

Maternal and Infant Sciences: A Grand Challenge Programme on Preterm Birth

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✘ { Sudhir Tiwari* } The Problem and Dimensions Globally, Preterm Birth (PTB) is the single largest cause of neonatal deaths. A birth that takes place before the mother has been pregnant for at least 37 weeks construes a preterm birth. In India, among the total 27 million babies born annually, 3.6 million babies are born preterm, and over 300,000 of these preterm babies die each year because of associated complications. India, with its highest number of PTBs and the highest number of preterm deaths worldwide, contributes 25% of the overall global preterm related deaths. The effects of PTB extend beyond the early infancy with substantial long-term consequences in late childhood and adult life. Rationale for Undertaking this Study, Goals, Outlay and Possible Impact

A major reason for our inability to significantly reduce the burden of preterm birth is that the causes of preterm birth are not fully understood. Preterm birth is likely caused by a combination of physical, environmental and biological factors. Biological factors appear to be the predominant causes that predispose a woman to deliver babies preterm. To collect scientific information on pregnancy that may lead to a preterm birth, a woman has to be identified early in pregnancy, followed up through the duration of pregnancy during which clinical and life-style information must be collected. Biological changes taking place during this period must also be assayed by collecting blood and other biological materials from the pregnant woman. Further, because differences in biological responses and life-style factors are enormous among pregnant woman, information needs to be collected on a large cohort. After a series of national and international consultations, the Department of Biotechnology (DBT), Ministry of Science and Technology, Government of India has launched a major national programme to identify the correlates, causes and predictive biomarkers of preterm birth under its Grand Challenge Programme. The first-phase of the programme has a total financial outlay of Rs. 48.85 crore for a period of 5 years. Overall long term goals:

- stratify women early in pregnancy or before conception into various levels of risk of PTB,
- identify simple and better prediction tools that will recognize the optimal time of prediction & clinical intervention,
- develop additional strategies to identify presence of unusual/novel microbes that could serve as biomarkers,
- identify focused remedies targeting one or more mechanistic pathways (e.g. infection, inflammation, hormonal), and
- apply currently available interventions (tocolytic agents) based on better understanding of biological mechanisms. The scientific success of this programme is bound to have a major ripple-effect on discovery of preventive therapies. It will contribute significantly towards reduction in infant and maternal mortality rates. Partnerships The PTB programme is establishing a hospital-based cohort of pregnant women starting from the first trimester, each of whom will be followed up until delivery. The cohort is being established in a district hospital in Gurgaon, Haryana. Because of the multifactorial nature of preterm birth, scientific expertise from multiple domains of clinical, biological and statistical sciences are required. Therefore, cross-disciplinary platform is being used to bridge expertise from disparate fields, such as, pediatrics, gynecology, infectious disease biology, epidemiology, microbiology, immunology, cellular & molecular biology, genetics, statistics and computational & systems biology. Research Team: 1. Translational Health Science and Technology Institute (THSTI), Gurgaon: An autonomous Institute of Department of Biotechnology, Ministry of Science and Technology, Govt. of India · Pediatric Biology Centre at THSTI is the main coordinator of the program. · Centre for Human Microbial Ecology at THSTI is responsible for the microbiome analyses. 2. Gurgaon General Hospital, district hospital of Gurgaon in Haryana, is the main study site. 3. Safdarjung Hospital, New Delhi, will be responsible for the subjects referred from Gurgaon General Hospital during the study; Gurgaon General Hospital has a formal arrangement for referrals to Safdarjung Hospital. 3. National Institute of Biomedical Genomics, Kalyani, West Bengal, an autonomous institute of DBT, Ministry of Science and Technology,

Govt. of India is responsible for genomic and epigenomic assays. 4. Regional Centre for Biotechnology, Gurgaon category-II institution under the auspices of UNESCO, established by DBT, Ministry of Science and Technology, Govt. of India is responsible for proteomic analysis. 5. Clinical Development Services Agency, Gurgaon an extramural unit of THSTI is responsible for external monitoring and data management of the study. 6. Maulana Azad Medical College and All India Institute of Medical Sciences, New Delhi are providing scientific inputs and technical guidance. In addition to these institutions, the Health Department, Govt. of Haryana, Tata Consultancy Services, Department of Health Research and the Indian Council of Medical Research/Department of Health Research are also actively involved. Global Quality Assurance The data and biospecimens being collected in this study are of paramount value, not only for the present time but also for a long period into the future. Therefore, it is critical to collect and store data and biospecimens under globally-accepted quality assurance protocols. These protocols have been established with guidance from the World Health Organisation. Data storage and sharing will be under the guidelines being established by the Global Alliance for Genomics & Health (GA4GH), of which DBT is a partner. DBT is also a member of the Global Coalition to Advance Preterm Birth Research (G-CAPR), that has a primary mission to identify and advance priority research through expanded networks, communications, and collaborations among organizations to fund the research needed to reduce preterm birth at the international level. Management and Monitoring A dedicated research team comprised of research physicians, nurses, attendants, field workers and field supervisors are stationed at Gurgaon General Hospital to facilitate relevant data collection. There is a separate project management team comprised of specialized groups looking after quality assurance, site and the data management. A separate room has been identified for taking informed consent from participants interested in participating in the study. The Programme is being monitored by a Steering Committee represented by eminent national and international experts in important domain areas who are responsible for strategic guidance. A Programme Management Committee has been formed to address matters related to scientific, technical and financial aspects on regular basis and report to the Steering Committee.

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