

## **Encouraging Operational Research in Tuberculosis at Medical Colleges: What is Required ?**

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The Government of India (GOI), recognizing the public health importance of tuberculosis (TB) control, had initiated the Revised National Tuberculosis Control Programme (RNTCP) adopting the DOTS strategy in 1997; by March 2006, RNTCP had covered the entire population of the country (1). The RNTCP has the unique distinction of recognizing the importance of Medical Colleges in TB control, the first by any public health programme in the country (2-4). The RNTCP conceived and implemented the unique experiment of involving medical college faculty who are academicians in the public health programme for TB control (5). Over the last decade, the success of medical college involvement in TB control has yielded substantial results.

Under RNTCP medical colleges have played a significant role in service delivery, advocacy, training and operational research, contributing to 25% of TB suspects referred for diagnosis; 23% of 'new smear-positives' diagnosed; 7% of DOT provision within medical college; and 86% treatment success rate among new smear-positive patients (5). Furthermore, medical colleges also make significant contributions to diagnosis and treatment of human immunodeficiency virus (HIV)-TB co-infection, development of laboratory infrastructure for early diagnosis of multidrug-resistant and/or extensively drug-resistant TB (M/XDR-TB) and DOTS-Plus sites for treatment of drug-resistant cases (5).

Another unique aspect of the RNTCP has been the attempt by the programme to encourage the conduct of operational research (OR) relevant to Programme needs by providing funds. To facilitate this State OR committees were formed in all the States with medical colleges and Zonal OR committees were formed in all the zones. The OR Committees sanction funding for research projects. The RNTCP also provides a consolidated grant amount of Rs 20,000 for postgraduate thesis work conducted on OR topics relevant to the Programme needs. At least one postgraduate thesis grant is awarded per medical college per year by the RNTCP (5,6).

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Research conducted at medical colleges on RNTCP has yielded encouraging results. A prospective, multicentre, observational study (7) conducted at four teaching hospitals of medical colleges assessed the efficacy and safety of Category III DOTS treatment under RNTCP (intermittent thrice-weekly rifampicin, isoniazid and pyrazinamide for 2 months, followed by rifampicin and isoniazid for 4 months) in immune-competent patients with uncomplicated small unilateral pleural effusion (<1500 ml). In this study (n=351) (7), a successful outcome, defined as clinical response with complete resolution on ultrasound examination at 6 months was evident in 274 patients (78.1%); efficacy was found to be 88.9% (excluding defaulters), and 94% among those completing follow-up as per protocol.

Another multicentre prospective study (8) conducted at eight RNTCP operational sites in medical colleges in India, evaluated the 6-month efficacy of Category III DOTS treatment for TB peripheral lymphadenopathy and the need for prolongation of treatment to 9 months for non-resolution of lymphadenopathy at 6 months. Category III treatment resulted in resolution of lymphadenopathy at the end of 6 months in 517/551 (93.8%) patients. There was no evidence of additional benefits of prolonging treatment to 9 months.

Although Category III no longer exists in the RNTCP, the results generated at teaching hospitals attached to medical colleges have established the efficacy of thrice-weekly intermittent treatment in extra-pulmonary TB under programme conditions. Furthermore, ongoing studies assessing the efficacy of RNTCP DOTS treatment in abdominal TB, extra-spinal osteoarticular TB, female genital TB are expected to provide evidence needed to guide policy makers and programme managers (9). The RNTCP should the potential of making available generic protocols for conducting research in thrust areas relevant to current needs of the programme, and facilitate the conduct of multicentre OR studies in medical colleges.

However, the response to conducting OR relevant to programme needs at most other medical colleges in the country has been mixed. Many of the research proposals, though based on good research questions, lack in robust methodology and budgeting resulting in need for repeated revision and resubmission that has been time consuming and frustrating to the faculty. The incompletely written or poorly written research protocols by medical college faculty are not

unique to OR proposals in TB alone; such experiences are common with research proposals submitted by medical college faculty to other funding agencies as well. A major reason for this is due to the fact that majority of the faculty doctors in medical colleges lack formal training in research methodology. The enthusiasm to carry out research and the scientific spirit of the medical college faculty is often hampered by lack of training in research methodology, research grant writing and non-availability of biostatistical help at medical college level.

There is an urgent need for RNTCP to help medical college faculty overcome these obstacles and actively support the medical colleges in carrying out OR projects. Measures such as regularly conducting “basic research methodology and protocol writing workshops” once at each state-level every six months and one other time in conjunction with the State Task Force (STF) and Zonal Task Force (ZTF) meetings so as to facilitate research methodology capacity building, coupled with simplifying the flow of funds in a reasonable time-frame can go a long way to nurture conduct of OR at medical colleges that can help in the development of the programme’s future policies. This kind of effort if sustained over a few years can improve the quality of research proposals being submitted and enhance the overall quality of research relevant to programme needs.

## REFERENCES

1. Granich R, Chauhan LS. The Revised National Tuberculosis Control Programme (RNTCP). In: Sharma SK, Mohan A, editors. Tuberculosis. 2nd ed. New Delhi: Jaypee Brothers Medical Publishers; 2009. p. 894-917.
2. Narain JP, Correman E, Nath LM. The role of medical colleges 4. in tuberculosis control. In: Sharma SK, Mohan A, editors. Tuberculosis. 2nd ed. New Delhi: Jaypee Brothers Medical Publishers; 2009.p. 839-45.
3. Medical College Conference on RNTCP, Bangalore, 5. September 15, 2001. Available from: <http://www.tbcindia.nic.in/Press%20release%20Bangalore.html>. Accessed on December 22, 2013.
4. AIIMS-WHO Meeting on the Involvement of Medical 6. Schools in TB and STI/HIV Control. Report on an Informal Consultation on November 28-30, 2001 and Follow-up meeting on April 29, 2002.
5. Sharma SK, Mohan A, Chauhan LS, Narain JP, Kumar P, Behera D, et al; Task Force for Involvement of Medical Colleges in Revised National Tuberculosis Control Programme. Contribution of medical colleges to tuberculosis control in India under the Revised National Tuberculosis Control Programme (RNTCP): lessons learnt & challenges ahead. Indian J Med Res 2013;137:283-94.
6. Sachdeva KS, Kumar A, Dewan P, Kumar A, Satyanarayana S. New vision for Revised National Tuberculosis Control Programme (RNTCP): Universal access - "Reaching the un-reached". Indian J Med Res 2012; 135 : 690-4.
7. Sharma SK, Solanki R, Mohan A, Jain NK, Chauhan LS; Pleural Effusion Study Group. Outcomes of Category III DOTS treatment in immunocompetent patients with tuberculosis pleural effusion. Int J Tuberc Lung Dis 2012;16:1505-9.
8. Jindal SK, Aggarwal AN, Gupta D, Ahmed Z, Gupta 16. KB, Janmeja AK, et al. Tuberculous lymphadenopathy: a multicentre operational study of 6-month thrice weekly directly observed treatment. Int J Tuberc Lung Dis 2013;17:234-9.
9. Central TB Division, Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India. TB India 2013. Revised National TB Control Programme. Annual Status Report. New Delhi: Central TB Division, Directorate General of Health Services, Ministry of Health and Family Welfare; 2013.