

COMMENT

The ethics of compulsory notification of tuberculosis

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Abstract

The Government of India has passed a notification making the non-reporting of tuberculosis (TB) by a clinical establishment a punishable offence. This article examines this move from an ethical standpoint. One of the main ethical concerns relates to the violation of patient confidentiality that may result from this. Also as regards improvement in patient care, there appears to be a poor cost-benefit ratio in terms of the actionable data obtained by this. There may be possible adverse consequences by a limiting of access to care due to penalising of non-reporting. In terms of the bigger picture, the notification may lead to an increased tension between the private sector and Government. Moreover, it is the position of the authors that such a step distracts attention from the more important issues that plague TB care in India today.

The government of India recently passed a notification making the non-reporting of tuberculosis (TB) cases by clinical establishments, including private practitioners and pharmacists, a punishable offence (1). Non-reporting may now be deemed either a "Negligent act likely to spread infection of disease dangerous to life" or a "Malignant act likely to spread infection of disease dangerous to life" under sections 269 and 270 of the Indian Penal Code, 1860. This will be punishable with either a fine or a period of imprisonment of up to 6 months or 2 years, depending upon the section invoked (1).

It is entirely reasonable for a government, which takes the responsibility to ensure treatment of everyone with a particular disease, to collect data from all care providers about the said disease in order to establish its true burden and to

plan policy. This is even more so in the case of a communicable disease where prevention is closely intertwined with early diagnosis and treatment and where there is, in addition, the dimension of drug resistance to be dealt with (2).

And to be clear, despite the furore that this notification has caused, mandatory reporting of TB is not new. It had already been made compulsory by a gazette notification back in 2012 (3). However, making such non-reporting a punishable offence is cause for serious concern and symptomatic of the lack of foresight and the tokenism that ails Indian health policy making today. The concerns with this move can be discussed under the following broad categories:

- violation of patient privacy
- poor cost-benefit ratio in terms of actionable data obtained
- unintended harmful consequences of mandatory reporting
- possible widening of the divide between the Government sector and the private sector.
- distraction from the more urgent issues with the TB programme today

The second principle of the Code of Ethics for Public Health proposed by the American Public Health Association states that community health should be achieved in a way that respects the rights of individuals in the community (4). Without doubt, mandatory reporting infringes on the patients' right to confidentiality (5). This is especially a matter of concern in a society where there is a lot of stigma surrounding TB (6). There is also the question of the balance between the fiduciary duty of the doctor to the patient and that to the government. While there might be situations where the benefit of setting aside the doctor's fiduciary duty to the patient is justified in terms of public benefit accrued, we argue that this new policy is not one of them.

The public health goals that this notification seeks to achieve are unclear and it is unacceptable when one considers that (aside from ethical concerns) a significant amount of time, energy, and money will be spent in the pursuit of prosecutorial processes. If the goal is to have a more complete database on disease trends, it should be noted that for the purposes of planning a programme, metadata is of little use. Representative sample surveys provide high quality data with significantly less input required for data collection, not to mention the fact that the confidentiality of patient data is maintained. If the purpose is to ensure that all patients receive care as per Standards for TB care (7), then it is not clear how reporting will lead to or

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ensure care. There appears to be no established pathway to provide feedback on the quality of care, both regarding diagnosis and treatment, to the private providers of care (1). Nor indeed is there any safety mechanism for intervention in the case of a patient who is being provided grossly inappropriate care, for example, with an inadequate drug regimen. Will the government intervene in such a situation? And if not what is the ethical justification for collecting information that is not being acted on for the patient's immediate benefit?

We fear that the enforcement of the regulation/notification may go one of two ways the first possibility is that, like its predecessor, it will be ignored by the clinical establishment, (8). And while this may not adversely affect the existing care of TB patients, laws that are not enforceable on account of their conceptual framework are counterproductive, as they normalise a disregard for the law. If it is ever actually enforced (even if only by means of a few high-profile convictions), it may well cause harm to the status quo. The private medical sector, when faced with the option of "mandatory reporting" with its inevitable burden of red tape and privacy concerns versus the option of "no treatment and referral," may opt (as it often does, for example, in medico-legal cases) for "no treatment." (9) Where does that leave about half of all TB patients who currently seek care in the private sector(10)? Around the world, lessons from other programmes that employ strictly enforced mandatory reporting, like child abuse programmes (where early interventions are far more critical), suggest that mandatory reporting is often a deterrent to patients accessing care (11).

This coercion may further alienate a private sector that already has a fair amount of distrust of the Revised National Tuberculosis Control Programme (RNTCP) and the quality of care provided therein. Distrust that is not entirely misplaced when one considers that the RNTCP, until recently, stuck to policies like alternate day drug treatment when it has been clear for a long time that this is inappropriate and most private practitioners have switched to daily treatment (12).

But perhaps the biggest problem with this notification is that it turns the conversation away from the real and burning challenges that face the national TB programme today. For example, how do we standardise extra-pulmonary TB diagnosis which suffers from many inherent challenges such as obtaining microbiological specimens in both the public and the private sectors? How do we upscale our drug and sensitivity testing (DST), which is clearly the need of the hour, so that it is available to all newly diagnosed patients? A universal DST aims to tackle the emergence of multi-drug resistance (MDR) by ensuring that all newly-diagnosed patients have drug sensitivity testing as opposed to only those deemed to be at a high risk for this (13). While the upscale is awaited, how do we screen for Isoniazid (INH) mono-resistance? How do we work on nutrition in the face of overwhelming evidence that this is critical for successful treatment?

Perhaps the only critical piece of data that needs analysis for policy planning is why are 50 % of TB patients seeking care in the private sector (10) ? For a programme that provides (or claims to provide) not only completely free treatment but also transport and nutrition allowances as well as financial incentives, why does one need any reporting at all? Why is there no queue outside the door? While the concerns about the private sector in health being unethical, substandard, and responsible for gross errors in TB diagnosis and treatment may be justified, it is chilling to realise that 2.2 million TB patients still prefer to seek this care (and pay for it) rather than access public health services (14).

TB care in India, more than that of any other disease, makes evident the fallacy of a policy trend that increasingly outsources one of the most critical responsibilities of the state, ie. healthcare, to the private sector. Examples of this outsourcing trend include insurance packages that incentivise private inpatient care under Rashtriya Swasthya Bima Yojana (RSBY) or the recent disturbing privatisation of the Chhattisgarh community health centres (15, 16). In the absence of a robust general primary and secondary care system, a health programme (even a vertical one), especially one where early diagnosis and appropriate treatment is key, cannot be sustainable.

It is time for all stakeholders in TB care to come together and take decisions that can have an actual impact on the present state of affairs. With the spectre of drug-resistant TB looming large, failure to do so even now would most certainly constitute a "Negligent act likely to spread infection of disease dangerous to life." Can the state be booked for being negligent and allowing the spread of a drug-resistant disease endangering people?

References

1. Ministry of Health and Family Welfare, Govt of India. Gazette notification. F.No. Z-28015/2/2012-TB. New Delhi: MoHFW;2018 March 6[cited 2018 Apr 22]; Available from: <http://egazette.nic.in/WriteReadData/2018/183924.pdf>
2. Uplekar M, Atre S, Wells WA, Weil D, Lopez R, Migliori GB, Raviglione M. Mandatory tuberculosis case notification in high tuberculosis-incidence countries: policy and practice. *Eur Respir J*. 2016 Dec[cited 2018 Sep 25];48(6):1571–81. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/27824601> <https://erj.ersjournals.com/content/early/2016/10/20/13993003.00956-2016>
3. Ministry of Health and Family Welfare, Govt of India. Gazette notification Z-28015/2/2012 - TB. New Delhi:MoHFW; 2012 May 7 [cited 2018 Apr 22]. Available from: <https://tbcindia.gov.in/> <https://tbcindia.gov.in/showfile.php?lid=3136> ???
4. Thomas JC, Sage M, Dillenberg J, Guillory VJ. A code of ethics for public health. *Am J Public Health*. 2002 Jul [cited 2018 Nov 15];92(7):1057–9. Available from: <https://ajph.aphapublications.org/doi/full/10.2105/AJPH.92.7.1057>
5. Philip S, Isaakidis P, Sagili KD, Meharunnisa A, Mrithyunjayan S, Kumar AM. "They know, they agree, but they don't do";—the paradox of tuberculosis case notification by private practitioners in Alappuzha district, Kerala, India. *PLoS One*. 2015 May 24[cited 2018 Apr 12];10(4):e0123286. Available from: <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0123286>
6. Chakrabarty A, Basu P, Ali KM, Sarkar AK, Ghosh D. Tuberculosis related stigma and its effect on the delay for sputum examination under the Revised National Tuberculosis Control Program in India. *Indian J Tuberc*. 2018 Apr [cited 2018 Nov 17];65(2):145–51. Available from: <https://>

- www.researchgate.net/publication/320128411_Tuberculosis_related_stigma_and_its_effect_on_the_delay_for_sputum_examination_under_the_Revised_National_Tuberculosis_Control_Program_in_India
7. World Health Organization, Central TB Division, Ministry of Health & Family Welfare, Government of India and World Health Organization, Country Office for India. Standards for T.B care in India. 2014 . Available from <https://tbcindia.gov.in/showfile.php?lid=30618>.
 8. Reaching the unreached. *The Hindu.com*. 2018 Mar 25 [cited 2018 Apr 12]. Available from: <http://www.thehindu.com/sci-tech/health/reaching-the-unreached/article23344422.ece>
 9. Ranjan R, Kumar S, Pattanayak RD, Dhawan A, Sagar R. (De-) criminalization of attempted suicide in India: A review. *Ind Psychiatry J*. 2014;23:4-9
 10. Yellappa V, Lefèvre P, Battaglioli T, Devadasan N, Van Der Stuyft P. Patients pathways to tuberculosis diagnosis and treatment in a fragmented health system: a qualitative study from a south Indian district. *BMC Public Health*. 2017 [cited 2018 Apr 22];17:635. Available from: <https://bmcpubhealth.biomedcentral.com/track/pdf/10.1186/s12889-017-4627-7?site=bmcpubhealth.biomedcentral.com>
 11. Raz M. Unintended Consequences of Expanded Mandatory Reporting Laws. *Pediatrics*. 2017 Mar [cited 2018 Jul 3];139(4):e20163511. Available from: <https://pediatrics.aappublications.org/content/139/4/e20163511>
 12. Chang KC, Leung CC, Grosset J, Yew WW. Treatment of tuberculosis and optimal dosing schedules. *Thorax*. 2011 Nov 1 [cited 2018 Jul 3];66(11):997–1007. Available from: <https://jhu.pure.elsevier.com/en/publications/treatment-of-tuberculosis-and-optimal-dosing-schedules-4>
 13. Sachdeva K S, Raizada N, Gupta R S., Nair S A, Denkinger C, Paramasivan C N, Kulsange S, Thakur R, Dewan P, Boehme C, Arinaminpathy N. The Potential Impact of Up-Front Drug Sensitivity Testing on India's Epidemic of Multi-Drug Resistant Tuberculosis. *PloS One*. 2015;10(7):e0131438. doi:10.1371/journal.pone.0131438
 14. Arinaminpathy N, Batra D, Khaparde S, Vualnam T, Maheshwari N, Sharma L, Nair SA, Dewan P. The number of privately treated tuberculosis cases in India: an estimation from drug sales data. *Lancet Infect Dis*. 2016 Nov 1 [cited 2018 Apr 22];16(11):1255–60. Available from: http://bmi.icmr.org.in/itrc/images/pdf/Arinaminpathy_et_al._2016.pdf
 15. Ministry of Labour and Employment, Govt of India. Rashtriya Swasthya Bima Yojna. New Delhi;2008 [cited 2018 Apr 22]. Available from: <https://www.india.gov.in/spotlight/rashtriya-swasthya-bima-yojana#rsby6>
 16. Times News Network. Chhattisgarh to hand over 9 CHCs to private players, opposition cries foul | Raipur News - Times of India [Internet]. 2018 Mar 23 [cited 2018 Apr 22]. Available from: <https://timesofindia.indiatimes.com/city/raipur/chhattisgarh-to-hand-over-9-chcs-to-private-players-opposition-cries-foul/articleshow/63423269.cms>