Minutes of the Seventh National DOTS-Plus Committee Meeting

LRS Institute, New Delhi, 11th and 12th July 2011

The 7th meeting of the National DOTS Plus Committee was held on 11th – 12th July 2011 at the Conference Hall, 2nd Floor, OPD Building, LRS Institute, New Delhi. The list of participants is at Annex-I.

Day 1 – 11th July 2011

Dr Ashok Kumar, DDG (TB) welcomed all the participants and informed about the re-constitution the National DOTS Plus Committee. He informed that the tenure of this committee will be at least 3 years and it will meet at least twice in a year or more, if required. He shared the revised scope of work and terms of reference of the committee. DDG-TB also informed about the encouraging progress in scaling up of DOTS Plus activities in the last one year. He highlighted that scaling up of quality services to prevent and manage M/XDR TB has been taken as the focus in the 12th five year National Strategic Plan (2012-17) by the planning commission's working group on communicable diseases as well as CTD and requested the committee to provide the technical guidance to the programme. He also informed that due to unavoidable circumstance, Dr SK Jindal, Chairman of the committee has conveyed his inability to participate in the meeting and requested Dr Behera to Chair the meeting.

Dr Behera, thanked DDG TB and extended a warm welcome to all the members to the meeting at LRS institute. He highlighted that there are 99,000 estimated MDR TB cases emerging annually in the country and the practical challenges in scale up of DOTS Plus services are enormous. However, under the new leadership and vast public health experience of Dr Ashok Kumar (DDG TB), he expressed confidence that the programme will be able to achieve quality scale up of DOTS Plus Services across the country in phased manner. He stressed that the slow pace of the laboratory scale up plan will pose a challenge. He also expressed the concern that clinicians are facing with service delivery to the MDR TB cases hailing from the districts and states that are yet to be covered under RNTCP DOTS Plus Services and emphasized on the need on linking up these states with no lab capacity with accredited laboratories in the country to address the issue of partial and inequitable access to quality services till nation wide scale-up envisioned is achieved. He added that sustaining the quality of accredited laboratories, further building their capacity to conduct quality assured second line DST, scaling up rapid newer diagnostic tests like LPA, exploring future technologies like GeneXpert and exploring legislative measures to prevent irrational use and abuse of anti-TB drugs are other challenges that the committee need to advise the CTD on ways to address them. He requested the committee members to deliberate and give strong recommendations to the programme over the next two days.

This was followed by a presentation on **"Status of DOTS Plus Implementation in India" by Dr Sachdeva, CMO, CTD**. It was informed that as on March 2011, 27 C-DST Labs are accredited for Solid C-DST that includes 19 Govt Labs (4 NRLs + 15 IRLs) and 8 other sector laboratories. Moreover, 4 C-DST labs are currently providing diagnostic services for MDR TB suspects using Line Probe Assay (LPA). At the end of 1st quarter 2011, 15 States are implementing DOTS Plus services to cover ~331.5 million (26%) population in 150/658 (23%) districts. The remaining states are preparing to initiate services before the end of 2011. Also, 16/658 (2.4%) districts from AP (1) and Maharashtra (15) have switched to MDR TB suspect criteria of all S+ RT cases in 1Q'11 under CTD's intimation. Since the inception of DOTS Plus services in India, a cumulative total of 22695 MDR TB Suspects have been examined for diagnosis; 6069 MDR TB cases (27%) have been confirmed and 4217 MDR TB cases (69%) have been initiated on Category IV treatment through 25 DOTS Plus Sites. Of the 1426 MDR TB cases registered on CAT IV treatment up to 4th quarter 2009, only 756 (53%) cases were alive, on treatment and culture negative at 12 months after treatment initiation. This was due to the fact that 168 (12%) remained culture positive and 186 (13%) had died at 12 months after treatment initiation; however 180 (13%) had defaulted treatment, 132 (9%) had culture results not known. It was informed that the underperforming states were directed during the recent RNTCP Bi-annual Review meeting to pay urgent attention and further analyze the reasons and

institute corrective actions especially to ensure timely follow up cultures of all MDR TB cases and intensify prompt retrieval actions of patients interrupting treatment. The treatment outcomes of MDR TB for the initial pilot sites in Gujarat and Maharashtra showed that out of the cumulative total of 182 MDR TB Cases registered for treatment 31-33 months earlier (3Q07-3Q08), 83 cases (46%) have been successfully completed treatment while 36 cases (20%) died, 25 cases (14%) failed and 37 cases (20%) defaulted treatment. It was informed that the CTD is intensively reviewing the status of DOTS Plus scale up in various states against the state plans submitted in November 2010. All the preparatory states have been directed to complete their state appraisals for the first phase or the immediate next phase as applicable and send request for CTD appraisal by mid July 2011. Also, review of progress by states in DOTS Plus scale-up activities against the state scale up plans will be conduced along with STOs, STDC Directors and RNTCP State HQ Consultants in the month of August 2011 and on quarterly basis thereafter.

The presentation was followed by a discussion in which the following points were highlighted.

- In response to the query by Dr Singla on the estimates of MDR TB for India, it was informed that although 99,000 (73,000 in S+ve) MDR TB cases emerging annually as per WHO estimates, the MDR rates based on Drug Resistance Surveillance of Gujarat has been applied to the WHO estimates of incident TB cases, there is likely to be upward revision of TB estimates and eventually MDR TB estimates based on the recent national epidemiological consultation held by CTD with national and international experts. Dr Sachdeva also clarified that out of these estimated cases, ~ 30 – 35 thousand cases are detectable under the programme and that's the priority while further strategies are needed to be evolved to capture cases outside the programme.
- In response to the query by Dr Sarin on whether any prevalence estimates of MDR TB are available for India, it was informed that there are no prevalence estimates as DST in community based prevalence surveys is not yet a policy. However, two estimates are likely to be introduced by WHO that includes i. MDR TB detectable by the programme and ii. MDR TB cases emerging annually.
- In response to the concern raised by Dr Behera on why the whole states are not yet covered under RNTCP DOTS Plus programme, it was informed that the critical limiting issues are the challenges of procurement of quality assured second line anti-TB drugs, variations in laboratory capacity to diagnose MDR TB and identification and up-gradation of DOTS Plus Sites within the states. The programme has taken a graded approach of scale up by geography and suspects criteria aligning it over time with the expected availability of drugs and laboratory capacity. The quality of preparatory activities is also ascertained by CTD for every district and state through the DOTS Plus central appraisal systems and periodic checks by CTD. Many states are not yet ready and proceeding slower than planned, CTD is supporting them to expedite their preparations. This has been the core issue of review with STO and Consultants at the recent RNTCP Bi-annual Review meeting and another series of state wise meetings is planned in August / September '11. DDG –TB stressed that phase wise expansion is the ideal approach to ensure quality scale-up of DOTS Plus services.
- In response to the query by Dr Sarin if CTD will allow the states that have capacity to purchase second line anti-TB drugs to do so themselves, it was clarified that national-level procurement of quality assured drugs is a key principle of TB control programmes, and that has not changed with DOTS Plus. Except in exceptional circumstances (e.g. prior Kanamycin shortage, Cat V drugs where national specification not previously available) local procurement of anti TB drugs is strongly discouraged under the Programme.
- In response to the query by Dr Sharma on large number of confirmed MDR TB cases (~30%) not initiated on treatment, it was informed that this information is specifically reviewed during STO Consultant's meeting where pre-treatment deaths, migration, refusal and private treatment initiation by patients due to delay in diagnosis with solid C-DST were sited as the common reasons. The national consolidation of this information is difficult as this is not part of the quarterly reports for DOTS Plus under the programme, although this has been taken up as an operational research in 4 districts of AP with support of UNION and WHO.

- The committee decided that since the treatment outcomes of the initial 5 quarters of implementation are available when a highly selected group of chronic re-treatment cases were included in the programme as MDR TB suspects, it is too early to draw any inferences from the treatment outcomes.
- In view of the nomenclature for "DOTS Plus" replaced by "Programmatic Management of Drug Resistant TB (PMDT)" at the international level and most countries of the world having adopted it, Dr Sachdeva requested the committee to take a decision on re-naming the programme accordingly.

Recommendations of National DOTS Plus Committee:

- *The committee appreciated CTD's approach of phase wise expansion to ensure quality scale-up of DOTS Plus services in various states and recommended CTD to be more aggressive on monitoring the achievements of timelines for the scale up plan by every state.*
- *CTD should not allow states to procure their own drugs as this would lead to uncontrolled expansion that can be detrimental to the quality of care under the programme. There are also issues of quality assurance of TB drugs and this may lead to further augmentation of drug resistance in the community.*
- *CTD should expedite the scale-up of the 43 C-DST Labs listed in the Lab Scale-up Plan by ensuring up-gradation and accreditation for LPA and Liquid Culture systems along with solid C-DST systems as per the planned timelines.*
- *CTD to take up a multi-centric OR to analysis of the reasons for drop-outs of MDR TB cases after confirmation of diagnosis before treatment could be initiated.*
- *CTD to start using the nomenclature "Programmatic Management of Drug Resistant TB (PMDT)" in all future communications and guidelines. The existing guidelines, records and reports may be updated accordingly.*

The **National DOTS Plus Scale up Plan for 2011-2012**, an operational plan developed by consolidating the state wise DOTS Plus micro-plans developed during the series of meetings with 35 states organized by CTD at New Delhi in November 2010, was **presented by Dr Malik Parmar, WHO RNTCP Consultant – Drug Resistant TB (CTD)**. The salient messages from the presentation are summarized as follows:

- The RNTCP response to MDR TB was reiterated stressing the importance of prevention of MDR TB through sustained high-quality DOTS implementation, promoting rational use of anti-TB drugs and implementation of infection control measures. The RNTCP response to stop transmission of MDR TB include improving lab capacity for rapid diagnosis of MDR TB, effective treatment of MDR TB, initiation and rapid scale up of services and evaluation of the extent of second-line drug resistance and management strategies.
- The RNTCP DOTS Plus Vision was also reiterated as follows:
  - By 2011, RNTCP Category IV services will be introduced in all states with complete geographical coverage by 2012
  - By 2012-13, access to laboratory based quality assured MDR-TB diagnosis and treatment for
    - all smear positive re-treatment TB cases and
    - new cases who have failed an initial first-line drug treatment
  - By 2015, access to MDR-TB diagnosis and treatment for all smear positive TB (new* and re-treatment) cases registered under RNTCP early during their treatment
  - RNTCP plans to initiate at least 30,000 MDR cases on treatment annually by 2013
- The plan for patients to be tested and treated for MDR TB from 2010 – 2015 based on RNTCP 2012 goal of MDR diagnosis for all S+ retreatment patients was shared with the participants. It was informed that the National scale up plan was developed to ensure testing of the planned 1,12,000 suspects and enroll 23,000 planned MDR TB cases on treatment in the year 2011-2012 through 120 DOTS Plus sites upgraded to airborne infection control standards planned to be made functional across the country (@ 1/10 million population).
- The scaling up of services based on MDR TB suspects criteria as the districts / states move towards universal access used during the planning meetings are as follows:

- Criteria A (Currently used) = Failures of New Pulm. TB Cases, Failures and Non-Converters of S+ve Re-treatment Pulm. TB Cases and Smear Positive Contacts of confirmed MDR TB cases
- Criteria B (Next Level) = All Smear Positive Re-Treatment Pulm. TB cases registered for treatment (Relapse, TAD, Failure and Others)
- Criteria C (Universal access) = All Smear Positive Pulm. TB Cases (New* and RT) registered for treatment early during their treatment

- The Outputs of the National Scale up plan were presented as follows:
  - Scale-up by Geography and Suspects Criteria (Jan 2011 – Dec 2012)
    - It is planned to test 131516 MDR TB suspects and initiate treatment for 24326 MDR TB cases cumulatively over a period of 2 years (2011-2012) with an exponential increase over 8 quarters.
    - It is planned to rollout services in at least one district in all 35 states in the year 2011. The scale up by geography and suspects criteria is described in the table below:

Active	**2010**	**2011**	**2012**
States*	12	35	35
Total Districts	140	390	605
Criteria A	139	246	319
Criteria B	1	141	251
Criteria C	0	3	35

* States with at least 1 district implementing

  - MDR Cases v/s Drug Envelop (Jan 2011 – Dec 2012)
    - As per the consolidated plan, the enrollment plan of MDR TB cases for treatment is 24326 over the next 2 years is aligned with the available drug course envelop of 22222 throughout the 2 years course except in the 4th quarter 2012 (after deducting the backfill requirement for patients put on treatment till Dec '10 and their further treatment till Dec ' 11), where there is a possibility of over enrolling by 2104 courses. This is driven by the fact that most of the states have planned to enroll more cases compared to their drug envelop with the exception of Gujarat. The UTs will be supplied drugs in the form of PWB from the State Drug Store of the adjoining large state.
    - The delicate balance of enrollments and drug envelops need to be maintained. The states those are likely to over enroll or under enroll against their plan need to do so with prior intimation to CTD well in advance. This need to be monitored every quarter.
  - Scale-up of Culture DST Laboratories by States:
    - As per the lab scale up plan, 43 C-DST labs will be established with enhanced capacity including rapid diagnosis through LPA and liquid culture in 33 labs.
    - The list and current status of the 43 labs for establishment of solid C-DST and LPA were discussed with the states. As on March 2011, 27 C-DST Labs are accredited for Solid C-DST that includes 19 Govt Labs and 8 other sector laboratories. Moreover, 4 C-DST labs are currently providing diagnostic services for MDR TB suspects using Line Probe Assay (LPA).
    - Over and above this, there are ~ 30 Private / Medical Colleges / ICMR laboratories identified by the states to engage with for purchase of laboratory services after these have been accredited under RNTCP.
    - Although the cumulative laboratory capacity exceeded the enrollment plan of MDR TB suspect's at the national level over the next 2 years, there are variations by states. The suspect's enrollment plans of states like Bihar, J&K, Punjab, Chhattisgarh, 8 North Eastern States will exceed their available laboratory capacity and will need to be linked to another accredited lab or purchase services from private accredited labs under RNTCP C-DST Schemes.
    - The following key policy changes made after the decision at the 19th National Laboratory Committee Meeting were reiterated with the committee members:

- Laboratories should have capacity to perform culture using conventional methods (either solid or liquid culture) before LPA accreditation process to enable examination of follow up specimens from MDR TB patients on treatment (which will be assessed by the NRL during an OSE based on the existing lab performance indicators).
- Once the infrastructure facility in the lab has been developed and assessed by the NRL, RT and PT will be completed by NRL and confirmation of satisfactory performance in proficiency testing will be communicated to CTD. It was recommended that CTD will then send the accreditation certificate electronically to the concerned lab with a copy to the NRL.
- It was suggested to accredit new laboratories only for INH and Rif initially; DST for SM and EMB can be taken in a phased manner. It was also proposed to make routine DST for HROK (Isoniazide, Rifampicin, Ofloxacin and Kanamycin) instead of HRES. It was decided that this may be started at IRL Ahmedabad and Hyderabad.

- Scale-up of DOTS Plus Sites by States:
  - As per RNTCP norm, every state need to establish a DOTS Plus Site while larger states have to establish DOTS Plus sites @ 1/10 million population. The UTs may be linked up to the neighboring large state.
  - The states of Uttar Pradesh, Bihar, Tamil Nadu, Andhra Pradesh, Maharashtra, Karnataka, Rajasthan, Gujarat, Haryana, Orissa, Punjab and West Bengal have planned DOTS Plus Sites less than their eligibility based on population norm. These states need to submit the final list of DOTS Plus Sites to CTD.
  - At the same time, the states of Delhi, Meghalaya, Arunachal Pradesh, Himachal Pradesh, Manipur, Jammu & Kashmir and Uttarakhand have planned DOTS Plus Sites more than their eligibility based on population norm. These states also need to reconsider the number of sites and the state need submit the final list of DOTS Plus Sites to CTD within the next 15 days with justification of excess number proposed.

- Demand for National DOTS Plus Training due to the scale up plan:
  - The national scale up plan will pose a huge demand on the national training activities. CTD has worked out the following strategy to meet these demands:
    - Developed 4th National DOTS Plus Training Centre at Trivandrum, Kerala in Dec ‘10
    - Training batches arranged @ 2 per month with batch size ~ 40 (240 trainees / quarter)
    - Apart from CTD and National Institutes, trainers from experienced states (DP Site Committee, STDC, WHO Consultants) identified as national facilitators.
    - Developed annual training calendar and monitor progress
    - State to send their requests for training as per plan and ensure complete participation of nominated candidates at the national trainings.
  - Since Dec ’10, 14 national training batches have been arranged where ~ 520 key staffs were trained. The state teams and phase 1 districts of all remaining preparatory states were trained up to Feb ’10, giving each state a decent 10 months time to roll out services in 2011 as per the RNTCP vision.
- Demand for National DOTS Plus Appraisals due to the scale up plan:
  - The national scale up plan will also pose a huge demand on the national DOTS Plus appraisal activities. CTD has worked out the following strategy to meet these demands:
    - CTD Appraisal format simplified and normative guidelines (like CIE) developed
    - Core Group developed to conduct Appraisals – STOs, STDC Directors, DP Site Committee, WHO Consultants and External Resources from Partners.
    - DO sent from CTD to states to fast-track lab accreditations, civil works for DP Sites (AIC), SDS, DDS and HRD.
    - State appraisals of all districts and its compliance before CTD appraisals
    - Develop CTD appraisal matrix and calendar
    - Arrange Multiple team of Core Group members to conduct simultaneous appraisals

- The committee was informed about the following key action points directed to all States during the RNTCP Bi-annual STO Consultant's meeting for the next 2 quarters:
  - Preparatory states to roll out services after CTD appraisal and approval in 2011 (if required with external lab linkage)
  - States to ensure geographical expansion including switch to LPA for diagnosis and from criteria A – B as planned under intimation of CTD
  - Check resources (lab capacity, drugs available) before switching suspect criteria
  - Fast track all preparations specified in the DO from DDG TB sent to all states on 10th May 2011 (lab accreditations / linkage, civil works for DP Sites [AIC], SDS, DDS and HRD)
- The committee was also informed about the following opportunities to scale up DOTS Plus services in various states as planned:
  - Diagnosis by LPA wherever available - now a policy endorsed at 19th Lab Committee meeting
  - Labs performing Solid Culture with LPA Accreditation completed, can start service after appraisals of districts linked along with the process of Solid DST proficiency testing
  - Checklist for Switch to LPA and Criteria B developed
  - National DOTS Plus Trainings
    - 4th Training centre developed at Kerala
    - National Training calendar developed
    - All preparatory states (Phase 1) trained by Feb 2011
  - Drugs being procured as planned
    - For 2011 - 8000 courses being delivered in tranches
    - For 2012 – 15000 courses approved by GLC. Order being placed
  - Guidelines for SLD Storage Amended – Install A/C at SDS and DDS
- The states were also informed that they need submit their request for CTD appraisal of districts by phases as per their state plans, as the slow pace of requests from states for CTD appraisals may pose a threat to the timely scale up DOTS Plus services in the country.
- It was informed that all states were directed to take the necessary administrative and technical approval of their respective state DOTS Plus scale up plans submitted to CTD with their respective State officials like PHS, DHS, MD NRHM and discuss the plan with the State DOTS Plus Committee, Site Committees and DTOs.

The presentation was followed by a discussion in which the following points were highlighted.

- The committee appreciated the efforts taken by CTD in this kind of a planning exercise which was the need of the time to give proper direction to the national DOTS Plus scale up activities.
- In response to the concerns raised by Dr Behera about the delays in North Eastern States, DDG suggested to hold special DOTS Plus review meeting by CTD with all North Eastern States and requested STO Assam to organize the same at Guwahati on 28th – 29th July 2011.
- In response to the query by Dr Sharma on whether the decision on laboratories performing solid culture with LPA accreditation can start service along with the process of solid DST proficiency testing applies to the laboratory at AIIMS, it was clarified that the decision is applicable to AIIMS and as soon as CTD issues the LPA Accreditation certificate to AIIMS Lab, a set of DOTS Plus implementing districts will be linked for diagnosis and follow up services by STO Delhi.
- In response to the query by Dr Sharma on the status of pilot implementation of Guidelines on Airborne Infection Control in Health Care and other settings, the committee was updated that the provisional guidelines were disseminated to all states and hosted on the TBCINDIA website with directives to prioritize implementation in high risk settings like MDR TB wards (DOTS Plus Sites), ART Centers, TB C-DST Laboratories etc; the baseline facility AIC risk assessments are completed in all 35 facilities of the 3 pilot states and the reports are under approval of

ministry, the guidelines were shared with all medical colleges through the series of Zonal Task Force and National Task Force workshops in 2010 and the summary recommendations of the AIC guidelines are presented and discussed in all National DOTS Plus Training batches.

- In response to the query by Dr Behera and Dr Sharma on including of more culture and DST laboratories under RNTCP from the microbiology department of various medical colleges, it was informed that the programme has been encouraging medical colleges with adequate C-DST capacity to apply for accreditation. It was reiterated that over and above the 43 C-DST Laboratories, there are ~ 30 more laboratories from Medical College, Private Sector and ICMR proposed in the state plans that the programme is considering for accreditation.
- In response to the query by Dr Behera and Dr Sharma on the role of LPA when newer automated diagnostics like XpertGene gets established, it was informed that the programme is planning to undertake a field demonstration study of XpertGene at sub-district level in India in the year 2011-12 to establish the resources required for its introduction, stability of the equipment in the country's climatic conditions, its positioning in the diagnostic algorithm under the programme settings. It was further informed that the cost per LPA test is much less compared to XpertGene and Second Line DST is possible with LPA. Moreover, automated LPA is being developed although it is yet to be endorsed by WHO.
- In response to the query by the members on how MDR TB estimates were calculated, it was informed that the current estimates of India are based on the state representative Drug Resistance Surveillance of Gujarat states. It was further informed that the DRS survey of AP has been completed and the results will be published shortly while DRS Survey of Western UP is being conduced by JALMA. Also, the DRS surveys will be taken up in Tamil Nadu and Rajasthan in 2011 and in Madhya Pradesh and West Bengal in 2012.
- The committee cautioned CTD on the possibility of influx of large number of patients from the private sector on rolling out suspect Criteria B i.e. suspecting MDR in S+ve re-treatment cases during diagnosis. STO AP shared the experience of rolling out suspect Criteria B in Hyderabad where although the suspects load increased by 10 folds and MDR TB cases were diagnosed by 4 folds compared to suspects Criteria A i.e. all failures and S+ve contacts; it was difficult to determine the proportion of influx from the private sector. However, the suspects actually examined were close to the estimates indicating that the influx from private sector may not be high as anticipated.

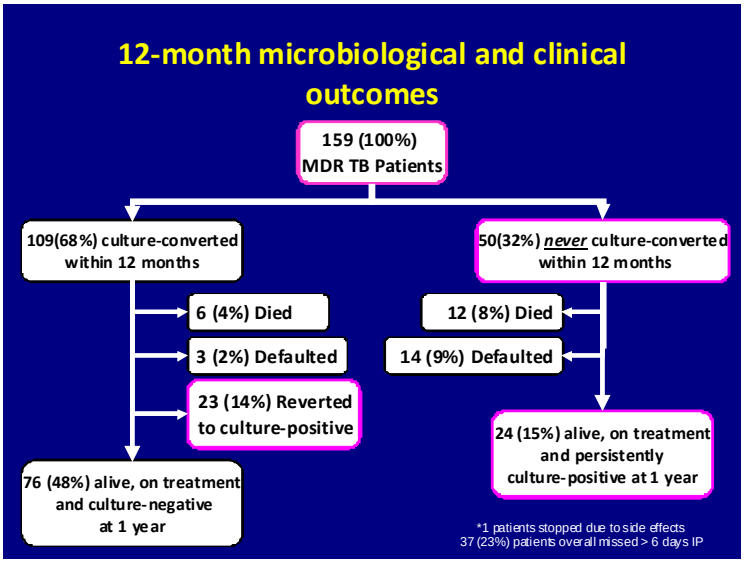
Recommendations of National DOTS Plus Committee:

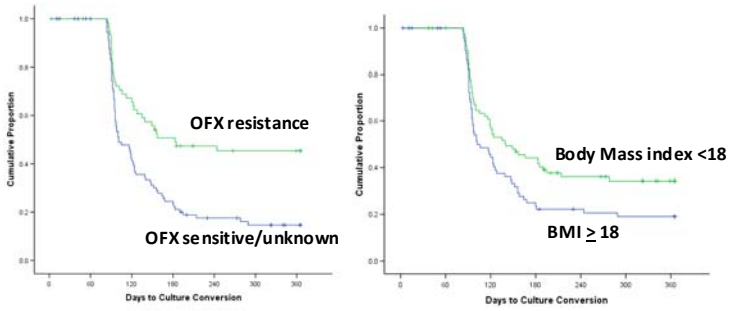
- *The National DOTS Plus Scale up plan for 2011-12 is endorsed by the committee and it must be formally documented, published and widely disseminated by CTD.*
- *The National DOTS Plus Scale up plan for 2011-12 should be sent to all states requesting them to adhere to the timelines for completion of all critical preparatory activities including CTD appraisals as per the planned timelines to ascertain that the national scale up timelines are met.*
- *CTD should finalize the laboratory back up for all the states that are not likely to have their own state laboratory accredited in 2011-12 by linking them to the RNTCP accredited laboratories at NRLs or adjoining state IRLs or private laboratories under C-DST Scheme.*
- *CTD should closely monitor the status of accreditation of 43 C-DST Labs (including LPA and Liquid culture) against the planned timelines. Encourage more medical colleges and share guidelines to apply for accreditation.*
- *CTD should aggressively implement and monitor the roll out of quality services by every state to meet the timelines of scale up by geography and suspect's criteria as per the plan.*
- *CTD should allow small states like Goa, 7 North East states (except Assam) and all Union Territories to initiate services with Criteria B and move to Criteria C as soon as services are established on ground in these areas.*
- *CTD should take support from all national institutes like LRS, NTI, JALMA and TRC for facilitating national trainings as well as participating in CTD appraisals and all NRLs must come forward to support CTD to meet the national DOTS Plus scale-up challenges.*

- *Capacity building and accreditation to conduct Second Line DST at IRL Ahmedabad and Hyderabad to be expedited and subsequently scaled –up to all accredited laboratories in other states.*
- *The National Guidelines on Airborne Infection Control should be shared with MCI to make it an integral part of their assessment of medical colleges for recognition.*

This was followed by a presentation on "**Association of poor culture-conversion with fluoroquinolone resistance in Gujarat"** presented **by Dr RN Solanki, DOTS Plus Site, BJMC, Ahmedabad** with support from **Dr Puneet Dewan, WHO**. The salient findings from the presentation are summarized as follows:

- With poor initial microbiological outcomes in initial DOTS Plus pilot cohort that prompted detailed analysis as the rationale, a Retrospective cohort study of MDR TB patients registered Aug 2007–March 2009 was conducted with the objective to evaluate interim 12-month outcomes and risk factors for culture conversion among MDR-TB patients treated in DOTS Plus pilot project in Gujarat. Second-line drug (SLD) susceptibility testing results were provided by TRC Chennai (SNRL).
- The baseline characteristics of this cohort include 63% males, 2% HIV infected, median duration of prior treatment was 18 months, median number of prior TB treatment episodes were 3, 73% were <45 kg weight, 52% had BMI <18; 69% had cavitary disease. At baseline, 74% had HRES resistance; 40% had any Ofx resistance, 18% had any Eto resistance; 12% had Ofx and Eto resistance and 4% had Ofx, KM + Eto resistance (XDR).





– The 12-month microbiological and clinical outcomes of the 159 MDR TB Patients included in the study are shown in the adjoining flow chart. Only 48% were alive, on treatment and culture-negative while 15% were alive, on treatment and culture positive at 1 year. Moreover, 14% had reverted to culture positive after having culture converted.

- Overall 68% achieved initial culture-conversion and the median days to culture conversion was 122 days.
- The following 3 risk factors were found to have a statistically significant association with Non-Conversion ($p < 0.05$):
  - Body mass index < 18
  - Ofloxacin Resistance
  - Missed > 6 days IP treatment
- It was summarized that very high prevalence of FQ resistance was observed in initial MDR treatment cohorts. Although the numbers of patients were small, patients were highly treatment experienced and all had failed re-treatment regimen. Poor 12-month interim outcomes were observed with low initial culture conversion and high re-version. Ofx resistance, low BMI, and missing 1-week during IP independently associated with initial non-conversion.

- The extended cohort data from Gujarat was presented by Dr Solanki revealed that culture conversions continue to remain low in FQ resistance.

This was followed by a presentation on **"Results of second line drug resistance among MDR TB isolates of patients enrolling in RNTCP Cat 4 from the state of Gujarat and Andhra Pradesh being done at TRC"** presented **by Dr Vanaja Kumar, TRC Chennai**. The salient findings from the presentation are summarized as follows:

- The results of Second Line DST for 1287 MDR TB culture isolates of patients on samples received at TRC from different states (Gujarat, Andhra Pradesh, Kerala, Tamil Nadu) from January 2009 to July 2011 were presented and the findings are summarized in the table below:

Consolidated Results (All States)	Diagnostic samples (622)	DRS Samples (170)	FU samples (160)
	Nos. (%)	Nos. (%)	Nos. (%)
Kanamycin	1 (0.16)	5 (2.9)	14 (8.7)
Ofloxacin	244 (39.2)	20 (11.7)	47 (29.3)
Kanamycin+ Ofloxacin	21(3.3)	5 (2.9)	34 (21.2)
Sensitive to two drugs	356 (57.2)	140 (82.3)	65 (40.6)

- Ofloxacin mono-resistance in isolates received by TRC Chennai for diagnosis from various states was also to the tune of 39.2% that co-related with the Gujarat interim analysis in the initial MDR TB Cohort

The presentations were followed by a discussion in which the following points were highlighted.

- Dr Singla commented on the interim cohort analysis of Gujarat that the findings are also supported by LRS study that outcomes of patients with FQ resistance were as poor as that of XDR TB cases. He further added that cavitatory lesions and KM resistance can also be significant contributors; however, it needs more data for analysis.
- Dr Sharma exclaimed that the committee needs to consider treatment options for Ofloxacin resistance that is to the tune of ~40%. He further suggested that this analysis points out that the committee need to re-look at the standardized treatment regimen for MDR TB Cases (Category IV regimen) under the programme.
- In response to the suggestion for the need to further discuss the observation by Dr Sharma of 29% Ethionamide resistance seen in MDR TB culture isolates at diagnosis in Gujarat, it was clarified that Eto resistance was studied as an independent risk factor and was not found to be significantly associated with poor culture conversion.

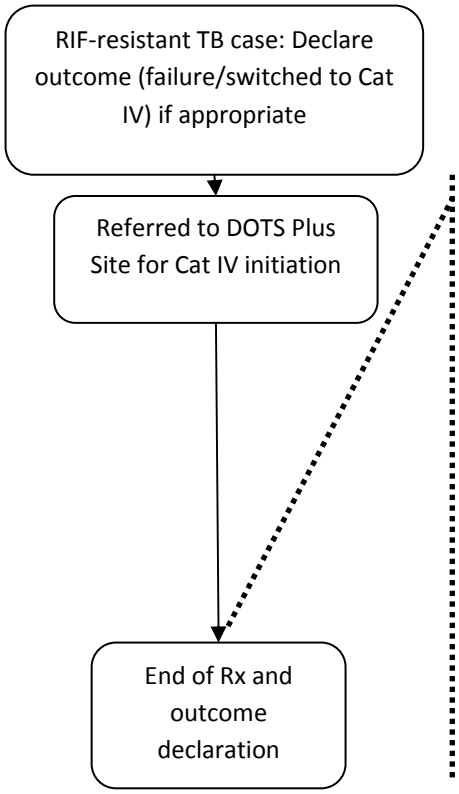
Recommendations of National DOTS Plus Committee:

- *For management of Ofx mono resistance, the committee could not reach a consensus in-spite of detailed deliberation on various permutation and combination of other reserved drugs like Moxifloxacin, High Dose INH, High Dose Levofloxacin, Clofazimine etc. It was recommended that a Sub-Committee be constituted to review the available evidences on management of Ofx mono-resistant cases and suggest alternative regimen to manage such cases.*
- *The committee revisited the standardized treatment regimen for MDR TB Cases (Category IV regimen) currently used under the programme. In view of the poor treatment outcomes observed in the initial cohorts, the high prevalence of ETO resistance at baseline, and the need to better align with international dosing recommendations, the committee recommended that the High Dose Levofloxacin (250 mg, 750 mg and 1000 mg) be considered as part of the standard regimen for all MDR TB patients to be initiated on treatment hence forth. This is clearly not an adequate response to the challenge of OFX resistance, but an optimization of the existing regimen.*
- *CTD should request DCGI to issue a formal letter to all chemists regarding the sale of Fluoroquinolones and other Antibiotics under Schedule H only on prescription of a qualified doctor. DCGI may also be requested to develop stringent mechanisms to enforce this, to avoid its abuse and irrational use to prevent development of resistance to these precious drugs.*

➢ *CTD should expedite the capacity building of the NRLs and all accredited C-DST Labs to conduct DST on Second Line Anti-TB Drugs and get accredited for SLDST under RNTCP.*

This was followed **discussion on management of MDR TB Cases with FQ/KM mono-resistance detected early during the course of MDR treatment** facilitated by **Dr Puneet Dewan, WHO SEARO.** The salient points discussed are summarized as follows:

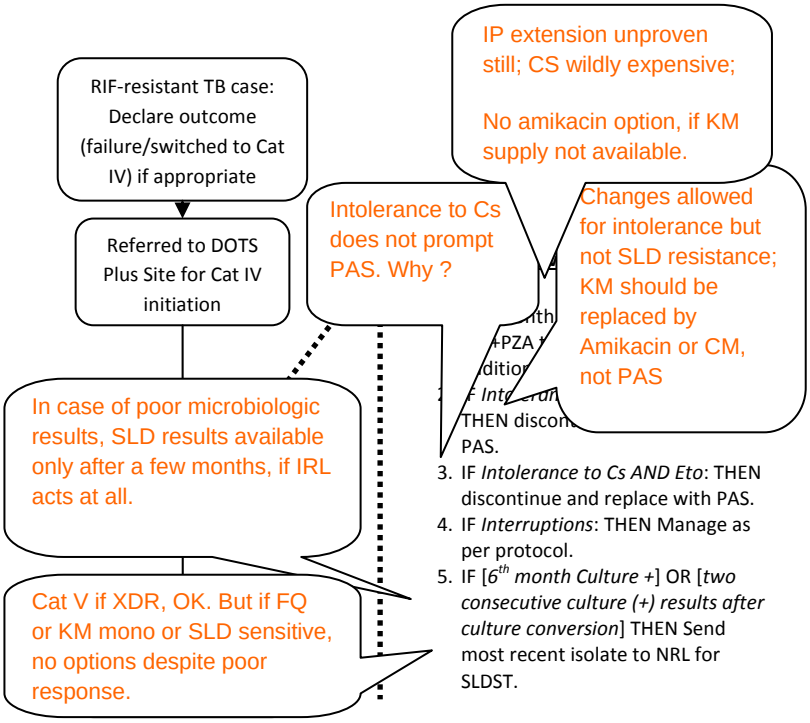
- The current RTNCP DOTS Plus treatment guidelines are depicted in the adjoining flow chart:



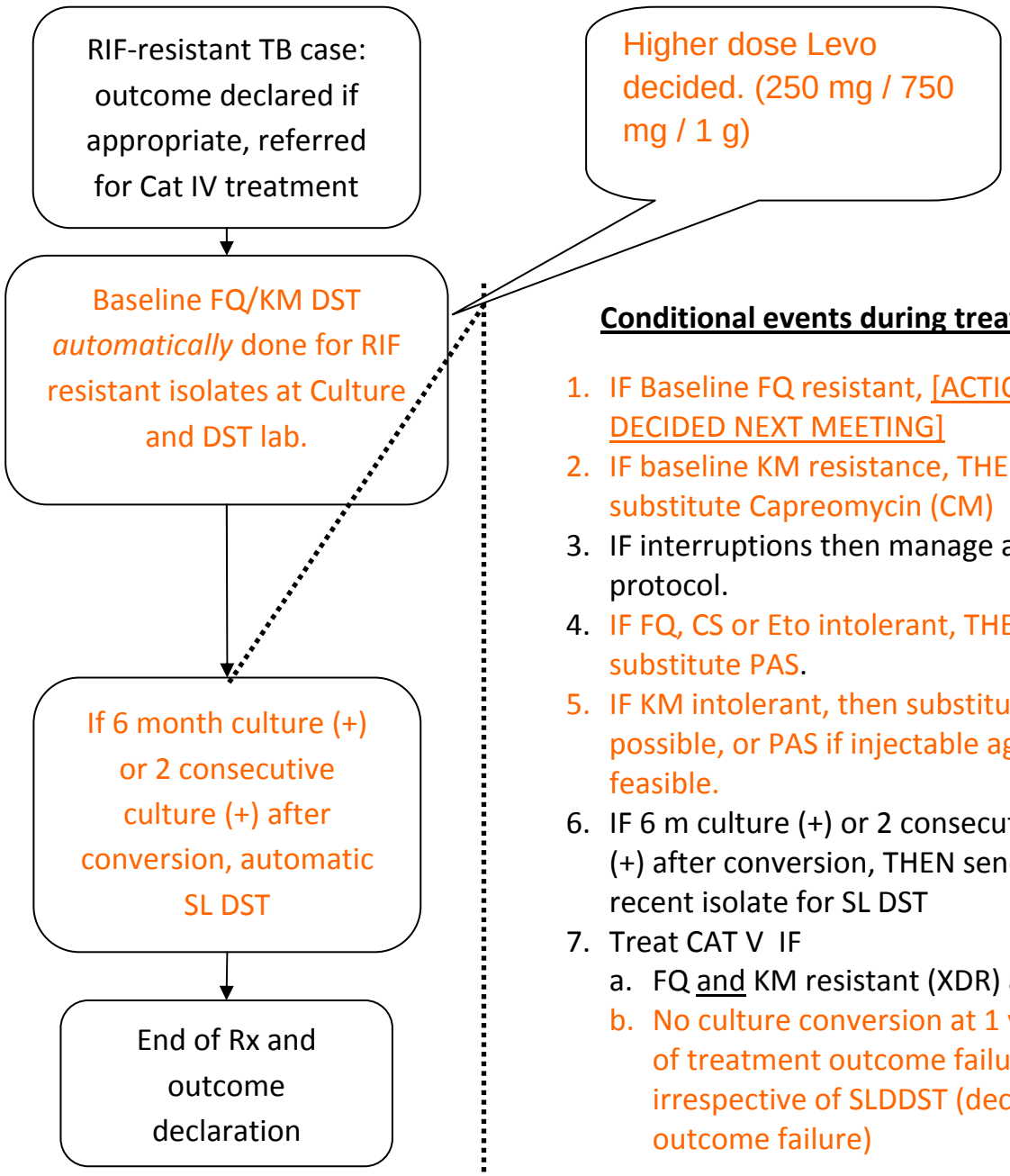
Conditional events during treatment

1. IF 4 month culture (+) THEN extend KM+PZA till culture -, up to 3 additional months.
2. IF *Intolerance to Km or Ofx or Eto*: THEN discontinue and replace with PAS.
3. IF *Intolerance to Cs AND Eto*: THEN discontinue and replace with PAS.
4. IF *Interruptions*: THEN Manage as per protocol.
5. IF [*6th month Culture +*] OR [*two consecutive culture (+) results after culture conversion*] THEN Send most recent isolate to NRL for SLDST.
   → IF [Ofx+KM] resistant THEN Cat V

- The issues with current guidelines were highlighted for discussion as per the flow chart below:



- The **possible alternative treatment algorithm** was highlighted for discussion as per the flow chart below:



The presentations were followed by a discussion in which the following points were highlighted.

- In response to the suggestion to expedite capacity building of labs to undertake SLD DST, it was clarified that this can be done however; the programme is limited by the challenges and capacity of procurement of quality assured second line drugs and management of XDR TB.

Recommendations of National DOTS Plus Committee:

- *Capacity of NRLs and RNTCP accredited C-DST laboratories should be enhanced in phased manner for conducting second line DST for surveillance purpose and the committee should take a final decision on alternative regimen for Ofloxacin resistant cases. That subcommittee was suggested to address the following questions:*

- *Recommended regimen for cases with OFX resistance at baseline*
- *Recommended regimen for cases with OFX resistance in the context of persistant culture-positivity or culture reversion (i.e. consecutive positive results after culture conversion)*
- *Recommended regimen for cases with no culture conversion at 1 year or cases with end-of-treatment failure outcome, irrespective of SL DST results.*
- *Integrate above into a single 'conditional' treatment algorithm*

- *DST for HROK can be included in training and accreditation process of laboratories since the beginning.*
- *Accelerate shift to earlier diagnosis of MDR TB (Criteria A to B to C) and use of rapid diagnostics (LPA, Liquid Culture) to reduce opportunities for FQ exposure to avert augmentation of resistance among MDR TB patients.*
- *Clarify criteria for second-line DST, to include automatic SL DST for patients with positive 6 month culture isolate, or 2 consecutive culture positive results after conversion. C+DST labs will have to keep longitudinal history of patient results to be able to assess and interpret when additional testing is required.*

This was followed by a presentation on **"Follow-up cultures for MDR-TB patients – 2 v/s 1 specimens"** presented **by Dr Sharath B, WHO RNTCP Consultant – Public Health Specialist (CTD)**. The salient findings from the presentation are summarized as follows:

- The 17th Lab committee meeting recommended to undertake a brief OR to assess the impact of a reduction in the number of follow up sputum specimens from 2 to 1 for MDR-TB patients. Thus, a retrospective record review study was undertaken at CTD to assess the sensitivity and negative predictive value of single specimen strategy, by analyzing the results of follow-up culture (by month) of specimen A and B (positive, negative, contaminated and NTM or unknown for other reasons) for 2372 patients from the primary culture registers of 7 IRLs for a period from 4Q09 to 1Q10.
- The results of A and B samples were found to be similar in all types of results (positive, negative and contaminated)
- Further analysis showed that Sensitivity and Negative Predictive Value of single "A" specimen strategy are 82% and 96.5% respectively with minor increase of instances requiring resubmission of specimens. However, the overall lab specimen processing workload reduced by ~33% in proposed policy that would *increase* laboratory capacity for diagnosis of MDR TB.

The presentations were followed by a discussion in which the following points were highlighted.

- In response to the query by Dr Sarin on disaggregate information b/w IP and CP follow ups and spot or morning specimen, it was clarified that the study was record based and these specific points were not considered during the analysis. Moreover, although by convention "A" sample is spot and "B" is morning sample, it is difficult to ascertain from the records as this information is not recorded in the lab register. He suggested that if the committee considers shifting to one sample for follow up, it should be a morning sample.
- In response to the query on whether liquid culture can compensate for the additional yield from a second sample in solid culture, Dr Vanaja clarified that colonization of other flora and hence chance for contamination is more in culture positives. Thus, with liquid culture the contaminations may lead to less effective measure compared to an additional sample.
- Dr Puneet highlighted that since there would be minority of positive results in the 2nd sample will have very little clinical impact. He further highlighted that international guidelines recommend one specimen and most countries in the world are implementing this. Moreover, operational cost of 2nd sample is very high by virtue of visit by staff, collection and transport of samples, processing of an additional sample per patient absorbing the lab capacity for diagnosis etc.

Recommendations of National DOTS Plus Committee:

- *Further evidence is required for considering reduction in the number of follow up specimen for follow up culture from 2 samples to 1 sample. This may be undertaken by CTD and presented for a decision at the next Lab committee meeting.*

This was followed by a presentation on **"Technical specification for 2nd line drug for CATEGORY V regimen for programmatic management of XDR TB"** presented **by Dr Devesh Gupta, CMO, CTD**. The salient messages from the presentation are summarized as follows:

- The RNTCP Guidelines for diagnosis and management of XDR TB as well as the Category V treatment regimen, dosages of the second line drugs in the two weight bands that was developed and approved at the 6th National DOTS Plus Committee meeting was reiterated.
- The constitution of the Technical Committee for formulating the Technical specifications and the specifications developed by the committee in terms of description of drugs as per international pharmacopeia, labeling on vials/tablets/capsules as well as on millboard / greybeard box including warning required for "Schedule H Drug" to confirm to the requirements under Rule 96 of Drugs and Cosmetic Act; storage and shelf life requirements were shared with the committee as per the table below:

Sr. No	Drug	Strength	Shelf-life	Storage Conditions
1	Capreomycin Injection	1000 mg	24 months	Store protected from moisture at a temperature not exceeding 25 degree C.
2		750 mg		
3		500 mg		
	Sterile water for injection	5 ml		Store in a single dose container in a cool, dry place.
4	Moxifloxacin Tablet	400 mg		
5	Clofazimine Capsule IP	200 mg		
6	Clofazimine Capsule IP	100 mg		
7	Linezolid Tablet	600 mg	36 months	
8	Amoxicillin + Potassium Clavulanate	500 mg 125 mg	24 months	
9	Pyridoxine Tablet	100 mg	36 months	
10	Clarithromycin Tablet	500 mg	24 months	
11	Sodium Para Amino Salicylate Granules	100 gm container		

- The committee was appraised that the technical specifications were finalized by the Technical Committee in April, 2011 and a letter was sent to all States on 27th April, 2011 with the following directives:
    - Enclosing Tech Specs of drugs required for treatment of XDR-TB patients
    - Informing States to procure XDR drugs only through local shopping method
    - Procurement to be done using RNTCP 'Miscellaneous' Head
    - Ensure procurement through RNTCP Procurement Guidelines
- The status of procurement of SLD by both funding streams namely Global Fund and World Bank were shared with the committee. It was informed that large volumes of Cycloserine 250 mg tablets, Ethionamide 250 mg tablets, Levofloxacin 250 mg and 500 mg tablets are available in the State Drug Stores.
- The following challenges in 2nd line drug procurement through GLC/GDF mechanisms and remedial actions were discussed:

Challenges	Remedial Actions
States not implementing as per PMDT plan. Risk of drug expiry	Monitoring & transfers planned

GLC/GDF supply : Inj Km-500 mg & 1 gm and Eth-200 mg (2010-11) not being supplied – No Pre-qualified supplier	May propose procurement from GOI for these drugs
Na-PAS being made available in 9.2 gms equivalent to 4 g of aminosalycylic acid	To be put up to Tech group. Have stocks at present to last till 2013

The presentations were followed by a discussion in which the following points were highlighted.

- Concerns were raised by Dr Gaikwad, STO Maharashtra about procurement of XDR TB Drugs from miscellaneous head as per the current guidelines as it is difficult to sustain in future and requested CTD to consider provision of separate head outside miscellaneous for procurement of XDR TB drugs in the next 5 years plan. Dr Sachdeva responded that this will be considered in the National Strategic Plan (2012-17).

Recommendations of National DOTS Plus Committee:

- *CTD may have to request Global Fund to provide KM 1 gm if 500 mg is not available. However, if Global Fund is not able to supply either strengths of KM (500mg & 1gm), CTD may go ahead with GOI procurement of quality assured second line drugs through World Bank funds as the patients must receive uninterrupted supply of second line drugs.*
- *The committee agreed with increasing the dose of Ethambutol in the weight band > 45 kg from 1000 mg to 1200 mg daily. Since Ethambutol (200 mg) is required only for > 45 kg weight band, CTD may request GLC/GDF to procure equal quantity of Ethambutol (400 mg) instead of Ethambutol (200 mg).*
- *Technical specification for PAS Tablets may be developed by CTD after ascertaining the bio-availability and pharmacokinetics.*
- *CTD may make provisions in the National Strategic Plan (2012-17) to allow states to budget and book the expenditure for procurement of XDR TB drugs under the head of "Procurement of Drugs" instead of "Miscellaneous Head"*
- *CTD should consider planning and budgeting the procurement of Second Line Drugs in the National Strategic Plan – 2012-17, with national level procurement. Till then, the arrangement of local procurement of XDR TB regimen drugs by the states made by CTD may continue.*
- *CTD may develop the technical specifications for Amikacin to be used in case of Km resistance and intolerance respectively.*

Day 2 – 12th July 2011

Dr Behera invited Dr KS Sachdeva, CMO, CTD to present the "DOTS Plus Guidelines – Technical and Operational Updates proposed". The methods adopted to identify the gaps in guidelines include facilitators meeting during National Trainings held from December 2010 – April 2011 and a Core team of RNTCP Consultants from implementing districts met in April 2011 where they were allotted chapters to identify technical and operational gaps and suggest updates to overcome these gaps in the current version of the guidelines. The foreseen updates were some cross cutting updates, some chapter specific updates and including job-aides and revised PPM schemes. It was informed that the core team will again meet in August – September 2011 to incorporate the decisions taken by the committee and include the technical and operational updates in the guidelines.

The cross cutting updates were as follows:

- RNTCP PIP II provisions under RNTCP revised financial norm need to be added in relevant sections.
- Job Aides developed based on GLC Mission Recommendations being pilot tested in 4 states, to be added in relevant chapters & annexure
- Intensified TB HIV package interventions (HIV Status / CPT / ART) to be integrated in relevant chapters and all records & reports

- Standardize specifications of sample packaging with cold chain considerations and treatment boxes (Andhra Pradesh & Gujarat Models)
- Add sections on LPA/Liquid culture & transition by suspects criteria (A-B-C) towards universal access including in Records & Reports
- Replace Ofx/Lfx with Lfx alone
- Add chapter on Supervision, Monitoring and Evaluation for Preparatory and Implementing states
  - DOTS Plus Appraisals
  - Quarterly Reports
  - Track-sheets on milestones in Scale-up plans
  - Frequency & tools for supervision by cadre and supervisory checklists
  - Monitoring indicators
  - Evaluation formats etc.
- ACSM – Infection Control, Cough Hygiene, Counseling Tools
- Re-organization overall sequence of the write-up

Recommendations of National DOTS Plus Committee:

- *A separate chapter on Airborne Infection Control (a concise summary of administrative, environmental and personal protective control measures) may be added in the National DOTS Plus Guidelines with special emphasis on MDR TB ward and patient education on cough hygiene, cough etiquette and sputum disposal.*

The chapter specific updates presented were as follows:

Section: Background, Framework and Human Resources under DOTS Plus

Chapter-3: Government Commitment and Coordination

1. Composition of State DOTS Plus Committee, DOTS Plus Site Committee and proposed new DOTS Plus Site Scheme for non government institutes:

Current Guidelines	**Proposed Updates**	**Justification**
– Composition for State DOTS Plus Committee members not defined	– Composition for State DOTS Plus Committee members defined	– Clarity to states
– Formulation for DOTS Plus Site Committee members not defined	– DOTS Plus Site Committee members defined	– Clarity to states
– No scheme for DOTS Plus Site Scheme	– DOTS Plus Site Scheme for Private Medical College/Hospital/NGO proposed	– In areas with no Government facility available for DOTS Plus Site.

Recommendations of National DOTS Plus Committee:

- *The committee recommended the **Composition of State DOTS Plus Committee** as follows:*

Title	**Designated officials**
Chairperson	Principal Secretary / Secretary (Health)
Vice Chairperson	Director of Health Services
Member	Mission Director (NRHM)
Member	Director of Medical Education
Member Secretary	State TB Officer
Member	Director STDC
Member	Chairperson State Task Force
Member	Microbiologist-IRL

Members	Chairperson of DOTS Plus Site Committees in the state
Members	2 Eminent Chest Physicians.
Member	State Headquarter RNTCP Consultant
Member	1 representative each from any 2 NGOs working in TB programme.
Member	1 representative from professional bodies like IMA.

- *The committee recommended the **Composition of DOTS Plus Site Committee** as follows:*

Title	**Designated officials**
Chairperson	Medical Superintendent / Director of the institute
Vice Chairperson	HOD Respiratory Medicine / General Medicine
Member Secretary	Senior Medical Officer - DOTS Plus Site
Member	HOD Respiratory Medicine / General Medicine
Member	HOD Microbiology / IRL Microbiologist
Member	HOD Psychiatry
Member	HOD Gynaecology
Member	HOD ENT
Member	TB Coordinator of DOTS Plus Site
Member	1 Eminent Pulmonologist
Member	DTO of the district where DOTS Plus Site is located
Special Invitees	DTOs of the districts linked (as and when needed)

The chairperson can co-opt other specialist as required. The routine clinical decisions can be taken by the available doctor and informed to the DOTS Plus Site Committee in subsequent meetings.

- *The committee recommended the **Proposed DOTS Plus Site Scheme** for NGOs/Private Hospital to include the clauses as follows:*

Requirement from Institute	– It should be preferably a Tertiary Care Hospital – Separate Ward for Male & Female should be available – All the DOTS Plus services (beds, investigations and ancillary drugs for ADR) to be provided free of cost to the patient – Relevant specialties like Pulmonologist, Physician, Psychiatrist, Dermatologist & Gynecologist etc. should be available or linkages for these services are established – DOTS Plus Site Committee to be formed – National Training of DOTS Plus Site doctors in DOTS Plus (including Chairperson) – National Air Borne Infection Control Guidelines has to be implemented for up-gradation and ward SOPs – Laboratory Investigation facility to be made available as per DOTS Plus guidelines – Ancillary drugs to be provided as per DOTS Plus Site Committee`s advise – Management of Adverse Drug reactions as per DOTS Plus Guidelines – Doctors and Nursing staff should be available from the institute – Records and Reports to be maintained for DOTS Plus – Quarterly reports to be submitted electronically
Provision from RNTCP	– Remuneration of Sr. MO-DPS & SA/TB HV – Training, formats and registers for DOTS Plus – Second Line Anti TB Drugs – Computer and Internet Facility – <u>Further, only for non government institutes under MoU with state</u> ▪ Reimbursement of laboratory investigations, ancillary drug support ▪ Bed Charges up to 800/day/patient (including consultant's charges, investigations, ancillary drugs and food)

- *All the Medical Colleges located at a place where the state proposes to have a DOTS Plus Site must be established in the Government Medical College Hospital under the auspices of Department of Pulmonary Medicine or Department of Medicine (if the former department does not exist). The committee also recommended that MCI should be requested to make this a mandatory condition in their recognition process.*
- *The above requirements for the institute must be mandatorily provided by the Government Medical College / Institutes including free laboratory investigations and ancillary drug supply as part of their commitment for which no reimbursement will be available from the programme. However, the government medical colleges / institutes will be eligible for all the provisions from RNTCP along with a one time provision of up to Rs.10 lacs for up-gradation of the ward to incorporate airborne infection control measures instead of the bed charges.*
- *Private Hospitals and NGO Hospital should be considered at places where a government medical college is not available to serve as DOTS Plus Site and the scheme must be considered by the state in consultation with CTD.*
- *CTD may develop the Scheme for DOTS Plus Site in private institutes and seek approval of the ministry before widely disseminating it.*

Chapter-11: Human Resources

1. Senior DOTS Plus & TB HIV Supervisor and Counselor for DOTS Plus Sites:

Current Guidelines	Proposed Change	Justification
Policy: Manpower - – Senior DOTS Plus & TB HIV Supervisor - One per district.	– Change in Nomenclature as Senior DOTS Plus /TBHIV Coordinator – Additional Sr. DOTS Plus/TB HIV Coordinator for districts with >5 million population – Two wheeler for mobility support – TA/DA as per RNTCP norms from Misc. Head	– Effective monitoring and supervision possible for bigger districts. – Visit to DOTS Plus Observation centre, ICTCs ,ART centers for coordination
– No Counselor/TB HV at DOTS Plus Site	– Counselor/TB HV at DOTS Plus Site	– Intensify patient counseling during initiation of treatment and help in long term adherence of treatment – Coordination with districts

Recommendations of National DOTS Plus Committee:

- *Change the nomenclature as Senior DOTS Plus / TB HIV Coordinator with immediate effect and update the guidelines accordingly.*
- *CTD to consider additional Sr. DOTS Plus / TB HIV Coordinator for districts with > 5 million population, mobility support, TA/DA as per RNTCP norm.*
- *CTD to consider provision of a Counselor at the DOTS Plus Site in the National Strategic Plan (2012-17)*

2. TOR, Job Responsibilities of various cadre of staff and training details for Induction and Retraining:

Current Guidelines	Proposed Changes
– Challenges in HRD for DOTS-Plus	– Reorganized and rephrased in the draft document.
– Framework for HRD	
– Key strategies for RNTCP in reaching the goal	
– System for HRD for DOTS-Plus	
– No TOR & Job responsibilities mentioned for MOTC, DOTS Plus Site MO, SA, Sr. DOTS Plus –TB HIV Supervisor, SDS Pharmacist, SDS Store Assistant, District and PHI	– TOR and job responsibilities for MOTC, DOTS Plus Site MO, SA, Sr. DOTS Plus Supervisor, SDS Pharmacist, SDS Store Assistant, District and PHI Pharmacist, ANM, MPW,

Pharmacist, ANM, MPW, DOTS Plus Provider, TB HV – No functions of State Drug Store enumerated	DOTS Plus provider, TB HV. – Functions of State Drug Store added
– Job responsibilities for STO/STDC,DTO,MOPHI, STS STLS,DMC LT was present	– Job responsibilities for STO/STDC, DTO, MOPHI, STS, STLS, and DMC LT have to be modified.
– Training details for Induction and Retraining of field staff not in guidelines	Training details for Induction and Retraining be added as Annexure 19

Recommendations of National DOTS Plus Committee:

- *The committee agreed to all of the proposed changes in table above and recommended to update the guidelines in the relevant sections accordingly.*

Section: Case Finding and Laboratory aspects

Chapter-4: Case Finding and Definitions
Chapter-5: Diagnosis and Evaluation
Chapter-6: Laboratory aspects

1. Flow of Chapters from Case finding to Treatment Initiation:

Current Guidelines	Proposed Change
– Case finding and definitions – CF strategy, Definitions, Bacteriology, cohort analysis – Diagnosis and Evaluation – Objectives, Patient flow, culture and DST (diagnostic, follow-up), PTE, Monitoring and Progress, – Laboratory aspects – Network, Job responsibilities of labs, homogenization and decontamination, Inoculation and incubation, Culture examination and identification, Identification tests, R&R, DST methods, accreditation	– Case finding - MDR-TB suspect definition, – Flow of patient from periphery to C-DST lab – Specimen collection, transport – Lab diagnosis and results – Solid, Liquid, LPA and any other, R&R, MDR case definition, Lab capacity – Accreditation – Flow of Diagnosed case for treatment – Patient to DOTS plus site (PHI,TU,DTC,DP site) – Structure of DP Site – Place, DP committee, HR, TORs – Flow of patient at DP Site ▪ For PT evaluation, Rx initiation ▪ Special situations (ADR, Rx completion) – Transition from Diagnosis / Follow-up

Recommendations of National DOTS Plus Committee:

- *The committee agreed to all of the proposed changes in the flow of chapters as per the table above and recommended to update the guidelines in the relevant sections accordingly.*

2. Definition of Multi-Drug Resistant TB Suspect:

Current Guidelines	Proposed Change
Current Policy: (Criteria A) – Cat I failure and Cat II S+ve at 4th month or later – Sm+ contacts of MDR TB	– **Criteria A** - All failures of new TB cases (on CAT I), S+ve Re-treatment cases who remain S+ve at 4m or later (on CAT II), *All Pulm TB cases* who are contacts of known MDR TB case – **Criteria B** - All Re-treatment Sm + at diagnosis & *any S+ve follow up of new or RT cases* – **Criteria C** - *RT smear negative cases at diagnosis, HIV TB co-infected cases* in addition to the suspects in Criteria B

Recommendations of National DOTS Plus Committee:

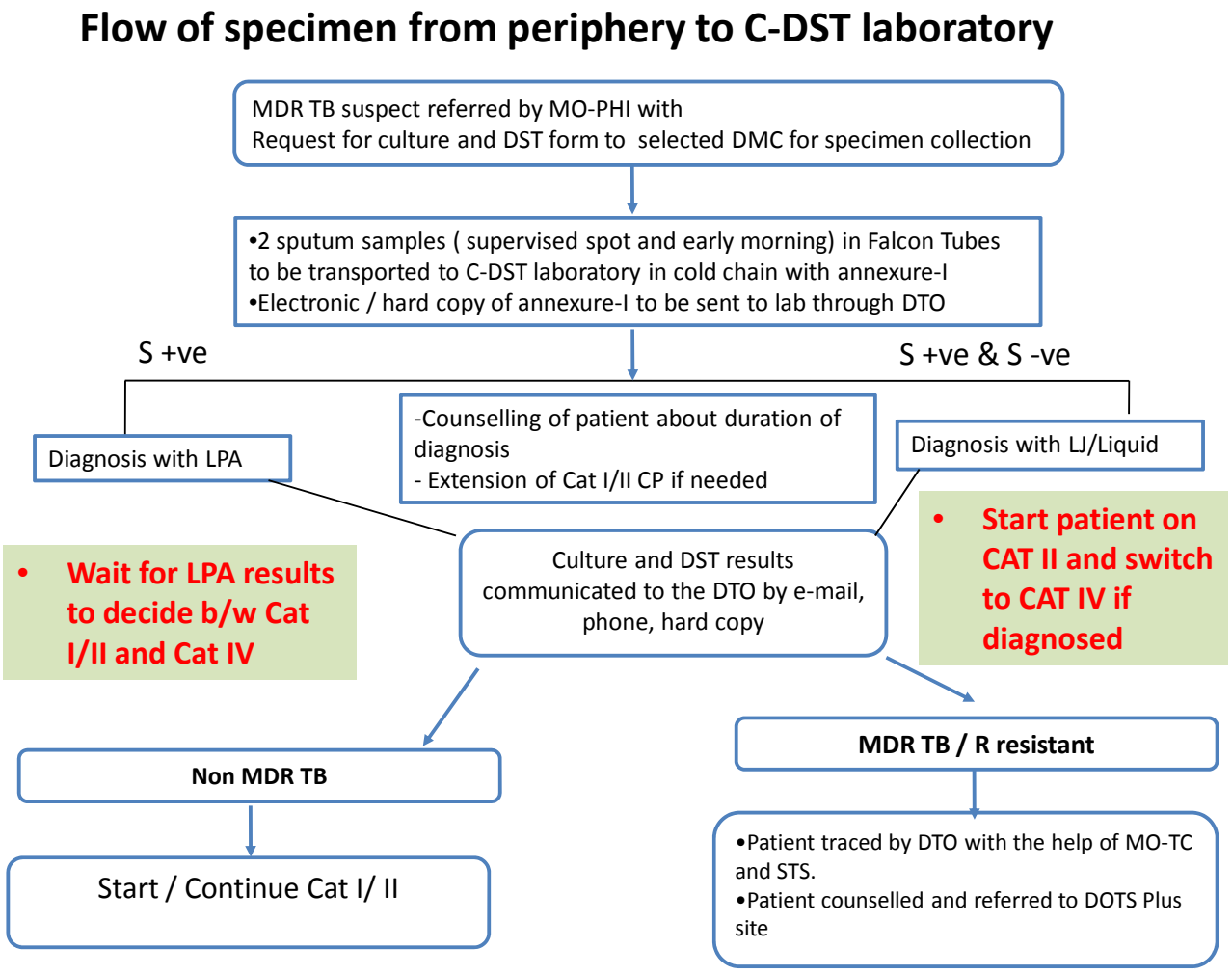
➢ *The committee deliberated on the graded definitions of MDR TB suspect; agreed to the proposed changes in the graded definitions as per the table above and recommended to update the guidelines in the relevant sections accordingly.*

3. Flow of specimen from periphery to C-DST laboratory:

– The committee deliberated on the flow of specimen and considering the need for further decentralization of the sample collection sites as the number of suspects are expected to increase as the country scale's up by geography and MDR TB suspect criteria over the next 2 years.

Recommendations of National DOTS Plus Committee:

➢ *The committee agreed to the proposed changes as per the flowchart below and recommended to refine it further at CTD and update the guidelines in the relevant sections accordingly.*

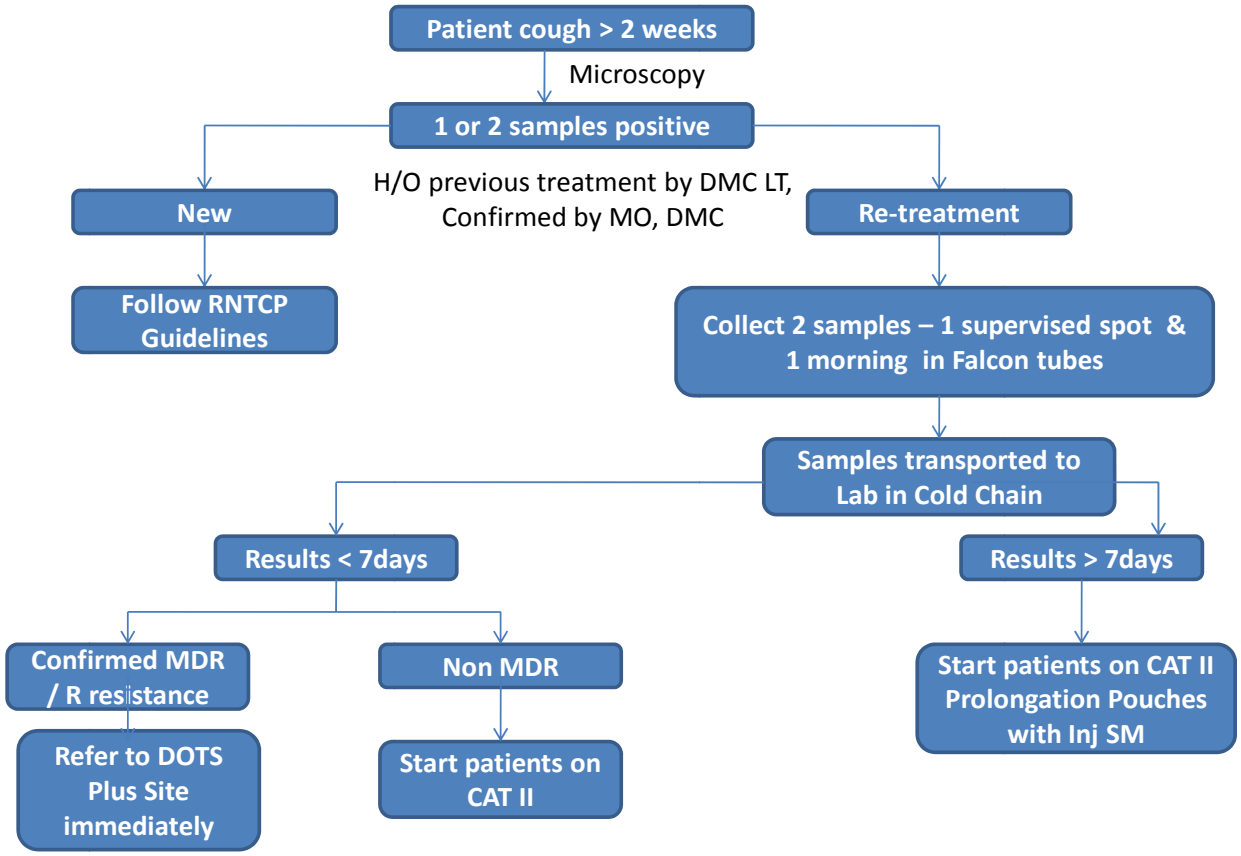


4. Normative Guidance for switching from MDR TB Suspect's Criteria A to Criteria B (All S+ve RT Cases):

– The normative guidance for switching from MDR TB Suspect's criteria A to criteria B (all S+ve RT Cases) was shared with the committee. These include

- the flow chart on "Protocol for switching to Criteria B subjected to C-DST"

Protocol for switching to MDR TB Suspect Criteria B subjected to C-DST



For any FU S+ve, DMC LT to trigger suspect identification. Patient switched to CAT IV if confirmed

- Checklist for switching over the MDR TB criteria's from 'A' to 'B'

Logistics	• Availability of Culture & DST forms, Clinical information form and falcon tubes • Availability of sputum transportation box and mechanism to carry the sample to IRL (sputum transportation mechanism) • Identification of key person (to co-ordinate the transport mechanism)
Trainings	• Training of MOs/LTs, MO-DMCs, MOTUs, STSs, TBHVs & STLSs on history taking, confirmation of retreatment case & collection of sample. [Medical officer must cross verify to check if the sample has been sent for C&DST]
Supervision and monitoring	• Database of Health care personnel → Names of contact person at DMC + Names of MO DMC + TBHV + STS + STLS + MOTU→ So once the results are out → can be communicated to concerned staff through SMS & to DTC through e-mail
Drugs and treatment services	• Availability of Beds in the DOTS plus site • Availability of adequate drugs (Cat – IV) at the district level • Availability of loose SM injection with syringes from the state • If there is a delay of more than 7 days for declaring the C&DST result, patient must be put on treatment with Prolongation Pouches and loose SM injections

- Clinical Information Form to be used by districts implementing Criteria B to confirm a Re-treatment case at the time of diagnosis based on past history of anti-TB treatment

CLINICAL INFORMATION FORM (New Annexure)

(Circle the designation of person conducting the interview: LT / MO / STS*/ MO-TC)**

District . . . . . **TB Unit** . . . . . .

Designated Microscopy Centre: . . . . . **DMC Lab No :** . . . . . .

- **Specimen Code:** . . . . . .

A) IDENTIFICATION OF THE PATIENT

Name: . . . . . .

Permanent address with land marks: . . . . . .

State and district of origin |_____|

Sex: |___| **Male** |___| **Female** **Age:** . . . . . **(in completed years)**

Date of sputum collection: **C** ..... **(3rd specimen)** **D** ..... **(4th specimen)**

Results of first two smears at the MC (to be entered by LT / MO and STS only)

MC Lab No.	Specimen	Result
	A	
	B	

TB number: (if allotted) . . . . . Date registered: (DD .... / MM ... / Yr .....)

Date of Starting Treatment (DD .... / MM ... / Yr .....)

B - HISTORY GIVEN BY THE PATIENT

Patient has been previously treated for TB for more than a month:

Yes |____| go to B1 **No** |____| consider as New case

B1 - Information about previous treatment

- How long and how many times was the patient treated? . . . . . .
- Which drugs were used for treatment? Non-DOTS/ DOTS/ both

Has the patient consumed any second line anti-TB drugs for more than a month: Yes / No

- Outcome of the last treatment according to the patient: Cured |___| Not cured |___| Unknown |___|
- Previous TB No _____ _____ and Category _ _____ ____

C - MEDICAL RECORDS

After extensive checking through the medical files and other documents available in the health centre and the patient, have you discovered that the patient has been treated/ registered for tuberculosis treatment before under RNTCP? No |___| Yes |___|

If the answer is yes, what was the outcome of the last course of chemotherapy?

Cured |___| Treatment completed |___| Defaulted |___| Failed |___| Transferred out |___|

Name, signature and seal of the Responsible officer:

Recommendations of National DOTS Plus Committee:

- *The committee approved the proposed normative guidelines for switching from MDR TB Suspect Criteria A to B and recommended to update the guidelines to include a version of the above flow chart on Protocol for switching to Criteria B subjected to C-DST after CTD editing to include the revised Criteria B (any follow-up smear-positive for testing); Checklist for switching over the MDR TB criteria's from 'A' to 'B' and the Clinical Information Form in the relevant sections of the guidelines, records and reports accordingly.*
- *CTD should review the preparedness of the districts/states before permitting them to switch to Criteria B.*

5. Specimen Collection and Transport:

– Two innovative models for specimen collection and transport using fresh samples in falcon tubes to be transported in cold chain using gel packs and their technical specifications developed by Gujarat (4 specimens capacity box for transport of samples from peripheral DMCs) and Andhra Pradesh (18 specimen capacity box for transport of samples from DMCs at TUs/DTCs) were shared with the committee.

– The following changes proposed in the guidelines were also discussed:

Current Guidelines	Proposed Change
Policy: – Mc Cartney bottles with CPC	– Fresh samples in Falcon tubes under Cold Chain
– Operational aspects: Training, preparation, transportation, logistics in context of Mc Cartney Bottles with CPC	– Training, logistics, packing and transportation, specification – for falcon tubes, transport box & linking with courier agencies in context of Fresh samples in falcon tubes under Cold Chain – Note on revised schemes – SCT, C-DST with LPA/LC

Recommendations of National DOTS Plus Committee:

- *The committee approved the proposed changes in the policy of collecting fresh samples in falcon tubes for transportation under cold chain as this has also been endorsed during the 19th Lab committee meeting.*
- *All states and districts should establish sample transport system in cold chain irrespective of the time taken for transport considering the hot climatic conditions in most of the states during most of the year.*
- *The committee appreciated the innovative models for sample collection and transport in cold chain from Gujarat and Andhra Pradesh and recommended that the technical specifications be included in the guidelines along with the updates required in operational aspects of using falcon tubes to collect fresh samples and transport them under cold chain including training, logistics, bio-safe three layer packing and transport systems at the relevant sections.*

6. Inclusion of Newer Diagnostic Techniques & its Accreditation Process:

Current Guidelines	Proposed Change
Policy: – Solid Culture & DST	– Add LPA & Liquid Culture (wherever available) to Solid Culture and DST for diagnosis – Add Liquid Culture (wherever available) and Solid Culture for Follow up – Introduce future technologies like GeneX-pert, LAMP, Tru-Array etc.
Policy: – Only Solid C-DST accreditation process described	– LPA – LPA accreditation with Liquid/Solid backup (Need not have liquid/solid accreditation for follow up culture) – Liquid/Solid – Liquid/Solid C-DST accreditation for HR OK
– Operational: Infrastructure, HR, Training, accreditation	– Infrastructure, HR, Training, Accreditation, equipments, reagents, – Revised schemes to include new diagnostics

Recommendations of National DOTS Plus Committee:

- *In view of the fact that there are accredited laboratories already implementing LPA (4 labs) and Liquid Culture (1 lab) under RNTCP and the country plans to scale up and accredit 43 labs for LPA and 33 labs for liquid culture, the committee agreed to the proposed changes in the use of rapid diagnostic techniques (LPA/Liquid Culture) and their accreditation mechanisms approved in the 19th lab committee meeting as per the table above and recommended to update the guidelines in the relevant sections accordingly.*
- *Build capacity of the NRLs and in turn all the 43 labs to conduct solid C-DST accreditation for HR and second line drugs like OK (Ofx and Km).*
- *Introduction of other newer diagnostics techniques should be considered by CTD after an appropriate validation and demonstration of the operational feasibility, sensitivity, specificity, reliability of the test and position the test in the diagnostic algorithm rationally under guidance of the National Laboratory Committee as has been the case with LPA and Liquid Culture systems.*

7. Number of Samples for Follow Up Examination:

Current Guidelines	Proposed Change
Policy: 4 samples collected for follow up – 2 samples for smear – 2 samples for culture	– Single sample (Early morning) – Further Evidence to be reviewed in 20th Lab committee meeting
– Operational: – Infrastructure, HR, Training, Accreditation, equipments, reagents.	– Infrastructure, HR, Training, Accreditation, equipments, reagents.

This has been described in details earlier.

8. Revisions in Culture & DST Scheme under RNTCP NGO PP Schemes:

– The limitations in the current C-DST Scheme leading to poor uptake by the private labs in terms of lack of newer diagnostics, no payment in case of contamination and the need for consideration of Second Line DST were deliberated upon by the committee.
– The final consensus that was reached during the deliberation are summarized in the table below:

Technology	Diagnosis (culture+DST) (Per specimen)	Follow-up (Per specimen)
LJ (Solid Culture)	Rs. 400 per Culture (2S) Rs. 1200 per DST for HR (1S) Rs.1600 per DST for HR OK (1S)	Rs.400 per Culture (2C)
LPA	Rs. 2000 per LPA for HR (1S)	-
Liquid Culture	Rs. 400 per Culture (2S) Rs. 1600 per DST for HR (1S) Rs.2000 per DST for HR OK (1S)	Rs.400 per Culture (2S)

Recommendations of National DOTS Plus Committee:

- *The committee recommended that the current C-DST scheme needs to be revised to address the limitations taking the following points into consideration:*
  - *The revised rates proposed in the table above are competitive enough and reasonable for consideration by CTD during revision of the existing C-DST scheme.*
  - *RNTCP accreditation from all drugs must be mandatory for all other sector laboratories*
  - *Payment of repeat test for contaminated samples should be permissible only up - to 4% in Solid Culture (LJ media) and 8% for Liquid Culture and 10% invalid results in LPA. No payment for repeat test beyond this ceiling.*
- *CTD may revise the Scheme and seek approval of the ministry before widely disseminating it.*

9. Revisions in Sputum Transport Scheme under RNTCP NGO PP Schemes:

– The current Sputum Transport Scheme does not have provisions for transport of samples for culture and DST under cold chain. The proposed updates required in this scheme were deliberated upon by the committee.

– The final consensus that was reached during the deliberation are summarized in the table below:

From Pick up point to C& DST laboratory	1 Kg box	2 Kg box
0-50 Km	Up to Rs.250	Up to Rs.300
50- 200 km	Up to Rs.300	Up to Rs.350
200-500	Up to Rs.320	Up to Rs.375
500 and above	Up to Rs.375	Up to Rs.450

Recommendations of National DOTS Plus Committee:

- *CTD to revise the Sputum Transport scheme to include transport of samples for C-DST taking the following points into consideration:*
  - *The rates proposed in the table above are competitive enough and reasonable for consideration by CTD during revision of the existing Sputum Transport scheme.*
  - *For difficult areas (tribal, hilly, desert areas, islands), 10% extra cost may be considered.*
  - *Transportation to be done within 0-48 hrs with cold chain*
  - *Delivery beyond 48 hours will not be paid*
- *If the local rates are beyond the ceiling in the above table, this needs to be reviewed for consideration by the state / district health society (TB Sub-Committee).*
- *CTD may revise the Scheme and seek approval of the ministry before widely disseminating it.*

Section: Treatment of MDR TB

Chapter-7: Treatment of Multi-Drug Resistant TB
Chapter-8: Monitoring and Management of Adverse Drug Reactions
Chapter-9: MDR TB in Special Situations
Chapter-10: Treatment Delivery and Adherences

1. Substitution with PAS for intolerance and mono resistance to Km/Ofx:

Current Guidelines	Proposed Change	Justification
– PAS in case of intolerance to one bactericidal and 2 bacteriostatic drug	PAS – In case of intolerance i.e. severe ADR leading to discontinuation of drug to (any of the drug in MDR TB regimen) OR (4 second line drugs) Implication – Procurement – Size and specification of PWBs	– Compensating the regimen due to loss of drug due to resistance / intolerance
– No guidance on management of Ofx or Km mono resistance	– Substitute with PAS (? for either initial resistance or patient failing) OR – Switch to CAT V	– Resistance Level to Quinolones

Recommendations of National DOTS Plus Committee:

- *The committee recommended that the PAS can be substituted in case of intolerance i.e. severe ADR leading to discontinuation of drug to any of the drug in the MDR TB Regimen (CAT IV).*

- *For management of patients with Km mono resistance, the committee recommended replacement of Km with Capreomycin and recommended CTD to work out Technical Specifications and initiate procurement for Capreomycin.*
- *For management of patients with OFX resistance, subcommittee established as above.*

2. Proposed Pediatric doses of 2nd line Drugs for patients weighing < 16 kg:

Current Guidelines	Proposed Change	Justification
– No guidelines for treatment of cases < 16 kg	– Doses of 2nd line drugs to be used in mg/kg body weight for such cases – DPS to decide doses - Standardized regimen with individualized doses – PWBs to be prepared at SDS and send to the District Implication – Since these individualized PWB would be prepared from the loose drugs in the formulation already available in the programme, no major implication	– Weight band available for patient weighing 16 Kg onwards – Since such patients would not be many no separate weight band for these is being recommended

Recommendations of National DOTS Plus Committee:

- *The committee reviewed the dosages for cases < 16 kg suggested in the Guidelines for Programmatic Management of Drug Resistant TB, Emergency Update-2008 and recommended CTD to use the dosages of 2nd line drugs for MDR TB cases in pediatric age group weighing < 16 kg as per the table below:*

Drug	***Daily Dose – mg/kg body weight***
Kanamycin	*15-30*
Levofloxacin	*7.5-10*
Ethionamide	*15-20*
Cycloserine	*15-20*
PAS	*150*
Ethambutol	*25*
Pyrazinamide	*30-40*

3. Additional dosage of 2nd line Drugs for patients weighing > 70 kg:

Current Guidelines	Proposed Change	Justification
– highest weight band as > 45 kg	– Drugs in addition to PWB for > 45 Kg to be used for patient weighing > 70 kg – Calculation suggest adding of Ethionamide, Cycloserine and Pyrazinamide - 250mg each – PWBs to be prepared at SDS and send to the District Implication – Since these PWB would be prepared from the loose drugs already available in the programme, no major implication	– Weight band available for patient weighing >45 Kg and the dosage may not be adequate for patients weighing > 70 kg

Recommendations of National DOTS Plus Committee:

- *The committee reviewed the dosages for higher weight patients suggested in the WHO Guidelines for Programmatic Management of Drug Resistant TB, Emergency Update-2008 and recommended CTD to use additional dosages of some 2nd line drugs for MDR TB cases in patients weighing > 70 kg taking the dosage to Kanamycin (1 gm),*

Ethionamide (1 gm), Cycloserin (1 gm), Ethambutol (1.6 gm) and Pyrazinamide (2 gm). All these are well within the maximum permissible dosage for each drugs as per the WHO guidelines. The standard Category IV regimen will now include High Dose Levofloxacin (250 mg, 750 mg and 1000 mg). Also, the dosage for Ethambutol for 45-70 kg is increased from 1000 mg to 1200 mg.

4. Shifting weight bands:

Current Guidelines	Proposed Change	Justification
– For shifting the patient to higher/lower weight band range – Decision making point DP Site Committee	– Decision making point DTO and intimation to DP Site Committee	– avoid patients visit to DP Site – decrease workload for DP Site

Recommendations of National DOTS Plus Committee:

- *The committee approved that decision for shifting the patients to higher / lower weight bands can be taken by the DTO under intimation to DP Site Committee.*

5. Follow up Sputum Smears and Cultures in MDR TB cases:

Current Guidelines	Proposed Change	Justification
– 4 samples for F/U 2 for Smear and 2 for Culture	– 1 early morning specimen in Falcon Tube (Fresh Samples) – No Smear Examination at DMC	– Substantial decrease in lab work load without affecting the yield – Smear being done at C/DST lab – Patient convenience
– All Follow-ups on Solid Media	– IP follow-ups only in liquid Media where available. If liquid Media is not available it would be done in solid media – CP follow-ups only in solid Media	– Early results in IP would help in making decisions for shifting from IP to CP – Avoidance of extension of IP waiting for F/U results – CP follow ups in Solid because of higher yield
– Decision of shifting from IP to CP on the basis of 4th month culture report (become issue if 5 month report is positive at the end of IP with liquid culture)	– Decision of shifting from IP to CP should be based on latest (4/5) culture result available at 4th Month or beyond	– Different results at 4/5/6 months of IP affect decision making
– 6 month culture isolate sent for 2nd line DST	– 4 M culture isolate for 2nd line DST (instead of 6) – Persistent Positivity – any two consecutive culture taken one month apart are positive – Culture Reversion - any two consecutive culture taken one month apart are positive after culture conversion	– early detection of other resistance – become important when planning for adding PAS in cases of Q resistance
– Follow up schedules as per months after initiation of treatment	– As per number of doses (90, 120, 150 ……..)	– 4 month after the initiation of treatment patient might have actually consumed lesser number of doses due to treatment interruptions

Recommendations of National DOTS Plus Committee:

The committee deliberated on all of the above issues in the guidelines and made the following recommendations:

- *Further evidence is required for considering reduction in the number of follow up specimen for follow up culture from 2 samples to 1 sample.*
- *However, the 2 additional samples collected in sputum cups for follow up smear microscopy at DMCs are to be discontinued based on the above justification keeping in view the fact that no clinical action is taken on those results, they add operational complexity and are burdensome for patients and programme, the programme has enough data of smear and culture results for undertaking any co-relational studies.*
- *Wherever available, follow-up sputum culture to be done using liquid culture for all IP follow ups and critical follow ups in CP like 21, 24 and any additional monthly follow up in the last 6 months may preferentially done with Liquid culture wherever available. For the rest of the follow up cultures and wherever liquid culture is not available, solid media will be used for follow up.*
- *Decision of shifting from IP to CP should be based on the latest (4/5) month culture results available at 4th Month or beyond considering the lower turn around time (TAT) likely wherever liquid culture follow up examination is considered.*
- *Clarify criteria for second-line DST, to include automatic SL DST for patients with positive 6 month culture isolate, or the latest isolate in cases with 2 consecutive culture positive results after conversion.*
- *Follow up schedules as per months after initiation of treatment may be linked to the actual number of doses consumed in cases with treatment interruptions.*

6. Category V treatment:

Current Guidelines	**Proposed Change**	**Justification**
– Category V treatment after concurrence of the Central TB Division	– CTD concurrence not needed – DPSC can take decision and initiate – Such cases to be reported to CTD – Drugs to be procured by State – Specification need to be put in guidelines and communicated to states	– DPSC has professional experts – CTD must have information of such cases for review and future planning
– No guidelines for Mx of patients other that MDR/R resistance	– Section on Mx of DR TB patients other than MDR and R resistance – Regimen to be designed after review of available literature, references, drug profiles, – Policy to be developed for Mx of H resistant cases	– Poor Treatment outcomes in patients with H resistance. – H resistance is usually combined with resistance to other drugs
– No guidelines for Mx of EP TB patients with MDR/R resistance	– Policy to be developed for Mx of EP TB patients with MDR/R resistance	

Recommendations of National DOTS Plus Committee:

- *The committee approved that the decision and initiation of Category V regimen to manage bacteriological confirmed XDR TB cases from RNTCP Accredited laboratory or NRLs, using drugs procured by the state as per the technical specifications shared by CTD and such cases to be reported to CTD. Due to the urgent need to collect experience on these Cat V treatments under programme conditions, Separate patient-wise information would be collected quarterly for all XDR patients on treatment, with standard summary from existing tools/job aides of clinical course, side effects, complication, and treatment response, and sent to the national level for compilation.*

- *For the management of DR TB patients other than MDR and Rif mono-resistant cases, it was decided that a sub-committee be constituted to conduct an extensive review of available evidences, drug profiles and suggest effective regimen to managing such cases in a month to CTD.*
- *Management of bacteriologically confirmed Extra Pulmonary MDR TB patients can be considered by the programme provided the diagnosis is made by an RNTCP C-DST Laboratory as the lab staff is trained to do C-DST with all types of samples during their national trainings.*
- *Refresher training on EP specimen processing should be included in all national trainings for C+DST and SL DST.*
- *Treatment regimen and schedule for EP MDR TB cases will remain the same as for pulmonary MDR TB, patients must be registered in the DOTS Plus TB Register and the treatment outcome of treatment completed will be considered. Standard guidance on assessing treatment completion would be included in the revised guidelines.*

7. Treatment Outcomes and Transit patients management:

Current Guidelines	**Proposed Change**	**Justification**
– Mx of patient who interrupt treatment and return back for treatment	– Patients resuming treatment after having defaulted should be given the new outcome of treatment i.e. re declaration of outcome	– Declared 'defaulted' is actually taking treatment.
– Doses in transit (DPS to DC, DC to DPS for ADR, DC to District Hospital for ADR or any other co morbidity) not counted	– Drugs in transit for medical reasons to be counted – Patients need to be given unsupervised doses out of PWB in certain situations – Admission in District Hospital – Cover for the travel to and from DPS for ADR / co-morbidity	– Treatment is prolonged to great extent in some cases – These Patients are more likely to get admitted for ADR / co-morbidity – Loose drugs are not available at Districts, in case of hospitalization / transit due to medical reason has to be taken from PWB

Recommendations of National DOTS Plus Committee:

- *The committee approved that patients resuming treatment after having defaulted (stopped treatment for > 2 months) should be given a new treatment outcome i.e. re-declaration of the treatment outcome.*
- *The committee agreed that the drugs provided to the patients to cover for transit period as per the DOTS Plus Guidelines may be counted as unsupervised doses. However, as far as possible efforts should be made by the district staff to restrict these transit doses as per the DOTS Plus Guidelines.*
- *The committee recommended that the specific follow up months to be considered to define cure and failure i.e. 12, 15, 18, 21 and 24 should be clearly mentioned in the definition.*

8. Operational changes proposed in the Guidelines:

Current Guidelines	**Proposed Change**	**Justification**
– Ofloxacin	– Levofloxacin to replace ofloxacin – available stock of ofloxacin to be consumed first	
– PTE at district for those who refuse to go to DPS – in district in consultation with DPS	– Patients clinical information sheet to be send to DPS along with investigation reports	– Kerala experience
– No section on Mx of XDR TB	– New chapter on Management of XDR TB – Diagnosis – Cat. V regimen – F/Us	– Decision Taken in 6th NDPC , not included in guidelines / modules

	– Recording and reporting – Drugs and Logistics	
– Mention about Transfer out / feed back mechanism but no format	– Addition of Section on Transfer out & Feedback Mechanism with formats and explanations to produce more clarity	– to produce clarity to field staff as patients shifting from one district to other may not actually be Transferred Out
– ADRs are Described	Tables – Minor vs. Major – Common vs. Rare – Complaint / ADR / possible offending drug/what to do – When to refer to higher institutions	– Better understanding
– Section on MDR TB / HIV	– Include Intensified TB HIV Package – Treatment Cards – DOTS Plus TB/HIV register – Reports – Latest NACO / WHO guidelines for ART – IRIS with clinical details	– Introduction of Intensified TB/HIV package of services – New ART Guidelines
– Socioeconomic interventions	– Add a para on Relocation of Family and – Vocational Re-habilitation by NGOs – Elaborate on mechanisms of linkage with Social Welfare Schemes. – Add role of civil society partners and – NGOs in addressing this need of the – patients.	– Promote / suggesting ways for rehabilitation of needy MDR TB patients

Recommendations of National DOTS Plus Committee:

- *The committee agreed to that patients resuming treatment after having defaulted (stopped treatment for > 2 months) should be given a new treatment outcome at the end of treatment i.e. re-declaration of the treatment outcome.*

Section: Second Line Drugs Logistic Management & Recording Reporting

Chapter-12: Logistics of Second Line anti-TB Drugs

1. Shift Second Line Drug Logistic Management from 3 monthly PWB to 1 monthly PWB system:

Current Guidelines	**Proposed Change**
– Drugs supplied as 3 monthly IP and CP boxes	– Conversion to Type A (Core Cat IV box) and Type B (IP-plus box)
– Unit of measurement is "3 monthly box". Supply to district and below district as 3 monthly boxes.	– Unit of measurement from "3 monthly box" to "1 monthly box". Supply to district and below district as one monthly boxes for uninterrupted supply with defined buffer stock of monthly boxes for District and TU drug store.
– Basis of 3m PWB supply is currently based on district requirement (treatment initiation)	– Basis of supply to be based on trend of consumption based on A & B box with unit of measurement as "1 month box"

Current System (3m box)			Proposed System (1m box)	
Weight band	IP	CP	Type A (Core CAT IV box)	Type B (IP Plus box)
1	5	15	20	5
2	10	30	40	10
3	5	15	20	5
	IP = Km Z Cs Eto Lfx E Pyridoxine	CP = Cs Eto Lfx E Pyridoxine	A = Cs Eto Lfx E Pyridoxine	B = Km Z

As per the Proposed System:
IP Box of a weight band = Type A box + Type B box of same weight band
CP Box of a weight band = Type A box of same weight band

Recommendations of National DOTS Plus Committee:

- *The committee approved the proposed system after reviewing the justifications for this change and recommended CTD to disseminate complete guidelines including updated recording and reporting formats for ensuring this shift at the implementing states and districts.*
- *The committee recommended that the State Drug Store of Gujarat be requested to undertake a quick pilot of implementing the new system for a month and share the experience as well as the specifications of the new drug boxes with CTD as soon as possible.*

Chapter-13: Recording and Reporting System

2. Proposed changes and updates required in the recording and reporting system:

Current Guidelines	Proposed Change	Justification
DOTS Plus TB register – Maintained at DOTS Plus Site – No space for HIV, CPT and ART	– Additional DOTS plus TB register to be available at DTC to maintain the information of patients in the district by DOTS Plus TB-HIV supervisor. – Registration and providing TB No. function remains with DOTS Plus Site and shared with districts. – Separate column introduced for HIV testing, CPT & ART initiation date to be introduced.	– Enhance accountability of Districts for case holding. – District is just having treatment cards for monitoring the patients; handling of data and monitoring the programs needs a concise register. – TBHIV documentation and reporting for Cat IV group can be done.
Request for Culture & DST form	– Add name of TU and Suspect Criteria for C-DST (A, B, C)	– C&DST lab to have these two information
Annexure II – Drug-o-gram	– To be replaced with Clinical Information Form.	– No exclusion criteria presently, previous history of patient required at DOTS plus site and is included in clinical history format (job aide). – No utility in sending to the lab or at any other level. – Clinical Information Form needed to segregate new and re-treatment cases at time of diagnosis of TB while using MDR TB Suspect Criteria B (All S+ RT cases).
Job-Aides	– Add Job-Aides in Annexure	– As per recommendation of GLC mission
DOTS plus TB treatment	– Add following information:	– Addition:

Card	1. Name of TU and Suspect Criteria for C-DST (A, B, C) 2. Table on TB-HIV 3. Type of C-DST test (LPA,LC,LJ) 4. Recording of CP to start on fresh line 5. Follow up table to include no. of doses instead of no. of months 6. Replace Ofx with Lfx – <u>Remove following information:</u> 7. Previous Cat I/II – date of registration, date of outcome 8. Smear result of the DMC table	1. Aligned with the TB register, Lab register. 2. TBHIV table included. 3. Information required in TB register included in treatment card. 4. CP recording of drug consumption to start on fresh line for clear demarcation. 5. Follow up to be done on no. of doses instead of no. months, so recording of every 30th dose to be marked e.g. 30, 60, 90, 120 <u>Removal:</u> 1.Not required and difficult to get information on Date of registration of Cat II / I, no utility; 2. Smear examination during follow ups at district level to go away; so table removed on page 2. 3. Ofx removed as will not be used routinely.

<u>Recommendations of National DOTS Plus Committee:</u>

- *The committee approved the proposed changes in the records and reports after reviewing the justifications for the changes and recommended CTD to disseminate complete guidelines including updated recording and reporting formats to the implementing states and districts.*

The Chairperson finally invited Dr Malik Parmar, RNTCP Consultant – Drug Resistant TB, CTD to present the "Appraisal, Supervision, Monitoring and Evaluation in DOTS Plus". The salient messages from this presentation are as follows:

Stage	Preparatory States / Districts	Implementing States / Districts
Supervision		• Supervisory checklists for various levels (DP Site, District, TU, DMC, and Patient) - NEW
Monitoring	• Quarterly status report on Preparatory activities for DOTS Plus scale-up – State & District (NEW) • Monitoring indicators on DOTS Plus Coverage introduced (NEW)	• DOTS Plus Quarterly Report • CF, 6m Int, 12m CC, TO • Quarterly Lab Reports • Monitoring indicators on DOTS implementation introduced (NEW) • Lab Monitoring Indicators
Evaluation	• DOTS Plus Appraisal Protocol – State & Central level (UPDATED) • IE formats to include 1 page for preparatory states / districts (UPDATED)	• IE formats to include section for implementing states / districts with assess progress on scale up plan, visits to DP Sites, C-DST Lab, Drug Stores, Patients interview etc. (UPDATED)

– The appraisals, supervision, monitoring and evaluation strategy of RNTCP for DOTS Plus services has been updated and introduced to the states.
– The organization of Appraisals, Supervision, Monitoring and Evaluation activities and the requisite tools are classified in the adjoining table
– The following Job Aides for DOTS Plus services have also been developed by CTD that will be pilot tested in 4 states in June 2011:

1. Patient Clinical Information Booklet – DOT Plus Site
2. Standard Counseling Tool for MDR TB Patients

3. MDRTB suspect line list – DMC, TU, DTC
4. Flow Charts - Diagnosis, Treatment, Ambulatory DOT, Recording, Reporting
5. Supervisory checklist for MDR TB - DOTS Plus Site, District, TU, DMC, and Patient Interview
6. Monitoring and management of ADR

– A set of monitoring indicators for coverage, case finding, interim and final outcomes was introduced in the RNTCP Annual Status Report – TB India 2011 and will be regularly published in all quarterly and annual performance report. These indicators were used for reviewing the status with the states during the RNTCP Bi-annual STO Consultant's Meeting.
– The committee was informed that all the Job aide are being pilot tested in the month of July 2011 in Rajasthan, Orissa, Jharkhand and Maharashtra state, the feedback will be available in the month of August 2011 that would guide further rolling out of job aides in various implementing states.

Recommendations of National DOTS Plus Committee:

- *The committee appreciated the efforts of CTD in devising the organizational structure of appraisals supervision, monitoring and evaluation and recommended to incorporate these in the updated guidelines as well as the strategy document for supervision and monitoring.*
- *The committee recommended that the quarterly reports on preparatory activities for DOTS Plus from State and District level be introduced from 3rd quarter 2011 onwards and CTD should closely monitor its submission and analyze the information on quarterly basis.*

In the concluding session the following recommendations were made by the Chairperson:

- *Some more number of experienced pulmonologist may be included as member in the National DOTS Plus Committee*
- *National DOTS Plus Committee members to participate at the periodic GLC Missions*
- *The DOTS Plus Guidelines to be updated within a month after the minutes of the meeting are finalized and approved*
- *The Nursing training module to be updated by LRS Institute after the DOTS Plus Guidelines is updated.*
- *A core group to finalize the regimen for Ofloxacin mono resistant cases after extensive search of available evidences was established under the leadership of Dr Sharma, with Dr Rupak Singla, Dr RN Solanki, Dr Rohit Sarin, Dr Ranjani Ramachandran, Dr Puneet Dewan, Dr Malik Parmar and Dr Sharath.*
- *A core group to develop standard training curriculum and module writing group was established under the leadership of Dr Sachdeva with Dr Solaki, Dr Sarin, Dr Singla, Dr Somshekhar, STOs from 2 experienced states and 5 members from the Core group of RNTCP Consultants working on the DOTS Plus Guidelines revision. Dr Malik Parmar would coordinate with all members for final consolidation of the module.*

Dr Behera concluded the meeting by thanking all the members of the National DOTS Plus Committee for their active participation. Dr Ashok Kumar, DDG TB also expressed his gratitude to all the committee members for their valuable contributions in the deliberations during the meeting. He especially thanked Dr Behera, for chairing the meeting and for the excellent arrangements made at the LRS Institute for organization of the meeting.

List of Participants

Annex-I

1. Dr D Behera, Director, LRSI, New Delhi
2. Dr Ira Ray, Former Addl. DGHS/Director NIB & Consultant Microbiologist, New Delhi
3. Dr Ashok Kumar, DDG (TB), CTD, New Delhi
4. Dr S K Sharma, AIIMS, New Delhi
5. Dr P Kumar, Director, NTI, Bangalore
6. Dr K Sachdeva, CMO, CTD
7. Dr Devesh Gupta, CMO, CTD
8. Dr Rohit Sarin, LRS Institute, New Delhi
9. Dr Rupak Singla, LRS Institute, New Delhi
10. Dr R N Solanki, BJ Medical College, Ahmedabad
11. Dr Vanaja Kumar, TRC, Chennai
12. Dr (Maj.) Gaikwad, State TB Officer, Maharashtra
13. Dr Srinivas Rao, State TB Officer, Andhra Pradesh
14. Dr PS Bordoloi, State TB Officer, Assam
15. Dr Puneet Dewan, WHO-India, New Delhi
16. Dr Ranjini Ramachandran, WHO SEARO, New Delhi
17. Dr Balasangameshwar, FIND, New Delhi
18. Dr Neeraj Raizada, FIND, New Delhi
19. Dr Rahul Thakur, FIND, New Delhi
20. Dr Malik Parmar, WHO RNTCP Consultant – DR TB, CTD, New Delhi
21. Dr Sharath B, WHO RNTCP Consultant – Lab, CTD, New Delhi
22. Ms. Ritu Khushu, SAMS, CTD, New Delhi
23. Mr. Manoj Kumar, SAMS, CTD, New Delhi