

To: Raymonde Goudou COFFIE Minister of Health 16ème Etage-Tour C Cité Administrative Abidjan-Plateau Cote d'Ivoire

CC: Raoul Konan KOUADIO Joseph NANGUIE

14 June 2016

RE: Recommendation to roll out LAM testing for TB in some people with HIV in Cote d'Ivoire

Dear Dr. Goudou COFFIE

We are writing to recommend you to ensure the introduction of a useful new test to detect tuberculosis (TB) in extremely vulnerable populations in Cote d'Ivoire. TB is one of the leading killers of Ivoirians. TB has been particularly difficult to diagnose in people with HIV with low immunity or advanced disease, who are at extremely high risk of developing TB and having poor outcomes from TB. Fortunately, a simple, inexpensive new test called the lipoarabinomannan or LAM test, has demonstrated impact in this population.

The test, marketed as the Determine TB LAM Ag test by Alere, is a rapid point-of-care test that detects in urine the presence of antigens associated with TB. As such, it is simpler to use and more sensitive in people with HIV than many other sputum-based diagnostic methods for TB, as sputum is difficult to produce, and extrapulmonary or paucibacillary TB disease are more common in people with HIV. The World Health Organization (WHO) recommends the use of this test as a preliminary test to rule in TB in people with HIV with CD4 counts below $100/\mathrm{mm}^3$ or who are seriously ill.¹

A recent randomized controlled study demonstrated the utility of LAM testing in guiding TB treatment initiation and reducing mortality in people with advanced HIV.² Researchers randomized over two thousand hospitalized people with HIV to receive either LAM plus routine diagnostic tests for TB (smear-microscopy, GeneXpert MTB/RIF, and culture) or routine diagnostic tests alone. The simple addition of LAM testing reduced all-cause 8-week mortality by four percentage points, with a relative risk reduction of 17%. Using LAM tests ensured more patients were started on TB treatment, and that treatment initiation occurred earlier than in patients not receiving LAM testing. Earlier treatment is important

World Health Organization. The use of lateral flow urine lipoarabinomannan assay (LF-LAM) for the diagnosis and screening of active tuberculosis in people living with HIV. Geneva: World Health Organization; 2015. Available from: http://www.who.int/tb/areas-of-work/laboratory/policy statement lam web.pdf (Accessed 2016 March 1)

² Peter JG, Zijenah LS, Chanda D, et al. Effect on mortality of point-of-care, urine-based lipoarabinomannan testing to guide tuberculosis treatment initiation in HIV-positive hospital inpatients: a pragmatic, parallel-group, multicountry, open-label, randomised controlled trial. Lancet: 2016 Mar 9. http://dx.doi.org/10.1016/S0140-6736(15)01092-2.



not only for the individual's health, but also for reducing infectiousness, as TB is rapidly rendered non-infectious once appropriate therapy is started.³

LAM testing is the first TB diagnostic test ever with a demonstrated mortality benefit in a clinical trial. It is also the first truly point-of-care test to be recommended by the WHO. It has no infrastructural or biosafety requirements. And, at a cost of just USD \$2.66 per test, it is extremely affordable.

Côte d'Ivoire has made significant efforts in the fight against tuberculosis. The National Tuberculosis Programme in association with the technical and financial partners such as WHO, PEPFAR and the Global Fund has achieved important results on the field. The availability of many GeneXpet MTB / RIF is a concrete proof of the efforts engaged to address TB and HIV-associated TB. We urge you to continue in this way and provide immediate access to the life-saving, simple, affordable (and likely cost-saving) intervention of LAM testing. We request that you take steps to procure this product urgently, facilitate its registration in Cote d'Ivoire as soon as possible, and ensure its availability in the public sector. Additional research will be useful in guiding the implementation, but should not delay access, as with current evidence the potential benefits of LAM testing far outweigh the potential risks. A proposed approach for roll out is to initially make the test available along with staff training as a pilot in large TB centers, and then eventually to all district hospitals in the country. We urge you to ensure that the NTP integrates the LAM test in its strategic plan so as to secure funding from the Global Fund and other donors for its implementation.

We look forward to hearing of your plans to secure availability of LAM testing in Cote d'Ivoire. We kindly request your response by June 21, and that you begin making the LAM assay available in large TB centers as soon as possible. Please direct your response to Patrick Agbassi at yvan.agbassi@sciencespo.fr.

Respectfully submitted,
Collectif des Organisations de Lutte contre la Tuberculose et les Maladies Respiratoires de
Côte d'Ivoire (COLTMR)
Global TB Community Advisory Board (TB CAB)
Global Coalition of TB Activists (GCTA)

³ Dharmadhikari AS, Mphahlele M, Venter K, et al. Rapid impact of effective treatment on transmission of multidrugresistant tuberculosis. Int J Tuberc Lung Dis. 2014Sep;18(9):1019-25. doi: 10.5588/ijtld.13.0834.