

# Standard No.CEA/ICTC- 012

# **Clinical Establishment Act Standard for Integrated Counseling and Testing Centre**

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## Introduction

In 2010 Clinical Establishments (Registration and Regulation) Act, 2010 has been enacted by the Central Government to provide for registration and regulation of all clinical establishments in the country with a view to prescribe the minimum standards of facilities and services provided by them.

The Ministry has notified the “National Council for Clinical Establishments” and ‘The Clinical Establishments (Central Government) Rules, 2012” under this Act vide Gazette. *This Act is applicable to all kinds of clinical establishments from the public and private sectors, of all recognized systems of medicine including single doctor clinics. The only exception will be establishments run by the Armed forces.*

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## Integrated Counseling and Testing Centre

### 1. Definition:

- 1.1 An integrated counselling and testing centre is a place where a person is counselled and tested and checked for HIV, Tuberculosis, ANC and postnatal follow up on his own free will or as advised by a medical provider.
- 1.2 An ICTC shall be located in health facilities owned by the government, in the private/not for-profit sector, in public sector organizations/other government departments such as the Railways, Employees' State Insurance Department (ESID), etc. and in sectors where nongovernmental organizations (NGOs) have a presence.
- 1.3 In the health facility, the ICTC shall be well coordinated with the Department of Medicine, Microbiology, Obstetrics and Gynecology, Pediatrics, Psychiatry, Dermatology, Preventive and Social Medicine, etc.

### 2. Scope

- 2.1 Provision of basic information on modes of transmission and prevention of HIV/AIDS, ANC for promoting behavioral change and reducing vulnerability.
- 2.2 Preventive health education.
- 2.3 Psychosocial support.
- 2.4 Referral and linkages.
- 2.5 Monitoring and supervision.
- 2.6 Training of existing staff.
- 2.7 ICTCs can be classified into two types:
  - a) Fixed-facility ICTCs
  - b) Mobile ICTCs
- 2.8 **Fixed-facility ICTCs:**
  - 2.8.1 Fixed-facility ICTCs are those that are located within an existing health-care facility/ hospital/centre.

2.8.2 A fixed-facility ICTC can be of two types:

- a) “Stand-alone”: ICTC having a full-time counsellor and laboratory technician who undertake HIV counselling and testing. Such facilities exist in medical colleges and district hospitals, and in some sub district hospitals.
- b) “Facility-integrated”: ICTC which does not have full-time staff and provides HIV counselling and testing as a service along with other services. Existing staff such as the auxiliary nurse midwife (ANM)/staff nurse/health visitor/laboratory technician (LT)/pharmacist are expected to undertake HIV counselling and testing. Such ICTCs will usually be established in facilities that do not have a very large client load and where it would be uneconomical to establish a stand-alone ICTC.
- c) Such facilities are 24-hour PHCs as well as private sector/not-for-profit hospitals, private laboratories, public sector organization-run hospitals or facilities, and in the NGO sector.

## **2.9 Mobile ICTCs**

2.9.1 Mobile ICTCs is the one which take healthservices into the community.

2.9.2 A mobile ICTC is a temporary clinic with flexible working hours in hard-to-reach areas, where services are provided ranging from regular health check-up, syndromic treatment for STI/reproductive tract infection (RTI) and other minor ailments, antenatal care, immunization, as well as HIV counselling and testing services.

2.9.3 Mobile ICTCs can thus cater to a larger audience and be a more effective preventive intervention by ensuring the reach of services.

## **3. Infrastructure Requirements**

### **3.1. Signage**

3.1 The ICTC centre shall have all appropriate signage in at least local languages.

3.2 The building shall have sign board displaying Integrated Counselling and Testing Centre at prominent location.

3.3 NACO logo shall be used for illiterate clients to locate the ICTC.

**3.3.1 Following informative signage shall be displayed:**

- a. Registration details of the ICTC as applicable
- b. Timings of the facility and services

**3.3.2 Following safety signage shall be displayed:**

- a) Appropriate fire exit signage.
- b) Signage for no smoking in prominent places.

**3.4 Facility Premises**

- 3.4.1 In a facility, the ICTC shall be located in a place that is easily accessible and visible to the public.
- 3.4.2 The ICTC shall consist of a counselling room and a blood collection and testing room.
- 3.4.3 The counselling room shall be an enclosed space, ideally 10' X 10' in area so that one-on-one and one-on-group counselling sessions may be undertaken in an atmosphere of privacy.
- 3.4.4 The blood collection room shall have an area of at least 10' x 10'. Blood testing could be done either in the blood collection room or in the main laboratory of the facility.
- 3.4.5 The facility shall be developed and maintained to provide safe, clean and hygienic environment for clients, their families, staff and visitors.
- 3.4.6 The facility shall be well illuminated and ventilated.
- 3.4.7 The facility shall have provision of water and electricity through regular or alternate sources.
- 3.4.8 The facility shall provide appropriate privacy during provision of services.
- 3.4.9 The facility shall have provision for hand washing arrangements.
- 3.4.10 The facility shall have appropriate communication facilities like telephone, internet etc.

3.4.11 A mobile ICTC shall consist of a van with a room to conduct a general examination and counseling, and a space for the collection and processing of blood samples, etc.

3.4.12 Mobile ICTC shall have a team of paramedical health-care providers (a health educator/ANM, counselor and Lab Technician).

Refer Annexure 1 for norms for setting up an ICTC.

### **3.5 Furniture and Fixtures**

3.5.1 Furniture and fixtures shall be available in accordance with the activities and workload of the ICTC,

3.5.2 The furniture and fixtures shall be functional. For indicative list of items refer to Annexure 2 (This list is indicative and not exhaustive).

## **4. Human Resource Requirement**

4.1 The ICTC shall have qualified and/or trained staff as per the scope of services provided.

4.2 Personnel record containing personal and professional information shall be maintained for each staff.

4.3 Periodic skill enhancement/up gradation /refresher trainings shall be provided for all categories of the staff relevant to their job profile.

4.4 All health care staff shall be made aware of the hospital Post Exposure Prophylaxis (PEP) procedures and the name and contact information of the PEP focal point/person as well as the location where the PEP drugs are stored. For Human Resource requirement refer to Annexure 3.

## **5. Equipment/Instruments/Consumables**

5.1 The centre shall ensure that the minimum space, as well as equipment and communication material required for an ICTC is provided.

5.2 The centre shall ensure that blood testing is done either in the blood collection room or in the main laboratory of the facility.

5.3 The centre shall ensure that adequate equipment is available to meet the work load requirement.



- 5.4 All equipment shall be in good working condition at all times.
- 5.5 The centre have provision of periodic inspection, cleaning and maintenance of the equipment. An equipment log book shall be maintained for all major equipment. For indicative list of equipment/instrument refer to Annexure 4 (this list is indicative and not exhaustive).
- 5.6 **The ICTC shall ensure availability of:**
- a) Information, education and communication (IEC) material required for an ICTC such as flip charts, posters, etc.
  - b) Rapid HIV testing kits.
  - c) Protective kits and prophylactic drugs for post-exposure prophylaxis (PEP) for staff.

## **6. Support Service**

### **6.1. Waste Management**

- 6.1.1 Segregation, collection, transportation, storage and disposal of biomedical waste shall be as per Bio medical waste handling rules, 1998.

## **7. Legal/Statutory Requirements**

- 7.1 Every application shall be accompanied with the documents confirming compliance with local regulations and law.

## **8. Record Maintenance and Reporting**

- 8.1 Records shall be maintained in physical or digital format.
- 8.2 Confidentiality, security and integrity of records shall be maintained.
- 8.3 Record shall contain at least Registration number, client details like name, address, district, phone number and brief history, etc.
- 8.4 The minimum medical records to be maintained and nature of information to be provided by the Clinical Establishments shall be as prescribed in CEA rules of the Act.
- 8.5 The centre shall maintain health information and statistics in respect of national programmes, notifiable diseases and emergencies/disasters/

epidemics and furnish the same to the district authorities in the prescribed formats and frequency.

- 8.6 The centre shall have various registers maintained as per Annexure 5 (This list is indicative not exhaustive).

## **9. Others**

### **9.1 Registration**

9.1.1 Every client/patient visiting the facility shall be registered at the registration counter.

9.1.2 All the relevant records pertaining to the programme shall be maintained.

### **9.2 Consent and Assessment**

9.2.1 **Informed Consent:** Informed consent shall be obtained from the client / patient/ next of kin/ legal guardian as and when required as per the prevailing guidelines / rules and regulations in the language patient can understand (e.g. HIV testing).

9.2.2 Each client/patient shall undergo an assessment and the same shall be documented legibly in relevant record.

9.2.3 ICTC shall ensure that each client/patient is provided pre-test information/counselling, post-test counseling and follow-up counselling in a friendly atmosphere.

9.2.4 In ICTCs which do not have a doctor such as mobile ICTCs and ICTCs located in hot spots, the counsellor is authorized to sign the counselling and testing reports after duly verifying the records. The ICTC manager shall cross-check at regular intervals the reports signed by the counsellor.

9.2.5 Records of all such assessments shall be maintained as per applicable laws.

### **9.3 Infection Control**

9.3.1 Adherence to standard precautions shall be maintained by all staff.

9.3.2 Running tap water for hand washing of staff shall be available.

9.3.3 Sanitation of the toilets and hygiene of the staff shall be maintained.

- 9.3.4 Mopping of all areas with clean mops and disinfectant shall be done at least once a day.
- 9.3.5 Adequate amount of bleaching solution shall be available for disinfection purpose and mopping of all areas with disinfectant shall be done at least once a day.
- 9.3.6 Facility for syringe and needle destruction shall be available and practiced.
- 9.3.7 Drugs for PEP shall be made available to any staff member who is accidentally exposed to HIV in all facilities which have an ICTC as early as 2 hours and within 24 hours of the accidental exposure and not later than 72 hours.
- 9.3.8 The facility shall have an assigned PEP focal point/person.

## **10. References**

- 10.1 Operational Guidelines for Integrated Counseling and Testing Centres, July 2007, National Aids Control Organization, Ministry of Health and Family welfare, Government of India and its amendments if any.

## Annexure 1

### Norms for Setting up an ICTC

#### 1. Government health sector

An ICTC can be set up in any government health facility such as a medical college, district hospital, subdistrict hospital, community health centre (CHC) or a 24-hour primary health centre (PHC) which caters to a population of 30,000–40,000 and has:

- a) a minimum of 30 beds,
- b) >50 deliveries in a month, or
- c) a TB microscopy centre.

#### 2. Private/not-for-profit sector

ICTCs can be set up in the private/not-for-profit sector in a facility which meets any of the criteria given below:

- a) Maternity homes/hospitals with >50 deliveries in a month in “A” and “B” category
- b) Districts and >100 deliveries in a month in “C” and “D” category districts;
- c) Hospitals/clinics which treat >100 TB patients in a month;
- d) Hospitals/clinics which have a case load of >100 sexually transmitted infections (STIs) in a month;
- e) Diagnostic laboratories which perform >150 diagnostic HIV tests in a month;
- f) Industrial zones that employ a large number of people, particularly migrants/casual
- g) Labour on an informal/contractual basis.

#### 3. Public sector/other government departments

ICTCs can be set up by public sector organizations/other government departments. Some suggested locations are:

- a) Railway stations and bus terminals located at major junctions on trunk routes and
- b) handle a large volume of passengers every day;
- c) Central prisons with a large number of inmates;
- d) Health facilities run by State/Central Police Organizations/Armed Forces;
- e) Health facilities run by public sector organizations catering to large volumes of  
a. migrant workers;
- f) Health facilities run by public sector organizations which handle >100 deliveries in a month or have a TB microscopy centre;
- g) Public sector organizations such as those in the mining industry which employ large number of persons, particularly migrants/casual labour;
- h) University campuses.

#### **4. NGO sector**

##### **4.1 ICTCs can be set up in the NGO sector in**

- a) Hot spots such as dhabas, halting points on highways, markets, fairs, etc. where there is a congregation of high-risk groups and their clients;
- b) TB microscopy centres/Reproductive and Child Health (RCH) centres run by NGOs.

An ICTC may be located in health facilities owned by the government, in the private/not for-profit sector, in public sector organizations/other government departments such as the Railways, Employees' State Insurance Department (ESID), etc. and in sectors where nongovernmental organizations (NGOs) have a presence. In the health facility, the ICTC should be well coordinated with the Department of Medicine, Microbiology, Obstetrics and Gynaecology, Paediatrics, Psychiatry, Dermatology, Preventive and Social Medicine, etc. As the HIV test is a relatively low-cost test and since the risk perception is generally low, travelling a long distance to get tested could be a strong disincentive. Therefore, it is important to ensure that facilities for counselling and testing be located as close to the people as possible. ICTCs should ideally be located such that they provide maximum access to at-risk/vulnerable populations.

**Annexure 2**

**Furniture and Fixtures**

**The minimum requirement of furniture for a counselling room in an ICTC are:**

- a) Desk for the counselor.
- b) 10–15 chairs for one-on-one and group counselling sessions as well as for the waiting area.
- c) Lockable filing cabinet for keeping records.
- d) Computer with printer and UPS.
- e) Computer table, preferably with a chair.
- f) Waste basket.
- g) TV and DVD player in a lockable stand for provision of information on HIV/AIDS, non-communicable disease, etc. to clients.
- h) Posters and information materials on the walls.
- i) Communication aids such as flip charts.
- j) Condom use demonstration models.
- k) Leaflets/pamphlets as take-home material for clients.

**Annexure 3**

**Human Resource Requirements**

- 1.1 Manager (Medical officer)-1:** The administrative head of the facility where the ICTC is located must identify and nominate a medical officer as manager in-charge of the ICTC.
- 1.2 Counsellor-1:** The counsellor should be a graduate in Psychology/Social Work/Sociology/Anthropology/ Human Development or hold a diploma in Nursing with a minimum of 3–5 years of experience in the field of HIV/AIDS. In the case of those recruited from the community of people infected with or affected by HIV/AIDS, graduates from any field or those with a diploma in Nursing may be considered if they have a minimum of one year of experience in the field of HIV/AIDS.
- 1.3 Lab Technican-1:** Should hold a Diploma in Medical Laboratory Technology (DMLT) from an institution which is approved by the state government. The services of existing LTs who do not hold a DMLT may be continued if they have done a Certificate Course in Medical Laboratory Technology and have more than 5 years' experience of working in the ICTC.
- 1.4 An outreach worker would be necessary in high-prevalence districts:** Outreach workers should be educated at least till the eighth standard with reasonable writing and speaking skills, and should be from the community of people who are infected with or affected by HIV/AIDS. A person affected with HIV/AIDS may be the spouse or the son/daughter of a person infected with HIV/AIDS. It is desirable that outreach workers should have passed the tenth standard and are women. Outreach workers are recommended only in ICTCs which are located in high-prevalence settings such as in A and B category districts.

**Annexure 4**

**Equipments / Instruments / Consumables**

- 1. The equipment required for testing in an ICTC are:**
  - a) Refrigerator
  - b) Centrifuge
  - c) Needle destroyer
  - d) Micropipette
  - e) Colour-coded waste disposal bins.
  
- 2. The consumables required for collection and testing of blood in an ICTC are:**
  - a) Sterile needles and syringes
  - b) Disposable gloves
  - c) Vials and tubes for collection and storage of blood
  - d) Cotton swabs
  - e) Cleaning material such as spirit/antiseptic lotion
  - f) Bleach/hypochlorite solution
  - g) Microtips for use in micropipettes.
  - h) Prophylactic nevirapine tablets and syrup (for HIV-positive pregnant women and their infants).
  - i) Contraceptives.



**Annexure 5**

**Records / Registers to be maintained:**

- a) PID Register for General Clients and Pregnant Women
- b) ICTC Register for General Clients (Non-ANC Cases)
- c) ICTC Register for ANC Clients
- d) ICTC Post-natal Follow-up Register
- e) ICTC HIV–TB Collaborative Activities Register
- f) Laboratory register
- g) Stock Register
- h) Monthly reports
- i) Monthly ICTC report on the number of clients counselled, tested, HIV status, NVP administration, and gender and age-wise distribution
- j) Monthly HIV–TB report on HIV–TB collaborative activities
- k) Details of referrals to and from various facilities
- l) Stock of drugs, equipment and consumables

**Glossary**

<b>Voluntary</b>	Seeking knowledge of the HIV status is voluntary. The decision to pursue testing for HIV must be made by the client who seeks counselling and testing services.
<b>Client</b>	A person seeking health-care services, including in an ICTC, is a client and not a patient. Patients are considered passive recipients of treatment/care/hospitalization, whereas clients are “consumers” who make a choice whether or not to avail of a certain service.
<b>“Self-referred clients”</b>	“Self-referred clients” or direct walk-in clients are clients who present themselves at the ICTC of their own volition and free will. The motivation to visit and avail of ICTC services could be based on individual risk behaviour or information and advice received, for example, from a newspaper advertisement, a friend, sexual partner or NGO.
<b>“Provider-referred clients”</b>	“Provider-referred clients” are clients who are referred by health-care providers to the ICTC for HIV counselling and testing based on clinical symptoms suggestive of an HIV infection. An HIV test as part of the medical investigation can be beneficial for their ongoing medical care and treatment. The decision to undergo an HIV test is voluntary but should be encouraged in view of the clinical benefits. Not undergoing an HIV test should not lead to withholding required medical investigations or operations.
<b>Confidential</b>	Information gathered during counselling must not be shared with others. The HIV test result must be reported only to the client unless the client states the desire to share the test result with a family member, partner or close friend. Confidentiality is defined as the state of being “private”. Maintaining the client's privacy by restricting access to personal and confidential information, especially HIV test results, demonstrates sensitivity towards and respect for the basic rights of the client.
<b>Informed consent for HIV testing</b>	The client agrees to HIV testing through giving his/her informed consent. Informed consent is a deliberate and autonomous permission given by a client to a health-care provider to proceed with the proposed HIV test procedure. This permission is based on an adequate understanding of the advantages, risks, potential consequences and implications of an HIV test result,

	<p>which could be both positive and negative. This permission is entirely the choice of the client and can never be implied or presumed.</p>
<b>Informed consent for HIV testing of minors</b>	<p>The law gives paramount importance to the best interests of the child. In the context of HIV/AIDS, the best interests of the child are served by promoting access to information and services including counselling and testing services. Whenever possible, minors are encouraged to involve their parents/guardians in supervising their health care. However, unwillingness to inform parents/guardians should not interfere with the minor's access to information and services. Access to ICTC services should be available to children and young people under the age of 18 years based on an assessment of their evolving capacities and their ability to comprehend the nature and implications of HIV/AIDS and an HIV test result. It is the role of the trained counsellor to assess these abilities.</p> <p>However, the informed consent of parents/guardians is required prior to testing minors for HIV.</p>