Annual Report

2024–2025

Projahnmo
Research Foundation

Projahnmo Research Foundation (PRF)

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Photo credit: PRF

VISION

Build a healthier generation

MISSION

To promote the health and well-being of families across the life course, with a special focus on mothers, newborns, and children.

GOAL

To contribute to building a healthier generation by generating robust evidence and translating it into policies and programs, through strategic partnerships with national and international institutions.

VALUES

Integrity, technical excellence, collaboration, and compliance

ACRONYMS

ACS: Antenatal Corticosteroid
AI: Artificial Intelligence
BACTEC: Blood Culture System
BLAAAST: Bangladesh Lung Auscultation AI for Antibiotic Stewardship Randomized Controlled Trial
CA: Clinical Assistant
CRF: Case Report Form
DSS: Demographic Surveillance System
EC: Executive Committee
GoB: Government of Bangladesh
HDH: Habiganj District Hospital
icddr,b: International Centre for Diarrhoeal Disease Research, Bangladesh
ICF: Informed Consent Form
IRB: Institutional Review Board
JHSPH: Johns Hopkins School of Public Health
LMICs: Low- and Middle-Income Countries
MOHFW: Ministry of Health and Family Welfare
NCDs: Non-Communicable Diseases
NVD: Normal Vaginal Delivery
PCR: Polymerase Chain Reaction
PRF: Projahnmo Research Foundation
RA: Research Assistant
RSV: Respiratory Syncytial Virus
SDH: Sunamganj District Hospital
SWMCH: Sylhet Women's Medical College Hospital
T2D: Type 2 Diabetes
USAID: United States Agency for International Development
ZUHC: Zakiganj Upazila Health Complex
AGM: Annual General Meeting
AMANHI: Alliance for Maternal and Newborn Health Improvement
BMRC: Bangladesh Medical Research Council
BMGF: Bill and Melinda Gates Foundation
CRO: Clinical Research Organization
CSF: Cerebrospinal Fluid
DGDA: Directorate General of Drug Administration
EQIS: E-Patient Quality Improvement and Standardization
HEARTS-D: WHO HEARTS-D Guidelines (for diabetes management)
ICT: Information and Communication Technology
IR: Implementation Research
JHU: Johns Hopkins University
KMC: Kangaroo Mother Care
MDH: Moulvibazar District Hospital
MWRA: Married Women of Reproductive Age
NREC: National Research Ethics Committee
PCV: Pneumococcal Conjugate Vaccine
PHCC: Primary Health Care Center
PI: Principal Investigator
PSBI: Possible Serious Bacterial Infection
RESPIRE: Research Unit on Respiratory Health
SATT: Simplified Antibiotic Treatment Trial
SOMCH: Sylhet MAG Osmani Medical College Hospital
SOP: Standard Operating Procedure
TRC: Technical Review Committee
WHO: World Health Organization

CONTENTS

Message from the Founder

I am pleased to share a message of reflection and optimism alongside this year's Annual Report. With deep appreciation, I extend my warmest greetings to all members of the Projahnmo Research Foundation (PRF), our dedicated team, valued partners, and generous donors. Your unwavering support and collaboration have been instrumental in advancing our mission throughout the fiscal year from July 2024 to June 2025.

What began as a collaborative research initiative under the leadership of Johns Hopkins University has grown into a nationally recognized institution at the forefront of maternal, newborn, and child health in Bangladesh. Guided by a vision of healthier generations, PRF has remained steadfast in its mission to generate high-quality evidence, inform policy, and drive meaningful change.

Our work has contributed to a measurable reduction in newborn mortality and has helped shape national and global health strategies through rigorous research and impactful publications. These achievements are a testament to the dedication of our multidisciplinary team, the enduring support of our partners, including the Ministry of Health and Family Welfare, and, above all, the trust of the communities we serve.

As we look to the future, we do so with hope, confidence, and renewed purpose. PRF is committed to advancing innovation, strengthening partnerships, and expanding impact, ensuring that every mother, newborn, and child not only survives but thrives. Together, we will continue to turn evidence into action and build a healthier, more equitable future for generations to come.

With heartfelt appreciation and unwavering commitment,

Abdullah Baqui

Abdullah H. Baqui, MBBS, MPH, DrPH
Founder and Senior Adviser
Projahnmo Research Foundation

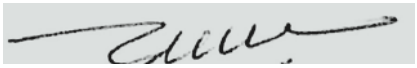
Message from the President

It gives me great pleasure to present the Annual Activity Report of the Projahnmo Research Foundation (PRF) for the fiscal year 2024–2025. This report reflects our team's unwavering dedication to advancing public health through rigorous research and meaningful partnerships.

Over the past year, PRF has continued to implement high-impact clinical-epidemiological studies, discovery research, clinical trials, and implementation research, with a particular focus on maternal, newborn, and child health. We have also played a key role in Phase-3 vaccine trials, an area of growing importance in global health. Our operational capabilities, including well-established demographic surveillance systems, hospital-based clinical trial platforms, state-of-the-art laboratories, and robust data systems, have enabled us to uphold scientific excellence and programmatic relevance.

Looking ahead, as we expand our scope to address emerging challenges such as non-communicable diseases and aging, PRF remains firmly committed to generating actionable evidence and translating it into policies and programs that improve the lives of those most in need.

We are deeply grateful to our partners, donors, and the communities we serve for their continued trust and collaboration.



Prof. Dr. Chowdhury Ali Kawser, MBBS, FCPS, PhD
President
Projahnmo Research Foundation

PRF AT A GLANCE

Year of Establishment

Projahnmo Research Foundation (PRF):

Registered with NGO Affairs Bureau in 2017.

Registered as a Clinical Research Organization (CRO) under DGDA in 2018.

Focus

Committed to improving the health and survival of mothers, newborns, children, and families across all age groups.

Coverage Area

PRF operates in 18 districts and 38 secondary or tertiary-level hospitals and maintains a rural surveillance site in Zakiganj Upazila of Sylhet District.

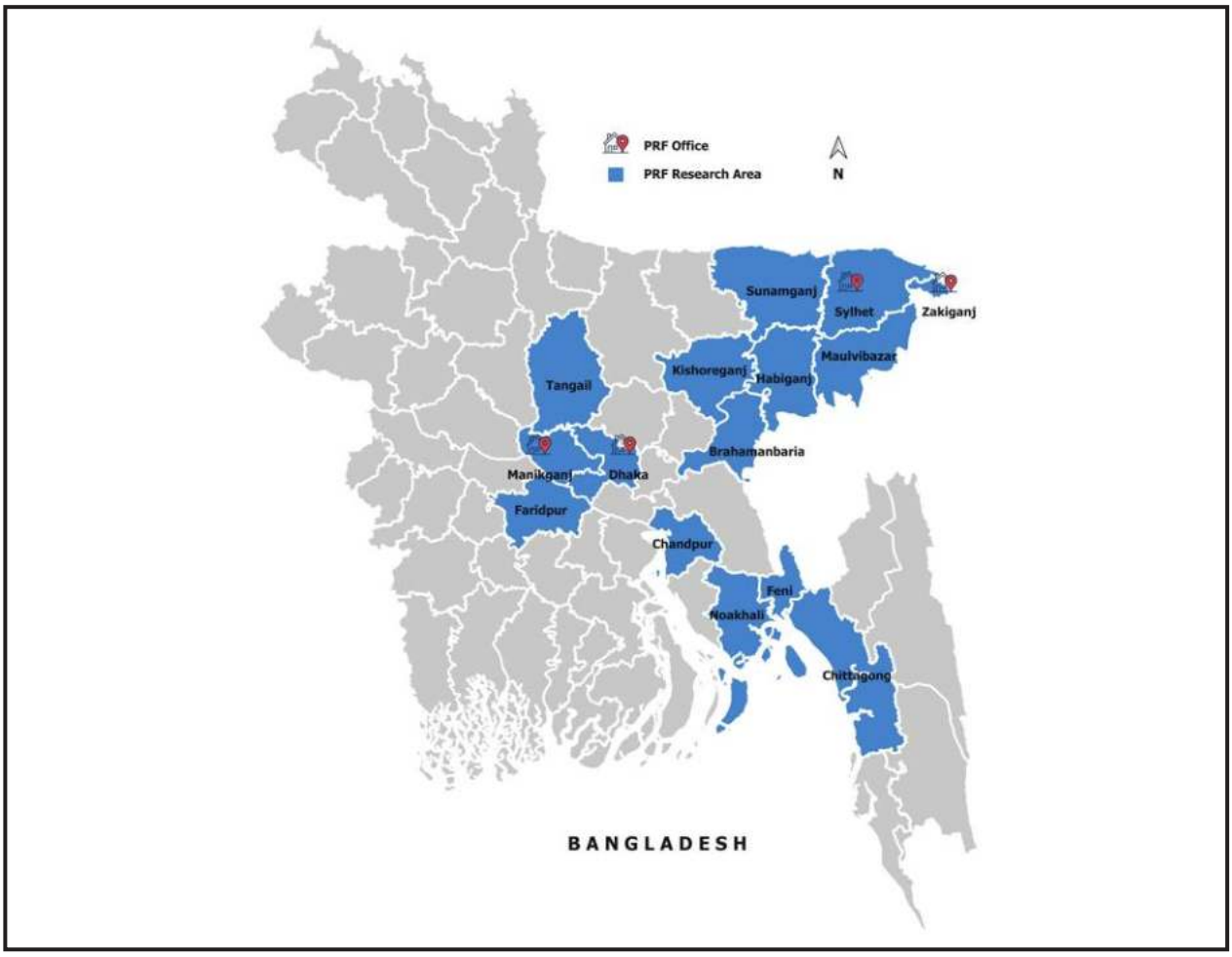


Photo of Bangladesh map showing PRF working districts

Key Activities

PRF is engaged in high-priority clinical-epidemiological studies, formative research, and the design and evaluation of interventions through clinical trials in the areas of maternal, newborn, and child health (MNCH) and vaccines, and implementation research. PRF also supports policy and program development for the Bangladesh Ministry of Health and Family Welfare (MOHFW) and the World Health Organization.

Our Team

- **Multi-disciplinary Team of Investigators**: Experts in Biostatistics, Epidemiology, Microbiology, Neonatology, Obstetrics and Gynecology, Pediatrics, Pediatric Infectious Disease, Pediatric Pulmonology, Social Science, Vaccine Science, Virology, Information Technology from different collaborative institutions/universities/academicians.
- **Staff:** PRF has 339 staff, which includes 105 physicians and 110 paramedics/nurses/midwives.

PRF staff group photo

PRF Governance

General body

Following the constitution of the PRF, the General Body of PRF consists of 33 members. As per the constitution and Rules and Regulations of PRF, the General Body elects the Executive Committee for 05 (five) years. The Annual General Meeting 2024 was held on 30 March 2024 in its own premises at PRF Dhaka office. The meeting was Chaired by the President Professor Dr. Chowdhury Ali Kawser and the general members participated in agenda-wise discussions. The AGM approved the decisions, activities, and initiatives taken by the Executive Committee in 2024, particularly approved the report of Activities 2024, Audit Report 2023, Revised Budget 2023-24 and Annual Budget 2024-25.

It needs to be mentioned that the existing Executive Committee (2020–2025) was elected for five years by the general members in the AGM 2020. Dr Iqbal Kabir was elected as the President. Because of his ill health, the EC nominated Prof. Dr. Chowdhury Ali Kawser, senior VP to President following the PRF constitution. After the untimely demise of Dr Iqbal Kabir, Prof. Dr. Chowdhury Ali Kawser is now working as the President of the PRF.

Executive Committee

The 07 (seven) members of PRF's Executive Committee comprise distinguished professionals and researchers, who bring their diverse skills and experiences to their governance roles. The current Executive Committee is for the period of 2020–2025.

The immediate past president was the late Dr. AKM Iqbal Kabir, a distinguished medical doctor, clinical researcher, and public health specialist. He earned his MBBS from Dhaka Medical College, MD from Case Western Reserve University, USA, and PhD in Clinical Nutrition from INFS, University of Dhaka. Dr. Kabir served as President of the Executive Committee at Projahnmo Research Foundation from 2018. Prior to that, he spent 35 years at icddrb as a Senior Scientist and Clinical Consultant. With over 200 publications and numerous conference presentations, Dr. Kabir made significant contributions to medical research. He passed away on 11 January 2024.

Executive Committee

Professor Dr. Chowdhury Ali Kawser
President

Professor Chowdhury Ali Kawser, with a career spanning over 40 years, holds an MBBS from Dhaka Medical College, FCPS in Pediatrics, and a PhD from Southampton University. He served at Bangladesh Medical University from 1978 to 2017 and held key positions, including Pro-Vice Chancellor and Chair of Pediatrics. Dr. Kawser has contributed extensively to national health committees, including as Chair of NITAG (2019–2022), and developed guidelines for national vaccine programs. He has over 100 publications and was involved in international health advisory groups.

Dr. Md. Abdul Quaiyum: Vice-President

Dr. Md. Abdul Quaiyum graduated from Dhaka Medical College in 1982 and worked extensively on maternal and child health research at icddr,b. He has over 25 years of experience in maternal and neonatal health.

Mrs. Nazma Begum: General Secretary

Mrs. Nazma Begum is a highly experienced Data Management expert with over 25 years of experience. She has contributed to several publications in the field of child health and nutrition.

Dr. Dipak Kumar Mitra: Treasurer

Dr. Dipak Kumar Mitra, a physician with a PhD in epidemiology from Johns Hopkins University and an MPH from Harvard. Currently, he is a Professor and Dean of Life Science at North South University.

Prof. Saleha Begum Chowdhury: Member

Prof. Saleha Begum Chowdhury, with an MBBS from Chittagong Medical College, and FCPS from BCPS. She pioneered PMTCT services in Bangladesh and established the University Fistula Center at BMU. She had served as Secretary General of the Obstetrical and Gynaecology Society of Bangladesh.

Abdullah Mahmud: Member

Abdullah Mahmud, with a Master's in International Health from Uppsala University, has 29 years of experience in public health research at icddr,b. His research focuses on improving health outcomes for mothers, newborns, and children. He led studies in collaboration with global partners and has authored 89 scientific publications.

Dr. Salahuddin Ahmed: Member

Dr. Salahuddin Ahmed, a medical doctor with a PhD (University of Edinburgh) in global health, has over 24 years of experience in public health research. He focuses on improving the health of mothers and children in low-resource settings. Dr. Ahmed is Executive Director of Projahnmo Research Foundation and has published over 100 scientific articles.

INTRODUCTION

Projahnmo Research Foundation (PRF) is one of Bangladesh's leading non-governmental research organizations, dedicated to improving the health and survival of mothers, newborns, children and the elderly population. Since its inception, PRF has been at the forefront of conducting high-priority clinical-epidemiological studies and implementation research, generating evidence that has significantly influenced national and global health policies.

PRF's work is rooted in a community-based approach, focusing on translational research that bridges the gap between scientific discovery and practical application. Our efforts contribute significantly to public health by designing and testing interventions and providing crucial policy and program support to the Bangladesh Ministry of Health and Family Welfare (MOH&FW) and the World Health Organization (WHO).

This annual report highlights PRF's key achievements, ongoing initiatives from July 2024 to June 2025, reflecting our unwavering commitment to fostering a Bangladesh where every woman, newborn, and child can achieve the highest level of physical and mental health. We continue to expand our partnerships and leverage our expertise to address the evolving health needs of the population, including the growing burden of non-communicable diseases, and to ensure that no one is left behind in the pursuit of better health outcomes.

OVERVIEW

Foundation and History

Founded in 2001 by the International Center for Maternal and Newborn Health (ICMNH) at the Johns Hopkins Bloomberg School of Public Health (BSPH), the Projahnmo Study Group was established to develop, evaluate, and scale culturally appropriate, cost-effective interventions to save the lives of mothers and newborns in Bangladesh and in similar settings. Initiated as a research partnership with the Ministry of Health and Family Welfare and leading Bangladeshi institutions, the program has grown into a nationally and internationally recognized platform for clinical trials, discovery research, and implementation research, and a driver of policy influence.

To sustain and institutionalize its work, in 2017, the Projahnmo Research Foundation (PRF) was established as a local NGO. In partnership with ICMNH/BSPH, PRF leads high-impact clinical trials, population-based studies, and policy-relevant implementation research across 18 districts, with its flagship site in Sylhet district.

Strategic Objectives

- To conduct high-priority clinical-epidemiological and implementation research to generate evidence for improving maternal, newborn, and child health.
- To design and test effective health interventions for vulnerable populations.
- To provide evidence-based policy and program support to the Bangladesh MoHFW and the WHO.
- To expand partnerships with national and international entities to enhance research capacity and impact.
- To contribute to addressing emerging health challenges, including non-communicable diseases (NCDs).

Research Areas

PRF has been working in a community setting, initially focusing on reducing child mortality. Although progress has been made, newborn mortality remains a significant challenge. Recognizing the broader challenges that families face, PRF has expanded its efforts to address family health comprehensively. This expansion now includes child health, non-communicable diseases (NCDs), and mental health.

PRF's research portfolio is diverse and spans multiple domains:

Maternal, Neonatal, and Childhood Health

This area remains a primary focus, with ongoing studies aimed at improving the health and survival of mothers, newborns, and children. We studied biological insights and biomarkers related to pre-eclampsia, stillbirth, preterm birth, small for gestational age, and impaired child growth and neurodevelopment.

Notably, PRF is involved in research to improve pneumonia case management using AI technology to detect cases and is also conducting studies on nutritional management of growth faltering, probiotics, and child development.

Non-Communicable Diseases (NCDs)

In response to Bangladesh's evolving health landscape, PRF has expanded its focus to include NCDs, which are becoming increasingly prevalent across both urban and rural areas. This shift aligns with the broader health transition, and PRF’s research now includes studies aimed at controlling diabetes, hypertension and mental health.

Vaccine and Drug Trials

PRF is actively engaged in conducting multi-country vaccine trials and expanding its portfolio to include multi-country drug trials, as part of a growing commitment to addressing global health challenges.

Sample processing and entry into system in a phase 3 vaccine trial

Climate Change Research

PRF is focusing on addressing the growing health impacts of climate change. With extensive field infrastructure, trained personnel, and experience in epidemiological surveillance, PRF is undertaking cutting-edge research to explore the links between climate change, air pollution, and reproductive and respiratory health.

Discovery and Implementation Research

In addition to biomarker discovery in perinatal outcomes, PRF is focusing on improving the coverage, quality, and equity of preventive and curative health interventions. Recent implementation research studies include those aimed at improving diabetes care, which integrates community-to-facility service provision to implement the WHO HEARTS-D guidelines for diabetes control and prevention. In neonatal care, the immediate Kangaroo Mother Care (iKMC) Implementation Research seeks to scale up immediate Kangaroo Mother Care (iKMC) at district hospitals with neonatal intensive care units, aiming to reduce neonatal mortality and improve outcomes for preterm and low birth weight infants. Additionally, PRF is conducting research on pediatric infection management, with the PSBI Caregiver-Centric Study, which evaluates the impact of outpatient and home-based care for infants with possible serious bacterial infections (PSBI) on caregiver empowerment and their ability to manage infant care. Furthermore, in the area of preterm birth management, the Antenatal Corticosteroids Implementation Research (ACS IR)

focuses on scaling up the use of ACS for women at risk of preterm birth to improve neonatal outcomes, particularly in low-resource settings.

PRF's work is driven by the needs of the population and aims to generate high-quality evidence for health improvement. The research areas not only contribute to scientific knowledge but also provide critical policy and program support to Bangladesh's Ministry of Health and Family Welfare (MoHFW) and the World Health Organization (WHO).

AI, Machine Learning and Digital Health Research

PRF has focused on integrating AI, machine learning, and digital health research since its inception and has conducted several groundbreaking studies, such as the use of digital auscultation to improve childhood pneumonia diagnosis. Currently, PRF is implementing several studies focusing on those areas in collaboration with several universities in the USA, UK, and Australia.

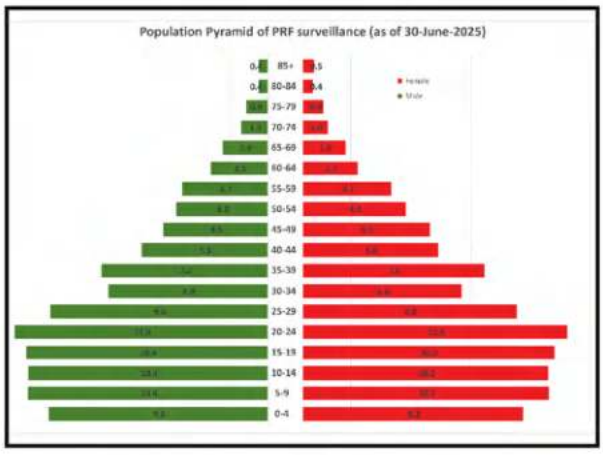
Health and Demographic Surveillance

PRF operates a robust Demographic Surveillance System (DSS) to maintain a longitudinal database of households.

Rural Demographic Surveillance

A basic DSS is established in Zakiganj upazila of Sylhet, Bangladesh, with an estimated population of 230,000. The purpose of the DSS is to maintain a longitudinal database of

CHW on the way to surveillance visit



Population pyramid, Surveillance area

households with a particular focus on married women of reproductive age (MWRA) and under-five children, allowing us to conduct high-quality epidemiological research, intervention trials and observational studies. The DSS provides background data for developing and designing study concepts focusing on local needs.

Hospital Surveillance

Working closely with the Bangladesh MoHFW, PRF has established facility-based surveillance within the MoHFW hospital outpatient clinics and inpatient obstetric and pediatric wards in 38 hospitals across Bangladesh. This includes:

1. Hospital based clinical research and clinical care

The Projahnmo Research Foundation (PRF) has a longstanding commitment to hospital-based clinical research and care, particularly in the domains of maternal, neonatal, and child health. Collaborating with institutions like Johns Hopkins University and World Health Organization, PRF conducts rigorous clinical trials and implementation research to improve health outcomes in Bangladesh.

PRF's hospital-based research encompasses both clinical trials and implementation studies aimed at enhancing healthcare delivery and patient outcomes.

Physician assessment and clinical care at District Hospital, Sunamganj

Beyond research, PRF integrates clinical care into its activities, ensuring that study findings are translated into practical healthcare improvements. The PRF's hospital-based studies often involve close collaboration with healthcare providers to implement and evaluate interventions directly within clinical settings. PRF also focuses on building local capacity through training programs for healthcare professionals. Positions such as Study Physicians and Research Assistants are integral to the execution of hospital-based studies, and these roles often require candidates with experience in clinical research and a strong understanding of hospital operations.

Samples stored at -80° C at PRF biorepository

2. Study Laboratory

PRF maintains a state-of-the-art laboratory at its field sites in Zakiganj and Sylhet, equipped with biosafety cabinets, comprehensive biospecimen management and analysis system. These laboratories have the capacity to collect, process, store, and ship various biological specimens, including blood, urine, placenta, stool, saliva, and breastmilk samples.

3. Capabilities

The laboratory is fully equipped to handle a wide range of biospecimens for research purposes. In addition to the primary tasks of collection and processing, the lab also specializes in specimen storage to ensure sample integrity over time.

4. Equipment

The labs are equipped with essential instruments to support high-quality research and specimen handling:

- Biosafety cabinets (2)
- Refrigerated centrifuge machines (3)
- -80°C freezers (13)
- -20°C freezers (3)
- Refrigerators (6)
- Microscopes (1)
- Liquid nitrogen cylinders (6)
- Dry shippers (4)

Sample processing at PRF Lab, Zakiganj

5. Biobank

PRF has also established one of the largest biobanks in South Asia, with approximately 250,000 biological samples collected from 3,000 women and their infants throughout pregnancy, delivery, and the post-partum period. This biobank is supported by thirteen -80°C freezers, all equipped with online Uninterruptible Power Supply (UPS) systems and a double generator backup to ensure sample integrity and safety. The biobank has also preserved additional study samples, such as urine, nasal swabs and blood, for future analysis.

Biorepository at PRF Sylhet

Data Management

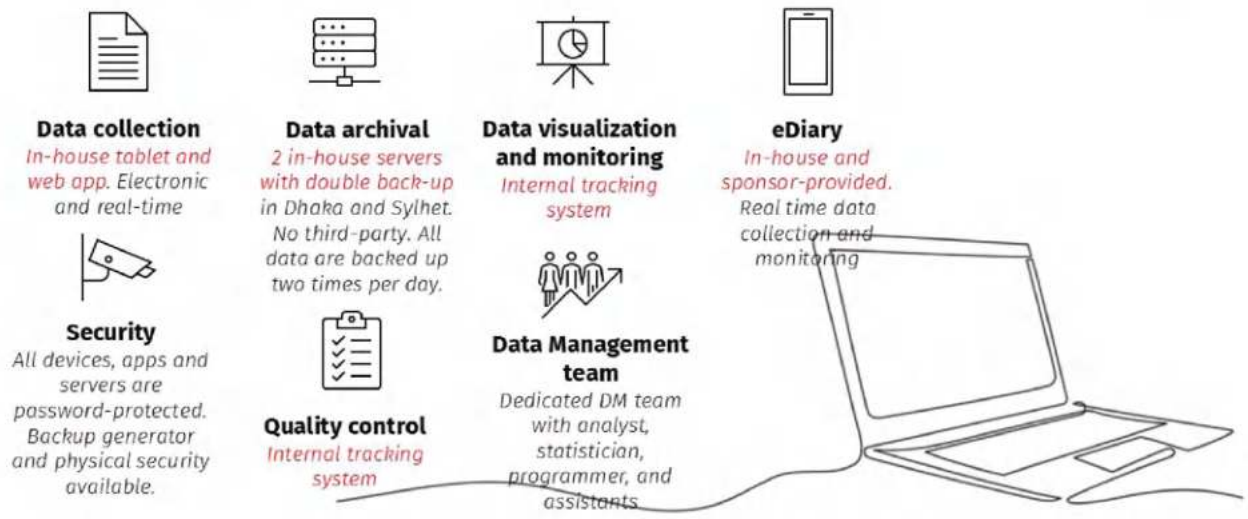
PRF employs a sophisticated data management system to ensure the integrity and accessibility of research data.

1. Data Capture

We collect data using tablets with real-time synchronization on our servers located at the Sylhet and Dhaka offices.

2. Data Archival

The study databases are stored in dedicated and password-protected servers housed in PRF offices in Sylhet and Dhaka. Two in-house servers with double back-up are maintained in Dhaka and Sylhet. No third-party storage is used. For the sponsor-provided data entry and archival system for regulatory vaccine trials, data is stored and archived using the specific software provided by the sponsor following the trial specific SOP.



PRF Data management system, monitoring and QC

3. Data Visualization and Monitoring

An internal tracking system is used for data visualization and monitoring, allowing project managers to check the system and identify data collection discrepancies routinely.

4. Quality Control

We maintain a robust internal tracking system to ensure high-quality data management and integrity throughout the data collection process. This system is designed to monitor each phase of data handling, from collection to storage, and ensures that data are processed correctly and efficiently.

5. Data Security

Data management, Zakiganj, Sylhet

Data security is a top priority in our data management system. All computers and tablets used for data entry are password-protected to prevent unauthorized access. Access to the server is strictly limited to key personnel only, ensuring that sensitive data is handled by authorized individuals. Additionally, all devices, applications, and servers are secured with strong password protection. To ensure data continuity, we have backup generators in place, and physical security measures are implemented to safeguard the hardware and data storage facilities.

PRF Works align with SDG Goals

PRF's research and intervention activities are inherently aligned with the Sustainable Development Goals (SDGs), particularly those related to health and well-being. Our work directly contributes to:

- **Goal 1: No Poverty**: By improving health outcomes, PRF indirectly contributes to poverty reduction, as health is a critical determinant of economic well-being.
- **Goal 3: Good Health and Well-being**: By focusing on maternal, newborn, and child health, and addressing non-communicable diseases, PRF directly supports targets related to reducing maternal and child mortality, combating diseases, and promoting universal health coverage.
- **Goal 5: Gender Equality**: Many of PRF's interventions and research focus on women's and girls' health, contributing to gender equality.
- **Goal 17: Partnerships for the Goals**: PRF's extensive collaborations with national and international partners exemplify this goal, fostering a collaborative approach to achieving sustainable development.

SUMMARY OF ACTIVITIES (2024-2025)

Research and Intervention Implementation

During the reporting period, PRF continued to conduct high-priority clinical-epidemiological studies, vaccine trials and implementation research studies. Our teams at the Sylhet rural site, Sylhet urban site and Manikganj, along with staff at 38 hospitals, were actively engaged in capacity building of service providers, strengthening health system, providing required equipment and logistics, data collection, community engagement, and intervention delivery, ensuring the rigorous execution of research protocols and generating robust evidence.

Policy and Program Support

PRF actively provided evidence-based policy and program support to the Bangladesh MoHFW and the WHO. This involved sharing research findings through policy briefs and technical consultations, participating in national health policy development workshops, and providing technical assistance for program implementation

National Neonatal Health Strategy Meeting at Ministry

Capacity Building

PRF is committed to strengthening public health research capacity both internally and externally. Our capacity-building initiatives included ongoing training for field teams on data collection and ethical research practices, and professional development opportunities for investigators and other scientific staff. All staff are trained in detailed protocol and Standard Operating Procedures (SOPs) before commencing work.

Partnership Development

Collaborating with academic institutions to foster research skills among future public health professionals.

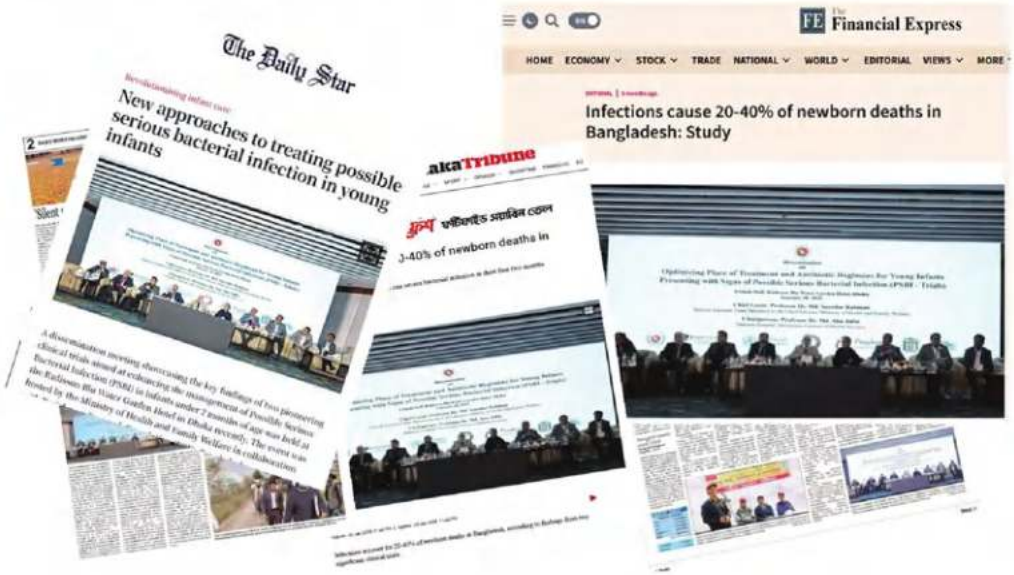
Knowledge Dissemination

Organizing seminars, workshops, and presentations to share research methodologies and findings with the broader scientific and public health communities.

Dissemination program of Digital Auscultation Study

Information and Communication

PRF maintains robust information and communication systems to facilitate research activities and disseminate findings, including publication through peer-reviewed scientific articles, reports, and policy briefs.



Patient Public Involvement (PPI)

Patient public involvement meeting at Zakiganj

Projahnmo Research Foundation (PRF) organized a patient public involvement group (PPIG) consisting of 20 members involving caregivers of under 5 children and community representatives (community leaders, teachers, religious leader, community volunteers) and community health care providers (CHCP). PPIG members played an important role in design and planning, implementation, analysis, and dissemination of different projects of Projahnmo Research Foundation. Regular meetings are conducted with the PPI group and the study team to provide updates on the study's progress and address challenges encountered during implementation. Their active involvement ensures the research remains patient-centered and addresses real-world concerns.

PROGRESS and ACHIEVEMENT (2024-2025)

The fiscal year 2024–2025 observed significant progress in PRF's research portfolio, with several major studies either initiated or substantially progressed. Below is a summary of key recently completed or ongoing projects:

1. **A Phase 2/3, Randomized, Observer-Blind, Placebo-Controlled Study to Evaluate the Safety and Efficacy of mRNA-1345, an mRNA Vaccine Targeting Respiratory Syncytial Virus (RSV), in Adults ≥ 60 Years of Age.**

Study Period: July 2022 – June 2025

Sample Size: 1171

Donor: Moderna TX.

Project Description:

Background: Pneumonia and other lower respiratory tract infections account for a significant portion of the disease burden in older adults. In 2015, lower respiratory infections were estimated to have caused 1.27 million deaths among older individuals across 195 countries. Respiratory syncytial virus (RSV) has been identified as a major contributor to acute respiratory disease (ARD) in older adults, especially those with comorbidities ("high risk") such as chronic lung or heart disease.

Participant assessment during screening

Participant home visit by investigators of JHU and Vice President from Moderna

This Phase 3, FDA-regulated clinical trial was sponsored by Moderna TX, Inc. and conducted across more than 250 sites in countries including Bangladesh, Europe, Asia, Africa, and the Americas. In Bangladesh, the trial was jointly conducted by Projahnmo Research Foundation (PRF) and the Johns Hopkins Bloomberg School of Public Health (JHSPH) at two sites in Sylhet.

Objective: The primary objective of this trial was to evaluate the safety and tolerability of the mRNA-1345 vaccine, and to assess the efficacy of a single dose of the vaccine in preventing the first episode of RSV-associated lower respiratory tract disease (RSV-LRTD) compared to placebo, from 14 days post-injection through 12 months post-injection.

Method: Participants were adults aged 60 years and older, with 20% aged over 75. The study included a vaccination phase (Day 1 to Day 29) and a surveillance phase (Day 15 through Month 24).

Vaccine trial Staff group photo with the investigators

There was a screening period of up to 14 days before the study injection, followed by a single study injection on Day 1. Each participant was followed for 24 months. Study site visits were scheduled for Day 1, Day 15, Day 29, Day 181, Day 365, Day 546, and Day 730. Participants underwent weekly active surveillance through e-diary entries reporting any respiratory illness symptoms.

Investigator meeting at Johns Hopkins Bloomberg School of Public Health

The U.S. Food and Drug Administration approved mRESVIA (mRNA-1345) in May 2024 for the prevention of RSV-associated lower respiratory tract disease in adults aged 60 years and older (*https://investors.modernatx.com/news/news-details/2024/Moderna-Receives-U.S.-FDA-Approval-for-RSV-Vaccine-mRESVIAR/default.aspx*).

The FDA's approval of mRESVIA is based on positive data from the Phase 3 clinical trial ConquerRSV. The primary analysis with 3.7 months of median follow-up found a vaccine

efficacy against RSV lower respiratory tract disease (LRTD) of 83.7% (95.88% CI 66.0%, 92.2%) (Lisen Lu, Muyang Yang, Deqiang Deng, Xiujuan Shi, Jonathan F. Lovell, Honglin Jin, Nanovaccines: Antigen selection, stabilization, adjuvantation, formulation, and evaluation, Coordination Chemistry Reviews, 541, (216806), (2025). https://doi.org/10.1016/j.ccr.2025.216806)

2. Optimizing place of treatment and antibiotic regimens for young infants presenting with signs of possible serious bacterial infection.

Study Period: March 2020- June 2025

Sample Size: 2160

Donor: WHO (World Health Organization)

Project Description:

Background: Neonatal mortality rate has substantially declined over the last few decades, but still an estimated 2.5 million neonatal deaths occur worldwide annually accounting for 46% of under-five year old child deaths. In Bangladesh, the neonatal mortality rate is 30 deaths per 1,000 live births; it accounts for 67% of all under-5 deaths (BDHS 2017-2018). Neonatal infections account for about 35% of all neonatal deaths in South Asia and sub-Saharan Africa. The WHO IMCI algorithm classifies neonates and young infants with clinically suspected sepsis as "Possible Serious Bacterial Infection (PSBI)". This classification is based on seven clinical signs – fast breathing in 0-6 day old babies, severe chest indrawing, high body temperature (≥ 38 °C), low body temperature (<35.5 °C), not able to feed at all or not feeding well/stopped feeding well, convulsions, and movement only when stimulated or no movement at all. WHO guidelines recommend that young infants with PSBI should be managed in a hospital with injectable antibiotics and supportive care. When referral to hospital is not feasible, the WHO guideline recommends further classification of these infants into those who are critically ill and those who have clinical severe infection. Infants with clinical severe infection (CSI) can be managed on an outpatient basis with injectable gentamicin for 2 days and oral amoxicillin for 7 days based on clinical trials from Africa, known as AFRINEST and Asia, known as SATT.

A study physician accessing a young infant

Implementation research on the above guidelines has demonstrated that outpatient treatment is safe and effective when hospitalization is not feasible. But it is not possible, however, to conclude that out-patient treatment of young infants with CSI is superior to in-patient treatment from this observational data. It is possible that despite having the same signs, young infants who were admitted to hospitals had more severe disease or their treatments were delayed, or hospitals did not provide adequate quality care. In addition, hospitalization has inherent risks, particularly that of nosocomial infection with multi-drug resistant pathogens. PSBI trial includes two concurrent multi-country studies which are being conducted at seven sites of six countries (Bangladesh, Ethiopia, 2 sites of India, Nigeria, Pakistan, and Tanzania) and coordinated by WHO.

Independent Outcome Assessment Visit at patient`s home

Objective: The overall goal of this PSBI trial is to generate knowledge that will allow us to hospitalize only those young infants (0-59 days) with possible serious bacterial infections (PSBI) who need hospitalization, identify infants who can be treated safely on outpatient basis and identify infants who need hospitalization but improve early and can continue their treatment at home.

The overall goal of this PSBI trial is to generate knowledge that will allow us to hospitalize only those young infants (0-59 days) with possible serious bacterial infections (PSBI) who need hospitalization, identify infants who can be treated safely on outpatient basis and identify infants who need hospitalization but improve early and can continue their treatment at home.

WHO team visit to study site

This trial will be restricted to a sub-set of PSBI, known as clinical severe infection (CSI), that excludes critical illness.

The primary objective of Study-1 is to measure the effect of outpatient treatment on clinical outcome (death within 2 weeks of initiation of treatment, deterioration during the 7-day treatment period or persistence of the presenting CSI sign after the 7-day treatment period),

compared with inpatient treatment in young infants (0-59 days old) with only one low-mortality risk sign of CSI.

Method: In Bangladesh site Projahnmo Research Foundation is conducting this study in four hospitals in Sylhet Division (three District level hospitals and one Upazila Health Complex) and targeting to enroll 1000 young infants in Study-1 and 750 young infants in Study-2. There are two open-label, two-arm, individually randomized controlled trials within this study. Study-1 hypothesizes that young infants with only one low-mortality risk sign of CSI [fast breathing in 0-6 day old babies, severe chest indrawing, high body temperature (≥ 38 °C)] presenting to outpatient/emergency department of a hospital, who receive outpatient treatment, will experience a better, or at least non-inferior, clinical outcome than young infants that receive inpatient treatment.

The main hypothesis of Study-2 is that the clinical outcome in young infants with a moderate-mortality risk sign [low body temperature (<35.5 ° C), not feeding well/stopped feeding well and movement only when stimulated] or two or more signs of CSI who clinically improve 48 hours after initiation of treatment and have a negative CRP test, who are discharged and received oral amoxicillin for next 5 days will be non-inferior to the outcome of those who will continue inpatient hospital injectable antibiotic treatment for the next 5 days.

3. Community use of digital auscultation to improve diagnosis of childhood pneumonia in Sylhet, Bangladesh.

Study Period: September 2018- December 2024

Sample Size: 1003

Donor: This research was commissioned by the UK National Institute for Health Research (NIHR) Global Health Research Unit on Respiratory Health (RESPIRE) at the University of Edinburgh, using UK Official Development Assistance (ODA) funding.

Project Description:

A digital stethoscope

Background: Childhood pneumonia is the second leading cause of death in under-five children globally. In Bangladesh, the annual incidence of pneumonia is 36 per 100 child-years, and pneumonia still accounts for 16% of under-five deaths. The Integrated Management of Childhood Illness (IMCI) guidelines have proven the most important childhood pneumonia interventions for low-resource settings to date. The IMCI pneumonia guidelines are sensitive but non-specific in order to ensure that children with possible pneumonia

receive antibiotic treatment. As a result, while the guidelines miss few children with pneumonia (high sensitivity), many children who do not have pneumonia incorrectly receive antibiotics (low specificity), resulting in antibiotic overuse. Innovations to improve the specificity of the IMCI pneumonia criteria are needed, especially considering ongoing concerns about rising antibiotic resistance.

The IMCI guidelines do not include lung auscultation in their pneumonia definition for frontline healthcare workers. However, inclusion of auscultation is challenging because a

Auscultation with a digital stethoscope by a Community Health Care Provider (CHCP).

DA Study team

lot of experience is required to interpret lung sounds, and inter-rater variability is high regardless of the healthcare providers training level. After Rene Laennec's invention of monoaural version of stethoscope in 1816, many improvements have occurred. Recently, an innovative, low-cost digital auscultation device was developed especially for children called Smartscope, which can amplify sound up to 100-fold, filter background noises, record sounds, and can transfer sounds to smartphones, tablets, computers for additional post-processing. Machine learning artificial intelligence techniques can be used in this device to auto-analysis sounds to make a diagnosis or treatment decision. The inclusion of adventitious sound classifications in current IMCI guidelines has the potential to increase the accuracy of pneumonia diagnosis. However, there is a paucity of evidence related to the feasibility and effectiveness of introducing digital auscultation devices in primary care facilities.

Objectives:

• To assess whether lung sounds recorded using the Smartscope in children by CHCP at Community Clinic (CC) meet pre-defined quality thresholds established by experts.

• Determine the reliability and performance of the Smartscope Respiratory Detector automated analysis algorithm on lung sounds recorded by CHCP using the Smartscope, compared to reference interpretations by a paediatric listening panel.

District level stakeholder engagement meeting

Method: In a cross-sectional design, Community Health Care Providers (CHCP), who are the first level government health center's service provider, recorded lung sounds using a novel digital stethoscope known as Smartscope, of 1003 children younger than five years with possible pneumonia at Community Clinics in Zakiganj upazila of Sylhet district, Bangladesh. A standardized paediatric listening panel classified the recorded lung sounds into different categories, e.g. no wheeze and no crackle, crackles only, wheeze only, both crackles and wheeze, or uninterpretable, to serve as the reference standard. Smartscope Respiratory Detector automated analysis algorithm was used to analyze lung sounds recorded by CHCP using the Smartscope and were compared to reference interpretations by a pediatric listening panel to determine the reliability and performance of the algorithm.

This study is assessing whether lung sounds recorded using Smartscope in children by CHCP meet pre-defined quality thresholds established by experts as well as the reliability and performance of the automated analysis algorithm on lung sounds, compared to reference interpretations by a pediatric listening panel.

District level stakeholder engagement meeting

4. A Phase 3b, non-randomized, open label, multi country, cohort study to describe the safety of study participants who received RSVPreF3 maternal vaccination (any dose) or controls from previous RSV MAT studies during any pregnancy conceived post vaccination/control.

Study Period: July 2023- July 2025

Sample Size: 84

Donor: GlaxoSmithKline

Project Description:

Background

GSK developed an investigational Respiratory Syncytial Virus (RSV) vaccine for administration to pregnant women, with the aim of preventing medically assessed, RSV-associated lower respiratory tract illnesses (LRTIs) in their infants by transfer of maternal antibodies. The primary endpoint for efficacy in the development program was their infants' protection from RSV for the first 6 months of life. The vaccine candidate is an engineered version of the RSV fusion (F) surface glycoprotein, stabilized in the pre-fusion conformation (RSVPreF3).

GSK Vaccine trial team, PRF

Several Phase I to Phase III studies were conducted in pregnant and non-pregnant women (RSV MAT studies). In all RSV MAT studies, the study participants received one dose of RSV MAT vaccine (or control) except in RSV MAT-011 study, where some participants received a second dose. For participants in MAT-011 study who received a second dose, any pregnancy conceived after first dose will be considered in this study; MAT-011 participants enrolled in the prospective cohort will be followed for pregnancies conceived up to 2 years post last dose. In studies with non-pregnant women, the study participants were followed up to 6 months post vaccination. In studies including pregnant women, safety of the candidate vaccine was evaluated in maternal participants for up to 6 months after delivery. Safety in infants was evaluated for up to 12 months after birth. Safety evaluation included assessment of medically attended AEs, serious adverse events, pregnancy outcomes, and pregnancy-related and infant adverse events of special interest (AESIs). Following review of the data collected from the RSV MAT-009 study in pregnant women, a safety signal was identified. An imbalance in the proportion of preterm births was observed in infants born to vaccinated mothers who received RSV maternal vaccine versus those who received placebo. The safety signal was investigated and based on the

above observations, GSK decided to stop enrolment and vaccination for all actively enrolling RSV MAT studies as of 28 February 2022. From this date, no new pregnant or non-pregnant women were enrolled or vaccinated in the studies. Children born to participating pregnant women vaccinated before this date but delivered after 28 February 2022 continued to be followed-up in these studies. Safety monitoring of all enrolled participants continued during the rest of the study period.

As the safety signal identified is pregnancy-related and related to neonatal events, GSK decided to continue to evaluate safety of RSVPreF3 in pregnancies conceived after the prior study vaccination. This current study will enroll women who were enrolled in the RSV MAT-001, RSV MAT-004, RSV MAT-010, RSV MAT-011, RSV MAT-009, RSV MAT-012 or RSV MAT-039 studies (hereafter referred as RSV MAT studies) and record information about their pregnancies conceived post-study vaccination (if they occur prior to/during the current study period). To clarify, for those enrolled in prior studies of pregnant women (i.e., RSV MAT-004, RSV MAT-009, RSV MAT-012), this study will follow up the subsequent pregnancies conceived after the prior study pregnancy in which RSVPreF3 vaccination (or control) was administered.

Objectives:

Primary objectives:

To describe the incidence of pregnancy outcomes, pregnancy related adverse events of special interest (AESIs) and infant AESIs during the first pregnancy conceived within 2 years post-vaccination in participants enrolled in RSV MAT studies (by study arm, those previously received RSVPreF3 and control) up to Day 42 post-delivery.

Secondary objectives:

- To describe the incidence of pregnancy outcomes, pregnancy related adverse events of special interest (AESIs) and infant AESIs during any pregnancy conceived within 2 years post-vaccination in participants enrolled in RSV MAT studies (by study arm, those previously received RSVPreF3 and control) up to Day 42 post-delivery.

To describe the incidence of selected pregnancy outcomes, pregnancy related AESIs and infant AESIs by risk status and by selected risk factors for or causes of those events/outcomes during pregnancies conceived within 2 years post-vaccination in participants enrolled in RSV MAT studies (by study arm, those previously received RSVPreF3 and control) up to day 42 post-delivery.

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Methods:

This study was conducted in Projahnmo Research site in Sylhet. In this study, participants

in the prospective cohort study who were within 2 years + 2 months after vaccination/control or had ongoing pregnancies (pregnancies prior to Day 42 post-delivery) at the time of study enrollment were included. Eligible pregnant women were identified by the study staff through telephonic contact. All participants were followed up for 2 years + 2 months post-RSVPreF3 or control vaccination to record any pregnancy conceived within 2 years post-vaccine/control. If the participant was pregnant at 2 years post-vaccine/control, study follow-up continued until day 42 post-delivery. Medical data related to any pregnancy conceived post-RSV MAT (RSVPreF3) vaccine and any control (placebo, Tdap, or influenza vaccine) were collected from the date of the start of the current study pregnancy up to day 42 (approximately 6 weeks) post-delivery. Infants were enrolled at delivery, and all relevant medical data until Day 42 post-delivery were collected. In the retrospective cohort study, participants who were more than 2 years after vaccination/control and were not currently pregnant at the time of study enrollment were included. Medical data related to any pregnancy conceived post-RSVPreF3 vaccine or any control (placebo, Tdap, or influenza vaccine) through study enrollment (even if the pregnancy was conceived after 2 years post-vaccine/control) were collected retrospectively from the date of the start of the current study pregnancy up to Day 42 (approximately 6 weeks) post-delivery. Infants were enrolled with the maternal participants at Visit 1, and all relevant medical data until Day 42 post-delivery were retrieved.

5. Efficacy of probiotic supplementation in preterm and small for gestational age infants: A multi-centre, placebo-controlled, individually-randomised trial (Probiotics in preterm and small for gestational age infants, PROPS trial)

Study period: July 2025 to December 2027

Donor: Bill & Melinda Gates Foundation through World Health Organization

Partners: Johns Hopkins University; World Health Organization

Project Description:

Background: Preterm and small-for-gestational-age (SGA) infants face higher mortality risks and are vulnerable to infections, malabsorption, growth failure, and other adverse health outcomes. Existing studies suggest that probiotics may offer health benefits for this group, but research is limited by small sample sizes and potential biases. WHO and other global health bodies have emphasized the need for high-quality trials to generate robust evidence.

Objective: The overall aim of the trial is to assess the effect of probiotic supplementation on mortality, morbidity, and growth in preterm or term SGA infants in the first six months of life. For preterm infants, the primary objective is to assess the effectiveness of probiotic supplementation on mortality from enrolment to six months of age. For term SGA infants, the primary objective is to assess the effectiveness of probiotic supplementation on underweight-free survival over the same period.

Lab visit by Dr Kayur Mehta (John`s Hopkins University)

Methods: We are conducting a double-blind, individually randomized, placebo-controlled, parallel-group clinical trial in hospitals across Bangladesh, Ethiopia, Kenya, Nigeria, and

Meeting with hospital doctors and investigators

Pakistan, with follow-up through home visits. In Bangladesh, we are recruiting infants at Sylhet Osmani Medical College Hospital and Sylhet Women's Medical College Hospital. We are enrolling a total of 14,000 preterm and term SGA infants within 48 hours of birth, including 3,100 from Bangladesh. Supplementation begins at enrollment and continues for 28 days. The intervention group receives probiotics, while the control group receives a placebo. Our independent assessment team conducts outcome assessments every four weeks until the infants reach six months of age.

Significance: The findings from this trial will contribute to updating WHO recommendations and developing new guidelines for probiotic supplementation in preterm and SGA infants. This will inform policy and practice, improving evidence of certainty on critical outcomes and optimizing probiotic use in high-burden low-resource settings.

6. The E-Patient Quality Improvement & Standardization—EQIS—Platform to Improve Clinical Care in Bangladesh

Study Period: June 2024 – December 2026

Donor: Peabody Health Philanthropies and Elias & Sultana Foundation

Project Description:

Background: Poor clinical care remains a significant global health challenge, particularly in LMICs. The outcomes of poor-quality care are devastating, especially in the field of maternal and paediatric care. Although there have been remarkable changes in both fields, there is still a pressing need to improve and standardize clinical care further and reduce preventable deaths. The e-Patient Quality Improvement Simulation (EQIS) tool offers a promising solution by providing a systematic approach to improving clinical practices, identifying areas for improvement, and ultimately enhancing patient outcomes. The aim of this study is to evaluate the use and impact of the EQIS platform to improve and standardize clinical care in resource-poor settings, starting with maternal and paediatric care.

Objective: The primary objective of the study is to determine the effectiveness of the EQIS platform for standardizing maternal and paediatric clinical practice for physicians in the selected hospitals in Bangladesh.

Method: This is an observational cohort study which is evaluating the serial performance of physicians on the use of EQIS tools across six evaluation points over a period of 24 months and the pre and post impact assessment from patients. The study is conducted in five hospitals in Dhaka, Bangladesh. These hospitals are:

1. Shaheed Suhrawardy Medical College and Hospital
2. Ashulia Women and Children hospital
3. Institute of Mother and Child Health (IMCH)
4. Dr. MR Khan Shishu Hospital
5. Obstetrical and Gynecological Society of Bangladesh (OGSB) Hospital

Sample size: 551 physicians who provide maternal and pediatric care

These expected study outcomes are:
1. Improve adherence to evidence-based guidelines: The implementation of the EQIS tool is expected to enhance healthcare providers' adherence to established guidelines for maternal and paediatric clinical care which will contribute to standardizing care practices.
2. Standardization of care practices: The EQIS tool's implementation is expected to lead to greater consistency and standardization of care practices across healthcare providers within the resource-poor setting. This outcome will help reduce variations in care quality and promote a more systematic approach to clinical care.
3. Strengthened healthcare systems: Through the implementation of the EQIS tool, the study expects to identify areas for improvement in healthcare systems and infrastructure. Recommendations based on the study findings can help guide system-level changes, resource allocation, and capacity-building initiatives to strengthen maternal and paediatric clinical care in resource-poor settings.
4. Knowledge generation and dissemination: The study is expected to generate new knowledge on the effectiveness and impact of the EQIS tool in improving clinical care in resource-poor settings.

7. Global Platform for Maternal and Newborn Health

Study Period: July 2024 to December 2025

Sample Size: 22,000 medical records of delivered women during the study period, 400 postpartum women, 1300 healthcare providers.

Donor: Burnet Institute, Australia and World Health Organization (WHO).

Project Description:

Background: The lack of reliable epidemiological data on childbirth interventions in LMICs poses a major obstacle to implementing successful methods without a thorough grasp of the underlying causes. It is crucial to assess the standard of care during childbirth and immediately after to identify factors that contribute to suboptimal results for women, fetuses, and newborns. The Global Platform for Maternal and Newborn Health study aims to use a network of healthcare institutions from several countries to regularly analyze the quality of care and the resulting health outcomes. The purpose of this platform is to observe and track compliance with guidelines, identify patterns, and support the implementation of WHO recommendations based on solid data. This will establish a strong framework for improving maternity and newborn healthcare in the region.

Objectives: The objectives are to evaluate the quality of intrapartum and early postnatal care provided to women and newborns in participating health facilities by measuring:
1. Coverage of key intrapartum and early postnatal care practices in participating health facilities and whether key WHO intrapartum and early postnatal care recommendations are being implemented.
2. Women's experiences of intrapartum and early postnatal care in participating health facilities.
3. Frequency of key maternal and newborn health outcomes related to the intrapartum and immediate postnatal period.

Method: This is a multi-country cross-sectional hospital-based observational study. In Bangladesh, two divisions—Dhaka and Chattogram—have been chosen for this study. A total of 13 hospitals were selected. The selected hospitals are:

GMP study team meeting

In Dhaka division:

i. Dhaka Medical College Hospital
ii. Shaheed Suhrawardy Medical College Hospital
iii. Ad-Din Women's Medical College Hospital
iv. Mohammadpur Fertility Services and Training Centre
v. Institute of Child and Mother Health (ICMH)
vi. Kishoreganj 250 Bed District Sadar Hospital
vii. Institute of Woman and Child Health and Ashulia Women and Children Hospital

In Chattogram division:

i. Chittagong Medical College Hospital
ii. Feni 250 Bed District Sadar Hospital
iii. Chandpur 250 Bed General Hospital
iv. Noakhali 250 Bed General Hospital
v. Chattogram Maa-O-Shishu Hospital
vi. Red Crescent Maternity Hospital

We monitored around 21,000 births in over three months across the selected hospitals in Bangladesh. We conducted provider interviews (1200 providers) with all selected hospitals. Prior to discharge, 400 women were interviewed in each hospital to determine their perceptions and experiences with healthcare.

The study aims to create and maintain a platform that will analyze the quality of intrapartum and early postnatal care on a global scale during the course of the Sustainable Development Goals (SDG) effort.

8. Climate Change, Lung Function, and Respiratory Disease Patterns in the Adult Population of Sylhet, Bangladesh

Study period: June 2025 to September 2026

Donor: The UK National Institute for Health Research (NIHR) through Global Health Research Unit on Respiratory Health (RESPIRE) at the University of Edinburgh

Project Description:

Background: Bangladesh is among the top ten most climate-affected countries globally. The alarming progression of climate change is linked to the increasing levels of ambient air pollution, posing significant hazards to human health. Climate change can have a negative impact on lung function, exacerbating respiratory conditions, especially for adults and the elderly. However, the pattern of respiratory diseases in relation to climate change and air pollution has not been adequately studied in Bangladesh. Furthermore, there is a scarcity of lung function status data, hindering the assessment of changes in lung function related to climate and air quality parameters.

Objectives:

1. Establish a baseline database on various climate parameters, ambient air pollution, and lung function status among the adult population in Bangladesh.
2. Assess the respiratory disease patterns over the last 10 years among the adult population attending selected hospitals in Sylhet, Bangladesh, and its relationship with climate parameters and ambient air pollution.

Methods: Objective 1 is a community-based cross-sectional study which is being conducted in an urban site (Sylhet city) and in a rural site (Zakiganj sub-district) in Sylhet, Bangladesh. We are measuring lung function of adult participants aged 40 and above using spirometer. We are also measuring temperature, humidity, and rainfall using appropriate meteorological instruments. Additionally, PM2.5 and PM10 levels are being measured using air quality monitors. Objective 2 is a hospital-based secondary data collection study which is being conducted using data for the last 10 years from the inpatient departments of two hospitals: one urban hospital and one rural hospital in Sylhet, Bangladesh. We are extracting respiratory diseases in adults aged 40 and above from selected hospitals. Additionally, we are collecting climate and air pollution data for the last 10 years from the Department of Meteorology and the Department of Environment, respectively.

Significance: Developing a baseline database and analysing historical disease patterns will enable effective public health interventions and policies to mitigate environmental health impacts, ultimately improving population health and well-being in Bangladesh.

9. Nutritional management of growth faltering in infants aged under six months in Asia and Africa (BRANCH study)

Study Period: January 2023 to March 2027

Sample Size: 2100 pregnant women and their 1800 live birth babies

Sponsor: Bill and Melinda Gates Foundation (BMGF) through World Health Organization (WHO).

Project Description:

Background: Growth stagnation in newborns under six months of age is a significant problem. Growth stalls can be brought on by a number of significant factors. One of the main causes is inadequate breastfeeding, especially in preterm and low birth weight infants. In South Asia, 25–30% of babies and 10%–15% of those in Sub–Saharan Africa were LBW. Preterm births affect between 11% and 15% of infants in South Asia and 7–9% of infants in Sub-Saharan Africa. Similarly, South Asia (30–35%) had a higher rate of small-for-gestational-age (SGA) births than Sub-Saharan Africa (20–30%). To lessen the burden of waste on the population, it is crucial to identify and manage growth that is faltering in all of these groups, not just the vulnerable ones.

Objective: The overall aim of this study is to determine the effect of nutritional supplementation in infants aged 0-6 months of age that does not respond to intensive breastfeeding support and assessment and treatment of common clinical causes of growth faltering, compared with intensive breastfeeding support alone on mortality, morbidity and growth in infants aged 0-6 months in low resource settings in South Asia and Sub-Saharan Africa.

The primary objective is to determine the effect of nutritional supplementation on wasting free survival at 6 months of age. The secondary objective is to determine the effect of the intervention on common childhood morbidities, underweight, wasting, severe wasting, and concurrent wasting

Participant home visit by BRANCH investigators and study staff

and stunting, the effect of the intervention on the primary outcome in subgroups based on birth weight and gestational age at birth (term AGA, preterm AGA, term SGA, preterm SGA), to optimize breastfeeding support for vulnerable newborns and all infants with growth faltering in low-resource settings in South Asia and Sub-Saharan Africa and document breastfeeding practices in both intervention and comparison arms, to develop operational guidance on breastfeeding and intensive lactation support that can be used across LMICs.

Method: This is a multi-center, parallel-arm, individually randomized, non-blinded, controlled community-based study of 11,000 infants implemented in 7 countries: three in Asia (Bangladesh, India, and Pakistan) and four in Africa (Ethiopia, Nigeria, Tanzania, and Uganda). The participants are enrolling from the pregnant women and their index babies of Projahnmo surveillance area. Infants are enrolled and monitored for 6 months after giving informed consent on day 7 of delivery. In Bangladesh, we are expected to enroll 1,800 newborns on their seventh day of life over the course of 18 months. Due to the 1:1 enrollment ratio in this individually randomized trial, each study arm will have around 900 newborn participants. Mothers of infants identified with a growth pattern that is suggestive or indicative of growth faltering should have received all supports they need to exclusively breastfeed their infants before any additional milk supplement is offered.

Counselling session by a Peer Counsellor

In addition to optimizing feeding practices for well and sick infants alike, underlying medical conditions, especially infections, must be identified and treated as part of the management strategy. After that, while preterm infants are at higher risk of growth faltering, the largest number of infants experiencing growth faltering and related adverse outcomes are term infants and especially those who are small-for-gestational-age. The primary and secondary outcomes will be assessed when the infant reaches 6 months of age.

10. The WHO Antenatal Corticosteroids for Improving Outcomes in Preterm Newborns (ACTION) Trials--ACTION III: A multi-country, multi-centre, three-arm, parallel group, double-blind, placebo-controlled, randomized trial of two doses of antenatal corticosteroids for women with a high probability of birth in the late preterm period in hospitals in low-resource countries to improve newborn outcomes.

Study Period: May 2022- June 2026

Sample Size: 2400

Donor: WHO (World Health Organization)

Project Description:

Background: Every year, an estimated 15 million babies are born preterm, and the majority of these births occur in the late preterm period (gestation 34 to <37 weeks). Preterm birth complications are the leading cause of death among children under 5 years of age, responsible for approximately one million deaths in 2015. Approximately 80% of all preterm births occur in South Asia and Sub-Saharan Africa. Preterm neonates are at an increased risk of a range of short- and long-term respiratory, infectious and neurological morbidities.

Glucocorticoids play a very important role in normal foetal development, especially on

ACTION III Trial Team

pulmonary maturation, brain development and foetal growth. Antenatal Corticosteroids (ACS) have long been regarded as a cornerstone intervention in preventing neonatal deaths and severe morbidities due to preterm birth.

However, current evidence suggests there is equipoise on the question of the benefits and harms of use of ACS in late preterm birth, particularly in low resource settings and recommends further studies on the role of ACS in late preterm period. The WHO guidelines on the use of ACS in preterm birth provides clear guidance on the use of ACS in early preterm birth. However, the guidelines currently do not provide a recommendation on the use of ACS in late preterm period because of a lack of conclusive evidence. The

ACTION III trial aimed to fill this evidence gap and help inform future WHO guidelines on ACS use in the late preterm period.

Objectives: The primary objectives of this trial were:

1. To compare the effect of an ACS regimen of dexamethasone phosphate (6mg q12h) for 4 doses or until birth, whichever is earlier (Dexa-4x6mg) to placebo on a composite outcome of stillbirth, neonatal death or use of respiratory support within 72 hours of life, when given to pregnant women with a high probability birth in the late preterm period (34+0 to 36+5 weeks gestation) in hospitals in low resource settings.
2. To compare the effect of an ACS regimen of betamethasone phosphate (2mg q12h) for 4 doses or until birth, whichever is earlier (Beta-4x2mg) to placebo on a composite outcome of stillbirth, neonatal death or use of respiratory support within 72 hours of life, when given to pregnant women with a high probability of birth in the late preterm period (34+0 to 36+5 weeks gestation) in hospitals in low resource settings.
3. To compare the effect of an ACS regimen of dexamethasone phosphate 4x6mg q12h to a regimen of betamethasone phosphate 4x2mg IM q12h, on a composite outcome of stillbirth, neonatal death or use of respiratory support within 72 hours of life, when given to pregnant women with a high probability birth in the late preterm period (34+0 to 36+5 weeks gestation) in hospitals in low resource settings.

Method: ACTION III is a parallel group, three-arm, individually randomized, double-blind, placebo-controlled trial of two ACS regimens, dexamethasone phosphate 4x6mg q12h regimen and betamethasone phosphate 4x2mg q 12h regimen, given to women with a high probability of preterm birth in the late preterm period to improve neonatal outcomes. The trial is multi-country and multi-center, is being implemented in 24 hospitals across Bangladesh, India, Kenya, Nigeria, and Pakistan, where the WHO ACS treatment criteria can reasonably be met. In Bangladesh, the trial is implemented in five hospitals. Trial activities are facility-based, with community follow-up of recruited women and newborns up to 28 completed days of life.

11. Implementation Research to Scale-up and Evaluate the Impact of Antenatal Corticosteroids on Preterm Newborn Outcomes (ACS-IR)

Study Period: January 2023 to December 2027

Donor: Bill and Melinda Gates Foundation (BMGF) through World Health Organization (WHO).

Project Description:

Background: Worldwide, preterm birth is the primary cause of death, illness, and permanent disability in children under the age of five. One of the key therapies for lowering the negative effects of preterm birth is antenatal corticosteroids (ACS). Although ACS coverage in preterm labor is high (>90%) in high-income countries, it is still inadequate in many low- and middle-income countries (LMICs). The new findings of ACTION-I Trial – the largest placebo-controlled trial on ACS efficacy and safety to date – are reassuring. However, effective translation of these findings into routine practice in low-resource countries requires several safeguards to ensure ACS is used safely.

WHO delegates visiting Manikganj study site

Data collection by a Research Assistant

Objectives:

- To develop and optimize an implementation model that can achieve high coverage of safe ACS use through iterative cycles of formative research, implementation, concurrent program learning, and outcome measurement in one health administrative area (district) in each country.
- To scale up the above optimized ACS implementation model to six health administrative areas (districts) and evaluate the impact of the scale-up on neonatal mortality.

Method: This is a multi-country implementation research study coordinated by WHO. During the model's deployment and optimization, a time series design is used to assess changes in coverage, safety, and process outcomes. A 70% safe ACS coverage rate in the ACS-implementing facilities will be considered to be the "ideal" ACS implementation approach. The optimization of the ACS implementation model is

expected to take roughly two years, during which time we anticipate an increasing trend in the ACS safe coverage metric, a sign of progress in the implementation. The impact of the model's optimization on coverage will be compared using a before-and-after analysis. Using a cluster-randomized design, the optimized implementation model will be expanded to eight districts across Bangladesh. The optimized model will be implemented in the 18 hospitals and 79 private clinics in the following districts from July 2025: Tangail, Kishoreganj, Faridpur, Feni, Sylhet, Noakhali, Brahmanbaria, Moulovibazar.

MIS data review by foreign delegates

12. Integrating immediate Kangaroo Mother Care into district hospitals with a level 2 neonatal intensive care unit: Implementation Research

Study Period: January 2023 to August 2026

Donor: Bill and Melinda Gates Foundation (BMGF) through World Health Organization (WHO).

Project Description:

International KMC awareness day

Background: KMC (Kangaroo Mother Care) is defined as early, prolonged, and continuous skin-to-skin contact between mother and her preterm or LBW newborn, and exclusive breastfeeding or breastmilk feeding. The results of a WHO-coordinated randomized controlled trial of the effects of immediate Kangaroo Mother Care (iKMC) revealed that risks are comparatively lower in intervention group than the controlled group. The Conventional KMC was associated with a reduction in mortality from the baseline of about 25-30% in 2015 to about 16% in the control group during the study period.

Recent evaluations and analyses of country programs have identified several factors that impact the implementation and scale-up of KMC. These factors include the health system's lack of leadership support and priority, personnel availability and training, insufficient funding and allocation of resources, and community acceptance. The study demonstrated that context-adapted models, grounded in implementation science, can be utilised to achieve high KMC coverage.

So, this study will be conducted in six sites, two in Africa (Ethiopia and Nigeria) and four in South Asia (Bangladesh and India) as these countries have a high burden of LBW and neonatal mortality; they contribute substantially to the global burden; and there is a strong commitment of the government to improving hospital-based care for preterm or LBW infants.

IKMC practicing while using CPAP

Objectives:

• To develop an implementation model that will add iKMC to functional systems of care for LBW infants. This model will provide necessary care including iKMC (skin-to-skin contact and breastmilk feeding), respiratory support, warmth, monitoring, and prevention and treatment of infections in newborn care units. The model will transform level 2 NICU to level 2 Mother-Newborn Special Care Units (m-SNCU) in health administrative areas.

FGD with recently delivered women in Manikganj

• To scale up the model to multiple administrative areas using a stepped wedge design and evaluate its impact on neonatal health outcomes including neonatal mortality, and identify potential barriers, facilitators, and the investments needed.

• To support national governments in four countries (Bangladesh, Ethiopia, India and Nigeria) to scale up iKMC at national levels.

Method: The study will be conducted in two phases: In a model development phase, an implementation model will be developed in each health administrative area (such as 1-2 districts) in each participating site. The final model will be scaled up across multiple health administrative areas (districts) concurrently; It will maintain data-driven learning through robust monitoring and adaptive quality improvement.

For the initial study phase, we propose a mixed-methods design that uses both qualitative and quantitative methods. In the first six months, following the preparatory phase of the study, we will conduct formative research to do a systems level diagnosis and identify gaps, barriers, and enablers for implementing iKMC. This will be followed by development of an initial implementation model, its implementation in a hospital with a level 2 unit at district level, continued qualitative and quantitative data collection, analysis, and use to iteratively improve the model until 80% coverage and quality of iKMC is achieved. Specifically, we will use the Consolidated Framework for Implementation Research in the Generic Implementation Framework to guide the process learning activities and include key concepts from the Dynamic Adaptation Process in implementation.

13. Efficacy of antenatal corticosteroids on the lung function of premature children in Bangladesh: BiLDing-ACTION (Bangladesh Infant Lung Function and Diagnosis-Antenatal Corticosteroids for Improving Outcomes in Preterm Newborns)

Study period: January 2025 to March 2027

Donor: Thrasher Research Fund

Partners: Johns Hopkins School of Medicine, USA; Johns Hopkins Bloomberg School of Public Health, USA; University of Szeged, Hungary; University of Cape Town, South Africa.

Project Description:

Background: Preterm birth is a major global health concern, particularly in low-resource settings like South Asia and sub-Saharan Africa. Preterm infants are susceptible to lung injury, which can lead to chronic lung disease later in life. This study seeks to explore whether antenatal corticosteroid (ACS) can mitigate lung problems in these populations.

Lung function test of a young infant at study site

Objectives:

- Determine whether antenatal dexamethasone, versus placebo, improves lung function among premature 5-year-old children born <34 weeks' gestation.

- Determine if antenatal dexamethasone, compared to placebo, improves lung growth and development among late preterm infants (34 weeks to <37 weeks) over the first two years of life.
- Compare lung function among premature 5-year-old children born <34 weeks' gestation to age and 5-year-old children born at term (37 weeks or later).
- Compare lung function among late preterm infants over the first two years of life to that of children born at term (37 weeks of gestation or later).

Methods: In this prospective cohort study, we are following children whose mothers were previously enrolled in the ACS trials, which were conducted in Dhaka and Sylhet, and who delivered baby at a gestational age <37 weeks. Additionally, we are recruiting term-born children of the same age groups as a comparison group. The total sample size is 696. We are performing lung function tests using respiratory oscillometry and tidal breathing analysis at 6 months, at 2 years and at 5 years.

Meeting with hospital staff

Primary outcomes include pre-bronchodilator mean resistance at 7 Hz (R7), mean Lung Clearance Index (LCI), and severe respiratory disease.

Significance: This study will provide critical data on whether antenatal corticosteroid therapy offers sustained pulmonary benefits in preterm infants from low-resource settings. Findings will inform global neonatal care policies and improve respiratory health outcomes for preterm infants both in Bangladesh and worldwide.

14. Antenatal dexamethasone for preterm birth and long-term health outcomes in children: a pilot follow-up cohort study of ACTION-I trial participants in Sylhet, Bangladesh

Study Period: February 2024 to July 2025

Donor: Burnet Institute, Melbourne, Australia

Background and Rationale:

Preterm birth complications are the leading cause of death in neonates and children under 5 years of age. Compared to term born babies, preterm-born babies are more likely to develop a range of short and long-term morbidities, including respiratory complications, neurodevelopmental disorders, behavioral problems, and learning difficulties. Antenatal

corticosteroids (ACS) are a critical intervention for mitigating the short-term effects of preterm birth. ACS administered to women at risk of preterm birth prior to 34 weeks' gestation significantly reduced the risk of short-term neonatal mortality and morbidities. However, current knowledge regarding the long-term health effects of ACS remained limited and somewhat conflicting. The WHO ACTION-I trial was a multi-country, placebo-controlled, randomized trial that evaluated the efficacy and safety of antenatal dexamethasone in women at risk of imminent preterm birth between 26 weeks to <34 weeks of gestation. The study recruited 2,852 women in 29 hospitals in Bangladesh, India, Kenya, Nigeria and Pakistan, between December 2017 to November 2019. The trial collected outcome data until 28 days postnatal and demonstrated that antenatal dexamethasone reduced neonatal death by 28 days of life. Thus, a pilot study was designed to inform the decision to conduct future, larger follow-up studies in the ACTION-I population.

Objectives:

The general objective of this pilot study was to assess participant follow-up and to provide data to estimate the parameters required to design a definitive follow-up cohort study. The specific objectives were:

To assess how many ACTION-I participants could be contacted and were willing to participate in a follow-up study in Sylhet, Bangladesh.

- To determine the prevalence of long-term child health outcomes of interest, to inform development of a future, definitive follow-up cohort study.
- To evaluate the effects of ACS exposure prior to 34 weeks' gestation compared to placebo on neurodevelopmental, survival, growth, and health-related quality of life at 5 years' corrected age in participating children in Sylhet, Bangladesh.
- To collect and synthesise data, from which the sample size of a definitive follow-up cohort study could be estimated.

Sample size

In Sylhet, there were 259 live births among 259 randomized women, of which 181 infants survived to 28 completed days after birth. As this was a pilot study with a fixed number of potentially eligible participants, we aimed to identify and re-enrol as many as possible of the 181 children.

Potential Impact

This pilot study informed the decision to conduct future, larger follow-up studies in the ACTION-I population. It also generated critical new data on the long-term effects of exposure to dexamethasone during pregnancy.

15. Using ongoing newborn intervention trials to obtain additional data critical to maternal, fetal and newborn health in a harmonized way in Sylhet District, Bangladesh: the AMANHI (Alliance for Maternal and Newborn Health Improvement) cohort study.

Study Period: August 2014 - December 2025

Sample Size: 3000

Donor: Bill and Melinda Gates Foundation (BMGF) through World Health Organization (WHO).

Project Description:

Background: The umbrella study, which is being conducted by the Alliance for Maternal and Newborn Health Improvement (AMANHI), aims to better understand the epidemiology of maternal morbidity and mortality, stillbirths, and neonatal deaths, the relationships between maternal morbidity and care and maternal, fetal, and neonatal outcomes, the biological underpinnings of these relationships, and the evaluation of less complex methods for accurate gestational age determination in several countries including Bangladesh and coordinated by WHO.

measuring OFC in a newborn

Placental sample collection

Objectives:

i) Identify causes of maternal, and neonatal deaths and stillbirths using standardized verbal autopsy method;
ii) Measure morbidities during pregnancy, childbirths and postpartum period (e.g., pre-eclampsia, eclampsia) and identify their association with adverse pregnancy outcomes (e.g. stillbirths, preterm births and intrauterine growth retardation);
iii) Identify simpler tools to detect preterm births by community health workers; and
iv) Create a biorepository of maternal, neonatal and paternal biological samples to detect biological and genetic markers of adverse pregnancy outcomes.

In 2016, the study received additional support to include child growth and development outcomes (All Children Thrive; ACT). The ACT study involves continued enrollment and follow-up of pregnant women, collection of some additional specimens to be added to the biorepository, follow-up of the babies born to the mothers and longitudinally assess their growth and neurodevelopment during first 3 years of life. The main aim of ACT is to measure the trajectory of growth and development in a well-defined cohort of preterm birth, growth restricted, and normal newborns in order to find the underlying biological mechanisms and/or predictors of differential growth and performance on test of cognitive, motor and language development.

Image 54: Sample processing at study lab

Method: The AMANHI Biorepository study is being implemented in Bangladesh, Pakistan and Tanzania to initially test hypothesized biological markers as predictors of important maternal, fetal, and child health outcomes (e.g., pre-eclampsia, eclampsia, stillbirths, preterm births and intrauterine growth retardation), and to use this opportunity to establish a repository of biological samples for testing as new hypotheses, methods and technologies become available.

Between 21 August 2014 and 30 August 2017, we have enrolled 3,000 women in early pregnancies (8-19 weeks of gestation) in Sylhet, Bangladesh, collected biospecimens from the enrolled women, their husbands, and babies and stored the samples at -800C in the Biobanks located at Sylhet and Dhaka. The Biobank contains various specimens including maternal and umbilical cord blood, plasma, serum, urine, placental tissue, saliva, and stool that are amenable to proteomic, transcriptomic, metabolomic, genomic and microbiomic analyses. All these samples will be linked to numerous epidemiological and phenotypic data with unique study identification numbers.

We are now collaborating with other AMANHI sites, consortiums and several US-based technology partners to identify markers of preterm birth using the bio-specimens that we have collected. Our collaborative work with the University of Iowa is to test existing models of gestational age prediction using newborn metabolic profiles and build new models using bio-banked cord blood specimens. We are collaborating with Stanford University to examine whether blood and urine samples can be used for state-of-the-art biologic analytic inquiries to identify proteomic, transcriptomic and metabolomic markers of preterm birth. The collaborative work with Cincinnati Children's Hospital Medical

Center is to determine the genetic variants that influence preterm birth risk in women. Our collaboration with a US company, Sera Prognostics, is aimed at identifying proteomic markers of preterm birth and ultimately to develop a point of care diagnostic test for the accurate and early prediction of preterm birth in early pregnancy.

The AMANHI method papers have been published in 2016 and 2017 (AMANHI Mortality Cohort Study Group, J Glob Health. 2016; AMANHI Maternal Morbidity Study Group, J Glob Health. 2016; AMANHI Gestational Age Study Group, J Glob Health. 2017; AMANHI Bio-banking Study Group, J Glob Health. 2017). The paper on population-based rates, timing, and causes of maternal deaths, stillbirths, and neonatal deaths in South Asia and sub-Saharan Africa has been published in 2018 (AMANHI Mortality Study Group, Lancet Glob Health. 2018). The paper on direct maternal morbidity and the risk of pregnancy-related deaths, stillbirths, and neonatal deaths has recently been published in 2021 (AMANHI Maternal Morbidity Study Group, PLOS Medicine. 2021).

16. Field-testing and validation of the Global Scale for Early Development (GSED) for 0- to 3-year-old children

Study period: June 2023 to December 2026

Sample size: The sample size was estimated 400 children aged 5 years.

Donor: World Health Organization (WHO)

Project Description:

Background: While the importance of early development has been well recognized globally, universal measures designed to quantify early child development (ECD) are lacking, particularly for the youngest children. Measurement tools are necessary not only for tracking progress toward meeting global policy goals, but also for informing resource allocation and programming to provide the necessary support to enable children to reach their developmental potential. Current measures of child development range from proxy measures to detailed measures of individual performance that can be expensive, culturally inappropriate, or time-intensive to administer. Neither these proxy measures nor the individual measures are adequate for program evaluation. As yet, there are no widely accepted universal measures of early child development that can be applied at the population level for children under 3 years of age.

Objective: The overarching aim of the Global Scale for Early Development (GSED) Project is to develop a robust, universal and psychometrically sound scale to measure development of children aged 0-3 years through two measurement instruments. This study aims at the validation of the instruments with the specific objectives to (i) test the feasibility of the proposed procedures for set up, training and data collection within

countries, and obtain feedback on feasibility and domain alignment on items proposed to be in the prototype instruments; and (ii) determine the psychometric properties of the GSED instruments (short and long form).
The objective of the predictive component is to establish predictive validity of D-scores obtained for children between 0-3 years of age (using the GSED) for later outcomes across developmental domains (global and socio-emotional development, school readiness and executive functioning) at preschool-age of 3.5 years, and at school entry age of 5 years.

National level meeting with stakeholders

Method: This is a prospective study in children 0-41 months of age. The study sample is selected using an age and sex stratification. This study utilizes a multiple-method approach to assess the feasibility and cross-cultural validity of a tool to measure child development through piloting and field testing in three countries of Asia and Africa. The study adds a longitudinal component (the 'predictive validity study'), following up participants from cohorts that are already enrolled in the previous study at two-time points (ages 3.5 and 5 years). In Bangladesh, the study is conducted in Projahnmo field site in Sylhet.

17. Development of Population Norms for Early Childhood Development Under 36 Months (GSED 2.0)

Study period: January 2024 to December 2026

Sample size:

- **Term cohort:** 304 children
- **Preterm cohort:** 144 children

Donor: World Health Organization (WHO)

Project Description:

Background: Globally, there is an urgent need for standardized, age-normed tools to measure early childhood development (ECD), especially for children under 36 months. Existing tools often fail to meet the practical and cultural needs of diverse populations

and are either proxy-based or resource-intensive. The Global Scale for Early Development (GSED) initiative aims to close this gap by developing a reliable, universal measure that can assess ECD at scale and inform policies and programs to improve child outcomes.

Objective:

Primary Objective:

To develop a global, age-normed distribution of GSED scores for children aged 0 to <36 months.

Secondary Objectives:
i. To use the established norms as references to determine on- and off-track developmental trajectories for specific ages at both the population and programmatic levels.
ii. To explore adjustments for accurate measurement of child development in moderate and late preterm infants using these distributions.

GSED Team

Method: This is a multicenter, prospective, mixed-method study combining cross-sectional and longitudinal panel designs. The study is being conducted in twelve countries, including Bangladesh, to ensure cross-cultural validity.

In Bangladesh, the study is implemented in Sylhet, Sunamganj, Habiganj, and Moulvibazar districts. The study population includes both term and preterm children aged 0–41 months.

- Children are enrolled and assessed across up to five rounds (T1 to T5).
- Interval between rounds:
    - Every 3 months for children under 12 months
    - Every 6 months for children aged 12 months or more

- The feasibility phase was conducted from April 8 to May 20, 2024, followed by the implementation of Phase 2.
- Recruitment is done through hospital registries, with screening and pre-consent, followed by home visits and developmental assessments.

Collaborating institutions:

- Sylhet MAG Osmani Medical College Hospital
- Sylhet Women's Medical College Hospital
- Jalalabad Ragib-Rabeya Medical College Hospital
- North East Medical College and Hospital
- Ibn Sina Hospital Sylhet Limited
- Al Haramain Hospital Private Limited

18. Evaluating the Impact of PSBI Management on Caregiver-Centric Outcomes

Study Period: March 2025 to June 2025

Donor: World Health Organization

Project Description:

Background: The possible serious bacterial infections (PSBI) trials have shown the clinical non-inferiority of outpatient and home-based care compared to prolonged hospitalization for managing serious bacterial infections in young infants. Despite these findings, caregiver-centric outcomes, such as decision-making agency, knowledge retention, and emotional and financial burdens, remain underexplored.

Objective: This study aims to evaluate caregiver-centric outcomes in outpatient and home-based care compared to prolonged hospitalization for managing PSBI in young infants.

Method: This mixed-methods study includes both quantitative and qualitative components to assess caregiver experiences and outcomes. The study population consists of mothers or primary caregivers of infants enrolled in Trials 1 and 2 in Sylhet Division who have completed treatment and follow-up. Quantitative data are collected from 200 caregivers using structured surveys that assess decision-making agency, knowledge retention, emotional and financial impact, and satisfaction with care. Additionally, 40 in-depth interviews are conducted to explore caregiver experiences with home- versus hospital-based care and barriers to adherence. The primary outcome is

caregiver empowerment and agency, while secondary outcomes include knowledge retention, adherence, emotional and financial impact, and satisfaction.

Significance: This study addresses a critical gap by integrating caregiver perspectives into the evaluation of PSBI management strategies. The results will guide the development of care models that improve adherence, reduce caregiver burdens, and optimize infant health outcomes, ultimately informing patient-centered policy reforms.

19. Bangladesh Lung Auscultation AI for Antibiotic Stewardship Randomized Controlled Trial (The BLAAST Trial)

Study period: January 2025 to December 2029

Donor: National Institutes of Health (NIH), USA

Project Description:

Background: Acute lower respiratory infections are a leading cause of death among children in low- and middle-income countries (LMICs) like Bangladesh. According to the Integrated Management of Childhood Illness (IMCI) guidelines, children with respiratory symptoms are assessed, and antibiotics are recommended if they are classified as having pneumonia. However, with high coverage of pneumococcal conjugate vaccine (PCV) and Haemophilus influenzae type B (Hib) vaccination, most cases classified as pneumonia may be due to viral infections, such as respiratory syncytial virus (RSV), and may not require antibiotics. Innovative child friendly tools like automated digital stethoscopes can improve the diagnosis of respiratory illnesses, safely reduce the unnecessary use of antibiotics, and are suitable for implementation in LMICs. These advancements are urgently required to improve antibiotic stewardship and address the rising threat of antibiotic resistance globally.

Objectives:

1. Efficacy - Determine whether treatment failure frequency among children in rural Bangladesh managed by IMCI guidelines enhanced by a novel automated digital stethoscope ('enhanced IMCI') is non-inferior to IMCI guidelines alone.
2. Implementation - Assess digital auscultation implementation and antibiotic use during pediatric respiratory care in rural Bangladesh to inform strategies of antibiotic stewardship.
3. Cost effectiveness - Determine whether an 'enhanced IMCI' strategy of digital auscultation is a sustainable alternative to standard care for children in rural Bangladesh.

Methods:

Objective 1 is a randomized, double-blinded, placebo-controlled, non-inferiority trial. We are recruiting 2,500 children aged 2-59 months who are presenting with non-severe

pneumonia (fast breathing and/or chest indrawing, with the absence of a WHO-defined danger sign) to the study hospitals of Zakiganj and Beanibazar in Sylhet District. We are recording lung sounds for all eligible children. Children in the control group are receiving amoxicillin syrup per IMCI pneumonia guidelines, while those in the intervention group are receiving amoxicillin syrup or placebo based on the automated algorithm's lung sound classification. Community health workers are following up with the children at home on days 2, 3, 5, 7, and 14. The primary outcome is treatment failure within seven days, and the secondary outcome is treatment failure and relapsed by day 14.

Objective 2 is a prospective observational study of participating health care workers (HCWs), conducted in parallel with the trial, where we are enrolling 60 HCWs, 24 caregivers, and 180 children.

For Objective 3, we are conducting an economic evaluation to estimate cost-effectiveness, considering the opportunity costs of a digital auscultation strategy expected to reduce antibiotic use in children.

Significance: This study affords a unique opportunity to evaluate the efficacy of clinical guidelines enhanced by an automated digital stethoscope on child pneumonia outcomes in Bangladesh, if digital auscultation may be instrumental in the wider antibiotic stewardship strategy, and whether a digital stethoscope diagnostic tool is cost-effective in the care of children with respiratory illnesses.

20. Leveraging community-to-facility service provision to implement the World Health Organization HEARTS-D guidelines in Sylhet, Bangladesh for improving diabetes control and prevention (HEARTS-D for Bangladesh)

Study period: January 2025 to December 2029

Donor: National Institute of Health (NIH), USA

Partner: Florida International University, Johns Hopkins University, University of Texas Health Science Center at Houston, World Health Organization

Project Description:

Background: Type 2 Diabetes (T2D) is increasing rapidly in low- and middle-income countries (LMICs), particularly in urban settings where the majority of affected individuals reside. Bangladesh has one of the highest burdens of T2D globally. The WHO HEARTS-D module is an evidence-based strategy aimed at strengthening diabetes management through standardized guidelines. However, its effective adoption into routine urban primary care in Bangladesh is hindered by systemic challenges, including limited

integration with existing health systems, inadequate workforce capacity, and insufficient monitoring mechanisms.

Objective: This study aims to develop an optimized community-to-facility implementation model to strengthen urban healthcare for T2D management in Bangladesh using the WHO HEARTS-D module. This will also evaluate the optimized implementation model to investigate its impact and effectiveness on T2D care in an urban setting in Bangladesh.

Methods: We are conducting this implementation research in Sylhet City Corporation, Sylhet. The study population includes individuals aged 35 years or older who are at risk of developing T2D and reside in the study area. Additionally, the study includes participants from healthcare facilities, including healthcare providers and community stakeholders relevant to local T2D care (e.g., local physicians, non-physician health workers, community health workers, and local community leaders), to facilitate the qualitative research components of the study.
We are using mixed-methods design including both qualitative and quantitative research methodologies. First, a formative research method is used to identify barriers and facilitators for community-to-facility WHO HEARTS-D module implementation to design and optimize the initial implementation model. Concurrent program learning using qualitative research and outcome measurement while implementing the initial model in routine care settings are used to improve the model iteratively until a high coverage of T2D care using the WHO HEARTS-D module is achieved. This process will produce the final, optimized WHO HEARTS-D implementation model, developed from the perspective of sustainable scale-up. Second, the optimized implementation model will be evaluated by a type-2, hybrid implementation/effectiveness cluster-randomized trial. This trial will evaluate the program implementation and effectiveness of the final optimized model.

Significance: The study will help gather evidence to implement the WHO HEARTS-D guideline in community settings, leveraging a whole-of-community approach to effectively address the T2D burden in Bangladesh and other LMICs.

COLLABORATORS AND PARTNERS

PRF believes in the power of collaboration to achieve its mission. We work intimately with the Bangladesh Ministry of Health and Family Welfare (MOHFW) for the implementation of our activities, maintaining partnerships at national and local levels. Additionally, we collaborate with several reputed universities and research organizations, both national and international, including:

- **Academic and Research Institutions**:
    - Bangladesh Medical University (BMU)
    - Cincinnati Children's Hospital, USA
    - International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b)
    - Johns Hopkins University, USA
    - Mayo Clinic
    - Max Plank, Germany
    - Metabolon, Inc.
    - North South University
    - Sapient Bioanalytics, USA
    - Sera Prognostics, USA
    - Sylhet MAG Osmani Medical College Hospital
    - Stanford University, USA
    - University of California, Davis, CA, USA (UCD)
    - University of California at San Francisco, USA
    - University of Edinburgh, UK
    - University of IOWA, USA
- **Hospitals/Study Clinics (Partners for pivotal trials across Bangladesh)**:
    - Dhaka Medical College Hospital
    - Sylhet MAG Osmani Medical College Hospital, Sylhet
    - Manikganj Medical College Hospital, Manikganj
    - District Hospital, Manikganj

- Sylhet Women's Medical College Hospital, Sylhet
- Monno Medical College & Hospital, Manikganj
- Jalalabad Ragib Rabeya Medical College Hospital, Sylhet
- Ad-Din Women's Medical College Hospital, Dhaka
- Mohammadpur Fertility Services and Training Center (MFSTC), Dhaka
- Ashulia Women and Children Hospital, Dhaka
- Institute of Child and Mother Health (ICMH), Matuail, Dhaka
- OGSB Hospital & IRCH, Dhaka
- Dr. M R Khan Shishu Hospital and Institute of Child Health, Dhaka

- **Professional Bodies**:
  - Bangladesh Neonatal Forum (BNF)
  - Bangladesh Paediatric Association (BPA)
  - Bangladesh Perinatal Society (BPS)
  - Obstetrical and Gynecological Society of Bangladesh (OGSB)

MOU signing between PRF and OGSB

Donors

Our research and operational activities are supported by multiple donors. We are grateful for the invaluable contributions of our funding partners, who enable us to conduct high-quality research and provide essential public health support.

Selected present and past Donors/Sponsors:

- Bill and Melinda Gates Foundation (BMGF)
- Elias & Sultana Foundation
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- Moderna
- Novavax
- National Institute of Health, USA
- National Institute for Health Research (NIHR) (UK)
- Peabody Health Philanthropies, USA
- RESPIRE, UK
- Save The Children
- Thrasher Research Fund
- USAID
- World Health Organization (WHO)

CONCLUSION

Since its inception, the Projahnmo Research Foundation (PRF) has played a pivotal role in advancing maternal, newborn, and child health in Bangladesh through rigorous, evidence-based research. Over the years, we have broadened our scope to address the health of all age groups and expanded our work to include endemic and emerging infectious diseases, non-communicable diseases, and the effects of climate change. Our unwavering commitment to generating high-quality scientific evidence and translating it into actionable policies and programs reflects our dedication to improving public health outcomes.

The successes highlighted in this report are a testament to the collaborative spirit of our dedicated team, the trust of the communities we serve, and the invaluable support of our partners and donors.

Looking ahead, PRF remains steadfast in its mission to respond to the evolving health landscape, push the frontiers of research—including in areas such as ageing, NCDs, and pandemic preparedness—and strengthen its contributions to national and global health priorities. Through continued innovation, collaboration, and commitment, PRF aspires to solidify further its role as a leader in public health research, contributing to a healthier and more equitable Bangladesh and beyond.


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PROPS Trial Workshop


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