



Without Prevention Programming, is DOTS Enough to Reduce the Incidence of Tuberculosis?

Observational Analysis from Mayapuri Slum, New Delhi

Jennifer Sault

Jennifer Sault is currently finishing her B.Sc. in Microbiology & Immunology and International Development Studies. As a passionate humanitarian, she hopes to continue her career in charitable administration (as she has done with organizations such as End Poverty Now, Fair Trade Manitoba, Save Darfur Canada and, most recently, the 21st Century Leaders), in order to facilitate the implementation of health and education programs globally.

Tuberculosis (TB) is one of the top ten largest contributors to global mortality: in 2012, an estimated 8.6 million people developed TB and 1.3 million died as a result (WHO 2013). India has been ranked as the country with the highest prevalence of TB (occupying 25.6% of the global total), with 2.2 million of the above-cited incidence cases occurring within the country (WHO 2013). As such, TB represents a serious public health problem within India's borders. Furthermore, due to the epidemiology of the disease, those who are at highest risk are generally those at the lowest end of the economic spectrum. TB threatens to continually entangle the cycle of disease and poverty, with profound socio-economic effects.

Through the Direct Observed Treatment Short-course (DOTS) of the World Health Organization (WHO), excellent outcomes are being achieved worldwide through improved diagnostics and treatment of TB. However, the transmission of TB in high-risk areas throughout India continues to impede the success of DOTS and threatens the ability to control the burden of the disease. Incidence has increased in India since 2009 by 10%, from 2 million to 2.2 million (WHO 2013). DOTS's primary focus is on the final stages of TB control, from diagnostics to completion of treatment. Prevention of TB is not, however, a primary focus in the DOTS programme; where present in policy, it is evident that prevention is lacking in practice. To reduce transmission – and thereby incidence – prevention needs to play a more extensive role in high-risk communities.

While the DOTS programme is most needed in vulnerable demographics in order to counter the relatively higher incidence, the greatest difficulties are also found in these areas. Over one-third of Delhi's population of approx-

imately 15 million live in urban slums, and a considerable proportion are at high risk of developing TB in their lifetime: 40% of people in New Delhi are infected with the *Mycobacterium tuberculosis* bacilli, and 10% of these patients will present with active infection (Jaramillo 1999). In slums, although these statistics are unknown, it is logical to assume that infection is prevalent at a rate higher than the city's average due to the strain of poverty-associated risk factors such as overcrowding, indoor pollution, decreased nutrition, increased susceptibility to disease, and others.

The purpose of this paper is to explore the continued increase in incidence in many urban slums in Northern India under the protective umbrella of DOTS, through direct observations made in one of Delhi's slums, Mayapuri. After outlining the need for TB care in urban slums, the current available programming, and its impact in TB-prone areas, this paper concludes that necessary outcomes are not being achieved in Mayapuri slum due to the lack of front-end preventative measures needed to reduce the transmission of TB. This paper then identifies viable interventions that are currently overlooked and have the potential to be incorporated into the DOTS programme for further effective anti-TB practice. By focusing on a grassroots example of DOTS implementation in a representative slum, the purely diagnostic/treatment-focused approach of DOTS is challenged.

Methods

Observations were made in Mayapuri slum while working in collaboration with a clinic operated by a Non-Governmental Organization (NGO) in the community. This clinic functions as the DOTS centre for Mayapuri's population

and thus enables the observation of community-based DOTS treatment and informal interactions with TB patients and workers. Special attention was paid to the process of DOTS implementation, modes of TB transmission, social risk factors, and TB-related challenges present in the community. Similar observations were made with three other DOTS-NGOs in Delhi. Concurrently, a review was conducted through the PubMed database on the literature relevant to TB treatment in Delhi since DOTS was formulated in 1993. Findings were then integrated to present a fact-based recollection of DOTS implementation in Mayapuri and slums throughout Delhi.

Mayapuri as a Case Study

Mayapuri slum is located in western New Delhi between the Mayapuri Phase I and Phase II industrial zones and the city's main railway line. Over approximately 10,000 inhabitants live along a long, thin stretch of over 2 km, in many places just feet away from the railway track. Most residents are originally from rural Uttar Pradesh and have family outside of Delhi. The slum has slowly developed over the last twenty years and, while there is still some population mobility, the slum has an established community. Results from a randomized survey of 50 Mayapuri Phase II households conducted by the National Institute of Urban Affairs in Delhi shows that there are approximately 5 people to each household, 62% of which are less than 22.5 squared meters. All 50 households have access to water, but 13 households claim this to be inadequate supply and a further 29 claim that they have supply only sometimes, both due to water pressure and/or distance. All 50 households have access to a community toilet, bathe in a public stand-post, and have illegal

connection to electricity (NIUA 2004).

There are no private or government clinics, but there is one community centre clinic that provides DOTS care and has a doctor present two mornings per week. This centre also provides vaccinations, pre- and post-natal care, and encourages community mobilization through the facilitation of numerous working groups and educational programming. Mayapuri is presented with unique challenges due to its location, including above-average levels of pollution due to being directly next to an industrial area, safety hazards such as sharp metal debris and the adjacent train tracks, population density, and extreme poverty. Otherwise, it is a typical example of the marginalized urban demographic in northern India that is most affected by TB.

TB Epidemiology and Risk Factors Relevant to Urban slums

TB's etiological agent is *Mycobacterium tuberculosis*, an acid-fast, airborne bacillus that is spread by close contact, primarily from sputum-positive patients. With such easily spread pathogens, high-density populations are particularly at risk (Narayanan et al 2002). TB presents with a cough lasting longer than three weeks, and is prone to re-activation if not properly treated (Jawahar 2003). It is a serious infection that was traditionally associated with death prior to the adaptation of recent chemotherapeutic techniques to counter the infection. It is now a treatable disease (drugs in current use have a 95% success rate), though stigma around the disease still remains (Ahmed et al 2009).

Inactive infection is common within these areas; in most cases it progresses to its active state where the immune system is compromised or lung tissue is damaged. Additional risk fac-

tors include HIV/AIDS, diabetes, malignancies, malnutrition, stress, tobacco smoke, alcoholism, and potentially, indoor pollution (Lönnroth et al 2009; Smith 2002; Srivastava 2005). TB has socio-economic causes and effects: it is created by and propels the conditions of poverty through imposing additional economic constraints. The highest risk demographic are the most impoverished; lower educational attainment, wages, quality of housing, and social status within one's community are all variables which affect one's likelihood of contracting TB (Ompad et al 2008). In addition, TB is prevalent among disaster-stricken or mobile populations, both of which are frequently characteristics of growing slum communities.

These risk factors not only propagate TB among impoverished populations, but also present additional challenges to existing TB control programmes: centre accessibility, costs, inconvenience, and stigma are among the limiting factors to receiving treatment (Ogden 1999). Programmes also have a multitude of policy and efficiency problems. A study following DOTS patients in Kerala gave evidence that approximately a quarter of DOTS patients are not under direct observation while on treatment, undermining the goals of DOTS and resulting in increased relapse of infections despite recorded cures (Balasubramanian et al 2000). Another less transparent programme inadequacy is that many centres will not prescribe DOTS to a patient with risk factors that decrease his likelihood of completing the treatment course as this will lead to increased treatment resistance (Multi Drug Resistant strains) (Singh et al 2002). The risk factors for incomplete treatment, or 'defaulting', overlap with the risk factors for the disease; mobile, poverty-stricken populations are most affected. Thirty-seven

percent of the TB-positive population in New Delhi during a cohort study were denied short course therapy under direct observation due to this hesitation (Balasubramanian et al 2000). Challenges are greater for the vulnerable to receive successful treatment.

TB Programmes

Stop TB Strategy, DOTS, and the Millennium Development Goals

The DOTS programme underpins the Stop TB Strategy and has been the leading intervention in TB care since its conception in 1994 (WHO, 2006). It has five main components: diagnosis of pulmonary TB primarily by sputum microscopy; treatment administration under direct observation; regular drug supply; monitor of the patient's progress to cure by follow-up sputum tests; and procurement of administrative and political commitment (Jawahar 2003). This programme focuses on early detection and successful treatment as a means to achieve the following goals: a cure rate of 85% and a detection rate of 70% for smear-positive patients (WHO 2006); halt and begin to reverse the current incidence rate by 2015, as corresponds to the Millennium Development Goal 6C for infectious disease (UN 2013); and, in the long term, lowering of TB incidence to one in one million by 2050 (Lönnroth et al. 2009). If accomplished, the disease would be effectively eradicated.

DOTS was subsequently implemented in India by the Revised National Tuberculosis Control Programme (RNTCP) in 1997. A need for a strategic approach was defined following studies on the inefficacy of previous TB treatments in the country: in 1992, less than half of patients with TB had received an accurate

diagnosis and even fewer were successfully treated (Khatri et al 2002). A nationwide TB approach has been implemented since then, with outstanding results in the areas of diagnostics, treatment, and ultimate cure rates; since RNTCP's execution, treatment success rates have tripled from 25% to 86% and mortality rates have been cut sevenfold from 29% to 4% (Central TB Division 2009).

As for the World Health Organization targets (85% cure rate among new sputum positive cases and 70% case-detection rate, the latter which serves as the best measure for incidence), India is on target: the treatment success rate is 88% for new smear-positive cases and a 71% case-detection rate has been reached (Central TB Division 2013). In short, outstanding results are being achieved by DOTS.

There is reason to doubt the impact of these successes on incidence, however. On a global scale, incidence is declining at a rate of just 1% per year (WHO 2009). If the goal of eliminating TB by 2050 is to be met, incidence must fall by an average of 16% annually over the next 40 years (Lönnroth et al 2009). Additionally, in India, incidence has increased by 10% since 2009 from 2 million to 2.2 million (WHO 2013). Furthermore, the 70% detection rate is not accurate among people living in slums: several states in Northern India have not yet obtained notable declines (Marias et al 2009). Additionally, there is evidence to believe that these rates are overvalued due to both false negatives and underreporting; the “missed cases” – *people who were either not diagnosed or diagnosed and not reported* – are estimated at 2.9 million globally, of which 31% of these cases are in India (WHO 2013). As the strategy underpinning DOTS relies on sputum testing instead of X-rays to diagnose, numerous Ex-

tra-Pulmonary TB (EPT) cases are overlooked, resulting in false positives and an apparently lowered incidence (Chadha 2005). Finally, DOTS failed to report an estimated 3.7 million cases in 2007, an additional 40% of global TB incidence (Marias et al 2009). In communities such as Mayapuri, incidence is growing and there is little evidence to suggest that they will soon halt or decline in response to increased cure rates.

As incidence remains high despite DOTS, it is doubtful that treatment programmes are leading to advances in case detection. In a study measuring the correlation between the programme's successful implementation and reduced case notification ratios, it was suggested that DOTS has had little to no effect on the incidence of TB (Dye et al 2008). The explanations for these results were either that statistics were invalid; that insufficient time had passed to see results in reduced incidence; that there was a rise in new TB cases after treatment, offsetting any advances in transmission; or that early diagnosis and curative treatment are not enough to prevent the transmission of TB. The two final conclusions are the most probable, and raise concerns about the current implementation of DOTS. Ultimately, there is reason to doubt that DOTS is efficacious in reducing incidence. Without a reduction in case incidence, there is evidence of ongoing transmission, infection and disease.

TB Treatment in Mayapuri

Similar concerns are raised in case-specific examples; despite a comprehensive treatment system, little can be observed in terms of preventative measures to address transmission and case incidence.

Great success has indeed been observed

with DOTS: the strategy is widespread throughout Delhi and is utilized in public, private, and NGO-operated clinics. The services provided to each slum are dependent on its location relative to a DOTS centre. For many slums, especially the newer ones, there are no available DOTS centres within reach; however, this is quickly changing due to NGO interventions that ensure the provision of DOTS distributors in many communities. Mayapuri is no exception to this, and is fortunate to have a community clinic in its enclosure that uses DOTS.

Once patients are assigned to the center, they are delegated their anti-TB drug box with their allotted medication for 6 months. As prescribed by DOTS, a community health worker oversees their progress, follows up on missed doses, and works to reduce stigma by speaking with the diagnosed and their families. Due to such initiatives, DOTS is stimulating notable decreases in default rates, increases in cure rates, and superior results from diagnosis onwards.

There is little evidence of action against TB transmission, however. Residents of slums still have difficult challenges to face in obtaining DOTS treatment. As is common of many DOTS dispensaries, the community clinic in Mayapuri does not have the technology to conduct sputum smears nor chest X-rays; thus, suspected TB patients are referred to the next closest centre, which is over forty minutes away from the tracks (by bus, in traffic). The reasons for patient hesitation to seek diagnosis become obvious when compounding travel expenses with the opportunity cost for labourers, in addition to other social factors such as stigma. Other challenges also impact individual incentive to visit diagnostic stations: for many women especially, it is difficult to leave family responsi-

bilities and some fear stigma and family disapproval. This particular hardship is demonstrated by the significantly lower case-notification of females compared to males in India (Balasubramanian 2004). All of these social challenges prevent the early diagnosis of TB and result in continued transmission.

A delay in diagnoses of sputum-positive patients living in a slum is predicted to infect ten to fifteen other individuals (Operation Asha, 2009). One out of ten persons infected with TB will develop the active form, i.e., present with symptoms (Jaramillo, 1999). Once one family member becomes infected with TB, it is common to see an uncontrollable spread among the entire household and surrounding families in densely populated areas, such as Mayapuri.

The DOTS programme endeavours to drastically reduce incidence through the early detection of TB. Although the time required to medically diagnose TB has improved, this decrease is not sufficient to offset TB transmission. What is currently lacking in TB control programmes, such as those present in Mayapuri, are preventative measures that will result in reduced transmission prior to diagnosis. Although some organizations are mobilizing education initiatives and discussing the need for interventions such as family screening, there are currently no distinguishable internal propositions for policy amendments to further address TB incidence. Unless altered, the transmission of TB will continue in these disadvantaged communities faster than it can be countered. In other words, there is a need for prevention in TB control.

Preventative Measures

From Policy to Practice

None of the components of the original DOTS intervention address prevention. The Stop TB Partnership, on the other hand, is a strategy established in 2006 which enhances DOTS by addressing its areas of weakness. Although its central philosophy still preaches the benefits of cure-rates and medical detection, its six principal components also incorporate social variables that are applicable to prevention initiatives. They include the following: (i) pursuit of high-quality DOTS expansion and enhancement; (ii) address of the emerging issues of HIV-associated TB and multi-drug resistant (MDR)-TB; (iii) contribution to health system strengthening, (improved financing, information, and communication with other health initiatives to improve innovation); (iv) engagement of all care providers, extending beyond public health providers to the realm of private practitioners, etc; (v) empowerment of people and communities afflicted by TB; and (vi) promotion of research (WHO 2006).

The goal of reducing incidence is integrated into these components as a long-term consequence of improved DOTS functioning. Improved accessibility to DOTS is assured with the first and fourth measures. As per the first, since 1997, DOTS coverage has increased from less than 20 million (2% of India's population) to more than 1 billion people (90%) (Sharma 2006). It is likely that these efforts will reduce the hesitations of many to adhere to the TB treatment and will increase cure rates even further. The fourth component is reflected in the Public-Private Mix approach Delhi has used in recent years; engaging private providers has made TB diagnosis and treatment through

DOTS more accessible. It is arguable, however, that more numerous and effective medical distribution centres will contribute to early detection and reduced incidence as an imminent result of increased programming.

The second and third components of addressing HIV-TB and MDR-TB will also directly contribute to improving cure rates and, through doing so, indirectly affect incidence through reducing the potential to transmit active infection. The increased susceptibility to and infection of TB in people who are HIV-positive (HIV-TB) has also had a large impact on incidence. HIV-TB has a profound global health complication, resulting in increased case detection of TB in some countries, particularly in sub-Saharan Africa, and while much less, also in India. In 2002, out of the 4 million people infected with HIV in India, half were infected with latent TB and 140,000 additional cases were seen in re-activation alone, representing a 10% increase in TB incidence from a relatively low HIV rate (Khatri et al 2002). If HIV-TB can be halted, a large proportion of global infections will be eradicated and future incidence will be reduced. Similarly, the third component of the Stop TB Partnership of reducing the emergence of multi-drug-resistant TB will result in a decline of future TB prevalence. Increased and continued funding (iii) will give DOTS sustainability, TB-control, and, in general, the support it needs for the eradication of TB. Perhaps here, through increased communication and innovation, there is an open platform for coordinating ideas to control TB transmission.

The fifth element of empowering those with TB is one unconventional to the early diagnosis and treatment mandate persistent elsewhere, and one which could increase preventative measures. A campaign similar to

this is found in Delhi as part of the RNTCP's Advocacy, Communication and Social Mobilization (ACSM) unit. ACSM works to disseminate information, education, and communication on the stigma around TB and to empower individuals to mobilize on early detection and treatment adherence (Central TB Division 2008). Though the activities of this campaign are widespread throughout India, in Mayapuri and numerous other locations this intervention has yet to be effected. Although ACSM has been implemented alongside RNTCP's DOTS since 1997 in India, this has not resulted in a decline in incidence.. More research needs to be conducted to assess this goal in practice and its efficacy. There is no reason to doubt, however, that successful community participation and education fosters early diagnosis and reduces the social stigma that prevents individuals from seeking treatment.

To enable and promote research for innovative diagnostics, cures, and vaccines (vi) is to define the future of TB control. It is an integral component of improving methods to cure TB, to the extent that it will bring down rates of transmission, and find advances that will eliminate the need for treatment through effective prevention. This is a goal that may shift emphasis within DOTS to focus on preventative measures when further developments are discovered.

Room for Policy Prescription

Neither the utilization of existing advancements nor the technologies to reduce transmission are included in DOTS or the Stop TB Partnership. For instance, the Bacille Calmette-Guerin (BCG) vaccination has been in use since 1921 and, although there have been varying conclusions around its efficacy, it has

been proven to considerably reduce the risk of active TB and death when given at birth. The overall protective rate is 50% against TB infections, 78% against pulmonary TB, 64% against tuberculosis meningitis, and 71% against death (Colditz et al 1994). It is recommended by the World Health Organization as part of their Expanded Program on Immunization for Infants (England et al 2007), yet is not evident in either DOTS policy or practice.

With a high prevalence rate of TB, active case detection through close-contact screening and surveys can be conducted in high-risk communities to ensure early diagnosis at a level capable of abating transmission. As has been illustrated, detection of active cases decreases the infectious period by approximately 50%, halving the transmission of TB. When cure rates are above 70%, active case detection has the potential to essentially eliminate transmission of non-self-reporting persons (Borgdorff et al 2002). These estimates are determined from conducting randomized surveys in vulnerable communities and show significant results. Strategic screening among those with a higher risk for TB (HIV-infected populations or close contacts) also proves to be an effective tactic. Although DOTS prescribes direct observation of patients by a community health worker, it is not written into policy to screen contacts for contracting TB (WHO 2006; WHO 2009; Central TB Division 2009). As these health workers are already monitoring patients, perhaps there is strategic gain to be found in combining efforts to screen family members and neighbours with patient visits or frequent surveys. Targeting vulnerable communities with screening and active case detection can be successful.

Also not encountered in policy or practice is the use of preventative therapy in reduc-

ing the infection and reactivation of latent TB. Such an approach would need to be pursued strategically to avoid multi-drug resistant TB (MDR-TB), but it also has the potential to contain TB transmission. Chemoprophylaxis (preventative therapy) provides protection during the period of exposure and secondary prophylaxis can be provided to prevent re-activation of latent infections. Contact management and preventative therapy were not observed in Mayapuri and are rarely identified in literature. Yet, results can be achieved through the strategic use of preventative therapy in countering TB transmission, especially when targeting those at high risk for infection and individuals in close contact with sputum-positive patients (Marias et al 2009).

Reducing poverty and eliminating the most pertinent risk factors for TB will undoubtedly decrease TB transmission. Campaigns for the provision of adequate nutrition, sanitary living conditions or even, reduction of indoor pollution all support viable preventative measures. These measures will also be beneficial to governments as they address the socio-economic impact of the disease. This approach has the capacity to both counter TB and uplift vulnerable communities such as Mayapuri. No literature on these alternative interventions can be found in DOTS strategies, but they could potentially be combined with efforts surrounding social mobilization and innovative joint partnerships between existing programmes.

Discussion & Limitations

To integrate the above measures, policy-makers must face pressure to ensure comprehensive coverage in TB care from start to finish. Although a difficult task, TB prevention is estimated to be more cost-effective than

DOTS if accompanied by clear program aims and adherence to guidelines (Marias et al 2009). No conclusive studies have yet been conducted on the cost-effectiveness of preventative therapy in contacts or those with latent infection; BCG, on the other hand, has been proven to be equally as cost-effective as DOTS (Borgdorff et al 2002). Prevention can have a strong place in policy and practice with proper funding and methodology.

Scaling up DOTS to include these additional costs may be the reason underlying the dismissal of preventative measures. The funding gap for 2014 and 2015 for DOTS is US \$1.6 billion per year (WHO 2013); there is a profound strain on governments to upkeep DOTS. Governments may be hesitant to dedicate further commitment and funding without concrete evidence on the cost-effectiveness of prevention. Throughout literature pertaining to prevention, as well, there is hope for more cost-effective and beneficial vaccines/medications (Marias et al 2009; Borgdorff et al 2002; Narayanan et al 2002). Now that the genome of *Mycobacterium tuberculosis* is known, it is likely that new innovative techniques will appear in the next decade.

It is also important to note that, although the arguments in this paper are based in fact, Mayapuri is only one community and the analysis used in this paper was conducted over a short time. Assumptions therein many therefore overlook the efforts of numerous small-scale initiatives. DOTS is dually adopted and adapted by multiple organizations, centres, and others, many of which may be integrating preventative measures into their programming and further addressing TB transmission.

Additionally, the findings in Mayapuri are strictly observational. Where possible, all

observations were supported by a literature review, but these results would nonetheless benefit greatly from empirical evidence. More research needs to be conducted to confirm continued TB transmission, especially due to a delay in self-reporting. Also, while many of the above observations are true of Mayapuri today, there is a wide range of variance between different urban slums and DOTS programmes.

Conclusion

TB programmes are integral to TB control, treatment, and prevention of death for many hundreds of thousands each year; outstanding results are being achieved by the DOTS programme in particular. Although the extent is not definitive, the transmission of TB in high-risk areas is significant in outpacing the current successes of these initiatives and is impeding future TB control and programme sustainability. It is not enough to presume early detection and high cure rates preclude the further transmission of TB. While the Stop TB Strategy is introducing minimal preventative measures, they are indirect measures and do not emphasize countering TB transmission. Furthermore, if they are capable of abating incidence, these prescriptions require further attention to effect change in practice. Several other measures can be undertaken to compliment DOTS and ensure success, including vaccinations, contact screening, preventative therapy, community empowerment, and poverty-alleviation and risk factor reduction campaigns. In face of so many potential preventative interventions, TB control programmes are thus confronted with a challenge: to address the root causes of TB and protect the livelihoods of the otherwise vulnerable. With preventative measures, DOTS has the capacity to not only ensure the control of

TB, but to mobilize for its elimination.

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