

Manage TB
Dr. Kirankumar Rade
WHO Country office for India, New Delhi
Lecture – 66


TB Notification
Session 01

Welcome to this session on Tuberculosis Notification.

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Introduction

- TB remains a major public health challenge in India
- Major killer among infectious diseases
- Highest TB burden in India despite of National TB Programme since 1962
- 2/3rd of TB patients seek care from private sector
- Private sector remained outside the public health schemes
- TB was notifiable in few states / corporations since long..... but not really implemented



Manage TB

ICMR - National Institute for Research in Tuberculosis (NIRT)
www.nirt.res.in

We all know that tuberculosis remains a major public health challenge in India. TB is the major killer amongst all the infectious diseases. Despite of national TB programme since 1962 and all the efforts tuberculosis burden in India remains the highest in the world, there are reasons for this two third of the patients TB patients seek care from private sector, despite of private sector engagement schemes, patients going to the private sector remained outside the ambit of the tuberculosis programme in India.

Though tuberculosis was notifiable in few states, corporations since many years many decades, but still really not very well implemented.

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TB Notification Order

First Amendment - 21 July 2015



Notification of TB cases

2.08192012 TB
Government of India
Ministry of Health and Family Welfare
New Delhi
Dated: 27 May 2012

Notification of TB cases

TB continues to be a major public health problem accounting for substantial morbidity and mortality in the country. Early diagnosis and complete treatment of TB is the cornerstone of TB prevention and control strategy. Inappropriate diagnosis and incomplete treatment with anti-TB drugs may contribute to complications, disease spread and emergence of Drug Resistant TB.

In order to ensure proper TB diagnosis and case management, reduce TB transmission and address the problems of emergence and spread of Drug Resistant TB, it is essential to have complete information of all TB cases. Therefore, the healthcare providers shall notify every TB case to local authorities in District Health Officer / Chief Medical Officer of a district and Municipal health Officer of a Municipal Corporation (Monthly every month in a given format attached).

For the purpose of case notification, a TB case is defined as below:

- A patient diagnosed with at least one sputum specimen positive for acid fast bacilli, or Culture-positive for Mycobacterium tuberculosis, or RNTCP endorsed Rapid Diagnostic, molecular test positive for Mycobacterium tuberculosis.
- OR
- A patient diagnosed clinically as a case of tuberculosis, without microbiologic confirmation, and treated on anti-TB drugs.

For the purpose of this notification, healthcare providers will include clinical establishments run or managed by the Government (including local authorities), private or NGO sectors and/or individual practitioners.

For more detailed information, the concerned State TB Officers / District TB Officers, whose details are available on [www.tbcindia.gov.in](http://tbcindia.gov.in), may be contacted.


Encl: As mentioned

Shyam Sankar
Under Secretary to the Government of India

Copy for immediate further necessary action, to:

- All Principal Secretaries / Secretaries of Health of States / UTs
- All Directors of Health Services of States / UTs
- All State TB Officers of States / UTs

With the request to kindly immediately bring the order to the notice of all concerned for compliance, in their respective State / UT



ANSHU PRAKASH, I.A.S.
Chief of Civil Supply
New Delhi
22001102

GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
NIRMAAN BHAVAN, NEW DELHI-110011

First Amendment - 21 July 2015

Notification of TB cases - Amendment

D.O. No. Z.08192015 TB
21 July 2015

Dear Sir,

Following amendments are made in Case Order No. Z.08192012 TB dated 27 May 2012 in context with notification of TB cases:

- For the purpose of case notification, a TB case is defined as follows:
 - A patient diagnosed with at least one clinical specimen positive for acid fast bacilli, or Culture-positive for Mycobacterium tuberculosis or Rapid Diagnostic, molecular test positive for Mycobacterium tuberculosis.
 - OR
 - A patient diagnosed clinically as a case of tuberculosis, without microbiologic confirmation, and treated on anti-TB drugs.
- Once private practitioner notifies TB patient information following actions will be taken by local public health staff of general health system of Government in local bodies and visited in NRI/OCI:
 - Follow home visit as per convenience of patient.
 - Recording of TB patient and family members.
 - Treatment adherence and follow-up supervision assessment completion.
 - Contact tracing, compliance assessment, initiation of TB components and referring TB symptoms/signs to eligible centers.
 - Offering HIV testing, Drug Susceptibility Testing (DST), if available.
- All laboratories shall notify TB cases with information as per Annexure 1 and medical practitioners, Clinics, Hospitals, Nursing homes shall notify TB cases with information as per Annexure 2.

For more detailed information, concerned District TB Officers may be contacted, whose details are available on www.tbcindia.gov.in and <http://tbcindia.gov.in>.

With regards,

Yours sincerely,
Anshu Prakash

Second Amendment expected in December 2017

So, this was one of the reasons on 7th May 2012, TB notification order was issued by the central government, which makes it mandatory for all the laboratories, the practitioners and the hospitals who either diagnose or treat to notify to the nodal officers at the district level. Immediately after that 21st July 2015 the first amendment came. There were reasons for this we will see in detail whatever reasons and another amendment is expected soon in December 2017.

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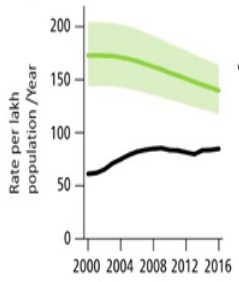
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Current status of TB notification

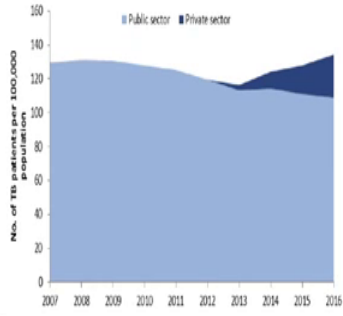
Global scenario

Case notification rates (new and relapse cases, all forms) compared with estimated TB incidence rates (green)



WHO, Global report, 2017

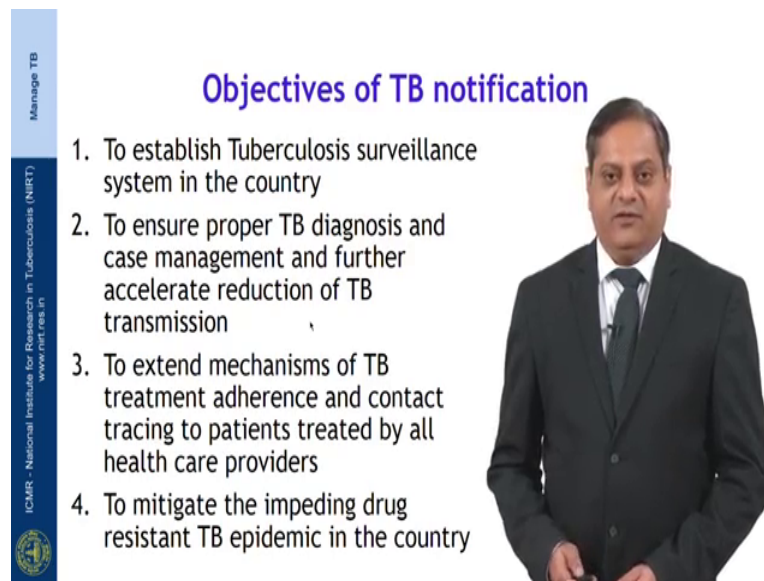
Trend in TB notification in India from public and private sector



RNTCP status report, 2017

If we see globally and in India also and compare it, there is a gap between the total notification rate and the expected incidence. Globally the incidence rate is going down while the notification was stationary, but recently in last 3-4 years the notification rate has increased which we can see on the left side. On the right side, we can see more or less the notification by the programme was stationary over last 6-7 years and which has increased which was started declining 4 years before it has again started increasing bit implementation of TB notification in India.

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The slide features a vertical blue bar on the left with the text 'Manage TB' at the top, 'ICMR - National Institute for Research in Tuberculosis (NIRT)' in the middle, and the website 'www.nirt.res.in' at the bottom. The main title is 'Objectives of TB notification' in blue. To the right of the text is a photograph of a man in a dark suit and tie. The list of objectives is as follows:

1. To establish Tuberculosis surveillance system in the country
2. To ensure proper TB diagnosis and case management and further accelerate reduction of TB transmission
3. To extend mechanisms of TB treatment adherence and contact tracing to patients treated by all health care providers
4. To mitigate the impending drug resistant TB epidemic in the country

So, we will see what are the objectives of this TB notification? It is to establish tuberculosis surveillance system in the country, to ensure proper TB diagnosis and case management and further accelerate reduction of tuberculosis transmission. To extend the mechanism of TB treatment adherence, contact tracings to patients not only treated in the public sector, but also in the private sector. To mitigate the impending drug resistant tuberculosis epidemic in the country by a bringing in embed all the patients including the private sector in the ambit of care including the follow up.

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Why TB notification is important?

- **Surveillance** is the key for tackling any menace of disease - Notification is first crucial step
- Patient benefit has to be central - Public health action is needed
- Quality of care is important and so is coverage



So, why this TB notification is important? We all know surveillance is the key for tackling any menace of a disease, notification is the first step. Patient benefit should be at the center, public health action is needed and unless and until it is done any notification will not have any value. It also intends to improve the quality of care and so, is the coverage unless and until we saw the patient, which were outside the ambit of the care being treated in the private sector unless and until the way those were covered the quality of care is improved, we are unlikely to reach our main aim of TB control in this country.


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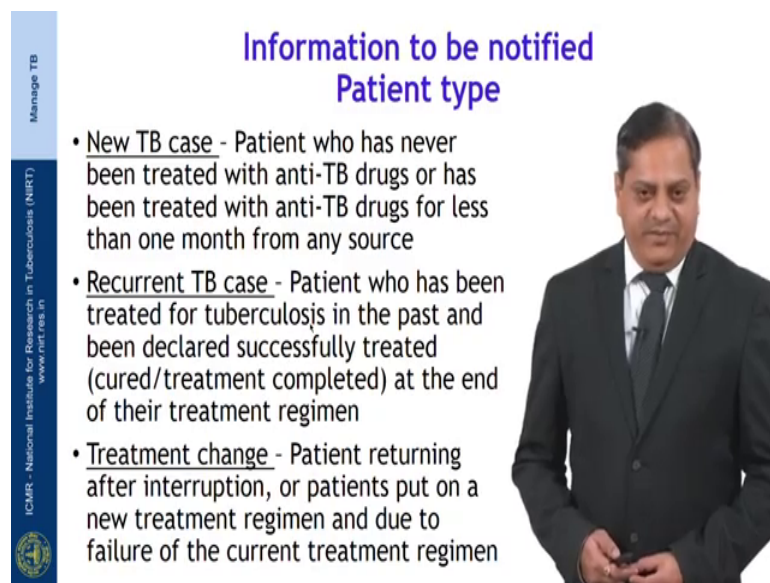
Information to be notified Basis of TB diagnosis

- Microbiologically-confirmed TB case - Patient diagnosed with at least one clinical specimen positive for acid fast bacilli, or culture-positive for *M.tb*, or RNTCP-approved rapid diagnostic molecular test positive for TB
- or
- Clinical TB case - Patient diagnosed clinically as TB, without microbiologic confirmation and initiated on anti-TB drugs



So, what is the information that is required to be notified, what is the basis of TB diagnosis? There are two types first is microbiologically confirmed tuberculosis and by definition, a TB patient diagnosed with at least one clinical specimen positive for acid fast bacilli or culture positive for mycobacterium tuberculosis; by or RNTCP approved diagnostic molecular test, positive for tuberculosis will amount to a microbiologically confirmed TB case. Or it can be a clinical TB case, a patient diagnosed clinically as TB without microbiological confirmation and initiated on TB anti TB drugs.

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The slide features a vertical blue bar on the left with the text 'Manage TB' at the top, 'ICMR - National Institute for Research in Tuberculosis (NIRT)' in the middle, and 'www.nirt.res.in' at the bottom. The main title is 'Information to be notified Patient type'. The content includes a bulleted list of three patient types and a photograph of a man in a dark suit and tie.

Information to be notified
Patient type

- New TB case - Patient who has never been treated with anti-TB drugs or has been treated with anti-TB drugs for less than one month from any source
- Recurrent TB case - Patient who has been treated for tuberculosis in the past and been declared successfully treated (cured/treatment completed) at the end of their treatment regimen
- Treatment change - Patient returning after interruption, or patients put on a new treatment regimen and due to failure of the current treatment regimen

So, these are the information basis of diagnosis that needs to be reported. Then what is the type of the patient there are three types of patient that is included in the notification. First is the new TB case a patient who has never been treated with anti TB drugs or has been treated with anti TB drugs for less than 1 month, from any source whether it is public or private amongst to a new case.


It can be a recurrent case if the patient has been treated for tuberculosis in the past and has been declared successfully treated at includes cured patients and treatment completed at the end of their treatment regimen. And treatment change is are the patients returning after interruption or the patients put on new regimen, new treatment regimen and due to failure of the current treatment regimen.

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Information to be notified Site of disease

- Pulmonary TB case - Patient with TB of the lungs (with or without involvement of any extra-pulmonary locations)
- Extra-pulmonary TB case - Patient with TB of any organ other than the lungs, such as pleura, lymph nodes, intestines, genito-urinary tract, skin, bones and joints, meninges of the brain, etc, diagnosed with microbiological, histological, radiological, or strong clinical evidence




These will be the treatment change patient so; these are the types of patients that the treating facility has to notify. Now what are the site of disease? We all know there are the site of the disease is can be either a pulmonary that is a patient with tuberculosis of lungs with or without involvement of any extra pulmonary locations. And the other type is extra pulmonary TB case that is the patient with tuberculosis of any organ other than the lungs such as pleura, lymph, nodes, intestines genito urinary tract skin bones joints meninges etcetera diagnosed with microbiological, histological, radiological or strong clinical evidence.

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Information to be notified Rifampicin resistance

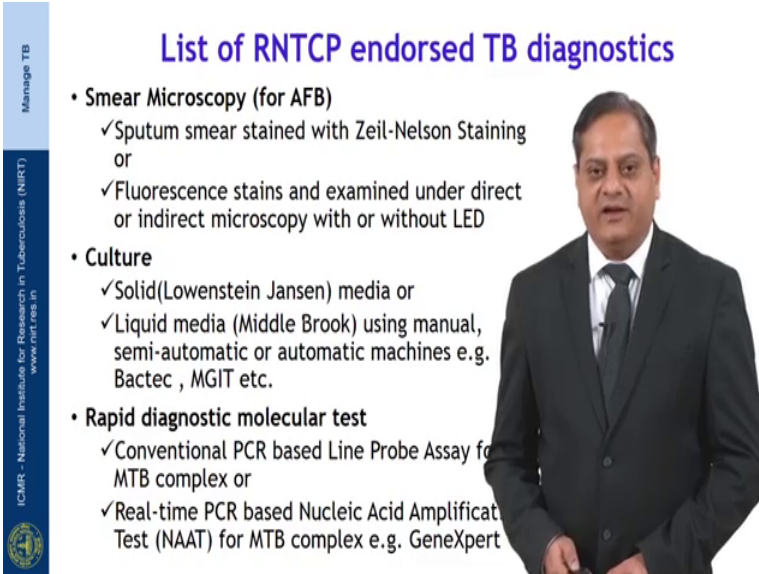
- Rifampicin resistant - Drug susceptibility test result from a RNTCP-certified laboratory or WRD (WHO-endorsed Rapid Diagnostics) drug susceptibility test report showing resistance to rifampicin
- Rifampicin sensitive - Patient with a drug susceptibility test result from a RNTCP-certified laboratory or WRD drug susceptibility test report showing sensitivity to rifampicin
- Not available - Patient without a drug susceptibility test result from a RNTCP-certified laboratory or WRD drug susceptibility test report



We also need to think about rifampicin resistance and that has been included when we report, when we notify a tuberculosis case. So, what is expected? A definition of rifampicin resistance case is drugs susceptibility test result from RNTCP certified laboratory or WHO endorsed rapid diagnostics drug susceptibility test report, showing the resistance to rifampicin. And what is the rifampicin in sensitive case? A patient with a drug susceptibility result from same RNTCP certified laboratory or WHO endorsed rapid molecular test, which are the drug susceptibility test results showing drug sensitivity to rifampicin.

Now, there will be instances there will be situations, where you do not have the DST the drugs susceptibility test are done or the result is not available. In such case the test result is not available, but that needs to be reported over a period of time the intension is to increase these drugs susceptibility testing and by policy within the programme now, universal drugs susceptibility testing for rifampicin is the policy.

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List of RNTCP endorsed TB diagnostics

- **Smear Microscopy (for AFB)**
 - ✓ Sputum smear stained with Zeil-Nelson Staining or
 - ✓ Fluorescence stains and examined under direct or indirect microscopy with or without LED
- **Culture**
 - ✓ Solid (Lowenstein Jansen) media or
 - ✓ Liquid media (Middle Brook) using manual, semi-automatic or automatic machines e.g. Bactec, MGIT etc.
- **Rapid diagnostic molecular test**
 - ✓ Conventional PCR based Line Probe Assay for MTB complex or
 - ✓ Real-time PCR based Nucleic Acid Amplification Test (NAAT) for MTB complex e.g. GeneXpert

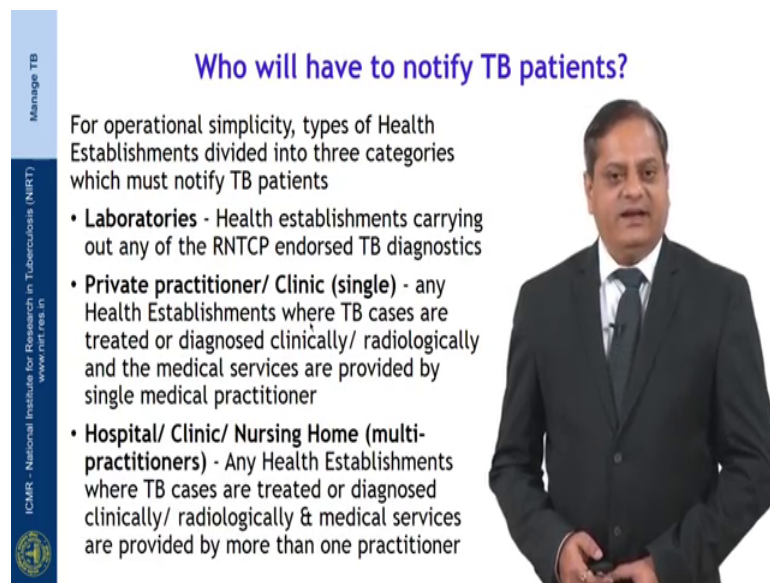
Vertical text on the left side of the slide: Manage TB, ICMR - National Institute for Research in Tuberculosis (NIRT), www.nirt.res.in

Photograph of a man in a dark suit and tie, standing and speaking.

Now, what are the RNTCP endorsed TB diagnostics? We talk about this smear microscopy for AFB, sputum smear stained with Zeil-Nelson staining or fluorescence stains examined under direct or indirect microscopy with or without a LED is smear microscopy, which is endorsed. For culture it is the either solid culture with lj media or with liquid culture, whether it is semi automatic or automatic that is bactec or MGIT.

And there are rapid diagnostic molecular test which includes, which includes the real time PCR based line probe assay for MTB complex or the nucleic acid amplification test NAAT test one of example is genexpert which is already there, we call it CB NAAT cartridge based nucleic acid amplification test in India and the another one is coming soon which is being validated as true NAAT. So, these are the RNTCP endorsed TB diagnostics.

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The slide features a vertical blue bar on the left with the text 'Manage TB' at the top, 'ICMR - National Institute for Research in Tuberculosis (NIRT)' in the middle, and the website 'www.nirt.res.in' at the bottom. The main title is 'Who will have to notify TB patients?'. Below the title, it states: 'For operational simplicity, types of Health Establishments divided into three categories which must notify TB patients'. To the right of the text is a photograph of a man in a dark suit and tie. The text lists three categories:

- **Laboratories** - Health establishments carrying out any of the RNTCP endorsed TB diagnostics
- **Private practitioner/ Clinic (single)** - any Health Establishments where TB cases are treated or diagnosed clinically/ radiologically and the medical services are provided by single medical practitioner
- **Hospital/ Clinic/ Nursing Home (multi-practitioners)** - Any Health Establishments where TB cases are treated or diagnosed clinically/ radiologically & medical services are provided by more than one practitioner

Now, who is expected to notify a TB patients? We saw for operational purposes the health establishments are divided into three categories, who are expected to notify TB patients. First is laboratories these are the laboratories where the RNTCP endorsed diagnostics takes place and the TB patients are diagnosed. Private practitioners or clinics which are single any health establishment, where a TB case patient is treated or diagnosed clinically or radiologically, and the medical services are provided by a single medical practitioner. Then there a second one third one is hospital clinics, nursing homes, which are multi practitioners. Means these are the hospitals or clinics were more than 1 treating physician is diagnosing or treating patients.

The operational reason for this is that, the nodal TB officer district TB officer has to deal with more than one doctor in hospitals where multi practitioners are working.

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Whom to notify TB patients?

- TB patients can be notified to District nodal officer for TB
- Updated list and contact details (including mobile numbers & email IDs) of District TB Officers is available on following websites

www.tbcindia.gov.in

www.nikshay.gov.in

So, whom to notify this; TB patients as a practitioner, as a health establishment, TB patients can be notified through a district nodal officer for tuberculosis. The updated list and the contact details including the addresses, mobile numbers, email ids of all district TB officers are available on the official website of RNTCP that is TBC India dot gov dot in and nikshay dot gov dot in.

So, these are the two websites, where the updated list of all the contact details of the district TB officers were responsible for ensuring TB notification in the district is list is available.

