Checklist for Quality Assurance on HIV Voluntary Counseling and Testing services (VCT) in Community Settings

(Version 2.1)

Community Forum on AIDS

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Preamble

In Hong Kong, HIV Voluntary Counselling and Testing (VCT) Services has been provided by various non-governmental organizations in the past decade, either in centre-based or outreach settings. The growing popularity of HIV testing service providers in community settings has led to a need for guidelines to benchmark practices and uphold standards of service. In 2009, The Quality Assurance Guidelines on HIV Voluntary Counselling and Testing (VCT) Services in Community Settings (The Guideline) was drafted, and subsequently endorsed by members of the Community Forum on AIDS (CFA) during the fourteenth meeting in July 2009. The Guideline served to provide basic guidance for service providers to take reference for improvement of their VCT service, with the purpose of upholding the standard of service provision as a whole. It is not a regulatory guideline for licensing purpose.

During the 14th CFA meeting, members agreed that DH would take the role of providing technical support for capacity building and training for frontline workers responsible for delivering VCT services. It is not in a position to recommend individual brand(s) of HIV rapid test kits.

Members also agreed that actual implementation of The Guideline should be revisited after one year. While internal assessment by the service providers were expected, they were also encouraged to invite an external party or authorized body to assess the standard of their VCT service. In case ISO accreditation was not feasible due to resource constraint, the service providers could make arrangement among themselves to visit each other on a regular basis with a view of sharing experience and improving the quality of service.

In order to facilitate evaluation of VCT services in community settings, DH has drafted a checklist in early 2013 based on The Guideline. It is hoped by using the same common checklist, internal audit of the VCT service could be carried out in a more systematic, structural and unified way across different service providers. It is reminded that the checklist is used as a tool for evaluation. It should not be regarded as a replacement of The Guideline, which should be always be observed by service providers.

Suggestions on the conduction of internal audit and completion of the checklist are illustrated as follows.

Purposes of the checklist:

1. For the service providers to regularly assess the organization's compliance to The Guideline, so that remedial measures could be implemented when necessary;
2. As a mean to detect any difficulty commonly encountered by service providers during implementation of The Guideline, so that DH and other relevant parties may provide appropriate technical support;
3. As a written documentation for quality control of the VCT services.

Levels of assessment:

This checklist assesses the quality of VCT service at two levels, including the organization level (Part A), and the individual level (Part B).

Organization level (Part A) - it mainly concerns about the structures of the VCT service providing organizations and the presence of quality assurance mechanisms (such as policy, organization, personnel, training and equipment);

Individual level (Part B) - it mainly concerns about the performance of individual workers. Organizations could use their own checklist for individual worker assessment.

Suggested implementation of the internal audit

Responsible person:	Each VCT service providing organization should at least appoint one to two persons responsible to conduct the internal audit;
Venue:	The checklist is mainly used for centre-based VCT service. It could also be used at outreach services as far as appropriate;
Audit period:	Once a year, from 1 April to 31 March next year;
Coverage for Part B:	Every VCT worker should be assessed once a year;
Reporting of results:	Service providers are expected to briefly report their audit results of Part A to DH for aggregate analysis and presentation during CFA meeting after the end of each audit period;
Deliverables:	Service providers should keep a proper record of the whole internal audit report (Part A and B) in case future reference is needed.

Checklist for Quality Assurance on HIV Voluntary Counseling and Testing Services (VCT) in Community Settings

(Part A - Organization level)

Instructions:

1. Part A consists of 6 Sections :

    - Section 1 – Organization of VCT Service
    - Section 2 – Training of the relevant personnel
    - Section 3 – Assessment on competency of personnel in performing VCT
    - Section 4 – Infection control
    - Section 5 – Documentation and monitoring
    - Section 6 – Quality control of test kits

2. This part of assessment on the organization is expected to be carried out at least once every year by the person(s) appointed as the internal auditors of the organizations.

3. Should any of the item could not be achieved in all VCT sites, please mark down the reason under the “Remarks” box.

Part A. Assessment at the organizational level

Date of assessment: _____ **Venue of assessment:** _____

Name of assessor: _____

Part A. Section 1. Organization of VCT Service (P 1/1)

A. Policy and management	**1=Yes 0=No**	**Remarks**
1. A designated person(s) is responsible for managing the VCT service		
2. A protocol for VCT is in place		
a. Inputs from board / medical advisors has been incorporated into the VCT protocol		
3. Written testing instructions and site-specific (e.g. centre, outreach) procedures are provided		
4. A well-established referral mechanism is in place for further confirmatory tests or follow up		
5. Have a set policy on age of consent based on the organization's capacity and safeguards		
6. Preset timeline for review, retain and destroy records on personnel training, temperature logs of test kits and external controls, external control result logs and test results logs		
7. Written policy to ensure VCT clients have the rights of self-determination, confidentiality, protection from discrimination and access to accurate and comprehensive information		
B. Environmental settings for conducting VCT	**1=Yes 0=No**	**Remarks**
1. Provision of a private room with good lighting and hygienic condition		
C. Inventory management of test and control kits	**1=Yes 0=No**	**Remarks**
1. Maintain sufficient supplies of unexpired test and control kits (at least one control kit per lot).		
2. A refrigerator for storage of test and control kits OR continuous air conditioning is available.		
3. Thermometers available for measuring the storage and testing area with ≤ 1^{o}C error.		
4. The thermometers have recording function for minimum and maximum temperatures.		

Part A. Section 2. Training of the relevant personnel (P 1/2)

A. Organization of the training	1=Yes 0=No	Remarks
1. A designated person(s) is responsible for personnel training on VCT		
2. Personnel training record is in place (including coverage and training content)		
B. Coverage of the training	**%**	**Remarks**
1. Percentage of personnel performing VCT who had ever received external training, e.g. by DH		Reason for <50%:
2. Percentage of personnel performing VCT who had ever received internal training		Reason for <50%:
3. Percentage of personnel performing VCT who received update training (including basic or refresher VCT training) in the past 1 year		Reason for <50%:

Part A. Section 2. Training of the relevant personnel (P 2/2)

C. Content of basic training	1=Covered 0=Not covered	Remarks
1. How to integrate testing into the overall HIV prevention program		
2. How to provide pre-test counseling		
3. How to perform the test including external controls		
4. Infection control with reference to concurrent guidelines:		
a. Standard precautions		
b. Accident and dangerous occurrences (needle stick injury)		
c. Post-exposure management		
5. Interpretation of test results and post-test counseling		
6. How to handle sensitive and emergency issues e.g. legal liability and age of consent, psychological reaction etc.		
7. How to perform proper documentation:		
a. Confidentiality and privacy		
b. Testing procedure and results		
c. Infection control issue		
d. Quality control (e.g. checking and recording of temperature, expiry date, invalid and contradictory results; conducting and recording external control etc.)		

Part A. Section 3. Assessment on competency of personnel performing VCT (P 1/1)

A. Assessment mechanism	**1=Yes 0=No**	**Remarks**
1. Well documented plan and protocol covering areas to be assessed, and made known to relevant personnel		
2. A designated person responsible for staff competency assessment		
3. Use Part B of this checklist for individual assessment		
4. At least annual assessment of individual competency		
5. Documentation of individual competency assessment result		
B. Areas of individual competency assessment	**1=Covered 0=Not Covered**	**Remarks**
1. Pre-test counseling skills and confidentiality issue		
2. Procedure of VCT		
3. Interpretation and documentation of results		
4. Infection control measures *(go to Part A Section 4 "Infection Control carried out by the organization")*		
5. Post-test counseling skills under scenarios of different results		
6. Crisis management		
7. Procedure of confirmatory blood taking if applicable		

Part A. Section 4. Infection control (P 1/1)

A. Management	1=Yes 0=No	Remarks
1. A designated person(s) is responsible for all matters related to infection control		
2. Regular checking of hand hygiene facilities (e.g. soap, alcohol and water) and personal protective equipment (PPE) (e.g. surgical masks, gloves) are available and accessible.		
3. A log book for recording accidents or dangerous occurrences (e.g. needle stick injury) is in place		
4. Regular review of accidents or dangerous occurrences for taking corrective and preventive actions		
5. Posters on steps for hand washing is posted up		

B. Areas of individual competency assessment	1=Covered 0=Not Covered	Remarks
1. Hand hygiene		
2. Use of personal protective equipment (e.g. glove, surgical mask)		
3. Sharps management		
4. Bio-hazardous wastes disposal		
5. Disinfection of contaminated articles and environment		
6. Handling of accidents including needle-sticks injuries		
7. Post-exposure management (e.g. mucosal contact)		
8. Proper notification and documentation of accidents in a log book		

Part A. Section 5. Documentation and monitoring (P 1/1)

A. Temperature logs	**1=Yes 0=No**	**Remarks**
1. Log book for temperature is used *(an example can be found in Appendix I of The Guideline)*		
2. The minimum and maximum temperature since last measurement of the storage area of test kits and/or control kits are recorded each working day.		
3. The minimum and maximum room temperature since last measurement of the testing area are recorded each working day.		
B. External control result logs	**1=Yes 0=No**	**Remarks**
1. Log book for QC is used *(an example can be found in Appendix II of The Guideline) (go to Part A, Section 6, "Quality Control of test kits carried out by the organization")*		
C. Test results logs	**1=Yes 0=No**	**Remarks**
1. For every VCT conducted, test kit, lot number, test result, personnel performing the test and any confirmatory test done are recorded.		
D. Overall	**1=Yes 0=No**	**Remarks**
1. Keep all the above records (A,B,C) in proper places and review periodically		
2. All personnel involved know well the locations of these records		

Part A. Section 6. Quality control of test kits (P 1/2)

A. Management of QC	1=Yes 0=No	Remarks
1. A designated person(s) is responsible for QC of test kits (e.g. checking and recording of temperature, expiry date, invalid and contradictory results etc.)		
2. QC test kits provided by the manufacturers are used (if applicable)		
3. Specimens of known HIV-infected persons are used as positive control (if applicable)		
4. Regularly remind VCT–providing personnel about the timing and procedure of QC		
B. Timing for conducting QC	**1=Yes 0=No**	**Remarks**
1. When opening a new test kit lot or a new shipment of test kits is received		
2. If the temperature of the test kit storage area has ever fell outside 2-27^{o}C (or outside temperature range specified by the manufacturer)		
3. If the temperature of the testing area has ever fell outside 15-27^{o}C (or outside temperature range specified by the manufacturer)		

Part A. Section 6. Quality Control of test kits (P 2/2)

C. Documentation of QC results	1=Yes 0=No	Remarks
1. Date and time of control testing		
2. Lot number and expiration date of test kit		
3. Lot number and expiration date of control kit		
4. Control results		
5. Corrective action taken if control results are unacceptable		

D. Regular statistics for key QC indicators	1=Yes 0=No	Remarks
1. Record invalid results (control line not appear) for diagnostic and QC tests – frequency, brand, lot number		
2. Record contradictory results (different from confirmatory test) for diagnostic and QC tests – frequency, brand, lot number		
3. Record number of negative rapid test results per month		
4. Record number of positive rapid test results per month		
5. Record number of positive confirmatory test results per month (if applicable)		

Checklist for Quality Assurance on HIV Voluntary Counseling and Testing Services (VCT) in Community Settings

(Part B – Individual level)

Instructions:

1. This part consists of 4 Sections :
    - Section 1 – HIV Counseling and testing skills
    - Section 2 – Infection Control skills and knowledge
    - Section 3 – Documentation of consultation process and test results
    - Section 4 – Knowledge on Quality Control

2. This assessment on individual personnel is expected to be conducted under a real VCT service situation (practical (P) assessment). Should the assessment scenario could not cover some of the items listed, assessors are encouraged to assess the individual's relevant knowledge or ability by either oral test (O) or role play (RP).

3. Each of the VCT-providing personnel is encouraged to be assessed at least once a year. If certain items have not been evaluated or could not be assessed during the current assessment, please note down and evaluate these items again in the next assessment.

Part B. Assessment on competency of individual personnel

Date of assessment: _____ **Venue of assessment:_____**

Name of personnel being assessed:_____ **Name of assessor: _____**

Part B. Section 1. HIV Counseling and Testing skills (P 1/4)

A. Pre-test counseling	**1=achieved 0= not achieved**	**Format of assessment (Practical (P)/Oral (O)/Role play (RP)**
1. Welcome the client in a private setting		
2. Check client's particulars and previous attendance		
3. Explain about the test procedures and reassure about confidentiality		
4. Discuss potential implications of a positive and negative test results		
5. Explore client's risk behavior and conduct HIV risk assessment when necessary		
6. Provide clients advice and health education to address their concerns		
7. Obtain client's consent		
Remarks		

Part B. Section 1. HIV Counseling and Testing skills (P 2/4)

B. Procedure of carrying out HIV testing	**1=achieved 0= not achieved**	**Format of assessment (Practical (P)/Oral (O)/Role play (RP)**
1. Record test kit lots		
2. Perform the test according to the instruction given by the manufacturers		
3. Follow biohazard safety precautions during whole process; clean up and dispose of bio-hazardous waste properly ➔ *go to "Section 2– Infection Control"*		
4. Explain the results to client		
5. Collect, process and transport confirmatory test specimens if applicable		
6. Documentation of the procedure and results ➔ *go to "Section 3 – Documentation of consultation process and test results"*		
Remarks		

Part B. Section 1. HIV Counseling and Testing skills (P 3/4)

C. Post-test counseling	1=achieved, 0= not achieved		
Scenarios of different test results	**Negative**	**Positive**	**Invalid**
Format of assessment : (Practical (P)/ Oral (O / Role play (RP))			
1. Explain "window period"		N/A	
2. Plan of risk reduction / prevent further transmission			
3. Remind regular HIV test		N/A	
4. Need for further confirmatory test / FU test			
5. Assess clients' emotion			
6. Remind to call for advice if necessary			
7. Referral if necessary (DH / HA)			
8. Explain treatment + chronic nature			
9. Advise partner referral	N/A		N/A
10. Documentation of important discussion items ➔ *go to "Section 3 – Documentation of consultation process and test results"*			
Remarks:			

Part B. Section 1. HIV Counseling and Testing skills (P 4/4)

D. Crisis Counseling	1=achieved 0= not achieved	Format of assessment (Practical (P)/Oral (O)/Role play (RP)
1. Encourage expression of feelings		
2. Explore the precipitation factors		
3. Review client's strengths to cope with the current crisis		
4. Summarize client's current situation and ensure client understand		
5. Select the most important issue to work on initially		
6. Provide help lines or other sources of support		
Remarks		

Part B. Section 2. Infection Control (P 1⁄3)

A. Infectious precautions	1=achieved 0= not achieved	Format of assessment (Practical (P)/Oral (O)/Role play (RP)
1. Hand Hygiene		
a. before and after procedural contact with client;		
b. immediately if contaminated with blood, body fluids and after glove removal		
c. use soap and water when visibly soiled or feel that it is dirty		
d. use alcohol-based handrub if not visibly soiled		
e. demonstrate the hand hygiene technique (include 7 steps)		
2. Personal protective equipment (PPE)		
a. when there is direct contact or possibility of contact with blood, body fluids, mucous membranes and wounds of clients;		
b. change gloves between care of different clients		
c. change gloves when they are torn, visibly contaminated with blood and in case of needle-stick injury.		
d. wear surgical mask when staff or clients have fever or respiratory symptoms.		
e. used PPE are discarded properly after use		
Remarks		

Part B. Section 2. Infection Control (P 2/3)

A. Infectious precautions	1=achieved 0= not achieved	Format of assessment (Practical (P)/Oral (O)/Role play (RP)
3. Sharps management		
a. Place used needles and sharps in a puncture resistant box instead of recap, b. The puncture resistant box should be 3/4 full and then sealed up before discard.		
4. Medical wastes disposal		
a. Discard disposable equipment and accessories appropriately		
5. Environmental Hygiene		
a. For <u>blood</u>, the staff knows how to cleanse the visible matter with disposable absorbent material soaked with 1% (add one part of household bleach into 4 parts of water) hypochlorite solution. Rinse with water after leaving it for 10 minutes.		
b. For <u>body fluid</u>, the staff knows how to cleanse the visible matter with disposable absorbent material soaked with 0.1% (add one part of household bleach into 49 parts of water) hypochlorite solution. Rinse with water after leaving it for 30 minutes.		
c. The staff demonstrates how to clean environmental surface with common housekeeping procedures (e.g. 1:99 hypochlorite solution).		
<u>Remarks:</u>		

Part B. Section 2. Infection Control (P 3/3)

B. Accidents and Dangerous Occurrences	1=achieved 0= not achieved	Format of assessment (Practical (P)/Oral (O)/Role play (RP)
a. The staff knows who to notify supervisors of accidents and dangerous occurrences especially needle-sticks injuries.		
b. The staff knows the need to record all notified accidents in a log book specifically kept for this purpose.		

C. Post-Exposure Management	1=achieved 0= not achieved	Format of assessment (Practical (P)/Oral (O)/Role play (RP)
a. The staff demonstrates thorough wound washing with soap and water before disinfected and dressed		
b. For mucosal contact (e.g. spillage into the eyes), the staff knows that the exposed part should be washed immediately and liberally with running water.		
c. The staff knows the need to seek medical advice for risk assessment and proper post-exposure management after exposed to mucosal contact.		
Remarks:		

Part B. Section 3. Documentation of consultation process and test result (P 1/1)

Please note: For this section, assessors are also encouraged to review the past consultation notes written by individual staff for assessing their long term performance on documentation.

Proper documentation of the followings during VCT	**1=achieved 0= not achieved**	**Format of assessment (Practical (P)/Oral (O)/Role play (RP)**
1. Date and time of testing		
2. Test kit lot number and expiration date		
3. Identifier for the person being tested		
4. Identifier of the staff who performed the test		
5. Test results (a) rapid test		
(b) confirmatory test (if any)		
6. Important issues discussed (e.g. Follow up actions, advice, suicidal ideation, referral, etc) Note 1		
7. Action taken if the result was invalid		
8. Whether confirmatory testing was requested		
9. Type of specimen sent for confirmation		
10. Confirmatory test results when available		
11. Place referred for positive test results (Rapid test / conventional test)		
Remarks:		

Note 1: Documentation of important discussion issues unrelated to traceability is not required by The Guideline. However, service providers are encouraged to record these issues as listed in this checklist as an example of good practice.

Part B. Section 4. Quality Control (P 1/1)

Staff showed knowledge on the followings:	1=achieved 0= not achieved	Format of assessment (Practical (P)/Oral (O)/Role play (RP)
1. Time to conduct QC:		
a. When opening a new test kit lot		
b. Whenever a new shipment of test kits is received		
c. If the temperature of the test kit storage area falls outside 2-27 degree Celsius (or outside temperature range specified by the manufacturer)		
d. If the temperature of the testing area falls outside 15-27 degree Celsius (or outside temperature range specified by the manufacturer)		
e. At monthly intervals		
2. Managing significant QC problems:		
a. Report significant problems, especially those concerning the accuracy of rapid HIV test in use, to the appropriate supervisory personnel immediately		
b. Notify manufacturer where necessary		
3. Documentation of QC results:		
a. Know where to find the log book for logging QC		
Remarks:		