause of death among young adults globally (UNAIDS, 2012). To alleviate this major challenge, Global Fund for AIDS, Tuberculosis and

Malaria (GFATM); the WHO's Three by Five initiative; and the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) initiated major activities to enhance HIV prevention and treatment services (GFTAM, 2003; Kendall, 2012; World Health Organization, 2003a). HIV testing and counseling (HTC) remains the key entry point into prevention, care and treatment programs. It has been

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proven that early treatment reduces ability to transmit HIV (treatment as prevention). It is therefore important to increase HIV testing in the general and key populations. To identify individuals requiring HIV prevention, treatment, care and support in order to achieve the goals of these initiatives, millions of persons would require HIV testing (De Cock et al., 2003; World Health Organization, 2005). In 2010, the national sero-prevalence of HIV in Nigeria was estimated at 4.1% (Federal Ministry of Health, Nigeria, 2010). With only about 14% knowing their status (Federal Ministry of Health, Nigeria, 2008), the need to expand HIV testing and counseling services became obvious. Family Health International-360 (FHI-360) Nigeria in collaboration with Society for Family Health (SFH) using PEPFAR and GFATM funding supported expansion of HTC services to more than 250 sites in the country. Identification and correction of gaps impeding quality service delivery at HTC sites is fundamental to the provision of reliable test results.

Quality has basically been defined as meeting standards (Kusum and Silva, 2005) guaranteed through a well-defined quality system aimed at ensuring consistency, reproducibility, traceability and efficacy of the testing service provided. The International Organization for Standardization (ISO) defines a quality system as the organizational structure, responsibilities, procedures, processes and resources for implementing quality management (Kusum and Silva, 2005). Guidelines for HTC centers have been established by various organizations for various settings (CDC, 2007; Community Forum on AIDS, 2009; WHO/AFRO and CDC, 2003). All these emphasize certain aspects of basic quality systems that would ensure accurate and reliable outcomes of testing. Generally, the challenges of performing rapid HIV testing on a wide scale have been identified as lack of trained staff, poor infrastructure and weak quality assurance program (Kline et al., 1994 Andersson et al., 1997 Stetler et al., 1997) To ensure standard quality of testing, maintain consistency and check the validity of results generated from the HTC centers, country guidelines recommend implementation of various aspects of an external quality assurance scheme ranging from proficiency testing to retesting (Community Forum on AIDS, 2009; Federal Ministry of Health, Nigeria, 2011) The World Health Organization Regional Office for Africa actually advocates implementation of rapid HIV testing with a system of continuous quality assurance that includes site visits (World Health Organization, 2003b). On-site monitoring or evaluation is a component of EQA accomplished by a careful on-site observation of the testing processes and procedures, carried out by a knowledgeable person or team. It is a process that uses evidence-based standards to measure the extent to which a facility adheres to these standards. Where gaps exist between desired and actual delivery of care, it is necessary to implement interventions to close such gaps (JHPIEGO Corporation, 2004).

There is presently a dearth of evidence-based interventions for improvements appropriate for use in HTC sites in resource poor settings. In order to generate reliable evidence for use within the framework of on-site monitoring module of an EQA program, a checklist detailing the required standards that allows for assessment of all parts of the quality system is needed. Existing guidelines and tools to monitor and evaluate HTC services do not focus on testing methods and quality but on the operational aspects of sites and counselling approach (Chimzizi et al., 2005 UNAIDS, 2000) An onsite monitoring and evaluation was undertaken to identify gaps in 242 HTC sites in Nigeria with the view of recommending appropriate interventions and action plan to address the gaps and monitor improvements overtime. This paper provides an overview of the general process utilized for establishing an EQA on-site monitoring program for the HTC sites.

#### **METHODOLOGY**

A cross-sectional quantitative audit of the quality management system was conducted in 242 HTC sites in 25 states of Nigeria including the Federal Capital Territory (FCT) where PEPFAR and GFTAM is implementing HTC programs. Data collection was done using a checklist adapted from WHO/AFRO Laboratory Strengthening Checklist Level II (World Health Organization., 2009). The HTC sites visited were located in private and public health facilities and were distributed at both Primary Health Care (PHC) and secondary level of health care delivery in Nigeria. Some were in rural communities' while the others were in urban centers. HIV testing at these sites was conducted following the National HIV testing algorithm in the country.

#### Planning and organization

Staff from FHI-360, SFH, Planned Parenthood Federation of Nigeria (PPFN) and the respective States Ministry of Health (SMoH) constituted an EQA planning committee. The committee adapted the checklist, identified and train assessors, and plan logistics for the assessment. The assessors were grouped into 32 teams of between two to three members. Each team had a State Quality Officer (SQO), an external consultant and either a PPFN or FHI-360 staff. Each team had an average of eight HTC sites to assess which translates into one team of assessors per state except where states had 12 or more sites in which case two teams were assigned.

#### Development of HTC on-site monitoring checklist and training

The WHO African regional office in 2009 developed a laboratory quality improvement scheme that recognizes incremental progress that is measurable over time on a tiered stepwise ranking (Gershy-Damet et al., 2010). This approach uses internationally accepted standards, adaptable to the resource limited environment. The WHO/AFRO Laboratory Strengthening Checklist Level II (World Health Organization, 2009) was adapted for HTC sites and used for this exercise. Guided by the WHO standards, FHI-360 developed guidelines to use and score the checklist to ensure standardization and uniformity. The checklist covered the following quality systems essentials (QSE); human resources, organization and personnel, documents and records, inventory management, process control

**Table 1.** Classification of HTC sites according to percentage score based on WHO/AFRO stepwise grading system.

Step	Scores (%)	No. HCT- sites	% (n=242)
0	< 55	36	14.9
1	55-64	52	21.5
2	65-74	64	26.5
3	75-84	53	21.9
4	85-94	36	14.9
5	≥95	1	0.4

and internal quality assessment, external quality assessment and safety standards expected at an HTC site. A one day orientation and training was held for 71 assessors prior to the commencement of the field visits. The objectives of the training were on how to use the assessment tool and to plan logistics for and approach to the conduct of the assessment. Inputs from the assessors were used to finalize the scoring guideline. Areas of compliance assessed were scored in three categories: not compliant (score = 0), partially compliant (score = 1) and compliant (score = 2). To classify the quality status of the sites, a five-step performance grading system based on percentage score was adapted from the WHO-AFRO quality improvement stepwise approach (Gershy-Damet et al., 2010). Briefly, the checklist allows for the rating of a facility's quality status by using a zero to five step rating, calculated as follows: less than 55% = 0-step, 55 to 64% = one-step, 65 to 74%; = 2-step, 75 to 84%; =3-step, 85 to 94% = 4-step and 95% and above = 5-star.

#### Field visits

The on-site assessment was conducted for five days in December, 2009 in 242 sites in 25 states where PEPFAR and GFTAM is implementing HTC programmes. The states visited were Adamawa, Akwa Ibom, Anambra, Benue, Borno, Cross River, Delta, Edo, Enugu, Gombe, Imo, Kaduna, Kano, Katsina, Kogi, Lagos, Nasarawa, Niger, Ogun, Oyo, Plateau, Rivers, Sokoto, Taraba and the FCT. The three HTC sites in Bayelsa State (General Hospital Brass, Comprehensive Health Centers Okpoama and Twon Brass) were not visited for security reasons. The assessment teams were led by the respective State Quality Officers (SQO) and SFH consultants (in states with two teams). The SQO were experienced medical laboratory practitioners with the mandate of their states MoH to oversee laboratory quality issues.

#### Data management and analysis of outcome variables

Data was captured on MS Excel spreadsheet and collated centrally. After the assessment, each team submitted the completed checklist. The FHI-360 team, at the country office collated and crosschecked all data received from the field to ensure quality. Data entry files from all the states including the FCT were merged to one dataset and imported to StataSE 10 (StataCorp, College Station, TX) for analysis on outcomes from QSE's detailed on the checklist. An exploratory data analysis was carried out to check for inconsistencies. Mean percentage scores were computed for each quality system essentials according to the compliance scoring system (not compliant (score = 0), partially compliant (score = 1) and compliant (score = 2). In addition, the mean percentage scores for each QSE were disaggregated by type of facility (that is, PHCs vs. secondary facilities, private vs. public facilities). Differences in mean percentage scores for each essential between PHCs and

secondary facilities, private and public facilities were tested using ttest. A 5% level of significance was considered significant for all analysis.

#### **RESULTS**

Majority (81%) of the sites assessed were public health facilities and the rest (19%) were private facilities. Proportion of Primary Health Care (PHC) and secondary facilities assessed were 43% (104/242) and 57% (138/242), respectively.

# Site classification based on WHO/AFRO stepwise grading system

Only 0.4% (n = 1) of the sites was found to be at the highest level of the WHO/AFRO quality performance grading (step 5). Approximately, 15, 22, 26, 22 and 15% of the HTC-sites were found to be on step 4, Step 3, Step 2, Step 1 and Step 0, respectively (Table 1). This finding varied by facility type (Figures 1 and 2). A higher proportion of secondary compared with the PHC facilities were found on Step 3 (26.1% vs. 16.4%) and Step 4 (21.7% vs. 5.8%) (P-value < 0.001). Similarly, a higher proportion of public facilities compared with private facilities were found on Step 3 (23.4% vs. 15.6%) and Step 4 (16.8% vs. 6.7%) (P-value = 0.002).

# Performance based on the various quality systems essentials (QSE) and type of facility

Mean percentage score was highest for human resources where all facilities scored 100%. This was followed by safety [82.15% (80.12 to 84.19)] and information management [80.68% (78.72 to 82.64)]. However, the mean percentage score was lowest for proficiency testing [21.54 (17.33 to 25.76)]. All quality system essentials assessed varied between PHC facilities and secondary facilities. However, these differences were statistically significant for all quality system essentials except for information management and safety (Table 2). This variation was further seen in private and public facilities (Table 3).

#### **DISCUSSION**

Findings from this assessment show that the HTC sites are on various levels of the quality ladder. Majority of the sites performed at Step 2 (64/242; 26.5%) of the five level grading systems indicating general low level quality performance. This indicates the need for the development and implementation of quality improvement strategy to address the identified gap. The use of the scoring and performance grading system in the assessment would

Table 2. Mean percentage scores of various quality system essentials in Primary Health Care (PHC) and secondary facilities.

Quality System Essentials	All facilities Mean% score (95% C.I)	PHCs Mean% score (95% C.I)	Secondary facilities Mean% score (95% C.I)	P-value
Human Resources	100	100	100	-
Organization and Personnel	74.69 (72.83 – 76.54)	72.36 (69.74-74.97)	76.45 (73.87 – 79.03)	0.03
Documents and Records	71.90 (68.16 -75.64)	65.93 (59.96 – 71.91)	76.40 (71.70 – 81.10)	0.01
Inventory Management	74.36 (72.59 - 76.13)	70.54 (68.21 – 72.87)	77.24 (74.77 – 79.71)	< 0.001
Information Management	80.68 (78.72 - 82.64)	79.69 (76.93 – 82.44)	81.43 (78.67 – 84.20)	0.39
Process Control and Internal Quality Assessment	47.93 (44.80 - 51.07)	40.87 (36.88 – 44.85)	53.26 (48.82 – 57.70)	< 0.001
External Quality Assessment (Proficiency Testing)	21.54 (17.33 – 25.76)	12.46 (8.20 - 16.72)	27.99 (21.63 – 34.34)	< 0.001
Safety	82.15 (80.12 - 84.19)	79.81 (76.70 – 82.91)	83.92 (81.23 – 86.61)	0.05

**Table 3.** Mean percentage scores of various quality system essentials in private and public facilities.

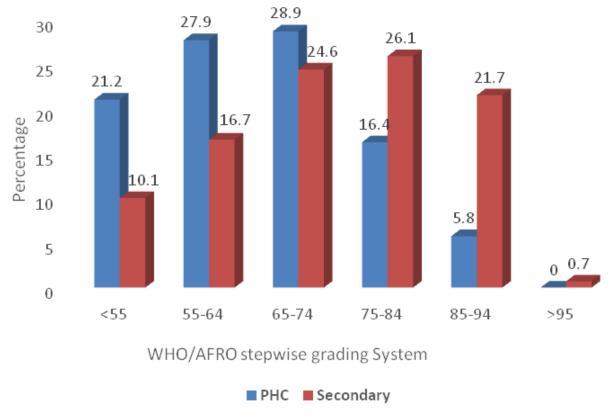
Quality System Essentials	Private facilities	Public facilities	P-value
Quality System Essentials	Mean % score (95% C.I)	Mean % score (95% C.I)	r-value
Human Resources	100	100	-
Organization and Personnel	72.78 (67.76– 77.80)	75.13 (73.13 – 77.12)	0.33
Documents and Records	52.22 (43.12 -61.32)	76.40 (72.53 – 80.27)	< 0.001
Inventory Management	70.40 (66.05 – 74.76)	75.27 (73.34 – 77.19)	0.04
Information Management	74.17 (68.89 – 799.44)	82.17 (80.12 – 84.22)	< 0.001
Process Control and Internal Quality Assessment	36.00 (29.18 – 42.82)	50.66 (47.23 – 54.09)	< 0.001
External Quality Assessment (Proficiency Testing)	16.28 (7.94 – 24.62)	22.76 (17.93 – 27.59)	0.24
Safety	79.31 (74.44 – 84.17)	82.80 (80.55 – 85.05)	0.19

ensure measurable improvements over time. The findings also show that quality management systems are more entrenched in secondary than in PHC facilities and more in public than private settings. Probably because health program implementers and the Government of Nigeria focus more on secondary and public health facilities in trainings and system strengthening activities. Efforts should therefore be made to ensure that health strengthening programs are more all-inclusive.

The mean percentage score for each quality system essential was also analyzed. The score varied for the different quality system essentials, the highest being human resources where all facilities scored 100%, being compliant in human resource based on work load analysis of patient to staff ratio of 15:1 per day according to national standards for HTC services (Federal Ministry of Health, Nigeria, 2011). This is at variance with the appropriate manpower challenge in the health sector generally seen in Nigeria. This positive

outcome could be attributed to task-shifting generally being practiced for testing and counseling services. Benefits of task shifting to address health care workers shortage has been reported in some sub-Saharan African countries (Zachariah et al., 2009; Munga et al., 2012).

Other key areas of strength identified for the HTC sites are information management and safety as shown by the high mean percentage scores. This could be attributed to the reporting requirement of funders which expects appropriate



**Figure 1.** Percentage of HTC sites according to WHO/AFRO stepwise grading system in Primary Health Care (PHC) and secondary facility.

documentation for requisition and re-supply of commodities. Availability of funding also ensures provision of appropriate safety gadgets. In contrast, the key areas of weakness are process control/internal quality assessment and external quality assessment. The absence of external quality assurance systems had been reported in a similar study in Malawi (Chimzizi et al., 2005). These findings call for the need to improve human and institutional capacity for quality control and assessments of HIV testing to ensure accurate, reproducible and reliable HIV test results. There is significant difference in performance to QSE between the PHCs and secondary facilities and between private and public health facilities. This indicates a higher quality of HTC service delivery in secondary facilities than in primary and in public than in private health facilities. These results are comparable to other studies that showed the quality of service delivery in private facilities to be low when compared to public facilities (Patouillard et al., 2007; Konde-Lule et al., 2010).

Due to some methodological limitations such as lack of randomization, exclusion of some sites due to security reasons and the assessors were not evaluated after the one-day training to ensure the accuracy of using the checklist, the findings may not be sweeping.

#### **CONCLUSION AND RECOMMENDATIONS**

The outcomes of this assessment show that on-site monitoring component of the external quality assessment (EQA) is feasible. The method used was productive and successful. Grading the HTC sites into performance level according to the percentage scores provides evidence against which any quality improvement intervention can be measured. It is expected that putting in place appropriate quality improvement measures based on the gaps identified per site would ensure progress up the quality ladder which can be monitored over time. The percentage grading approach used will enable the measurement of any improvements following interventions. The findings call for quality improvement efforts at testing sites. It is therefore important to institutionalize regular on-site monitoring and evaluation at HTC sites. This will enable the identification of areas of weakness to address for continuous quality improvement. At the program level, it is recommended that the individual facilities checklist be further analyzed after each audit to identify site specific gaps for each QSE assessed. This should be used to provide feedback to the facilities. It is expected that at the facility level, a team of appropriate personnel would

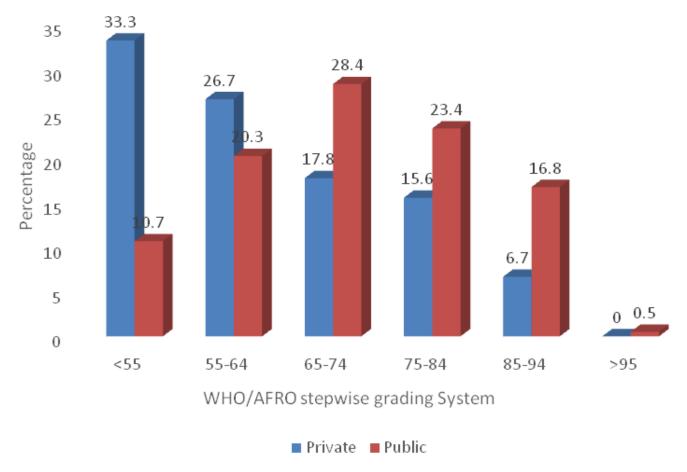


Figure 2. Percentage of HTC sites according to WHO/AFRO stepwise grading system in private and public facility.

would analyze the results of the site assessment, identify facility specific gaps and recommend remedial interventions to address the gaps. Managements of the affected facilities should provide the necessary resources, develop action plans and implement them to ensure that proposed remedial actions are fully undertaken.

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#### **Conflict of Interests**

The author(s) have not declared any conflict of interest.

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