Tuberculosis Screening and IPT: Experience from India

Dr B.B.Rewari
WHO National consultant
Care , Support and Treatment
National Programme Officer (ART)
National AIDS Control Organization
New Delhi-110001,

The 17th Core Group Meeting of the TB/HIV Working Group
9-10 November 2011 , Beijing, People's Republic of CHINA

NACO

TB HIV

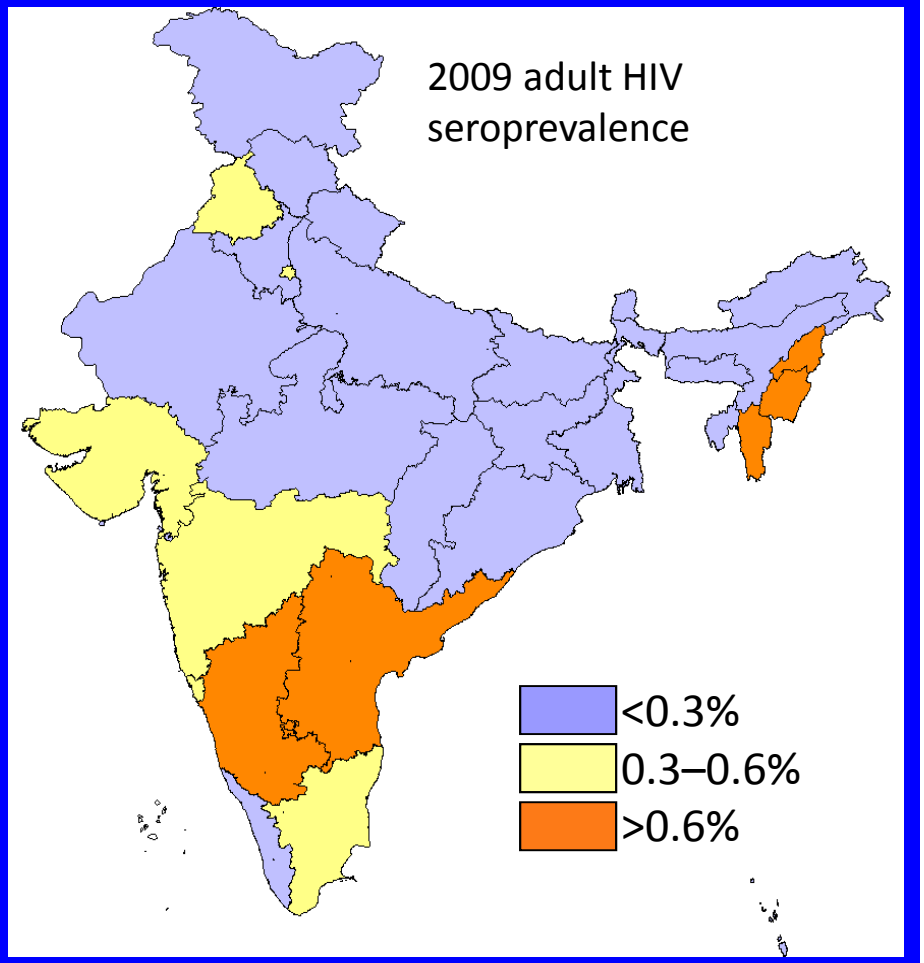
DOTS
Pura course Pakka ilaaj

This talk will cover

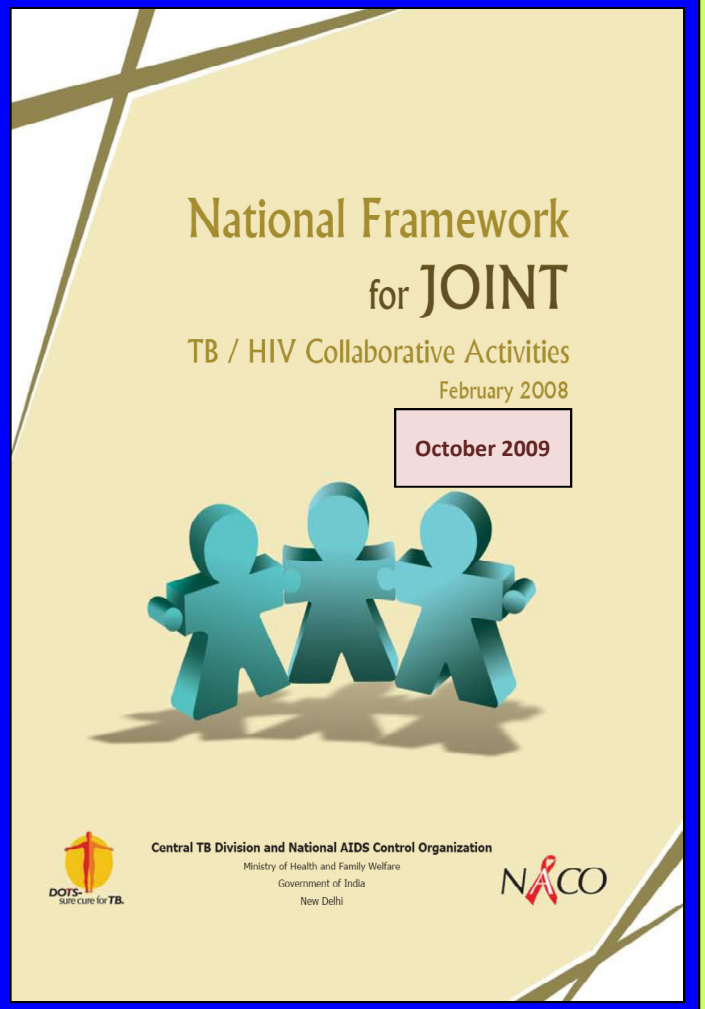
- TB/HIV scenario in India
- Status of implementation of TB/HIV collaborative activities in India
- Experience of expansion of Intensified TB case Finding (ICF) activities at HIV diagnosis and Treatment centres in India
- Issues in adoption of Isoniazid Preventive Therapy (IPT)

Burden of HIV and TB in India

- HIV: Concentrated
  - 0.3% adult prevalence
  - 2.4 million persons
  - 3rd Highest in numbers
  - Heterogeneous distrib**ution**
  - NACP (National AIDS Control Programme)
- TB: Everywhere
  - About 2.3 m incident TB cases/yr
  - Highest burden (26%), though 18th in incidence
  - 5% (110,000) HIV-infected with high mortality
  - RNTCP (Revised National TB Control Programme)



National TB/HIV Policy



1. 2001– First TB/HIV "*Joint Action Plan*" /Policy document developed
2. **National (policy) framework developed in 2007.(** Revised in 2008 and October 2009)
4. **Framework** includes policy guidelines for
   - Establish the mechanisms for coordination
   - Decrease the burden of TB among PLHIV
   - Decrease the impact of HIV in TB patients

National TB/HIV Policy Framework

- **Objectives:**

- To strengthen the mechanisms for coordination between RNTCP and NACP at National, State and District levels.
- To decrease morbidity and mortality due to tuberculosis among persons living with HIV/AIDS.
- To decrease the impact of HIV in tuberculosis patients and provide access to HIV related care and support to HIV- infected TB patients

TB/HIV activities under National TB/HIV policy frame work

- To decrease burden of HIV in TB patients

  Intensified TB/HIV Package

  - » Routine offer of HIV testing to TB patients
  - » Decentralized provision of CPT and
  - » Linkage to ART services

- To decrease burden of TB in PLHIV

  Intensified TB Case Finding at

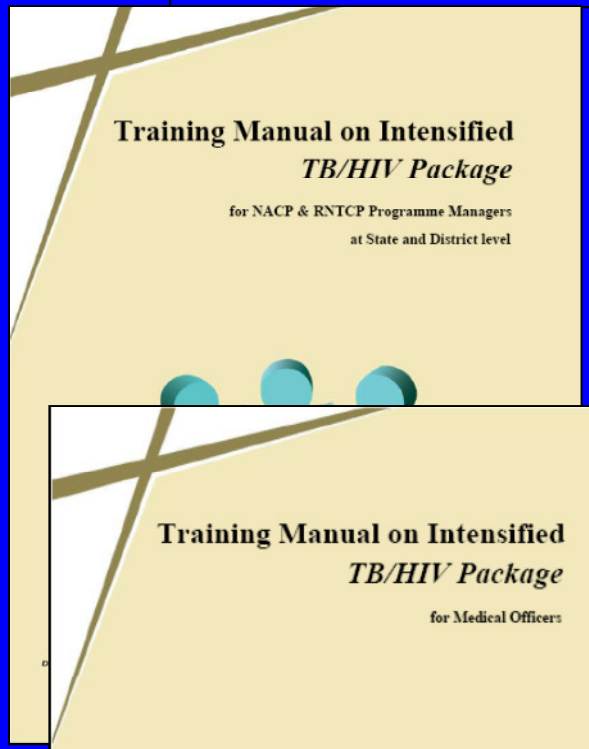
  ICTC and ART Centres

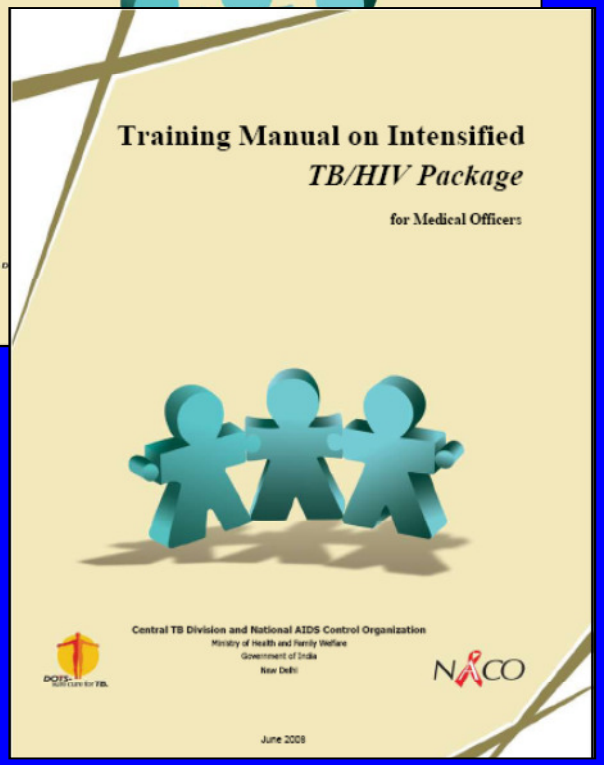
- To prevent TB among PLHIV

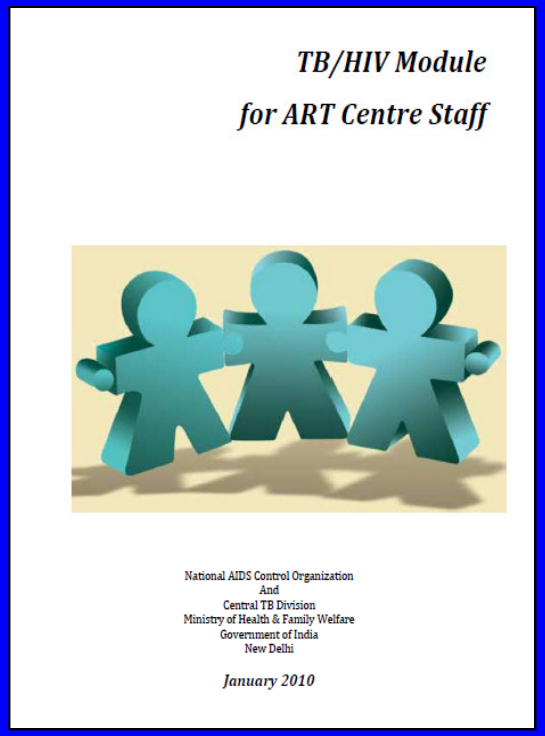
  IPT –operational study initiated

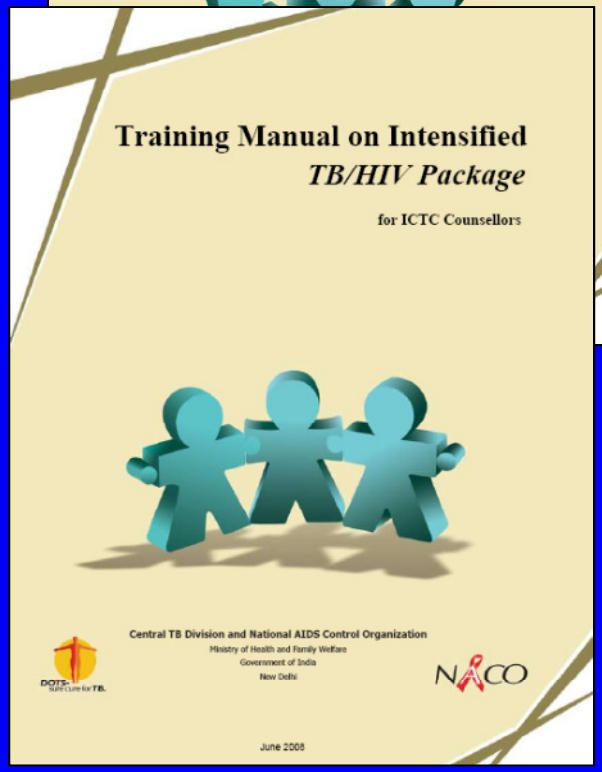
  TB infection control in HIV care settings

Standard TB/HIV Training Modules









Prepared Jointly by
NACP and RNTCP

Available at www.nacoonline.org

Implementation-Commitment at highest Level

T-11020/143/08-NACO/BSD (HIV-TB)
Government of India
Ministry of Health and Family Welfare
Department of AIDS Control
(National AIDS Control Organization)

6th Floor, Chanderlok Building
36, Janpath, New Delhi-110001
Date: 8th June,2010

To

The Project Director
State AIDS Control Societies
Uttar Pradesh, Madhya Pradesh, Chhattisgarh, Haryana, Jharkhand, Uttarakhand, Himachal Pradesh, Arunachal Pradesh, Meghalaya, Sikkim and Tripura.

Sub: Rolling out the Intensified Package of HIV-TB collaborative activities in your state

An Intensified Package of HIV-TB collaborative activity is being rolled out in a phased manner since 2008. By the end of 2009-10, 18 states have started implementing it and have shown a significant increase in detection of HIV infected TB patients. Considering this, it has been decided by the National Technical Working Group (NTWG) for HIV-TB to roll it out in your state in the FY 2010-11. The services made available under this package are:

- Routine referral of all TB patients for HIV counselling and testing
- Provision of CPT for all HIV/TB infected TB patients through the decentralized drug delivery system of RNTCP
- Linkage to care and support services, including ART
- Revised recording and reporting of TB/HIV activities

To facilitate the roll out the key action points for the SACS are:

A. Organize training of Master Trainers' for your state by the national experts. The proposed training will be of 2 days duration based on the modules jointly prepared by the CTD and NACO.
B. These master trainers would then conduct training in each of the district for all the key staff involved in TB/HIV collaborative activities. The funds for district level training will be provided by SACS.
C. Activities to be done at SACS:
   - Procurement of Cotrimoxazole for all HIV infected TB patients. This drug is included in the approved list of drugs requir… purchased out of funds availa…
   - Printing of forms, registers an…

Kindly issue necessary directions to all c… for these activities at the earliest.

Yours faithfully,

(Dr. Damodar Bachani)
Deputy Director General

Copy for information:
1. PPS to Secretary (DAC) and DG, NACO
2. Deputy Director General, Central TB Division, Nirman Bhawan

No. Z - 28015/13/2005 -TB
(Central TB Division)
Directorate General of Health Services

Nirman Bhawan, New Delhi - 110108
Dated: 9th June 2010

To

The State TB Officer
(Utter Pradesh, Madhya Pradesh, Chhattisgarh, Haryana, Jharkhand, Uttarakhand, Himachal Pradesh, Arunachal Pradesh, Meghalaya, Sikkim and Tripura)

Subject: **Rolling Out Intensified Package of TB-HIV Collaborative Activities.**

Intensified Package of HIV –TB collaborative activities have been rolled out in 18 states (6 high prevalence states and Goa, Mizoram, Pondicherry in 2008, Delhi, Gujarat, Assam, Kerala, Punjab, Rajasthan, West Bengal, Orissa and Chandigarh in 2009). In order to detect all HIV+ve TB patients and provide them TB treatment under RNTCP and necessary HIV care and support under NACP, it has been decided at the National level to roll out the Intensified Package of TB-HIV collaborative activities across the country in a phased manner and cover the entire country by 2012.

In this regards, DDG (NACO) has written a letter (copy enclosed, which is self explanatory) to the Project Director State AIDS Control Society of your state with detailed enumeration of activities to be undertaken by the state for rolling out the Intensified TB/HIV Package in the state.

…essary steps in implementing

Yours Sincerely

(Dr. L.S. Chauhan)
DDG (TB)

Letters issued by both National programmes for smooth implementation

Co-ordination Mechanisms

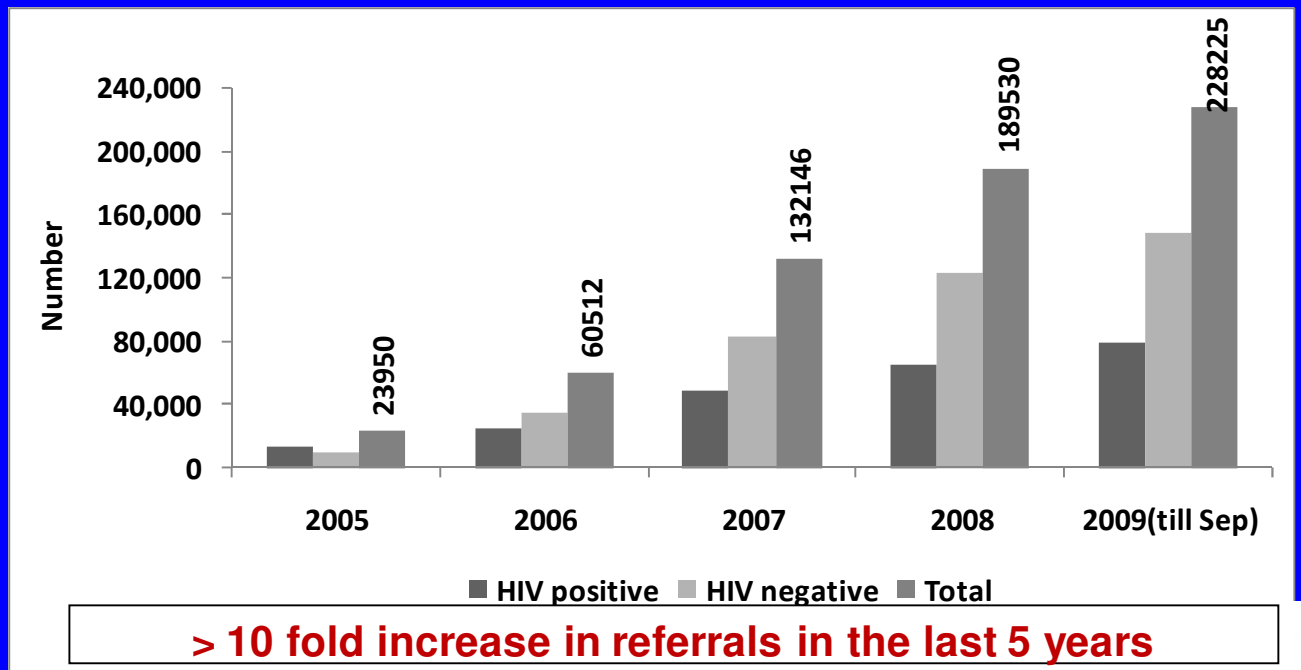
Level	Chair	Mechanism	Frequency of meeting	Mandate
National	DDG TB / DDG BSD NACO	National technical working Group **(NTWG)**	Quarterly Meeting	Policy decisions, review
	DG NACO/JS RNTCP	Annual Review of TB/HIV Collaborative activities at National and State level		
State	Principal Secretary Health	State Coordination Committee **(SCC)**	Bi-annual	Policy decisions at state level
	PD-SACS / STO	State technical working Group **(SWG)**	Quarterly	Review
District	District collector/DM	District Coordination Committee **(DCC)**	Quarterly	Review
	DTO-DAPCU / HIV Nodal officer	HIV-TB coordination meeting	Monthly	Review

Process-Intensified TB Case Finding at HIV care settings –Joint Reporting

TB suspects referred from ICTC to RNTCP:

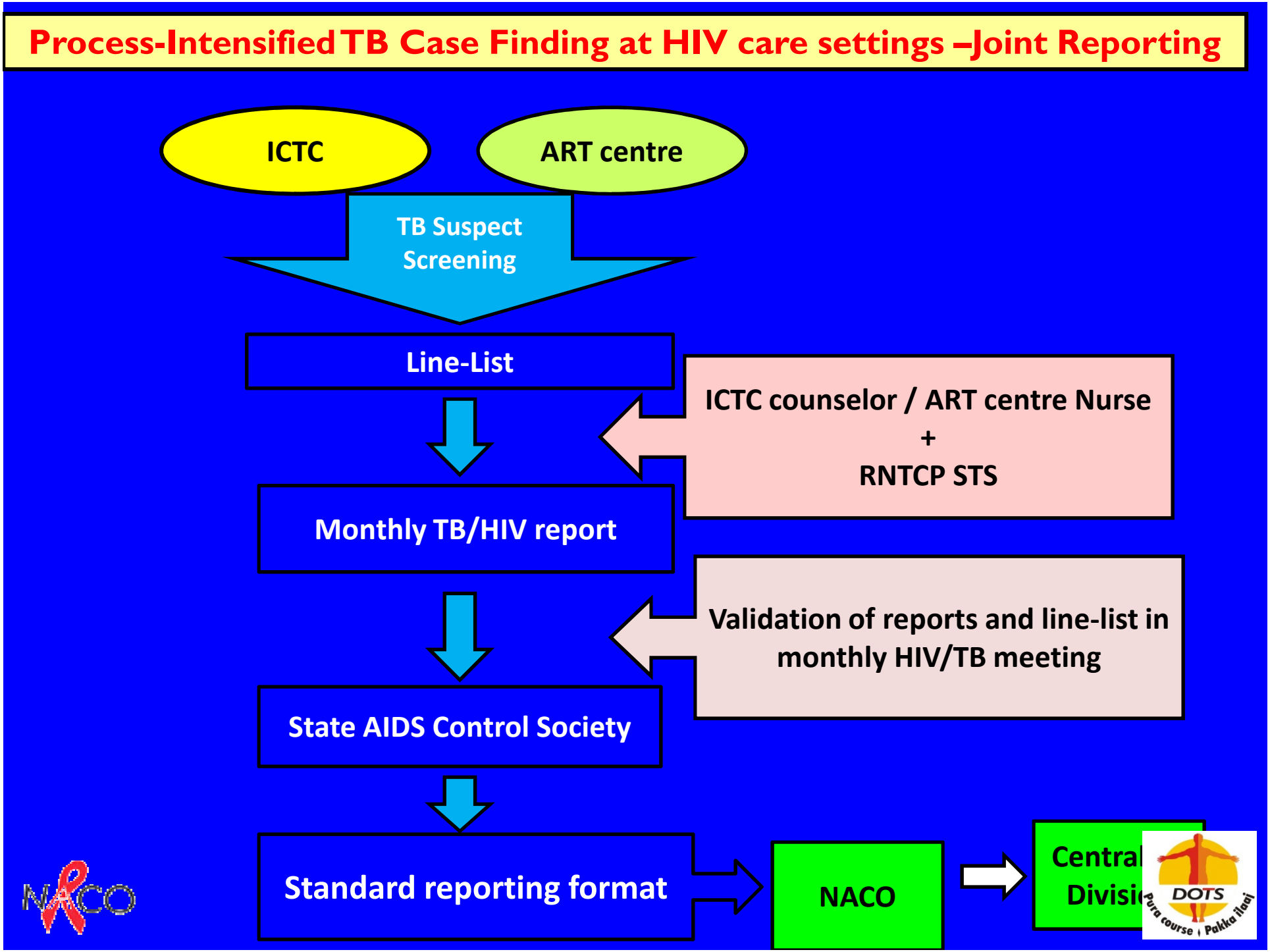
•The symptomatic patients attending ICTC suspected to have TB are being referred to RNTCP for Sputum smear Microscopy, irrespective of their HIV status, as a part of **Intensified HIV- TB package**. Over the last five years, there is a significant increase in the referrals to RNTCP for TB case detection.

TB suspects referred from ICTC for evaluation, 2005-2009:



> 10 fold increase in referrals in the last 5 years

Process-Intensified TB Case Finding at HIV care settings –Joint Reporting



Process--Intensified TB/HIV package (TB programme) -reporting

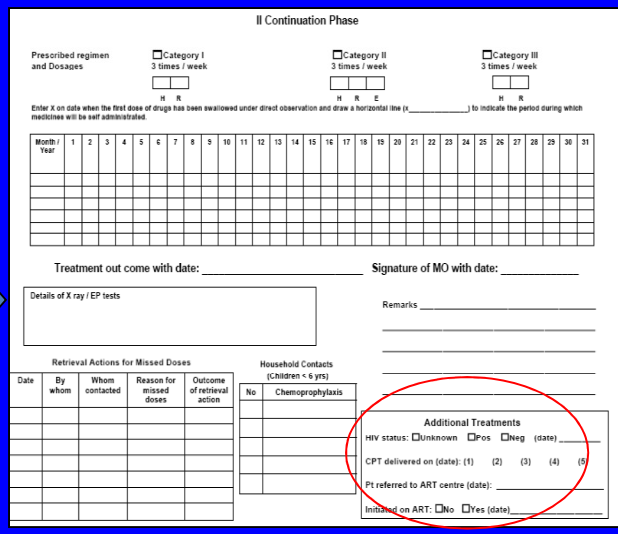
Documentation of HIV status on TB Treatment Card

Patient history of HIV test

Result of HIV test brought by patients (ICTC referral form)

Informed by counselor - "Shared confidentiality"

Provider at PHI



RNTCP TB register

Quarterly reports

Central TB division

NACO

Process--TB Documentation at ART centre on Patient White Card

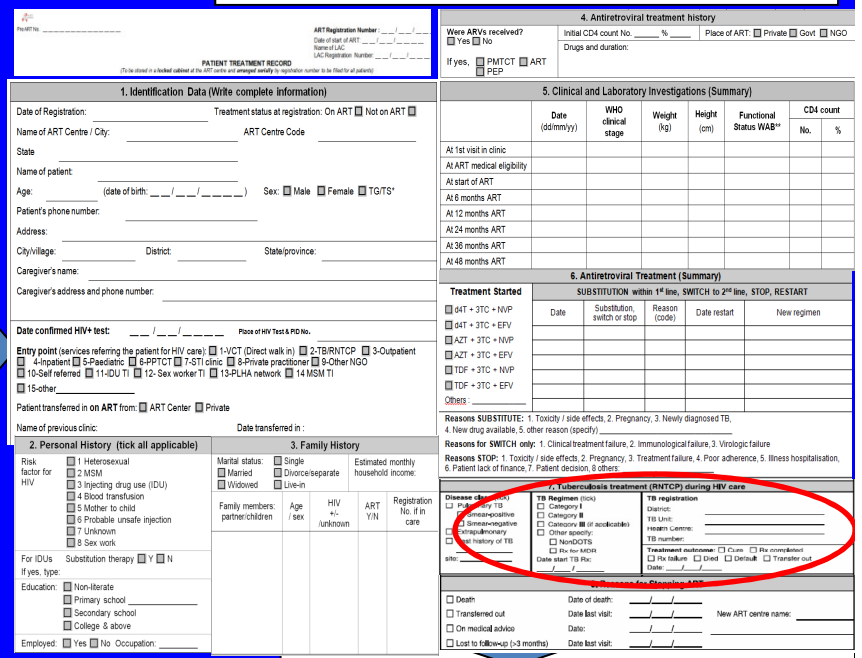
Baseline screening during Pre ART registration

Symptom based screening on every visit to ART centre for any reason

Patients referred from Tb programme

Provider at ART centre

Documentation of TB status on ART Treatment Card


PATIENT TREATMENT RECORD

1. Identification Data (Write complete information)

2. Personal History (tick all applicable)

3. Family History

4. Antiretroviral treatment history

5. Clinical and Laboratory Investigations (Summary)

6. Antiretroviral Treatment (Summary)

7. Tuberculosis treatment (RNTCP) during HIV care

8. Reasons for Stopping ART

ART register

PLHA software

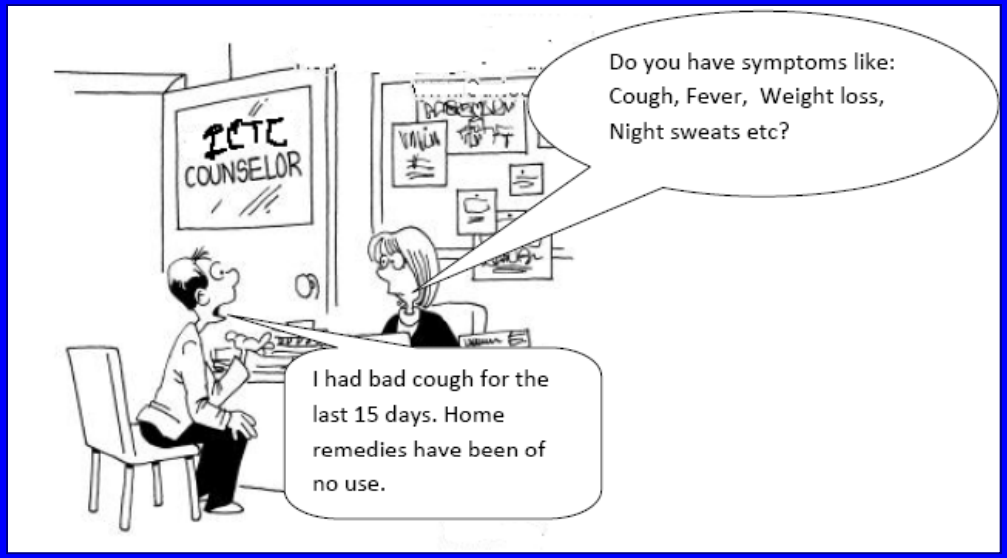
CMIS , NACO

Intensified TB case finding (ICF)

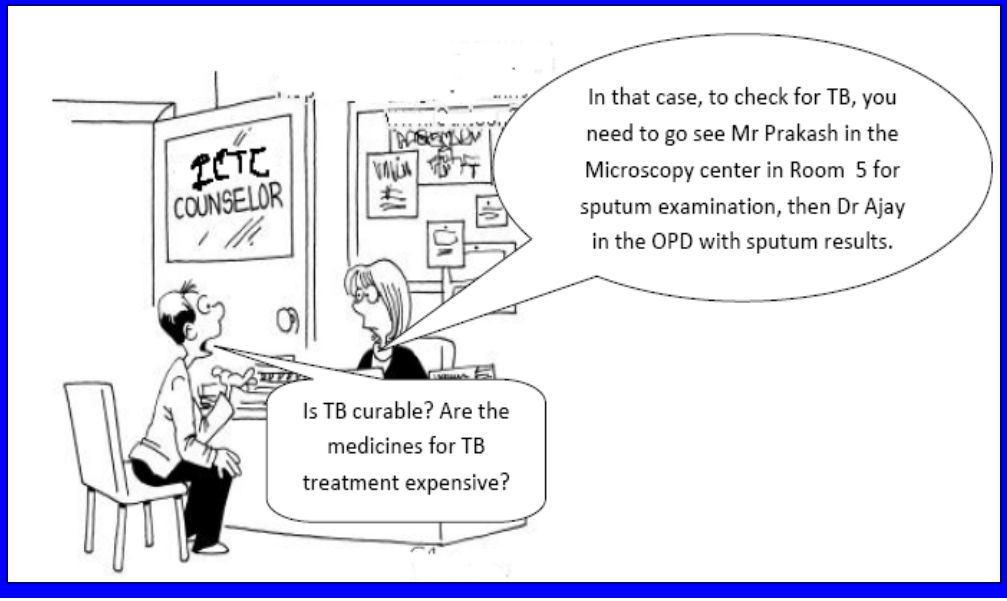
- ICF activity at HIV diagnostic centres (ICTC) across the country since 2008
- ICF at ART Centres with standardized R&R introduced and Rapidly expanded in 2010

How ICF works in India ? (1)

- Counselors (ART centre staff nurse) expected to ask all clients about TB symptoms, cough of 2 weeks duration and others

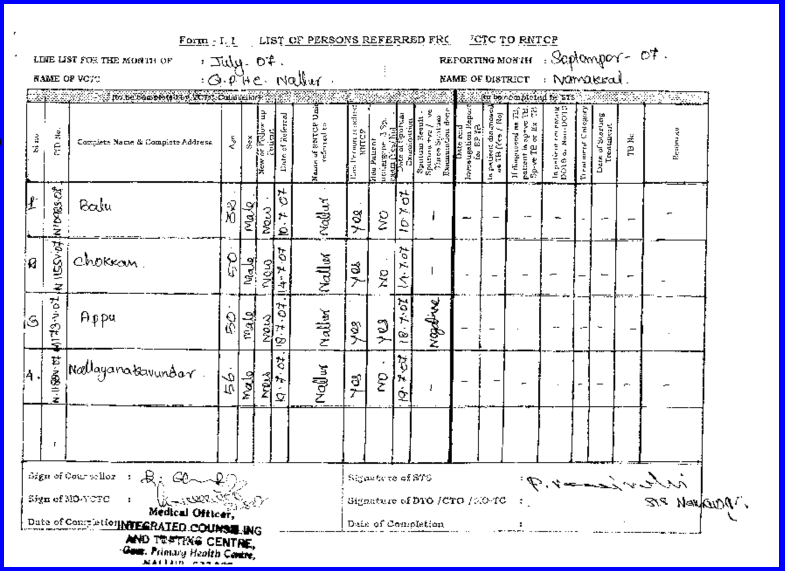


- Clients (PLHIV at ART centres) with symptoms, cough of any duration, referred to Microscopy Center using sputum referral form



How ICF works in India ? (2)

- All the referrals are recorded on a line-list, which is shared with TB programme supervisor
- TB programme supervisor check his record and completes details on
  - Status of referral
  - Diagnostic outcome
  - TB treatment initiation
- Monthly VCT report prepared jointly



Form - I. 1 LIST OF PERSONS REFERRED FROM VCTC TO RNTCP

LINE LIST FOR THE MONTH OF : July. 07. REPORTING MONTH : September - 07.

NAME OF VCTC : G.P.H.C. Nallur. NAME OF DISTRICT : Namakkal.

(to be completed by VCTC Counsellor) (to be completed by STS)

S.No	PID No.	Complete Name & Complete Address	Age	Sex	New or Follow up Patient	Date of Referral	Name of RNTCP Unit referred to	Has Person reached RNTCP	Has Patient undergone 3 Sputum (Yes/No)	Date of Sputum Examination	Sputum Result - Sputum +ve / -ve Three Sputum Examination done	Date and Investigation Report for EP TB	Is patient diagnosed as TB (Yes / No)	If diagnosed as TB, patient is Sp+ve TB, Sp-ve TB or Ex TB	Is patient on DOTS or Non-DOTS	Treatment Category	Date of Starting Treatment	TB No.	Remarks
1	[illegible]	Balu	38	Male	New	10.7.07	Nallur	Yes	No	10.7.07	-	-	-	-	-	-	-	-	-
2	N 1155/07	Chokkan	50	Male	New	14.7.07	Nallur	Yes	No	14.7.07	-	-	-	-	-	-	-	-	-
3	N1173/07	Appu	50	Male	New	18.7.07	Nallur	Yes	Yes	18.7.07	Negative	-	-	-	-	-	-	-	-
4	[illegible]	Nallayanakavundar	56	Male	New	19.7.07	Nallur	Yes	No	19.7.07	-	-	-	-	-	-	-	-	-

Sign of Counsellor :

Sign of MO-VCTC :

Medical Officer, INTEGRATED COUNSELLING AND TESTING CENTRE, Govt. Primary Health Centre, NALLUR

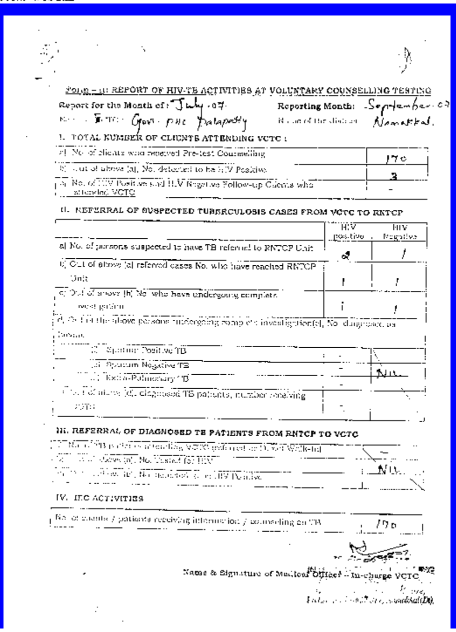
Date of Completion

Signature of STS :

Signature of DTO / CTO / MO-TC :

Date of Completion :

STS Namakkal



Form - II: REPORT OF HIV-TB ACTIVITIES AT VOLUNTARY COUNSELLING TESTING

Report for the Month of : July - 07. Reporting Month: September - 07

Name of VCTC : Govt. PHC Palapatty. Name of the district : Namakkal.

I. TOTAL NUMBER OF CLIENTS ATTENDING VCTC :

a) No. of clients who received Pre-test Counselling	170
b) Out of above (a), No. detected to be HIV Positive	3
c) No. of HIV Positive and HIV Negative Follow-up Clients who attended VCTC	-

II. REFERRAL OF SUSPECTED TUBERCULOSIS CASES FROM VCTC TO RNTCP

	HIV positive	HIV Negative
a) No. of persons suspected to have TB referred to RNTCP Unit	2	1
b) Out of above (a) referred cases No. who have reached RNTCP Unit	1	1
c) Out of above (b) No. who have undergone complete investigation	1	1
d) Out of the above persons undergoing complete investigation(s), No. diagnosed as having		
(i) Sputum Positive TB	-	
(ii) Sputum Negative TB	-	Nil
(iii) Extra-Pulmonary TB	-	
e) Out of above (d), diagnosed TB patients, number receiving DOTS	-	

III. REFERRAL OF DIAGNOSED TB PATIENTS FROM RNTCP TO VCTC

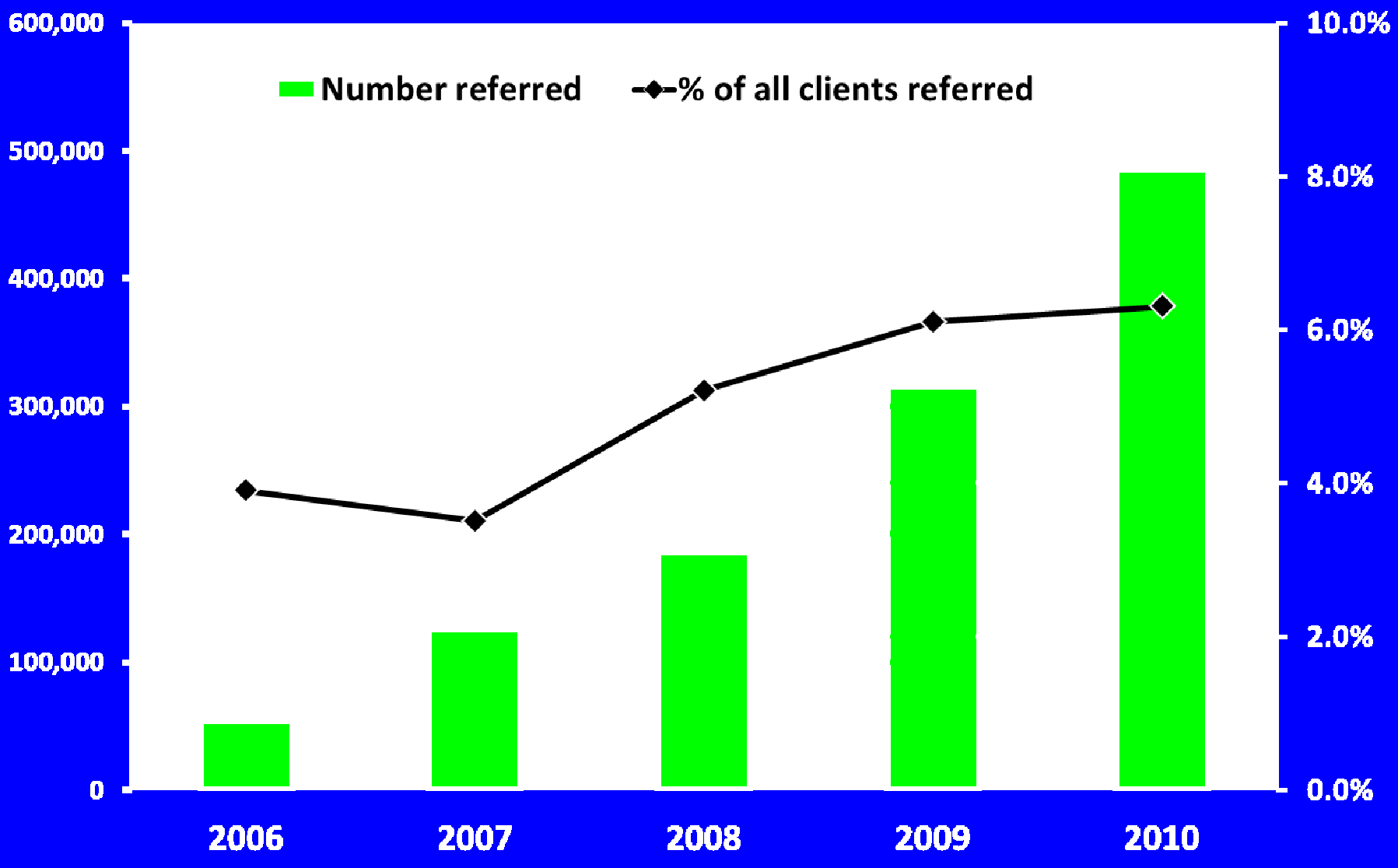
(a) No. of TB patients attending VCTC referred or Direct Walk-in	-
(b) Out of above (a), No. Tested for HIV	Nil
(c) Out of above (b), No. detected to be HIV Positive	

IV. IEC ACTIVITIES

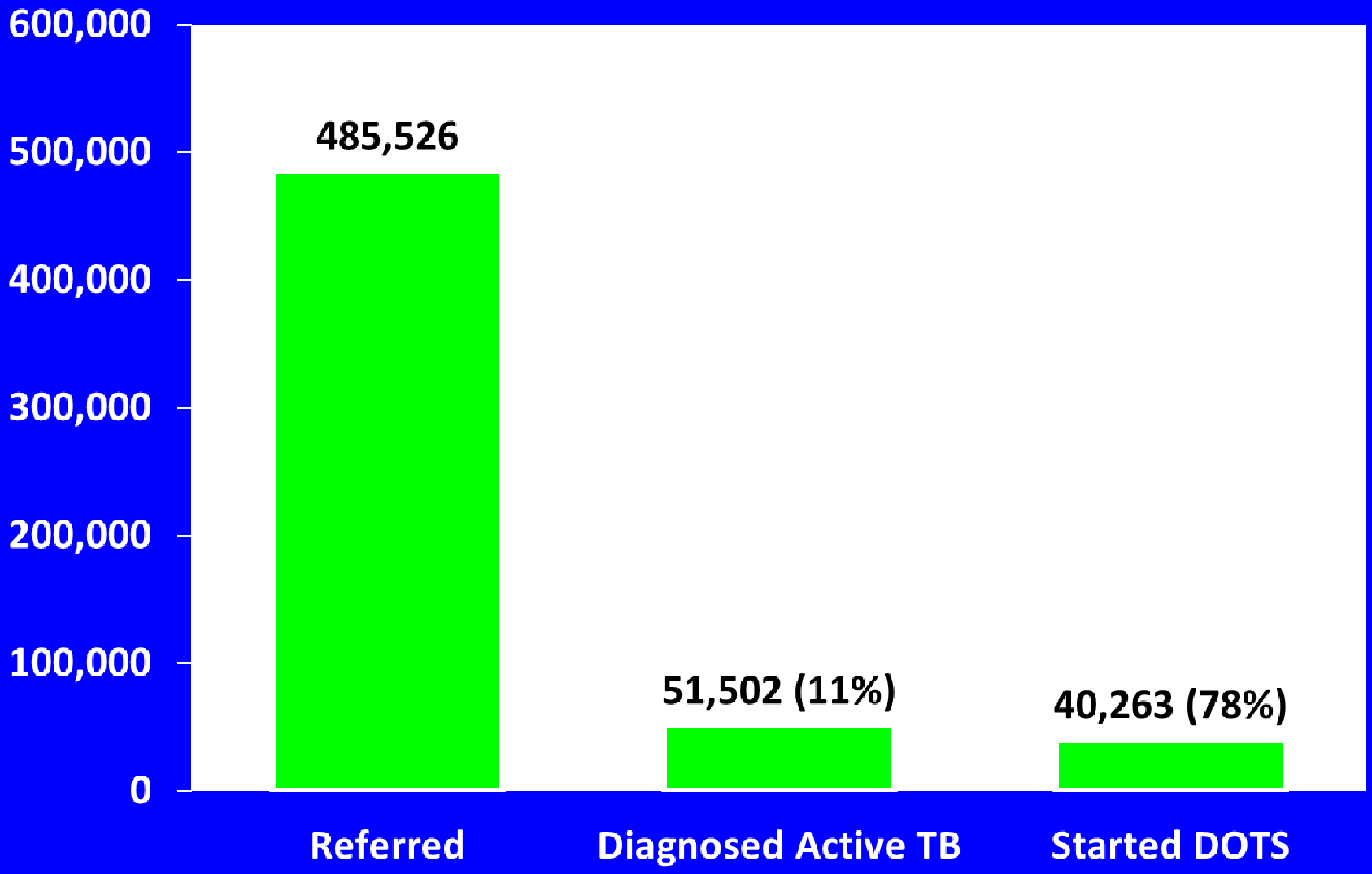
No. of clients / patients receiving information / counselling on TB	170

Name & Signature of Medical Officer - In-charge VCTC

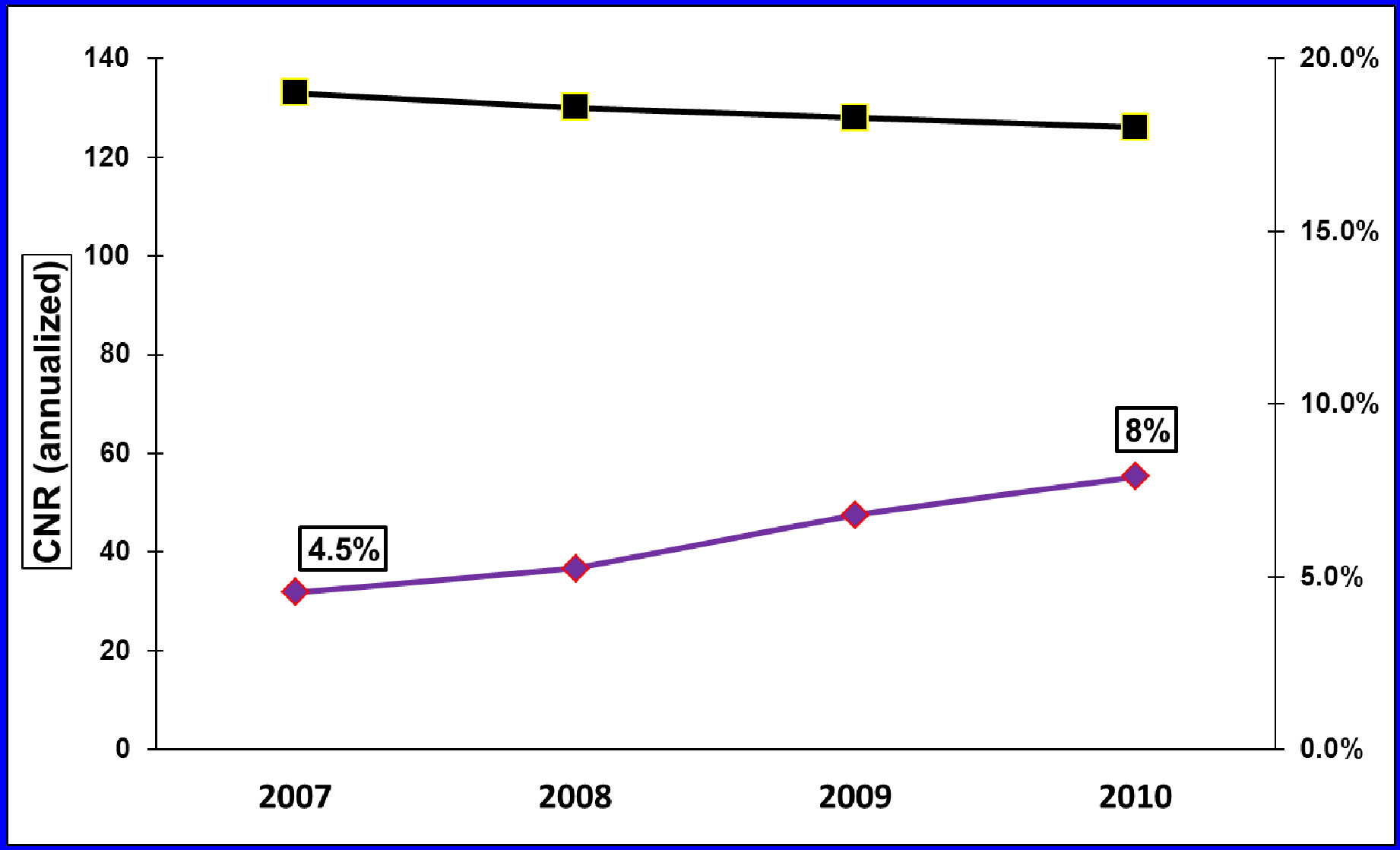
ICF at ICTC - referral of clients for TB diagnostic evaluation, 2006–2010



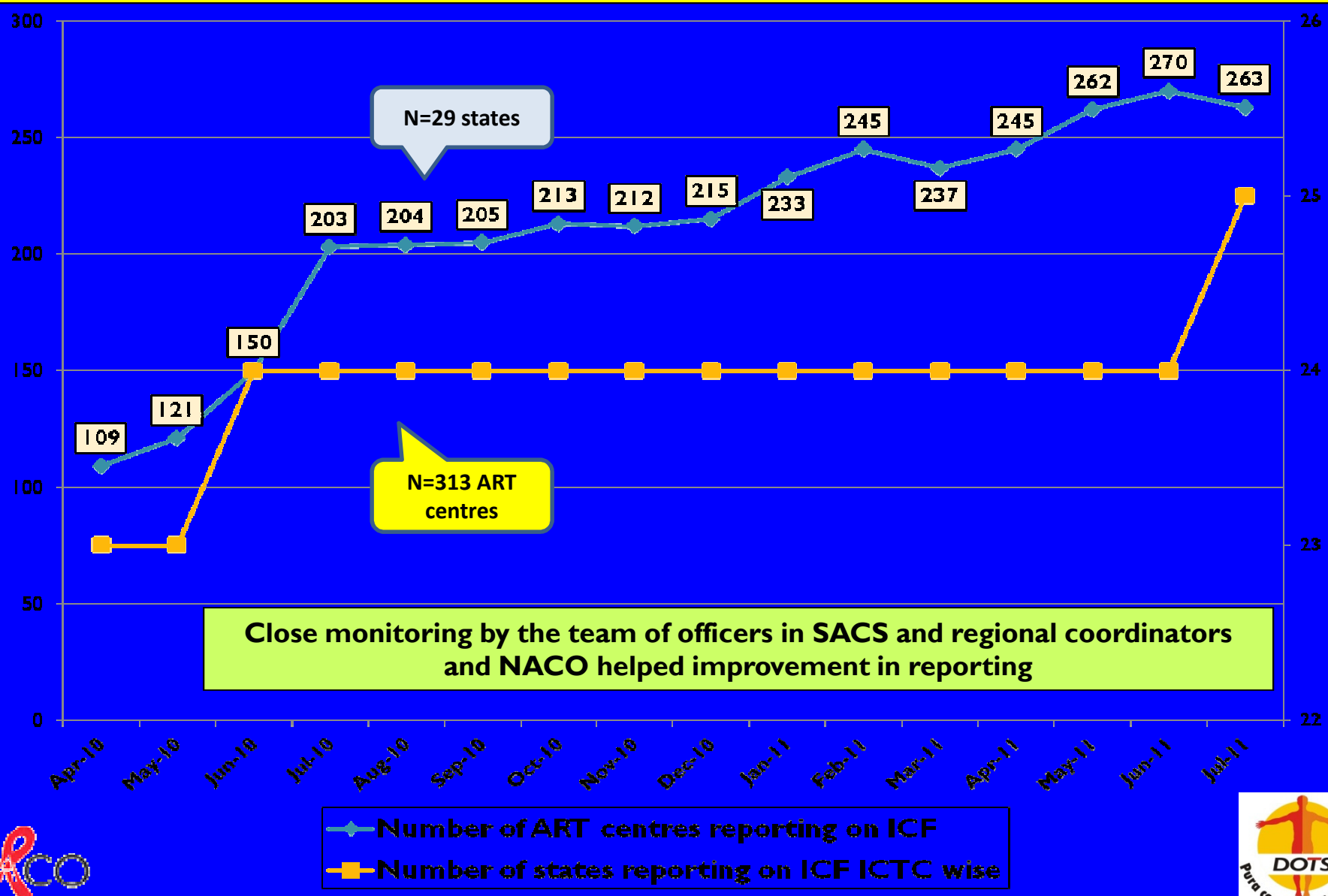
Outcomes of ICTC Clients Referred for TB Screening, 2010



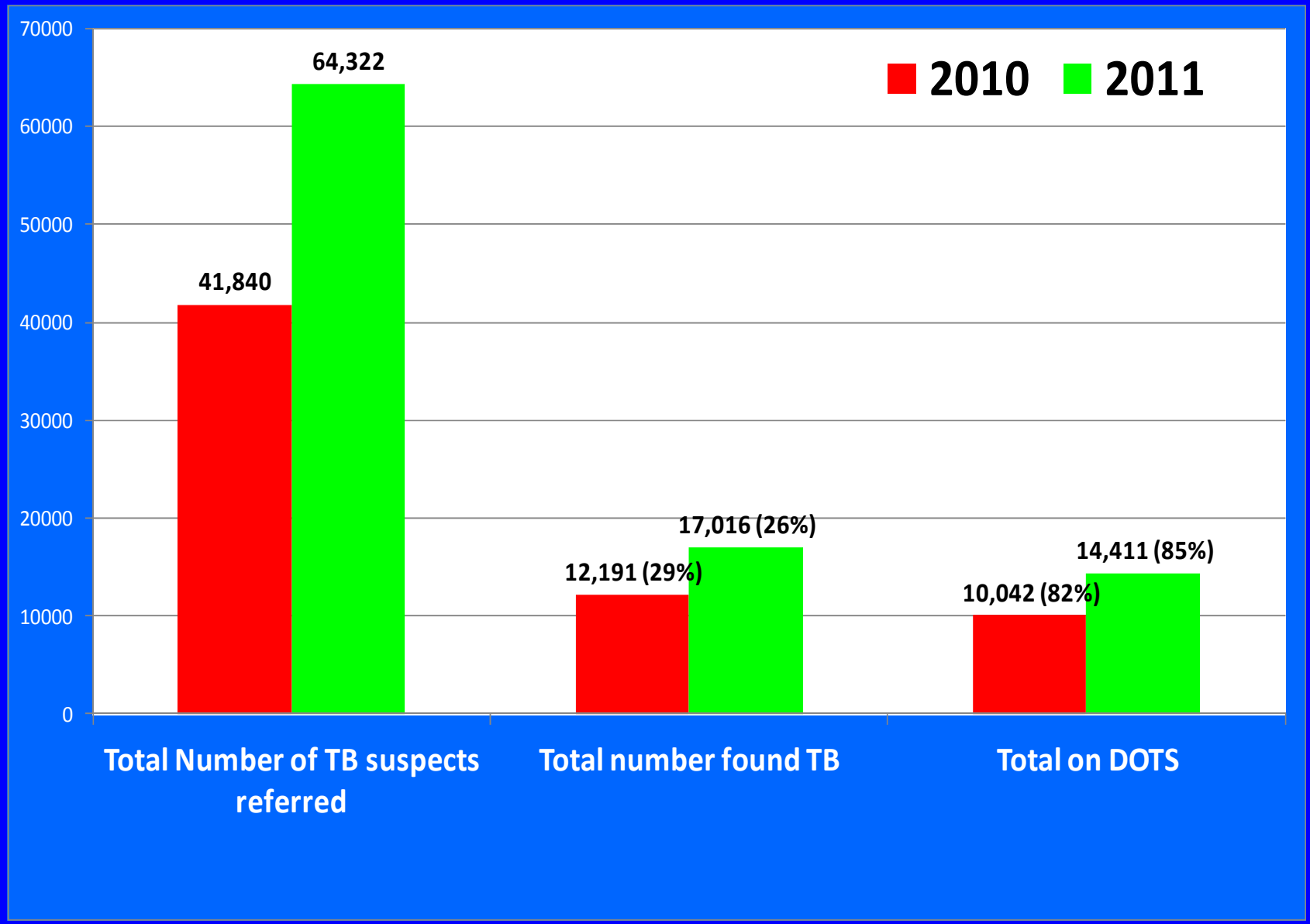
Contribution of ICF at ICTC to TB Case Notification, 7 high HIV states of India



Progress--Reporting of Intensified TB case Finding (ICF) at HIV testing centres (ICTC) and ART centres in India (2010-11)



Outcomes of ART patient Referred for TB Screening



Challenges

- Ensuring implementation and reporting by all ICTC and ART centres
- Ensuring Quality reporting –enhanced monitoring

Way Ahead

- Sputum smear microscopy has low sensitivity - adoption of rapid TB diagnostics for PLHIV
- Expansion of definition of “TB suspect” to widen net of eligible patients for early detection
- Expansion of ICF to other HIV care settings –TI projects for HRG, Community Care Centres and Link-ART centres etc.
- Strengthen implementation of Airborne Infection Control in HIV care settings
- Adoption and expansion of IPT –based on OR

Isoniazid Preventive Therapy

Concerns around adoption of IPT for national scale-up

- Exclusion of active TB challenging
  - Limited access to culture and DST for complete evaluation for ruling out TB
- Fear of Drug resistance: Emergence and “Breakthrough TB”
  - Questions around efficacy of IPT given early initiation of ART (<350)
  - Questions around optimum duration of IPT -6 months Vs. extended
  - Evidence supporting use of IPT among Tuberculin skin test positives only
  - Lack of availability of standardized Tuberculin & its Strength (TU)
  - Immunosuppression issues in use of TST
  - Non-standardized tuberculin Induration size in Indian conditions
- Poor adherence to IPT is expected in a person who is largely asymptomatic (for TB)

Concerns around adoption of IPT for national scale-up …(1)

- Challenges in operationalization-
  - workload at ART centres
  - Feasibility of decentralized delivery of IPT
  - Monitoring of adherence to IPT specially among those on pre-ART

Evidence reviewed by National Technical Working Group for TB/HIV -international

Outcome	Studies	Patients	RR (95% CI)
Probable, confirmed or possible TB	8	4136	0.67 (0.51,0.87)
- TST positive	4	1311	0.36 (0.22,0.61)
- TST negative	7	2490	0.86 (0.59,1.26)
- TST unknown	2	335	0.86 (0.48,1.52)
Confirmed TB	4	2063	0.72 (0.47,1.11)
- TST positive	1	112	0.13 (0.01, 2.32)
- TST negative	3	1021	0.76 (0.36,1.61)
- TST unknown	2	930	0.79 (0.46,1.36)

(Akollo et al 2010 Cochrane Review)

Preventive chemotherapy (IPT) reduces overall risk of developing TB by upto 33%

Evidence reviewed by National Technical Working Group for TB/HIV : Efficacy as compared to ART alone

Study	Total cases / total person-years	Setting		Naive	ART	IPT	IPT+ART
Golub, AIDS 2007	391/17140	Brazil	Incidence Per 100 person-yrs	4.0 (3.4-4.7)	1.9 (1.6-2.2)	1.3 (0.4-2.9)	0.8 (0.4-1.7)
Golub, AIDS 2009	267/4287	South Africa	Incidence Per 100 person-yrs	7.1 (6.2-8.2)	4.6 (3.46.2)	5.2 (3.4-7.8)	1.1 (0.2-0.8)

Evidence reviewed by
National Technical Working Group for TB/HIV -India

Control cohort	6.9 per 100 PY
6 EH cohort	2.4 per 100 PY
36 H cohort	1.5 per 100 PY

Comparison of TB incidence rate per 100 person years

(Swaminathan et al, CROI 2010)

IPT operational feasibility cum efficacy study -Ongoing

OBJECTIVES

- To assess the effectiveness of simple algorithms to exclude active TB prior to IPT initiation
- To assess the feasibility of providing IPT for PLHIV attending ART centres in India.
- To assess the effectiveness of IPT in PLHIV (at different CD4 counts and both pre-ART and on ART) initiated on IPT in India
- To measure number needed to screen (NNS) and number needed to treat (NNT) to prevent one case of TB

Study design: Prospective cohort study

Mid-term review: June 2012, decisions on expansion

Measures to prevent TB among PLHIV

- **Early Initiation of ART**: The NACO has taken decision to initiate ART at CD4 count <350 irrespective of clinical stage and at any CD count in clinical stage III and IV
- **All TB patients to be initiated on ART irrespective of CD count**
- **Isoniazid Preventive Treatment (IPT):** An feasibility cum efficacy study has been approved by NACO at 12 ART centres across the country
- **Measures for Airborne Infection control:**
  - Basic activities like fast tracking of patients with cough, promotion of cough hygiene measures, use of mask and hand washing being implemented at ART Centres
  - Structural changes are being advocated with general health system

NACO

DOTS
Pura course, Pakka ilaaj

Tuberculosis in antiretroviral treatment services in resource-limited settings: addressing the challenges of screening and diagnosis

Lawn SD, Wood R; Journal of Infectious Diseases 204 Suppl 4 S1159-67 (Nov 2011)

- **……. Screening and diagnosis of TB in this clinical setting is difficult. However, progress has been made in defining a high-sensitivity, standardized symptom screening tool that assesses a combination of symptoms, rather than relying on report of cough alone. Moreover, newly emerging diagnostic tools show great promise in providing more rapid diagnosis of TB, which is predominantly sputum smear-negative. Further development and implementation of these tools is vital to permit rapid and effective screening for TB in ART services, which is an essential component of patient care**

Thank you