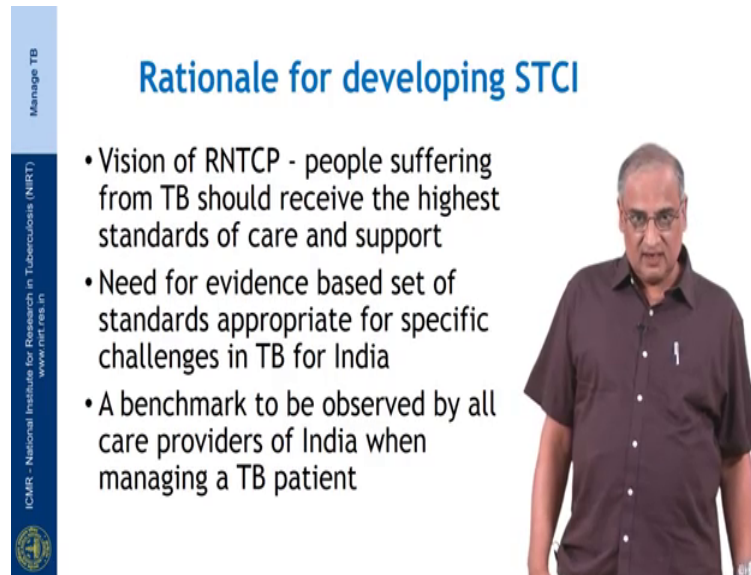


Manage TB
Dr. Mohan Natrajan
Department of Clinical Research
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Lecture – 70
Standards for TB Care in India (STCI)
Session 01


Hello everybody I am Dr. Mohan Natrajan and today I will be talking to you about Standards for TB Care in India.

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Rationale for developing STCI

- Vision of RNTCP - people suffering from TB should receive the highest standards of care and support
- Need for evidence based set of standards appropriate for specific challenges in TB for India
- A benchmark to be observed by all care providers of India when managing a TB patient



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

Now, the reason for developing the standards was the perception that people suffering from TB should receive the highest standard of care and support.


To achieve this we need an evidence base set of standards which are which was appropriate for a country and this finally resulted in a document whose prime purpose is to serve as a benchmark, which would be observed by all care providers of tuberculosis in India.

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Development of STCI

- Central TB Division, Govt of India
- Technical assistance from WHO Country Office for India
- Contributions from National TB institutions in India ,TB Experts and Program Managers
- International standards taken into consideration
- 26 standards
- Released in 2014



Now, several groups had contributed to the development of this document. This includes the central TB division the Government of India, WHO country office for India with contributions from National TB institutes as well as TB Experts and Program Managers.

Now, international standards were taken into consideration in formulating the standards and a set of 26 standards were developed which were released in 2014.

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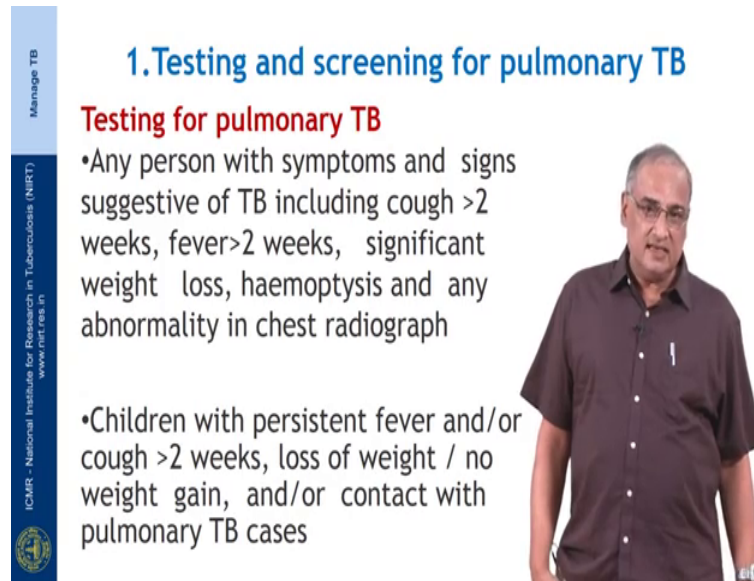
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List of standards in STCI

S.No	Standard	S.No	Standard
1	Testing and screening for PTB	14	Maintain records for TB patients
2	Diagnostic technology	15	Contact investigation
3	Testing for EPTB	16	Isoniazid prophylactic therapy
4	Diagnosis of HIV and DR-TB	17	Airborne infection control
5	Probable TB	18	Quality assurance systems
6	Pediatric TB	19	Panchayati Raj Institutions
7	Treatment with 1 st line regimen	20	Health education
8	Monitoring treatment response	21	Death audit
9	DR-TB management	22	Information on TB prevention, care seeking
10	Addressing TB-HIV, co-morbidity	23	Free and quality services
11	Treatment adherence	24	Respect, confidentiality, sensitivity
12	Public Health responsibility	25	Care, support - social welfare program
13	TB notification	26	Addressing counseling, other needs

We have a list of 26 standards as I mentioned before of which the first 11 standards deal with diagnosis and treatment.

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The slide features a vertical banner 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 '1. Testing and screening for pulmonary TB'. Below it is the sub-heading 'Testing for pulmonary TB'. Two bullet points describe testing criteria for adults and children. A man in a dark shirt is standing on the right side of the slide.

1. Testing and screening for pulmonary TB

Testing for pulmonary TB

- Any person with symptoms and signs suggestive of TB including cough >2 weeks, fever>2 weeks, significant weight loss, haemoptysis and any abnormality in chest radiograph
- Children with persistent fever and/or cough >2 weeks, loss of weight / no weight gain, and/or contact with pulmonary TB cases

The first standard deals with the testing and screening for pulmonary tuberculosis. The testing for pulmonary tuberculosis is done in any person with symptoms and signs suggestive of tuberculosis including cough greater than 2 weeks, fever greater than 2 weeks, significant weight loss, haemoptysis or any abnormality being showed in the chest radiograph.

Likewise in children those children with persistent fever and or having cough greater than 2 weeks, showing loss of weight or no weight gain and a contact with pulmonary tube TB cases need testing.

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1. Testing and screening for pulmonary TB

Screening for PTB

- People living with HIV (PLHIV), malnourished, diabetics, cancer patients, patients on immunosuppressant or maintenance steroid therapy
- Enhanced case finding in high risk populations - health care workers, prisoners, slum dwellers, certain occupational groups (miners)



As far as screening has concerned screening is done with in people living with HIV, in the malnourished, diabetics, cancer patients, those on immunosuppressant therapy or maintenance steroid therapy.

It is also done in instances where there is an enhance chance of finding tuberculosis and these include health care workers, prisoners, slum dwellers and certain occupational groups like miners.

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2. Diagnostic technology

1. **Microbiological confirmation on sputum** - Quality assured sputum test for microbiological confirmation in all presumptive TB
2. **Chest X-ray as screening tool** - To increase sensitivity of diagnostic algorithm
3. **TST and IGRA** - Not recommended for diagnosis of active TB. Standardized TST in children as complementary test
4. **CB-NAAT** - Preferred first diagnostic test in children, PLHIV

Serological tests - Banned, not recommended for TB diagnosis

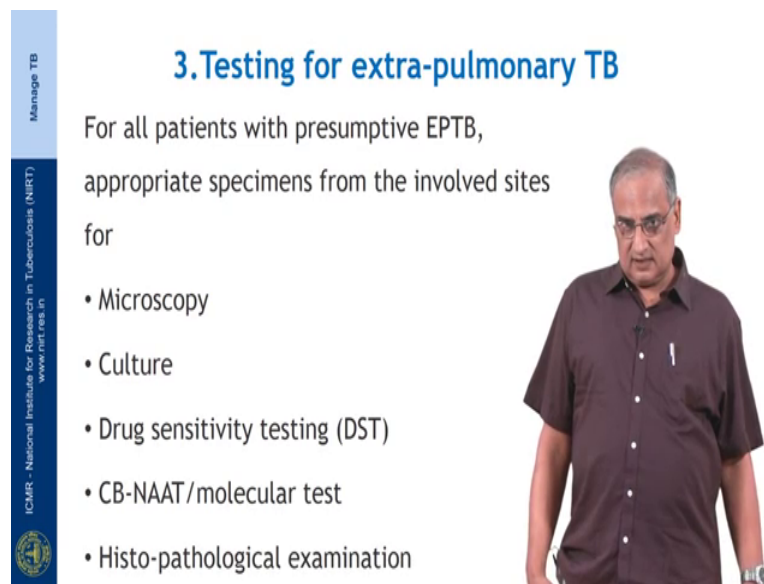


The second standard deals with diagnostic technology, you are aware of a praised aspect in the previous modules I will just mention them once again. The prime diagnostic technology involves the micro biological confirmation on sputum of M tuberculosis for which quality assured sputum test should be done in all presumptive tuberculosis cases.

Chest X-ray is used as a screening tool to increase the diagnostic algorithm sensitivity. Tuberculosis skin test and interference gamma release assays are not recommended for diagnosis of active tuberculosis; however, a standardized tubercule skin test in children can be used as a complementary test in diagnosis.

A lately available test is the CB-NAAT that is the cartridge based nucleic acid amplification test which is the preferred first diagnostic search in children and in people living with HIV. Here, I would like to emphasize one fact that is serological tests are not recommended for diagnostics are in fact, banned by the Government of India.

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3. Testing for extra-pulmonary TB

For all patients with presumptive EPTB, appropriate specimens from the involved sites for

- Microscopy
- Culture
- Drug sensitivity testing (DST)
- CB-NAAT/molecular test
- Histo-pathological examination

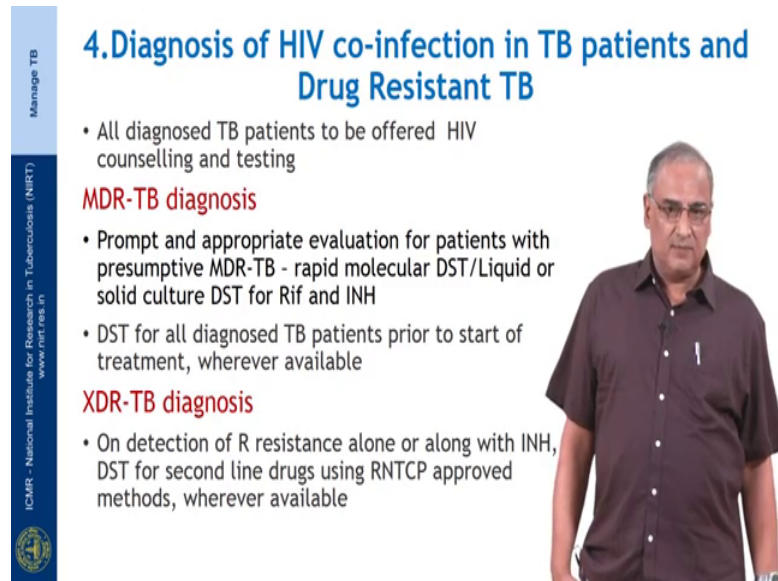
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The slide features a vertical blue bar on the left with the text 'ICMR - National Institute for Research in Tuberculosis (NIRT)' and 'www.nirt.res.in'. To the right of the bar is the title '3. Testing for extra-pulmonary TB' in blue. Below the title is the text 'For all patients with presumptive EPTB, appropriate specimens from the involved sites for' followed by a bulleted list of diagnostic methods: 'Microscopy', 'Culture', 'Drug sensitivity testing (DST)', 'CB-NAAT/molecular test', and 'Histo-pathological examination'. On the right side of the slide is a photograph of a man with glasses wearing a dark purple short-sleeved shirt.

In the testing for extra pulmonary tuberculosis all patients having presumptive extra pulmonary tuberculosis, we need to take appropriate specimens from the involved sites and these specimens are examined by microscopy, culture is performed on them, as a drug sensitivity testing, CB-NAAT and Histo-pathology.

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4. Diagnosis of HIV co-infection in TB patients and Drug Resistant TB


- All diagnosed TB patients to be offered HIV counselling and testing

MDR-TB diagnosis

- Prompt and appropriate evaluation for patients with presumptive MDR-TB - rapid molecular DST/Liquid or solid culture DST for Rif and INH
- DST for all diagnosed TB patients prior to start of treatment, wherever available

XDR-TB diagnosis

- On detection of R resistance alone or along with INH, DST for second line drugs using RNTCP approved methods, wherever available



The fourth standards deals with the diagnosis of the HIV co infection in TB patients as well as of drug resistant tuberculosis. Now all persons diagnosed with TB patients should be offered HIV counseling. For simple reason that tuberculosis happens to be the most common opportunity diagnostic infection in HIV infected individuals; the diagnosis of MDR TB.

So, in the for the diagnosis of MDR TB a prompt and appropriate evaluation for patients with presumptive MDR TB should be done and this evolve specially a rapid molecular DST or liquid or solid culture DST for rifampicin and INH resistance and where possible DST has to be done for all diagnosed TB patients prior to start of therapy.

XDR-TB diagnosis; on the detection of rifampicin resistance along with INH resistance or alone DST for second line drugs using RNTCP upload methods are done wherever it is available.


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5. Probable TB

- Presumptive TB patients without microbiological confirmation but with strong clinical and other evidence can be considered as probable TB
- Attempt to obtain culture on appropriate specimen when they are found to be negative on rapid molecular test



Standard 5 defines the category of probable tuberculosis. Presumptive tuberculosis patients without microbiological confirmation but with strong clinical or the evidence are considered as probable tuberculosis. Here we should try to obtain culture on a appropriate specimen when they are found to be negative on a molecular test.


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6. Pediatric TB

- **Diagnosis of pediatric TB** - Quality assured diagnostic test, preferably CB-NAAT, smear microscopy or culture in respiratory specimens of presumptive pediatric TB
- **Diagnosis of Probable pediatric TB**
 - Negative or unavailable microbiological results
 - Abnormalities consistent with TB on radiography, a history of exposure to PTB case, evidence of TB infection (positive TST) and clinical findings suggestive of TB
- **Pediatric extra-pulmonary TB** - Appropriate specimens from the presumed sites of involvement for rapid molecular test, microscopy, culture, DST and histo-pathological examination

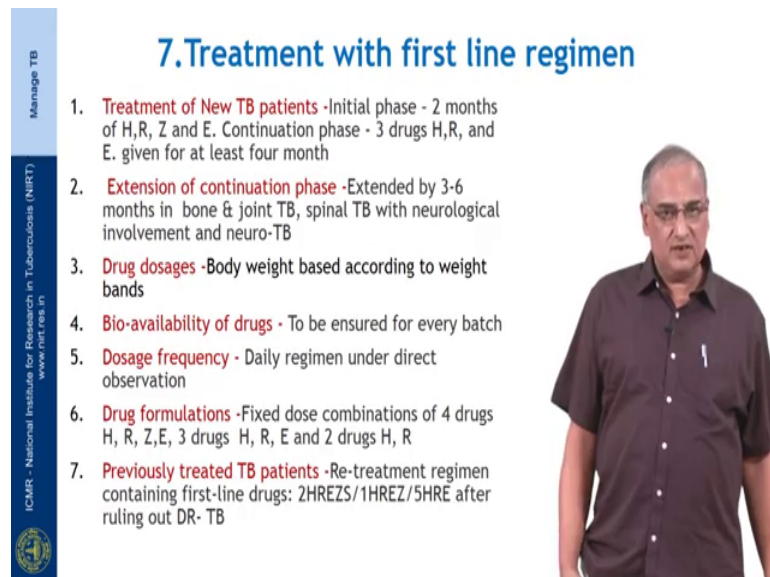


Standard 6 deals with pediatric tuberculosis; In the diagnosis of pediatric TB a quality assured diagnostic test preferably CB-NAAT, smear microscopy or culture in respiratory specimens is done in presumptive pediatric tuberculosis. In the instance of probable

pediatric TB, the situation arises when the microbiological results are either negative or unavailable and where abnormalities consistent with TB are seen on radiography, a history of exposure to pulmonary tuberculosis cases present or there is evidence of TB infection in the form of a positive tuberculin skin test and clinical findings which are present suggest tuberculosis.

Pediatric extra pulmonary tuberculosis like in adult extra pulmonary tuberculosis, we need an appropriate specimen from the presumed site of involvement for examination by a rapid molecular test, by microscopy, culture, DST and histo-pathological examination.

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7. Treatment with first line regimen

1. **Treatment of New TB patients** -Initial phase - 2 months of H,R, Z and E. Continuation phase - 3 drugs H,R, and E. given for at least four month
2. **Extension of continuation phase** -Extended by 3-6 months in bone & joint TB, spinal TB with neurological involvement and neuro-TB
3. **Drug dosages** -Body weight based according to weight bands
4. **Bio-availability of drugs** - To be ensured for every batch
5. **Dosage frequency** - Daily regimen under direct observation
6. **Drug formulations** -Fixed dose combinations of 4 drugs H, R, Z,E, 3 drugs H, R, E and 2 drugs H, R
7. **Previously treated TB patients** -Re-treatment regimen containing first-line drugs: 2HREZS/1HREZ/5HRE after ruling out DR- TB

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Standard 7 deals with treatment with the first line regimen; Here again you would have been well acquainted with the previous module should have told you about treatment in details. So, I will just go through it in a rapid manner. The treatment of new TB patients you all know consists of initial phase of 2 months with 4 drugs and a continuation phase with 3 drugs given for a period of 4 months.

Extension of continuation phase is extended in the case of bone and joint TB, spinal TB and neurological TB, the extension could be by 3 to 6 months. Drug dosages usually body weight based this is based on weight bands. Bio-availability of these drugs have to be ensured and their frequency of administration is daily. Fixed drug formulations are now available and this are combination of either 4 drugs, 3 drugs or 2

drugs and these are now recommended for you to use in the treatment of tuberculosis patients.

Now, in the instance of previously treated TB patients re-treatment regimen introduces streptomycin for the first 2 months and subsequently we have another 5 stages of total duration of 8 months of treatment.

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The slide is titled "8. Monitoring treatment response" and contains a list of six points. To the right of the list is a photograph of a man in a dark shirt. The slide also features a vertical blue bar on the left with the text "Manage TB" and "ICMR - National Institute for Research in Tuberculosis (NIRT) www.nirt.res.in".

1. **Follow up sputum microscopy** -New/re-treatment PTB - one specimen at completion of intensive phase and at end of treatment
2. **Extension of intensive phase** - Not recommended
3. **Offer DST in follow up sputum positive cases** - at any time during treatment - DST for HR DST for Ofloxacin and Kanamycin if R - resistant
4. **Response to treatment in EPTB** -Assessed clinically, radiologically and other relevant investigations
5. **Response to treatment in children** - Assessed clinically, radiologically and other relevant investigations if unable to produce sputum
6. **Long- term follow up** -Clinical and/or sputum examination at 6 &12 months after treatment completion

Now, in the monitoring of treatment responses; this is done by a follow up sputum microscopy where in both new and re-treatment PTB-one specimen is taken at completion of intensive phase and one at the end of treatment phase. Extension of the intensive phase is not recommended and where there is a culture positivity we offer DST for INH and rifampicin resistance and where such is detected we also to DST for Ofloxacin and Kynamycin resistance.

Now, the response to treatment in extra pulmonary TB is primarily clinical with support from radiological and other investigations. Likewise, the response to treatment in children assessed clinically, radiologically and with other relevant investigations. Long term follow up is advocated in the form of clinical and sputum examination which is done at 6 months and 12 months following treatment.


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9. Drug resistant TB management

- 1. Treatment of M/XDR-TB (or R resistant TB)**
After confirmation by quality assured test
Treated with quality assured second-line anti-TB drugs
- 2. Model of care for drug resistant TB**
Mainly ambulatory
Short initial hospitalization period, if required
- 3. Regimen for MDR - TB**
 - At least four drugs (second line) to which the organisms are susceptible, or presumed susceptible
 - At least a later-generation fluoroquinolone (levofloxacin) and an aminoglycoside (Kanamycin or Amikacin)



Now, standard 9 deals with the management of drug resistant tuberculosis, treatment of MDR and XDR-TB. So, this is primarily done after confirmation by a quality assured test and the treatment is carried out with quality assured anti-TB drugs.

The model of care is primarily ambulatory and a short initial hospitalization period is done if it is felt necessary. The regimen for MDR TB uses at least 4 drugs that are second line drugs to which the organisms are susceptible or presumed to be susceptible and at least one later generation fluoroquinolone and aminoglycoside are added to the regimen.


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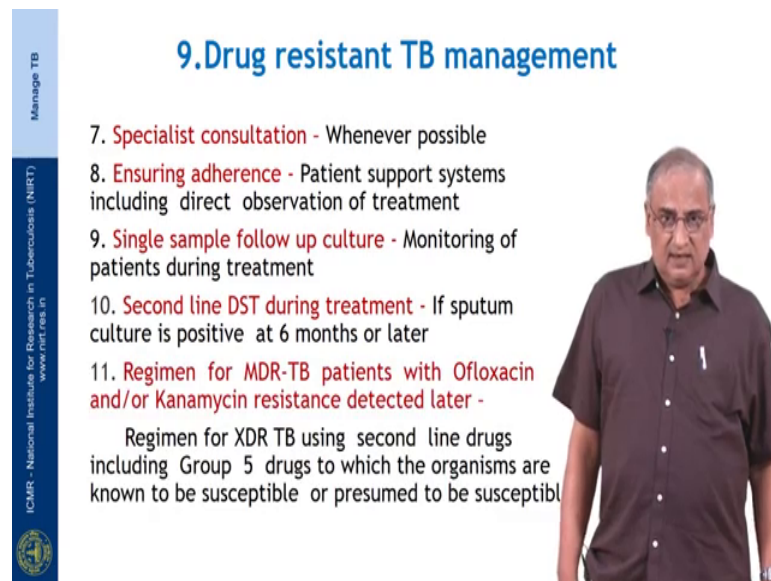
9. Drug resistant TB management

- 4. Regimen for MDR-TB with O and/or K resistance detected early** -Modify regimen during early intensive phase, preferably not later than 4 - 6 weeks
- 5. Evaluate for surgery** -At initiation of treatment and/or during follow up
- 6. Treatment duration in MDR-TB** -At least 24 months in new MDR- TB patients with intensive phase of treatment of 6 - 9 months



The regimen for MDR-TB where there is Ofloxacin or Kanamycin resistance when detected early. The regimen has to be modified during the early intensive phase preferably not later than 4 to 6 weeks. Every patient should be evaluated for surgery at initiation of treatment and during follow up and the treatment duration for MDR TB is at least 24 months with the intensive phase being of 6 to 9 months.

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9. Drug resistant TB management

7. **Specialist consultation** - Whenever possible
8. **Ensuring adherence** - Patient support systems including direct observation of treatment
9. **Single sample follow up culture** - Monitoring of patients during treatment
10. **Second line DST during treatment** - If sputum culture is positive at 6 months or later
11. **Regimen for MDR-TB patients with Ofloxacin and/or Kanamycin resistance detected later -**
Regimen for XDR TB using second line drugs including Group 5 drugs to which the organisms are known to be susceptible or presumed to be susceptible

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A specialist consultation is done wherever it is possible and patient adherence to the treatment is necessary more so as the duration of treatment is long. Sample follow up of culture is done as a form of monitoring of patients during treatment and if the sputum culture is positive at 6 months or later a second line DST is performed.

Now, the regimen for MDR TB patients with Ofloxacin and a Kanamycin resistance which is detected late, here the regimen for XDR TB is used where second line drug including group 5 drugs are added to which the organisms are either known to be susceptible or presumed to be susceptible.

With this we come to the end of session one of this topic.

Thank you for your attention.