

CHAPTER 18

Category IV recording and reporting system

18.1 Chapter objectives

This chapter describes the information system for patients who are entered in the Category IV Register, with the objective of recording information needed to monitor programme performance and treatment outcomes. It defines the minimum instruments and variables of the system that are necessary to implement and monitor Category IV treatment.

18.2 Aims of the information system

The aims of the information system are twofold:

1. To allow managers of national TB control programmes at different levels to monitor overall programme performance as a basis for programme and policy developments. Performance indicators include:
 - the outcome of patients with drug-resistant TB, including MDR-TB,
 - the results of Category IV treatment, and the results in subgroups.
2. To aid staff in treatment units to provide adequate management of individual patients.

18.3 Scope of the information system

The information system for treatment of drug-resistant TB is based upon, and is an extension of, the basic DOTS information system (1–4). The forms have therefore been designed to be as similar as possible to the standard forms used in DOTS programmes.

This system does not include all of the detailed information that treatment units may need to manage individual patients; that information is contained in clinical records and other special forms used in the wards or clinics, and depends on local requirements and practices.

While this core information system will be applicable across settings, the reporting forms can be modified as necessary to suit the local context. For instance, additional variables that are considered valuable in specific situations can be included.

18.4 Main forms/registers and flow of information

This section describes the core set of forms that enable proper recording of diagnosis, monitoring and care, in addition to the reporting of outcomes of Category IV treatment. Chapter 4 defines the case registration groups and outcome definitions.

18.4.1 Category IV Treatment Card (Form 01)

This card is a key instrument for health staff who administer drugs to patients on a daily basis. A patient registered for Category IV treatment should have a Category IV Treatment Card completed by the health-care worker. The card should be updated daily by ticking off the supervised administration of drugs. The card represents the primary source of information to complete and periodically update the Category IV Register.

When a patient moves (for example from a specialized hospital to a province or district of origin after the first months of treatment), 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.

The Category IV Treatment Card contains the following sections:

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- **Basic demographic and clinical information.** Name, address, sex, age, weight, etc.
- **Category IV registration number.** This is a new unique identification number for each patient who enters Category IV.
- **Date of Category IV registration.**
- **Previous district TB registration number and date of registration.**
- **Registration group according to history of previous antituberculosis treatment.** The five registration groups have been defined in Chapter 4, section 4.5. For the purpose of the recording and reporting system, patients should be further classified according to the treatment outcomes: failed, defaulted and relapse. For this reason, seven registration groups will be used. Group assignment is determined by history of previous treatment at the time of collection of the sputum sample that was later used to confirm MDR-TB.
 1. **New.** Patients who have never received antituberculosis treatment, or who have received treatment for less than one month. This includes patients who had DST at the start of a WHO Category I regimen and are then switched to a Category IV regimen because of resistance (see Chapter 4, section 4.5).
 2. **Relapse.** Patients previously treated for tuberculosis who have been declared cured or treatment completed, and then diagnosed with MDR-TB.

3. **Treatment after default.** Patients who return to treatment with confirmed MDR-TB after interruption of treatment for two months or more.
 4. **Treatment after failure of first treatment.** Patients who return after the first treatment has failed.
 5. **Treatment after failure of re-treatment.** Patients who return after the re-treatment has failed.
 6. **Transfer in.** Category IV patients who have been transferred from another register for treatment of drug-resistant TB to continue Category IV treatment. Their outcomes should be reported to the transferring unit so that it can report their outcomes in the cohort in which they originally started Category IV treatment. This group is excluded from the quarterly reports of the receiving unit on registration and treatment result.
 7. **Other.** Category IV patients who do not fit the above definition. This group includes Category IV patients who were treated outside DOTS programmes and for whom the outcome of the latest treatment is unknown.
- **Previous treatment episodes.** This section lists and describes any previous antituberculosis treatment and outcomes. Start with the most distant treatment and label it number 1. The specific drugs can be placed in the block according to the standard code for antituberculosis regimens described in Chapter 7, section 7.6 (abbreviations are also given on the front of the treatment card). The outcome of any previous treatment is also noted here (cured, completed, failed or defaulted).
 - **Used second-line drugs previously?** In this section answer “yes” if the patient received any of the second-line drugs listed on the front of the chart for the treatment of TB for more than one month. Otherwise answer “no”.
 - **HIV information.** This section records whether HIV testing was ever done, the date of the test and whether the patient is on ART and/or co-trimoxazole preventive therapy (CPT).
 - **Review panel meetings.** These guidelines promote the idea of periodic meetings with the group of caregivers involved with Category IV patients. This section provides a space to record any major changes by the panel.

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- **Monitoring of smear and culture.** Record the date, sample number and result of smear and culture. The date of the smear and culture that determined the registration of the patient in Category IV should also be recorded. Month “0” is the time of sputum sample collection at the start of the Category IV regimen. Requirements for monitoring of smear and culture are described in Chapter 11.

- **DST results.** Record the date and results of all DST performed.

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- **Regimen.** The initial Category IV regimen is recorded on the treatment card and any change to it is recorded in the same section. One line is used for each date on which a drug (or drugs) is changed. If drug dosage is progressively increased (for example, starting 250 mg of ethionamide daily and increasing by 250 mg thrice daily until the full dose is reached), this is usually not recorded on the treatment card but should be recorded in the patient's medical record.
- **Record of daily observed administration of drugs.** One line per month makes it easy to assess adherence. One box is marked for each day the treatment is administered. Some programmes may prefer to design treatment cards with a more detailed system where a box is checked for each drug daily, since there may be some irregularity in administration of drugs.
- **Weight, laboratory and X-ray monitoring.** These items can be recorded on the treatment card in the monthly drug administration section in the last column. Recommendations regarding the interval for monitoring these indicators can be found in Chapter 11.
- **Outcome of treatment.** At the end of treatment the outcome should be recorded on the treatment card. Chapter 4 provides definitions of treatment outcomes.

18.4.2 Category IV Register (Form 02)

These guidelines recommend a system in which the national TB control programme has two registers: a District Tuberculosis Register and a Category IV Register.

The District Tuberculosis Register is the traditional register used by DOTS programmes in which all TB patients are first registered. In order to integrate the treatment of Categories I, II, III and IV, this register will need to be modified in three ways:

1. If culture is being done in addition to smear examination in a substantial number of cases, space for dates of collection and results must be added to both the initial testing and the follow-up areas.
2. An area to record DST must be added – one or two columns for date of collection of DST and for the drugs that are being tested.
3. Any patient who is switched to a Category IV regimen because of resistance (without meeting the formal criteria of failure) should be noted as such. These patients are removed from the outcome analysis of Categories I, II and III (their final outcome will be noted in the Category IV Register).

Patients who have mono- or poly-resistant TB that requires minor adjustments of drugs should stay in the District Tuberculosis Register, where the adjustment of their regimen should be recorded. However, if such patients are suspected to have developed MDR-TB and are being placed on a new regimen designed to treat MDR-TB, they should be placed in the Category IV Register, which is described below.

The Category IV Register is the record of all patients who meet the diagnostic criteria for Category IV regimens (see Chapter 4, section 4.1, for a general definition of Category IV patients; individual country protocol may define in greater detail who enters Category IV treatments – see Chapter 5). This register allows quick assessment of the implementation of Category IV, facilitating quarterly reporting and analysis of case-finding and treatment outcomes.

The national TB control programme should define where the Category IV Register will be located. If the first months of Category IV treatment are centralized to one treatment unit (usually hospitalized, sometimes ambulatory), this unit should have a Category IV Register. If part or all of the Category IV treatment takes place at the provincial or district levels, and the number of cases in the province or district is considerable, there should be a provincial or district Category IV Register.

The Category IV Register is completed using information from the Category IV Treatment Card and should be updated regularly with any new information. Usually only the first eight columns are filled in at the initial registration; the rest of the registration information is completed from the treatment card over time.

The person responsible for the Category IV Register should enter the patient into the Category IV Register as soon as the patient is determined to meet the diagnostic criteria to enter Category IV, which is defined by the programme protocol (i.e. some programmes may routinely record failures of Category II regimens in the Category IV Register). This point will define the date of Category IV registration. Patients should be recorded consecutively by their date of registration. There should be a clear separation (extra line) when a new quarter is started.

Some patients registered in Category IV may later prove to have drug-susceptible disease when the DST results become available. Patients who are wrongly registered as Category IV can safely return to a Category I, II or III treatment regimen and should do so. It is recommended that they be crossed out of the Category IV Register (but with their names left legible) and a comment noted in the last column that they have drug-susceptible disease. The DST results should be completed in the Category IV Register. Patients who are entered in the Category IV Register and whose DST results subsequently show mono- or poly resistance, but not MDR-TB, can also complete their treatment in the traditional District Tuberculosis Register; the regimen is

adjusted according to the DST pattern (see Chapter 8). All patients who are switched back should be analysed in their original line in the District Tuberculosis Register. They do not need to appear in Forms 07, 08 and 09.

All patients for whom a Category IV regimen is indicated should be entered in the Category IV Register, whether or not a Category IV treatment is started.

The following information is recorded in the Category IV Register:

- **Category IV registration number.** This is a unique identification number for each patient who enters Category IV.
- **Date of registration.**
- **Name, sex, date of birth, address.**
- **District TB registration number.** All patients should have been entered in a District Tuberculosis Register. A patient who for any reason has never been registered in the District Tuberculosis Register should be registered there and the number transferred to the Category IV Register.
- **Site of disease.** Pulmonary or extrapulmonary (note: a patient who has both pulmonary and extrapulmonary disease should be recorded as a pulmonary case).
- **Registration group.** Described in Chapter 4.
- **Second-line drugs already received.** State “yes” or “no” (see explanation for Form 01 above).
- **DST.** Date and results. Patients may have had more than one DST. Enter the DST that resulted in the patient being registered as a Category IV patient. If the DST is pending it should be filled in when the results are known. Follow-up DSTs are not recorded in the register. If the patient has more than one DST, results are recorded on the treatment card.
- **Reason for Category IV registration.** Reasons include confirmed MDR-TB or suspected MDR-TB, which is defined by the country protocol. Although it can be determined that patients have MDR-TB from the DST columns for H and R, the register should have a separate column that differentiates documented MDR-TB patients from suspected Category IV patients.
- **Category IV regimen.** Record the initial Category IV regimen using the drug abbreviations and enter the date the regimen was started.
- **Smear and culture monitoring results.** Date and outcome. Instructions and codes for recording smear and culture outcomes are summarized on page 4 of the register (Form 02).
- **Final outcome.** See Chapter 4 for definitions.

- **HIV status.** If available.
- **Comments.** This section is reserved for any additional information.

18.4.3 Patient identity card (Form 03)

A patient in whom TB is diagnosed should have a patient identity card completed by the health-care provider at the same time that the treatment card is completed. The card should be kept by the patient. The card, which is wallet-sized, contains the name, age, sex, TB identification number, essential information about the treatment (start date, regimen, allergies and severe adverse effects to medications), and the health centre where the patient will receive treatment. It also has a place to write the date of the next appointment.

18.4.4 Request for sputum examination (Form 04)

A sputum smear examination is needed in all cases of suspected TB. When smear examination alone is requested, the regular DOTS request for sputum examination can be used. When requesting culture and/or DST, Form 04 should be used. The first part of Form 04 is exactly the same as that recommended for DOTS programmes (since culture is also carried out on specimens sent for smear); the middle portion of the form is for requesting culture and DST; the last section is used for reporting the results. The completed form is then sent promptly to the treating unit with the results.

18.4.5 Laboratory registers (Forms 05 and 06)

Laboratories will have separate registers for sputum smear microscopy and culture, while reference laboratories carrying out DST should have an additional DST register. Form 05 is based on the sputum smear microscopy laboratory register for DOTS. It should be used as the primary laboratory register recording results on smear, whether this test is done for diagnosis or for monitoring. Form 06 is the laboratory register used to record culture results. The DST register should be compared regularly with the Category IV Register to ensure that all resistant cases are entered in the Category IV Register and in the quarterly reports on case-finding.

18.4.6 Quarterly report on Category IV case registration (Form 07)

The quarterly report is completed from the Category IV Register and is designed to report the number of patients registered in diagnostic Category IV and how many were started on Category IV regimens. A considerable delay usually occurs between registration and the start of treatment, so the information gives an approximate indication of the coverage of treatment. The quarterly report also shows how many patients with MDR-TB were registered during the quarter, by type of case.

This report should be completed with a delay of one quarter, to allow time

for culture and DST results to be available. For instance, TB patients registered during the first quarter of a year (1 January to 31 March), should be reported in the quarterly report after 1 July.

18.4.7 Six-month interim outcome assessment (Form 08)

Each quarterly cohort defined by date of the start of Category IV treatment should have an interim or preliminary outcome report. This report should be prepared by the central TB unit and based on the Category IV Register. A delay of 2 to 3 years occurs before final results are known, so it is helpful for programmatic monitoring to report preliminary results for all cohorts.

These guidelines recommend reporting interim results at 9 months after the closing day of the cohort. This allows culture information at 6 months of treatment to be included for all patients in the cohort. For instance, TB patients who started treatment during the first quarter of a year (1 January to 31 March), should have the “Six-Month Interim Outcome Assessment Form” filled out from 1 January of the following year.

In situations where it is important to measure the treatment coverage (the proportion of registered cases that are started on treatment), an additional form could be used to compare the number of patients with confirmed MDR-TB who are registered during the quarter with the number of these cases that were started on treatment.

18.4.8 Annual report of treatment outcome of Category IV regimens (Form 09)

This report shows the final result of treatment by year since the start of treatment, in total and stratified by smear and culture results and by patient registration category. Since treatment is of long duration, the results reflect retrospectively the management of treatment over a prolonged period. Form 09 is completed at both 24 and 36 months after the last patient starts treatment in the cohort. Most of the patients will have finished treatment by 24 months and this allows preliminary assessment of cure rates. Since a few patients may be on treatment for longer than 24 months, the form is completed again at 36 months after the last patient in the cohort starts treatment. The 36-month evaluation is considered the final *Treatment Cohort Analysis* result.

As noted above, patients who are entered into the Category IV Register but later found to have drug-susceptible forms of TB are placed back in the District Tuberculosis Register and their outcome is recorded there.

18.5 Addressing the backlog of patients defined as “chronic cases”

Many programmes may have a large group of patients defined as “chronic cases” (those who are still sputum smear-positive after supervised re-treat-

ment; proven or suspected MDR-TB) (*I*) from previous years waiting to enter a new Category IV regimen. Programmes that have not yet started Category IV treatment should keep a list of such patients. When Category IV treatment becomes available, chronic cases with evidence of active disease should be registered in the Category IV Register and treatment started.

As the Category IV treatment programme progresses, the list of patients defined as chronic cases will become smaller and eventually it will include only cases that have failed Category IV treatment.

18.6 Other programme indicators

In addition to the 6-month indicators and the final outcome of MDR-TB treatment cohorts, programmes should examine other programme indicators. Some suggested programme indicators are:

- Burden of MDR-TB defined as the absolute number of MDR-TB cases among new cases, and re-treatment cases including failures of Category IV regimens.
- Percentage of MDR-TB among different treatment history groups: new, relapses, return after default, failures of Category I, failures of re-treatment.
- DST coverage in different treatment history groups: new, relapses, return after default, failures of Category I, failures of re-treatment.
- MDR-TB treatment coverage (number of patients placed on treatment divided by the total number of MDR-TB patients notified). This indicator can be analysed separately for each treatment history group.

18.7 Computerized systems

All the forms can be handwritten. However, an electronic version entering the data from the Category IV treatment card (Form 01) is highly desirable since it facilitates better quality of information as well as data analysis. The Category IV Register and Forms 07–09 can then be generated easily from the computerized register.

The forms discussed in this chapter are available on the WHO Stop TB web site (www.stoptb.org). In addition, alternative versions of forms for programmes doing DST in all new patients will be placed on the web site.

18.8 Training

The information system for drug-resistant TB 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 the quality of the information.