**Review Comments and Recommendations**Title: The ethics of compulsory TB notification  
  
1. Importance of the paper: The topic is relevant and need to be discussed from bioethical perspective.  
  
2. Is it topical? It’s relevant to the country’s policy and practice. Suitable for IJME.  
  
3. Originality: No plagiarism noticed.  
  
  
4. Conclusions: The paper has unwarranted interpretation, not well-developed concepts, important omissions, loose generalizations and too much biased speculations.

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| **From the manuscript** | **Reviewer’s comments** |
| “The concerns with this move can be discussed under the following broad categories -….” | Discussing the concerns under broad categories was a good idea. |
| “poor cost-benefit ratio in terms of actionable data obtained” | The conclusion is not clear to the reviewer. It would be good to clarify what are the costs involved in mandatory notification? Also, what are the benefits- to the program and benefits to the patients? And kindly substantiate how this is “poor”. |
| Paragraph starting with:  “Indeed, for the purposes of planning a program it is generally acknowledged that meta-data is of little use…………….” | Reviewer agrees with the authors in this regard.  However, while going through the Gazette notification [[F.No. Z-28015/2/2012-TBi] the reviewer understood that the purpose of Mandatory Notification is “to ensure proper tuberculosis diagnosis and its management in patients and their contacts and to reduce tuberculosis transmission and further to address the problems of emergence and spread of Drug Resistant-Tuberculosis, it is essential to collect complete information of all tuberculosis patients. Now, therefore, in the interest of public health to control and prevent the tuberculosis disease it is essential to collect information of all patients” Reviewer understood mandatory notification as a measure to provide highest standards of care to each individual patient and not to obtain meta-data.  Request the authors to kindly clarify the purpose of mandatory notification and discuss the issues based on this. |
| First of all, there is so far little evidence to suggest that any significant analysis or policy change has come about from the notification data of 2012 onwards. | Reviewer has gone through National Strategic plan for TB 2017-2025 and 2012-2017, partnership guidelines for private sector engagement 2014, Annual TB India reports 2012-18. Reviewer could find analysis of notification data and major policy changes in the program in this regard.  Request the authors to kindly quote evidences for the same if any. |
| “Further, for all practical and administrative purposes it is a completely un-enforceable law…….” | Reviewer agrees with the philosophy that if not enforced “…. normalize a disregard for the law”. However, reviewer felt that authors were prejudistic in stating that it is an un-enforceable law. |
| “mandatory reporting” with it’s inevitable burden of red tape and privacy concerns vs. the option of “no treatment and referral” may opt (as it often does, for example, in medico-legal cases ) for “no treatment”. | This is an important concern.  Reviewer had gone through the private sector engagement strategies planned in National Strategic Plan 2017-25. NSP’s key thrust area is private sector engagement and the vision states that “patient should get highest standards of treatment from providers of their choice”. Government will make sure that patients reaching the private sector will have access to free diagnostics, free treatment, extend support for all public health actions for patients, build capacity of private sector……through private sector engagements”. Even incentives for private sector for ensuring complete treatment to the patients have been described. Reviewer understood that measures to reduce catastrophic cost to patients reaching private sector by providing Direct Benefit Transfer to all notified patients has already been rolled out. Regulatory approach has been described as one among the last strategies in ensuring Standards of TB Care to the patients approaching private sector.  Reviewer felt that manuscript is blind on such a larger private sector engagement plans and initiatives. Request the authors to kindly discuss this concern with larger private sector engagement plans |
| “This coercion may further alienate a private sector that already has a fair amount of distrust of the RNTCP and the quality of care provided therein.  Distrust that is not entirely misplaced when one considers that the RNTCP stuck to policies like alternate day treatment until recently when it was clear for long before that this is inappropriate and most private practitioners had switched to daily treatment. (6)” | Reviewer agrees with the author’s concerns that coercion “alone” will increase the gap.  Reviewer understood that RNTCP new Technical and Operational guidelines and newer initiatives are in line with the Standards of TB Care in India which has been developed by experts from all sectors. Standards of TB Care in India enlists the minimum set of standards that every patient should receive irrespective of the provider. RNTCP has currently all policies based on mutually agreed STCI. Reviewer felt that the RNTCP and its plan to support private sector to ensure STCI by extending free diagnostics, free treatment, Drug Susceptibility testing and public health actions to all patients reaching private sector also will decrease the mistrust.  Kindly consider discussing “coercion alone” and “coercion along with private sector engagement plans” and mutual trust. |
| Para starting with: “It is not clear whether any action will be taken against private practitioners who do report cases but step away from the RNTCP guidelines for treatment” | While going through all the documents, reviewer understood that IPC sections are only for notification of TB which is the first step in ensuring the Standards of TB care to the patient.  NTP has clearly written its vision as “patient should get highest standards of care from providers of their choice”. What reviewer understood is that RNTCP is adopting policies based on STCI which has been developed by experts from all sectors. Government’s vision  is to ensure STCI to all patients and nowhere reviewer could find that Government is insisting that everybody should follow RNTCP.  Reviewer request the author to kindly clarify the concepts of mandatory notification and avoid misinterpretations. |
| But perhaps the biggest problem with this notification is that it turns away the conversation from the real and burning challenges that face the national tuberculosis program today. Like - how do we standardize extra-pulmonary tuberculosis diagnosis in both public and private sector? How do we upscale our DST so it is available to all newly diagnosed patients when this is clearly the need of the hour? While the upscale is awaited how do we screen for INH mono-resistance? How do we work on nutrition in the face of overwhelming evidence that this is critical in successful treatment? | This could have been an important point.  Reviewer had gone through STCI which talks about Standards about extrapulmonary TB also, Index TB guidelines, National Strategic Plan which talks about DST upscalation and INH mono resistance detection and TB-Nutrition collaboration framework. Reviewer understood that policy and plan exist for these concerns and many of these have been implemented already and works are in progress with regional variations. |
| Para…. ”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?...”  “Because in general, the system that a patient uses for their less serious illnesses such as acid peptic disease and viral fever is ultimately the system they will use for the chronic cough that turns out to be tuberculosis.” | These are important area that need to be discussed.  Quality improvements in public sectors and building systems in Public sectors could be highlighted as the “burning challenges”.  But reviewer felt that presentation could have been made a bit scientific and, in a language, suitable for reputed medical journals. |
| “Can the state be booked for being negligent and allowing spread of drug resistance and endangering other people?” | This is a good point to highlight. The Government which is responsible for ensuring care to its citizens either though “public” or “private” sectors need to be made accountable by law. |
| **Other Major Omissions** | |
| The Gazette notification states that “local public health staff of general health system of rural or urban local bodies, not taking appropriate public health action on receiving tuberculosis patient notification is equally liable for attracting punishments under IPC 269 and IPC 270”  Reviewer felt that authors discussed the entire notification order as an action against private sector while that is not the case. It would be good to discuss the above clause. The above clause makes the intention of notification clearer as to ensure better standards of TB care to the patients approaching private sector. But how this could be done without breaching confidentiality and protecting the right of individuals is an important discussion point. | |

6. Other comments

Reviewer felt that though the topic is important and relevant to be discussed, the authors had highlighted this only from the perspective of private sector management/practitioners. This could have been better if discussed from patient’s perspectives also.

Also, reviewer request the authors to read about private sector engagement plans in National Strategic Plan, partnership schemes in RNTCP and Standards of TB care in India to have a clearer understanding and discuss the mandatory notification of TB in the context of all the existing plans and policies.   
  
6. Recommendation  
  
 Accept with major modifications in substance  
  
  
7. Separate comments for the author

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Please let us know whether you would like your name to be published as a reviewer of the manuscript.

I would like to, but only after seeing the revised article.