

Development of diagnostics for pediatric infections

Anne-Laure Page, Epicentre, France

Background

Bacterial infections remain the leading cause of child mortality in sub-Saharan Africa. In the absence of simple and rapid diagnostic tests, treatment remains probabilistic and may lead to unnecessary use of antibiotics. We engaged in a collaboration with Institut Pasteur (IP) to bring together biological, clinical and field expertise to develop field-adapted diagnostic tests for pediatric bacterial infections.

After signing an agreement framing the legal, financial and organizational aspects of the collaboration, we launched a call for proposals inviting research units from IP and its international network, in partnership with technological institutions, to submit projects. A steering committee including members from IP, MSF and Epicentre was in charge of selecting the project and following its progress. The selected project, called “Child’s Play”, aimed at developing an automated and integrated molecular assay for the simultaneous detection of the five leading bacterial causes of severe illnesses among children in Africa: *Streptococcus pneumoniae*, *Salmonella spp.*, *Staphylococcus aureus*, *Haemophilus influenzae* and *Escherichia coli*.

The molecular assays showed good analytical sensitivity and specificity using blood samples spiked with bacteria. Integration and automatization in a microfluidic cartridge revealed numerous challenges that were

partly solved during the project. However, when tested on clinical samples from febrile patients collected in Mali and Uganda, less than half of the samples positive by blood culture were detected by the molecular assays. This might reflect lower sensitivity of molecular methods compared to culture when used directly on blood. Considering the limited anticipated clinical impact of such a test, the steering committee decided not to move the project forward.

This collaboration highlighted various legal, institutional, scientific and technological obstacles in the development of diagnostic tests. Although many of them were overcome through collaborative efforts, the project failed to reach sufficient clinical relevance to move to the next challenging step of industrialization.

A collaboration to develop an automated assay for the detection of the leading bacterial causes of pediatric infections revealed numerous legal, institutional and scientific challenges.