

Researchers successfully develop a rotavirus vaccine which could benefit millions of children

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Credit: Murdoch Children's Research Institute

Researchers from the Murdoch Children's Research Institute (MCRI) have developed a rotavirus vaccine that provides earlier protection from dehydrating diarrhoea for infants and young children.

Diarrhoea is one of the leading causes of child illness and death, and rotavirus is the most common cause of severe diarrhoea. Globally rotavirus causes approximately 215,000 deaths in <u>children</u> under five years.



In a world-first clinical trial conducted in Indonesia, the RV3-BB vaccine was administered to babies soon after birth. Current rotavirus vaccines can only be administered to children older than six weeks, which leaves newborn babies particularly vulnerable to rotavirus infection.

The oral vaccine was given in three single doses, the first within five days of birth. A small volume of liquid placed in the baby's mouth provided protection against severe rotavirus gastroenteritis. The results, published in the *New England Journal of Medicine*, have found that after 3 doses of RV3-BB administered from birth, 94 per cent of infants were protected in their first year of life and 75 per cent of infants for up to 18 months of age against severe rotavirus gastroenteritis.

Professor Julie Bines, the study's lead researcher from MCRI; a professor at the University of Melbourne; and a prominent gastroenterologist at the Royal Children's Hospital, further emphasised the importance of the birth dose.

"In low resource settings, birth offers the best opportunity for contact between mother, baby and health services. RV3-BB provides an ideal vaccination opportunity. This disease doesn't discriminate – without vaccination it infects children worldwide under the age of five – irrespective of what environment you live in," Professor Bines said.

The vaccines that are currently available work very well in places like Australia, the US and Europe but they don't seem to work as well in low income settings in Africa and Asia where severe gastroenteritis is common and many children die. The RV3-BB vaccine has been shown to be remarkably effective against severe rotavirus disease in Indonesia. Indonesia has a high burden of rotavirus infection and as yet has not introduced a rotavirus vaccine into their National Immunisation Program. Rotavirus gastroenteritis is estimated to cause 10,000 child



deaths, over 200,000 hospitalisations and almost 600,000 clinic presentations in children under 5 in Indonesia every year. The Indonesian based clinical trial was conducted in collaboration with the Universitas Gadjah Mada, in Yogyakarta; and the Indonesian vaccine manufacturer, PT Biofarma.

The World Health Organisation recommends that all children receive a rotavirus vaccine, however approximately 94 million infants still do not have access to the vaccine. In an effort to make rotavirus vaccine more readily accessible to infants worldwide, MCRI seek to license RV3-BB to manufacturers able to produce vaccines at large scale and at an accessible price. MCRI have been working with the Indonesian vaccine manufacturer PT BioFarma under license to produce the RV3-BB vaccine.

Duncan Steele, Deputy Director and Strategic Lead for Enteric Vaccines at the Bill & Melinda Gates Foundation noted that "Thanks to increased investments in global health in the last 25 years, we have seen dramatic improvements in child health but it is unconscionable that children are still dying by the hundreds of thousands every year from diseases that are preventable and curable, such as diarrhoea. We know rotavirus vaccines work to save young lives and prevent hospitalizations in every country where they are used. The successful clinical trial in Indonesia, coupled with commitment from Biofarma PT to produce the vaccine, provides confidence in a vaccine that has the potential to have a major impact in Indonesia, and ultimately globally. Furthermore, the vision of the Australian research team in pursuing a global clinical development, including clinical trials in Australia, New Zealand, Indonesia and Africa highlights the promise of a birth dose rotavirus vaccine for all children."

The success of the RV3-BB vaccine represents a significant scientific and global health achievement. It is the culmination of more than four decades of work which started with Professor Ruth Bishop and the



discovery of rotavirus, and critical work done at MCRI to understand more about this important virus. The RV3-BB vaccine is based on a strain that was isolated by Professor Bishop, Professor Graeme Barnes and their colleagues in the nurseries of the Royal Women's Hospital, which did not cause symptoms in the babies who were infected and instead provided them with protection against severe gastroenteritis.

The esteemed Australian immunologist, Sir Gus Nossal, sees the discovery as a "great hallmark of Australian science".

"In 1973, Professor Ruth Bishop led a team of researchers to make one of the most important Australian contributions to global child health," Professor Bines said. "Our aim is to build on this legacy by developing an effective <u>rotavirus vaccine</u> that prevents rotavirus disease from birth for the world's children."

Victoria's Lead Scientist, Dr. Amanda Caples said, "This study enhances the reputation of Victoria's infectious disease researchers in tackling global child health problems. It is a major milestone in the development of a safe and effective Rotavirus <u>vaccine</u> led by Melbourne's Royal Children's Hospital and MCRI."

Provided by Murdoch Children's Research Institute

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