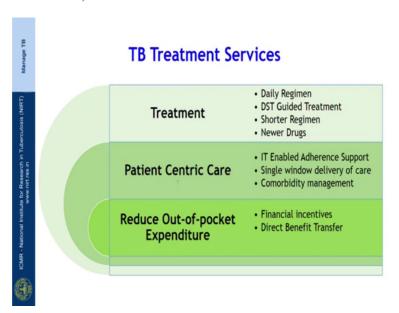
Manage TB Dr. Raghuram Rao DGHS, Ministry of Health and Family Welfare Government of India, New Delhi

Lecture – 63 Services offered by RNTCP Session 02

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Once diagnosed, there are various treatment options that are available under the program, and these services are provided free of cost. And the program is now providing fixed dose combinations, and of the first line drugs, and in a daily dosage form according to the weight of the patient, so these are available. Then there is for drug resistance TB, we have with introduction of CBNAAT, these facilities are available at the district level, and would further be scaled up to build or sub district levels also.

And, so the clinician is now in a position to be able to provide DST guided treatment, which means that he can do drug sensitivity, and identify the right combination of drugs that can be provided to the drug resistant cases, you know that we have under the program. The program also is coming up with the shorter regimens for a drug resistant TB to reduce the convent duration of treatments from the conventional regimen of almost 24 months to come down to as low as 9 to 11 months and this thing.

The program has also introduced newer drugs like bedaquiline, and delamanid that is coming up, and these are newer drugs that have been recommended by the WHO, and

have already been adopted by this program. These are the services that are available for treatment. And for the program not only provides treatment, but also provides supportive support in terms of a providing adherence support using information technology. There are several tools we will talk a little bit about it in the subsequent slides.

Also in cases of co morbidities especially with HIV, TB, where the program has started providing single window services for the HIV patients. So, the AIT medical officer is trained, and equipped, and drugs have been made available to him to diagnose and initiate anti tuberculosis treatment at the AIT center itself. So, the patient does not have to move around to different centers for initiation of treatment.

Also the program is trying to provide support for reducing the out-of-pocket expenditure by incentivizing certain aspects for giving incentives to the dot product. The treatment supporters, and to the patient also to help him take care of his travel, or to take care of his nutritional requirements that he may have during this thing.

And during the course of treatment, the financial benefits that are provided under the program are now being provided through the DBT mechanism - direct benefit transfer, where the money is transferred directly into the patient's account using Aadhar based authentication. So that the drugs and the treatment is provided to him at a place very closest to his house or to his place of residence, and the benefits and the social protection or that is required to him is also directly provided in a transparent manner.

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National Institute for Research in Tuberculosis (NIRT) www.nit.res.in

Treatment of TB

Type of TB Case	Treatment regimen in IP	Treatment regimen in CP
New	(2) HRZE	(4) HRE
Previously treated	(2) HRZES + (1) HRZE	(5) HRE



For treatment of tray or tuberculosis under the program, the cases are classified in our in to two based on a newly new case of tuberculosis or a previously treated case of tuberculosis. A new case of tuberculosis is one which in which the patient has not taken anti tuberculosis treatment for at least a month. And in if he is taken anti tuberculosis treatment for more than a month in his previous history, he would be considered as a previously treated case, and given appropriate treatment.

So, for a new case the intensive phase covers you know four drugs, which are now provided in a fixed dose combination, and the drugs that are there in that combination are isoniazid rifampicin pyrazinamide, and ethambutol. And the intensive phase is given for 2 months at the end of intensive phase, the patient is then initiated on continuation phase, which goes on for 4 months, and the program is now providing INH rifampicin, and ethambutol as our combination in a fixed dose combination for 4 months.

So, a new case of tuberculosis gets 2 months of intensive phase, and 4 months of continuation phase. So, a duration treatment duration of 6 months for a previously treated cases apart from the HRZE, that we say for or the first line drugs additionally streptomycin is added into his treatment regime, and this is given for 2 months streptomycin, and after that he is given a HRZE the fixed dose combination for another month, and that covers the intensive phase for previously treated cases. And for the continuation phase the drugs are the same that we given you in a new case or similar to a new case INH rifampicin, and ethambutol in a combination of a single pill, and it is given for 5 month duration.

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Treatment of TB > Drugs given daily, according to body weight No need for extension of IP > CP in both new and previously treated cases may be extended by 12-24 weeks in certain forms of TB like CNS TB, Skeletal TB, Disseminated TB etc. based on clinical decision of the treating physician. Extension beyond 12 weeks should only be on recommendation of experts of the concerned field. Loose Drugs would be needed as substitutions in case of adverse drug reaction or with co-morbid conditions.

So, this is how the treatment regimes are given under the program for tuberculosis in the public and facilities across the country. The advantages of going into fixed dose combination based on the experiences that we the program has achieved over the years. The program has moved to fixed dose combination and daily regime, and this is also now the program is able to provide these drugs based on the body weight.

So, these FDC combinations are available in and are is you know helping us to provide a treatment according to the weight of the patient. So, that the right level of drugs is available in his body, and the outcomes are better. Also there is no need for any extension of the intensive phase, and in both the you know the continuation phase in the both new and previously treated cases.

Of course, the you know based on the scenarios, which the clinical clinician can decide for different certain forms of tuberculosis like neural tuberculosis or like you know the tuberculosis of the bone or spine, it is up to the clinician, and he can extend the continuation phase, if he feels it is a appropriate.

In cases with where you know our extension is given beyond 12 weeks, they should only be given on the recommendation of a subject experts based on the type of tuberculosis. And they of course, if there is any adverse reaction that the patient experiences, then there are loose drugs that are also available under the program so that the right combination of drugs can be given to him.

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Treatment of TB - Adult

	Weight	Number of ta	Inj. Sm	
	category	Intensive	Continuation	
		phase	phase	
		HRZE	HRE	
		75/150/400/	75/150/275	gm
		275		
www.nirt.res.in	25-39 kg	2	2	0.5
	40-54 kg	3	3	0.75
	55-69 kg	4	4.	1
	≥70	5	5	1

- In patients aged > 50 years, maximum dose of streptomycin should be 0.75gm.
- Adults weighing < 25 kg will be given loose drugs as per body weight.
- Tab pyridoxine for Alcoholics, Malnourished persons, Pregnant and lactating women, Patients with chronic renal failure, diabetes, HIV infection



In the adult the fixed dose combinations that are available under the program like I said for you know based on the body weight of the patient. You will see that there are these drugs are available in as a single pill, and it has combination of a HRZE in the intensive phase in dosage of INH at 75 milligrams, 150 milligrams for rifampicin, 400 of pyrazinamide, and 275 with ethambutol. And this combination the single pill for a weight band of a 25 to 39 the patient has to take 2 pills at a time.

And likewise so as his body weight increases in different slabs you will see that the patient has to take 3 tablets, 4 tablets or 5 tablets that is available. And similarly in the continuation phase the patient has to take two tablets of those of the FDC, but the FDC now is not HRZE, but it is HRE you know. So, it is called 3 FDC in the continuation phase and 4 FDC in the intensive phase. So, he takes 2 tablets of that and 2, 3, 4 or 5 based on his weight band. And streptomycin is you know added for retreatment cases that continue separately that is not available in the fixed dose combination form.

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Treatment of TB - Paediatric

Weight category	Number of tablets (dispersible FDCs)				
	Intensive phase		Continuation phase		Inj. Sm
	HRZ	E	HR	Е	
	50/75/150	100	50/75	100	mg
4-7 kg	1	1	1	1	100
8-11 kg	2	2	2	2	150
12-15 kg	3	3	3	3	200
16-24 kg	4	4	4	4	300
25-29 kg	3 + 1A*	3	3 + 1A*	3	400
30-39 kg	2 + 2A*	2	2 + 2A°	2	500

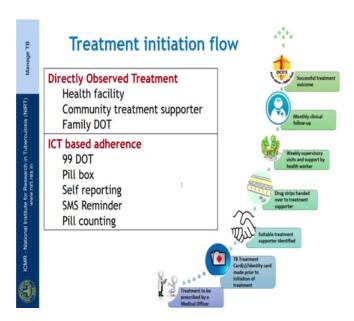


A=Adult FDC (HRZE = 75/150/400/275; HRE = 75/150/275)

For the pediatric cases also the drugs are now available in fixed dose combination and it is also child friendly. The drugs are available you know flavored taste. So, that you know the children can take appropriate treatment rightly. So, in the pediatric age group again these fixed dose combinations ethambutol is something being a hygroscopic, you know formulation is not currently available in the fixed dose combinations. So, the FDC has INH rifampicin and pyrazinamide, and ethambutol is given separately.

However, even the ethambutol tablet is you know disposable, and it is available. So, based on the weight band or the patient the child has to take 1, 2 or 3 tablets, which are disposable and flavored, and he takes it. As the weight band increases if the child is about 25 kilos, of one tablet of the adult form is added into it for the intensive phase, and similarly for the continuation phase. So, these are the different drugs that we have for adult as well as pediatric form, and in the fixed dose combinations, which is very patient friendly, and it helps in the reduces the pill burden, it helps in treatment adherence and compliance.

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These are drugs that are given under the program is provided through direct observed as a direct observed treatment, so the patient is supervised physically by someone. So, the these services are being now to help the patient take those medicines he I mean it would be very difficult to expect him to come to a health facility every day.

So, of course, you if he is willing these services are available in the health facility, or there is a community treatment supporter that can be identified based on the convenience of the patient, and including a family member is now could be a treatment supporter himself. And, so the drugs are given to the treatment supporter, it could be a family member, it could be a community, where a fellow out there in the community very wherever the patient wants to get it, or if the patient wants to come to the physical facility, they can also come to the public health facility nearest public health facility.

Apart from giving the medicines, there are other IT interventions, where which I told about to help in adherence of those patients. There are tools like what is called as 99 DOTS, wherein the patient just has to after you opens the blister, there is of a random phone number behind it or toll free number, the patient just has to give a missed call, and the system identifies that the patient has opened and taken the drug.

Similarly, there is a tool called as a pillbox, which is again every time the patient opens the box, now to take the drugs, and a log goes into the system, and the system identifies that the patient is taken that drug. And there are other options available of SMS; you

know the program gives reminder SMS's to the patient, who is registered with the program; so to remind him for taking the drugs or to remind him for coming for follow up investigations. So, these are the different adherence support that is available under the program.

So, once a patient is diagnosed, and a medical officer decides to initiate him on treatment, or treatment card, and or treatment patient ID card is generated, it is then it decides on the I mean the medical officer decides on the category of treatment that is to be given to him either a new or a previously treated. So, these drugs are available, and once these drugs are available the treatment supporter for the patient is identified, and this is identified mutually by the patient and the provider.

So, whatever is convenient for the patient any person he wants to identify as a statement supporter, these drugs are transferred to that treatment supporter, and he is advised, and counseled, and explained on all the requirements of you know monitoring treatment including recording and reporting of the dispensing of drugs.

Once the treatment supporter is identified, and drugs are made available to him, the treatment supporter, and the patient is also you know visited by a health care provider like the N M or the senior treatment supervisor, which is available under the program, they go and weekly ensure that whether the treatment supporter is you know providing drugs and recording and reporting it in the right manner.

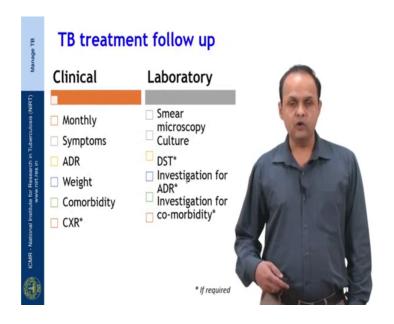
Once these you know a treatment supporter continues to provide all these things, all the drugs to the patient also the follow up investigations as per the requirements is you know ensured, and the information is entered into MIS system called as Nikshay in the program.

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The various treatment support structures like, I said already includes you know, counseling or treatment supporter is identified IT based adherence; tools are available with that adverse drug reactions are being monitored closely. There is nutritional support that is being provided, and various other you know support mechanisms are now being made available to the patient. And these support structures are you know being provided to ensure that the patient is you know taking the treatment, and completing the entire course of treatment, and becomes a clinically you know free of a tuberculosis.

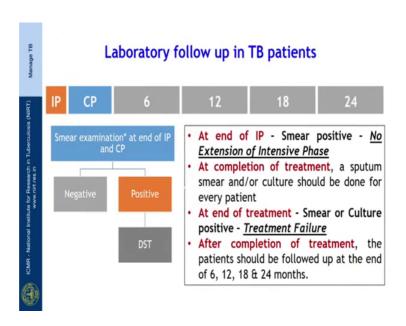
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The follow up like, I said that is required for a tuberculosis patient there is a clinical follow up, which is supported by laboratories investigations also. So, monthly even if the treatment supporter is a right next door, the patient is expected to come once a month to be examined by the medical officer or to the nearest public health facility, where he is he can come and get his checkups also. There it during those monthly visits, and screenings these symptoms are you know the various symptomatic examination, now looking for adverse drug reactions, they wait now monitoring the wait, and looking for other comorbidities, and x-ray if required all these services are available even for follow up.

And the laboratory support that is required for follow up in terms of smear microscopy, or drug susceptibility testing that is required or investigations. Any other investigations for maybe adverse drug reactions that come in or for co-morbidities like, HIV or diabetes or any other co-morbidity if the clinician is suspecting, those investigations are also followed up.

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The follow up protocol has now been revised, you know initially in the earlier times once the patient has completed his a intensive phase, continuation phase, and end of treatment the patient is discharged from the program, the follow up for mechanism was not there. Now, the follow up mechanism is available, and after treatment completion also the patient is followed up right up to 24 months, you know at frequencies of 6 months, 12 months, 18 months, and 24 months after its completion of treatment.

And once he is completed his treatment at all these subsequent visits, and there are smear or culture is you know done to ensure that the patient does not relapse or does not have a reinfection of tuberculosis. So, based on the follow up investigations earlier after the intensive phase, there is we know if these sputum smear continues to be positive, he is now offered culture DST, I mean the molecular technology CBNAAT is there to identify drug resistance.

So, the concept of extension of IP is no more there. So, once at the end of internship phase, if the patient is continues to be smear positive, he is offered the you know DST, and first line DST, and based on the DST, he is provided the appropriate regimen if change in regimen is required

Thank you for the patient listening to this session.