Stepwise Process for Improving the Quality of HIV Rapid and Recency Testing (SPI-RRT) Checklist

**SPI-RRT Checklist**

Version 3.5

9/9/2019

**PART A: CHARACTERISTICS OF THE FACILITY OR TESTING POINT AUDITED**

Before completing the checklist, it is important to characterize the testing point to be audited. Please provide relevant information in the summary table below.

|  |  |  |
| --- | --- | --- |
| **Date of Audit** (dd/mm/yyyy)**: 10/7/2019** | **Audit Start Time (hh:mm) : 01:30 pm** | **Audit Round No: 1** |
| **Testing Facility Name: Site C** | **Testing Facility ID** (if applicable) N/A |
| **Type of testing point** (Circle One)**VCT/HTC PITC PMTCT TB clinic Laboratory Treatment Center Other** (Specify) OPD |
| **Physical Address:** |
| **Level** (Circle One and specify name) **Region/Province/Zone:**  **District:**  **Referral center:** √ **Health center:**  **Dispensary:** **Health Post:** **Other** (Please specify to reflect country context):  | **Affiliation** (Circle One)√ **Government** **Private** **Faith-based Organization** **Non-governmental organization** **Other:** |
| **Number of Testers at Site: 2** | **Number of clients tested for HIV:** **Past Month: 6 Past Quarter: 13** |
| **Number of newly identified HIV positives:****Past Month: 6 Past Quarter: 13** | **Number of HIV negatives:****Past Month: 15 Past Quarter: 27** |
| **Number of newly identified HIV positives tested by RTRI :****Past Month: 6 Past Quarter: 13** | **Number of Recent by RTRI or RITA:****Past Month: 2 Past Quarter: 2** |
| **Name of the Auditor 1: Sansa Stark** | **Name of the Auditor 2: Eddard Stark** |

**PART B. SPI- RRT Checklist**

For each of the sections listed below, please check **Yes, Partial or No**, where applicable. Indicate “**Yes**” only when all elements are satisfactorily present. Provide comments for each “**Partial**” or “**No**” response. State N/A in the comments section if “not applicable” where appropriate (\*).

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **SECTION** | **YES** | **Partial** | **NO** | **Comments** | **Score** |
| 1. **PERSONNEL TRAINING AND CERTIFICATION**
 | **10** |
| 1.1 | Have all testers received a comprehensive training on HIV rapid testing using the nationally approved curriculum? |  |  | √ | No documentation of training |  |
| 1.2 | Are the testers trained on the use of standardized HIV testing registers/logbooks? |  |  | √ | No documentation of training |  |
| 1.3 | Are the testers trained on external quality assessment (EQA) or proficiency testing (PT) process? |  |  | √ | No documentation of training |  |
| 1.4 | Are the testers trained on quality control (QC) process? |  |  | √ | No documentation of training |  |
| 1.5 | Are the testers trained on safety and waste management procedures and practices? |  |  | √ | No documentation of training |  |
| 1.6 | Have all testers received a refresher training within the last two years? |  |  | √ | No documentation of refresher training |  |
| 1.7 | Are there records indicating all testers have demonstrated competency in HIV rapid testing prior to client testing? | √ |  |  | There is documentation of competency testing during supervisory visit |  |
| 1.8 | Have all testers been certified through a national certification program?  |  |  | √ | No certification program in country |  |
| 1.9 | Are only certified testers performing HIV rapid testing at the site? |  |  | √ | No certification program in country |  |
| 1.10 | Are all testers re-certified periodically (e.g., every two years)? |  |  | √ | No certification program in country |  |
| 1. **PERSONNEL TRAINING AND CERTIFICATION SCORE**
 | 1 |
| **2.0 PHYSICAL FACILITY** | **5** |
| 2.1 | Is there a designated area for HIV testing? | √ |  |  |  |  |
| 2.2 | Is the testing area clean and organized for HIV rapid testing? | √ |  |  |  |  |
| 2.3 | Is sufficient lighting available in the designated testing area? | √ |  |  |  |  |
| 2.4 | Are the test kits kept in a temperature controlled environment based on the manufacturers’ instructions? |  |  | √ | HIV RT kits stored in testing area in cabinet while RTRI kits stored in pharmacy |  |
| 2.5 | Is there sufficient and secure storage space for test kits and other consumables? | √ |  |  |  | 4 |
| 1. **PHYSICAL FACILITY SCORE**
 |  |
| **3.0 SAFETY** | **11** |
| 3.1 | Are there SOPs and/or job aides in place to implement safety practices? |  | √ |  | Missing job aides for managing blood and body fluids or handling needle stick injuries. Only job aid/SOP on site is segregating waste |  |
| 3.2 |  Are there SOPs and/or job aides in place to address accidental exposure to potentially infectious body fluids through a needle stick injury, splash or other sharps injury? |  |  | √ | No documentation |  |
| 3.3 |  Are testers and those visiting the testing area following the safety practices outlined in the SOPs and/or job aides? |  | √ |  |  |  |
| 3.4 | Is personal protective equipment (PPE) always available to testers? | √ |  |  | Professional counselor has cloth lab coat and the lay counselor has a cloth lab apron |  |
| 3.5 | Is PPE properly used by all testers consistently throughout the testing process? | √ |  |  |  |  |
| 3.6 | Is there clean water and soap available for hand washing? | √ |  |  |  |  |
| 3.7  | Are testers washing their hands before and after testing each client? | √ |  |  |  |  |
| 3.8 | Is there an appropriate disinfectant to clean the work area available? |  |  | √ | No disinfectant available at the site |  |
| 3.9 | Are sharps, infectious, and non-infectious waste segregated and disposed of properly? | √ |  |  |  |  |
| 3.10 | Is infectious waste securely stored and not accessible to the public prior to disposal? | √ |  |  |  |  |
| 3.11 | Are infectious and non-infectious waste containers emptied regularly per the SOP and/or job aides? | √ |  |  |  |  |
| 1. **SAFETY SCORE**
 | 8 |
| 1. **PRE-TESTING PHASE**
 | **12** |
| 4.1 | Are there national HIV testing guidelines available at the testing point?  | √ |  |  |  |  |
| 4.2 |  Is the national HIV testing algorithm(s) consistently being used at the testing site? | √ |  |  |  |  |
| 4.3 |  Are there SOPs and/or job aides in place for the national HIV rapid test algorithm and each HIV rapid test used in the testing algorithm? | √ |  |  |  |  |
| 4.4 |  Are only nationally approved HIV rapid test kits available for use? | √ |  |  |  |  |
| 4.5 |  Are all the test kits currently in use within the expiration date? | √ |  |  |  |  |
| 4.6 |  Are test kits labeled with date received and initials of the person who received them? |  | √ |  | HIV RT Test kits were not labeled with date and initials. RTRI did have date and initials. |  |
| 4.7 |  Are all required test kit components (i.e. test device, buffer, sample collection device, etc.) and supplies available prior to testing? | √ |  |  |  |  |
| 4.8 | Is there a process in place for stock management? | √ |  |  | Stock maintained at pharmacy |  |
| 4.9 | Are job aides on client sample (i.e. blood) collection available and posted at the testing point? | √ |  |  |  |  |
| 4.10 | Are there sufficient supplies available for client blood collection (i.e. lancet, gauze, alcohol swab, etc.)? |  | √ |  | Did not see enough alcohol swab and gauze for blood collection. Testers uses lancets from Determine kit. |  |
| 4.11 | Are there SOPs and/or job aides describing how client identification should be recorded in the HIV testing register? | √ |  |  | Noted in HTS register |  |
| 4.12 | Are client identifiers recorded in the HIV testing register and on test devices per SOPs and/or job aide? | √ |  |  | Guidelines state name as identified. They don’t use unique IDs. |  |
| **4.0 PRE-TESTING PHASE SCORE** | 11 |
| 1. **TESTING PHASE**
 | 9 |
| 5.1 | Are SOPs and/or job aides on HIV testing procedures and the national testing algorithm being referred to and followed during testing? | √ |  |  |  |  |
| 5.2 | Are timers available and used routinely for HIV rapid testing? | √ |  |  |  |  |
| 5.3 | Are sample collection devices (e.g., capillary tube, loop, disposable pipettes, etc.) used accurately? | √ |  |  |  |  |
| 5.4 | Are testing procedures adequately followed? | √ |  |  |  |  |
| 5.5 | Are external positive and negative quality control (QC) specimens routinely used (e.g., daily, weekly or monthly) according to SOPs or guidelines? | √ |  |  |  |  |
| 5.6 | Are QC results properly recorded? | √ |  |  |  |  |
| 5.7 | Are incorrect and/or invalid QC results properly recorded? | √ |  |  |  |  |
| 5.8 | Are appropriate steps taken and documented when QC results are incorrect and/or invalid? | √ |  |  |  |  |
| 5.9 | Are QC records reviewed by the person in charge routinely? |  |  | √ | No documentation of review |  |
| **5.0 TESTING PHASE SCORE** | 8 |
| 1. **POST TESTING PHASE - DOCUMENTS AND RECORDS**
 | **9** |
| 6.1 | Is there a national standardized HIV rapid testing register/logbook that includes all of the key quality elements available and in use? | √ |  |  |  |  |
| 6.2 |  Are all the elements in the register/ logbook recorded/captured correctly? (e.g., client demographics, kit names, lot numbers, expiration dates, tester name, individual and final HIV results, etc.)? | √ |  |  |  |  |
| 6.3 |  Is the total summary at the end of each page of the register/logbooks complied accurately?  |  |  | √ | The HTS registers do not have a field for entering total number of reactive, nonreactive and invalid results |  |
| 6.4 |  Are invalid test results recorded in the register/logbook and then repeated? | √ |  |  |  |  |
| 6.5 |  Are the register/logbook pages routinely reviewed for accuracy and completeness by the person in charge? |  |  | √ | No documentation of review |  |
| 6.6 | Are all client documents and records securely kept throughout all phases of the testing process? | √ |  |  |  |  |
| 6.7 | Are all registers/logbooks and other documents kept in a secure location when not in use? | √ |  |  |  |  |
| 6.8 | Are registers/logbooks properly labeled and archived when full? |  |  | √ | No archiving system in place |  |
| **6.0 POST TESTING PHASE - DOCUMENTS AND RECORDS SCORE** | 5 |
| 1. **EXTERNAL QUALITY Assessment (PT/EQA, SITE SUPERVISION AND RETESTING)**
 | **8** |
| 7.1 | Is the testing point enrolled in an EQA/PT program? | √ |  |  |  |  |
| 7.2 | Do all testers at the testing point test the EQA/PT samples? | √ |  |  | The PT program is targets sites not individual testers. Testers rotate with each PT round |  |
| 7.3 | Does the person in charge at the testing point review the /PT results before submission to NRL or designee? | √ |  |  |  |  |
| 7.4 | Is an EQA/PT report received from NRL and reviewed by testers and/or the person in charge at the testing point? | √ |  |  |  |  |
| 7.5 | Does the testing point implement corrective action in case of unsatisfactory results? | √ |  |  | The PT results are returned to the site and on the back of the PT result form there is a section to document corrective actions for PT failures.  |  |
| 7.6 | Does the testing point receive periodic supervisory visits? |  |  | √ | No documentation of supervisory visits |  |
| 7.7 | Is feedback provided during supervisory visit and documented? |  |  | √ | No documentation of supervisory visits |  |
| 7.8 | If testers need to be retrained, are they being retrained during the supervisory visit? |  |  | √ | No documentation of supervisory visits |  |
| **7.0 EXTERNAL QUALITY ASSESSMENT (PT AND SUPERVISION) SCORE** | 5 |
| **If the country has implemented the Rapid Test for Recent Infection (RTRI) proceed with questions 8.1-8.10.** **Otherwise, STOP here.** |
| 1. **HIV-1 RECENT INFECTION SURVEILLANCE USING THE RAPID TEST FOR RECENT INFECTION**
 | **11** |
| 8.1\* | Have all testers received a comprehensive training on RTRI? |  |  | √ | Testers say they are trained but no documentation of training. |  |
| 8.2\* | Are there records indicating all testers have demonstrated competency in RTRI prior to testing? |  |  | √ |  |  |
| 8.3\* | Are all current versions of recency SOPs and/or job aids readily available at the site?  | √ |  |  |  |  |
| 8.4\* | Is there a sufficient supply of RTRI tests available at the site?Please provide number of tests currently available……. | √ |  |  |  |  |
| 8.5\* | Are the test kits kept in a temperature controlled environment based on the manufacturers’ instructions? |  | √ |  | RTRI kits stored at pharmacy but temperature is not being monitored |  |
| 8.6\* | Are RTRI testing procedures being followed (i.e. right volume of sample using correct sample application device, correct read time using timer, correct result interpretation)? | √ |  |  |  |  |
| 8.7\* | Are the RTRI results documented in the data capture form or logbook correctly (e.g. client demographics, kit name, lot number, expiration dates, tester name, RTRI visual results and recency interpretation)? | √ |  |  |  |  |
| 8.8\* | Are external positive and negative quality control (QC) specimens routinely used (at least monthly) for RTRI and reviewed by person in charge? | √ |  |  |  |  |
| 8.9\* | Are QC results for RTRI properly recorded (e.g. kit name, lot number, expiration dates, tester name, RTRI visual results and recency interpretation for each level of QC)? | √ |  |  |  |  |
| 8.10\* | Are appropriate steps taken and documented when RTRI QC results are incorrect? | √ |  |  |  |  |
| 8.11\* | Are invalid test results recorded in the data capture form/register/logbook? If yes, how many in the last 3 months……0…… | √ |  |  |  |  |
| **8.0**  **HIV-1 RECENT INFECTION SURVEILLANCE USING THE RAPID TEST FOR RECENT INFECTION SCORE** | 8.5 |

\*Those marked with an asterisk are only applicable to sites where sample retesting is performed.

|  |
| --- |
| **Audit End Time (hh:mm): 2:30pm** |

**PART C: SCORING CRITERIA**

Each element marked will be assigned a point value:

* Items marked “Yes” receive 1 point each.
* Items marked “Partial” receive 0.5 point each.
* Items marked “No” receive 0 point each.

Total points scored for each section should be tallied and recorded at the end of the section.

The overall total points obtained by each HIV testing point audited will be weighed to correspond to a specific performance level.

|  |  |  |
| --- | --- | --- |
| **Levels** | **% Score** | **Description of results** |
| Level 0  | Less than 40%  | Needs improvement in all areas and immediate remediation |
| Level 1  | 40% - 59%  | Needs improvement in specific areas |
| Level 2  | 60%-79% | Partially eligible |
| Level 3  | 80%-89% | Close to national site certification |
| Level 4  | 90% or higher | Eligible to national site certification |

**Part D. Auditor’s Summation Report for SPI-RRT Audit**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Facility Name: |  | No. of Tester(s): |  | **Section** | **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** | **Total** |
| Site Type: |  | Audit Start Time (hh:mm) : |  | **Score Received** |  |  |  |  |  |  |  |  | **a =** |
| **Expected Score** | **10** | **5** | **11** | **12** | **9** | **9** | **8** | **11** | **b =** |
| Site code (if applicable): |  | Audit End Time (hh:mm): |  | **% Score = (a/b) x 100 = (\_\_\_\_\_\_\_\_\_\_\_\_\_/\_\_\_\_\_\_\_\_\_) x 100 = \_\_\_\_\_\_\_\_\_\_%****Performance Level:** **0 1 2 3 4** **(<40%) (40-59%) (60-79%) (89-90%) (>90%)** |
| Staff Audited Name: | Duration of Audit: |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Section No.** | **Deficiency/Issue observed**  | **Auditor’s****Comments**  | **Correction Actions** | **Recommendations** |
| **Immediate** | **Follow up** | **Actions** | **Timeline / Person responsible** |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

|  |  |  |
| --- | --- | --- |
| Staff Audited Signature: |  | Auditor Name and Signature: |
| Person in Charge Name and Signature: |  | Date (dd/mm/yyyy):  |