



## EDITORIAL: TB-SPEED TOWARDS THE END OF THE PROJECT

Since the resumption of inclusions, TB-Speed has been able to maintain the activities despite an overall drop in sick children attending the TB-Speed study sites. Fortunately, the project obtained a 1 year no-cost extension by both Unitaïd and L'Initiative. The official TB-Speed project end date is now September 2022. The new key dates concerning the different outputs are detailed in the "News on the project" section of this newsletter.

Despite these delays and time lags, the TB-Speed project was able to contribute with data and experience to the revision of the 2021 WHO pediatric TB guidelines and operational handbook. The project contributed with data on the diagnostic accuracy of Xpert Ultra from gastric aspirate and stool, shared confidential and preliminary results on acceptability and feasibility on the nasopharyngeal aspirate and stool specimen collection, on the head-to-head comparison of different stool processing methods before Xpert Ultra testing and experience in decentralising childhood TB diagnosis.

At the same time, TB-Speed is preparing for the Union Conference on Lung Health of October 2021: the last one before the end of the project. 7 contributions to the Union 2021 were accepted: 2 symposia, 2 oral presentations and 3 E-Posters. A late breaker abstract was submitted, primary endpoint results of the TB-Speed pneumonia study.

This is a great opportunity to start presenting the first project results, despite the delay due to the Covid-19 pandemic.

The project extension postponed the dates of the international and national result dissemination symposia. The international dissemination symposium will take place June 8-10, 2022 in Maputo, Mozambique, and national dissemination symposia will be organized in each country in July 2022.

Dr Olivier Marcy  
Project Director & Coordinating Investigator

Dr Maryline Bonnet  
Coordinating Investigator

Dr Eric Wobudeya  
Coordinating Investigator

## FOCUS: TB-SPEED TECHNICAL PARTNERS

Among the technical partners, two are directly involved in improving sample collection.

### CAMTech: Development of a nasopharyngeal aspirate (NPA) manual prototype

As part of Output 4, members of the Consortium for Affordable Medical Technologies (CAMTech) team have been developing a hand-powered NPA device in Uganda, called the 'Manual-ly-Operated Aspiration Pump' (MOAP).

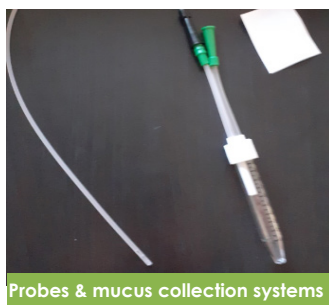
Moving through several iterations, it is now in its 5th prototype and can aspirate experimental mucus (liquid soap) in 15-second intervals, has endured hundreds of test runs, and is being refined by end-user feedback in the field. This manual device could be a very useful alternative device to the battery operated aspirator system that are expensive and still need electricity to charge batteries. Chrispus Mbusa, Project Coordinator and Engineer, and Dr. Johnes Obungoloch, co-PI, have worked hard to create a device that is effective, simple to use and robust. We anticipate more NPA teams to begin testing the device.

Simultaneously, CAMTech has lead the development of Target Product Profile for NPA device to help providers identifying suitable devices and support future development.



A TB-SPEED study nurse (Paul Kakwenza) testing the MOAP

### MSF-Logistique: Central supply of diagnostic equipment and material and NPA market screening



Probes & mucus collection systems

The 2 MSF-Logistique missions in the TB-Speed project are the International supply of medical equipment & material, and a market screening of NPA equipment and material.

44 GeneXpert GX with real time PCR system were shipped to the 7 countries, and 19 mobile medical imaging devices with digitalization system were shipped to 6 countries.

MSF-Logistique conducted a market screening to identify electrical battery-operated devices for mucus aspiration for NPA at low level of health care facility in resource limited countries according to predefined TPP.

## IN THIS NEWSLETTER

Page 1  
EDITORIAL  
FOCUS

Page 2  
HEADLIGHT NEWS  
NEWS ON THE PROJECT  
NEWS FROM THE FIELD

## WRITING TEAM

Project director  
Olivier Marcy  
Output lead communication  
Maryline Bonnet  
Output 6 communication manager  
Nicolas Koskas  
Output 5 project manager  
Martin Harker  
MSF-Logistique  
Doris Art-Hilaes, Paul-Damien Château  
CAMTech  
Ryan Carroll

Université de Bordeaux  
146 rue Léo Saignat  
33076 BORDEAUX - FRANCE

## FUNDERS

This project is made possible thanks to the funding of Unitaïd and L'Initiative 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



## SUBJECT

TB-Speed published in the Tuberculosis journal results of an *in vitro* study to develop a centrifuge-free stool processing method for the use of Xpert Ultra testing from stool for TB diagnosis at low level of health care facility in high burden settings.

## DESCRIPTION

Stool samples are interesting alternatives to respiratory samples for bacteriological confirmation of childhood tuberculosis but require intensive laboratory processing before molecular testing to remove PCR inhibitors and debris.

In this study, we aimed to optimize a method based on a sucrose-flotation that showed good sensitivity for childhood tuberculosis diagnosis.

In an *in vitro* study conducted by IRD at the University Hospital of Montpellier, using Xpert Ultra on stool samples spiked with defined bacterial concentrations of Mycobacterium Tuberculosis, we compared different simplification parameters to the reference sucrose-flotation method.

Best methods were selected based on the rate of invalid/error results and on sensitivity, compared to the reference method. The final optimized method gave 10% invalid/error results and a sensitivity of 70% vs 63% compared to the reference method. This pre-clinical study was able to develop a centrifuge-free processing method that is currently evaluated in an *in vivo* study in children with presumptive TB in Uganda and Zambia (TB-Speed stool processing study).

In this study, the method is compared with two other centrifuge-free processing methods.

## AUTHORS

Manon Lounnas, Abibatou Diack, Mark P. Nicol, Sara Eyangoh, Eric Wobudeya, Olivier Marcy, Sylvain Godreuil, Maryline Bonnet.

Laboratory development of a simple stool sample processing method diagnosis of pediatric tuberculosis using Xpert Ultra. Tuberculosis, 2020; 125: 102002.

## LINK TO THE PUBLICATION

TB-Speed publication is online on [Science Direct](https://doi.org/10.1016/j.tube.2020.102002)

## NEWS ON THE PROJECT

### END OF OUTPUT 2 INCLUSIONS

TB-Speed Pneumonia study ended its inclusions on March 30th, 2021. For this study testing a simple and systematic TB molecular detection strategy based on Xpert Ultra tests performed on NPA and stool samples on the day of admission of young children with severe pneumonia. 2571 children were enrolled since March 2019. 1171 children enrolled in the intervention arm of the study were proposed a NPA & stool sample collection.



Xpert Ultra test, Cameroon



Nasopharyngeal Aspiration, Zambia

97% of them had NPA successfully collected and tested for tuberculosis. and 80% had stool collected and tested. This is the first study evaluating such diagnostic approach in this group of children at high risk of mortality.

### START OF DATA COLLECTION ON OUTPUT 5

TB-Speed Output 5 is evaluating the cost effectiveness of each of the novel diagnostic approaches that are being implemented in the TB-Speed studies.

Information is now collected on what equipment, supplies and staffing are required to provide TB-Speed interventions compared with the usual care currently given to children with presumptive TB.

The collection of the prices for each of these health care resources in each of the 7 TB-Speed countries is also conducted.

When this data has been collected it will be combined with the effectiveness results reported by the TB-Speed studies to provide information that will inform national decision-makers on which interventions will provide the greatest benefit and could be affordable to implement for a whole country.

### NO-COST EXTENSION: NEW DEADLINES

DECENTRALISATION	Intervention		Follow up	Final Results
PNEUMONIA	Enrolment	Follow up	Final Results	
HIV	Enrolment		Follow up	Final Results
SAM	Enrolment		Follow up	Final Results
STOOL PROCESSING	Enrolment		Follow up	Final Results
COST-EFFECTIVENESS	Cost Data Collection		Cost-effectiveness Analysis	

Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4  
2021 2022

Union Conference on Lung Health 2021

National Restitution Symposium

International Restitution Symposium

Preparing Union Conference 2021

the last one before the end of TB-Speed project



## NEWS FROM THE FIELD

### VIRTUAL MONITORING

The COVID-19 pandemic and the resulting limitation of travel has led TB-Speed to set up an international virtual monitoring protocol visits, with international Clinical Research Associates (CRA) acting remotely, and national CRA on site.

The tablet provided to the national Data Manager in order to test the RedCAP application and a secure FTPs access are used for the exchange of information.

### TB-SPEED CONTRIBUTIONS TO UNION CONF 2021

#### 2 Symposia

- . Closing the gap on pediatric TB diagnosis: TB-Speed and CaP TB
- . Diagnosis of tuberculosis in children with severe pneumonia

#### 2 Oral Presentations

- . Feasibility and yield of systematic tuberculosis molecular testing in children with severe pneumonia in countries with high tuberculosis incidence
- . Implementing a systematic and rapid Xpert® MTB/RIF Ultra tuberculosis detection of NPA in children with severe pneumonia: Lessons learned in 6 high incidence countries

#### 3 E-Posters

- . Acceptability of nasopharyngeal aspirate and stool sample collection for tuberculosis diagnosis in children with severe pneumonia – parents' and health care workers' perspective
- . Ultra on stool samples from children with presumptive TB: head-to-head comparison of three centrifuge-free stool processing methods
- . Development and implementation of training on simplified Chest X-ray interpretation for childhood