

**SHORT COMMUNICATION****Operational research leading to rapid national policy change: tuberculosis-diabetes collaboration in India**A. M. V. Kumar,¹ S. Satyanarayana,¹ N. C. Wilson,¹ S. S. Chadha,¹ D. Gupta,² S. Nair,³ R. Zachariah,⁴ A. Kapur,⁵ A. D. Harries^{6,7}<http://dx.doi.org/10.5588/pha.14.0012>

In 2011, bi-directional screening for tuberculosis (TB) and diabetes mellitus (DM) was recommended by the World Health Organization (WHO), although how best to implement the activity was not clear. In India, with early engagement of national programme managers and all important stakeholders, a countrywide, multicentre operational research (OR) project was designed in October 2011 and completed in 2012. The results led to a rapid national policy decision to routinely screen all TB patients for DM in September 2012. The process, experience and enablers of implementing this unique and successful collaborative model of operational research are presented.

The interaction between tuberculosis (TB) and diabetes mellitus (DM) has been well documented: DM patients are at higher risk of developing TB, and individuals with both DM and TB are at higher risk of poor treatment outcomes.¹ To address this dual burden, in 2011 the World Health Organization (WHO) and the International Union Against Tuberculosis and Lung Disease (The Union) developed a collaborative framework for care and control of TB and DM that recommended that countries undertake several activities, including bidirectional screening for TB and DM.² However, the operational guidelines on how best to implement this intervention in programme settings were lacking.

To bridge this gap, a countrywide, multicentre operational research (OR) project was designed and conducted in India in 2012 by The Union South-East Asia office in collaboration with the Indian Revised National Tuberculosis Control Programme (RNTCP), the National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS), the WHO and other stakeholders within the country. Financial support for meetings and for project coordination was provided by the World Diabetes Foundation (WDF). Results from this OR led to a national policy decision in September 2012 to routinely screen all TB patients notified under the RNTCP for DM in India. This decision was achieved in a short time frame within just a year of project conception.^{3,4} What factors made this rapid translation of evidence to policy possible? In this article, we describe the experience of implementing this collaborative model of operational research that led to policy change, and highlight some of the main enablers.

ASPECT OF INTEREST

The timeline of key events from the conception of OR to the policy decision is described in Table 1. Briefly, it started with a national stakeholders meeting in October 2011 to agree broadly on the necessity for TB-DM collaboration and the need to generate high-quality evidence for programme decisions using well-planned OR. Key principles about where to conduct the OR, how to screen for DM and TB and how to record and report the findings were discussed and agreed upon.

Following this meeting, a national protocol was developed, OR sites were identified (based on their willingness to participate in the study) and ethics approval was obtained for writing up the findings. Staff from the participating sites were then trained in screening, recording and reporting procedures. The quality of the protocol implementation was monitored by supervisory visits and submitted reports were validated by cross-matching the data with the records. An interim analysis in August 2012 showed that it was feasible to perform bi-directional screening, and that screening identified a significant proportion of undiagnosed DM among TB patients. This led the programme managers of the RNTCP and NPCDCS to decide on the policy change in September 2012, before the full study results were available. After completion of the study, a data analysis and writing workshop was conducted, resulting in several publications.^{3,4,6} A final national stakeholders meeting was held soon after, at which the findings and policy decisions were presented to a large audience. A training manual was drafted for health care workers based on the experience of the OR project which details the screening procedures and recording and reporting mechanisms to be conducted under the RNTCP. The key factors that enabled this national policy change are summarised in Table 2.

DISCUSSION

The OR project was carried out rapidly with programme and stakeholder participation, and the findings were swiftly translated into national policy. There were several important enabling factors. First, OR was conducted on a topic that was of direct relevance to both programmes. India has the highest burden of TB in the world and the second highest burden of DM,^{7,8}

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TABLE 1 Timelines and events leading up to national policy change on joint TB and DM collaboration in India

Key event and timeline	Description
First National Stakeholders Meeting (October 2011)	This was a 2-day meeting conducted under the leadership of the national programme managers of the RNTCP and NPCDCS and attended by 36 participants, including state programme managers of selected states, representatives of medical colleges caring for TB and DM patients and national research institutes, WHO-RNTCP national and field consultants, representatives of donor agencies such as WDF and USAID, and technical agencies such as the WHO and The Union. During this meeting, all were informed about the joint WHO-Union framework for TB-DM collaborative activities, reviewed the available in-country data on the TB-DM burden and discussed the need for bi-directional screening in India. A broad consensus was reached on procedures for screening, monitoring, recording and reporting and potential sites for conducting the OR. The sites were selected on the basis of a broad representation of different types of health facility (primary, secondary and tertiary) and countrywide coverage. It was also observed that minimal additional dedicated funding was needed and that this OR could be implemented by utilising existing resources within the two programmes
Protocol development and ethics approval (November 2011)	Based on the recommendations of the national stakeholder meeting, a protocol was developed by the senior researchers of The Union, finalised in consultation with the RNTCP and NPCDCS and submitted to the Ethics Advisory Group of The Union, Paris, France, with a request for expedited ethics review; approval was received within 2 weeks. As the OR was to be implemented under routine programme conditions, the need for informed consent was waived. The national programme manager wrote to the institutional ethics committees of all the study sites describing the national importance of the study and requesting expedited local ethics approval
Protocol finalisation and training workshops (December 2011 and January 2012)	Two–three staff officers from each of the participating OR sites (eight tertiary care hospitals and eight TB units, comprising 67 peripheral health facilities working under the RNTCP) were involved in finalisation of the protocols and underwent training on the standard procedures. These trained personnel in turn trained other health care workers at their respective sites
Logistics (January–February 2012)	The data collection formats (patient treatment cards, registers, quarterly report forms) were printed and couriered to the study sites in the month of January 2012. While most sites had facilities for performing blood glucose tests, glucometers were procured and supplied to some of the sites.
OR implementation and data collection (January–September 2012)	Implementation of activities started in the first quarter of 2012, with some sites starting in January and others in February or March. It was agreed that data would be reported in quarterly (Q) cohorts: Q1-2012 (January–March), Q2-2012 (April–June), and Q3-2012 (July–September) via e-mail to the national programmes, with a copy to The Union for collation. The quarterly reports had to be submitted in standardised formats within a month of the end of the quarter, and this was monitored
Site supervision (January–September 2012)	Supervisory field visits to OR sites were undertaken jointly by the RNTCP and The Union to oversee protocol implementation, identify logistic challenges and initiate mid-course corrections, if required
Interim analysis and appraisal of the findings by national programme managers (August 2012)	At the request of the national programme managers, an interim analysis of the data was undertaken and results were shared in July 2012. The findings were convincing, thus persuading the national programme manager(s) to consider wider and national policy decisions
Policy decision (September 2012)	A national policy decision on screening all TB patients for DM was taken and formally communicated to all states and districts. A training module, based on the protocol used for the OR, was developed to train the health care workers in implementing the new policy, with operational details of recording and reporting under routine settings being agreed and shared with the states
First data analysis and writing workshop (end of October–early November 2012)	Data analysis and paper writing was undertaken in a 4-day workshop conducted and attended by the representatives of all the study sites. With our philosophy of being inclusive, everyone involved in the OR was invited to co-author on the papers. ⁵ The papers were submitted for publication in an international journal and published in May 2013. ^{3,4}
Second data analysis and writing workshop (April 2013)	Individual sites were supported through another 4-day workshop in 2013 to analyse and write up their experiences at site level: these findings were published in a TB-DM supplement in Public Health Action in December 2013
Final national stakeholders meeting (April 2013)	A half-day national meeting was held with 42 participants, including the national programme managers, representatives of medical colleges and national research institutes, WHO-RNTCP national and field consultants, representatives of donor agencies (such as WDF) and technical agencies (such as the WHO and The Union). The purpose was to present and discuss the results of the OR, the implications of the findings and the policy decisions

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TABLE 2 Enabling factors for rapid translation of evidence to policy on TB and DM collaboration, India

Enabling factors

- Direct relevance of the operational research topic to the national programmes and their formal ratification
- Engagement of national programme managers during conception of the research questions and throughout all stages of the operational research
- A philosophy of being inclusive that fostered participation by all stakeholders
- Partnership model: collaboration between international technical organisations, donor agencies and national institutes under the stewardship of the national programmes
- High-quality technical assistance in design, conduct, analysis and publication of research
- Expedited ethics review and approval
- Ensuring adherence to agreed timelines by all stakeholders by providing ongoing support
- Effective dissemination including interim analysis and direct appraisal of programme managers with the research findings
- Fast-tracked scientific writing for publication
- Project coordination and efficient logistic support by a non-governmental organisation

TB = tuberculosis; DM = diabetes mellitus.

and interaction between the two diseases is of major public health importance.

Second, the national programme managers were involved from the conception of the OR to the dissemination of findings and eventual publication. The approach of involving them early on in the process fostered their sense of ownership and responsibility, which in our opinion was key to making rapid progress. This is in contrast to much research in which the publication milestone has become the end-point, with little consideration given to what happens afterwards. As such, engagement with programme managers and policy makers is not seen as a priority.^{9,10}

Third, the participation of key stakeholders (for example, technical and donor agencies) working in TB and DM care in the country helped to achieve a national consensus and wide ownership of the results, thus creating many advocates for policy change.

Fourth, there was high-quality technical assistance from senior researchers of The Union, the WHO and national research institutes right from protocol development to data analysis and drafting scientific manuscripts.

Ethics approval, which often delays research projects, was rapidly obtained. As there was approval from the Ethics Advisory Group of The Union and a communication from the national programme manager(s) reiterating the national importance of the OR, the need to assess feasibility of bidirectional screening under routine conditions and the fact that the study involved extracting data from records with no patient interview, the institutional ethics committees of the participating sites also expedited ethics approval and waived the need for individual informed consent.

Fifth, the inclusive philosophy meant that all stakeholders were involved at the different stages of the research process and were deservedly credited as co-authors of papers in line with the criteria of the International Committee of Medical Journal Editors.¹¹ While it was a challenge to achieve consensus among such a large group, innovative approaches were employed as described elsewhere.⁵

Sixth, collaborative research projects involving multiple partners often face implementation delays for a variety of reasons. We undertook several pre-emptive measures to mitigate delays, including prior agreement and strict monitoring of adherence to project timelines, supervisory site visits and leadership by the national programmes, all of which helped to identify and resolve logistic issues in a timely fashion.

Finally, The Union (a non-governmental organisation) undertook the responsibility for coordinating the project logistics —

support that was very much welcomed by the national programme managers. With the policy and operational guidance for implementation now in place, the next major challenges are to ensure that it is implemented on the ground and to monitor its impact on health outcomes. While TB services are available throughout the country, the same cannot be said of DM care services, which are currently available only in around 100 districts. The success of this joint collaboration will thus depend heavily on the pace of scale-up of the NPCDCS, which aims to expand DM care services to the entire country by 2017.

In conclusion, this model of operational research, which fostered a high sense of ownership and which was propelled by the national programme managers in collaboration with the technical and donor agencies, worked rapidly and efficiently. This experience offers useful lessons for the future.

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En 2011, un double dépistage de la tuberculose (TB) et du diabète (DM) a été recommandé par l'Organisation Mondiale de la Santé (OMS), mais il n'a pas été précisé clairement comment mettre en œuvre au mieux cette activité. En Inde, grâce à l'engagement précoce des directeurs de programmes nationaux et de tous les partenaires importants, un projet national de recherche opérationnelle (OR)

multicentrique a été conçu en octobre 2011 et achevé en 2012. Les résultats ont rapidement amené à une décision politique nationale de dépister en routine tous les patients TB à la recherche de DM en septembre 2012. Cet article présente la procédure et l'expérience de ceux qui ont mis en œuvre ce modèle collaboratif de recherche opérationnelle assez unique et fructueux.

En el 2011, la Organización Mundial de la Salud recomendó la detección bidireccional de la tuberculosis (TB) y la diabetes sacarina (DM), aunque no fue claro cuál sería el mejor mecanismo de ejecución de la iniciativa. En la India, con la participación temprana de los gestores del programa nacional y todos los principales interesados directos, se formuló un proyecto multicéntrico de investigación operativa de ámbito nacional en octubre del 2011 y

se completó en el 2012. Los resultados llevaron a una rápida decisión política de alcance nacional en septiembre del 2012, de practicar la detección sistemática de la DM en todos los pacientes con diagnóstico de TB. En el presente artículo se describe el proceso, las experiencias y los factores facilitadores de la ejecución de este excepcional y eficaz modelo colaborativo de investigación operativa.