

Australia to undertake clinical studies of needle-free vaccine patch

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With a \$1.12 million funding, clinical studies at the University of Sydney to look at the potential of needle-free delivery for at-risk groups



University of Sydney researchers have been awarded \$1.12 million in funding via the Innovative Manufacturing CRC (IMCRC) to undertake independent clinical research studies to understand the potential of needle-free vaccine delivery for at-risk groups. This grant reflects matched funding from Commonwealth Government funded IMCRC and Vaxxas, an Australian biotechnology company.

The two upcoming clinical studies are designed to evaluate the safety, feasibility, acceptability and usability of self-administration of Vaxxas' vaccine delivery technology using an inactive substance. They will focus on older adults and healthcare professionals who are more likely to be impacted by pandemic influenza and SARS-COV-2.

Lead researcher Professor Rachel Skinner from the University of Sydney's Faculty of Medicine and Health and Kids Research in the Sydney Children's Hospital Network said the device presents potential advantages compared to vaccination using a needle and syringe.

The device is a one square-centimetre of biocompatible polymer, smaller than a postage stamp, covered in thousands of micro-projections which are invisible to the naked eye. These are coated with a vaccine formulation, with the goal of penetrating the protective outer layer of the skin to deliver the vaccine to cell layers immediately under the skin, rich in immune cells.

The device is applied to the skin using a disposable applicator that contains the product. The vaccine technology is still under development and has not yet been approved for use.

"The goal is for the device to only require a small dose of vaccine to generate the same level of immune response in the recipient," said Professor Skinner.

"The device doesn't require refrigeration making it easy and cheap to transport and store. It is designed to be simple to use, with the potential to be self-administered."

Cristyn Davies, a Research Fellow in the Faculty of Medicine and Health and Kids Research, said the trials aim to simulate vaccination in a pandemic situation, focusing on priority groups susceptible to infection such as the elderly, and healthcare workers who are required to care for infectious patients.

“The studies will use an excipient, an inactive substance which is of the same texture as a vaccine, to test the effectiveness of the device at delivery of the substance into the skin.”

“With older populations, we are particularly interested to see how the technology works with those with aged, delicate skin. In both groups, we will test whether it’s feasible and acceptable for them to self-administer the patch, which could prove critical for many populations during a pandemic situation.”

Professor Rachel Skinner said that the new studies build on earlier studies carried out by the team in 2019-2020 to test the usability and acceptability of the device among parents, clinicians and immunisation nurses at Sydney Children’s Hospital Network, and assess cost-benefits on logistical parameters like supply chain, compared to conventional immunisation. The results are yet to be published.

David Chuter, CEO and Managing Director of IMCRC, highlighted the importance of the studies in expediting the refinement of the design and manufacturing of the device.

“With Vaxxas planning to begin manufacturing the new needle-free vaccine delivery technology by early 2022, this IMCRC research project is vital to refine the device and fast-track its commercialisation process. These studies will assess the safety and acceptability of managing this technology within the healthcare community, with the results being fed back into the design and manufacturing process which is currently set up in Australia.”