

The ethics of including persons deprived of liberty in tuberculosis vaccine trials

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Background/Introduction: Developing a safe and effective vaccine against tuberculosis (TB) for adolescents and adults could have a major impact on the global TB burden. A TB vaccine trial requires large samples from a population facing high incidence of TB who can be followed over time. The high TB incidence in low- and middle-income country prisons underscores the critical need for interventions like vaccines for these populations. Yet, due to many countries' wrongful treatment of persons deprived of liberty (PDL), and the specific history of abusive treatment of PDL in medical research, there are widespread concerns about including PDL in vaccine trials, leading to their frequent exclusion.

Methods: We examine existing human subjects protection regulation and recommendations for research involving PDL, and the ethical concerns underlying them, and review additional potential concerns. We propose ways to preempt or mitigate these concerns as they apply to TB vaccine research including PDL.

Results: TB vaccine trials that include PDL pose challenges such as threats to autonomy and risks of coercion. A framework for evaluating TB vaccine study protocols including PDL, and for identifying and mitigating remaining ethical challenges, is proposed. In particular, we recommend measures to prevent duress and enhance the autonomy of PDLs' consent; and to keep the risk-benefit balance favorable to PDL participants.

Discussion and Conclusion: Generalized exclusion of PDL from TB vaccine trials precludes PDLs' access to a potentially protective intervention, and PDL's legitimate exercise of personal autonomy regarding their health. It also delays or foregoes the potential global public health gains from a TB vaccine, which would serve PDL and other disadvantaged groups in particular. With appropriate safeguards and oversight, it could be possible to offer PDL the chance to participate in trials of TB vaccines while protecting their rights, health and autonomy.

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Conflicts of Interest

None

