

Neonatal Sepsis

R&D PROGRAMME SNAPSHOT

Neonatal Sepsis: A Global Concern

Neonatal sepsis is a serious life threatening condition among newborn babies resulting from blood stream infections such as meningitis and pneumonia. The incidence of neonatal sepsis threatens the sustainable development goal (SDG) targets for child survival. The current available standard of care in many countries is increasingly becoming less effective as antibiotic resistance grows.

In an increasing number of middle-income countries which are seeing booming numbers of hospital births, neonatal sepsis is often associated with very high mortality rates. This is because it is often transmitted in hospital settings where multidrug-resistant (MDR) gram-negative bacteria can thrive in the absence of effective infection control measures. At the same time, many babies also die

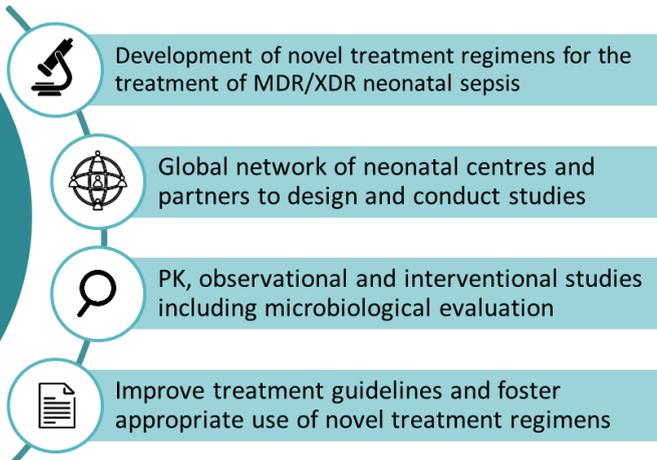
unnecessarily in community settings because they do not have access to early treatment.

Antimicrobial resistance is a serious concern for neonatal sepsis – a recent study estimated that globally, 214,000 neonatal sepsis deaths resulted from drug-resistant infections. The inability to effectively treat neonatal sepsis leads to wasted resources, poor treatment outcomes, and the generation and spread of yet more resistant bacteria. Addressing this serious public health threat and achieving the child survival SDG targets means countries must continue scaling up proven life-saving interventions and capitalise on the current global political momentum to address prevention, diagnosis and treatment needs of sepsis – including the adoption on Sepsis at the World Health Assembly in May 2017.

Neonatal sepsis R&D Strategy

MAIN GOALS

- Fill evidence base gap in treatment practice
- Deliver an empirical treatment addressing drug-resistant Gram-negative pathogens
- Develop a treatment for confirmed multi-drug Gram-negative pathogens



GARDP's Neonatal Sepsis R&D Programme

The GARDP Neonatal Sepsis Programme aims to provide an evidence-base for the use of antibiotics, both old and new, in neonates with serious bacterial infection. Its core objectives are to:

- Develop a new empiric treatment for use in areas with high resistance to the current recommended treatment (Ampicillin & Gentamicin)
- Develop evidence-based treatment(s) against confirmed multi-drug resistant (MDR) gram-negative infections.

Two Target Product Profiles (TPPs) have been developed to guide the strategy, which include long term objectives such as the development of formulations that are adapted for use in babies. GARDP will also work with the WHO and other relevant stakeholders to ensure that R&D for new treatments encompass solid stewardship – to ensure antibiotics are effectively conserved, and appropriately used – and affordable and sustainable access strategies.

Partnering on a Global Scale

To realise its ambition to develop new treatment regimens for neonatal sepsis, GARDP is developing an expert global advisory group to tackle patient management issues, and setting up a global network of centres to conduct clinical trials, as well as pharmacokinetic, observational and intervention studies to determine the efficacy and safety of new treatments.

The Neonatal Sepsis Programme therefore constitutes an international, multidisciplinary partnership of experts, institutions and research centres from Bangladesh, Belgium, Brazil, China, Greece, India, Italy, Kenya, South Africa, Thailand, Uganda, United Kingdom and Vietnam. It highlights neonatal sepsis' truly global burden.

Partners include the Indian Council for Medical Research, the All India Institute of Medical Sciences, the Kenya Medical Research Institute, St George's University and the Medical Research Council-Clinical Trials Unit, University College London, UK and the PENTA-ID Foundation, Italy.

Supporting the Neonatal Sepsis Programme

The estimated cost of this seven-year programme is €69.8 million. Private, public, and in-kind contributions are equally valuable to develop much-needed new antibiotic treatments for babies that succumb to sepsis.

About GARDP

Launched in 2016 by WHO and DNDi, the Global Antibiotic Research & Development Partnership (GARDP) aims to develop and deliver new treatments for bacterial infections where drug resistance is present or emerging, or for which inadequate treatment exists, while endeavouring to ensure sustainable access. GARDP is currently operating within DNDi, which provides its governance.