

Women's and Children's Health Research Unit

Jawaharlal Nehru Medical College

KLE Academy of Higher Education and Research

(Deemed-to-be-University U/S 3 and 12 B of the UGC Act 1956)

Belagavi Karnataka India



WHO Collaborating Centre
for Research in Maternal and Perinatal Health



Global Network
for Women's and Children's Health Research
*Eunice Kennedy Shriver National Institute
of Child Health and Human Development*



Australian Government
National Health and
Medical Research Council



ARPAN - Accelerating Research and
Progress in maternal And Newborn health:
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Karnatak Lingayat Education Society

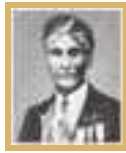
Belagavi, Karnataka, India

Established 1916



Founders of KLE Society & 'Saptarshis' - The Seven Great Teachers

FOUNDERS



Shri V. G. Naik Bahadur Desai



Rao Bahadur R. C. Artal



Rao Bahadur V. A. Anigol

SAPTARISHIS



Shri B. S. Hanchinal



Shri H. F. Kattimani



Shri B. B. Mamdapur



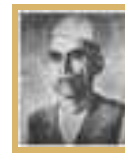
Shri M. R. Sakhare



Shri S. S. Basavanal



Shri P. R. Chikodi



Shri V. V. Patil



KARNATAK LINGAYAT EDUCATION (KLE) SOCIETY, BELAGAVI

(Transforming Lives through Education, Healthcare & Research)

The Karnatak Lingayat Education (KLE) Society was established in the year 1916 by Seven dedicated teachers aptly called as **"SAPTARSHIS"** viz. Shri Basappa Siddalingappa Hanchinal,

Dr Huchhayya Fakirayya Kattimani, Shri Basavantappa Balappa Mamadapur, Shri Maharudrappa Revappa Sakhare, Shri Shivalingappa Shivayogappa Basavanal, Shri Panditappa Ramappa Chikodi and Sardar Veerangouda Veerabasangouda Patil, who sacrificed lucrative career and dedicated their lives for the cause of education. They were supported by three benevolent patrons Shrimant Sardar Veerabhadrappe Gunappa Naik Bahadur Desai of Chachadi, Shri Rao Bahadur Rudragouda Chanagouda Artal and Shri Rao Bahadur Vijappa Adivappa Anigol.

KLE Society which has been engaged in societal transformation for over 10 decades today manages over **310** Institutions which include Schools, Colleges, Health Care Institutions, Technical Institutions, Research Centres, Business schools and Community Radio Stations. The institutions spread across almost all the districts of Karnataka, parts of Maharashtra, Goa, and New Delhi nurture the academic aspirations and healthcare needs of thousands of people in the region and beyond.

The hallmark of the organization is its commitment to providing equal opportunities to individuals regardless of origin and nationality. Institutions of KLE in both the urban and rural areas are equipped with state-of-the-art infrastructure and incorporate modern methods of teaching and learning. The wide spectrum of courses offered along with the ambience and work culture conducive to holistic learning make KLE institutions rank among the most preferred destinations for studies and research. Establishment of KLE Academy of Higher Education and Research (Deemed University) and the KLE Technological University have paved the way for an autonomy that facilitates the incorporation of modern interventions to facilitate the nurturing of skilled professionals.

Collaborations with universities in the US, UK and Malaysia have enabled cross cultural and multi-disciplinary learning along with recognition as a global destination of high- quality education. With nearly 1,38,000 students pursuing their academic dreams under the expert tutelage of over 18,000 faculty members, domain experts and allied professionals, the organization continues its tryst with the humungous task of empowering individuals into successful and responsible citizens.

Venturing into Healthcare in the year 1996 with the establishment of the 1,000 beds hospital at Belagavi,



Dr Prabhakar B Kore

CHAIRMAN, KLE SOCIETY &
CHANCELLOR, KAHER, BELAGAVI

KLE continues to build on its mission to provide modern healthcare at affordable costs and today boasts of a healthcare capacity of over 4,000 beds including 1,900 Charitable beds. The services rendered also include Cancer Care, Physiotherapy, Dentistry, Homeopathy and Ayurveda. Forging of research collaborations with international organizations including National Institute of Health, WHO, Bill & Melinda Gates Foundation, Thomas Jefferson University, etc has enabled the healthcare initiatives to make a global impact especially in Maternal and Child Health, Diabetes and other domains. Continually making inroads into the rural areas with modern establishments, KLE is taking the best of healthcare to the poor and needy.

To ensure holistic contributions to the development of the rural community, the KLE Society has established the School of Agriculture. This enables students from the farming community to inculcate knowledge and modern practices that pave the way for adoption of modern technologies, better planning and consequently an enhanced agricultural output. Taking forward the cause of the welfare of the farming community, the KLE Society in association with the Indian Council for Agricultural Research, has established the KLE - Krishi Vigyan Kendra at Mattikoppa. The Research Centre through its outreach programs is providing continual assistance to farmers in the region and beyond.

The architect of "Global KLE" is Dr Prabhakar Kore, the Chairman of the organization since 1984. Under his unparalleled leadership, the KLE Institutions have reached enviable heights. Redefining and redesigning the work methodology and philosophy, he and his team of Members of the Board of the Management have enabled the organization to match and supersede the commitments and goals envisioned by the founding fathers.

The KLE Society celebrated its "Centenary" on **13th Nov 2016** with an event graced by the inspirational presence of Honorable **Prime Minister Shri Narendra Modi** who addressed a congregation of over one lakh members at the District Stadium KLE Society's J N Medical College campus. Lauding the visionary initiative of the founders and the foresight of the current leadership of KLE Society, Shri Modi proposed a roadmap for the organization, visualizing its emergence as one among the top centres of learning at the international level. The organization has been relentlessly striving to live up to the faith imposed by the honourable leader.





Honorary Degree of Doctor of Science being conferred on **Dr Prabhakar Kore**, Chairman, KLE Society & Chancellor, KLE Academy of Higher Education and Research (KAHER) at Thomas Jefferson University, Philadelphia, PA, USA.

It is a matter of great pride to the entire KLE Family that the prestigious **Honorary Degree of Doctor of Science** being conferred upon **Dr Prabhakar Kore**, Honorable Chairman, KLE Society and Chancellor, KLE Academy of Higher Education and Research (KAHER) in recognition of his relentless efforts in furthering the cause of Education, Health care and Research for the upliftment of the society at large in this part of the country. The recognition is made special by the fact that TJU is among the top ranked and prestigious universities in USA. In addition to this, his relentless efforts to establish and foster the collaboration between KLE and Thomas Jefferson University (TJU), Philadelphia USA was indeed noteworthy. The honorary degree of Doctor of Science was presented to him on 25 May 2022 at the graduation ceremony for Thomas Jefferson University in Philadelphia.

Dr Kore has been instrumental in taking the KLE Society and KAHER to new heights. He has not only created world class infrastructure in a Tier II city like Belagavi but has also ensured a very high quality of traditional and professional education, high caliber research and state of the art, affordable healthcare facilities through a modern hospital for the poor and needy.

OBITUARY



Dr. B. S. Kodkany

Former Professor of OBG and
Former Director, KAHER Research Foundation, Belagavi

With profound sadness, we condole the departure of Dr B S Kodkany from our midst on 22nd February 2024. Dr B S Kodkany has given 60 years of selfless services to KLE as an inspiring educator, Emeritus Professor, Teacher of Teachers, a great Researcher and a distinguished Academician with many awards of national and international repute including Dr B C Roy award. He was a renowned Gynaecologist and had earned a special place in the hearts of students and faculty.

REMEMBERING HIM WITH FOND REVERENCE



**KLE ACADEMY OF HIGHER EDUCATION AND
RESEARCH, BELAGAVI, KARNATAKA**

(Deemed-to-be- University)

Accredited at 'A+' Grade by NAAC (3rd Cycle) | Placed in Category 'A' by MoE (Govt)

KLE FAMILY



KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH (KAHER)

(Deemed-to-be-University U/S 3 and 12B of the UGC Act 1956)
Belagavi, Karnataka

The KLE Academy of Higher Education and Research was established as a “Deemed to be University” on 13th April 2006 and through its **11** constituent colleges, is imparting education in the disciplines of Medical, Dental, Pharmacy, Ayurveda, Homeopathy, Physiotherapy, Nursing Science and Allied Health Sciences. Within a short span of **18** years, it has emerged as one of the top providers of quality health sciences education. It has the unique distinction of being placed in category “A” by the Government of India (MHRD) and is accredited at the 'A+' Grade (3rd Cycle) by the NAAC with a CGPA score 3.39 of 4.0. The Expert Committee of the UGC has recommended continuation of the Deemed-to-be-University status.

It is a matter of pride that the KAHER has been ranked **69th** top university among all Indian Universities by the National Institutional Ranking Framework (NIRF) instituted by Ministry of Human Resource Development, Government of India. The KAHER campus has been ranked **3rd Cleanest Campus** in the '**SWACHHTA Ranking - 2018**' of Higher Educational Institutions in the category 'University' and the Certificate / Citation has been awarded by the Ministry for Human Resource Development, Government of India. The KAHER has been ranked **2nd** top University at the State Level under 'Established Universities' category by Karnataka State Universities Ranking Framework of Government of Karnataka. The University has been ranked **66th** by QS India Ranking-2020 and also figures in the Times Higher Education World Ranking in 301 to 400 band. The Ethics Committee of the KAHER on account of its high operational standards has the unique distinction of being one of the very few ethics committees in India to be accredited by both national and international accreditation agencies. By securing accreditation from National Board of Accreditation for Healthcare Providers and Hospitals (NABH), the ethics committee is now compliant with the regulatory requirements of the Drugs Controller General of India for implementing industry sponsored clinical trials in the constituent colleges. The Ethics Committee has also obtained accreditation from the Forum for Ethical Review Committees in the Asian and Western Pacific Region (FERCAP), affiliated to the World Health Organization.



The University believes in collaborations and working together and benefiting from each other strengths. The University has more than 30 active national and international collaboration. The university has laid strong foundation for research with more than 230 Collaborations and MoUs for joint research projects; many from international funding agencies from USA, Europe, Australia and Canada. The faculties in last five years have more than 3,000 publications, 38 patents / technology transfers in 2015-2020 to its credit. The University has partnerships with several district health organizations and is working with 26 PHC clusters and also with the District Health System in the management of Primary Health Centres and Urban Health Centres under the Public-Private Initiative as part of the National Health Mission. Apart from this, the University has two Basic Health Science Research Centres, Central Research Facility in Ayurveda College and APJ Abdul Kalam Ayurtech Department in Ayurveda College, Drug Testing Laboratory, etc.

The India Centre at Thomas Jefferson University: KAHER formalized an MOU with Thomas Jefferson University (TJU) of Philadelphia, USA, one of the oldest universities and currently ranked among the top Ten Universities in the US to build on the existing research collaboration. The enhanced association for collaborative research and educational program was formalized with the signing of the MOU during the visit of President Dr Stephen K. Klasko and Associate Provost for Global Affairs Dr Richard Derman to Belagavi on 10th July 2017. This MoU is intended to strengthen the academic and research collaboration in the areas of Population Health, Integrated Medicine and Urology. As part of the said collaboration **"India Centre"** has been setup at TJU. The first faculty-exchange visit was accomplished during November 2017.



Inauguration of India Centre at Thomas Jefferson University by signing of Official MoU.



The Academic and Research collaboration between KAHER and TJU in the areas of Public Health, Urology and Integrative Medicine commenced in July 2017 and has been expanded to include Neurology, Radiology, Neonatology, Psychiatry, Nursing and Physiotherapy. It involves faculty and student exchange in addition to development of research grants. As a part of the collaboration “India Centre” has been set up at TJU. The first faculty-exchange visit has also been accomplished during November 2017. Following this 5 student exchange programs have been successfully completed with **32 students of JNMC visiting TJU.**

The India Centre for Studies at Thomas Jefferson University was inaugurated at Philadelphia on 26 May 2022. The Honorable Indian Ambassador to the United States of America and the Consulate General were the Guests of Honor. The Study Centre is fostering the academic and research collaboration between KAHER and Thomas Jefferson University. It is one among the four centers being set up by TJU, the other three being Italy, Ireland and Israel.





JAWAHARLAL NEHRU MEDICAL COLLEGE

KLE Academy of Higher Education and Research, Belagavi

Jawaharlal Nehru Medical College (JNMC) was established in 1963 under the able guidance and mature foresight of the Founder Dean, Late **Dr B. S. Jirge** with a vision to be a centre of excellence in Medical Education, Research, and Health Care services. The institution today is ranked among the top twenty medical colleges in India and provides education in all the disciplines of Medicine and allied Health Sciences, in an environment supportive of scholarship, research, integrity, critical thinking and self-directed learning. It also provides community oriented health care to individuals and families.

KLE Society's Dr Prabhakar Kore Charitable Hospital and Dr Prabhakar Kore Hospital and Medical Research Centre with 1,400 and 1,000 bed capacities respectively are the epicentres of under graduate, post graduate and post-doctoral training for students of JNMC. The institution is also managing two Primary Health Centres at Kinaye and Vantamuri and Two Urban Health Centres at Ashok Nagar and Rukmini Nagar under the Public Private Partnership. These provide students the much-needed exposure to primary level health care delivery in addition to opportunities for community-based research programs. The college also runs a rural hospital - Dr Kamal Medical Centre, 150 Km away at Ankola, Satellite ICUs at Hubli, Gokak & Jamkhandi.

The sprawling 100-acre self-contained JNMC campus has excellent infrastructure and learning resources that collectively provide a stimulating and enjoyable learning ambience. The hostels accommodate over 2,000 boys and girls. Additional student amenities within the campus include banks, ATMs, Post office, Indoor and Outdoor Stadium, Olympic standard swimming pool, auditorium, Garden with Musical Fountains, Prayer places, co-op store, book shop, canteens, parlour etc. The campus is Wi-Fi enabled, eco-friendly- being free of mobile, vehicles and plastics. The campus also houses a state-of-art KLE Centenary Convention Centre designed as per international standards.

Department of Medical Education (DOME) was established in 1994 to cater to advances in education technology pertaining to health science and research. The Medical Council of India recognized DOME as Regional Training Centre in 2011, and upgraded it to Nodal Centre for Training in Medical Education Technologies in 2014. DOME conducts several programs viz. Basic and Advanced courses in Medical Education Technology (MET); UG, PG & Interns Orientation programs and foundation courses; Basic Life Support and Advanced Cardiac Life Support workshops for paramedical workers. JNMC also has the distinction of offering Super-specialty courses in 8 disciplines viz. DM. in Cardiology, Neurology & Cardiac Anaesthesia and M.Ch. in Cardio Thoracic and Vascular Surgery, Urology, Plastic Surgery, Neuro-surgery & Paediatric Surgery.

The Anatomy Museum at JNMC has a collection of over 300 dissected specimens and 1,000 carefully preserved models. The Pathology Museum is among the best in Asia and has 2,330 well displayed, catalogued specimens in semi-circular bays distributed into 12 different systems of human body. Dr S. G. Desai Central Library has a rich collection of over **1,11,589** Books, **464** Print Journals, subscribes to **1,000+** e-Journals (both national and international) and magazines related to health sciences. It subscribes to online journals, databases like Proquest, UpToDate, Clinical Key, Wiley online library, Dynamed, Science Direct, LWW, BMJ, Wiley, Jaypee digital, Springer books and Thieme MedOne through HELINET consortium of RGUHS, Bengaluru, which is having an access to full text Journals. The digital library also maintains Institutional repository and hosts many free access databases such as National Digital Library, DOAJ, PMC, BMC and Springer Open. The PhD theses are uploaded in Shodhganga.

The JNMC Scientific Society conducts fortnightly clinical meetings wherein interesting cases of different specialities are discussed to facilitate a widening of the perspective of clinicians and breaking the barriers between the specialities. An annual CME to update practicing family physicians has been a regular activity of the society for the last **42 years**. A scientific, peer reviewed and indexed quarterly journal that draws contributions from national and international experts is also being published for the last **51 years**.



KLES DR. PRABHAKAR KORE HOSPITAL & MEDICAL RESEARCH CENTRE, BELAGAVI

KLE Society forayed into healthcare in 1986 with the establishment of a hospital at Belagavi. The facility was first upgraded into a **1,000** beds hospital in 1996 and subsequently into a **2,400** beds Hospital including **1,400** beds in the charitable section, being one of the biggest hospitals in Asia. It is currently ranked at No. **14** among the Best Hospitals in India. Aptly named as Dr Prabhakar Kore Hospital and Medical Research Centre, this hospital is committed to the objective of providing world class healthcare facilities at affordable costs. Accomplishing a major paradigm shift, KLE has thus facilitated the provision of high-quality diagnostics and comprehensive healthcare in a non-metropolitan region and the hospital has emerged as a lifeline for people in the region of North Karnataka, South Maharashtra and Goa.

The hospital set in a sprawling **16-acre** campus has basic specialties such as General Medicine, General Surgery, Orthopaedics, Ear Nose and Throat (ENT), Obstetrics & Gynaecology, Ophthalmology, Paediatrics, Dermatology, Respiratory Medicine, Psychiatry, etc. In addition, the hospital also offers super-speciality services in the disciplines of Cardiology, Cardiovascular and Thoracic Surgery, Urology, Nephrology, Neurology, Neuro-Surgery, Laparoscopic Surgery, Paediatric Surgery, Plastic & Reconstructive Surgery, Neonatology, Gastroenterology, Oncology, Surgical Oncology, Diabetology, Geriatrics, Assisted Reproduction Centre and Nuclear Medicine. The hospital is also equipped for 'Multi-Organ-Transplant Programme' that includes Kidney, Heart, Liver & Pancreas, Bone-Marrow (Benign), Cornea, Skin Bank & transplant. Hospital has treated more than **1,23,00,000** Out-patients; **11,07,000** In-patients and **3,15,000** surgeries along with a total of 1,050 health camps organized over a span of 28 years.



KLES Heart Foundation at the hospital has the credit of performing over **23,000** Bypass Surgeries and nearly 88,340 Cardiac Catheterization procedures since 1997. The 'First ever' Heart Transplant Surgery in North Karnataka was successfully carried out by team of Cardiovascular & Thoracic Surgeons the Hospital on 20th February, 2018. Following this **8** Successful Heart Transplant have been performed till September 2022 which is indeed phenomenal. KLES Kidney Foundation has performed over **61,280** surgeries including about **60** Kidney Transplants successfully. KLES Diabetes Centre stood among top **40** centres of India for creating awareness about Diabetes through various initiatives during the year 2017. KLES Vaccine Advocacy Centre is India's First Unit of Vaccine Advocacy forum (VAF - India) which undertakes vaccinations for the adults.

The clinical services are comprehensively supported by the state-of-the-art diagnostic and support facilities such as CT scan, MRI Scan, PET Scan, 'C' Arm with Image Intensifier, 800 mA X-ray machine, various endoscopes, Ultra-sonography, etc. A Gamma Camera is exclusively functioning for scanning thyroid gland, brain, bone and related studies. Hospital's Hitech Laboratory is accredited by National Accreditation Board for Laboratories (NABL). The Hospital has a modernized Blood Bank which has obtained the status of '**Regional Blood Bank**'.

KLES Dr. Prabhakar Kore Charitable Hospital

KLES Dr Prabhakar Kore Charitable Hospital is a teaching hospital attached to Jawaharlal Nehru Medical College. It is equipped with 1,700 beds and offers completely free health care services including stay, food, basic investigations and medicines to the needy patients, in all basic specialities. The JNMC medical faculty are a part of the professional staff that augment the healthcare services and also synergise the hospital activities. Thus, the healthcare services in this hospital are backed by a perfect blend of academics professionals, skilled and experienced doctors and trained support staff. The emphasis of the institution is on providing high quality services to the poor and needy by providing access to state of the art facilities and infrastructure.





DR. PRABHAKAR KORE BASIC SCIENCE RESEARCH CENTRE

KLE Academy of Higher Education and Research, Belagavi

KAHER's Dr. Prabhakar Kore Basic Science Research Centre, Belagavi with a built-up area of **10,000 sq. ft.** was established in 2012 with an aim to be a centre of excellence both in the basic research and in training and to nurture a multidisciplinary research team. The centre is dedicated to basic research and educational activities in various fields of health science disciplines at national and international level in Biopharmaceutics and Pharmaceutical Analysis, Microbiology, Molecular Biology, Cell Culture and Natural Product Research. Through technical knowledge acquired from vastly experienced and dedicated staff; the research centre is set with most modern equipments, where you will find the opportunities to be exceptional.

The Biopharmaceutics and Pharmaceutical Analysis laboratory is equipped with multiple instrumental techniques for quantitative and qualitative estimation of test samples, diffusion, dissolution and viscosity studies along with elemental analysis capabilities. The laboratory has remote access through LAN facility for each analytical instrument. The Natural Product Laboratory is providing a platform for exploratory



studies pertaining to the potential of the wide bio-diversity in India especially in context of drug development. The Molecular Biology Laboratory is equipped with instruments like PCR, Real Time PCR and Multiplex PCR techniques that are widely used in molecular research for genetic analysis, medical diagnostics, and forensic applications. The Medical Microbiology Laboratory has facilities for both aerobic and anaerobic culture, identification, characterization and preservations of various pathogens. Major focus is on different oral pathogens responsible for causing dental cavities, gingivitis, gum diseases and oral cancer. Another important aspect of studies undertaken is to determine the antimicrobial activity of various extracts on oral pathogens. Cell culture facility empowers the individuals for biocompatibility and anticancer effects of samples/drugs.

The center has published 116 research articles having cumulative impact factor 152.152 and 11 books / chapters since its inception. The center has produced 14 PhDs and presently 16 doctoral students are pursuing research at the BSRC.

In addition to the research activities, a Post Graduate programme [M.Sc. - Biotechnology] was started in 2018 at the research center under the faculty of Allied Sciences, J. N. Medical College, KAHER-Belagavi. The aim of the PG programme is to nurture, cultivate, promote biological scientists and create an ecosystem for innovation that enables development of technologies of social relevance.





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ICMR Centre for Clinical Trials

Jawaharlal Nehru Medical College (JNMC), Belagavi was designated as a site of Human Reproduction Research Collaborating Centre(HRRC) of Indian Council of Medical Research (ICMR) in 1984. The objectives were to strengthen the institutes for Implementing multi-center ICMR Research Protocols, Train Health Care Providers to support Health Care Delivery System in rural India and Train Health Professionals in Human Subjects Research. Since then research related to reproductive health became a part of academic activities at JNMC. With the establishment of Department of Medical Education (DOME) in January 1994 gave a newer perspective towards the scope of medical education and expanded the horizons.

In 1995, Workshop on Research Methodology for the faculty was conducted at JNMC in collaboration with ICMR & CONRAD University, USA by the Trainers from Centre of Disease Control (CDC), Atlanta, USA.

In February **1999**, an academic collaboration was established between JNMC and University of Illinois at Chicago (UIC), USA with the objective of strengthening Medical Education as well as to develop research capacity and clinical care services in Maternal and Child Health. As a part of this collaboration, a team of faculty visited UIC which further led to a series of faculty exchange program later. This strengthened the research culture and also laid a strong foundation for developing medical education technologies well ahead of many medical institutes in India.



The National Institute of Child Health and Human Development of the National Institutes of Health, USA for the first time ever formed a **Global Network for Women's and Children's Health Research** in the year **2001** to expand scientific knowledge, develop sustainable research infrastructures, and improve health outcomes for pregnant women and young children in developing countries by implementing community based research studies and accelerate the achievement of Millennium Development Goal 3 & 4 (and the present Sustainable Development Goal 3) to ensure healthy lives and promote well-being of mothers and children in low-and-middle income countries across Asia, Africa and Latin America. The initiative was generously supported by the Bill & Melinda Gates Foundation. In response to this initiative, JNMC, in collaboration with UIC, submitted a research proposal for funding and was selected as one of the original ten sites in the network from India, Pakistan, Tibet, Zambia, Democratic Republic of Congo, Argentina, Uruguay, Brazil, and Guatemala for the initial five years of funding. **JNMC is the only private institution to receive this research grant.** Realizing the Global Network mandate, JNMC established a **Women's and Children's Health Research Unit** in **2001**.



The Women's and Children's Health Research Unit of Jawaharlal Nehru Medical College of KLE Academy of Higher Education and Research (KAHER) (Deemed-to-be-University) has been conducting Community-Oriented Research activities aimed at decreasing maternal and child mortality since 2001. Over the past twenty years, JNMC's multi-disciplinary research team has conducted a number of community / hospital based research projects in collaboration with **27** international Universities and Research Institutes from USA, UK, Canada, South Africa, Australia, Uganda, Zambia and Argentina and **25** Medical Institutes, Universities and Research Institutes in India with funding support from World Health Organization, Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) Global Network for Women's and Children's Health Research, other NIH agencies, Bill & Melinda Gates Foundation (BMGF). The Children's Investment Fund Foundation (CIFF), American Academy of Pediatrics (AAP), Gynuity Health Projects, Thrasher Research Fund, Grand Challenges Canada, Department of Biotechnology (DBT) Govt. of India and the UK Medical Research Council (MRC). The results of these insightful research studies have had a profound impact at national and international levels in shaping public health policies. Till now Research Unit conducted more than 50 trials sponsored by various agencies and published more than **270** research articles out of these trials.



Dr Richard Derman, Associate Provost, Golbal Affairs, TJU, USA being felicitated at KLE Centenary Celebration by Mr. Nithin Gadkari, Union Minister for Road Transport and National Highways, Padma Shri Sudha Murthy, Chairman of Infosys Foundation and Dr Prabhakar Kore, Hon. Chairman KLE Society and Chancellor KAHER]

The Research Unit has been funded by **National Institute of Child Health and Human Development (NICHD) Global Network** since the inception of the network in 2001. Based on its commendable performance during the first cycle, the 'Research Unit' gained recognition as **one of the six among the ten sites** to be re-funded for fourth cycle of five years until 2023 and this has been further continued in the **Fifth Consecutive Cycle** of funding until 2030.



 Women's and Children's Health Research Unit Jawaharlal Nehru Medical College KLE Academy of Higher Education and Research <small>(Deemed-to-be-University U/S 3 and 12 B of the UGC Act 1956)</small> Belagavi Karnataka India			
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Dr Roopa M Bellad, MD Professor of Pediatrics		Dr Anita Dalal, MD Professor of Obstetrics and Gynecology	
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Dr Uday Wali, PhD Advisor, IT and Data Management Activities		Dr Amaresh Patil, MD Project Coordinator	
Dr Rajan Patil, PhD Professor of Epidemiology		Dr Bhushan Kulkarni, PhD Scientist Grade II, Biotechnology	
Dr Deepthy M S, PhD Research Scientist and Biostatistician		Dr Varsha Dhurde, PhD Nutrition Specialist	
Dr Ashwini Dandappannavar, PhD Medical Anthropologist		Mrs Sanyukta Patil, MSc Clinical Biochemistry	
Ms Kiran Nadgauda, MPT Pediatric Physiotherapy		Ms Harsha Behura, MPT Pediatric Physiotherapy	

The Women's and Children's Health Research Unit, Jawaharlal Nehru Medical College, KLE Academy of Higher Education and Research, Belagavi has been designated as a "WHO Collaborating Center for Research in Maternal and Perinatal Health" since **September 16, 2019** and based on its credentials and commendable work the designation of WHO-CC, has been further **extended for second cycle through August 2027**.



JNMC Women's and Children's Health Research Unit has received a unique distinction as **ICMR Center for Clinical Trials (ICCT)** w.e.f December 28, 2021. This is a part of the "**Indian Clinical Trial & Education Network (INTENT)**" launched by **Indian Council of Medical Research (ICMR)** and **Department of Health Research (DHR)** for a period of five years. The goal of INTENT is to enable, foster, and enrich clinical research by providing a platform for high-quality evidence generation through conduct of clinical trials, which will guide policy decisions regarding diseases and health problems of national and regional priority for India. Through this network, multi-centre Randomized Controlled Trials (RCTs) will be conducted across all levels of healthcare such as primary, secondary, and tertiary level, as well as community-based trials that can be pragmatic and would aid in answering the real-world clinical questions with wider generalizability of the findings.

In the pursuit of achieving higher accolades, the Women's and Children's Health Research Unit received a unique distinction as "**Indian Council of Medical Research (ICMR)- Collaborating Centre of Excellence**" in recognition for the unit's contribution to Biomedical Research w.e.f. September 1, 2023 and valid for five years till August 31, 2028. JNMC Research Unit was among the total of 128 applicants and the 25 institutes selected for this unique recognition. It is one among 3 institutes in the state of Karnataka to have gained this unique distinction. This ICMR Collaborating Centre of Excellence is modelled on the WHO Collaborating Centres concept with a goal to enable, foster, and enrich clinical research by providing a platform for high-quality evidence generation through conduct of clinical trials, which will guide policy decisions regarding diseases and health problems of national and regional priority for India.



Dr S S Goudar and Dr S M Dhaded receiving 'ICMR Collaborating Centre of Excellence'
 Recognition award by
 Dr Rajiv Bahl, Secretary to Government of India, Department of Health Research &
 Director - General, Indian Council of Medical Research at ICMR Headquarters, New Delhi



In addition, recently the research unit has received funding award **"Centre for Research Excellence"** with grant proposal **"Accelerating Research and Progress in Maternal & Newborn Health Centre for Research Excellence"** (ARPAN CRE) from October 2023 for a period of five years through **September 2028** from **National Health and Medical Research Council (NHMRC), Govt. of Australia.**

The Women's and Children's Health Research Unit is the 'ONLY CENTRE IN INDIA' with distinguished Recognitions from ICMR-DHR (GoI), WHO, NICHD-USA and NHMRC-Australia and, it is indeed a 'Unique Research Centre of Excellence' in the field of Women's and Children's Health Research.

The Research Unit has built a strong Public Private Partnership with the District Health Administration of the Belagavi, Bagalkot, Vijayapura, Davanagere, Dharwad-Hubballi, Gadag, Ballari and Raichur districts of Karnataka and Cuttack and Balasore districts of Odisha, Jaipur district of Rajasthan for implementing community / hospital-based interventions. Over the years, in Karnataka itself, the Research Unit has served a population of over 20 lakhs people residing in over 800 villages spread over twenty-three talukas of Belagavi, Bagalkot, Vijayapura, Davanagere, Dharwad-Hubballi, Gadag, Ballari and Raichur districts. This population is served by **116** Primary Health Centers, **15** Taluka Hospitals, **4** District Hospitals, **131** Private Hospitals and Clinics and **20** Academic Tertiary Care Centers. **1,995** Health Care Providers and health workers in these facilities have been trained for ethical conduct of research and data collection. It may be noted that Mothers and Newborns in these areas have been provided treatment free of cost as and when needed.

Currently the total number of staff working in various projects at different centers under Women's and Children's Health Research Unit is **2,260** viz. Faculty **140**, Research Officers **46**, Health Care Providers including Medical Officers and Research Nurses **471**, Other Health Care Workers **1,524** and Office Support Staff **79**.

When we look back our journey so far of nearly 4 decades, since the establishment of ICMR-HRRC, Partnering with NICHD Global Network till being designated as WHO Collaborating Centre and ICMR Collaborating Centre of Excellence, there has been a tremendous growth in terms of infrastructure, research capacity building and Women's and Children's Health Research Unit is recognised globally and most favoured site for the implementation of multi country, multisite research protocols both nationally as well as internationally. In addition to this many independent principal investigators have generated many grants which clearly aligns with the initial objectives building sustainable research capacity at institute and have continued nurturing many investigators for ethical conduct of Human Subjects Research.



Global



India



Karnataka

Research Priorities

1. Surveillance System

– Maternal Newborn Health Registry (MNHR)

2. Maternal Health

– Postpartum Hemorrhage (PPH)

- Hypertensive Disorders of Pregnancy (HDP)
- Maternal Nutrition
- Pregnancy Anaemia
- Tobacco use during pregnancy
- Optimizing Intrapartum care during labour
- Maternal Sepsis
- Cervical Cancer
- Prediction of High-risk Pregnancy
- Maternal Mental Health

3. Newborn Health

– Birth Asphyxia

- Preterm Birth
- Still Birth
- Infant Neurodevelopment
- Breastfeeding Support
- Infant Nutrition
- Newborn Sepsis
- Understanding adverse outcomes of pregnancy

4. Health System Strengthening

– Emergency Obstetric and Neonatal Care (EmONC)

- Safe Childbirth Checklist

5. Impact of COVID-19 on Maternal and Neonatal Health

- Clinical Outcomes of COVID-19 in Pregnancy and Perinatal Health

Maternal Newborn Health Registry

The '**Maternal Newborn Health Registry (MNHR)**' an essential component of the Global Network, is a prospective, population-based observational study to quantify trends in pregnancy outcomes, including stillbirths and neonatal and maternal mortality rates, in geographically defined low-resource areas. It has operated since 2008, enrolling all pregnant women residing in defined study clusters and tracking birth outcomes through 6 weeks post-delivery. As a part of registry, annual household survey is undertaken and all the eligible couples and Likely-to-Conceive women enlisted at every village level. They are being tracked by Accredited Social Health Activist (ASHA) and Registry Administrators (RAs) every month for early identification of the pregnancy and subsequent enrolment. This unique systematic tracking has been the baseline for many research protocols targeted to test the interventions for reducing maternal and newborn morbidity and mortality. The network's registry has the data of nearly 8,56,700 maternal and neonatal outcomes and Belagavi site has contributed more than 23% of the data with 1,92,600 outcomes as on April 2024. The registry data has contributed to many publications describing the epidemiology of maternal and newborn health in LMICs.

The MNH Registry created an opportunity to understand many aspects related to maternal and perinatal health. The pregnancy outcomes of many community-based trials were collected based on this registry viz. EmONC, ACT, Women First and ASPIRIN Trials. In addition to these, many prospective sub-studies were undertaken within the registry. Assessment of the Maternal Near Miss Events; Ultrasonography dating for assessment of Gestational Age; Socio-economic Status and its impact on the Maternal and Neonatal Health, Indications for Caesarean Section (LSCS) in LMIC countries, COVID-19 and Pregnancy outcomes and Screening for Maternal Post-partum Depression Study.

Impact: The unique system of identification of likely-to-conceive aiding early identification and tracking the pregnant women along with projecting the number of pregnant women to be enrolled in the registry was later adopted with essential modification by the Government of Karnataka and was implemented across the state as "Reproductive and Child Health Register (Village wise)". This system further strengthened Maternal and Child Tracking System.



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Research Studies Related to Maternal Health

Postpartum Haemorrhage

The first research project launched by the research unit was the community-based first ever placebo controlled, “Randomized controlled Trial of Oral Misoprostol for prevention of Postpartum Haemorrhage in women delivering at homes or sub-centres of four Primary Health Centre Areas of Belagavi District”.

Misoprostol is now endorsed by the Government of India for community level prevention of postpartum bleeding. The Belagavi site was the first GN site to initiate and complete data collection for the primary trial from September 2002 to December 2005. The primary publication arising from this trial was published in the October 7, 2006 issue of ‘The Lancet’. Belagavi site was the ‘First’ site to publish the research work among the NICHD Global Network Sites.



The skill of birth attendants in conducting delivery and management of the immediate postpartum period is a critical factor in determining the extent of blood loss after childbirth. Following the successful implementation of the Misoprostol trial, JNMC was identified by **World Health Organization** and the **Ministry of Health, Govt. of India** as nodal centre to develop modules for training Medical Officers and Auxiliary Nurse Midwives as well as the faculty of medical colleges in Karnataka in “**Skilled Birth Attendance**”. The trained faculty in turn has trained the Medical Officers working at 24 x 7 Primary Health Centers within their district. JNMC was entrusted with the responsibility of training Medical Officers of Belagavi District. The project was completed in December 2007.



In a project implemented during May 2003-April 2004, the 'Research Unit' developed a unique under-buttock blood collection drape with a calibrated receptacle for measuring postpartum blood loss for the Misoprostol trial. The BRASSS-V drape being more accurate than visual estimation of blood loss has particular utility for prompt detection of PPH and aids reduction of maternal morbidity and mortality in low resource settings. The drape, acknowledged by the international research community as a valid tool for measurement of postpartum blood loss, has been used in over 20 countries for measuring blood loss in over 2,00,000 women.

JNMC Research Unit conducted a subsequent Misoprostol trial **"Two community strategies comparing use of Misoprostol for early treatment/secondary prevention to primary prevention for postpartum haemorrhage: a randomized cluster non-inferiority study in Bijapur district, Karnataka, India"** in collaboration with Gynuity Health Projects, New York, USA, University of Illinois at Chicago, and University of California at San Francisco with funding from Bill & Melinda Gates Foundation, USA during January 2011 to August 2013. BLDE Deemed University's Sri B. M. Patil Medical College, Bijapur, India was the implementing partner for the study.

Impact: This study provided the critical evidence for the inclusion of Misoprostol on the **'World Health Organization's List of Essential Medicines'** for prevention of postpartum haemorrhage and stronger advocacy of Misoprostol for PPH prevention by the **'United Nation's Commission on Life-saving commodities for Maternal Health'**. It also prompted expansion of the registration and use of Misoprostol for prevention of postpartum bleeding, by the Ministries of Health of **26 countries**.



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Active Management of the Third Stage of Labour (AMTSL) reduces the occurrence of severe postpartum haemorrhage by approximately 60-70%. Controlled cord traction is one of those components of AMTSL which if implemented efficiently through proper training would have major implications for effective management of the third stage of labour at peripheral levels of health care. The World Health Organization took the initiative to address this important public health issue through the **“Active Management of the Third Stage of Labour without Controlled Cord Traction: A Randomized Non-Inferiority Controlled Trial”**. This hospital-based, multi-centre, individually randomized controlled trial, recruited 25,000 women delivering vaginally in health facilities in eight countries - Argentina, Egypt, India (JNMC), Kenya, Philippines, South Africa, Thailand and Uganda. Of these, the India site at J N Medical College, Belagavi enrolled 3,000 women at the affiliated KLES Dr Prabhakar Kore Hospital & Medical Research Center and the Primary Health Centers – **Kinaye** and **Handiganur**. The findings of this trial suggested that the control cord traction could be safely omitted from the bundle of AMTSL.

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Pursuing the quest for an “ideal uterotonic” in the prevention of PPH, one that matches the efficacy of Oxytocin but that is not heat labile, a **CHAMPION Trial** sponsored by the Department of Reproductive Health & Research, World Health Organization, Geneva, in partnership with Merck for Mothers was conducted between 2014 to 2017. The clinical trial **“A phase III, randomized, double- blind, active, controlled, multinational, multi-center, non-inferiority trial using carbetocin room temperature stable (RTS) for the prevention of postpartum haemorrhage during the third stage of labour in women delivering vaginally”** was designed to evaluate a new, proprietary heat stable formulation of Carbetocin. The Belagavi Research Unit and researchers from a total of **12** countries recruited nearly **30,000** subjects for a randomized trial conducted independently by WHO as part of its maternal and perinatal health research program (HRP) for the prevention and treatment of leading causes of maternal mortality. Notably, Belagavi site led the trial in **6** centers spread across different regions of India and contributed nearly a quarter of the total sample size to the trial. The results suggested that heat-stable carbetocin was non-inferior to oxytocin for the prevention of blood loss of at least **500** ml or the use of additional uterotonic agents.





Impact: This landmark trial drew the attention of global community as a result of which the **British Broadcasting Corporation (BBC)** provided a platform to discuss the salient features of the trial results. The results of this trial necessitated the updating of **WHO recommendations Uterotonics for Prevention of Postpartum Haemorrhage** in December 2018. This was also approved by Drug Controller General (India) (DCGI). As a result of this trial and favourable recommendation by WHO, The Ferring Pharmaceutical came up with a product Carbetocin Ferring (Carbetocin Injection 100 mcg/ml). The Global Launch of the product was done at KLES Dr Prabhakar Kore Hospital and Medical Research Centre, Belagavi on July 23, 2021.



RTS Carbetocin Ferring Global Launch July 23, 2021 at Belagavi





In order to assess the efficacy of Heat stable Carbetocin for the treatment of PPH, **“Heat-stable carbetocin for the treatment of postpartum haemorrhage: a phase III, randomized, double-blind, active controlled, multicountry, multicentre, non-inferiority trial” (WHO REACH)** has been initiated in Argentina, India, Kenya, Nigeria, South Africa, Uganda, and United Kingdom. The primary objective is to evaluate whether heat-stable carbetocin (HSC) is non-inferior to oxytocin for treatment of postpartum haemorrhage (PPH) in women who receive HSC for PPH prophylaxis, in the prevention of additional blood loss of 500 ml or more and to (i) evaluate the comparative effects of HSC versus oxytocin on haemodynamic outcomes when used for PPH treatment in women receiving HSC for prophylaxis; and (ii) evaluate the cost effectiveness of the PPH treatment with HSC compared to PPH treatment with oxytocin, if HSC is proven non-inferior. Participating women will be randomized to receive either intravenous HSC or oxytocin as the ‘first-line’ uterotonic for PPH treatment. Total sample size is 6,200 women with PPH following a vaginal birth, including the first 250 women enrolled for the safety component of the trial. JNMC is the lead site for implementing the trial at the various sites across the country viz. VIMS Ballari-Karnataka, SCB Medical College Cuttack-Odisha, MGIMS Wardha-Maharashtra, PGIMER Chandigarh and IMS-BHU Varanasi- Uttar Pradesh. The pilot phase has begun from March 2024. The trial is funded by UNDP-UNFPA-UNICEF-WHO-World Bank Special Programme of Research, Development and Research Training in Human Reproduction (HRP).

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Hypertensive Disorders of Pregnancy

The JNMC research team in collaboration with S Nijalingappa Medical College, Bagalkot and University of British Columbia, Vancouver, Canada is engaged in implementing a series of studies at Belagavi and Bagalkot districts; collectively referred to as the 'Community Level Interventions for Pre-Eclampsia (CLIP)' as part of PRE-EMPT initiative of the Bill & Melinda Gates Foundation. CLIP Trials included a study to determine baseline rates of preeclampsia in Karnataka State, an assessment of community health worker knowledge and management of preeclampsia, and a community-based cluster randomized controlled trial (RCT) to determine if a community-based package of care for women with hypertensive disorders of pregnancy can improve maternal and neonatal outcomes. Dr Prabhakar Kore, Chancellor of KLE University and Chairman, KLE Society inaugurated the research project in Delhi on November 12, 2013. More than 100 leading public health researchers in the area of maternal health from **13** countries including the representatives of WHO, Geneva and ICMR, New Delhi attended. The CLIP definitive Trail was conducted from November 2014 to October 2016. Though the study interventions together did not actually reduce the maternal and perinatal adverse outcomes, the study proved that addressing triage, initial treatment, and transport of women with pregnancy hypertension can be successfully performed by ASHAs and ANMs at primary care level. Additionally, community-only focus without facility enhancement is unlikely to yield improvements in maternal and perinatal outcomes.



Field implementation of Android app for guiding management of Pre-Eclampsia/Eclampsia





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Microlife CRADLE, a semi-automated device that was used in the CLIP Trial for detection of hypertension wastested in rural Africa and within India by the JNMC and King's College, London collaborative research team to further develop the device as an accurate and low-cost means to improve antenatal detection of pre-eclampsia as well as hypotension associated with postpartum haemorrhage and sepsis. The trial '**CRADLE 3 (Community Blood Pressure Measurement in Rural Africa and Asia: the Detection of Underlying Pre-eclampsia and Shock) Stepped-Wedge Randomised Control Trial**' in India was co-funded by the United Kingdom Medical Research Council and the Government of India, Department of Biotechnology.



Impact: Notably, the India CRADLE trial received the first ever **Newton Prize** for excellent research and innovation in support of economic development and social welfare in Newton Fund partner countries. This device was one of 30 (among 500) high impact innovations to save lives Reimagining Global Health, Innovation Countdown 2030 initiative.

***Recipient of the 1st ever
Newton Prize, which
carries a grant of
£2,00,000, recognizes
excellent research and
innovation in support of
economic development
and social welfare in
Newton Fund partner countries.***



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1. Beardmore-Gray A, Vousden N, Silverio SA, Charantimath U, Katageri G, Bellad M, Chinkoyo S, Vwalika B, Goudar S, Sandall J, Chappell LC, Shennan AH. Planned early delivery for late preterm pre-eclampsia in a low- and middle-income setting: a feasibility study. *Reprod Health*. 2021 Jun 2;18(1):110.
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A research grant was awarded to Kings College London and Women's and Children's Health Unit, JNMC, Belagavi from Newton Prize, Department for Business, Energy, and Industrial strategy for a collaborative project - **Vital Signs Alert Evaluating Shock Index in Pregnancy Anaemia (VeSPA)** to assess the correlation between shock index and anaemia and evaluate the utility of CRADLE VSA device to detect anaemia earlier in pregnancy. This was implemented at KLES Dr Prabhakar Kore Hospital and Medical Research Centre, Belagavi for a period of one-year 2018-19.

The CRADLE-4 Trial: Planned early delivery versus expectant management to reduce adverse pregnancy outcomes in pre-eclampsia in a low and middle-income setting has been initiated in 2019 to evaluate the intervention to reduce maternal mortality and morbidity based on a composite of outcomes during pregnancy and delivery, until primary hospital discharge and the impact of the intervention on short term neonatal outcomes in India (Belagavi, Bagalkot, Vijayapura and Hubballi) and Zambia. The study was completed in 2022.



Publication:

Beardmore-Gray A, Vousden N, Charantimath U, Katageri G, Bellad M, Kapembwa K, Chinkoyo S, Vwalika B, Clark M, Hunter R, Seed P, Goudar S, Chappell LC, Shennan A. Planned early delivery versus expectant management to reduce adverse pregnancy outcomes in pre-eclampsia in a low- and middle income setting: study protocol for a randomised controlled trial (CRADLE-4 Trial). *Trials*. 2020 Nov 23;21(1):960. doi: 10.1186/s13063-020-04888-w. PMID: 33228794

Simplified Treatment for Eclampsia Prevention using Magnesium sulfate: A phase III, randomized, open label, active controlled, multicountry, multicentre, non-inferiority trial of simplified magnesium sulfate regimen for eclampsia prophylaxis (The STEP-Mag Trial) is being implemented to evaluate the non inferiority of a simplified magnesium sulfate regimen [10 g intramuscular (IM) 12 hourly x 2 doses] compared with a standard magnesium sulfate regimen [either 4g intravenous (IV) loading dose, followed by a maintenance dose of 1g/hour until 24 hours ("Zuspan regimen") or 4g IV plus 10 g IM loading dose, followed by 5 g IM 4 hourly until 24 hours ("Pritchard regimen")] for the prevention of maternal eclamptic seizure. Additionally, the secondary objective of this trial is to evaluate superiority of magnesium sulfate 10g IM administered 12 hourly x 2 doses compared with a standard IV (Zuspan) or IM (Pritchard) magnesium sulfate regimen in the proportion of women experiencing adverse events indicative of magnesium toxicity. This study is being implemented at tertiary Medical Institutes at Davanagere, Raichur(Karnataka), Cuttack (Odisha) sponsored by Department of Reproductive Health & Research, World Health Organization, Geneva. The recruitment began by November 2022 and completed in April 2024. Global Trial centres include 8 low- and middle-income countries: Egypt, India, Kenya, Malawi, Nigeria, Rwanda, South Africa, and Uganda. This study is being implemented at tertiary Medical Institutes at Davanagere, Raichur, Gadag (Karnataka) and Cuttack (Odisha) sponsored by Department of Reproductive Health & Research, World Health Organization, Geneva. The recruitment was started in November 2022. Total sample size is 12,000 women, including 2,400 women for internal pilot. Currently, the recruitment of participants for the internal pilot phase which includes 792 participants from Indian sites has been completed and underway at the remaining sites.



Visit of Dr Soumya Swaminathan Director General of the Indian Council of Medical Research (ICMR) and Secretary of the Department of Health Research (Ministry of Health & Family Welfare) Government of India June 20, 2017

Maternal Nutrition

Nutritional deficiency poses the greatest challenge to early infant growth and development. Many strategies have been undertaken to address the widespread nutritional deficiencies of zinc and iron in older infants and toddlers. Sprinkles™ are a form of micronutrient supplement which is added to foods prepared in the home at the time of consumption; the micronutrient composition typically provides iron, zinc, and varying types and amounts of other micronutrients. To inform the choice of doses of zinc and iron in Sprinkles™ the research unit implemented a trial **"A Comparison of Two Iron Doses on Zinc Absorption from Sprinkles as Micronutrient Supplement"**.

The Global Network partnership between the University of Colorado, Denver and Guatemala site developed a trial "Women First: Pre-conception Maternal Nutrition Trial" to assess the benefits to the offspring of ensuring optimal maternal nutrition using micro and macro nutrient supplementation prior to conception compared to initiating the same supplementation beginning at 13 weeks of pregnancy and to providing pregnant women only standard of care without nutritional intervention. A second study phase is now active and designed to assess growth and development of offspring at various age intervals up to 24 months. Four Global Network sites (Belagavi, India; Guatemala; the Democratic Republic of the Congo; and Pakistan) have participated in this study funded by the Bill & Melinda Gates Foundation. The results suggested that in resource-poor rural or semi-rural populations in which there is a high prevalence of stunting, fetal growth was improved with maternal nutrition supplements commenced either before conception or late in the first trimester and provided to women irrespective of their own nutritional status.





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JNMC Research Unit was involved in the conduct of study on **“Zinc and Iron bioavailability from bio-fortified pearl millet”** in collaboration with University of Colorado Health Sciences Center, USA and sponsored by International Atomic Energy Agency, Vienna. The results demonstrated that quantities of both iron and zinc absorbed when iron and zinc bio-fortified pearl millet is fed to children aged 2 years as the major staple food, is more than adequate to meet the physiological requirements for these micronutrients.



Publication:

Kodkany BS, Bellad RM, Mahantshetti NS, Westcott JE, Krebs NF, Kemp JF, Hambidge KM. "Biofortification of Pearl Millet with Iron and Zinc in a Randomized Controlled Trial Increases Absorption of These Minerals above Physiologic Requirements in Young Children". J Nutr. 2013 Aug 7. PMID: 23843474

Pregnancy Anaemia

Anemia is a worldwide problem with iron deficiency being the most common cause. When occurring in pregnancy, anemia increases the risk of adverse maternal, fetal and neonatal outcomes, including maternal mortality, preterm and low birth weight (LBW) deliveries, perinatal and neonatal deaths, and long-term developmental sequelae in the surviving offspring. For close to 40 years, India's first-level treatment for anemia in pregnancy has been oral iron; however, side effects, poor adherence and low therapeutic impact are among reasons for consideration of a new paradigm for treatment of pregnant women with iron deficiency anemia. The Government of India has given high priority to reducing the prevalence of anemia in India, and several initiatives have been directed at this objective. The latest anemia strategy, built on prior strategies and supported by the Ministry of Health and Family Welfare, was presented in a 2018 publication, Anemia Mukht Bharat-Intensified National Iron Plus Initiative.



Realizing this need, **Reducing Anemia in Pregnancy in India: the RAPIDIRON Trial** was implemented in collaboration with Thomas Jefferson University, Philadelphia USA with J. N. Medical College, Belagavi , and S. M. S. Medical College, Jaipur, S N Medical College Bagalkote and RIMS Raichur being implementing partners. Enrolment was initiated from March 15, 2021 at Belagavi, Bagalkot and Raichur Districts of Karnataka and Jaipur District of Rajasthan and completed recruitment and follow up in February 2024. This study, a 3-arm, randomized-controlled trial designed to assess if a single dose of an intravenous (IV) iron formulation (Ferric Carboxymaltose in intervention arm 1 or Iron Isomaltoside, also known by the international non-proprietary name of Ferric Derisomaltose, in intervention arm 2), administered early in the second trimester of pregnancy for treatment of moderate iron deficiency anemia (IDA), will result in a greater percentage of pregnant participants in the IV iron arms achieving a normal for pregnancy Hb concentration of >11 g/dL in the third trimester at either a 30-34 week antenatal visit or based on blood collected prior to delivery when compared to the percentage of participants randomized to an active, comparator arm (arm 3) provided oral iron. Low birth weight (<2500 grams), one of several adverse pregnancy outcomes associated with IDA, is the other primary outcome. Across all the sites 50,466 women were screened and 4368 women were randomized; 4165 participants completed the follow up at 42 days (95.4%). Data analysis for the primary outcome has been completed and the primary result publication is underway.

As a follow up of this study, an additional component **RAPIDIRON KIDS Neurodevelopment Assessment**

funded by CIFF and **RAPIDIRON Neuroimaging Study** funded by BMGF have been initiated to assess the impact of the iron in infant neurodevelopment. This will be performed using the standard assessment for neuro-cognitive-language and motor skills at 24 months age. The RAPIDIRON KIDS Study has been initiated in October 2022. As on May 2024, total consented for the study are 538. 78% of children have completed 12 month visit. Two-year follow-up visit will start from August 2024. Similarly, RAPIDIRON Neuroimaging Study has been initiated in February 2023 in Belagavi is the only site. Total enrolment is 184 which include antenatal fetal MRI completed among 49 participants and 134 infant MRI will be done at 4, 12 and 24 months

Publications:

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Interventions addressing Postpartum Anemia: It is important to address other periods, particularly immediately after delivery when maternal hemoglobin values often drop precipitously. An intravenous (IV) iron infusion has been demonstrated to be a safe, effective intervention to reduce anemia during pregnancy but has not been adequately assessed during the postpartum period. Thus, this trial, **“Postpartum IV Iron to Treat Iron-Deficiency Anemia (PRIORITY Trial) A Randomized Controlled Trial of the Global Network for Women’s and Children’s Health Research”**, will determine if a single-dose intravenous (IV) infusion of iron is a more effective means of increasing prevalence of non-anemia than standard of care of oral iron (folate will be given to all participants as per local guidelines) among postpartum women with Hb 7-9.9 g/dL. This study also emphasises on the maternal functional indicators esp. the impact of the intervention on **Postpartum Depression, Quality of Life, Maternal fatigue and Mother & Infant Bonding**. This trial is implemented at all the Global Network sites of India (Belagavi & Nagpur), Pakistan, Bangladesh, Zambia, Democratic Republic of Congo, Kenya and Guatemala. Belagavi, India (GN08) is the lead site for the implementation of this trial. At Belagavi site, the study is being implemented in 3 General Hospitals of Gokak, Bailhongal and Hukkeri of Belagavi district. The PRIORITY Protocol Training for the GN Site Coordinators was organized at Belagavi in November 2022. Total global sample size is 4800. Belagavi site started the recruitment by end of May 2023 and as on May 2024, has screened 6300 women and randomized 645 participants. By then, 7 out of eight sites have begun enrolment with a total randomization of 2400 postpartum women.

The standard of care to treat anemia during pregnancy and postpartum in most LMICs is daily iron and folic acid (IFA) tablets, which have persistent challenges in distribution and adherence, calling for a change in approach. In LMICs, the use of IV iron during pregnancy and postpartum presents a novel, innovative opportunity to rapidly treat moderate anemia. To address the challenges and barriers, **Implementation research on postpartum IV iron in Global Network sites: A Prevention of Iron Deficiency Anemia Post-delivery (PRIORITY) sub-study** has been implemented at Belagavi-India and Pakistan sites along side of PRIORITY main trial since October 2023.



[GN Steering Committee Meeting Picture at Washington DC between 26 – 29 June 2022]





During a woman's pre-pregnancy reproductive years, heavy menstrual bleeding (HUB) is likely a most important contributor to high rates of anemia. The majority of women suffering from HUB have no underlying pathology, thus allowing for focused interventions to replete iron stores. There does not exist a validated instrument that could be easily utilized in LMICs that would convey meaningful associations between a woman's response to a series of focused questions and her hematologic findings referable to anemia. **"Validation of a Survey Instrument for Screening of Pre-Pregnant Women: the PREPSA SCALE"** study was planned to develop and validate the PREPSA scoring instrument in women of reproductive age prior to pregnancy. Total of 503 women were enrolled across 8 clusters of MNH registry. The primary analysis has been completed and publication is underway.





Tobacco Use among Pregnant Women

The research unit participated in a multi-site study, "Survey of Tobacco Use among Pregnant Women". The overall aim of this survey was to determine the prevalence of use of tobacco products including smokeless tobacco during pregnancy as well as ascertain the knowledge and beliefs regarding the hazards of tobacco products on the mother and child. National Cancer Institute was one of the co sponsors of this study. Although, the prevalence of tobacco smoking was very low in the study population, the use of smokeless tobacco during pregnancy and exposure to second-hand smoke in the family were significantly high. Further, awareness of the hazards of exposure to tobacco, both smoking and smokeless, on the mother and the newborn was also low, thus calling for renewed efforts to address the same. The primary publication arising from this study was selected for Faculty of 1,000 Medicine for the year 2008.

Publication:

Bloch M, Althabe F, Onyamboko M, MPH, Kaseba-Sata C, Castilla EE, Freire S, Garces AL, Parida S, Goudar SS, Kadir MM, Goco N, Thornberry J, Daniels M, Bartz J, Hartwell T, Moss N, Goldenberg RL. Tobacco Use and Environmental Tobacco Smoke Exposure During Pregnancy: An Investigative Survey of Women in Nine Developing Nations. Am J Public Health. 2008 Oct;98(10):1833-40.



Optimizing Intrapartum Care Services

JNMC Research Unit was involved in the conduct of a pilot study of an “Indicator to Measure Intrapartum Stillbirth and Immediate Neonatal Death” conducted among pregnant women admitted to 6 study hospitals in 4 low-income countries viz. India, Pakistan, Kenya and Democratic Republic of Congo, funded by National Institute of Child Health and Human Development and Engender Health and Maternal Health Task Force, USA from June 2011 to 2012. Foetal Heart Sounds were monitored using a specialized Sonoline B Foetal Doppler (DOPTONE). The results demonstrated the possibility of accurately determining the foetal viability on admission using this simple instrument which might form the basis of a low-cost sustainable program to monitor and evaluate efforts to improve the quality of care and thereby reducing the in-hospital perinatal mortality in low-income countries.

Publication:

Goldenberg RL, McClure EM, Kodkany B, Wembodinga G, Pasha O, Esamai F, Tshefu A, Patel A, Mabaye H, Goudar S, Saleem S, Waikar M, Langer A, Bose CL, Rubens CE, Wright LL, Moore J, Blanc A. A multi-country study of the "intrapartum stillbirth and early neonatal death indicator" in hospitals in low-resource settings. *Int J Gynaecol Obstet.* 2013 Sep;122(3):230-3.

The Partograph is an important clinical tool for monitoring a woman's progress during labour and childbirth that is in routine use worldwide. A revised version of the WHO Partograph – the “WHO Labour Care Guide (LCG)” – has been developed to make it easier for healthcare providers to routinely implement WHO's latest evidence-based recommendations on intrapartum care. **Evaluating the WHO Labour Care Guide in clinical settings study** aims to evaluate the usability, feasibility and acceptability of the LCG, and to explore barriers and facilitators to its use by healthcare providers in clinical settings. The study was conducted in Belagavi, Karnataka and Balasore, Odisha.

Impact: Based on this multi-site, multi-country study findings and the recommendations the WHO updated the Labour Care Guide in 2020.





The WHO Labour Care Guide (LCG) is a clinical tool that reflects WHO's latest guidelines for effective, respectful care during labour and childbirth. Implementing the LCG into routine care requires a strategy that effectively improves healthcare provider practices around intrapartum care. Such a strategy may optimize the use of Caesarean section, along with other health and women's experience of care outcomes.

Implementing the WHO Labour Care Guide to reduce the use of Caesarean section in four hospitals in India: a pragmatic, stepped wedge, cluster randomized pilot trial (LCG-CS study) was initiated to evaluate the effect of the LCG implementation strategy on caesarean section rate, evaluate the effect of the LCG implementation strategy on women's health and process of care outcomes and women's experiences of care and also to conduct a process evaluation on the implementation of the LCG strategy. The strategy will target the use of the LCG by maternity care providers, as well as promoting audit and feedback using the Robson Classification. The study was conducted between 1 July 2021 and 15 July 2022 in Davanagere (WCH affiliated to JJMMC, Gadag (GIMS), Ballari (VIMS) and General Hospital Gokak (Belagavi Dist.) of Karnataka. 26,331 women were enrolled, who gave birth to 26,595 babies in the four hospitals during the control and intervention periods and were included for analysis.

Findings from this multicentered, stepped-wedge, cluster-randomized pilot trial suggest that the LCG strategy is a promising intervention that can improve quality of labor and childbirth care, reducing overuse of intrapartum interventions. This study provides important evidence on the debate around the introduction of the LCG into routine clinical practice internationally. Further evaluation in larger-scale, definitive trials are warranted.

Publications:

1. Vogel JP, Comrie-Thomson L, Pingray V, Gadama L, Galadanci H, Goudar S, Laisser R, Lavender T, Lissauer D, Misra S, Pujar Y, Qureshi ZP, Amole T, Berrueta M, Dankishiya F, Gwako G, Homer CSE, Jobanputra J, Meja S, Nigri C, Mohaptra V, Osoti A, Roberti J, Solomon D, Suleiman M, Robbers G, Sutherland S, Vernekar S, Althabe F, Bonet M, Oladapo OT. Usability, acceptability, and feasibility of the World Health Organization Labour Care Guide: A mixed-methods, multicountry evaluation. *Birth*. 2021 Mar;48(1):66-75. doi: 10.1111/birt.12511. Epub 2020 Nov 22.
2. Vogel JP, Pingray V, Althabe F, Gibbons L, Berrueta M, Pujar Y, Somannavar M, Vernekar SS, Ciganda A, Rodriguez R, Welling SA, Revankar A, Bendigeri S, Kumar JA, Patil SB, Karinagannanavar A, Anteen RR, Pavithra MR, Shetty S, Latha B, Megha HM, Gaddi SS, Chikkagowdra S, Raghavendra B, Armari E, Scott N, Eddy K, Homer CSE, Goudar SS. Implementing the WHO Labour Care Guide to reduce the use of Caesarean section in four hospitals in India: protocol and statistical analysis plan for a pragmatic, stepped-wedge, cluster-randomized pilot trial. *Reprod Health*. 2023 Jan 20;20(1):18.
3. Vogel JP, Pujar Y, Vernekar SS, Armari E, Pingray V, Althabe F, Gibbons L, Berrueta M, Somannavar M, Ciganda A, Rodriguez R, Bendigeri S, Kumar JA, Patil SB, Karinagannanavar A, Anteen RR, Mallappa Ramachandrappa P, Shetty S, Bommanal L, Haralahalli Mallesh M, Gaddi SS, Chikkagowdra S, Raghavendra B, Homer CSE, Lavender T, Kushtagi P, Hofmeyr GJ, Derman R, Goudar S. Effects of the WHO Labour Care Guide on cesarean section in India: a pragmatic, stepped-wedge, cluster randomized pilot trial. *Nat Med*. 2024 Feb;30(2):463-469.
4. World Health Organization Labour Care Guide Research Prioritization Group. Global research priorities related to the World Health Organization Labour Care Guide: results of a global consultation. *Reprod Health*. 2023 Apr 7;20(1):57.

Maternal Sepsis Prevention

Maternal infections are among the most frequent causes of maternal deaths. These deaths from infections are not decreasing compared with deaths from other frequent causes of mortality. The JNMC Research Unit is implementing Global Network for Women's and Children's Health Research's common Protocol **"Prevention of Maternal and Neonatal Death/Infections with a Single Oral Dose of Azithromycin in Women in Labor (in Low- and Middle-income Countries): a Randomized Controlled Trial"** aimed at addressing the frequent but neglected cause of maternal morbidity and mortality. The trial is implemented in four General (Taluka) Hospitals viz. Bailhongal, Hukkeri, Guledagudda and Jamakhandi, S N Medical College Shri HSK Hospital, Bagalkote and BLDE Deemed-to-be-University Shri B M Patil Medical College Hospital, Vijayapura with a Grant Support from Bill & Melinda Gates Foundation. The main trial began in September 2022 after completing pilot and extended pilot phase. An additional sub-study to assess the Antimicrobial Resistance is also being implemented in the selected hospitals. The interim analysis of the study was undertaken in August 2022 and following the recommendations by DSMB the A-PLUS Trial stopped the recruitment on 16 August 2022 completing the global enrolment and randomization of 29,278 women. Belagavi site contributed the maximum enrolments of **5,628** (~20%). The AMR Sub study has enrolled 135 participants who will be followed up with multiple sample collections at the scheduled visit up to 12 months post-partum. BLDEU Shri B M Patil Medical College Hospital, Vijayapura with a Grant Support from Bill & Melinda Gates Foundation. The trial has completed the pilot phase and began the main trial in September 2020. An additional sub-study to assess the Antimicrobial Resistance is also being implemented in the selected hospitals.





Main findings of the study include: Of the total 29,278 women randomized, the incidence of maternal sepsis or death was lower in the azithromycin group than in the placebo group (RR 0.67), but the incidence of stillbirth or neonatal death or sepsis was similar. The difference in the maternal primary outcome appeared to be driven mainly by the incidence of sepsis; the incidence of death from any cause was 0.1% in the two groups. No change in the rates of neonatal sepsis in both the groups (RR 1.03). Additionally, no changes in the incidence of Stillbirth (RR 1.06) and Neonatal deaths (RR 1.03). Azithromycin was not associated with a higher incidence in adverse events. Among women planning a vaginal delivery, a single oral dose of azithromycin resulted in a significantly lower risk of maternal sepsis or death than placebo but had little effect on newborn sepsis or death.

Funding: Eunice Kennedy Shriver National Institute of Child Health and Human Development and the Bill & Melinda Gates Foundation.

Publications:

1. Tita ATN, Carlo WA, McClure EM, Mwenechanya M, Chomba E, Hemingway-Foday JJ, Kavi A, Metgud MC, Goudar SS, Derman R, Lokangaka A, Tshefu A, Bauserman M, Bose C, Shivkumar P, Waikar M, Patel A, Hibberd PL, Nyongesa P, Esamai F, Ekhuagere OA, Bucher S, Jessani S, Tikmani SS, Saleem S, Goldenberg RL, Billah SM, Lennox R, Haque R, Petri W, Figueroa L, Mazariegos M, Krebs NF, Moore JL, Nolen TL, Koso-Thomas M; A-PLUS Trial Group. Azithromycin to Prevent Sepsis or Death in Women Planning a Vaginal Birth. *N Engl J Med*. 2023 Mar 30;388(13):1161-1170.
2. Hemingway-Foday J, Tita A, Chomba E, Mwenechanya M, Mweemba T, Nolen T, Lokangaka A, Tshefu Kitoto A, Lomendje G, Hibberd PL, Patel A, Das PK, Kurhe K, Goudar SS, Kavi A, Metgud M, Saleem S, Tikmani SS, Esamai F, Nyongesa P, Sagwe A, Figueroa L, Mazariegos M, Billah SM, Haque R, Shahjahan Siraj M, Goldenberg RL, Bauserman M, Bose C, Liechty EA, Ekhuagere OA, Krebs NF, Derman R, Petri WA, Koso-Thomas M, McClure E, Carlo WA. Prevention of maternal and neonatal death/infections with a single oral dose of azithromycin in women in labour in low-income and middle-income countries (A-PLUS): a study protocol for a multinational, randomised placebo-controlled clinical trial. *BMJ Open*. 2023 Aug 30;13(8):e068487.

Cervical Cancer Prevention

The 'Research Unit' has diversified its research activities and is developing capacity and infrastructure, recruitment and retention strategies for undertaking clinical research related to prevention methods for cervical cancer among HIV-infected women in Belagavi district through the **"HIV – Cervical Cancer Prevention Research Project"**. A **"Preventive Gynaecologic Oncology Unit"** that has been set up at KLES Dr Prabhakar Kore Hospital and Medical Research Center, with substantial support from the grant. This facility is equipped with a colonoscopy unit for diagnosis of cervical cancer and offers 'Loop Electrosurgical Excision Procedure' for women diagnosed to have pre-cancerous lesions. As a member of the consortium led by National AIDS Research Institute, Pune, this unit emerged as a nodal centre for implementing trials focused on prevention and treatment of cervical cancer.

The WHO Guidelines for screening and treatment of precancerous lesions for cervical cancer prevention recommends a screen-and-treat approach for cervical cancer prevention, with cryotherapy being the first choice of treatment for women with a positive screen. The Performance, Safety and Efficacy of a New Cryotherapy Device for Cervical Dysplasia in Low- and Middle-Income Countries Study has been initiated to determine the performance characteristics of a new cryotherapy device, CryoPop, compared to standard cryotherapy equipment in women with normal cervical cytology. The study has been implemented at J N Medical College, Belagavi; Karnataka Institute of Medical Sciences (KIMS), Hubballi and Karnatak Cancer Therapy and Research Institute (KCTRI), Hubballi with the support of Johns Hopkins University (JHPIEGO), Baltimore, USA. More than **9,000** women in reproductive age group have been screened and about 15 women with High grade Squamous Intra-epithelial Lesions (HSIL) were treated with new CryoPop Device.

Publications:

1. Anderson JR, Yogeshkumar S, Lu E, Yenokyan G, Thaler K, Mensa M, Chikaraddi S, Lokare L, Gudadinni MR, Antartani R, Donimath K, Patil B, Bidri S, Goudar SS, Derman R, Dalal A; CryoPop Study Group. The CryoPop study: Screening for high-grade cervical dysplasia in Karnataka, India. BJOG. 2023 Nov;130 Suppl 3(Suppl 3):158-167
2. Yogeshkumar S, Anderson J, Lu E, Kenyi E, Mensa M, Thaler K, Antartani R, Donimath K, Patil B, Chikaraddi S, Bidri S, Biradar A, Gudadinni MR, Lokare L, Yenokyan G, Bellad MB, Goudar SS, Derman R, Revankar A, Patil H, Wani R, Kangle R, Chavan RY, Nagmoti MB, Kabadri YM, Reddy P, Vernekar S, Hipparagi S, Patil V, Dalal A. Safety and efficacy of the new CryoPop® cryotherapy device for cervical dysplasia in low- and middle-income countries: study protocol for a multicenter open-label non inferiority clinical trial with historical controls. Trials. 2021 Dec 13;22(1):915.



Prediction of high-risk pregnancy

IUGR is a well-established cause of stillbirth and is associated with neonatal death perinatal morbidity. Placental insufficiency remains the leading cause of IUGR as a consequence of poor utero placental blood flow, placental thrombi and infarctions. In most health facilities in LMIC's the common approach to assessing fetal growth restriction is serial symphysis fundal height measurements which have serious limitations. Early identification of these foetuses is not currently possible due to lack of ultrasound machines and skilled personnel in the periphery. Umbiflow is a device which is developed by South African researchers.

The accuracy of Umbiflow system in identifying at risk foetuses has been validated against a commercial pulse Doppler unit as a Gold Standard. **Prevalence and outcomes of abnormal continuous wave Doppler flow indices in unselected obstetric populations in low- and middle-income countries: The Umbiflow™ International Study** was implemented at 5 international sites viz. India (JNMC, Belagavi), South Africa, Kenya, Rwanda and Ghana in collaboration of University of Pretoria, Pretoria, South Africa with funding and technical support from World Health Organization. The study was conducted from January to December 2019. Belagavi, India site enrolled **1,405** participants of the **7,115** global sample.

Publication:

Vannevel V, Vogel JP, Pattinson RC, Adanu R, Charantimath U, Goudar SS, Gwako G, Kavi A, Maya E, Osoti A, Pujar Y, Qureshi ZP, Rulisa S, Botha T, Oladapo OT. Antenatal Doppler screening for fetuses at risk of adverse outcomes: a multicountry cohort study of the prevalence of abnormal resistance index in low-risk pregnant women. *BMJ Open*. 2022 Mar 16;12(3):e053622.





Maternal Mental Health

Mental Health Conditions, including postpartum depression, are experienced around childbirth (peripartum depression) or as a continuation of antenatal depression. In LMIC, children of mothers with postpartum depression have a higher risk of being stunted or underweight, as they are less likely to breastfeed and provided necessary care of their newborns. Maternal depression has also been associated with adverse psychological outcomes in children up to 10 years later. Thus **“Screening for Maternal Depression in MNHR Participants”** has been initiated at all the Global Network MNH Registry sites. This supplemental study has been proposed with an objective to screen the post-partum mothers using a rapid and effective screening tool - the Patient Health Questionnaire (PHQ-9) that has been used and validated globally, including in all GN sites and was initiated at all the sites from October 2021 and continued till October 2023 screening nearly 4200 postpartum women across eight primary health centres of Belagavi district.



Research Participation of Women in Clinical Trials

The JNMC Research Unit in collaboration with Burnet Institute, Melbourne, Australia has initiated **“Accelerating Innovation for Mothers: AIM-Gender”** project with an aim to understand the challenges and opportunities to scale up the participation of pregnant women in clinical trials. This was a mixed-methods study with the objective to assess the attitudes and perceptions of women, health workers and other stakeholders, and their views on facilitators and barriers, regarding the participation of pregnant women in clinical trials in maternal health. Total of 13 focus group discussion and 35 In-depth interviews conducted have been conducted with all the stakeholders. All focus group discussion and in-depth interviews were audio recorded and are process of transcription. The study data collection is complete and now the coding and analysis of the transcripts is in progress.



Research Studies Related to Newborn Health Birth Asphyxia

In order to address the issue of birth asphyxia, one of the leading causes of early newborn mortality, the 'Global Network' between 2005 and 2008 launched a major initiative of training community - based birth attendants in Neonatal Resuscitation for reducing early neonatal mortality in developing countries. The **“First Breath: Community Based Training and Intervention in Neonatal Resuscitation”** project was implemented at seven Global Network Sites located in South Asia, Africa and Central and South America including J N Medical College, Belagavi. Nearly 90 communities, 26 of them in Belagavi District, defined as geographical medical service-based area with approximately 500 births per year, participated in the study aimed at comparing the efficacy of **Neonatal Resuscitation Program (NRP) of the American Academy of Paediatrics with the Essential Newborn Care Course of the World Health Organization (WHO)** in reducing early neonatal mortality. More than 65,000 births, approximately 26,000 of them in 298 villages with a population of more than 8,90,000 in Belagavi District, were assessed over the two- and half-year study period at the participating GN sites. As part of the trial, over 1,100 birth attendants including Private Practitioners, Nurses, Auxiliary Nurse Midwives and Traditional Birth Attendants were trained for newborn resuscitation on three occasions.





Publications

1. Chomba E, Carlo WA, Goudar SS, Jehan I, Tshefu A, Garces A, Parida S, Althabe F, McClure EM, Derman RJ, Goldenberg RL, Bose C, Krebs NF, Panigrahi P, Buekens P, Wallace D, Moore J, Koso Thomas M, Wright LL; First Breath Study Group. Effects of Essential Newborn Care Training on Fresh Stillbirths and Early Neonatal Deaths by Maternal Education. *Neonatology*. 2016 Aug 20;111(1):61-67. PMID: 27544512
2. Garces A, McClure EM, Chomba E, Patel A, Pasha O, Tshefu A, Esamai F, Goudar S, Lokangaka A, Hamidge KM, Wright LL, Koso-Thomas M, Bose C, Carlo WA, Liechty EA, Hibberd PL, Bucher S, Whitworth R, Goldenberg RL. Home birth attendants in low income countries: who are they and what do they do? *BMC Pregnancy Childbirth*. 2012 May 14;12:34. doi: 10.1186/1471-2393-12-34. PMID:22583622
3. Patricia J. Kelly, Shivaprasad S. Goudar, Hrishikesh Chakraborty, Janet Moore, Richard Derman, Bhala Kodkany, Mrutyunjaya Bellad, Vijaya A. Naik, Mubashir Angolkar, Michele Bloch; Pregnant women and children's exposure to tobacco and solid fuel smoke in southwestern India – Informa Health Care, *J Matern Fetal Neonatal Med*. 2011 Jul;24(7):973-7. doi: 10.3109/14767058.2010.537411. Epub 2010 Dec 15. PMID: 21158490
4. Carlo WA, Goudar SS, Jehan I, Chomba E, Tshefu A, Garces A, Parida S, Althabe F, McClure EM, Derman RJ, Goldenberg RL, Bose C, Hambidge M, Panigrahi P, Buekens P, Chakraborty H, Hartwell TD, Moore J, Wright LL; for the First Breath Study Group. High Mortality Rates for Very Low Birth Weight Infants in Developing Countries Despite Training. *Pediatrics*. 2010 Nov;126(5):e1072-80. doi: 10.1542/peds.2010-1183. Epub 2010 Oct 11. PMID: 20937655
5. Waldemar A. Carlo, Shivaprasad S. Goudar, Imtiaz Jehan, Elwyn Chomba, Antoinette Tshefu, Ana Garces, Sailajanandan Parida, Fernando Althabe, Elizabeth M. McClure, Richard J. Derman, Robert L. Goldenberg, Carl Bose, Nancy F. Krebs, Pinaki Panigrahi, Pierre Buekens, Hrishikesh Chakraborty, Tyler D. Hartwell, Linda L. Wright, and First Breath Study Group. Newborn-Care Training and Perinatal Mortality in Developing Countries – *The New England Journal of Medicine*. 2010 Feb 18;362(7):614-23. doi:10.1056/NEJMs0806033. PMID:20164485
6. Elizabeth McClure, Linda L Wright, Robert L Goldenberg, S S Goudar, S N Parida, I Jehan, A Tshefu, E Chomba, Fernando Althabe, Ana Garces, Hillary Harris, Richard J Derman, Pinaki P, Cyril Engmann, Pierre Buekens, Michel H, Carlo WA. NICHD FIRST BREATH Study Group. The Global Network: A

prospective study of stillbirths in developing countries Am J Obstet Gynecol. 2007 Sep;197(3):247.e15. PMID: 17826406

The encouraging results of "First Breath: community-based training and intervention in neonatal resuscitation" led to the revision of the Neonatal Resuscitation Program (NRP) by the American Academy of Paediatrics (AAP) for community settings. The JNMC Research Unit was one of the five global sites selected by AAP for field testing the Helping Babies Breathe (HBB) curriculum. **"Field Implementation of Helping Babies Breathe"** project trained over 1,200 birth attendants working in 25 public sector (District Hospital, Belagavi, 7 Taluka hospitals, 2 community health centres and 15 primary health centres) and 8 private sector hospitals of Belagavi district for demonstrated resuscitation.

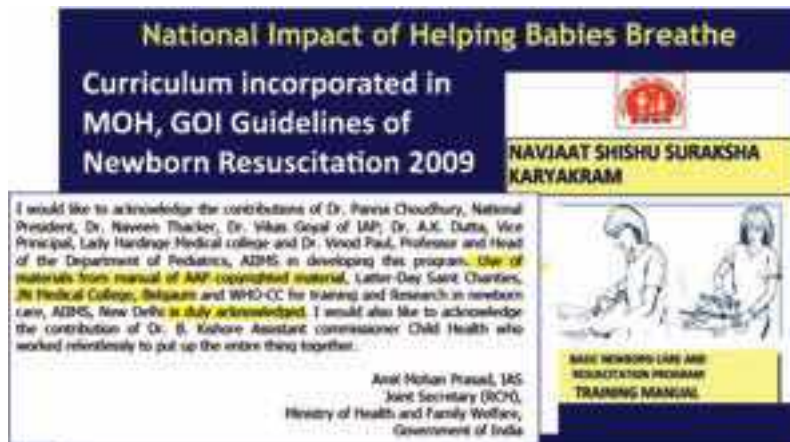
The Research Unit participated in the Global Network trial **'Evaluation of HELPING BABIES BREATHE in Belagavi, Kenya and Nagpur: Does implementation of HELPING BABIES BREATHE Save Lives?'** to test the effectiveness of the HBB curriculum in saving lives. The primary publication emanating from that trial was published in BMC Pregnancy and Childbirth in August 2016. As part of the HBB trial, a mobile based application was developed to assess if resuscitation began within the appropriate timeframe.



Publications

1. Bang A, Patel A, Bellad R, Gisore P, Goudar SS, Esamai F, Liechty EA, Meleth S, Goco N, Niermeyer S, Keenan W, Kamath-Rayne BD, Little GA, Clarke SB, Flanagan VA, Bucher S, Jain M, Mujawar N, Jain V, Rukunga J, Mahantshetti N, Dhaded S, Bhandankar M, McClure EM, Carlo WA, Wright LL, Hibberd PL. Helping Babies Breathe (HBB) training: What happens to knowledge and skills over time?; BMC Pregnancy Childbirth. 2016 Nov 22;16(1):364. PMID:27875999
2. Bellad RM, Bang A, Carlo WA, McClure EM, Meleth S, Goco N, Goudar SS, Derman RJ, Hibberd PL, Patel A, Esamai F, Bucher S, Gisore P, Wright LL; HBB Study Group. A pre-post study of a multi-country scale up of resuscitation training of facility birth attendants: does Helping Babies Breathe training save lives? BMC Pregnancy Childbirth. 2016 Aug 15;16(1):222. doi: 10.1186/s12884-016-0997-6. PMID: 27527831
3. Somannavar MS, Goudar SS, Revankar AP, Moore JL, McClure EM, Destefanis P, DeCain M, Goco N, Wright LL. Evaluating time between birth to cry or bag and mask ventilation using mobile delivery room timers in India: the NICHD Global Network's Helping Babies Breathe Trial. BMC Pediatr. 2015 Aug 6;15:93. doi: 10.1186/s12887-015-0408-6. PMID: 26245688
4. Bang A, Bellad R, Gisore P, Hibberd P, Patel A, Goudar S, Esamai F, Goco N, Meleth S, Derman RJ, Liechty EA, McClure E, Carlo WA, Wright LL. Implementation and evaluation of the Helping Babies Breathe curriculum in three resource limited settings: does Helping Babies Breathe save lives? A study protocol. BMC Pregnancy Childbirth. 2014 Mar 26;14:116. doi: 10.1186/1471-2393-14-116. PMID: 24670013
5. Goudar SS, Somannavar MS, Clark R, Lockyer JM, Revankar AP, Fidler HM, Sloan NL, Niermeyer S, Keenan WJ, Singhal N. Stillbirth and Newborn Mortality in India After Helping Babies Breathe® Training. Pediatrics. 2013 Feb;131(2):e344-52. doi: 10.1542/peds.2012-2112. Epub 2013 Jan 21. PMID: 23339215

Impact: Subsequently, HBB was incorporated into the neonatal resuscitation training curriculum of the Basic Newborn Care and Resuscitation program called "**Navajati Shishu Suraksha Karyakram**" (NSSK) of the Government of India.



Programs such as Helping Babies Breathe (HBB) have been proven effective in preventing adverse events following birth asphyxia. However, HBB falls short of sustained impact because ventilation skills decay rapidly and significantly over time. Effective ventilation for improved newborn survival requires birth attendants to both quickly achieve and maintain consistent, effective ventilation (e.g., good face-mask seal, correct rate of ventilation, and a patent airway) with minimal interruption. The Augmented Infant Resuscitator (AIR), empowers health workers to achieve effective ventilation more quickly and to maintain it for longer. Global Network for Women and Children's Health Research sites, JNMC, Belagavi, India and Eldoret/Moi University, Kenya in collaboration with Mbarara University of Science and Technology (MUST) and Massachusetts General Hospital/Harvard University, Boston will implementing **Augmented Infant Resuscitator (AIR): Transitioning a novel behaviour change innovation to drive newborn ventilation skills enhancement trial** to evaluate AIR devices as training tools to improve ventilation skills retention among health workers. In addition to evaluating the impact of the AIR device on provider ventilation skills retention, the lessons learnt from this cluster randomized trial will help to develop key product requirements for clinical use. The study was conducted in India and Kenya in collaboration with Mbarara University of Science and Technology (MUST) and Massachusetts General Hospital/Harvard University, Boston and funded by Grand Challenges Canada, Toronto, Canada. This Cluster randomized study aimed to understand potential effectiveness of AIR device in improving retention of newborn ventilation skills among skilled birth attendants in India and Kenya and ultimately to improve newborn resuscitative care and newborn outcomes. The study was conducted between March 2023 to February 2024 and included 104 skilled birth attendants from 12 public sector hospitals from Belagavi district in India apart from 133 from Kenya. The study results showed remarkable retention of skills (OSCE B/BMV). Objective ventilation skills improved, more so when feedback was on.



Preterm Birth

All research sites active in the Global Network including JNMC in 2011 implemented the **Trial of the Use of Antenatal Corticosteroids in Developing Countries (ACT Trial)**, an 18-month cluster randomized study between October 2011 and March 2014 to assess the feasibility, effectiveness, and safety of a multifaceted intervention designed to increase the use of antenatal corticosteroids among women at risk for preterm birth at all levels of health care in low-income and middle-income countries. Although the intervention effectively increased the use of antenatal corticosteroids there was unexpected increased mortality among babies delivered at term by mothers who had received ACS suspected to be high-risk for preterm delivery. These results prompted WHO to consider the available evidence on potential benefits of ACS were largely derived from higher-level hospitals in high-resource countries and the possible harms of expanding ACS coverage in resource-limited countries to guide its 2015 recommendations on ACS.



Publications:

1. Goldenberg RL, Thorsten VR, Althabe F, Saleem S, Garces A, Carlo WA, Pasha O, Chomba E, Goudar S, Esamai F, Krebs NF, Derman RJ, Liechty EA, Patel A, Hibberd PL, Buekens PM, Koso-Thomas M, Miodovnik M, Jobe AH, Wallace DD, Belizán JM, McClure EM. The global network antenatal corticosteroids trial: impact on stillbirth. *Reprod Health*. 2016 Jun 2;13(1):68.
2. Berrueta M, Hemingway-Foday J, Thorsten VR, Goldenberg RL, Carlo WA, Garces A, Patel A, Saleem S, Pasha O, Chomba E, Hibberd PL, Krebs NF, Goudar S, Derman RJ, Esamai F, Liechty EA, Moore JL, McClure EM, Koso-Thomas M, Buekens PM, Belizán JM, Althabe F. Use of antenatal corticosteroids at health facilities and communities in low-and-middle income countries. *Reprod Health*. 2016 May 27;13(1):66.
3. Klein K, McClure EM, Colaci D, Thorsten V, Hibberd PL, Esamai F, Garces A, Patel A, Saleem S, Pasha O, Chomba E, Carlo WA, Krebs NF, Goudar S, Derman RJ, Liechty EA, Koso-Thomas M, Buekens PM, Belizán JM, Goldenberg RL, Althabe F. The Antenatal Corticosteroids Trial (ACT): a secondary analysis to explore site differences in a multi-country trial. *Reprod Health*. 2016 May 24;13(1):64.
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There is important uncertainty as to whether antenatal corticosteroids (ACS) are safe and/or efficacious when used in facility settings in low-resource countries. WHO is coordinating the conduct of two concurrent trials on the efficacy of antenatal corticosteroids in women at imminent risk of early and late preterm birth '**The WHO Antenatal Corticosteroids for Improving Outcomes in Preterm Newborns (WHO-ACTION) trials**'. This is a parallel, two-arm, double-blind, randomized, placebo-controlled trial being implemented in 5 countries, 6 sites and 26 hospitals in Bangladesh, India (JNMC Research Unit), Kenya, Nigeria and Pakistan. Trial activities will be facility-based, with community follow up of recruited women and newborns to 28 completed days. The ACTION Trials was initially implemented as two components: **ACTION I** recruited early preterm deliveries (<34 weeks) predominantly assessed the efficacy of ACS and **ACTION II** recruited later preterm deliveries (34 to <37 weeks) assessing the safety of the ACS. The primary results of ACTION I Trial supported the use of dexamethasone among women

who were at risk of early preterm delivery in low resource settings resulted in significantly lower the risk of neonatal death without an increase in the incidence of possible bacterial infection. The primary paper has been published in NEJM in October, 2020.

In continuation in the series of ACTION Trials, ACTION III: **A multi-country, multi-centre, three- arm, parallel group, double-blind, placebo-controlled, randomized trial of standard-dose (6mg IM dexamethasone sodium phosphate administered every 12 hours, to a total of four doses) and low-dose antenatal corticosteroids (A single course of 2mg IM betamethasone administered every 12 hours, to a total of four doses)** study has been rolled out for women with a high probability of birth in the late preterm period in hospitals in low- resource countries to improve newborn outcomes has been initiated. Identical placebo, will be the third comparative arm. This trial is funded by Department of Reproductive Health Research, World Health Organization. Currently this study is being implemented at India (Belagavi and Delhi Site), Bangladesh, Kenya, and Pakistan. Under Belagavi site, The study includes 5 hospitals in Karnataka and Odisha states in India. The enrolment was started in India initially in two sites in July 2022 and three more sites were included in 2023. Till May 2024, 1322 women are recruited from these 5 hospitals and required study sample is proposed to be completed by March 2025.



Impact: The Director General of the World Health Organization at the 73rd World Health Assembly in Geneva on November 9, 2020 remarked “We led a huge international trial to show that in addition to its benefits in treating severe #COVID-19, #dexamethasone can also boost survival of premature babies when given to pregnant women at risk of preterm birth”- @DrTedros #HealthForAll #WHO73 He was referring to ACTION Trials that demonstrated that dexamethasone-a cheap and widely available glucocorticoid used to treat many conditions including rheumatic problems and severe allergies also accelerates fetal lung development and reduces respiratory problems at birth in preterm babies.

Publications:

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2. WHO ACTION Trials Collaborators; The World Health Organization ACTION-I (Antenatal Corticosteroids for Improving Outcomes in preterm Newborns) Trial: a multi-country, multi-centre, two-arm, parallel, double-blind, placebo-controlled, individually randomized trial of antenatal corticosteroids for women at risk of imminent birth in the early preterm period in hospitals in low resource countries; Trials. 2019 Aug 16;20(1):507.

As a continuation of this ACTION III Trial, a triple arm study has been planned to compare the efficacy and safety of Standard dose of Dexamethasone, Low dose Betamethasone as compared to a placebo.



“Pharmacokinetics and pharmacodynamics of antenatal corticosteroids when given to women at risk of late preterm birth” sub-study is being undertaken to study the Pharmacokinetics (PK) of betamethasone phosphate 2 mg IM administered every 12 hours and dexamethasone phosphate 6 mg IM administered every 12 hours in pregnant women at risk of late preterm birth using a population PK approach and to study Pharmacodynamics (PD) effects of betamethasone and dexamethasone in

the above doses on pregnant women; and to compare these parameters to those in pregnant women who do not receive either betamethasone or dexamethasone. The PK-PD sub-study will be conducted at four of the seven ACTION-III sites- two in Asia (Delhi, and Belgaum, India) and two in Africa (Ibadan and Ile-Ife, Nigeria), in a total of seven hospitals (one each in two India sites, 2 in Ibadan site and 2 in Ile Ife site). This study will be nested in the ongoing ACTION-III trial. A total of 300 participants (150 each in Nigeria and India respectively) will be enrolled in this PK-PD study. This will comprise 100 women from each of the three arms of the ACTION III trial. Trial is sponsored by WHO, Departments of Maternal, Newborn, Child, Adolescent health and Aging & Sexual reproductive health and research.



JNMC research unit participated in **“Clindamycin to reduce preterm birth in low resource setting: A randomized placebo controlled trial”** in collaboration with Christiana Care Health Services, USA with funding from Thrasher Research Fund to assess if pregnant women in rural areas with high vaginal pH levels that were treated with Clindamycin, were less likely to deliver preterm infants than pregnant women, also having high pH levels, who received a placebo. However, the study results found that this strategy did not decrease the rate of preterm birth in a rural community-based setting in India. The study also suggested that routine screening for an abnormal vaginal microbiome and treatment with clindamycin should not be undertaken in clinical practice.

Publications

1. Bellad MB, Hoffman MK, Mallapur AA, Charantimath US, Katageri GM, Ganachari MS, Kavi A, Ramdurg UY, Bannale SG, Revankar AP, Sloan NL, Kodkany BS, Goudar SS, Derman RJ. Clindamycin to reduce preterm birth in a low resource setting: a randomised placebo-controlled clinical trial. BJOG. 2018 May 22.
2. Hoffman MK, Bellad MB, Charantimath US, Kavi A, Nagmoti JM, Nagmoti MB, Mallapur AA, Katageri GM, Ramadurg UY, Bannale SG, Revankar AP, Ganachari MS, Derman RJ, Goudar SS; A Comparison of Colorimetric Assessment of Vaginal pH with Nugent Score for the Detection of Bacterial Vaginosis; Infect Dis Obstet Gynecol. 2017;2017:1040984.
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The Global Network implemented a multi-centric trial of **"Aspirin Supplementation for Pregnancy Indicated Risk Reduction in Nulliparous Women (ASPIRIN)"** to study the effects of low dose aspirin on prevention of preterm labour at the research sites of the Global Network for Women's and Children's Health Research. The Thomas Jefferson University-Christiana Care Health Services - J N Medical College collaborative research team is the lead investigator group that enrolled nearly 12,000 pregnancies for this placebo-controlled trial. The objective of this Global Network study is was to assess if low-dose aspirin administered to nulliparous, pregnant women beginning early in pregnancy can reduce preterm birth. This study has been implemented among the 16 PHC Clusters at Belagavi along with other GN Sites. Protocol Training for the ASPIRIN Trial Co-ordinators from the Global Network sites – India, Kenya, Zambia, Democratic Republic of Congo and Guatemala – was held at Belagavi during 14th to 18th November, 2016. The primary results of the trial suggested that in populations of nulliparous women with singleton pregnancies from low-income and middle-income countries, low-dose aspirin initiated between 6 weeks and 13 weeks of gestation resulted in a reduced incidence of preterm delivery before 37 weeks, and reduced perinatal mortality. The primary paper has been published January 25, 2021 issue of the Lancet.

Publications

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2. Hoffman MK, Goudar SS, Kodkany BS, Metgud M, Somannavar M, et al. Low-dose aspirin for the

prevention of preterm delivery in nulliparous women with a singleton pregnancy (ASPIRIN): a randomised, double-blind, placebo-controlled trial. *Lancet*. 2020 Jan 25;395(10220):285-293.

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7. Jessani S, Saleem S, Hoffman MK, Goudar SS, Derman RJ, Moore JL, et al. Association of haemoglobin levels in the first trimester and at 26-30 weeks with fetal and neonatal outcomes: a secondary analysis of the Global Network for Women's and Children's Health's ASPIRIN Trial. *BJOG*. 2021 Aug;128(9):1487-1496.
8. R. Araganji R, S. Somannavar M, Vernekar SS, Kavi A, Hoffman MK, Goudar SS. The utility of biomarkers in the prediction of preterm birth: A nested case control study of the ASPIRIN trial. *Biomedicine*. 2023 Feb. 26 [cited 2024 Feb. 29];43(1):114-9.
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10. Bauserman M, Leuba SI, Hemingway-Foday J, et al. The efficacy of low-dose aspirin in pregnancy among women in malaria-endemic countries. *BMC Pregnancy Childbirth*. 2022 Apr 10;22(1):303.





JNMC Research unit participated in **“Study of Cause of Death among Preterm Birth: Asia”** in collaboration with RTI International, USA and J J M Medical College Davanagere with funding from Bill & Melinda Gates Foundation, USA. The primary objective of the project is to conduct a prospective study in Asia (Karachi, Pakistan, and Belagavi, India) to determine the cause of deaths among preterm births (both live births and stillbirths). Secondary outcomes include determining the specific pathogens responsible for infection-related deaths, potential preventability of these deaths and interventions which may be effective in reducing mortality. The study enrolment was completed in February 2020. The primary outcome has been published in the Lancet Global Health in October 2022.

Publications

1. Goldenberg RL, Saleem S, Goudar SS, Silver RM, Tikmani SS, Guruprasad G, Dhaded SM, Yasmin H, Bano K, Somannavar MS, Yogeshkumar S, Hwang K, Aceituno A, Parlborg L, McClure EM; of the PURPOSE Study Group. Preventable stillbirths in India and Pakistan: a prospective, observational study. BJOG. 2021 Jun 26.
2. Feroz AS, Paganelli C, Bunei M, Eshetu B, Parveen S, Reza S, Sanji C, Tikmani SS, Goudar SS, Goudar G, Saleem S, McClure EM, Goldenberg RL. A comparison of MITS counseling and informed consent processes in Pakistan, India, Bangladesh, Kenya, and Ethiopia. Reprod Health. 2020 Aug 12;17(1):120.
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Infant Neurodevelopment

While 'First Breath' attempted reduction of early newborn mortality from birth asphyxia, it was speculated that the survivors may end up with varying degree of impaired neurological development. The burden on families and the communities assumes greater significance in view of the scarcity of supportive care available to children of rural population. The **"Brain Research to Ameliorate Impaired Neuro Development: Home-based intervention Trial (BRAIN HIT)"** addressed this concern by testing the feasibility of a home based early intervention program on babies resuscitated from birth asphyxia in improving their physical, mental and social development. The expertise developed by the home-based counsellors will be utilized for providing centre-based support to families of babies that have been successfully resuscitated. BRAIN-HIT study findings demonstrate that simple home-based strategies could be effective in reducing neurodevelopment disabilities in young children from low- and middle-income countries.



Publications

1. Do BT, Hansen NI, Bann C, Lander RL, Goudar SS, Pasha O, Chomba E, Dhaded SM, Thorsten VR, Wallander JL, Biasini FJ, Derman R, Goldenberg RL, Carlo WA. Associations between feeding practices and growth and neurodevelopmental outcomes at 36 months among children living in low- and low middle income countries who participated in the BRAIN-HIT trial. *BMC Nutr*. 2018;4(1):19.
2. Bann CM, Wallander JL, Do B, Thorsten V, Pasha O, Biasini FJ, Bellad R, Goudar S, Chomba E, McClure E, Carlo WA. Home-Based Early Intervention and the Influence of Family Resources on Cognitive Development. *Pediatrics*. 2016 Apr;137(4). pii: e20153766.
3. Biasini FJ, De Jong D, Ryan S, Thorsten V, Bann C, Bellad R, Mahantshetti NS, Dhaded SM, Pasha O, Chomba E, Goudar SS, Carlo WA, McClure E. Development of a 12 month screener based on items from the Bayley II Scales of Infant Development for use in Low Middle Income countries. *Early Hum Dev*. 2015 Apr;91(4):253-8.
4. Wallander JL, Biasini FJ, Thorsten V, Dhaded SM, de Jong DM, Chomba E, Pasha O, Goudar S, Wallace D, Chakraborty H, Wright LL, McClure E, Carlo WA. Dose of early intervention treatment during children's first 36 months of life is associated with developmental outcomes: an observational cohort study in three low/low-middle income countries. *BMC Pediatr*. 2014 Oct 25;14:281.
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8. Carlo WA1, Goudar SS, Pasha O, Chomba E, Wallander JL, Biasini FJ, McClure EM, Thorsten V, Chakraborty H, Wallace D, Shearer DL, Wright LL; Brain Research to Ameliorate Impaired Neurodevelopment-Home-Based Intervention Trial Committee and the National Institute of Child Health and Human Development Global Network for Women's and Children's Health Research Investigators. Randomized trial of early developmental intervention on outcomes in children after birth asphyxia in developing countries. *J Pediatr*. 2013 Apr;162(4):705-712.e3. 2012.09.052. Epub 2012 Nov 16.
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10. Jan L Wallander, Elizabeth McClure, Fred Biasini, Shivaprasad S Goudar, Omrana Pasha, Elwyn Chomba, Darlene Shearer, Linda Wright, Vanessa Thorsten, Hrishikesh Chakraborty, Sangappa M Dhaded, Niranjana S Mahantshetti, Roopa M Bellad, Zahid Abbasi, Waldemar Carlo for the BRAIN-HIT Investigators: Brain Research to Ameliorate Impaired Neurodevelopment - Home-based Intervention Trial (BRAIN-HIT) – BMC Pediatr. 2010 Apr 30;10:27.



The impact of maternal nutrition on neurodevelopment and growth of the offspring remains a potential trust area for research. **'Women First: Neurocognitive Development Assessment at 24 months of Age'** study looked at Neurodevelopment of offspring of mothers who received Nutrition Supplement during Preconception or Prenatally in Four Low Resource Settings to examine the effects of the maternal nutrition intervention in the Women First trial (WF:PMN Trial) on multiple domains of neurodevelopment in the offspring at 2 years of age.

Impaired neuro-cognitive development (ND) is very common in young children in low-middle income countries (LMIC) and represents a significant loss of human potential. The extent to which improved maternal nutrition, including during preconception period and/or the prenatal period, impacts offspring is unknown and therefore limits the development of effective interventions. The trial is being implemented to address this issue.

The **Sit Down and Play (SDP)** Project, a prospective static group comparison design study to determine the feasibility of implementation in a primary health centres in Belagavi, India. Process outcomes included success with recruitment, participant retention and ability to collect outcome measures. Clinical outcomes will incorporate measures of parenting behaviours to explore the potential impact of SDP on positive parenting outcomes and to identify factors affecting feasibility and acceptability of a brief parent-directed intervention in Belagavi, India.

Publication:

Shah R, Gustafson E, Dhaded S, Herekar V, Metgud D, Mastiholi S, Kim H, Goudar S, Atkins M. Integrating an Adapted, Low-Intensity Program to Promote Early Childhood Development in Routine Health Visits in Rural India: A Feasibility Study. *J Dev Behav Pediatr*. 2019 Dec 13.

Though neurodevelopmental delay is complex in its origins, preterm birth, hypertensive disorders of pregnancy (HDP) and chronic inflammation are known primary drivers. Recently concluded Global Network's ASPIRIN trial demonstrated that low dose aspirin (LDA) administered antenatally decreases the rate of preterm birth, preterm (HDP) and perinatal mortality. LDA has also long been known to decrease chronic inflammation. Despite the recent positive findings of the ASPIRIN trial, broad acceptance of low dose aspirin (LDA) may be tempered by concerns about effects on longitudinal neurodevelopment.

In contrast, if LDA is found to mitigate these risks, women would be further motivated to take LDA and professional societies to recommend LDA as a universal part of prenatal care. Hypothesising that antenatal LDA may prevent neurodevelopmental delay through its effect on preventing preterm birth & HDP and inhibiting chronic inflammation, '**Aspirin Supplementation for Pregnancy Indicated Risk Reduction in Nulliparous (ASPIRIN): Neurodevelopmental Follow-up Trial**' initiated at Belagavi and Bagalkot from December 2021 and has completed the BSID-III and ASQ-9 assessments of 116 babies at 36 months. Globally, 640 children September 2021 and June 2022. The Bayley-III cognitive composite score was noninferior between the two groups. Significant differences were not seen in the language composite score or the motor composite score. The proportion of children who had any component of the Bayley-III score lower than 70 did not differ between the two groups. Similarly, the communication, gross motor, fine motor, problem-solving, and personal-social components of the ASQ-3 did not differ between groups. Thus, Antenatal low dose aspirin exposure was not associated with altered neurodevelopmental outcomes at age 3 years.

Publication:

Hoffman MK, Goudar S, Dhaded S, Figueroa L, Mazariegos M, Krebs NF, Westcott J, Tikmani SS, Karim F, Saleem S, Goldenberg RL, Lokangaka A, Tshefu A, Bauserman M, Patel A, Das P, Hibberd P, Chomba E, Mwenchanya M, Carlo WA, Trotta M, Williams A, Moore J, Nolen T, Goco N, McClure EM, Lobo MA, Cunha AB, Derman RJ. Neurodevelopment of Children Whose Mothers Were Randomized to Low Dose Aspirin During Pregnancy. *Obstet Gynecol*. 2024 Apr 1;143(4):554-561.





Long-term neurodevelopmental disability in survivors of birth asphyxia is a major burden for children, families, and communities worldwide, especially in LMICs. Birth asphyxia also elicits an inflammatory process that can lead to brain injury. Azithromycin has anti-inflammatory properties and reduces brain injury in preclinical models of asphyxia. Hence, a strategy that has both anti-bactericidal and anti-inflammatory effects could improve the outcome in birth asphyxiated infants. Thus, azithromycin could be repurposed as a neuroprotective agent in at-risk fetuses (transplacental transfer) and babies (also breast milk transfer) with birth asphyxia. In the multi-center, multi-national Azithromycin-Prevention in Labor Use Study (A-PLUS trial) we have a unique opportunity to test the benefit of azithromycin in reducing the consequences of birth asphyxia by assessing neurodevelopmental impairment at 24 ± 1 month in survivors of birth asphyxia. Thus **“Single oral dose of azithromycin 2 gm to prevent maternal peripartum infection and newborn sepsis in laboring women (A-PLUS Trial): Repurposing azithromycin as a neuro-protector; a neurodevelopmental follow-up secondary study”** screening and data collection was initiated in February 2023. Global sample size is 420 and Belagavi site has screened 142 infants and has completed the assessments of 111 babies.



Breastfeeding Education Support

“Breastfeeding Education Support Tool for Baby (BEST4Baby)” project was funded by Fogarty International Center, National Institutes of Health, USA will utilize exploratory research and community involvement to design and integrate mobile technology, culturally-appropriate breastfeeding education, and a community-based approach to increase breastfeeding support to mothers. The initiative provided evidence that the BEST4Baby approach can achieve the public health objective of improving rates of exclusive breastfeeding for 6 months and continued breastfeeding for an appropriate time thereafter.



Publications:

1. Short VL, Bellad RM, Kelly PJ, Washio Y, Ma T, Chang K, Majantashetti NS, Charantimath US, Jaeger FJ, Lalakia P, Goudar SS, Derman R. Feasibility, acceptability, and preliminary impact of an mHealth supported breastfeeding peer counselor intervention in rural India. *Int J Gynaecol Obstet*. 2021 Jan 17. doi: 10.1002/ijgo.13599. PMID: 33454986
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Infant Nutrition

In 2011, the World Health Organization released the Guidelines on Optimal Feeding for Low Birthweight Infants in Low-and Middle-Income Countries (LMICs). However, 70% of the guidelines are based on “low or very low” quality of evidence, and the majority of research regarding mother’s own milk alternatives has been in high-income, hospital-based settings. There is a pressing lack of information about LBW infants in LMICs: existing feeding patterns; rates and causes of unsuccessful breastfeeding; and effective options for feeding, fortification, or supplementation with micronutrients. Forty global health organizations recently issued an urgent call to action to improve the evidence base, specifically for neonatal care units. **Low-birthweight Infant Feeding Exploration study (LIFE)** aimed to address these gaps with the overall study goal as to understand feeding options for LBW infants in LMIC settings, including current feeding practices, health outcomes, and potential interventions. The study is being implemented in four study sites located in three countries: Tanzania, Malawi, and India. JNMC Belagavi, JJMMC Davanagere, SSIMSRC Davanagere and SCB Medical College Cuttack are the sites in India.

In continuation of the above study, **“Low Birthweight and Preterm Infant Feeding Trial and Supportive Care Package (LIFT-UP)”** proposed to be conducted in India, Tanzania and Kenya in collaboration with Ariadne Labs, USA funded by Bill & Melinda Gates Foundation, USA. The study aims to improve feeding and growth outcomes among very low birthweight (LBW; $\leq 1.5\text{kg}$) or very preterm (<32 weeks gestational age) infants in the neonatal intensive care unit (NICU) in India, Malawi, and Tanzania. The regulatory approvals are being obtained and the study enrolment will be started by September 2024.





Facilitating a placental transfusion at birth improves iron stores and long-term neurodevelopmental outcomes in healthy term infants. Infants who are non-vigorous at birth and develop hypoxic ischemic encephalopathy (HIE) are likely to benefit from a placental transfusion. Thus to assess if umbilical cord milking compared to early cord clamping will improve short and long-term outcomes in neonates who are non-vigorous at birth, a multi-centre, cluster-randomized, crossover-controlled clinical trial of **Umbilical Cord Milking versus Early Cord Clamping on Short and Long-term Outcomes in Neonates Who are Non-Vigorous at Birth (CORDMILK Study)** is being implemented by JNMC Research Unit in India in collaboration with Thomas Jefferson University, Philadelphia, and Nemours Children's Hospital, Philadelphia, USA with funding from NIH, USA. Study sites include – Belagavi from Karnataka; Nagpur (4 hospitals), Wardha, Chandrapur and Pune from Maharashtra and Jaipur from Rajasthan. Total sample size is 3824 non-vigorous babies. Study has been initiated in October, 2022 and by May, 2024 about 1950 non-vigorous babies have been enrolled in the study.



Umbilical Cord Milking Study Team Training



Neonatal Sepsis Prevention

Neonatal infections are among the most frequent causes of neonatal deaths. These deaths from infections are not decreasing compared with deaths from other frequent causes of mortality. The JNMC Research Unit is implementing Global Network for Women's and Children's Health Research's common Protocol **"Prevention of Maternal and Neonatal Death/Infections with a Single Oral Dose of Azithromycin in Women in Labor (in Low- and Middle-income Countries): a Randomized Controlled Trial"** aimed at addressing the frequent but neglected cause of neonatal morbidity and mortality. The trial was implemented in four General (Taluka) Hospitals viz. Bailhongal, Hukkeri, Guledagudda and Jamakhandi, S N Medical College Shri HSK Hospital, Bagalkote and BLDEU Shri B M Patil Medical College Hospital, Vijayapura with a Grant Support from Bill & Melinda Gates Foundation. The results suggested no change in the rates of neonatal sepsis, neonatal death and still birth in both the groups. Azithromycin was not associated with a higher incidence in adverse events. Among women planning a vaginal delivery, a single oral dose of azithromycin had little effect on newborn sepsis or death.



Promoting MITS activities to determine cause of death among neonates and stillbirths in tertiary care teaching hospital project will be nested in this trial. This study will utilize Minimally invasive tissue sampling (MITS), also known as minimally invasive autopsy, involves post-mortem collection of fluid and solid tissue samples using biopsy needles as an alternative to complete diagnostic autopsy which is the "gold standard" for ascertaining cause of death.



Understanding Adverse Outcomes of Pregnancy

Despite decades of sustained investment, 300,000 women and 3 million newborns continue to die each year in the days surrounding childbirth. While there are many reasons for these unacceptable statistics, chief among them is a stubborn lack of progress in the development of new diagnostic and risk-stratification strategies appropriate for resource-poor settings. Indeed, most of the lab tests, monitoring technologies, drugs, and clinical approaches currently available for pregnancy care in the global south have not changed in 50 years. **Limiting Adverse Birth Outcomes in Resource-Limited Settings Prospective, Observational Cohort (LABOR) study** was planned to exhaustively document the course and outcomes of labor, delivery, and the immediate postpartum period in settings where the occurrence of adverse birth outcomes is high. The study also aimed to create the largest, most carefully documented observational cohort of labor and delivery ever assembled in the developing world. The goal is to precisely characterize the incidence of adverse labor outcomes and their measurable antecedents in diverse populations while carefully documenting patterns of care. Newer tools will be utilized in low-resource healthcare facilities for better risk stratification and earlier diagnosis to improve intrapartum outcomes. This study has been completed recruitment at KLE Hospital Belagavi, Karnataka and FMMC Balasore, Odisha with the funding from the Bill and Melinda Gates Foundation. Analysis of the results is underway.



Health System Intervention

"Evaluation of an Emergency Obstetrics and Newborn Care Intervention Package to Reduce Adverse Pregnancy Outcomes in Low Resource Settings (The EmONC Trial)" tested an integrated package of strategies for improving pregnancy outcomes. The strategies included creating awareness in the communities for birth planning and hospital transport, birth attendant training for early recognition of pregnancy and newborn complications, and hospital staff training in the management of obstetric and neonatal emergencies. Lessons learnt from this project suggest that achieving improvement in pregnancy outcomes in these settings will require substantially more obstetric and newborn care infrastructure and provider training and community mobilization alone will not be sufficient.



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'Implementation of the WHO Safe Childbirth Checklist program', a novel childbirth safety program for institutional births incorporating a 29-item checklist containing essential practices that target the major causes of childbirth-related mortality, was evaluated as a pilot, pre-post-intervention study in a sub-district level birth centre in Karnataka, India between July and December 2010 by JNMC Research Unit with a Collaborative effort with the World Health Organization and Harvard School of Public Health. The study demonstrated a significant improvement in the delivery of 28 out of 29 essential safety practices by health workers. This validation of the WHO Safe Childbirth Check List Program has resulted inclusion as one of the components in 'Maternal and Newborn Health Tool Kit' by the Ministry of Health & Family Welfare, Government of India.



Publication:

- Spector JM, Agrawal P, Kodkany B, Lipsitz S, Lashoher A, et al. (2012) Improving Quality of Care for Maternal and Newborn Health: Prospective Pilot Study of the WHO Safe Childbirth Checklist Program. PLoS ONE 7(4): e35151.

Using WHO Safe Childbirth Checklist, as a quality improvement tool, a matched-pair, cluster randomized controlled trial was conducted in 60 pairs of facilities across 24 districts of Uttar Pradesh, India to test the effect of 'BETTER BIRTH PROGRAM', an 8-month coaching-based implementation of Safe Childbirth Checklist, on a composite outcome of perinatal death, maternal death and maternal severe complications within 7 days after delivery. Outcomes assessed on 8 to 42 days after delivery were compared between the intervention and control groups. JNMC Research Unit investigators provided the technical consultation for the implementation of this study.



Dr Atul Gawande at the 2nd International Conference on Maternal and Newborn Health: Translating Research Evidence to Practice, Belagavi, Karnataka, India March 26-27, 2018

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Visit of Dr. Manoj V. Murhekar, Director & Scientist G
National Institute of Epidemiology (ICMR), Chennai, January 28, 2021

Impact of COVID-19 on Maternal and Neonatal Health

Clinical Outcomes of COVID-19 in Pregnancy and Perinatal Health

The World Health Organization declared the Coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) a global pandemic in March 2020. Since then, this pandemic has an impact on every aspect of human life. Even as the number of confirmed cases increased, evidence on the transmission, incidence and effect of SARS-CoV-2 infection in mothers and their babies remained limited. There was a need for standardised reporting and evidence on the clinical presentation, and maternal and perinatal outcomes of COVID-19 disease during or after pregnancy. Available evidences suggested that the adverse maternal or neonatal outcomes was uncertain, and limited to infection in the third trimester, with some cases of foetal distress and preterm birth reported.

WHO Country Office for India (WCO) initiated a virtual meeting of all WHO Collaborating centres on 4th June 2020. Following the meeting, four WHO Collaborating Centres working in the field of Maternal and Perinatal Health Research viz. AIIMS, New Delhi, PGIMER, Chandigarh, MGIMS, Sewagram and JNMC, Belagavi collaborated with WCO to participate in an nested case control study - **Standardizing Quality of evidence on clinical characteristics and outcomes of COVID-19 and Pregnancy (SCOPE)**. The study aimed at standardization of the treatment protocol of COVID infection in pregnancy and building capacity to support documentation of clinical outcome including co-morbidities, mode of transmission of infection of all mother and new-born admitted to WHO-CC/satellite hospitals with/without COVID infection. The study was implemented between April 2020 to March 2021, of which the data collection was between April - November 2020. Within this short span we were able to collect the data from 3,400 pregnant women who were tested positive for COVID-19 infection at all the WHO-CC Network of hospitals across 7 states and 1 Union Territory with almost pan India Representation with 1:2 matched controls (COVID-19 -ve). The satellite hospitals under JNMC WHO-CC managed to enrol 822 cases and 1,190 controls, second highest number after AIIMS New Delhi Network. The results indicated that Covid-19 infection predisposed to adverse maternal outcome in a large cohort of Covid positive pregnant women as compared to the negative controls. The neonatal outcome paper is under review.

The risk of spontaneous abortion, stillbirth, neonatal mortality and preterm birth are important questions to address in pregnant women infected with the COVID-19, as are the rates and types of congenital infections and malformations, and foetal growth restriction especially in LMIC settings. Each of these outcomes is likely associated with the gestational age at which the mother develops the infection. The Global Network for Women's and Children's Health Research through its prospective **Maternal and Newborn Health Registry** initiated '**COVID-19 prevalence during pregnancy and pregnancy outcomes in 8 low and middle-income sites**' as a supplemental study. Screening for COVID-19 antibody at delivery or in the post-partum period was adopted as a way to assess the extent of the COVID-19 pandemic in these locations and the trends in the proportion of the pregnant population infected with COVID-19 which can be correlated with the clinical presentation and outcomes. Another component of this study will be to determine mothers' knowledge, attitude and practices related to COVID-19 in pregnancy. The study was initiated at Belagavi site in the mid December 2020 and completed enrolment of 3,114 women in June 2022.

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Visit of US Health Secretary to JNMC Research Unit

Ms. Kathleen Sebelius, Secretary of Health, heading the department of Health and Human Services of the USA visited J N Medical College, Belagavi on **15th January, 2012** to observe the research activities conducted at the village level. Congratulating the JNMC research team for the outcomes in the community-based studies focused on women's and children's health, she lauded J. N. Medical College for its commitment to improve the health status of rural India. On this occasion, she lauded the leadership of Dr Prabhakar Kore and his encouragement to community-based research for the benefit of rural women and children and invited the team to participate in a meeting of the Global Network in Washington held in June 2012. Acknowledging the outstanding research contribution of the research team, she reaffirmed the continued support of US Government for the next five years through 2018.



Dissemination to the Stakeholders and Scaling up of the Activities

International PPH Congress – 2006

Women's and Children's Health Research unit of J N Medical College organized the International Congress on Evidence Based Interventions to Prevent Post-partum haemorrhage: Translating Research into Practice at Park Hyatt, Utorda, Goa from 12th to 15th July, 2006 to disseminate the Oral Misoprostol Trial conducted at JNMC between 2001 - 2006. Dr R. D. Pandit, Past President and Editor Emeritus, FOGSI, Mumbai was the chief guest and inaugurated the congress. 138 delegates from India, USA, Pakistan, Nepal, Bangladesh and Cambodia attended the congress.



PPH Congress - 2014

A PPH Congress was organised at Goa on 3rd and 4th September, 2014 to disseminate the results of another major trial - 'Two community strategies comparing use of misoprostol for early treatment / secondary prevention to primary prevention for postpartum haemorrhage: a randomized cluster non-inferiority study in Bijapur district, Karnataka, India' in collaboration with Gynuity Health Projects, New York, USA and University of Illinois at Chicago, and University of California at San Francisco with funding from Bill & Melinda Gates Foundation, USA

National Seminar on Interventions for Reducing Maternal and Newborn Mortality – 2014

Women's and Children's Health Research unit of J N Medical College organized the National Seminar on **"Interventions for Reducing Maternal and Newborn Mortality: Translating Research Evidence to Practice"** on 5th & 6th of September 2014. Chief Guest Dr. Sharanprakash Patil, Honourable Minister of State for Medical Education, Government of Karnataka inaugurated the event. The seminar provided an overview of the completed and on-going research projects with a main focus on Helping Babies Breathe Project. The key focus of the seminar was to share with various stakeholders - academicians, policy makers, representatives of national and international agencies working in the area of MNCH research, officials of the Ministry of Health – the evidence emanating from the research studies implemented by the research unit in Belagavi, Bagalkote and Bijapur (Vijayapura) districts.



International Conference on Maternal and Newborn Health Research 2016

To commemorate the Centenary of KLE Society (1916 - 2016), the JNMC Women's and Children's Health Research Unit, Belagavi organized the International Conference on Maternal and Newborn Health Research on 5th & 6th of March 2016. This conference witnessed the participation of nearly **400** delegates (364 national and 26 international delegates) and 30 resource persons from 14 countries including Argentina, USA, Canada, United Kingdom, Switzerland, Egypt, Kenya, Uganda, Nigeria, South Africa, Pakistan, Singapore and Thailand. This platform brought together leading experts from around the world to debate priority research areas besides providing evidence from a number of completed and ongoing research projects focused on reducing maternal and newborn mortality/morbidity from Postpartum Haemorrhage, Hypertensive Disorders of Pregnancy, Birth Asphyxia and Preterm Birth. It also provided an opportunity to review the regulatory environment pertaining to the conduct of clinical research. The key focus of the conference was to share with various stakeholders – academicians, policy makers, representatives of national and international agencies working in the area of MNCH research, officials of the Ministry of Health – the evidence emanating from the research studies implemented by the research unit in Belagavi, Bagalkot and Bijapur districts. **34** International and National Experts delivered guest lectures followed by interactive sessions



2nd International Conference on Maternal and Newborn Health - 2018

The JNMC Women's and Children's Health Research Unit, KAHER's J N Medical College, Belagavi hosted the 2nd International Conference on Maternal and Newborn Health on 26th & 27th of March 2018 to share the results of some recently concluded research studies viz., CLIP Study, Clindamycin Trial & Women First Trial to reduce Maternal and Newborn mortality and morbidity and initiate a dialogue with the key stakeholders including academic research community, program managers and policy makers, both nationally and globally. This conference brought together leading experts in the areas of maternal and newborn health from around the world to discuss future priority research areas. A total of 60 International delegates representing 22 Nationalities USA, UK, Canada, Denmark, Australia, etc. and 240 National delegates including the Obstetricians and Gynecologists, Pediatricians, Public Health Experts, Nutritionists, participated in this event.

The conference was inaugurated by Dr Harsh Vardhan, Hon'ble Union Minister of Science & Technology; Earth Sciences; and Environment, Forest and Climate Change, Government of India. Honorable Chairman, KLE Society & Member of Parliament of Rajya Sabha, Dr. Prabhakar Kore presided over the program. Dr Mark Tykonciski, Executive Vice President for Academic Affairs, Thomas Jefferson University and Dr. Tonse N K Raju, Chief of Pregnancy & Perinatology, NICHD, USA were the guests of honour. Representatives from WHO, NICHD, NIH, Bill & Melinda Gates foundation, ICMR, National Institute of Nutrition, members of KLE Society and various research scholars attended the conference. The conference comprised of Scientific Deliberations, Key Note Addresses and Panel Discussion on current issues in maternal and newborn health viz. Post-partum haemorrhage, Hypertensive disorders of pregnancy, Maternal Nutrition and Preterm Birth. This conference provided a platform to set new guidelines to improve maternal and newborn health.



3rd International Conference on Maternal and Newborn Health - 2022

Women's & Children's Health Research Unit, Jawaharlal Nehru Medical College, Belagavi organized the 3rd International Conference on Maternal, Newborn and Child Health at JNMC Campus, Belagavi from November 11 to 13, 2022. The results of various research studies undertaken to improve Maternal and New-Born Health, to reduce Mortality Rates & Formulate Policies at the National & Global Level. Honourable Minister of Large & Medium Industries, Government of Karnataka, Dr Murugesh Nirani was the Chief Guest and inaugurated the conference. Dr. Prabhakar Kore, Honourable Chairman, KLE Society presided the event

The Guests of Honour were: Dr. Richard J Derman Associate Provost, Global Affairs, Professor and Gynaecology, Thomas Jefferson University, Philadelphia, USA Dr. Pushapa Deo Chaudhary, WHO Country Office, New Delhi, Dr. Bharati Kulkarni, Indian Council of Medical Research, New Delhi, Dr. M Indumathi, Dept of Health and Family Welfare Services, Govt. of Karnataka, Dr. Marion Koso – Thomas, Eunice Kennedy Shriver National Institute of Child Health and Human Development, USA, Ms Renata Hoffstetter, Foundation for the National Institutes of Health, USA, Dr. Jian Yan, Project Manager, Bill and Melinda Gates Foundation, USA, Dr. Robert Justin Brown, Thrasher Research Fund, USA, Dr. B S Kodkany Emeritus Professor of OBGYN, KAHER, Belagavi, Dr. Robert Goldenberg, Columbia University School of Medicine, USA, Dr. Nancy Krebs, University of Colorado School of Medicine, USA, Dr. Elwyn Chomba, Levy Mwanawasa Medical University, Zambia, Dr. Archana Patel, Lata Medical Research Foundation, Nagpur, India, Dr. Elizabeth McClure, RTI International, North Carolina, USA, Dr. Jean Anderson, John Hopkins Medical Institutions, USA, Dr. Dilly OC Anumba, The University of Sheffield, UK, Dr. Matthew K Hoffman, Christiana Care Health Services USA, Dr. Robert M Silver, University of Utah Health, USA, Dr. Jeffrey S A Stringer, Director, University of North Carolina, USA, Dr. Joshua P Vogel Burnet Institute, Australia Dr. Katherine Semrau, Harvard T.H Chan School of Public Health, USA, Dr. Zubair H Aghai, Nemours Children's Hospital, Philadelphia USA.



Representatives from WHO, NICHD USA, National Institutes of Health, Bill and Melinda Gates Foundation, Christian Care Health Institute, USA, Concept Foundation, RTI International, USA, Columbia University, USA, Thomas Jefferson University, USA, University of Colorado, University of Sheffield, Canada, Capetown University, South Africa, St Thomas Hospital, London, UK participated in the conference. Representatives from Ministry of Health and Family Welfare, Government of India and Indian Council of Medical Research (ICMR) were also present at the conference. More than 300 participants from 12 countries including senior medical researchers, scientists, faculty members from OBGYN, Pediatrics and Community Medicine from different medical colleges and various institutes from United States of America, Australia, South Africa, Switzerland, United Kingdom, Democratic Republic of Congo, Zambia, Nigeria, Kenya, Guatemala, Bangladesh and India participated in the event.



WHO - CHAMPION TRIAL: Steering Committee Meetings at J. N. Medical College, Belagavi

The JNMC Women's and Children's Health Research Unit hosted the WHO – CHAMPION Trial Steering Committee Meeting at the JNMC Campus on 7th and 8th March, 2016. Delegates from 13 Countries viz. USA, UK, South Africa, Denmark, France, Nigeria, Brazil, Switzerland, Egypt, Kenya, Pakistan, Thailand, Uganda and from India, delegates from four participant states Maharashtra, Uttar Pradesh, Odisha and Karnataka participated in the meeting. Similarly, JNMC hosted a similar Steering Committee Meeting on 28th and 29th March, 2018. A total of 25 delegates from 12 countries participated in the meeting.



Global Launch of Heat Stable Carbetocin at KLE-JNMC, Belagavi

The results of CHAMPION Trial led to another major milestone for the J N M C Women's and Children's Health Research Unit. A journey that started 20 years ago with the first community based randomized, placebo-controlled of oral Misoprostol 600 mcg for prevention of postpartum haemorrhage and consequent reduction in maternal mortality, sees yet another major milestone with the release of Room Temperature Stable (upto 30 deg. C) RTS Carbetocin Ferring 100 mcg/ml. This was indeed an exciting and fulfilling journey from conception of the research (March 2013) through implementation of the trial (May 2016 to January 2018), publication of the results in New England Journal of Medicine (June 2018), updating of the W H O recommendations for the use of uterotonics for prevention of PPH (December 2018), inclusion in the W H O List of Essential List of Medicines (March 2019) to regulatory approval for manufacturing and marketing by Central Drugs Standard Control Organization (Drugs Controller General of India) (September 2018) culminating into the 'Global Launch of Heat Stable Carbetocin' for public use at a public sector pricing (INR 28.93 inclusive of GST) on par with standard Oxytocin on July 23, 2021 at Belagavi.



The Global Product Launch of RTS Carbetocin used for the prevention of postpartum haemorrhage, PPH was organised by JNMC Women's and Children's Health Research Unit, KLE Academy of Higher Education and Research (Deemed-to-be-University) at KLE Centenary Convention Center, JNMC Campus on July 23, 2021. The program was presided by Dr Prabhakar Kore, Chairman, KLE Society and Honourable Chancellor, KLE Academy of Higher Education and Research (KAHER), Belagavi and was attended by leading obstetricians including Dr Shanta Kumari, President, Federation of Obstetricians and Gynecologists Societies of India (FOGSI), Treasurer, International Federation of Gynecology and Obstetrics (FIGO), Senior Consultant OBGYN, Yashoda Hospitals, Hyderabad, Dr Hema Divakar, Consultant OBGYN & Medical Director, Divakar's Speciality Hospital, Bengaluru & Co-Chair FIGO Pregnancy and NCD Committee, Dr Sheela Mane, Past Vice-President FOGSI and Governing Council Member ICOG, Dr Basavaraj Sajjan, President, Karnataka State Obstetrics and Gynecology Association, Representatives from Ferring Pharmaceuticals, Switzerland - Mr. Sudheendra Kulkarni, Mr. Bhavin Vaid, Dr. Vishal Shah, Mr. Oleg Zurov, Ms. Monique Blom and Mr. Alok Dev were present during the program. The program was attended by the study investigators, obstetricians, doctors and research officers all over the country both offline as well as virtually.

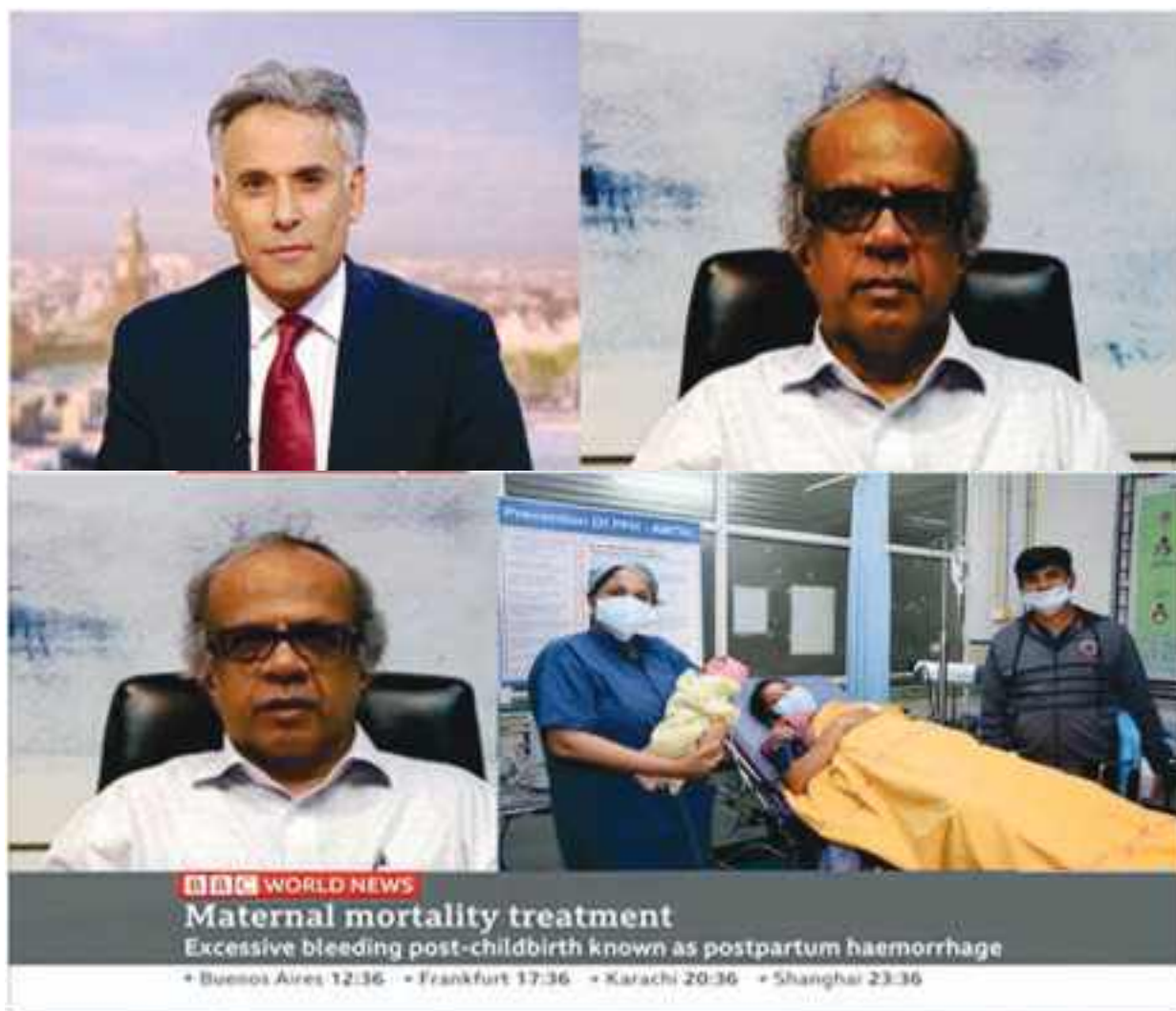
The First injection of RTS Carbetocin was administered at KLES Dr Prabhakar Kore Charitable Hospital, Belagavi by Dr Yeshita V Pu jar, Professor of OBGYN in presence of Officials from Ferring Pharmaceuticals on this day. JNMC Women's and Children's Health Research Unit donated 1000 medication ampules to KLES Dr Prabhakar Kore Charitable Hospital, Belagavi.

Following this, RTS Carbetocin Ferring-Global Virtual Launch Webinar was conducted on Monday, July 26, 2021. Dr Vivek Saoji, Vice-Chancellor, KAHER, gave the introductory remarks. Dr Richard J Derman, Associate Provost for Global Affairs & Director, Global Health Research, Professor, Obstetrics and Gynecology, Thomas Jefferson University, Philadelphia, PA, USA highlighted the Interventions for



Improving Maternal Outcomes. Dr Shivaprasad S Goudar, Professor of Physiology, J N Medical College & Director-Research, KAHER, briefed about the RTS Carbetocin Ferring - India Launch and its impact. Dr Yeshita V Pujar, Professor of OBGYN, J N Medical College, shared her experience of First Use of RTS Carbetocin Ferring. Dr S Shantha Kumari, President FOGSI, Dr Hema Divakar, Co-Chair FIGO Pregnancy & N C D Committee, Dr N Rajkumar, Deputy Director, Maternal Health, Department of Health and Family Welfare Services, Govt. of Karnataka, Bengaluru, Dr Mary-Ann Etiebet, Lead of Merck for Mothers, Kenilworth, NJ, USA and Mr Bhavin Vaid, Head of Corporate Communications and Public Affairs, Ferring Pharmaceuticals, Switzerland shared their views on this occasion. Dr Sarah Jarvis, General Practitioner, Broadcaster, Television Doctor, London, United Kingdom hosted the webinar.

This global launch drew the attention of the world and as a result, Mr. Matthew Amroliwala from British Broadcasting Corporation (BBC) conducted a live interview with Director-Research of KAHER and Principle Investigator (India) Dr Shivaprasad S Goudar on July 26, 2021 to mark the Global Product Launch of Heat Stable Carbetocin and discussed its impact on the health of mothers especially in low-and-middle income countries. The interview was broad casted in B B C World News at 9.10 pm IST on the same day.



WHO Collaborating Center for Research in Maternal and Perinatal Health

Women's and Children's Health Research Unit, Jawaharlal Nehru Medical College, KLE Academy of Higher Education and Research (Deemed-to-be-University), Belagavi is designated as a "WHO Collaborating Center for Research in Maternal and Perinatal Health" for a period of four years effective from September 16, 2019.

Terms of Reference:

1. In alignment with WHO goals, to provide capacity building through Research Methodology Workshops at country level.
2. To participate in collaborative research in the area of Maternal and Newborn Health developed under WHO's leadership.
3. As agreed with WHO, disseminate and scale up evidence based interventions in the area of Maternal and Newborn Health.

Subject areas of work:

1. Reproductive Health (excluding HIV/AIDS);
2. Health Promotion & Education; AND
3. Child & Maternal Health.

Planned activities:

1. Research;
2. Information Dissemination; and
3. Training and Education



Highlights:

Globally there are 825 WHO Collaborating Centers, of which currently India has 56 active Centers. Among these 56 currently active Indian WHO CCs, JNMC Research Unit is ONE of ONLY seven in the private sector (others being - Dr Mohan's Diabetes Hospital, Chennai; LV Prasad Hospital, Hyderabad; CMC, Vellore; SRM, Chennai; and Arvind Hospital, Madurai).

Among the FOUR WHO CCs in Karnataka, (NIMHANS - 2 centers, National Tuberculosis Institute) JNMC Research Unit is the ONLY ONE in the private sector.

WHO-CC Activities:

Workshop on Research Methodology and Grant Proposal Writing for Faculty of KLE Institute of Nursing Sciences, Belagavi.

Online Research Methodology and Grant Proposal Workshop was conducted by Dr Shivaprasad Goudar, Director WHO - CC and his colleagues Dr Manjunath S Somannavar and Dr Avinash Kavi between June 6 to July 17, 2020 for 20 faculty members of the KLE Institute of Nursing Sciences, Belagavi. The workshop was planned with online sessions once a week extended over 5 weeks period and focussed on: Biomedical research: setting the stage and transforming an idea into a research question; Study design and instrumentation; Sample size and sampling; data analysis plan; Monitoring data quality; time line and budget; Grant proposal writing. The participants worked as a group and weekly tasks were given to each of the groups to develop a grant proposal by the end of the course. Offline discussion was conducted to support them in formulating research proposal. Five grant proposals were prepared and were further subjected to the expert review by the faculty of Thomas Jefferson University, Philadelphia, USA with a likely possibility of the submission of the proposal for funding opportunities.

Research Methodology and Grant Proposal Workshop was conducted by Dr Shivaprasad Goudar, Director WHO-CC and his colleagues Dr Manjunath S Somannavar and Dr Avinash Kavi with a support from Dr Frances Jaeger, former Research Coordinator for TJU-JNMC Global Network for Women's and Children's Health Research Unit, during September 12 to 14, 2022 for 18 faculty members from Medicine, Dental, Ayurveda, Physiotherapy, Pharmacy, and Nursing Institutes of KAHAR, Belagavi. The workshop was focused on Grant proposal writing. The participants have been developing a grant proposal and the progress will be reviewed in person one-on-one basis during October and November 2022.

Knowledge Translation on Maternal and Perinatal Health Research Projects

The results of WHO - CHAMPION Trial was presented by Dr Yeshita Pujar at All India Congress of Obstetrics & Gynaecology (AICOG) held at Bhubaneswar on January 19, 2018 and at Bengaluru on January 10, 2019. The Indian sub-set analysis WHO CHAMPION Trial was presented by Dr Yeshita Pujar at the DCGI Advisory Board Meeting on September, 2019 held at Kolkata organized by Ferring Pharmaceuticals with an idea of launching the molecule in India. The Indian sub-set analysis WHO CHAMPION Trial was presented by Dr Sunil Vernekar at the DCGI Subject Expert Committee Meeting on October 15, 2019 held at New Delhi organized Drug Control General of India for the regulatory approval. The Heat Stable Carbetocin has been approved by Drug Control General of India for marketing in India during September, 2020. The global launch of the Carbetocin has been planned at Belagavi on July 23, 2021.

Dr. Shivaprasad Goudar was invited to International Confederation of Midwives' Triannual Congress at Bali, Indonesia between June 21-25, 2020 to participate and present in the symposium on 'Advocating for access to quality uterotonics for the prevention of post-partum haemorrhage, 'an ounce of prevention is worth a pound of cure'.

Dr Avinash Kavi was invited at UNICEF-WHO Joint Plenary Session on impact of COVID-19 Pandemic on Newborn Care Practices and Lessons Learnt at 40th Annual National Conference of National Neonatology Forum NEOCON-2021 held at Bengaluru on December 19, 2021. The results of recently completed WHO Collaborating Center SCOPE Study and MNH-COVID Study was presented.

Dr Yeshita Pujar participated as a panellist in panel discussion on Preventing Postpartum Haemorrhage where the needs are greatest: Heat Stable Carbetocin from Scientific Evidence to Implementation on October 26, 2021 organized by FIGO 2021 (Virtual).

Dr Yeshita Pujar presented "Heat Stable Carbetocin in Prevention of Postpartum Haemorrhage" at 31st KSOGA Conference on December 17-19, 2021 at Davanagere, Karnataka, India

Dr. Shivaprasad Goudar was invited to International Confederation of Midwives' Triannual Congress at Bali, Indonesia between June 21-25, 2020 to participate and present in the symposium on 'Advocating for access to quality uterotonics for the prevention of post-partum haemorrhage, 'an ounce of prevention is worth a pound of cure'. However, the meeting has been deferred to 2021 due to COVID 19 pandemic.

Dr Shivaprasad S Goudar presented "Heat Stable Uterotonics for Prevention of Postpartum Hemorrhage" during the panel presentation of the Consortium of Universities for Global Health (CUGH)-2022 March 28- April 1, 2022 (Virtual)

Dr S M Dhaded presented "The final words on antenatal corticosteroids – the ACTION Studies" at PRIME-TIME Conference on June 3-4, 2022 organized by S N Medical College, Bagalkot, Karnataka India. Dr Sunil Vernekar presented "Prevention of PPH: Current Perspective" at PRIME-TIME Conference on June 3-4, 2022 organized by S N Medical College, Bagalkot, Karnataka India.

Dr Yeshita Pujar participate in CME on Postpartum Haemorrhage Organized by the Department of Obstetrics and Gynecology, Jawaharlal Nehru Medical College, Belagavi on July 2, 2022

Dr Shivaprasad S Goudar and Dr Yeshita V Pujar attended the meeting on practice points on Postpartum Hemorrhage organized by Federation of Obstetric and Gynaecological Societies of India (FOGSI) on 15th July, 2022 at HICC, Hyderabad, India.

Dr Shivaprasad S Goudar participated in the event "For Every Mother in India" hosted by the Embassy of Switzerland in India in conjunction with Ferring's #ProjectFamily: Safe Birth initiative on Tuesday 13th September, 2022 at New Delhi, India.

Dr Yeshita Pujar presented "Heat Stable Carbetocin in Prevention of Postpartum Haemorrhage" at 32nd KSOGA Conference on September 23-25, 2022 at Hubballi, Karnataka, India.

Dr Sunil Vernekar visited Burnet Institute in Melbourne, Australia during 19 to 24 September 2022. This visit was done to complete the process evaluation which is one of the study components along with the discussion on publications based on the results of the present study. During the visit there were discussions on process evaluation and publications held with the PI of the study Dr Joshua Vogel and his team members.

Dr Yeshita Pujar presented "Heat Stable Carbetocin in prevention and treatment of PPH" at 3rd International Conference on Maternal, Newborn and Child Health on November 11-13, 2022 at Jawaharlal Nehru Medical College, Belagavi, Karnataka India

Dr Avinash Kavi presented "SCOPE: Standardization of COVID-19 in Pregnancy; WHO India study at 3rd International Conference on Maternal, Newborn and Child Health on November 11-13, 2022 at Jawaharlal Nehru Medical College, Belagavi, Karnataka India

Dr Yeshita Pujar participated as a panellist in panel discussion on preventing postpartum haemorrhage at 65th All India Congress of Obstetrics and Gynaecology at Kolkata on January 4-8, 2023

Collaborative Research Projects

We participated in the following studies sponsored by WHO.

- WHO ACTION (Antenatal Corticosteroids for Improving Outcomes in preterm Newborns) Trials. The status of the study implemented in all four Indian sites- Belgaum, Bijapur, Bagalkot and Cuttack under the leadership of J N M C Research Unit is as follows:
- ACTION I-Screened 952, Randomized 579, Delivered 579, and Follow up completed 579 (100%). Primary publication published in NEJM.
- ACTION II-Screened 1201, Randomized 778, Delivered 771, and Follow up completed 750.
- ACTION III-Assessment for an additional site at KIMS, Hubballi.
- Prevalence and outcomes of abnormal continuous wave Doppler flow indices in unselected obstetric populations in low- and middle-income countries: The Umbiflow™ International Study. A total of 1,724 women were screened and 1408 women were enrolled in the study beginning from January 1, 2019. The study documented 100% follow up which was completed on December 1, 2019. The data analysis and discussion has been completed and primary publication is underway.
- Evaluating the WHO Labour Care Guide in clinical settings. The study was implemented at Belagavi and Balasore. Enrolment started on October 3, 2019. Total screened - 609, Enrolled - 200. The follow up and data analysis have been completed. The results and recommendations led to WHO Modified Labour Care Guide in 2020.
- The WHO Country Office for India invited the WHO CCs working in the field of Maternal and Perinatal health Research in India to be a part of 'Standardization of COvid in PrEgnancy (SCOPE) - Standardizing of data collection and protocol for improving the Quality of evidence on clinical characteristics and outcomes of COVID-19 and Pregnancy' Study. We are collaborating with three other WHO-CCs at AI IMS, New Delhi; PG I MER, Chandigarh and MGIMS, Wardha in India. The data collection has been completed and the primary publication and technical report is underway.
- Simplified Treatment for Eclampsia Prevention using Magnesium sulfate: A phase III, randomized, open label, active controlled, multicountry, multicentre, non-inferiority trial of simplified magnesium sulfate regimen for eclampsia prophylaxis (The STEP-Mag Trial) is being implemented to evaluate the non-inferiority of a simplified magnesium sulfate regimen as compared to the existing regimes. This study is being implemented at tertiary Medical Institutes at Davanagere, Raichur (Karnataka), Cuttack (Odisha) and Jaipur (Rajasthan) sponsored by Department of Reproductive Health & Research, World Health Organization, Geneva.
- After the tremendous success of WHO-CARBETOCIN Trial, further is being scaled up to a facility based trial to assess the safety and efficacy of heat stable Carbetocin for PPH treatment, compared to oxytocin. The study will be further implemented at tertiary medical institutes across India.

Four WHO Collaborating Centres working in the field of Maternal and Perinatal Health Research including JNMC, Belagavi collaborated with WCO to participate in the nested case control study - Standardizing Quality of evidence on clinical characteristics and outcomes of COVID-19 and Pregnancy (SCOPE). The study aimed at standardization of the treatment protocol of COVID infection in pregnancy and building capacity to support documentation of clinical outcome including co-morbidities, mode of transmission of infection of all mother and new-born admitted to WHO-CC/satellite hospitals with/without COVID infection. The study was implemented between April 2020 and March 2021. Within this short span we were able to collect the data from 3400 pregnant women who were tested positive for COVID-19 infection at all the WHO-CC Network of hospitals across 7 states and 1 Union Territory with almost pan India Representation with 1:2 matched controls. The satellite hospitals under JNMC WHO-CC managed to enrol 940 cases and 1190 controls, second highest number after AIIMS New Delhi Network. The data analysis has been completed and the Maternal outcomes paper has been accepted for publication in PLOS ONE. The neonatal outcomes paper is being reviewed by the authors and it will be submitted for publication soon.

Implementing the 'WHO Labour Care Guide to reduce the use of Caesarean section in four hospitals in India: a pragmatic, stepped wedge, cluster randomized pilot trial'. This is a stepped-wedge, cluster-randomized pilot trial conducted in four hospitals in India, evaluating how the new WHO Labour Care Guide (LCG) can reduce Caesarean section rates and improve the quality of labour and childbirth care. An LCG implementation strategy was co-designed with local stakeholders and implemented in participating hospitals (compared to usual care) to assess its effects on Caesarean section use amongst women in Robson Group 1. The study aimed to develop and optimise a strategy for implementing the LCG (formative phase) and to evaluate the implementation of the LCG strategy compared with usual care (pilot trial phase). Dr Shivaprasad Goudar, Dr Yeshita Pujar, Dr Manjunath Somannavar and Dr Sunil Vernekar were involved as the central team members co-ordinating the implementation of this study in four public sector hospitals attached to Medical Colleges in Karnataka state in India. The enrolment for this study began in July 15, 2021 and was completed in July 15, 2022. During this period, total of 27,411 delivering women were enrolled in the study. The data cleaning process is under progress and will be completed by October 2022. The study analysis is proposed to be completed by October 2022.



WHO Labour Care Guide to reduce the use of Caesarean section in four hospitals in India: a pragmatic, stepped wedge, cluster randomized pilot trial Team

Community Engagement Board

The Women's and Children's Health Research Unit, J N Medical College, KLE Academy of Higher Education and Research, Belagavi, India is committed to the ethical conduct of research and has been active in addressing ethical challenges related to research in maternal and child health.

Community Engagement Board has been established to engage local stakeholders and continuing to involve the Ministries of Health at the local, state, and national level; incorporating Accredited Social Health Activists (ASHA) workers, peer counsellors, and auxiliary nurses into the research team as appropriate. Community Engagement Board (CEB) comprising of lay community members, health program officers, community leaders, representatives for the local rural self-government, will provide input on unmet research needs of most benefit to health care consumers and families, facilitate dissemination of research findings, and enable translation of research evidence into practice. One person from this group will be chosen to serve on the GN CEB as a representative from the TJU-JNMC Women's and Children's Health Research Unit.

Objective: The purpose of the board will be to provide a forum for local input regarding the relevancy of research conducted in their area, to assure that we remain sensitive to the needs of the community, and to assist with integrating research findings into local practice.

The group will be comprised of about 10-12 individuals including community leaders, social activists, health care consumers, previous home visitor assistants, ASHAs, state/district health officers, and educators. The international Research Coordinator will be the convener of biannual meetings, or as needed, when a new protocol is being proposed for the community.

CEB Constitution:

Chair: Deputy Director, Maternal Health, Department of Health and Family Welfare, Government of Karnataka (Ex-officio)

Co-chair: District Reproductive and Child Health Officer (Ex-officio), Belagavi



Review Meeting on December 19, 2020, Dr N Rajkumar,
Advisor for J N M C Women's and Children's Health Research Unit, Deputy Director Maternal Health,
Directorate of Health and Family Welfare Services, Government of Karnataka

Members:

- 1 Community Leader (Rural self-government representative)
- 1 Retired Senior Medical Officer
- 2 lay persons from community (among them at least one should have good command over English language)
- 1 ASHA/ ASHA Facilitator
- 1 NGO representative
- 1 Social worker
- 1 Representative from Social Welfare Organization
- 1 Representative from Woman self-help group
- Member Secretary: International Research Coordinator of GN Site 08

Functions of CEB:

- Review of protocol and consent of every GN Study Protocol
- Discuss the impact of the study implementation on the community
- Discuss and provide solutions for study implementation
- Provide guidance regarding the potential benefits of the research outcomes
- Facilitate dissemination of research findings
- Enable translation of research evidence into practice

One member of the CEB will represent GN Site 08 for the Central GN CEB. The CEB will meet at least twice a year and discuss the ongoing GN study proposals.

COLLABORATIONS

The Research Unit has research collaborations with the following international and national funding agencies, universities and institutions:

Sponsors: Governmental Agencies

1. World Health Organization, Geneva, Switzerland
2. National Institute of Health and Human Development, (NICHD), Bethesda, MD, USA
3. National Cancer Institute, National Institutes of Health, Bethesda, MD, USA
4. Medical Research Council, UK
5. National Institute of Neurological Diseases and Stroke, NIH, Bethesda, MD, USA
6. Fogarty International Center, Bethesda, MD, USA
7. USAID, Washington, USA
8. NORAD, Norway
9. International Atomic Energy Agency, Vienna, Austria
10. Indian Council of Medical Research, New Delhi, India
11. Department of Biotechnology, Govt. of India
12. National Health and Medical Research Council, Australia

Sponsors: Foundations /N GOs

1. Bill & Melinda Gates Foundation, USA
2. Thrasher Research Fund, USA
3. Merck for Mothers, USA
4. Children's Investment Fund Foundation, UK
5. Grand Challenges Canada, Canada
6. Concept Foundation, Geneva Switzerland

Collaborators International: Universities

1. Thomas Jefferson University, Philadelphia
2. Christiana Care Health System, Wilmington, DE
3. Columbia University, New York
4. University of North Carolina at Chapel Hill
5. Harvard T. H. Chan School of Public Health, Boston
6. Johns Hopkins Bloomberg School of Public Health, Baltimore
7. Nemours Children's Hospital, Wilmington Delaware
8. Massachusetts General Hospital, Harvard University, Boston
9. University of Illinois at Chicago, Chicago
10. University of Missouri at Kansas City, Kansas City
11. University of Alabama at Birmingham, Birmingham
12. University of Colorado Health Sciences Center, Denver
13. University of California, San Francisco
14. Vanderbilt University, Nashville, TN
15. Oregon Health & Science University, Portland, Oregon
16. King's College, London, UK

17. The University of Sheffield, UK
18. University of Zambia, Lusaka, Zambia
19. Burnet Institute, Australia
20. Institute for Clinical Effectiveness and Health Policy (IECS), Argentina
21. Mbarara University of Science and Technology, Uganda
22. University of British Columbia, Canada
23. University of Pretoria, Pretoria, South Africa

International: Research Institutes

1. RTI International, North Carolina, USA
2. Gynuity Health Projects, New York, USA
3. Program for Appropriate Technologies for Health (PATH), Seattle, USA
4. Obstetrx Inc, Wilsonville, USA

National: National Medical Colleges/Universities

1. B.V.V.S.'s S. N. Medical College, Bagalkot, Karnataka
2. BLDE University's Shri B. M. Patil Medical College, Vijayapura, Karnataka
3. J. J. M. Medical College, Davanagere, Karnataka
4. S S Institute of Medical Sciences and Research Center, Davanagere, Karnataka
5. Karnataka Institute of Medical Sciences (KIMS), Hubballi, Karnataka
6. Belgaum Institute of Medical Sciences (BIMS), Belagavi, Karnataka
7. Gadag Institute of Medical Sciences (GIMS), Gadag, Karnataka
8. Vijayanagar Institute of Medical Sciences (VIMS), Ballari, Karnataka
9. Raichur Institute of Medical Sciences, Raichur, Karnataka
10. S. C. B. Medical College, Cuttack, Odisha
11. Fakir Mohan Medical College & Hospital, Balasore, Odisha
12. Government Medical College, Nagpur, Maharashtra
13. Sawai Man Singh Medical College, Jaipur, Rajasthan
14. Mahatma Gandhi Institute of Medical Sciences, Sevagram, Wardha, Maharashtra
15. Indira Gandhi Government Medical College, Nagpur, Maharashtra
16. Daga Memorial Hospital, Nagpur, Maharashtra
17. All India Institute of Medical Sciences, Nagpur, Maharashtra
18. Institute of Medical Sciences, Banaras Hindu University, Varanasi, Uttar Pradesh
19. Post Graduate Institute of Medical Education & Research, Chandigarh
20. Government Medical College, Chandrapur, Maharashtra
21. Post Graduate Institute of Medical Education & Research, Bhubaneswar, Odisha
22. Yashwantrao Chavan Memorial Hospital, Pimpri, Pune, Maharashtra

National: Research Institutes

1. Model Rural Health Research Unit (MRHRU), Sirwar, Raichur, Karnataka
2. The Karnatak Cancer Therapy And Research Institute (KCTRI), Hubballi, Karnataka
3. Lata Medical Research Foundation, Nagpur, Maharashtra
4. ICMR - National Institute of Traditional Medicine (NITM), Belagavi (previously known as Regional Medical Research Centre)

**Women's and Children's Health Research Unit
KLE Academy of Higher Education and Research (Deemed-to-be-University)
J N Medical College, Belgaum, Karnataka, India**

ONGOING RESEARCH PROTOCOLS

1. "A Cluster Randomized clinical trial of umbilical cord milking compared to early cord clamping in preterm infants who are non-vigorous at birth" in collaboration with Nemours Children's Hospital, USA with funding from Thrasher Research Fund, USA (May 2025 – April 2028)
2. The views and experiences of women and antenatal care providers in India on maternal sleep position during pregnancy: protocol for a mixed-methods formative research study with funding from Burnet Institute, Melbourne, Australia **(May 2024 – April 2025)**
3. Low Birthweight and Preterm Infant Feeding Trial and Supportive Care Package (LIFT-UP) in collaboration with Ariadne Labs, USA with funding from Bill and Melinda Gates Foundation, USA (April 2023 – September 2026)
4. Implementation research on postpartum IV iron in Global Network sites: A Prevention of Iron Deficiency Anemia Post-delivery (PRIORITY) sub-study in collaboration with Thomas Jefferson University, Philadelphia, PA, USA and funding by Bill & Melinda Gates Foundation, USA **(June 2023 – November 2025)**
5. Prevention of Iron Deficiency Anemia Post-delivery (PRIORITY Trial) A Randomized Controlled Trial of the Global Network for Women's and Children's Health Research" in collaboration with Thomas Jefferson University, Philadelphia, PA, USA and funding by Global Network for Women's and Children's Health Research of the Eunice Kennedy Shriver National Institute of Child Health and Human Development, USA, Bill & Melinda Gates Foundation, USA and Foundation for the National Institutes of Health, USA **(November 2022 – November 2025). Total global sample size is 4,800. Belagavi site started the recruitment by end of May 2023 and as on May 2024, has screened 6,300 women and randomized 645 participants**
6. "Neuroimaging sub study of IV Iron RAPID IRON trial" in collaboration with Collaboration with Thomas Jefferson University, Nemours Children's Hospital, Philadelphia, University of Wisconsin and University of Minnesota and funding from Bill & Melinda Gates Foundation, USA. **(February 2023 – January 2026) Total enrolment is 184 which include antenatal fetal MRI completed among 49 participants and 134 infant MRI will be done at 4, 12 and 24 months**
7. "RAPIDIRON-Kids Study" in collaboration with Thomas Jefferson University, Philadelphia, PA, USA and funding by Children's Investment Fund Foundation (CIFF), UK **(February 2022-February 2026(Recruitment started November 2, 2022; Enrolled: 538 Participants))**
8. Single oral dose of azithromycin 2 gm to prevent maternal peripartum infection and newborn sepsis in laboring women (A-PLUS Trial): Repurposing azithromycin as a neuro-protector; a neurodevelopmental follow-up secondary study in collaboration with Thomas Jefferson University, Philadelphia, PA, USA and University of Alabama, Birmingham, USA with funding from Thrasher Research Fund, USA **(November 2022-December 2024) (# enrolments as on April 2024: 118)**
9. "A Cluster Randomized Clinical Trial of Umbilical Cord Milking versus Early Cord Clamping on Short and Long-term Outcomes in Neonates Who are Non-Vigorous at Birth" in collaboration with Nemours Children's Hospital and Thomas Jefferson University with funding from Eunice Kennedy Shriver National Institute of Child Health and Human Development, USA **(September 2021-September 2025) (Recruitment started November 1, 2022 and Enrolled: 1,950) (Sample size 3,442)**
10. "WHO ACTION-III TRIAL: A multi-country, multi-centre, three-arm, parallel group, double-blind, placebocontrolled, 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" sponsored by World Health Organization, Geneva, Switzerland **(November 2020 – March 2025) (Sample Size: Superiority comparison 1,929 and Non-inferiority Comparison: 2,184) (# enrolment till May 2024: 1,322)**
11. "Maternal and Newborn Health Registry (MNH Registry)", funded by the Global Network for Women's and Children's Health Research of the National Institute of Child Health and Human Development, USA **(January 2008 – May 2023) (# enrolments till April 2024: 1,92,600, All GN Sites total enrolments 8,56,700)**

**Women's and Children's Health Research Unit
KLE Academy of Higher Education and Research (Deemed-to-be-University)
J N Medical College, Belgaum, Karnataka, India**

UPCOMING RESEARCH PROTOCOLS

1. "Heat-stable carbetocin for the treatment of postpartum haemorrhage: a phase III, randomized, double-blind, active controlled, multicountry, multicentre, non-inferiority trial" (WHO REACH)" with funding from World Health Organization, Geneva, Switzerland.
2. "XSTAT Device for PPH Treatment" in collaboration with Concept Foundation, Geneva, Switzerland and Oregon Health & Science University with funding from Obstetrx, USA.

COMPLETED RESEARCH PROTOCOLS

1. "Accelerating Innovation for Mothers (AIM)-Gender: Understand and address barriers to pregnant women's participation in clinical trials" with funding from Concept Foundation, Geneva Switzerland **(May 2023 to April 2024) Total of 13 focus group discussion and 35 In-depth interviews conducted have been conducted with all the stake holders.**
2. "Reducing Anemia in Pregnancy in India: The RAPIDIRON Trial" in collaboration with Thomas Jefferson University, Philadelphia, PA, USA and funding by Children's Investment Fund Foundation (CIFF), UK **(September 2020 to August 2023) (# enrolments completed: 4,368) (Sample Size: 4,320)**
3. "A66014: Simplified Treatment for Eclampsia Prevention using Magnesium sulfate: A phase III, randomized, open label, active controlled, multicountry, multicentre, non-inferiority trial of simplified magnesium sulfate regimen for eclampsia prophylaxis (The STEP-Mag Trial)" with funding from World Health Organization, Geneva, Switzerland **(May 2021 – May 2024) (# enrolments completed: 792)**
4. "Augmented Infant Resuscitator (AIR)" in collaboration with Mbarara University of Science and Technology, Uganda and Massachusetts General Hospital, Harvard University, Boston with funding from Grand Challenges Canada **The study was conducted between March 2023 to February 2024 and included 104 skilled birth attendants from 12 public sector hospitals from Belagavi district in India apart from 133 from Kenya**
5. Validation of a Survey Instrument for Screening of Pre-Pregnant Women The PREPSA SCALE in collaboration with Thomas Jefferson University and funding from Global Network for Women's and Children's Health Research of the Eunice Kennedy Shriver National Institute of Child Health and Human Development, USA **(December 2022 – December 2023) (# enrolments completed: 503)**
6. "Prevention of Maternal and Neonatal Death/Infections With a Single Oral Dose of Azithromycin in Women in Labor (in Low- and Middle-income Countries): a Randomized Controlled Trial" funded by the Global Network for Women's and Children's Health Research of the Eunice Kennedy Shriver National Institute of Child Health and Human Development, USA **(May 2019 to February 2023) (# enrolments completed: 5,635) Global Sample Size: 29,278**
7. "Implementing the WHO Labour Care Guide to reduce the use of Caesarean section in four hospitals in India: a pragmatic, stepped wedge, cluster randomized pilot trial" in collaboration with Burnet Institute, Australia; Institute for Clinical Effectiveness and Health Policy (IECS), Buenos Aires – Argentina; and the World Health Organization with funding from Bill & Melinda Gates Foundation, USA **(November 2020 – October 2023) (# enrolments as on July 2022: 27,400) (Sample Size: 23,000)**
8. Limiting Adverse Birth Outcomes in Resource -Limited Settings – The LABOR Study" in collaboration with University of North Carolina at Chapel Hill, USA and funding by Bill & Melinda Gates Foundation, USA **(January 2020 to October 2022) (# enrolments completed: 4,017) Global Sample Size: 12,000**
9. "Low-birthweight Infant Feeding Exploration (LIFE)" project in collaboration with Ariadne Labs/Harvard T.H. Chan School of Public Health, Boston, MA and funded by Bill & Melinda Gates Foundation **(November 2018 to October 2022) (Data Collection completed for 600 Mothers and 510 Babies)**

10. "COVID-19 prevalence during pregnancy and pregnancy outcomes in 8 low and middle-income sites: MNH COVID-19" funded by the Global Network for Women's and Children's Health Research of the Eunice Kennedy Shriver National Institute of Child Health and Human Development, USA (August 2020 – June 2022) (**# enrolments completed: 3,114**) **Global Sample Size: 23,656**
11. "CRADLE-4: Can Reduction of Adverse pregnancy outcomes occur with planned DeLivery vs. Expectant management in pre-eclampsia?" in collaboration with King's College, London co-funded by UK Medical Research Council and Department of Biotechnology, Govt. of India (May 2019 to May 2022) (**India enrolments: 156 (77 in planned delivery and 79 in expectant management) and Zambia enrolments: 407 (205 in planned delivery and 202 in expectant management)**)
12. "Promoting MITS activities to determine cause of death among neonates and stillbirths in tertiary care teaching hospital" in collaboration with RTI International, NC, USA and funded by Bill & Melinda Gates Foundation, USA (May 2019 to March 2022) (**# enrolments: 30**)
13. "Aspirin Supplementation for Pregnancy Indicated Risk Reduction in Nulliparous (ASPIRIN): Neurodevelopmental Follow-up Trial" in collaboration with Thomas Jefferson University, Philadelphia, PA, USA and funding from Thrasher Research Fund, USA (December 2021 – June 2022) (**# enrolments: 116**) (**Global Sample Size: 625**)
14. "Study of Cause of Death among Preterm Birth: Asia" in collaboration with RTI International, USA and J J M Medical College Davangere with funding from Bill & Melinda Gates Foundation, USA (November 2017 – December 2021) (**# Mothers enrolled: 2,261; # Stillbirths enrolled: 377 and # Neonatal Deaths enrolled: 329**)
15. "Performance, Safety and Efficacy of a New Cryotherapy Device for Cervical Dysplasia in Low and Middle Income Countries" project in collaboration with Johns Hopkins Medical Institutions, Karnataka Institute of Medical Sciences, Hubballi and The Karnatak Cancer Therapy and Research Institute and funded by National Institute of Health/National Cancer Institute (NIH/NCI), USA (May 2019 to April 2021) (**# Screened: 9,129 and # Cryotherapy done: 15**)
16. "SCOPE - Standardization of COvid in PrEgnancy Standardizing of data collection and protocol for improving the Quality of evidence on clinical characteristics and outcomes of COVID-19 and Pregnancy" with funding from World Health Organization – Country Office for India, New Delhi (July 2020 – January 2021) (**Data collection completed: 938 Covid-19 cases and 1,190 controls**)
17. "The WHO ACTION (Antenatal Corticosteroids for Improving Outcomes in preterm Newborns) Trials:"
 - a. WHO ACTION-I TRIAL - A65913: A multi-country, multi-centre, two-arm, parallel, double-blind, placebo-controlled, randomized trial of antenatal corticosteroids for women at risk of imminent birth in the early preterm period in hospitals in low-resource countries to improve newborn outcomes. (**# enrolments: 579, recruited 20% of global sample size 2,852**)
 - b. WHO ACTION-II TRIAL - A65916: A multi-country, multi-centre, two-arm, parallel, double-blind, placebo-controlled, randomized trial of antenatal corticosteroids for women at risk of imminent birth in the late preterm period in hospitals in low-resource countries to improve newborn outcomes. (**# enrolments: 778 only in India**)

Sponsored by World Health Organization, Geneva from June 2017 to September 2020

18. "Breastfeeding Education Support Tool for Baby (BEST4Baby)" funded by Fogarty International

Center, National Institutes of Health, USA (October 2017 – September 2020)(# enrolments: 240 and 25 peer-counsellors trained)

19. "Sit Down and Play" in collaboration with University of Illinois at Chicago, USA and funded by Eunice Kennedy Shriver National Institute of Child Health and Human Development, USA (November 2019 – December 2020)(# enrolments: 47 children)
20. "Evaluating the WHO Labour Care Guide in clinical settings" Sponsored by World Health Organization, Geneva, Switzerland. (September 2019 to December 2019)(# Health Care Providers Trained: 26; # women enrolled: 201, recruited 16% of global sample size 1,226)
21. "Prevalence and outcomes of abnormal continuous wave Doppler flow indices in unselected obstetric populations in low- and middle income countries: The Umbiflow™ International Study (A65924)" Sponsored by World Health Organization, Geneva. (August 2018 to July 2019) (# enrolments: 1,415, recruited 20% of global sample size of 7,151)
22. "Vital signs alert Evaluating Shock index in Pregnancy Anaemia" project in collaboration with King's College London, UK and funded by Newton Prize, Department of Business, Energy and Individual Strategy (July 2018 – July 2019)
23. "Preconception Maternal Nutrition: A randomized trial" of the Global Network for Women's and Children's Health Research in Collaboration with the Bill and Melinda Gates Foundation (December 2012 – April 2019)(# enrolments: 1,824, recruited 24% of global sample size 7,376)
24. "Aspirin Supplementation for Pregnancy Indicated Risk Reduction In Nulliparas (ASPIRIN)" funded by the Global Network for Women's and Children's Health Research of the Eunice Kennedy Shriver National Institute of Child Health and Human Development, USA (May 2015 to April 2019) (# enrolments: 2,750, recruited 23% of global sample size of 11,976)
25. "The CLIP (Community Level Interventions for Pre- Eclampsia) Cluster Randomized Controlled Trial" in collaboration with University of British Columbia, Vancouver BC, Canada with funding from Bill and Melinda Gates Foundation, USA, (September 2012 to June 2018)(# enrolments: 14,783, recruited 21% of global sample size 69,330)
26. "Evaluation of the introduction of a novel device in the management of hypertension and shock in pregnancy in low-resource settings" in collaboration with King's College, London co-funded by UK Medical Research Council and Department of Biotechnology, Govt. of India (July 2015 to March 2018)(# enrolments: 23,853, recruited 4% of global sample size 5,36,233)
27. "A phase III, randomized, double- blind, active, controlled, multinational, multicenter, non-inferiority trial using carbetocin room temperature stable (RTS) for the prevention of postpartum haemorrhage during the third stage of labour in women delivering vaginally"- funded by Department of Reproductive Health & Research, World Health Organization, Geneva (July 2014 - June 2017) (# enrolments: 7,098, recruited 24% of global sample size 29,645)
28. "Clindamycin to reduce preterm birth in low resource setting: A randomized placebo controlled trial" in collaboration with Christiana Care Health Services, USA with funding from Thrasher Research Fund, USA, (March 2012 – March 2016)(# Screened: 6,476; # enrolments: 1,727)
29. "Evaluation of HELPING BABIES BREATHE in Belgaum, Kenya and Nagpur: Does implementation of HELPING BABIES BREATHE Save Lives?" project, funded by National Institute of Child Health and Human Development and Laerdal Foundation and Norwegian Agency for Development Cooperation

(Norad) (November 2011–October 2013)(# **Master Trainers Trained: 38 and # Birth Attendants trained: 460**)

30. “Antenatal Corticosteroids Trial in Preterm Births to Increase Neonatal Survival in Developing Countries (ACT) in Belgaum District, Karnataka, India” funded by National Institute of Child Health and Human Development, National Institutes of Health, USA. (September 2011 - October 2013) **(# enrolments: 18,175, recruited 18% of global sample size 98,137)**
31. “Two community strategies comparing use of misoprostol for early treatment/secondary prevention to primary prevention for postpartum hemorrhage: a randomized cluster non-inferiority study in Bijapur district, Karnataka, India” in collaboration with Gynuity Health Projects, New York, USA and University of Illinois at Chicago, and University of California at San Francisco with funding from Bill and Melinda Gates Foundation, USA (January 2011 to August 2013)(# **enrolments: Primary Prevention: 1,075 and Secondary Prevention: 1,957**)
32. “Zinc and Iron bioavailability from bio-fortified pearl millet” in collaboration with University of Colorado Health Sciences Center, USA and sponsored by International Atomic Energy Agency, Vienna. (May 2008 – September 2012)(# **enrolments: 44 children**)
33. “Pilot study of an Indicator to Measure Intrapartum Stillbirth and Immediate Neonatal Death” project, funded by National Institute of Child Health and Human Development and Engender Health and Maternal Health Task Force, (June 2011 – February 2012)(# **enrolments: 685, recruited 19% global sample size 3,593**)
34. “Evaluation of an Emergency Obstetrics and Newborn Care Intervention Package to Reduce Adverse Pregnancy Outcomes in Low Resource Settings (The EmONC Trial)” at 20 Primary Health Center Areas of Belgaum District ” funded by National Institute of Child Health and Human Development, National Institutes of Health, USA. (February 2009 - September 2011)**Facility Training: 497; HBLSS Training 698; Community Training or meeting: 2059; Providers Trained: 295; Total Facilities: 69; Core Groups: 667; Total Meetings: 33,802**)
35. “Brain Research to Ameliorate Impaired Neurodevelopment: Home-based Intervention Trial (BRAIN HIT)” funded by The National Institute of Child Health and Human Development (NICHD) and The National Institute of Neurological Disorders and Stroke (NINDS) Fogarty International Center. (August 2006 – September 2011)(# **enrolments: 159, recruited 39% global sample size 407**)
36. “Safe Childbirth Checklist” – Single Site Pilot Study, funded by The Children Investment Fund Foundation, USA. In collaboration with Harvard School of Public Health, Boston, USA. (July 2010 – December 2010)**We observed health workers attending to 499 birth events during the baseline period (July–September, 2010) and 795 birth events after introduction of the checklist program (September– December, 2010)**
37. “A Comparison of Two Iron Doses on Zinc Absorption from Sprinkles as Micronutrient Supplement” in collaboration with University of Colorado Health Sciences Center and sponsored by International Atomic Energy Agency, Vienna (October 2007 – September 2008)(# **enrolments: 30 children**)
38. “Field Implementation of the Helping Babies Breathe Initiative in Belgaum, Karnataka INDIA” funded by Global Implementation Task Force of American Academy of Pediatrics, USA, in collaboration with University of Calgary, Canada (August 2009 - June 2011)(**599 Birth Attendants trained**)
39. “Active Management of the Third Stage of Labour without Controlled Cord Traction: A Randomized

Non-Inferiority Controlled Trial” funded by RHR Division of World Health Organization, Geneva, Switzerland (March 2008 – February 2010)(# enrolments: 2,165, recruited 9% of global sample size 24,390)

40. “HIV – Cervical Cancer Prevention Research Project” NIH-ICMR funded Indo-US collaborative research grant for Vanderbilt University and the National AIDS Research Institute, Pune Consortium. (October 2007-September 2009)(# enrolments: 300)
41. “A Global Network Study To Estimate Gestational Age By Fundal Height – Tape Study” funded by National Institute of Child Health and Human Development, National Institutes of Health, USA. (September 2007 – August 2008)(# enrolments: 750, recruited 33% global sample size 2,434)
42. First Breath: Community-based Training and Intervention in Neonatal Resuscitation, funded by National Institute of Child Health and Human Development and National Institutes of Health, USA. (January 2005 – April 2008)(ENC Training for 1,181 Birth Attendants including 753 TBAs)
43. “Community-based Survey of Tobacco Use among pregnant women at 10 Primary Health Center Areas of Belgaum District”, funded by National Institute of Child Health and Human Development, National Institutes of Health, USA, National Cancer Institute. (November 2004 – February 2005) (# enrolments: 736, recruited 9% global sample size 7,961)
44. “A Randomized placebo-controlled trial of prophylactic misoprostol for prevention of postpartum haemorrhage at four primary health center areas of Belgaum District, Karnataka” funded by National Institute of Child Health and Human Development, National Institutes of Health, USA. (May 2001 – April 2006)(# enrolments: 1,620)

Publications:

JNMC Women's and Children's Health Research Unit

KLE Academy of Higher Education and Research's J N Medical College, Belagavi

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2. WHO ACTION Trials Collaborators. The World Health Organization Antenatal Corticosteroids for Improving Outcomes in preterm Newborns (ACTION-III) Trial: study protocol for a multi-country, multi-centre, double-blind, three-arm, placebo-controlled, individually randomized trial of antenatal corticosteroids for women at high probability of late preterm birth in hospitals in low- resource countries. *Trials.* 2024 Apr 12;25(1):258.
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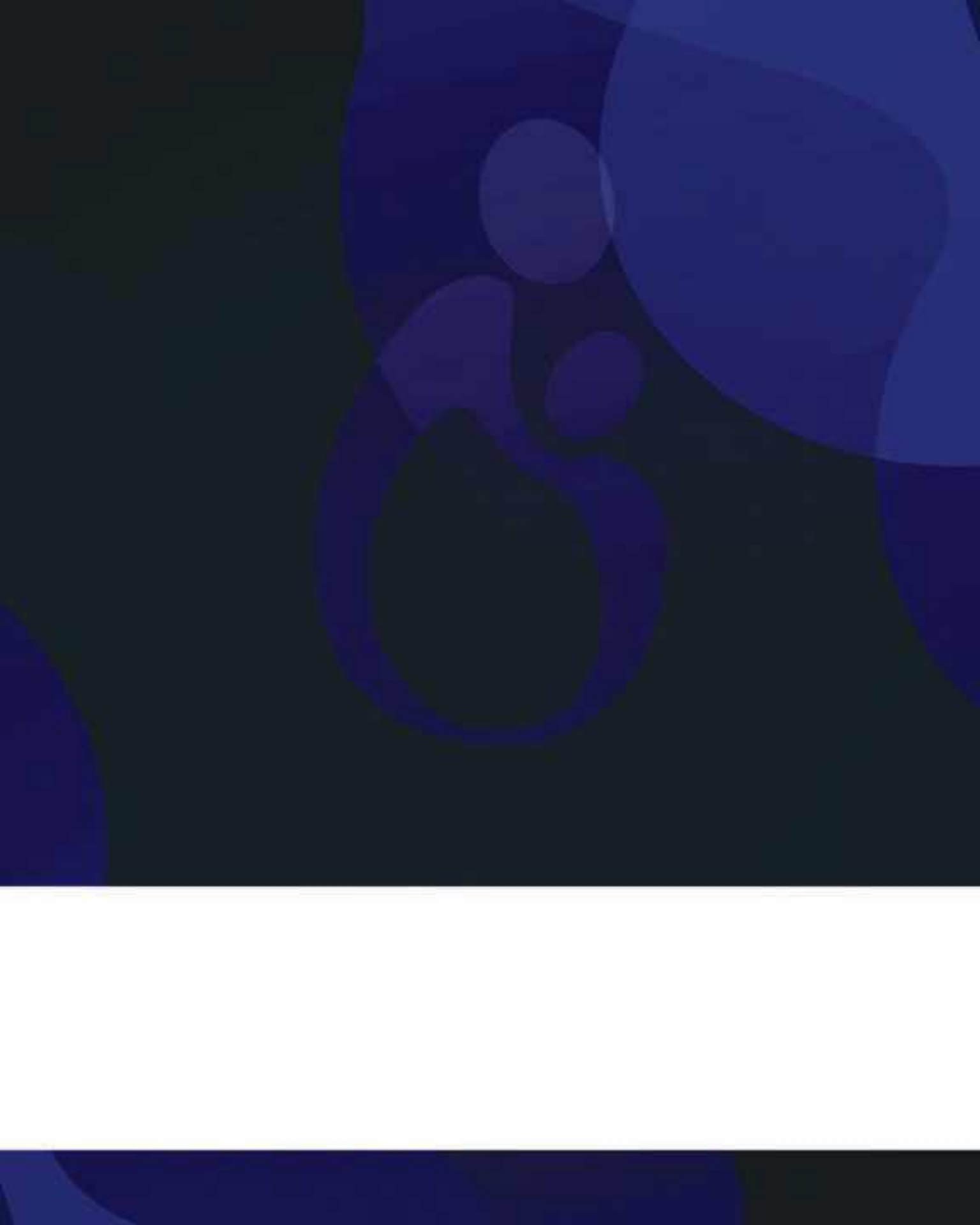
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FOR HEALTH PROFESSIONS EDUCATION AND RESEARCH AFFILIATION AND
SUPPORT AGREEMENT**

This **FIRST AMENDMENT TO THE INDIA CENTER AT JEFFERSON FOR HEALTH PROFESSIONS EDUCATION AND RESEARCH AFFILIATION AND SUPPORT AGREEMENT** ("First Amendment") is entered into by and between **THOMAS JEFFERSON UNIVERSITY** ("Jefferson") and **KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH-BELGAUM** ("KLE").

WHEREAS, Jefferson and KLE entered into **THE INDIA CENTER AT JEFFERSON FOR HEALTH PROFESSIONS EDUCATION AND RESEARCH AFFILIATION AND SUPPORT AGREEMENT** ("Agreement") effective July 26, 2017; and

WHEREAS, in accordance with Agreement Paragraph 2.2, Amendment, the parties desire to modify the terms of the Agreement to renew the term of the Agreement and change the funding support.

NOW, THEREFORE, in consideration of the mutual covenants herein contained and intending to be legally bound hereby, the parties agree as follows:

1. Article 1.1 shall be revised to read as "in priority areas that may include Integrative Medicine, Public Health, Urology, Neurology, Psychiatry, Radiology, Nursing Sciences, Physical/Rehabilitative/Occupational therapy and other areas that may be identified by mutual consultation".
2. Paragraph 2.1, Term shall be revised to read as follows:
 - 2.1. **Term.** This Agreement shall be effective as of the Agreement Effective Date and will remain in force for a period of two (2) years until 2019. The Term shall be renewed for an additional three (3) year period beginning July 1, 2019 and ending June 30, 2022 (the "Renewal Term"). All terms of the Agreement shall apply to the Renewal Term.
3. Paragraph 3.1, Support Funding shall be revised to read as follows:
 - 3.1 **Support Funding.** KLE shall provide funding to Jefferson for the India Center, which funding may be used to provide general program support to accomplish the goals and purpose of the India Center for the term of the Agreement, including but not limited to, salaries and personnel costs, materials and services, telephone, and overhead. KLE shall pay Jefferson One Hundred Thousand Dollars (\$100,000 US) annually during the Renewal Term.
4. Paragraph 3.2.1, shall be revised to read as "for two visitors for visits of one (1) to two (2) weeks in priority areas to include Integrative Medicine, Public Health, Urology, Neurology, Psychiatry, Radiology, Nursing Sciences, Physical/Rehabilitative/Occupational therapy and other areas that may be identified by mutual consultation".
5. The address noted in paragraph 9.8 for Jefferson's legal counsel shall be changed to: Thomas Jefferson University, Office of Legal Affairs, 834 Chestnut Street, Suite 400, Philadelphia, PA 19107, Attention: Chief Counsel.
6. This First Amendment is effective on June 1, 2019, (the "Amendment Effective Date").


7. This First Amendment to the Agreement is incorporated into and made part of the Agreement and all provisions of the Agreement not expressly modified or amended hereby shall remain in full force and effect.


IN WITNESS WHEREOF, the duly authorized representatives of Jefferson and KLE have executed this First Amendment to the Agreement as of the Amendment Effective Date.


**KLE ACADEMY OF HIGHER EDUCATION
AND RESEARCH, BELGAUM**


**THOMAS JEFFERSON UNIVERSITY,
PHILADELPHIA**


By: Dr. V D Patil
Its: Registrar


By: Richard J Derman, MD
Its: Associate Provost, Global Affairs


By: Dr. Vivek A Saoji
Its: Vice Chancellor


By: Mark L. Tykocinski, MD
Its: Provost


By: Dr. Prabhakar B. Kore
Its: Chancellor and Chairman


By: Stephen K Klasko, MD, MBA
Its: President Chief Executive Officer





5. The address noted in paragraph 9.8 for Jefferson's legal counsel shall be changed to: Thomas Jefferson University, Office of Legal Affairs, 834 Chestnut Street, Suite 400, Philadelphia, PA 19107, Attention: Chief Counsel.
6. This Second Amendment is effective on June 1, 2022, (the "Amendment Effective Date")
7. This Second Amendment to the Agreement is incorporated into and made part of the Agreement and all provisions of the Agreement not expressly modified or amended hereby shall remain in full force and effect.

IN WITNESS WHEREOF, the duly authorized representatives of Jefferson and KLE have executed this second Amendment to the Agreement as of the Amendment Effective Date.

**KLE ACADEMY OF HIGHER EDUCATION
AND RESEARCH, BELGAUM**

By: **Dr. Vivek A Saoji**
Its : Vice-Chancellor

By : **Dr. Prabhakar B. Kore**
Its : Chancellor and Chairman



**KLE ACADEMY OF HIGHER
EDUCATION & RESEARCH
BELAGAVI**
Deemed-to-be-University
(Formerly known as KLE University)

**THOMAS JEFFERSON UNIVERSITY,
PHILADELPHIA**

By : **Richard J Derman, MD**
It : Associate Provost, Global Affairs

By: **Mark L. Tykocinski, MD**
Its : Provost



Jefferson

Thomas Jefferson University

HOME OF SIDNEY KIMMEL MEDICAL COLLEGE





**Second AMENDMENT TO THE INDIA CENTER AT JEFFERSON
FOR HEALTH PROFESSIONS EDUCATION AND RESEARCH AFFILIATION AND
SUPPORT AGREEMENT**

This **Second AMENDMENT TO THE INDIA CENTER AT JEFFERSON FOR HEALTH PROFESSIONS EDUCATION AND RESEARCH AFFILIATION AND SUPPORT AGREEMENT ("Second Amendment")** is entered into by and between **THOMAS JEFFERSON UNIVERSITY ("Jefferson")** and **KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH-BELGAUM ("KLE")**.

WHEREAS, Jefferson and KLE entered into **THE INDIA CENTER AT JEFFERSON FOR HEALTH PROFESSIONS EDUCATION AND RESEARCH AFFILIATION AND SUPPORT AGREEMENT ("Agreement")** effective July 26, 2022; and

WHEREAS, in accordance with Agreement Paragraph 2.2, Amendment, the parties desire to modify the terms of the Agreement to renew the term of the Agreement and change the funding support.

NOW, THEREFORE, in consideration of the mutual covenants herein contained and intending to be legally bound hereby, the parties agree as follows:

1. Article 1.1 shall be revised to read as "in priority areas that may include Integrative Medicine, Public Health, Urology, Neurology, Psychiatry, Radiology, Nursing Sciences, Physical/Rehabilitative/Occupational therapy; Infectious Diseases, Metabolic and Nutritional Disorders, Digital health, AI and machine learning and Cancer Biology and other areas that may be identified by mutual consultation". To explore the possibilities of starting new Dual degree programs as per new NEP of India.
2. Paragraph 2.1, Term shall be revised to read as follows:

2.1. **Term.** This Agreement shall be effective as of the Agreement Effective Date and will remain in force for a period of two (2) years until 2024. The Term shall be renewed for an additional three (3) year period beginning July 1, 2024 and ending June 30, 2027 (the "**Renewal Term**"). All terms of the Agreement shall apply to the Renewal Term.
3. Paragraph 3.1, Support Funding shall be revised to read as follows:

3.1 **Support Funding.** KLE shall provide funding to Jefferson for the India Center, which funding may be used to provide general program support to accomplish the goals and purpose of the India Center for the term of the Agreement, including but not limited to, salaries and personnel costs, materials and services, telephone, and overhead. KLE shall pay Jefferson One Hundred Thousand Dollars (\$100,000 US) annually during the Renewal Term.
4. Paragraph 3.2.1, shall be revised to read as "for two visitors for visits of one (1) to two (2) weeks in priority areas to include Integrative Medicine, Public Health, Urology, Neurology, Psychiatry, Radiology, Nursing Sciences, Physical/Rehabilitative/Occupational therapy Infectious Diseases, Metabolic and Nutritional Disorders, Digital health, AI and machine learning and Cancer Biology and other areas that may be identified by mutual consultation". To explore the possibilities of starting new Dual degree programs as per new NEP of India