

Recording and reporting (Ch 18)

2. DOTS Plus Consultant course

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Aims of the information system

- Allow managers of NTPs to follow program performance
- Aid staff in individual patient management

Some indicators:

- DST coverage in different groups: new, relapses, return after default, failures of Category I, failures of re-treatment.
- Percentage of MDR-TB in these groups
- Burden of MDR-TB: absolute number of MDR-TB cases in new cases and the 3 retreatment groups reported during the year plus "chronics" at the end of the year
- MDR-TB treatment coverage: number of MDR-TB patients placed on Cat IV treatment among the total number of MDR-TB patients registered
- MDR-TB treatment result: interim 6-month and final

Forms and reports

- **Category IV Treatment card**
- **Category IV Register**
- Patient identity card
- Request for sputum examination
- Laboratory register for microscopy
- Laboratory register for culture
- **Quarterly report on Category IV case registration**
- **Quarterly six-month interim outcome assessment**
- **Annual report of treatment outcome of Category IV regimens.**

Challenges in Cat IV information

- Long duration of treatment
- Delay for diagnosis (DST result), treatment in the meantime
- Many variations and changes in treatment regimens

Category IV Treatment Card

- Key instrument for health staff who administer drugs to patients on a daily basis.
- Filled in when starts a patient on a Category IV treatment
- Updated daily by ticking off the supervised administration of drugs.
- Primary source of information to complete and periodically update the Category IV Register.
- When a patient moves the card, or a copy of the card, must follow the patient.
- A copy of this card may be used as a notification form and to record the final outcome of treatment.

Category IV Treatment Card

Name: Jose Lopez

Category IV Registration Number: 1/2002

Date of category IV registration: 5/1/2002

District TB Registration Number: 24/2000

Date of district TB registration: 4/9/2000

Address: Central market street 48

Country /District: Utopia/West

Treatment Centre: Health center #3

Sex: M/F

Age: 35 Date of Birth: __/__/__

Initial Weight(Kg): 54 Height(cm): __

Site: Pulmonary / Extrapulmonary/Both

If extrapulmonary, specific site: _____

Concilium meetings - dates and decisions:

Date	Decision	Next Date
15/1/2002	Start Cat IV treatment in Health center #3	15/4/2002
19/4/2002	Intermittent Kanamycin	19/7/2002
20/7/2002	Stop kanamycin	
15/1/2004	Stop treatment	

Registration Group defined by treatment history when the sputum was taken that showed MDR-TB	Choose only one
New	
Relapse	
After default	
After failure of first treatment	
After failure of retreatment	x
Transfer in (from another Category IV treatment unit).	
Other (including previously treated without known outcome status)	

HIV INFORMATION	
HIV Testing done:	<u>Y</u> /N/Unknown
Date of Test:	<u>5/4/2001</u> Result: <u>Neg</u>
Started on ART:	Y/N Date:
Started on CPT:	Y/N Date:

Previous Tuberculosis Treatment Episodes

NO.	Start Date (if unknown put year)	Regimen (write regimen in drug abbreviations)	Outcome
1	4/9/2000	Cat I (RHZE)	failure
2	15/2/2001	Cat II (RHZES)	failure

Used second-line drugs previously?

Yes	
No	x

If yes, specify: _____

Drug Abbreviations

First-line drugs

H = Isoniazid
R = Rifampicin
E = Ethambutol
Z = Pyrazinamide
S = Streptomycin
(T = Thiazetazone)

Second-line drugs

Am = Amikacin
Km = Kanamycin
Cm = Capreomycin
Cfx = Ciprofloxacin
Ofx = Ofloxacin
Lfx = Levofloxacin
Moxi = Moxifloxacin
Gati = Gatifloxacin
Pto = Prothionamide
Eto = Ethionamide
CS = Cycloserine
PAS = p-aminosalicylic acid

Problem:

- “The initial date is the date of the smear or culture closest to the start date before the treatment begins”:
 - Prior: sputum taken when cat 1 (or 2) treatment started, usually 2-4 months earlier
 - month 0: sputum taken when the cat IV treatment was started

Patient's Name ___ case 1

CATEGORY IV REGIMEN (Date treatment started and dosage (mg), change of dosage and stop of drugs):

Date	H	R	Z	E	S	Km	Am	Cm	FQ	Pto/Eto	Cs	PAS	Other	Comments
15/1/02			1750			1g			800 ofl	750	750	8g		
19/4/02			1750			1g			800 ofl	750	750	8g		K intermitt
20/7/02			1750						800 ofl	750	750	8g		Omit K

ADMINISTRATION OF DRUGS (one line per month):

Month	DAY																															Wt (Kg), Lab, X-ray	
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31		
Jan 02															0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	54
Feb	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
March	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
April	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0														56		
May					0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
June	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
July	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	56		
August	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
Sept	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0																		
Oct	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	57		
Nov	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
Dec	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
Jan 03	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	58		
Feb	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			

Mark in the boxes: O= directly observed
 N = Not supervised
 Ø = drugs not taken

Tuberculosis Program

Case 1

Patient's Name _____

Administration of drugs (continued)

Month	DAY																															Wt (Kg), Lab, X-ray	
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31		
Marc 03															0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
April	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	58
May	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
June	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
July	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	58	
August	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
Sept	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
Oct	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
Nov	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
Dec	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
Jan 04	0	0	0	0	0	0	0	0	0	0	0	0	0	0																			
Feb																																	

Mark in the boxes: O = directly observed
 N = Not supervised
 Ø = drugs not taken

Comments: _____

OUTCOME	Mark one	DATE
Cured	x	15/1/2004
Completed		
Died		
Failed		
Defaulted		
Transferred Out		

Where to locate the Cat. IV Register ?

- In the centralized unit designated to start cat IV treatment.
- If part or all of the Category IV treatment takes place at a peripheral level, and the number of cases there is considerable, there should be a local Category IV Register.

Category IV register

- All Cat IV patients will first have been entered in DOTS district register. Leaves the DOTS district register as "failure/switched to Cat IV treatment", then entered in Cat IV treatment register
- Allows quick assessment of implementation of DOTS Plus during supervisory visits
- Basis for quarterly reports and analysis

Cat IV register (II)

- The Category IV Register is the record of all patients who meet the diagnostic criteria for Category IV, whether or not Category IV treatment is started.
- Patients with mono- or poly-resistant TB who are suspected to have developed MDR-TB and are being placed on a Cat IV regimen, should be placed in the Category IV Register

Levels of the NTP

- (Federal)
- National
- Provincial/Regional
- District
- Sub-district/clinic

Destiny of patients entered as suspected MDR-TB:

- DST confirms MDR-TB
- DST shows not MDR-TB: crossed out of the Category IV register, return to a Category I, II or III treatment.
- No growth - clinical decision to continue Category IV treatment or not.

Quarterly report of case registration

- Completed with a delay of one quarter, to allow time for culture and DST results to be available in those started on Category IV treatment with suspicion of MDR-TB.
- Because of delays in Category IV treatment start, many patients will be registered with Category IV in one quarter and started on Category IV treatment in a later quarter.

Quarterly report on Category IV case registration

Name of district: _____ Patients registered in the Category IV register
 District No.: _____ during ___ quarter of year _____
 Name of district coordinator: _____ Date of completing this form: _____

Signature: _____

Block 1: Patients registered in Category IV and patients started on Category IV treatment

Patients	Confirmed MDRTB	Suspected MDRTB
With date of Category IV registration during the quarter		
With date of Category IV treatment start during the quarter		

Block 2: Confirmed MDRTB cases registered during the quarter by history of previous treatment

Pulmonary				New extra-pulmonary	Other*	Total
New	Previously treated					
	Relapse	After default	After failure of category 1 treatment	After failure of cat 2 treatment		

* other cases include previously treated pulmonary patients without known outcome status, and all previously treated extrapulmonary cases

Preliminary Six Month Interim Outcome Assessment Form

- Entry defined by quarter of treatment start
- Reporting at 9 months past the closing date allows culture information at 6 months of treatment to be included for all patients in the cohort.
- Only enter data from 6 months control

Six Month Interim Outcome Assessment (to be filled out 9 months after treatment start)

Name of Unit: _____

Date filled in: _____

Quarter treatment was started: _____

Date of the report: _____

	Number started on treatment	Smear and culture results at 6 months of treatment									No longer on treatment		
		Smear Negative			Smear Positive			Smear Unknown			Died	Default	Transfer Out
		Culture negative	Culture positive	Culture unknown	Culture negative	Culture positive	Culture unknown	Culture negative	Culture positive	Culture unknown			
MDR-TB documented cases:													
Suspected MDR-TB cases:													
TOTAL													

Annual Report of Treatment Outcome of Category IV Cases

- Shows the final result of treatment by year since the start of treatment, in total and stratified by smear and culture results and patient registration group.
- Since a few patients may be on treatment longer than 24 months, the form is completed again at 36 months after the last patient in the cohort starts treatment.

Annual report of treatment outcome of Category IV regimens

(to be filled in 24 and 36 months after the closing date of year of treatment)

Year Treatment started:_____

BLOCKS 1 AND 2 ARE FOR ALL PATIENTS THAT STARTED CATEGORY IV REGIMENS

	Cure	Treat- ment Comple te	Failure	Default	Died	Transferred Out to another DOTS-Plus program	Still on Treatment	Total
Block 1								
S+ C+								
S- C+								
S+ C-								
S- C-								
unknown								
Total								

S = smear, C = Culture

	Cure	Trea- ment Comple te	Failure	Default	Died	Transferred Out to another DOTS-Plus program	Still on Treatment	Total
Block 2								
New								
Relapse								
After default								
Failure after first treatment								
Failure after retreatment								
New Extrapulmonary TB								
Other								
Total								

How to analyse the data by calculating
and assessing main indicators

Some indicators:

- DST coverage in different groups: new, relapses, return after default, failures of Category I, failures of re-treatment.
- Percentage of MDR-TB in these groups
- Burden of MDR-TB: absolute number of MDR-TB cases in new cases and the 3 retreatment groups reported during the year plus "chronics" at the end of the year
- MDR-TB treatment coverage: number of MDR-TB patients placed on Cat IV treatment among the total number of MDR-TB patients registered
- MDR-TB treatment result: interim 6-month and final

Backlog of "chronic" cases

- NTPs that have not yet started Category IV treatment should keep a list of such patients.
- When Category IV treatment becomes available, chronic cases with signs of active disease should have DST, and if M;DR-TB is confirmed, be registered in the Category IV Register and started on treatment.
- As the Category IV treatment programme progresses the list of patients defined as chronic cases will become smaller and will eventually only include cases that have failed Category IV treatment.

How to count MDRTB cases - an example:

- Cases reported with TB during 2004 and who turned out to have MDRTB:
 - New
 - Previously treated: relapse, after default, after failure of cat 1, after failure of cat 2, other
- "Chronics": Cases diagnosed with MDRTB, who were not reported during 2004 and who are still alive at the end of 2004

Computerized systems:

- All forms can be handwritten
- An electronic version entering the data from the Category IV treatment card facilitates better quality of information as well as data analysis.
- Generate:
 - lists: Cat IV register
 - tables: quarterly reports

Use of computers in TB registers

- All forms can be handwritten.
- Data entry from the treatment card facilitates better quality of information as well as data analysis.
- Generate standard lists: similar to district TB register
 - quality control: names, smear, culture, drug resistance testing - by district and quarter, - flexibility?
- Generate standard tables: similar to quarterly reports
 - analysis: aggregated data, number of patients by category, district, quarter etc - flexibility?

Training and supervision

- The Cat IV information system requires basic knowledge of the DOTS information system, with additional training on the specifics of the forms.
- Regular supervisory visits by the central team to the units using the information system are fundamental to maintaining good quality of the information.

Optional supervisory tools:

- Coverage of Cat IV treatment
- Preliminary result of treatment

Drug susceptibility survey requirements:

- Representative data - how many of all culture confirmed cases are included, and if selected - randomly?
- Reliable drug susceptibility testing

	New cases		Previously treated	
	Number	%	Number	%
Number reported Cu+				
Number with DST result				
Sensitive to all				
Resistant to any drug				
Monoresistance:				
H				
R				
E				
S				
K				
MDRTB (at least to HR)				
HR				
HRE				
HRS				
HRK				
HRSE				
HRKE				
HRSK				
HRSEK				
Res H and more, not MDR				
HK				
HS				
HES				
HSK				
HESK				
Res R and more, not MDR				
RS				
RE				
RES				
REK				
RSK				
Other resistance: SE				
All resistant to H				
All resistant to R				

Estonia preliminary data (V.Hollo)

Estonia trends	Notified TB			MDRTB			MDRTB%			Decline notif 2003/2001	Decline ;MDRTB 2003-2001
	2001	2002	2003	2001	2002	2003	2001	2002	2003		
NEW pulm	204	196	195	24	32	29	11,8	16,3	14,9	4,4	-20,8
sm+cu+	204	196	195	24	32	29	11,8	16,3	14,9	4,4	-20,8
sm+cu-	8	7	5								
sm-/cu+	147	153	138	24	29	18	16,3	19,0	13,0	6,1	25,0
sm-cu-	123	95	97							21,1	
total	482	451	435	48	61	47	13,7	17,5	14,1	9,8	2,1
Relapse, def, failur	2001	2002	2003	2001	2002	2003	2001	2002	2003	-0,1	-0,1
sm+cu+	152	106	66	83	56	33	54,6	52,8	50,0	56,6	60,2
sm+cu-	1	3	3								
sm-/cu+	89	69	45	42	29	25	47,2	42,0	55,6	49,4	40,5
sm-cu-	32	21	18							43,8	
total	274	199	132	125	85	58	51,9	48,6	52,3	51,8	53,6

Estonia - preliminary data (V.Hollo)

	Notified TB			MDRTB			MDRTB%			Decline notif 2003/2001	Decline ;MDRTB 2003-2001
	2001	2002	2003	2001	2002	2003	2001	2002	2003		
Relapse	2001	2002	2003	2001	2002	2003	2001	2002	2003		
sm+cu+	54	49	28	23	18	15	42,6	36,7	53,6	48,1	34,8
sm-/cu+	52	44	32	22	17	16	42,3	38,6	50,0	38,5	27,3
total	106	93	60	45	35	31	42,5	37,6	51,7	43,4	31,1
After fail	2001	2002	2003	2001	2002	2003	2001	2002	2003		
sm+cu+	32	22	6	26	19	5	81,3	86,4	83,3	81,3	80,8
sm-/cu+	10	9	5	9	8	4	90,0	88,9	80,0	50,0	55,6
total	42	31	11	35	27	9	83,3	87,1	81,8	73,8	74,3
After defaukt	2001	2002	2003	2001	2002	2003	2001	2002	2003		
sm+cu+	66	35	32	34	19	13	51,5	54,3	40,6	51,5	61,8
sm-/cu+	27	16	8	11	4	5	40,7	25,0	62,5	70,4	54,5
total	93	51	40	45	23	18	48,4	45,1	45,0	57,0	60,0

Estonia - preliminary data treatment outcome (V.Hollo)

New and previously treated cu+ cases non-MDRTB							
Year	Notified	Evaluated	Cured/completed	Failed	Defaulted	Died	Still treated
2001	419	397	79,6	3	11,3	6	0
2002	378	365	82,7	1,4	6,8	7,9	1,1
MDRTB cu+ (new and previously treated)							
Year	Notified	Evaluated	Cured/completed	Failed	Defaulted	Died	Still treated
2001	179	152	42,8	21,7	18,4	15,8	1,3
2002	150	134	47,0	12,7	14,9	17,9	7,5

How to establish and implement
the Category IV Recording and
reporting system in an area?

Discuss for each area

- How is MDR-TB diagnosed and treated, which levels are involved, and how is MDR-TB recorded and reported?
- What is different in the system described in the WHO guidelines on drug resistant TB?
- How can the recording and reporting system for MDR-TB in your country be made compatible with the WHO recommendations? Make a brief plan of action how to implement a revised recording and reporting system