World Health Organization

FAQ on Multidrug Therapy (MDT)

Managing irregular treatment

What kind of harm can be done if patients are irregular in taking MDT?

The most serious harm that can be done if patients do not take MDT regularly is that the cure will be delayed or incomplete. The disease activity will progress and the patient may develop serious disabilities and deformities. These patients will become a source of infection to the community, in addition to perpetuating stigma generated by unsightly deformities. More seriously, if the irregularity is selective to one or the other drug in MDT then there is a possibility of drug resistance to multiple drugs. However, the WHO-recommended MDT regimens have been shown to be robust i.e. even if taken irregularly, they have benefited patients.

What should be done if a PB patient, 9 months after starting treatment, has not taken 6 monthly doses of MDT or if an MB patient has not completed 12 monthly doses of MDT 18 months after starting treatment?

Such situations should be exceptional or rare in a good programme which is providing MDT services without any inconvenience to the patient, keeping the patient fully informed of the importance of regular drug intake. However, if a patient is unable to complete the required number of doses in time, for any reason, the treatment regimen should be continued from where it was left off and the full course completed. Do not restart the regimen from the beginning. If the patient is properly advised at the time of diagnosis, in most cases it is possible to let the patient take full responsibility for his/her treatment.

What is a defaulter? What should be done if a defaulter comes back for treatment?

A defaulter is a patient who has not collected treatment for 12 consecutive months. Once a patient has been categorized as a defaulter this patient should be removed from the register. Before doing so, adequate efforts should be made to trace and persuade each defaulter to return for assessment and treatment. A defaulter who returns to the health centre for treatment and shows one or more of the following signs should be given a new course of MDT:

- reddish and/or elevated skin lesions appearance of new skin lesions since last examination
- new nerve involvement since last examination
- lepromatous nodules
- signs of erythema nodosum leprosum (ENL) or reversal reaction.

Relapse after treatment

After patients have stopped treatment, how does one recognize relapse? How can relapse be distinguished from the various types of reactions?

Relapse, in MB leprosy, is defined as the multiplication of M. leprae, suspected by the marked increase (at least 2+ over the previous value) in the BI at any single site, usually with evidence of clinical deterioration (new skin patches or nodules and/or new nerve damage). This can be confirmed in most cases by the growth of M. leprae in the mouse footpad system. Recognition of relapse in paucibacillary leprosy is somewhat difficult as it is hard to distinguish it from reversal reaction. In theory, a therapeutic test with corticosteroids may be able to distinguish between these two phenomena: definite improvement within four weeks of corticosteroid therapy denoting reversal reaction, and non-response to corticosteroids during the same period favouring the diagnosis of clinical relapse.

A small number of patients do not show any clinical or bacteriological improvement with MDT. How should these patients be managed?

There may be several reasons for such occurrences in a small number of patients. The two most important reasons may be very poor drug compliance and other concomitant, debilitating, intercurrent infection. The problem of poor compliance may be solved by supervised drug administration and health education. The problem of concomitant, intercurrent infection needs thorough investigation (including, where indicated, tests for HIV infection) and appropriate management. If these measures fail, it may be necessary to seek expert opinion.

Side effects

Does MDT expose patients to a higher risk of serious side-effects?

When more than one drug is used, naturally there is a risk of side-effects from each of the drugs used in the combination. However, in practice, the side-effects reported from the use of MDT in several hundreds of thousands of patients around the world show that most of them are mild and major side-effects are rare.
Does MDT increase the frequency and severity of lepra reactions?

The evidence available shows that there is a significant reduction in the frequency and severity of ENL (Type II) reactions in MB leprosy patients on MDT. It is possible that this is attributable to the anti-inflammatory effect of clofazimine. On the other hand, there seems to be a higher reporting of reversal reactions (Type I) in MB leprosy patients in the first year of MDT which then gradually declines. However, it is not clear whether this is because of more stringent follow-up of patients, which detects mild reactions that would otherwise have been missed, or whether there is a real increase in the incidence of reversal reactions.

How serious are the side-effects of clofazimine, such as discolouration and ichthyosis and how can they be managed?

How serious are the side-effects of clofazimine, such as discolouration and ichthyosis and how can they be managed?
The discolouration caused by clofazimine usually does not cause any serious problem, except for the fact that it may be cosmetically unacceptable to some patients. The accompanying ichthyosis may predispose to certain dermatitis, especially in dry climatic conditions. This can be reduced by moistening the skin, followed by regular application of vaseline or vegetable oils and avoidance of unnecessary exposure to bright sunlight.
How long does it take to reverse the discolouration caused by clofazimine?

The discolouration caused by clofazimine is completely reversible. It starts to appear by the third month of MDT and reaches its maximum intensity by the end of the first year. After discontinuation of MDT, the discolouration starts to diminish noticeably in six months and the skin returns to its normal colour at the end of one year after stopping MDT.

MDT and skin smears

Are skin smears a prerequisite for starting a patient on MDT?

No, skin smears are not a prerequisite for starting a patient on MDT. The clinical system of classification for the purpose of treatment includes the use of numbers of skin lesions and nerves involved as the basis for grouping the leprosy patients into MB and PB. If in doubt, the patient should be treated with MB regimen.

How often should skin smears be taken during and after the completion of MDT?

If reliable facilities for skin smears are available, then ideally all patients should have one examination at the start of treatment. This is to prevent an MB case being treated as PB. With fixed-duration treatment regimens, skin smears are not needed either to stop treatment or as a routine measure for follow-up of patients after completion of treatment.

In patients where clinical deterioration/relapse is suspected, skin smears should be taken from the most active sites. In view of the increasing prevalence of human immunodeficiency viruses (HIV) and hepatitis B infections in many countries where leprosy remains endemic, the number of skin-smear sites and the frequency of smear collection should be limited to a minimum.

It should be remembered that all skin-piercing procedures have the potential risk of transmitting HIV and hepatitis infections.