healthlink WORLDWIDE

Strengthening TB treatment

Photo by WHO/EPI

How to implement DOTS

This guide is designed to give a basic overview of the DOTS strategy, including the people who are involved and the resources that are needed to set up a successful programme. The Healthlink Worldwide website (www.healthlink.org.uk) has a list of references where you can find more information.

Why is DOTS needed?

Although health workers in many areas are working hard to diagnose and treat tuberculosis (TB), the number of people with TB is increasing rapidly. Some of the increase is due to the increasing HIV epidemic, but the number of TB cases is also increasing because of failures in existing treatment strategies for TB. People may be unable to access diagnosis and treatment for many different reasons (see below). Effective treatment of TB is important for individuals, their families and communities. People with active TB can spread TB to other members of their families or communities. They become sick, are unable to work or fulfil family commitments, and will eventually die if their TB is left untreated. People who stop TB treatment before completing the course can continue to spread TB and may develop drug resistance.

What is DOTS?

DOTS (Directly Observed Treatment, Short course) is a new treatment strategy for TB that aims to address these challenges. This strategy is usually implemented through local or national programmes. DOTS is based on the direct observation of people taking their TB drugs. However, the DOTS strategy includes much more than direct observation of treatment, as many factors are needed to ensure adequate and accessible TB care. These include:

- political commitment ensuring adequate funding
- education for people with TB and their communities
- reliable case detection using sputum smear microscopy to identify people with active TB
- standardised short course treatment for all people with smear positive TB
- direct observation and support for people taking drug treatment
- a regular and reliable supply of free drugs
- accurate record keeping to identify people who do not complete treatment
- effective monitoring both of people who are receiving treatment and of the performance of the DOTS programme as a whole.

DOTS can be used to treat new TB cases, people who have relapsed, people who have previously had treatment, but not finished the course, and people who need retreatment.

What makes DOTS different?

Many people cannot access TB treatment or do not complete their TB treatment because of:

- the need to take time off work or away from family
- the cost of travel to the health facility or of drug treatment
- a lack of available drugs
- the belief that because they feel better they are cured and can stop treatment
- having to take lots of different pills for a long time
- a lack of user-friendly health services (e.g. unfriendly staff or unfriendly opening times)
- needing permission to travel or to see a health worker (e.g. in some cultures women may need their husband's or father's permission to travel or may need to be accompanied by a family member if they visit a health worker).

Accessibility

The DOTS strategy aims to improve access to TB treatment by:

- making treatment and diagnosis free
- using standardised courses of treatment

- making treatment community-based, so people do not need to take time off work or from domestic responsibilities to go for treatment
- providing community education, so that people can recognise the symptoms of TB and go to a health worker for diagnosis and treatment.

People are more likely to seek diagnosis and treatment if treatment centres are close to where they live. People are also more likely to continue with treatment if it does not interfere with their work or family commitments. DOTS is most likely to be effective in a community setting. By training community health workers or community volunteers as treatment supporters people can have their treatment in a way that does not disrupt their everyday lives.

Support

The person observing treatment is called the treatment supporter. Observing treatment is not the only role of a treatment supporter, they can also provide the support, encouragement and counselling necessary to help people complete their course of treatment.

Currently, research confirms that the DOTS strategy works. However, it is unclear whether it is necessary to observe every dose of treatment or whether less frequent observation (e.g. weekly) is equally effective. Either way, the treatment supporter needs to be someone who is accessible, reliable and concerned for the health of the person with TB. The treatment supporter provides encouragement, checks that the correct number of tablets has been taken, and follows up people who miss treatment.

Monitoring

The recording and follow-up systems that are part of the DOTS strategy mean that both people taking treatment and the DOTS programme as a whole can be monitored effectively. People who stop treatment can be quickly identified and health workers or treatment supporters can work with them to understand their reasons for stopping treatment and try to find a solution. At district level, the TB officer can use the records that are part of the DOTS programme to assess the programme and identify any problems, which can then be tackled effectively.

Making a difference

DOTS is not the final solution to the TB crisis – diagnosis and treatment still need to be made easier for health workers and people with TB. However, with the current resources available, DOTS is probably the most effective way of treating TB and ensuring people complete treatment. In resource-poor countries, DOTS can improve the life of individuals with TB and the whole community.

How a DOTS programme works

Community education

What is it? The first step in encouraging people to seek treatment for TB is educating them about TB, its symptoms and its treatment, so people with symptoms will go to a health facility to seek diagnosis and treatment. Community education plays an important role in this process. Helping people to understand the importance of completing treatment plays an important role in encouraging them to continue taking their TB drugs for the complete six to eight month course.
Who does it? Health workers and community health workers.

Case detection

What is it? Screening people who come to health facilities who have had a cough for more than three weeks is seen by many health workers as the best way to identify people who have pulmonary TB. When the health worker suspects a person has TB and has discussed this with them, the person with suspected TB needs to provide three sputum samples.

Photo by WHO/EPI

Donating sputum for a test

The samples are collected over a 24 hour period: one when the person visits the health facility, one early next morning, and the next when the person with suspected TB returns to the health centre the following day. Samples are then sent to the diagnostic centre (or the person can travel to the diagnostic centre to provide samples).
Who does it? Health worker at DOTS treatment centre or diagnostic centre.

Diagnosis of sputum smear positive TB

What is it? Diagnosis of people with active TB is based on sputum smear microscopy (see page 6).

The laboratory staff complete a laboratory register and return the results of the sputum smears to the treatment centre.
Who does it? Laboratory technician.

Treatment

What is it? Treatment under the DOTS strategy consists of a combination of drugs taken over a six to eight month period. In the first two months (the initial phase), four drugs are taken together, while for the following four to six months (the continuation phase) fewer drugs are taken. If the treatment is carefully followed, a person with infectious pulmonary TB will stop being infectious within two to six weeks. Doctors at the diagnostic centre classify the person with TB and prescribe treatment according to national programme guidelines.

Counselling for people with TB can focus on:

- treatment and its possible side-effects
- the importance of continuing treatment until complete
- how to tell family members and encourage them to be screened for TB.

In some countries with a high burden of HIV, many people with TB will also be HIV-positive. People with TB can be counselled about this possibility, offered an HIV test, advised about the use of condoms and advised to consult a health worker if they become ill with chest or other illnesses.
Who does it? Doctor at diagnostic centre.

Direct observation

What is it? Direct observation of tablet taking during the intensive phase (at least in people with smear positive TB) is currently recommended in the DOTS strategy. However, on-going encouragement from the treatment supporter is the most important part, helping to ensure that people complete treatment and are cured.

Who does it? A treatment supporter — usually a community health worker or a community volunteer, but in some cases a health centre health worker or a work place supervisor, if this is more acceptable and convenient.

Support for people with TB

What is it? Treatment support is one of the most important features of the DOTS strategy. TB treatment continues for eight months and people with TB often need encouragement to complete their course of treatment. This is one of the most important aspects of the DOTS strategy.
Who does it? Treatment supporter.

Identifying people who stop treatment

What is it? It is important to identify people who stop treatment before their TB is cured. People who stop treatment can continue to spread TB to others. Interrupting or stopping treatment can also lead to drug resistance.

Treatment cards can help identify people who stop treatment quickly. These people can then be followed up and encouraged to continue with their treatment.

People who interrupt treatment should be encouraged to re-start treatment, but the management of such cases depends on:

- type of person, e.g. first TB treatment, multi-drug resistant TB, repeat treatment
- length of time the person took treatment
- length of interruption of treatment
- whether they are sputum smear negative or positive when returning to treatment.

People who interrupt treatment should be referred to a trained TB nurse or doctor, who can assess them and prescribe appropriate treatment.
Who does it? Treatment supporter, late patient tracers (who may be health workers at treatment centres or community health workers), health worker at a treatment centre.

Assessing the DOTS programme

What is it? Monitoring and evaluation of the performance of the DOTS programme using the standard supervision and reporting forms (see page 7). This allows early identification of problems and improvement of the programme.
Who does it? District TB officer.

Resources needed for a DOTS programme

The decision to introduce DOTS should be made jointly by the national TB programme and the district health or medical officer. The areas most suitable for first introducing DOTS are districts that are accessible, have a high TB burden and are already using standard short course treatment.

A successful DOTS programme needs: physical resources (e.g. a laboratory, a treatment centre, a reliable drugs supply) and human resources (well-trained laboratory staff and health workers).

Physical resources

DOTS diagnostic centre

A diagnostic centre is the place where people with longstanding cough and other respiratory symptoms are screened for TB and where people with TB can start their treatment. The centre should be easily accessible, well-equipped with a reliable supply of drugs and materials (see below), and have well-motivated and well-trained staff (see page 5), so the DOTS programme is likely to be successful and can be a model for future programmes.

What does a diagnostic centre do?

- Screens people with TB symptoms.
- Carries out sputum smear microscopy.
- Diagnoses TB.
- Registers people with active TB for treatment.
- Starts TB treatment.
- Works with person with TB to identify DOTS supervisor.
- Traces people who stop treatment.

Treatment centres

Many people will live a long way from the diagnostic centre, so treatment centres should be set up. Treatment centres do not diagnose people or start treatment, but are places people can collect their month's supply of drugs and have a monthly review meeting to check their progress. Staff at treatment centres also supervise treatment supporters, refer people with respiratory symptoms or side effects to diagnostic centres and trace people who stop taking treatment.

What does a treatment centre do?

- Identifies and refers people with suspected TB to diagnostic centre.
- Provides or arranges community-based treatment observation.
- Supplies TB drugs.
- Maintains case records.
- Traces people who stop treatment.
- Refers people with major side effects to diagnostic centre.
- Maintains stock books for drugs and materials.
- Supervises treatment supporters.

Laboratory and laboratory supplies

Reliable diagnosis of TB is important to identify everyone who has active TB and who needs treatment. The best way to do this is using sputum smear microscopy, which involves looking under a microscope to see if there are TB bacilli in the sputum sample of a person with suspected TB. Resources needed for good sputum smear microscopy include well-trained staff (see page 7) and well-maintained laboratory equipment.

Equipment needed includes microscopes, refrigerators, clean glass slides, sputum specimen pots, fresh reagents, and a supply of clean water. TB is highly infectious, so laboratories should have facilities to minimise the chances of workers becoming infected (e.g. by using fume cupboards, gloves, masks). Laboratory managers should ensure that there are enough reagents, slides and containers for the following three-month period using the same criteria as detailed below for maintaining a reliable drug supply. A quality control system should also be in place.

Arrangements also need to be made for sputum specimen pots to be available at all necessary health facilities and for the safe delivery of sputum specimens to the laboratory and reliable delivery of results back to the person prescribing treatment.

Laboratory managers should also make sure there are guidelines for safe disposal of slides, used reagents etc and that staff follow these guidelines. It is also important to ensure equipment is used correctly, taken care of (e.g. switching microscope off at the end of the day and covering it with a dust cover) and maintained regularly. Routine care and maintenance can improve the efficiency of equipment and keep it working longer. Managers can set up a system for reporting equipment defects and encourage staff to report problems quickly.

Uninterrupted supply of drugs

The most commonly used TB drugs are isoniazid, rifampicin, ethambutol, pyrazinamide, streptomycin (given by intramuscular injection) and thiacetazone. Thiacetazone is not recommended in areas where HIV infection is common because of side effects. Some of these drugs are available in combination preparations, for example isoniazid and rifampicin. Courses of treatment that contain both isoniazid and rifampicin are the most effective. Programmes should consult national guidelines

for treatment regimes.

Depending on the combination of drugs used, short course treatment usually lasts six or eight months. The treatment comprises:

- **An initial intensive phase** in which a combination of four drugs is taken daily for two months. This is to eliminate as many TB bacilli as possible and prevent the development of drug resistance. Most people will be smear negative (and non-infectious) after two months of treatment.
- **A continuation phase** in which fewer (usually two) drugs are taken. This phase continues for four to six months to ensure the person is completely cured and does not relapse.

People with TB often stop taking medicines because the drugs are not available. To prevent this, TB drugs should be free and an uninterrupted supply of drugs must be maintained. If people have to pay for drugs they may stop treatment as soon as they start to feel better in order to save money.

Treatment centres should hold enough drugs to treat all patients for four months and a 'buffer' stock of drugs, so that treatment can be continued if supplies are delayed. As a guide to ensuring sufficient stocks of TB drugs, the person who manages the drug supply should estimate the number of people who will be diagnosed with TB at the treatment centre over the next four months. Then they can calculate the quantity of drugs needed to provide all these people with a full course of treatment, double the amount and subtract the existing stock. This gives the quantity of drugs needed for four months and an adequate back-up stock in case of delays or interruptions in supply. This should be done for each of the drugs in the treatment regimes.

If TB drugs are out-of-stock, people should not be started on treatment using only some of the drugs in a recommended regimen, as this may lead to drug resistance. It is important to get all the drugs required, before starting treatment.

A health worker gives TB drugs to a patient

Photo by WHO/TDR/M Edwards

Human resources

Commitment at all levels of health service

Commitment to DOTS is necessary at all levels to ensure that essential resources, such as staff, drugs and laboratory supplies, are allocated. DOTS can involve public and private health services, non-governmental organisations and mission health services, private companies who provide health care for their workers, private practitioners, and the local community.

The decision to introduce DOTS is usually made jointly by the national programme and the district TB or medical officer. DOTS can be phased in giving priority to districts that are accessible, have a high number of cases of TB, are already using standard short course treatment and where there is a good chance of success.

Community involvement

Community co-operation is essential for a successful DOTS programme. DOTS committees can serve as a link between health services and local communities. DOTS committees should include motivated people including people with TB, health service managers, civic leaders, representatives of local organisations and local communities. Before DOTS is introduced, the district health officer can call a meeting with community members and leaders to introduce the DOTS programme and suggest forming a DOTS committee. The local community should be involved in the decision about who sits on the committee to ensure that the DOTS programme receives local support.

It is important that the DOTS committee has a clear idea of the activities and involvement required from it.

DOTS committees can:

- increase public awareness about TB in the community through advocacy and education
- support people in the community with TB by providing DOTS supervisors and people to follow-up those who stop treatment
- identify local problems in DOTS implementation and propose solutions at community level
- encourage co-operation between health institutions, health workers and NGOs
- protect health workers at treatment centres from undue political pressures.

The best size for the committee is about 10-15 people, who will need to meet at least every four months in the first year of the DOTS programme and as necessary after that. DOTS committees should ideally include people from each of the groups discussed below.

District TB officers

District TB officers have an important role to play in a successful DOTS programme. It is district TB officers who introduce the idea of DOTS to the district and local communities and suggest the idea for a DOTS committee. District TB officers are usually members of the DOTS committee.

In addition, district TB officers need to assess the training needs of

all those involved in the DOTS programme and plan (and sometimes carry out) training.

It is also district TB officers that carry out supervisory visits to check that guidelines are being followed and that staff are carrying out monitoring and recording procedures according to guidelines. Supervisory visits should cover feedback, education, guidance, co-ordination, problem solving and motivation.

Health workers and staff are more likely to have questions and encounter problems in the early stages, so more frequent supervision is needed during the first few months after introducing DOTS. After that, if there are no problems, the frequency of supervisory visits can be decreased.

A suggested timetable for supervision visits is every month for the first four months, every other month for the next four months and every quarter after that.

District TB officers will check TB registers at treatment centres and also compile and analyse case finding reports, smear conversion reports and treatment outcome reports (see page 8).

Laboratory technicians

The role of laboratory technicians is to correctly identify cases of active TB from sputum samples, using sputum smear microscopy. Laboratory technicians examine three samples from each person with suspected TB. If TB germs can be observed in a sample then the sample is sputum smear positive. If two of the three samples the person supplies are sputum smear positive then they are diagnosed as having active TB. Poorly trained staff or inadequate equipment can lead to misdiagnosis meaning that people with active TB do not receive treatment (and in some cases that people who do not have active TB are treated). Laboratory technicians also need to keep a register of samples received and results and to return a diagnosis report to the treatment centre.

Health workers

Health workers (i.e. qualified nurses and doctors at the diagnostic centre) need training in collecting sputum samples and giving people results of their sputum smear test. Doctors need to be able to classify people with TB correctly (e.g. as new case, retreatment, treatment lapsed) and prescribe drugs according to national guidelines.

Health workers at treatment centres are involved in keeping treatment cards for individuals, detecting and referring people who may have TB, reviewing individuals on a monthly basis and identifying and tracing people who stop treatment before it is complete. At the treatment centre health workers need to keep the TB register up-to-date and to ensure that the contents of the laboratory reports are transferred to the TB register. Health workers may also provide regular and routine supervision of treatment supporters, e.g. weekly visits to the treatment centre, regular meetings of all treatment supporters. During these visits the health workers check the treatment support card, ensuring that all treatments have been observed, and update the treatment card held at the treatment centre.

Community health workers

Community health workers, who may include traditional healers, are often involved in educating communities and people with TB about diagnosis and treatment. They can help to identify people with possible TB at community level and encourage them to go for diagnosis and treatment. Community health workers can also act as DOTS treatment supporters.

Late patient tracers

A variety of different health workers can be trained as late patient tracers. Their job is to identify people who have missed treatment (using treatment records) and follow these people up. Late patient tracers need training to ensure that they follow up people in a sensitive way and can help them identify why they have stopped treatment (although this may also involve other health workers) and encourage them to resume treatment.

Community volunteers

Community volunteers can be trained as treatment supporters. Community volunteers need to be reliable and accessible to the person taking treatment. All treatment supporters need to understand and carry out the seven essential components of treatment support.

1. Collect tablets on a monthly basis and store drugs correctly.
2. Direct observation of treatment (correct drugs and correct dosage).
3. Daily recording of treatment on treatment support card.
4. Understand the need for the person being treated to visit the treatment centre at the end of the intensive phase.
5. How to identify and refer side effects.
6. Discussing difficulties of treatment and how to overcome them.
7. Helping to trace and retrieve people who are late for or who stop treatment.

Supervision checklist for a district TB officer

- Make sure all staff are following national policies and guidelines and are maintaining records and reports correctly.
- Check that health workers strictly follow the First expired, First Out approach to drug dispensing to avoid expiry of shorter shelf-life drugs.
- Ensure that regular reporting on drug use and stocks is carried out.
- Check that the laboratory is working properly and that the laboratory technician is keeping all the slides for quality assurance.
- Check supplies, materials, drugs and equipment are stored correctly.
- Check safe disposal practices for sputum specimens, used reagents, etc.
- Check that centres are ordering sufficient quantities of drugs, reagents, equipment and forms.

Training people involved in DOTS

DOTS programmes should not be introduced until everyone involved has received appropriate training.

DOTS committee members
Training includes an introduction to DOTS and reasons for implementing the strategy. Training takes about one day at district level.

Laboratory technicians
Training in how to carry out sputum smear microscopy and to diagnose smears correctly. Training takes about 10 days at regional or district level.

Health workers at diagnostic centres
Training in treatment regimes and how to classify people with TB, and managing people who do not complete treatment or treating difficult cases of TB (e.g. people remaining positive after extended intensive phase, or those with extra-pulmonary TB). Training takes about six days at district level.

Health workers at treatment centres
Training in current thinking on TB and its treatment and overview of the DOTS strategy, community education, how to take sputum samples, how to observe treatment, and how to keep records. Training courses are about three to six days long at district level.

Late patient tracers
Training will probably take about one day. (This may be part of the training for health workers at treatment centres or community level if they are responsible for tracing people who stop treatment.)

Community health workers
Training in community education and how to observe treatment takes about one day at district level.

DOTS treatment supporters
All treatment supporters should be trained in how to observe treatment, how to fill in treatment support cards and how to support and encourage the person taking treatment. This training can be done at the DOTS treatment centre.

After these initial training courses, people will continue to benefit from 'refresher' training courses, continuous on-the-job training and support from managers and colleagues.

Monitoring and evaluating a DOTS programme

The two most important aspects of monitoring are reports on case finding and outcome of treatment and evaluation. Regular monitoring and evaluation are essential to ensure that policies are being followed, to provide on-the-job training and to help health workers to solve problems at a local level. Identifying and solving problems locally can help health workers to identify gaps in services and encourage them to try to adapt DOTS to suit people with TB (e.g. by travelling to a person's home or choosing someone in their local community to observe them taking treatment, instead of the person with TB having to travel to the health centre).

Treatment support cards

What are they? Cards filled in by the treatment supporter as they observe each dose of treatment.
What are they for? Provide a daily record of direct observation. Health workers can check the treatment support cards on supervisory visits to the treatment supporter.
Who fills them in? Treatment supporter.

Treatment cards

What are they? Each individual has a treatment card kept at the treatment centre, which health workers update at supervisory visits to treatment supporters or monthly review meetings with the person with TB.
What are they for? A central record of treatment observation, drug supply and progress at monthly review meetings. This process of record-keeping ensures that people who stop treatment can be quickly identified and followed up.
Who fills them in? Health worker at treatment centre.

TB register

What is it? A record of everyone in a district who is receiving treatment for TB.
What is it for? To ensure that all those with positive sputum smear results (i.e. those diagnosed with active TB) are receiving treatment.
Who fills it in? District TB officer.

Laboratory register

What is it? A record of the results of all the TB sputum smears carried from the laboratory (the diagnostic centre).

What is it for? For cross-checking with TB register to ensure all those with positive sputum smears are receiving treatment.

Who fills it in? Laboratory technicians.

Case finding reports

What are they? Quarterly reports on new cases and relapses of TB diagnosed and registered during a three-month period.

What are they for? Case finding reports can show progress towards improved detection and identification of people with TB.

Who fills them in? A member of staff at the diagnostic centre (probably the district TB officer) is responsible for filling in these reports. The case finding report needs to be checked against the TB register and the laboratory register to ensure it includes every person on the TB register.

Smear conversion reports

What are they? Every person being treated for TB should have a smear examination at two months (new treatments) or at three months (retreatments). The two-month smear conversion report is for people who were smear positive at the beginning of treatment. Follow up sputum examinations are essential to reduce the risk of treatment failure or relapse and to be able to evaluate cure rate.

What are they for? Smear conversion reports are a measure of response to treatment, and also give an early indication of the effectiveness of the treatment centre in providing DOTS. A change in smear conversion rates can help identify problems quickly (e.g. new staff who may not be properly trained) and solve them quickly (e.g. by providing appropriate training).

Ideally the smear conversion report should show that:

- the number of people with smear positive TB in the smear conversion report is the same as the number in the previous case finding report
- every person treated for TB has a smear examination result at the end of the intensive treatment phase
- the smear conversion rate is between 80 and 90%.

Who prepares them? Health workers at the TB treatment centre prepare the information for the report. The district health officer checks and analyses the results.

Information recorded by health workers is a vital part of effective TB treatment

Photo by WHO/J L Ray

Treatment outcome reports

What are they? Treatment outcome reports include information about how many of people with pulmonary TB, who were registered 12–15 months earlier, have successfully completed treatment and how many have not. Successful treatments include cured and treatment completed, while unsuccessful treatments include treatment failures, people who did not complete the full course of treatment, those who die, and people who transfer out of the programme.

What are they for? These reports can help to identify whether treatment arrangements are working effectively or not. Treatment outcome reports can be used to assess whether programmes are providing high level care or whether quality of care needs to be improved.

Who fills them in? District TB officers, using information available from previous reports, diagnostic and treatment centre registers.

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healthlink WORLDWIDE

Healthlink Worldwide
Cityside
40 Adler Street
London E1 1EE, UK
Tel: +44 (0)20 7539 1570
Fax: +44 (0)20 7539 1580
E-mail: publications@healthlink.org.uk
http://www.healthlink.org.uk