TB-Speed NEWSLETTER

N°2
October 2019

EDITORIAL

The TB-Speed HIV and TB-Speed SAM studies are now launched and ready to evaluate new tuberculosis diagnostic tools for children living with HIV or presenting severe acute malnutrition!

In October, the TB-Speed project has launched a new study evaluating a tuberculosis diagnostic algorithm for HIV-infected children with presumptive tuberculosis, the PAANTHER tuberculosis treatment decision algorithm that was just published in the medical journal Paediatrics*. This new diagnostic algorithm includes different steps: tuberculosis contact history, collection of several suggestive clinical signs, molecular (Xpert MTB/RIF) testing of nasopharyngeal aspirate and stool, chest radiography and abdominal ultrasound. Diagnostic decision is made with a scoring system integrating the different component. It has been developed in Burkina Faso, Cambodia, Cameroon, and Vietnam, where its sensitivity and specificity were 88.6% and 61.2% for tuberculosis diagnosis. We expect that this standardized and simplified approach to tuberculosis diagnosis, could be use at decentralized level in resource-limited countries with high HIV burden. The TB-Speed HIV study aims to validate the algorithm by testing it in four different countries, Cote d'Ivoire, Mozambique, Uganda and Zambia.

Children with severe acute malnutrition (SAM) are also at high risk of being underdiagnosed for tuberculosis despite the fact that malnutrition is a risk factor of developing tuberculosis and is associated with poor prognosis of tuberculosis treatment. The TB-Speed SAM study aims to develop and evaluate an innovative diagnostic algorithm/score for tuberculosis in children with SAM similar to the PAANTHER algorithm. The study is ready to start in Zambia and Uganda.

With these two new studies and the ongoing TB-Speed Pneumonia study, the TB-Speed project and teams are progressing toward adapted diagnosis tools and algorithm for the most vulnerable children.

Dr Olivier Marcy
Project Director & Coordinating Investigator

Dr Maryline Bonnet
Coordinating Investigator

Dr Eric Wobudeya
Coordinating Investigator

Marcy O, Borand L, Ung V, et al. A Treatment-Decision Score for HIV-Infected Children with Suspected Tuberculosis. Pediatrics. 2019;144 :e20182065

HEADLIGHT NEWS: THE TB-SPEED HIV & SAM STUDIES

TB-SPEED HIV

OBJECTIVE
Validation of the PAANTHER algorithm

STUDY INTERVENTION
. Xpert Ultra done on respiratory (nasopharyngeal aspirate, sputum), and stool samples
. Chest radiography
. Abdominal ultrasonography
. CRP, Monocytes-Lymphocytes Ratio
. Diagnostic decision based on a score validated in a previous study in HIV-infected children

DURATION
18 months of total study duration
. 12 months of enrolment
. 6 months of patient follow-up
From October 2019 to April 2021

STUDY POPULATION
550 Children aged 1 month to 14 years with a documented HIV-infection and presumptive TB

STUDY SITES
6 hospitals in 4 countries:
Côte d'Ivoire, Mozambique, Uganda and Zambia

TB-SPEED SAM

OBJECTIVE
Development of specific algorithm and diagnosis tools

STUDY INTERVENTION
. Xpert Ultra done on respiratory (nasopharyngeal aspirate, sputum) and stool samples
. Chest radiography
. Abdominal ultrasonography
. CRP, Monocytes-Lymphocytes Ratio
. Quantiferon test
. Diagnostic decision by clinicians using all results available

DURATION
12 months of total study duration
. 6 months of enrolment
. 6 months of patient follow-up
From October 2019 to November

STUDY POPULATION
720 Children aged below 5 years hospitalized with severe acute malnutrition

STUDY SITES
3 hospitals in 2 countries:
Uganda and Zambia

IN THIS NEWSLETTER

WRITING TEAM

Project Director
Olivier Marcy
Output Lead Communication
Maryline Bonnet
Global project manager
Angéline Serre
Communication manager
Emmanuelle Baillet

Contact
Université de Bordeaux
146 rue Léo Saignat
33076 BORDEAUX - FRANCE
emmanuelle.baillet@u-bordeaux.fr

FUNDERS

This project is made possible thanks to the funding of Unitaid and the 5% Intiative implemented by Expertise France and coordinated by the French ministry for Europe and Foreign Affairs.

SUPPORT

This project is also supported by the ANRS.

SPONSOR

This project is sponsored by INSERM.

FOLLOW US

@tb_speed
www.tb-speed.com

PARTNERSHIPS

FOCUS

TB-Speed SAM and TB-Speed HIV training in Zambia and Uganda

The TB-Speed HIV and SAM training took place at the University Teaching Hospital (UTH), Children's Hospital in Lusaka, Zambia from 18th to 21st June, 2019. It involved more than 15 participants including doctors, nurses, radiographers, laboratory scientist and site investigators from the two clinical sites involved in the implementation of the study namely the University Teaching Hospital (UTH) in Lusaka and Arthur Davison Children's hospital in the northern region of Zambia.

The training consisted of an overview of the TB SPEED SAM (Severe Acute Malnutrition) and HIV protocol, clinical and biological sample collection and patients follow up for these studies. The training sessions contributed to prepare the research site staff for the implementation of the studies protocol in line the project goals while ensuring compliance with the rules and legal requirements that apply to clinical research.

This training was an opportunity to share scientific and clinical practice expertise and to strength international collaboration between the University of Bordeaux and the Lusaka University Teaching Hospital.

TB-SPEED AT THE UNION CONFERENCE

The TB-Speed project will have four scientific presentations at the Union conference in Hyderabad India between the 29 October and 2nd November 2019.

- **Development of a simple stool processing method for diagnosis of intra-thoracic pediatric tuberculosis using GeneXpert MTB/RIF Ultra testing: results of an in vitro study**

  Saturday 2nd, November 2019 / 14h00-15h30
  Manon Lounnas (IRD, France)

- **Childhood TB diagnostic capacities in primary health care facilities in high TB burden countries: results from the TB-Speed cross-sectional descriptive survey**

  Saturday 2nd, November 2019 / 12h45-13h45
  Eric Wobudeya (MU-JHU, Uganda)

- **Healthcare professionals' perceptions on barriers and facilitators to childhood tuberculosis diagnosis in Côte d´Ivoire and Mozambique**

  Saturday 2nd, November 2019 / 12h45-13h45
  Joanna Orne-Gliemann (University of Bordeaux, France)

- **Availability and accessibility of TB diagnostic services for pediatric TB at the primary healthcare level: a multi-country survey**

  Thursday 31st, October 2019 / 14h00-15h30
  Eric Wobudeya (MU-JHU, Uganda)

NEWS ON THE PROJECT

- **UPDATE ON THE TB-SPEED PNEUMONIA STUDY (OUTPUT 2)**

  On September 30, a total of 1080 children were enrolled in the study and 6 Hospitals had switched to the TB-Speed intervention, implementing systematic detection of tuberculosis using molecular testing of nasopharyngeal aspirates and stool samples in children aged below 5 years with severe pneumonia.

- **TB-SPEED DECENTRALIZATION STUDY (OUTPUT 1)**

  The TB-Speed decentralisation study has been launched in July with the implementation of the observation phase.

- **TB-SPEED STOOL PROCESSING (OUTPUT 4)**

  The protocol of the study comparing three optimised stool processing methods for Xpert Ultra testing is approved by all ethics committees. Enrolment in the study will start in November in Zambia and Uganda.

- **3RD SCIENTIFIC ADVISORY BOARD MEETING**

  The 3rd Scientific Advisory Board meeting of the TB-Speed project took place in Bordeaux on September, 24th. Board members reviewed the first data of the TB-Speed Pneumonia study and preliminary data from the observation phase of the TB-Speed Decentralisation study and

- **NEW ANCILLARY STUDY**

  The ANRS has approved a new ancillary study on pharmacokinetic of antituberculosis drugs in HIV infected children and children with acute severe malnutrition in Zambia and Uganda

TB-Speed stool processing training session in Uganda

NEWS FROM THE FIELD

Observation phase of the TB-Speed decentralisation study

Between July and October, activities planned in the observation phase of the TB-Speed decentralisation study have started in two districts in Cambodia, Cameroon, Cote d'Ivoire, Mozambique, Sierra Leone, and Uganda.

This phase includes aggregated data collection from facility records and reports, a Knowledge Attitude and Practices survey of health staff on childhood tuberculosis, observation of practices on childhood tuberculosis screening, clinical and laboratory diagnosis, and interview of healthcare workers and key informants on challenges and opportunities for improved diagnosis of tuberculosis in children in health districts.

TB-Speed Decentralization study
KAP (Knowledge Attitude Practices) survey on childhood TB in Cameroon