

How to preserve prisoners' rights and safety in clinical research; a collaborative and unexpected process

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Introduction

The Infectious Diseases (ID) research team at Cardiff and Vale University Health Board will be contributing to a clinical trial comparing different regimens of TB treatment. Rates of Tuberculosis (TB) are high and rising among prisoners in the UK¹ which means UK prisoners are stakeholders in TB related research due to their increased risk of exposure and morbidity. Those who have worked in research delivery are likely to have delivered a study that has prisoners listed in the exclusion criteria. Prisoner participation in clinical research has been restricted internationally by regulatory bodies to protect prisoners from undue influence.

"As regards the issue of medical research with prisoners, it is clear that a very cautious approach must be followed, given the risk of prisoners' agreement to participate being influenced by their penal situation"²

Although prisoners have been deprived of their liberties, they should have the same access to healthcare as the country's population in



Plan

To ensure that prisoners have equitable access to clinical research I plan to develop strategies to facilitate prisoner participation in a clinical trial comparing the side effects of different regimens of approved TB treatments. My plans include:

- Liaising with the healthcare services at HMP Cardiff for guidance and advice.
- Developing a collaborative pathway with the team at HMP Cardiff HMP for facilitating prisoners who wish to participate in appropriate future research.

I plan to review these plans a year after the study opens to evaluate these efforts.

The Unexpected Journey

We did not foresee quite how little guidance there is for research delivery on prisoner participation in clinical research.

Some regard prisoners as unable to give informed consent as their consent cannot be freely given whilst incarcerated. Others argue that prisoners can participate in late phase studies and some argue that stopping prisoners from participating in research violates their rights. I cannot find a framework with established standards for prisoner participation in clinical research that is not in relation to their prison experience. IRAS forms have a section 'Do you plan to include any participants who are prisoners or young offenders?' and individual REC committees will

review this, however if not selected it is unclear if prisoners can participate and appears to be sponsor preference. Attempts to contact the Health Justice Research Network (HJRN) have been unsuccessful whilst developing this pathway and poster.



Local Collaboration

I decided to contact the team at HMP Cardiff and organised a meeting with Senior Nurse Kirsty John. We discussed the study, the follows up and data required from participants. We discussed barriers to delivering the study and developed the below strategy to facilitate enrolment.

On people's first night in prison, they have a 'first night screening' assessment, including a TB assessment. However prisoners can be poor historians and can be dismissive of this assessment due to the sudden, and often traumatic, events surrounding their imprisonment. This was an unexpected barrier. Telephone clinic appointments require escorts by prison guards and require being booked in advance. HMP Cardiff is a remand prison so has a high turnover of inmates, however prisoners who are undergoing medical treatment will have medical hold, where they do not move prisons if there is an end date in place for their treatment.

As a result, we have developed the below strategies to facilitate prisoner enrolment:

- Flag eligible patients with the prison healthcare team as early as possible.
- If the patient consents, flag follow up appointments early so the team can plan.
- Provide the prison team with study information, for reference.

Conclusion

There is minimal guidance for research delivery involving prisoners. This has been an unexpected barrier resulting in unanswered questions.

Collaboration between CAVUHB and HMP Cardiff is long established for routine clinical care. This plan allows for the same high standard of collaboration to extend into clinical research.

There is literature describing the barriers to prisoner participation in a variety of research areas and the lack of clarity in governance on the issue has acted as barrier.

1. UK Health Security Agency. (2023, March 07). *GOV.uk*. Retrieved from GOV.uk: <https://www.gov.uk/government/news/ukhsa-calls-for-a-renewed-effort-to-tackle-tb>

2. The European Committee for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment. (2004). *Extract from the 7th General Report [CPT/Inf (97) 10]*. Retrieved from <https://http://www.cpt.coe.int/en/documents/eng-standards-scr.pdf>

3. Anna Charles, H. D. (September 27, 2011). 'Equivalence of care' in prison medicine: is equivalence of process the right measure of equity? *Journal of Medical Ethics*.



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