

DEVELOPMENT OF NOVEL THERAPEUTICS TO TREAT INVASIVE GROUP A STREPTOCOCCUS AND STREPTOCOCCAL TOXIC SHOCK SYNDROME

Infections with group A streptococcus (Strep A) are highly prevalent in all sectors of society with estimates of over 600 million cases of streptococcal pharyngitis (tonsillitis) and over 160 million cases of streptococcal pyoderma (school sores) each year.

Most importantly, seemingly mild streptococcal infections can rapidly escalate to serious invasive Strep A disease (iSAD), which has a significant mortality rate. In approximately 20% of cases, iSAD is accompanied by a streptococcal toxic shock syndrome (STSS), which causes necrotising fasciitis, myositis or deep bruising and multi-organ failure. STSS has a fatality rate of up to 80% reported, even in the best equipped facilities.

Currently, there are no specific therapies available on the market to treat STSS, or the underlying invasive Strep A infection.

The Technology

Researchers at the Institute for Glycomics have developed an immunotherapeutic that neutralises both the STSS-causing bacterial exotoxins, as well as the bacteria responsible for the primary invasive Strep A infection. This could be used as a potential treatment for iSAD and STSS.

The immunotherapeutic takes advantage of monoclonal antibodies (mAbs) raised against both Strep A bacterial proteins and toxic superantigen proteins, secreted by the bacteria. This double-pronged approach has been a breakthrough in the development of an immunotherapeutic for iSAD and STSS.

iSAD Incidence and Market

The incidence rate for Strep A, and consequently iSAD and STSS is severely underestimated due to poor reporting in lower socio-economic countries, who are most at risk, particularly for invasive diseases.

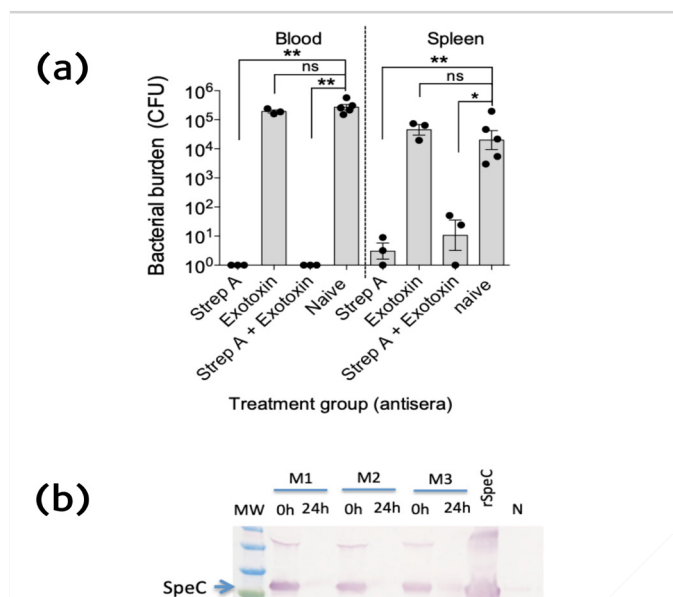
The overall incidence reported for iSAD is 2 to 4 cases per 100,000 people in developed countries. Periodic upsurges in incidence rates of STSS have been described in various countries, but the most recent reports show a worrying and sustained increase in incidence throughout Canada, particularly from 2013. In Alberta, the rates have dramatically increased from 4.2 to 10.2 cases per 100,000 people between 2003 and 2017.

In 2018, the UK reported an iSAD incidence 73% higher than the average for the previous five years. Similarly, Denmark reported an increase from 2.3 to 3.1 cases per 100,000 people between 2005 and 2011, with 10% of these presenting with STSS. Most at risk are the young and the elderly, and particularly those from developing countries.

Intravenous immunoglobulins (IVIG) are currently used as a last line of defence treatment for STSS, despite several studies indicating that it provides no significant improvement in patient survival. Treatment typically costs around \$10,000 per patient. It is expected that an efficacious treatment would secure 100% of the market share over IVIG, at equivalent cost.

Intellectual Property

Griffith University wholly owns a provisional patent describing



(a) Bacterial burden in Strep A-infected mice post-antisera treatment. (b) Mice sera demonstrating neutralisation of toxin by combination immunotherapy.

our immunotherapeutic to treat STSS and Strep A infection, filed in Australia. Title: Streptococcal Toxic Shock Syndrome, 2018901709.

Development Status

Our research team have recently proven proof-of-principle for the treatment of Strep A and STSS with an immunotherapeutic.

We are currently completing preclinical studies using mice mAbs prior to development and preclinical evaluation of humanised mAbs.

At the Institute for Glycomics, we have the expertise and capacity to complete preclinical development and evaluation, including toxicology, and tech transfer to a GMP manufacturing facility en route to clinical trials.

Opportunity for Partnership

The Institute for Glycomics has a strong track record for translating our preclinical or early-clinical technologies through strategic partnership with industry.

We are now seeking a partner with expertise in pharmaceutical manufacturing and clinical-stage development to co-develop and licence this STSS technology.



Contact us

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Research Leaders

The immunotherapeutic approach for treating Strep A and subsequent invasive disease has been developed by **Professor Michael Good AO** and **Dr Manisha Pandey**.

Professor Michael Good is an internationally recognised leader in the field of immunology and vaccine development. He is the recipient of the National Health and Medical Research Council Australia Fellowship and an Officer of the Order of Australia (AO) for contributions to medical research and education.

Professor Good is author of over 300 peer-reviewed publications and is co-inventor of more than 10 patent families.



About us

The Institute for Glycomics is a flagship biomedical research institute at Griffith University's Gold Coast campus in Queensland, Australia.

The Institute is one of only six of its kind in the world and has a strategic focus on translating drug and vaccine discovery research into clinical outcomes.

We have a strong track record in commercialisation and industry engagement, and our research leaders and business personnel have extensive experience in developing technologies for the commercial market.

With over 200 multidisciplinary researchers and support staff, the Institute for Glycomics is well positioned to deliver tangible clinical solutions for infectious diseases and cancer.

