VACCINATIONS REINVENTED

An innovative and pain-free vaccination system, that increases efficacy and safety of vaccine delivery, is a game changer for global vaccination programs helping to eliminate infectious disease.

Images: Top - A vaccine being delivered using the HD-MAP. Bottom - Scanning electron micrograph of the HD-MAP, each projection is 110 µm tall.



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SMALL SAMPLE

VACCINATIONS REINVENTED



CHALLENGE

Despite increasing vaccination coverage, the WHO estimates there are still 1.5 million deaths each year from vaccine-preventable diseases (VPD). This is due to a series of issues, including:

- Storage: Almost half of vaccines given in developing countries are thought to fail due to difficulties keeping the vaccine cold enough before use.
- Cost: A large dose of vaccine is needed for intramuscular injection because muscle is inefficient at producing an immune response. This increases production costs and reduces availability.
- Safety: Needles come with potential threats including needle-stick injuries to healthcare workers, particularly in HIV-endemic areas. They can also be traumatic, particularly for children, leading to needle-phobias and vaccine avoidance.
- Access: current vaccines must be administered by a healthcare professional, making it difficult to achieve adequate vaccination rates in remote regions or for people living in areas of political instability and conflict. This has tragically led to the recent reemergence of VPDs in countries such as Iraq, South Sudan, Syria, Yemen and the Congo.

RESEARCH

Prof. Mark Kendall, who started this work at the University of Queensland (UQ), has developed a device, dubbed the HD-MAP (previously known as Nanopatch™), that could revolutionise vaccine delivery. The HD-MAP is a one square-centimetre silicon patch covered with thousands of vaccinecoated micro-projections. These pass through the skin's outer layer to deliver the vaccine directly to the immune cells in the skin, which are more efficient at mounting an immune response than muscle. Tests showed that 1-2.5% of the dose currently used for influenza and polio vaccines was needed to elicit the same immune response.

Our microscopy facilities have been used in over 20 HD-MAP publications, from initial R&D to clinical trials. The first HD-MAPs were created by ANFF, another NCRIS facility, and optimised using scanning electron microscopy at our UQ facility.

Vaxxas, a company formed to commercialise the HD-MAP, has run successful clinical trials of polio and influenza vaccines and pre-clinical trials of COVID-19, dengue fever and human papillomavirus vaccines. World Health Organisation funded usability testing in Benin, Nepal, Vietnam and Australia which showed high acceptance rates. In 2020 clinical trials commenced to test if patients can self-administer the HD-MAP.

IMPACT

The HD-MAP is a game changer for global vaccination programs for several reasons:

- it uses a dry vaccine that does not need to be kept cold to be effective, tackling one of the greatest barriers to delivering effective vaccinations in developing countries
- the same amount of vaccine goes much further
- it can be administered by non-health professionals, increasing access
- it is pain free and reduces the burden on needle-phobic patients
- tests showed that it's more effective than competitor microarray patches.

Vaxxas has secured both global partnerships and investment, attracting over \$35 million in initial funding along with a deal with world leading vaccine producer, Merck, for further R&D and trials. Bill & Melinda Gates Foundation have provided two grants totalling \$14.25 million for preclinical development and trials for measles and rubella vaccinations.

Recently, Vaxxas and Harro Höfliger have partnered to develop the world's first high-throughput, manufacturing line for production of HD-MAP technology, producing up to 5 million vaccine products per week. They plan to have a pilot line operational by 2021 to support late stage clinical trials.

