



Challenges in conducting HIV-TB clinical research in Central Africa: Experience from the Republic of Congo

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HIV Situation in Republic of Congo

- People living with HIV: 89 000 [69 000 - 120 000]
- People living with HIV who know their status : 35 000
- Women aged 15 and over living with HIV represent the most affected population, 55 000⁷.
- Women aged 15 to 49 HIV prevalence rate 3.7 [2.8 - 5.0]
- Incidence of newly diagnosed HIV infections continues to increase.
- Adults aged 15 and over newly infected with HIV : 4100

HIV Situation in Republic of Congo

- Women aged 15 and over newly infected with HIV : 2700
- Children aged 0 to 14 living with HIV were 7700
- Children aged 0 to 14 newly infected with HIV : 1200
- Deaths due to AIDS among children aged 0 to 14 : <1000
- Orphans due to AIDS aged 0 to 17: 66 000
- People living with HIV who are on ART : 35%
- Children aged 0 to 14 receiving ART : 25% (UNAIDS, 2018)

TB Situation in Republic of Congo

- Incidence of TB is approximately 100 new cases per 100 000 per year
- Prevalence of HIV coinfection is estimated to be 5–19%.
- Number of MDR cases among notified pulmonary TB : 290.
- 2.5% of new cases and 21% of previously treated cases with MDR.
- HIV-positive TB incidence 5.7 (2.9–9.4) 108 (55–179)
- HIV-positive TB mortality 2.3 (1.2–3.8) 43 (22–72)

New and relapse TB case notifications, 2018 : 10 706

- % tested with rapid diagnostics at time of diagnosis : 9%

% with known HIV status : 19%

TB/HIV care in new and relapse TB patients, 2018

Patients with known HIV status who are HIV-positive : 553
(28%)

- on antiretroviral therapy : 273 (49%)

TB Project - Congo

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Phase I (2009-2014)

Conduct a basic epidemiological study on TB in Brazzaville in order to prepare future clinical trials in the antituberculosis reference center

Phase II (2017-2022)

Characterize the epidemiological profile of suspected TB patients consulted at the referral hospital Makélékélé in Brazzaville.

TB treatment also poses a challenge due to long term high pill-burden regimens, interactions between TB medication and cART, overlapping toxicity and adherence issues, high rates of multi-drug resistant TB (MDR-TB), concurrent hepatitis C coinfection, and injecting drug use .

Goals and challenges of TB therapy

Shorten therapy of latent TB infection.

Shorten and simplify the treatment of active, drug-sensitive TB.

Improve efficacy and shorten duration of therapy for drug-resistant disease.

Develop drugs for those with TB who are coinfectd with HIV that can be readily coadministered with ARVs.

Challenges in reaching these goals

- Elucidate the biological mechanisms of mycobacterial persistence and latency.
- Discover and develop new drugs that have novel mechanisms of action and are effective against persistent bacilli.
- Develop and validate biomarkers and surrogate endpoints that predict efficacy and thereby shorten clinical trial duration.

Challenges in reaching these goals

- Develop new preclinical approaches to identifying optimized drug combinations and new clinical and regulatory approaches to testing drug combinations in phase 2 and 3 clinical trials.
- Enhance capacity to conduct clinical trials.

Conclusion

- HIV and TB integration is not suboptimal and will need to be improved by addressing the systemic challenges affecting health service delivery, including strengthening supervision, training and the implementation of a change management programme.
- Support is needed on several levels to address the HIV but also emerging burden not only of TB-HIV coinfection and coinfections with hepatitis B and C.

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