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ICMR study leads to unique non-invasive method of SmaRT-PCR mask to detect tuberculosis in children

The mask is a modified version of N95 mask with a special gelatin membrane inside which collects all exhaled respiratory aerosols. This method of diagnosis, which was rolled out on a pilot basis, is completely non-invasive

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According to experts, India has a very high burden of TB cases in children -- about 28% of global cases are in India.

Diagnosing tuberculosis (TB) in children has been a challenge and unlike adults, children cannot produce sputum—which is the easiest and best sample for diagnosis of the illness. Now,

a four-year-long study funded by Indian Council of Medical Research (ICMR) has commenced to explore a unique method of finding TB in children using a SmaRT-PCR mask.

What is the SmaRT-PCR mask

The mask is a modified version of [N95 mask](#) with a special gelatin membrane inside. This membrane collects all exhaled respiratory aerosols. After a 10-minute sample collection procedure, the mask is removed. The membrane is then transferred into a stabilising solution after which RT-PCR is used to detect TB. These are one-time-use masks.

“We used this simple mask-based way to collect aerosols to understand the impact of treatment on the infectiousness of the bacteria. We were doing this in adults. What we realised during this study was that in some of the adults who were not able to produce sputum we were able to detect TB using these aerosols as well. This prompted us to explore if we can use the same approach to test TB in children who are unable to produce sputum,” Dr Nerges Mistry, Director of FMR said.

Nearly 30% of global cases of TB in children in India

“Globally, 1.3 million children are estimated to be having TB every year. India has a very high burden—about 27-28% of the childhood TB is in India. There are several challenges of diagnosing TB in children. First is that symptoms and signs of TB are very similar to many other childhood diseases. It is very difficult to differentiate TB-specific symptoms in children. When we do X-rays with children, the findings are very non-specific. This is unlike in adults, where the findings are very specific with cavity type of disease that can be easily identified,” Dr Kalpana Sriraman, Assistant Director (Research), Foundation for Medical Research (FMR) in the latest session of End TB Dialogues.

How is TB detected in children

Children have to go through invasive procedures like gastric lavage — it involves introducing a tube into the body and taking out the sample — which can be traumatic for the patients and their families, experts said. “This is also one big reason why many parents hesitate to come for a TB diagnosis. But if we do not diagnose TB and treat the disease, then mortality can be as high as 96%. In India, currently 70% of children are clinically diagnosed — they do not get the confirmatory bacteriological diagnosis which is required for guiding the correct treatment. This is why there is a huge push for developing non-sputum based diagnostics for children,” Dr Sriraman added.

SMaRT-PCR mask non-invasive method for TB diagnosis

Dr Ambreen Shaikh, Research Officer, TB Department of FMR said, “SMaRT-PCR procedure is completely non-invasive. The patient is asked to wear the modified gelatin mask for 10 minutes and asked to do some loud reading, talking or even singing and alternate it with some cough and breathing. This is a 10-minute sample collection protocol.” The pilot study was taken up in children (up to 15 years’ old) in [Mumbai](#) in collaboration with Wadia Children’s Hospital, J J Hospital and Dr Oswal’s clinic.

Dr Vikas Oswal told [The Indian Express](#) that the SmaRT-PCR method of diagnosing TB had a higher sensitivity as compared to that of a standard diagnosis. “The sensitivity of this method of using a modified mask and RT-PCR is 75%. Six samples that were negative for TB in Gene Xpert tested positive using SMaRT-PCR in the study pilot,” said Dr Shaikh.