

Hospital or home? Scripting a high point in the history of TB care and control

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"A concurrent comparison of home and sanatorium treatment of pulmonary tuberculosis in South India" – popularly referred to as the Madras Study, revolutionized the public health approach to tackling TB.¹ It "liberated" treatment of TB, which was confined to sanatoria and hospitals, to health centres and homes, making it available to the masses who needed it most. The study is unique in many respects. The 93-page long article with an appendix of ten radiographs of patients treated in the "home" series of the study covered only two of the seven key objectives! The study helped initiate a lasting and what later proved to be a highly productive collaboration among the Indian Council of Medical Research (ICMR), the British Medical Research Council (MRC) and the World Health Organization (WHO). The MRC seconded Dr Wallace Fox, who coordinated the study, to WHO. The study engaged 100 staff – 40 from Madras government and 60 employed by the ICMR. Distinctively, it began with setting up of a Centre specifically for the study – Tuberculosis Chemotherapy Centre, which successfully completed the study and continued to exist thereafter, albeit with a different name – the Tuberculosis Research Centre, to produce some more landmark studies especially chemotherapy trials, which also informed subsequent global TB control policies.

What prompted setting up this landmark study? The provision of TB care at that time was largely restricted to TB specialists who managed their patients in specialized hospital units and sanatoria. Hospitalization also facilitated treatment supervision and patient follow-up. The specialist physicians often doubted the feasibility and effectiveness of ambulatory treatment as it would not guarantee treatment adherence, allow disease transmission to the households and the community, and potentially increase the risk of development of drug-resistance. However, providing hospitalized treatment to all the TB patients was beyond the capacity of most resource-poor countries which carried a high burden of the disease. At the time of the study, India had an estimated 1.5 million infectious TB cases and only 23 000 TB beds in sanatoria and hospitals. A majority of these facilities were run by private entities and mainly served the rich patients who could afford them. Early anti-tuberculosis drugs producing good results had arrived, and a policy decision choosing between home-based treatment and hospital-based treatment had to be taken. Dr C. G. Pandit, the then Director of ICMR, had emphasized "...in a country where for a long time to come adequate facilities for the isolation and treatment of the active case of tuberculosis is not practicable, the importance of providing adequate treatment in the

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patients' homes cannot be overemphasized. There is reason to believe that by a controlled use of chemotherapeutic agents, it may be possible to evolve a method of treatment under home conditions which can break the chain of person to person infection and render an infectious person non-infectious. The study has now been undertaken...".² And indeed the study did transform forever, the way TB was treated worldwide. Isn't it an irony that similar questions are being posed today for the treatment of multidrug-resistant and extensively drug-resistant TB?³

The study compared the effect of standard TB treatment at that time – isoniazid (INH) and para-amino salicylic acid (PAS) for a period of 12 months – in two groups of patients in a controlled clinical trial. One group was treated under good conditions in a sanatorium according to the existing standards and the other under ordinary conditions at homes of the patients. The sanatorium-treated patients, despite prompt nursing care, good accommodation, adequate bed rest, and balanced diet, did not fare any better than the patients treated in their own, overcrowded homes, had limited rest and a poor diet. Importantly, in spite of random allocation, the home series had more severe disease than the sanatorium series. It is worthwhile mentioning some other momentous findings of the study¹

- (1) quiescence of the disease at one year and relapses in the subsequent four years showed no differences between home and sanatorium patients;⁴
- (2) a five-year follow up of close family contacts did not show any special risk for contacts of patients treated in homes;⁵
- (3) treatment in sanatorium was no safeguard against irregularity of drug intake. A significant unexpected finding was that sanatorium treatment posed greater

social problems such as difficulties in making patients stay for a long period and disruption of family life.

The interim findings of the study were immediately reviewed in the seventh report (1960) of the WHO expert committee on TB. The committee noted that countries with a large TB problem and limited resources should use their scarce resources for setting up programmes supporting domiciliary use of anti-TB drugs rather than for construction of hospitals. However, it was only after all the results of the follow-up of patients were available, that the WHO expert committee, in its eighth report in 1964, recommended unambiguously that "all financial resources and manpower available for TB control in developing countries be confined to organizing efficient ambulatory services and not to constructing new beds. TB beds, where they already exist, should be integrated into the ambulatory and domiciliary services so as to ensure their most rational use". The global uptake of WHO recommendations was not as swift as expected. Seven years later, Dr Halfdan Mahler, pointed out in his article - the tuberculosis programmes in the developing countries - another public health classic, the incorrect advice that developing countries continued to receive "in recent months", including "it is bad public health practice to treat a case of infectious tuberculosis at home".⁶ In fact, hospitalization of TB patients, for the initial two months or longer remained a common practice in most African countries until recently. Probably because the study was a demonstration in an Indian setting, its findings were eventually taken up more quickly in Asian countries. More recently, a WHO-assisted multi-country project and other studies have demonstrated feasibility, effectiveness and cost-effectiveness of community-based TB care in Africa.^{7,8}

This truly remarkable study sowed the seeds for the DOTS strategy launched by WHO in the mid-1990s which reactivated the dormant and disappearing TB programmes. A critical demonstration of this study was that although irregular drug intake was significantly more among home-treated patients, hospitalization was not a guarantee for regular drug intake unless the patient was actually seen swallowing every dose. Without labelling it, the study prompted the need for what became known as “directly observed treatment (DOT)” decades later. In fact, it was also Dr Wallace Fox who first discussed in-depth the need for direct observation of treatment in another article.⁹ Summarising the experiences in diverse non-tuberculous conditions including rheumatic fever, myxoedema, epilepsy and leprosy, he observed that self-administration of drugs presents problems in tuberculosis also, and more importantly, “these problems are not confined to ‘underdeveloped’ countries”. In order to investigate the ideal form of chemotherapy for the home treatment of pulmonary TB, he pointed out the need to “investigate regimens given daily or intermittently under direct observation”. DOT incorporating Dr Fox’s own words “direct observation” thus became the central plank of the five-point DOTS strategy that promoted globally close supervision of treatment as a means to ensure cure. Key components of subsequent global TB control strategies have been alluded to by listing some of the essential requirements of a domiciliary TB diagnosis and treatment programme in the concluding statement: “.....adequate supply of anti-tuberculosis drugs, enough staff, including a public health nurse and a social worker, transport, a small number of hospital beds for special cases, an efficient appointment system, a system of surprise checks on the cooperation of the patients in taking their medicines, reliable smear examination of

sputum for tubercle bacilli, and a welfare fund for especially needy patients”.

The issue of community-based versus hospital-based care has again come into sharp focus in scaling up programmatic management of drug-resistant TB (PMDT). Albeit based on limited evidence yet, WHO guidelines on PMDT suggest that community-based care provided by trained lay and community health workers can achieve comparable results and may help in decreasing nosocomial spread of drug-resistant disease.^{3,10,11} WHO now promotes a comprehensive approach to TB care and control: the Stop TB Strategy.¹² This approach, built on the DOTS strategy, emphasizes patient-centred care. It recommends that patient supervision should be humane and integrate personal support and counselling. The Stop TB Strategy also underscores the importance of community engagement in TB care.¹³ This is a call to communities to contribute to their own health in the spirit of the Alma-Ata Declaration of Health for All. It supports patient participation in community-based and home-based care schemes. The rights-based approach guarantees cost-effective access to care while safeguarding patients in their own community.¹⁴ This policy recommendation would not have been possible without a clear demonstration that ambulatory care is as safe and effective as the hospital-based care.

In conclusion, the Madras study¹ is among the most influential in the history of TB care and control. Together with subsequent chemotherapy trials, also conducted at the then Tuberculosis Chemotherapy Centre, it proved that modern chemotherapy regimens cured virtually all TB cases. Those who still doubt domiciliary treatment of multidrug resistant TB will likely be contradicted by the evidence that is now accumulating. The Madras study will always inspire and inform

policies that advocate reaching patients where they are and caring for them.

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