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 (GFATM, 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 on-site 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 GFATM 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...
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 (Gersh-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%; ≥85-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 Okpoama and Twn 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 t-test. 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.

<table>
<thead>
<tr>
<th>Quality System Essentials</th>
<th>All facilities</th>
<th>PHCs</th>
<th>Secondary facilities</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Human Resources</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>-</td>
</tr>
<tr>
<td>Organization and Personnel</td>
<td>74.69 (72.83 – 76.54)</td>
<td>72.36 (69.74-74.97)</td>
<td>76.45 (73.87 – 79.03)</td>
<td>0.03</td>
</tr>
<tr>
<td>Documents and Records</td>
<td>71.90 (68.16 -75.64)</td>
<td>65.93 (59.96 – 71.91)</td>
<td>76.40 (71.70 – 81.10)</td>
<td>0.01</td>
</tr>
<tr>
<td>Inventory Management</td>
<td>74.36 (72.59 - 76.13)</td>
<td>70.54 (68.21 – 72.87)</td>
<td>77.24 (74.77 – 79.71)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Information Management</td>
<td>80.68 (78.72 – 82.64)</td>
<td>76.99 (76.93 – 82.44)</td>
<td>81.43 (78.67 – 84.20)</td>
<td>0.39</td>
</tr>
<tr>
<td>Process Control and Internal Quality Assessment</td>
<td>47.93 (44.80 - 51.07)</td>
<td>40.87 (36.88 – 44.85)</td>
<td>53.26 (48.82 – 57.70)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>External Quality Assessment (Proficiency Testing)</td>
<td>21.54 (17.33 – 25.76)</td>
<td>12.46 (8.20 – 16.72)</td>
<td>27.99 (21.63 – 34.34)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Safety</td>
<td>82.15 (80.12 – 84.19)</td>
<td>79.81 (76.70 – 82.91)</td>
<td>83.92 (81.23 – 86.61)</td>
<td>0.05</td>
</tr>
</tbody>
</table>

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

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

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
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
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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