

Parent Information - BCG 10 Vaccine

Background

Australia has one of the lowest rates of Tuberculosis (TB) disease in the world, but it remains common in many countries throughout the world. TB is a disease caused by a bacteria called *Mycobacterium tuberculosis*. TB spreads through the air but it is not easy to catch. It affects the lungs in 70% of cases, but can also affect lymph nodes, the brain, kidneys, or spine.

It is more common for children to have TB that affects more than one part of the body (miliary TB) and brain inflammation (meningitis). As TB tends to be more serious in children, we recommend protection with BCG vaccine for children less than 5 years of age travelling to countries with high rates of TB.

BCG Vaccine

BCG stands for "Bacille Calmette-Guerin" and is named after the doctors who developed the vaccine. It has been used since the 1920s to prevent TB. The BCG vaccine was developed from a germ similar to TB called *Mycobacterium bovis*. The vaccine contains a live but very weakened part of the bacteria that has been processed so that it is not harmful to humans.

The BCG vaccine does not prevent someone being infected with the TB bacteria, but it prevents the development of the disease. It is specifically designed to prevent TB in children and can be given from birth onwards. The World Health Organization currently recommends a single lifetime dose.

Current BCG Vaccine Shortage

There is currently a worldwide shortage of BCG vaccine. Due to international manufacturing and supply issues, the current Australian Therapeutic Goods Administration (TGA) approved vaccine supply will end on the 31st December 2015. There is therefore no currently registered BCG vaccine product in Australia and it will not be available in the foreseeable future.

Replacement BCG Vaccine

A replacement BCG vaccine (called BCG 10-Polish strain) has been sourced by the Victorian Government Department Health and Human Services Immunisation Program. The BCG 10 is the only BCG vaccine that will be available in 2016. BCG 10 has been shown to be as effective and safe as the vaccines previously used in Australia but it is not registered or approved for marketing by the TGA in Australia.

As BCG 10 is not registered by the TGA, only Authorised Prescribers can access and give the vaccine. The TGA also requires consent forms to be completed by families before the vaccine can be given.

If you have any questions, please talk to your treating doctors who are specialists in BCG vaccine delivery.

What to expect

The BCG 10 vaccine is given in exactly the same way as other previous BCG vaccination. It is injected just under the skin of the left upper arm.

The vaccine is sometimes associated with common and rare side effects.

The usual expected reaction to any BCG vaccination is redness and/or a small lump at the injection site, followed by a small ulcer (open sore) a few weeks later (usually less than 1 cm in diameter). The ulcer may last from a few weeks to months before healing to a small flat scar. The same local reactions are seen with all BCG vaccines.

The RCH Immunisation service will be monitoring for any reactions after the BCG 10 vaccine is given. We recommend seeking medical advice, if you notice a severe reaction at the injection site, such as a large persistent discharging abscess, or if you notice swelling or tenderness of the glands ('lymph nodes') in the left armpit.

We will contact you 6-months after the vaccine to ask how things have gone since the vaccine was given and to monitor for short and long-term side effects.

For advice regarding local reactions contact for advice your General Practitioner and/ or the The Victorian vaccine safety service SAEFVIC at The Royal Children's Hospital, Melbourne (open business hours).

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