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## EIGHT MONTHS ON, STATES WAIT FOR 3HP TB PREVENTIVE DRUG

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Eight months after Prime Minister Narendra Modi <u>launched</u> the pan-India rollout of a shorter TB Preventive Treatment (TPT) in March 2023 called the 3HP — once-weekly isoniazid-rifapentine for 12 weeks — States are yet to receive the 3HP combination drug from the Central TB Division. Tamil Nadu and Kerala have already begun using 3HP for TB preventive treatment despite not receiving the drug supply.

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Currently, all household contacts of a person who has been recently diagnosed with pulmonary TB are tested for TB disease and those who do not have TB disease but have been infected with the bacteria are offered treatment to prevent the progression from latent infection to TB disease. Daily dose of isoniazid for six months, which is the current treatment protocol, translates to 180 pills. In contrast, the 3HP regimen of one combination drug a week for three months translates to 12 pills in all.

"Since treatment with 3HP involves only 12 doses, compliance is better, adverse effects of the drugs are less and treatment completion is better compared with 180 doses of isoniazid monotherapy," says Dr. Padmapriyadarsini, C, Director of the National Institute for Research in Tuberculosis (NIRT), Chennai. "TB disease should be ruled out before starting a person on preventive therapy. Also, other health conditions that may be contraindicated should be ruled out before starting on 3HP." According to the latest guidelines, all household contacts immaterial of age are eligible for TB preventive therapy once TB disease has been ruled out.

The 3HP regimen has been associated with a higher completion rate in all subgroups — adults with HIV, adults without HIV, and children and adolescents. According to the 2021 Guidelines for programmatic management of tuberculosis preventive treatment in India, the use of the shorter regimen was associated with "at least 20% greater treatment completion rate (82% vs 61%)".

Also, TPT using the 3HP drug is cheaper than isoniazid monotherapy for six months.

"No studies have shown that TB preventive therapy leads to drug resistance. But if active TB disease is not ruled out before starting TB preventive treatment, there is a risk of drug resistance setting in," says Dr. Padmapriyadarsini. "Doing a skin test to know latent TB infection status prior to starting prevention therapy helps in convincing young adults to start and complete the

treatment." Apparently, Health Technology Assessment had evaluated and found Cy-TB skin test for latent TB detection will be economical to the TB prevention therapy programme considering the number of TB cases and transmission that can be prevented and increased adherence to treatment.

While no head-to-head comparison trial between isoniazid for six months and 3HP has not been carried out in India, a trial has compared the two drug regimens in people living with HIV in South Africa. The trial found that the incidence of TB disease was the same in both the drug regimens. However, serious adverse reactions — hepatotoxicity — was significantly lower in people treated with 3HP.

While some States offer TB preventive therapy to those about to undergo organ transplantation, all States offer it to household contacts. "Though household contacts are considered at high risk of getting infected, less than 20% of infections can be attributed to household exposure, while the remaining infections could be attributed to community transmission," says Dr. Soumya Swaminathan, former Chief Scientist at WHO.

About 30-40% of the Indian population has latent TB infection, and 5-10% of those with latent infection will develop TB disease over the course of their lives. About half of those who develop TB disease will do so within the first two years of infection. According to the WHO, TB preventive therapy "can halt progression to TB disease very effectively for many years", thus preventing a large number of people from developing TB disease within two years of infection.

In high-burden countries such as India, the chances of reinfection after completing the TB preventive therapy are high, and such reinfection "may reverse this protection". Despite the likelihood of protection being reversed on reinfection, a WHO spokesperson tells *The Hindu* in an email that countries like India should invest in TB preventive therapy. "Yes, they should [invest in TPT]. Reinfection with TB after a course of TPT is certainly possible, but *M. tuberculosis* is less infectious than many other microorganisms so this eventuality should not stop programmes from investing in TPT," he says.

Combining TPT interventions with active TB case finding could achieve synergies," the spokesperson says. While 3HP can be offered to people who get reinfected, the WHO spokesperson says that currently there is no "good evidence on the additional benefits that this provides because of a number of technical issues. For example, there are no good tests that can confirm reinfection".

With smear microscopy forming the bulk of TB testing (despite its low sensitivity) and molecular testing constituting just 23%, should India prioritise molecular testing for all or should it also invest its finite resources into TB preventive therapy? The WHO spokesperson says India should invest more in TB screening using digital chest X-rays and molecular testing for TB disease confirmation. "TB preventive treatment like 3HP is an important accompaniment to this strategy, to protect TB-free individuals at risk from progressing to disease," he says. "Even if all this requires resources to reach the required scale, the return on investment is typically high, saving costs to both the services and society given the high price of undetected TB."

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