

Trial of Gates-Funded Vaccine Patch for Infants 'Successful,' Company Says

An Atlanta-based biotech company last week said it successfully concluded the first-ever clinical trial testing — with help from the Bill & Melinda Gates Foundation — of a microarray injection-free vaccine on children as young as 9 months old.

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An Atlanta-based [biotech company](#) last week said it successfully concluded the first-ever clinical trial testing of a [microarray injection-free vaccine](#) on children as young as 9 months old.

Micron Biomedical tested microneedle-based delivery of the measles-rubella (MR) vaccine on children in Gambia with backing from the Bill & Melinda Gates Foundation and the Centers for Disease Control and Prevention (CDC).

Microarray injections are administered via a [microneedle patch](#) that looks like a Band-Aid and is applied by pressing it to the skin. Once applied, microneedles penetrate the upper layer of the skin to deliver the vaccine.

The study, which researchers presented last week at the [Microneedles 2023](#) conference in Seattle, evaluated the safety, immunogenicity and acceptability of the leading commercially available MR vaccine from the Serum Institute of India delivered by Micron's microarray technology in adults, toddlers and infants.

Proponents of this vaccination method, such as [Gavi, the Vaccine Alliance](#) — of which the Gates Foundation is a founding member — call the patches “[the future of vaccination](#), where these lifesaving interventions are delivered painlessly, without the need for syringes or perhaps even trained medical professionals.”

“Supporting innovations in vaccine delivery is critical to addressing ongoing health inequities,” [James Goodson](#), co-investigator for the study and senior scientist and epidemiologist at the CDC's Global Immunization Division, said in the press release.

He added that the study also is a key step toward getting the patches licensed.

Developers tout the technology as painless — it feels like Velcro, they claim — and more thermostable than traditional vaccines.

This would make widespread global distribution of the vaccines easier, they said, particularly in developing areas that may lack infrastructure, such as refrigeration, and trained professionals.

Microneedle vaccine market worth billions

Micron's CEO, Steven Damon, said:

“Micron, with support from the Bill & Melinda Gates Foundation and the CDC, is thrilled to accomplish a [major milestone](#) in the future of injection-free administration of necessary and potentially life-saving vaccines and therapeutics.”

With this trial, the company remains at the forefront of bringing microarray-based vaccine products to market, Damon said.

The Gates Foundation, the CDC, Unicef, PATH — another heavily Gates-funded organization — and the Georgia Research Alliance provided Micron with \$40 million in funding to develop its microneedle patch technology.

In 2017, the Gates Foundation gave Micron a [\\$2.2 million grant](#) to develop the microneedle patch for the MR vaccine and another [\\$900 million](#) in 2022. Gates had previously awarded Micron \$2.5 million to develop a [microneedle patch for polio](#) as part of the foundation's [effort to eradicate polio](#).

In the last several months, Micron also received significant funding from investors like [Global Health Investment Corporation](#) and [LTS Lohmann](#). And less than two weeks ago, just before it presented the study results at the Microneedles 2023 conference, the company secured an additional [\\$3 million investment](#) from J2 Ventures, bringing its total [Series A funding](#) to \$17 million.

Series A funding, the first round of equity financing for a startup company after it has demonstrated some success with seed funding, precedes a public offering.

Trials for vaccine patches against [COVID-19](#), [seasonal influenza](#) and hepatitis B also are ongoing, while patches against [human papillomavirus](#), typhoid and rotavirus are in preclinical development.

The microneedle vaccine market for the [flu vaccine](#) alone is projected to reach [\\$2.3 billion by 2030](#).

Last year, [Mark Prausnitz, Ph.D.](#), co-founder and chief scientific advisor to Micron Biomedical [presented Micron's technology](#) at a White House panel discussion, Innovation in Vaccine Delivery.

The panel, chaired by [Dr. Francis Collins](#), then-director of the National Institutes of Health, explored “a path toward innovative, next-generation COVID-19 vaccines and vaccine delivery technologies.”

“This technology has revolutionary potential for extending the reach of vaccines in low resource settings and during pandemics,” David Hoey, president and CEO of Vaxxas, a biotechnology company based in Brisbane, Australia, told Gavi.

Hoey's company has patches against measles and rubella, COVID-19 and seasonal influenza in human trials.

‘Safe and well tolerated with no allergic reactions or related serious adverse events’

Forty-five adults, 120 toddlers (15-18 months old) and 120 infants (9-10 months old) were enrolled in the [clinical trial](#) and randomized to receive the MR vaccine either via Micron’s microarray or through subcutaneous injection, meaning beneath the skin.

The study has not yet been published, but in a [press release](#), Micron reported that vaccination by microarray was found to be “safe and well tolerated with no allergic reactions or related serious adverse events.”

The study reported similar seroprotection rates of approximately 90% or more after 42 days for the groups that received the microarray and subcutaneous injections.

“Generally, parents were very positive about the ability to vaccinate their young infants without a needle,” Damon said.

Transdermal patches have been available for illnesses such as motion sickness since 1979, but many types of medications cannot be delivered through the skin because the skin is an effective barrier.

[According to Gavi](#), vaccine developer Prausnitz spent years trying to develop ways to cross the skin barrier to aid in drug delivery, but it wasn’t until he began collaborating with people who had expertise in computer microchips that he was able to find ways to penetrate the skin’s natural barrier.

Then each vaccine needs its own formulation that can work with that technology.

Relocating ‘large scale clinical trials of untested or unapproved drugs to developing markets’

According to Fierce Pharma, Micron’s decision to roll out the first-ever test of the new technology on [children in Africa](#), “reflects a belief that microneedle technology is particularly well suited to the administration of vaccines in that part of the world.”

“Microneedle technology, such as this, is viewed as being a key component to measles control in sub-Saharan Africa and elsewhere. This reflects, amongst other things, the potential ease of delivery, reduced cold chain requirements and absence of sharps waste,” Ed Clarke, Ph.D., said in a statement.

Clarke, the London School of Hygiene and Tropical Medicine researcher leading the study, also received money from the Gates Foundation [to study other vaccines](#) in Gambia.

Many scholars have raised concerns that research conducted by international organizations in the global south, and by the Gates Foundation in particular, can lack accountability and lead to serious harms to the population being tested.

One paper published in the [Annual Survey of International and Comparative Law](#) found

“these health campaigns [carried out in India and Africa], under the guise of saving lives, have relocated large scale clinical trials of untested or unapproved drugs to developing markets where administering drugs is less regulated and cheaper.”

[The Lancet's editorial board](#) also raised questions about Gates-funded research in low-income settings, pointing to the foundation's [limited transparency](#) and tremendous power to direct health programs and research with its funding.

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