## Mystery clients to assess and improve quality of TB care in India

India accounts for 25% of global TB incidence. Poorly managed TB drives the epidemic and generates drug-resistance. There are no data on what really happens when a person with TB symptoms arrives at a clinic. Such "first-contacts" largely happen in the private sector where many providers lack medical qualifications. Thus, improving quality of TB care is a high priority for TB control in India.

India needs a strategy for measuring and improving quality of TB care. We will use "mystery clients" posing as TB patients to evaluate quality. This method could uncover variations in practice quality, and identify solutions to curb TB mismanagement.

Standardized patients (mystery clients) will be trained to present a consistent case of illness to health providers. This approach is superior to direct observations, medical records and exit interviews. Although regarded as the gold standard, it has never been used to assess TB care. This technique might pinpoint the specific deficiencies in TB management and inform tailored policy interventions.

Unlike prescription audits and hypothetical vignettes, which measure clinical knowledge and competence, the mystery client approach has been shown to accurately assess provider practice. This is important, since clinical practice can differ substantially from competence. This method was used in India to examine quality of care for angina, asthma and dysentery (Das J et al. Health Aff 2012). The study found low levels of medical training, correct diagnoses were rare, and incorrect treatments were widely prescribed. If such findings also apply to TB, it would dramatically change common perceptions of the underlying systemic issues in the management of TB, and influence TB control policies.

We propose three different case scenarios that standardized patients will be trained to present in representative samples of 100 public and 100 private providers (regardless of qualification) in Delhi and Mumbai (known hot-spots for drug-resistant TB). The first case will be of a patient with lymphatic TB, which is prevalent. In the second case, the patient brings her various examinations (e.g. chest x-rays, and blood tests for TB recently banned in India) that were prescribed by the standardized patient's doctor. We will randomize the standardized patients in two groups: one where test results will point to active pulmonary TB and one where the test results will point to the absence of TB. In the third case, the patient has ostensibly completed 6 months of TB drugs, but the symptoms have recurred suggesting drug-resistance. For all three cases, providers will be assessed on three dimensions: the fraction of essential checklist history and examinations completed, relative to the protocol described in the Indian Standards of TB Care, the accurate diagnosis of the case, and the treatment that they prescribe, as compared to the expected standard of care. Unlike data from direct observations of providers, data from standardized patients will be free from observation bias. Standardized patients will also permit estimates of case detection rates since TB is pre-specified in the

design. Our methodology will also allow for valid quality comparisons across different types of doctors and clinics. Key to the success of this study is script development and mystery clients training. Our collaborator (Jishnu Das) and our institutional partner in India (ISERDD) have successfully implemented the largest mystery client study in India (Health Affairs 2012;31:2774-84). We will build on their expertise and knowledge. Based on prior work, we expect each standardized patient interaction to cost under \$10, after initial script development and training. With scale, costs will be lower.

We would have proof of concept on the use of mystery clients to study quality of TB care, from public and private providers (qualified and unqualified). Lessons from our study will then enable the Revised National TB Control Programme (RNTCP) to consider implementation on a larger scale. Our study will help determine the costs, sampling procedure, and sample size for wider implementation. Based on the evidence for scale-up, the RNTCP could decide to incorporate the mystery client approach into the routine programme, to periodically check on quality of TB care, to establish quality improvement strategies, and ultimately ensure that all TB patients in India receive uniform, high quality care.

We will generate proof of concept data on the mystery client approach for TB in India. We will then engage the Indian National TB Control Programme to implement this health service delivery innovation on a larger scale, to support their goal of universal access to quality TB diagnosis and treatment.

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