



ANNUAL REPORT 2023



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Cover: African mother carry child in a traditional way in front of the hut.
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Letter from the management

CISMAC prioritizes high quality research that can contribute to equitably improve health, development and survival of mothers and children in low- and middle-income countries (LMICs). CISMAC's LMIC partners have by the end of 2023 concluded several of our large trials, including the [“pregnancy vitamin B12 study”](#) which provides evidence that, even in a population in which vitamin B12 deficiency is common, successfully supplementing pregnant and breastfeeding women with vitamin B12 does not provide their infants with a growth or measureable development benefit. The findings support the current WHO recommendation of not routinely supplementing pregnant women with vitamin B12, even in populations where deficiency of this vitamin is common. Such information on the lack of a beneficial effect, is important for informing policies and guidelines and avoiding waste of public resources, provided the intervention effect is estimated with sufficient statistical precision and without bias. This exclusion from public health guidelines of an intervention for which benefits are plausible can only be achieved if the trial is sufficiently large and implemented with high quality, which, again, is conditioned on the research teams' knowledge, skills, and attention to detail from the planning stage, during study implementation through to data analysis and writing of the ensuing [paper](#).

Additional completed trials include the:

- [RISE trial](#) which estimates the effect of economic support, comprehensive sexuality education and community dialogue on childbearing among adolescent girls in rural Zambia.
- [Zinc-sepsis trial](#), which estimates the effect on case fatality risk of 10 mg elemental zinc given daily to young North Indian infants under antibiotic treatment for clinical severe infection
- [Chlorhexidin trial](#) which estimates the effect of cleansing the umbilical cord stump with chlorhexidine on the risk of clinical severe infection in HIV-1-unexposed newborn Ugandan babies.

Furthermore, our trial that assesses non-specific effects of giving the [BCG vaccine](#) either at birth or at 14 weeks of age will soon complete the 1-year follow up of all its 4500 HIV-1-exposed babies. Finally, our most recently initiated trial, the [Small Baby Trial](#) in India, assesses the extent to which an intervention package of nutritional management and supportive stimulation can promote healthy infant growth among small for gestational age and preterm babies.

CISMAC adheres to the principles of [equitable research partnerships](#) between high-income country (HIC) and

LMIC institutions. We plan, implement, analyze and write up our studies as [joint efforts between all involved scientists](#). This is in our view not only a moral imperative but also contributes to high study quality. Moreover, it contributes to reciprocal learning which strengthens both the LMIC and the HIC institutions in developing and implementing other high quality studies.

As identified in our [strategic directions](#), the development of skills needed for research and for leadership is a fundamental activity that sets CISMAC apart from many other consortia that focus solely on research. We are proud to report that four of our PhD candidates this year successfully defended their PhD theses; for more details, please see a separate section in this report. We believe that strengthening our researchers' capacity in conceptual and methodological aspects of analytic epidemiology aimed at causal inference is best done by allowing them to take part in planning for and undertaking high quality studies as well as participating in advanced courses held by prominent scholars, such as [those we arranged at the University of Bergen \(UiB\) in 2022](#). An additional important way of learning analytic epidemiology is to teach this subject to others. We have therefore recently taken an initiative to arrange more courses where our younger researchers work together with prominent scholars to develop student active courses in advanced causal epidemiology to facilitate deeper learning among both students and faculty members. In the “EpiCap” initiative, we have teamed up with two of Norway's experts in university pedagogics, [Arild Raaheim](#) and [Monika Kvernenes](#). We hope that the initiative will contribute to sustain and expand upon the collaborations already established through CISMAC and foster research and learning that will contribute to equitably improve maternal and child health in low- and middle-income countries.

Bergen and Porto Alegre, December 2023



Halvor Sommerfelt
Halvor Sommerfelt,
Director



Ingvild F. Sandøy
Ingvild F. Sandøy
Deputy Director



Jose Martinez
Jose Martinez
Scientific Coordinator



Ane Straume
Ane Straume
Administrative Leader

RESEARCH INSIGHTS

CISMAC'S B₁₂ IN PREGNANCY STUDY

The importance of “negative studies”

High-quality studies that reveal effects that are too small to be translated into practice are often called “negative studies”, a term CISMAC objects to because such studies can curb investments that will not result in substantial health benefits.

In last year's report, we emphasized the importance of doing high-quality studies in order not only to identify effective interventions that can substantially improve maternal and child health, survival and development but also to estimate the effect of promising interventions that turn out not to carry such benefits. To create convincing evidence of no effect, not just finding that there is no convincing evidence of an effect, requires that the study is both large and of very high quality. ►

One of CISMAC’s most ambitious trials is an excellent example of such a study. The project was conducted in Nepal, and in 2023, the research team published a landmark paper in The Lancet on the [effect of vitamin B12 supplementation during pregnancy on infant growth and development](#). The trial showed that daily oral supplementation of women from their first trimester with 50 µg vitamin B₁₂ until their babies were 6 months of age did not increase baby length or their cognitive scores despite the fact that most of the women had low or marginal vitamin B₁₂ status. Characteristic of high-quality large trials, the effects were measured with very high statistical precision, giving a high degree of confidence that such supplementation was not effective in promoting infant linear growth or the cognitive development that can be measured at such a young age.

We spoke with Professor Tor Arne Strand, who was the Principal Investigator of CISMAC’s B₁₂ in Pregnancy study.



Little girl carrying baby on the back, Solukhumbu, Nepal.
Credit: hadynyah | iStock

Where in Nepal are you doing your research?

– Most of our research in Nepal is done in Bhaktapur. We established a research office with a pediatric clinic in a local hospital in 1998 and have had large research projects from this site without interruption ever since. These projects have included randomized controlled trials and observational studies on child health, growth, nutrition, vaccines, and environmental pollutants. The projects have employed between 15 and 50 local staff at all levels. We are proud to say that results from our studies have contributed to the recommendations to provide zinc to children with diarrhea. However, we are equally proud of our “negative” randomized trials as they also contribute to public health, giving knowledge about what is unnecessary to fix.

Why were you and the rest of the research team interested in studying the effects of vitamin B₁₂ supplementation on infant growth and development in a randomized controlled trial?

– For the last 25 years we have measured vitamin B₁₂ status in more than 10,000 women and children in Nepal and India where we have found that biochemically defined vitamin B₁₂ deficiency is common. In fact, according to the revised cut-offs used in some Norwegian hospitals, virtually all our participants should be classified as being B₁₂ deficient or at risk of deficiency. B₁₂ deficiency is reported from all over the world including in Norway. The cut-off to define deficiency is not widely agreed upon, for example if we use the most sensitive cut-off, as many as 2/3 of all Norwegian infants would be classified as deficient.

For the last 25 years, we have measured vitamin B₁₂ status in more than 10,000 women and children in Nepal and India where we have found that biochemically defined vitamin B₁₂ deficiency is common.

– This is of concern as B₁₂ is essential for growth and cognitive development. In our observational studies we also found that B₁₂ status was inversely associated with linear growth and child neurodevelopment.

– These observational findings are, however, not sufficient to change dietary recommendations but justify conducting RCTs.

Why do so many pregnant women in Nepal have low vitamin B₁₂ levels?

– They rely on a predominantly vegetarian diet.

Did you encounter any concerns from the ethics committees in Nepal and Norway regarding the provision of relatively high doses of vitamin B₁₂ already from the women’s first trimester?

– We have undertaken four large RCTs with vitamin B₁₂ supplementation; in the last of these, where we gave a high dose of vitamin B₁₂ or a placebo to pregnant Nepalese women, the Norwegian ethics committee (REK) would initially not approve our application. This was because it was considered unethical to give a placebo to a population with poor status. Their decision was based on the comments from one external expert. We got an opportunity to appeal, and REK sent our protocol to another external expert, whereafter REK approved our study.

Can you briefly describe how the team conducted the measurement of cognitive development in practice?

– We had a well-trained team of psychologists who undertook the testing in an optimal environment. We had three

TOR ARNE STRAND

M.D./Ph.D. from the University of Bergen

Professor at the University of Bergen and Lillehammer Hospital Trust

Works on randomized, placebo-controlled trials on nutrition, growth, and cognitive development and has collaborated with several South Asian institutions for more than 25 years.



Photo: vkm.no

rooms that were free from distractions and were dedicated to cognitive testing. Our studies in Bhaktapur have included cognitive testing since 2009.

You found no effect on growth and cognitive development at 12 months of age. Were there any areas of infant development, e.g. motor or social skills, in which there was any sign of an effect? And is it possible that an effect on cognitive development may be seen when the children grow older, e.g. when they enroll in school?

– Yes, in fact, although a secondary outcome, we observed a negative effect of vitamin B₁₂ supplementation on early infant motor performance, giving some reason for caution



FACTS

Study: [B12 IN PREGNANCY](#)

Location: Nepal

Principal Investigator: Tor Strand

Co-principal Investigators: Ram Chandyo and Laxman Shrestha

Co-investigators: Sudha Basnet, Ingrid Kvestad, Catherine Schwinger, Manjeswhori Ulak, Mari Hysing, Merina Shrestha, Suman Ranjitkar

Partners: Tribhuvan University, Nepal

Associated partners: Innlandet Hospital Trust, Norway, and Siddhi Memorial Foundation, Nepal

related to vitamin B₁₂ supplementation during pregnancy. We measured the effect on cognitive functioning using the Bayley Scales of Infant and Toddler Development (BSID). Some pediatric neurologists and developmental psychologists question this assessment's ability to pick up predictors of later functioning, so it is possible that any effects, whether positive or negative, could occur at an older age. It should also be noted that a similar, but smaller, study giving the same doses found a small effect of supplementation in one of the subtests of the BSID at 9 months of age. When these children were followed at a later age, there was no difference between the trial arms.

We are conducting a RCT on vitamin B₁₂ supplementation in Norwegian babies. This is also important as a substantial proportion of babies in Norway also have biochemical signs of deficiency.

What do you think could explain why the findings in your randomized controlled trial were different from those of previous experimental and observational studies?

– I think that the main reason for the discrepancy is confounding in the observational studies. It should also be noted that RCTs are not free from biases, usually biases that shift the effect measure estimates towards a null effect. It is possible that 1) the dose we gave wasn't sufficiently high or that the participants could not utilize B₁₂ because of, for example, other micronutrient deficiencies.

– It should be noted that all women who were given vitamin B₁₂ had a metabolic profile reflecting improved vitamin B₁₂ status as compared those who received placebo.

Do you have plans and resources to follow up these children so that you can identify any potential beneficial or adverse effects as they grow older, and development can perhaps be more reliably assessed?

– Yes, we got 12 million NOK from the Research Council of Norway and 400,000 NOK from Innlandet Hospital Trust to follow the children and their mothers for another 4 years.

Are there any vitamins or minerals that you think pregnant women should be advised to take to promote child growth and development?

– I think that the WHO guidelines are excellent. They do not recommend supplementation to all pregnant women, only iron and folic acid, Iodine, Calcium and vitamin D in some populations. And I think that certain populations, such as vegans, should take additional supplements.

It's difficult to avoid noticing that there were 24 per thousand stillbirths and infant deaths among the babies of the women who received placebo against only 8 per thousand such deaths among those who received vitamin B₁₂. Although the relative effect of 67% (most of it ascribed to a difference in stillbirth risk) is imprecisely estimated (95% confidence interval -23% to 91%), do you think the underlying difference may be caused by vitamin B₁₂?

– There are many such interesting, albeit imprecise, differences between the trial arms that we will explore in secondary analyses, and we have plans to pool our data with those from other studies. It is also possible that we must rely on other study designs such as case-control studies to address these questions.

You are also conducting some other studies on vitamin B₁₂. What are you examining in those studies?

– We are conducting an RCT on vitamin B₁₂ supplementation in Norwegian babies. This is also important as a substantial proportion of babies in Norway also have biochemical signs of deficiency.

To round off our discussion, which affordable measures do you think will most effectively promote infant and child growth and development in Nepal and other South Asian countries?

– Adequate healthcare, clean water and nutritious and clean food.



View of a pregnant woman on a black background.
Credit: Artem Merzlenko | Colourbox

BASED ON CISMALC'S KANGAROO MOTHER CARE STUDY:

WHO recommendations for care of low birth weight babies

In many South Asian countries, including India, approximately 1 in 4 babies are born with a birth weight of less than 2.5 kg. ►



Father with his preterm baby on his chest. Photo: Sarmila Mazumder.

These low birth weight (LBW) babies are born small for gestational age (SGA) and/or too early (preterm) and face a disproportionately high risk of severe illness and death as well as developmental impairments, including of physical growth. Globally, they contribute to nearly 4 out of 5 infant deaths. Enhancing their survival chances would accordingly substantially reduce child mortality in South Asia and low- and middle-income countries (LMICs) in other regions.

Our main study question was accordingly if providing these babies with KMC at home would give them a substantial survival benefit.

When we in year 2013 started to plan for our research on kangaroo mother care (KMC), hospital studies had shown that keeping LBW babies close to their mothers' chest, providing them with easy access to breast milk as well as

better temperature regulation, could substantially enhance their survival probabilities. The World Health Organization (WHO) had accordingly identified KMC in birth facilities as being one of the most promising interventions for promoting neonatal and infant survival, particularly in low-resource situations. However, in deprived settings, a high proportion of births happen outside health facilities and, although more and more women do have institutional births, they are often discharged to their homes early, i.e. within a day, even if their babies have LBW.

Learning whether KMC initiation at home, i.e. community-initiated KMC (cKMC), would be safe and effective would therefore importantly inform the development of both national (Indian) and global (WHO) guidelines on whether the existing recommendation could be extended to home-born babies and those discharged early from birth facilities. Our main study question was accordingly if providing these babies with KMC at home, whether initiated there or after a too short stay in a birth facility, would give them a substantial survival benefit. Such information would fill an important gap in the then available guidelines for preterm and other LBW babies.

Our research team at the [Society for Applied Studies](#) in India went through a careful process of defining a suitable study population and then launched a very large randomized

controlled trial of cKMC in Haryana, India. The process included in depth [formative research](#), publishing a [protocol](#) and launching the study in 2015. It was completed already in 2018, followed by rapid analysis and publication in 2019.

Our findings revealed that promoting cKMC can substantially and equitably improve survival in LBW infants.


Our findings revealed that promoting cKMC can [substantially](#) and [equitably](#) improve survival in LBW infants. Moreover, promoting cKMC also reduced the risk of severe infant illness and lowered the cost of care-seeking and the risk of family impoverishment, thereby offering them [financial risk protection](#). Moreover cKMC [reduced the prevalence of post-partum depressive symptoms](#) among the mothers of LBW infants.

Being by far the largest of its kind, this high-quality trial contributed the most important data to a systematic review and [meta-analysis](#) which constituted the base for the [new 2022-WHO recommendations for care of preterm and other low-birth-weight infants](#). They now state that [KMC](#)



Kangaroo mother care (KMC). Photo: Sarmila Mazumder.

[can be initiated in the health-care facility or at home](#). The WHO considers this a [strong advice](#), because it is based on high-certainty evidence and because it has the potential to substantially reduce disease burden. Thus, if scaled up to 80% coverage, [cKMC can prevent ¼ million low birth weight babies from dying every year](#).



FACTS

Study: [cKMC](#)

Location: Haryana, Indi, India

Principal Investigator: Sarmila Mazumder and Sunita Taneja, Society for Applied Studies, India

Co-principal Investigator: Halvor Sommerfelt

Partners: Society for Applied Studies, India and Centre for International Health, UiB

KMC PUBLICATIONS AND PRESS

Evidence base for WHO’s new (2022) guidelines for care of preterm and other low birth weight babies

Care of Preterm or Low Birthweight Infants Group. **New World Health Organization recommendations for care of preterm or low birth weight infants: health policy.** eClinicalMedicine 2023;63: 102155. <https://www.thelancet.com/action/showPdf?pii=S2589-5370%2823%2900332-2>

Dr Anshu Banerjee published presentation https://www.healthynewbornnetwork.org/hnn-content/uploads/Slides-for-launch_16May2023-2.pdf during WHO’s launch of Kangaroo Mother Care Global Position Paper and Implementation Strategy 16th of May 2023.

Sindhu Sivanandan and Mari Jeeva Sankar. 2022. **Kangaroo mother care for preterm or low birth weight infants: a systematic review and meta-analysis.** BMJ Global Health 2023; 8:e010728. <https://doi.org/10.1136/bmjgh-2022-010728>

The World Health Organization. 2022. **WHO recommendations for care of the preterm or low-birth-weight infant.** ISBN 978-92-4-005826-2 (electronic version); <https://iris.who.int/bitstream/handle/10665/363697/9789240058262-eng.pdf?sequence=1>

The World Health Organization. 2022. **WHO recommendations for care of the preterm or low-birth-weight infant.** Evidence base. Web supplement. ISBN 978-92-4-006005-0 (electronic version). <https://iris.who.int/bitstream/handle/10665/363699/9789240060050-eng.pdf>

Key CISMAC publications on KMC

Choudhary, T. S., S. Mazumder, Ø. A. Haaland, S. Taneja, R. Bahl, J. Martinez, M. K. Bhan, K. A. Johansson, H. Sommerfelt, N. Bhandari, and O. F. Norheim. 2021. **Health equity impact of community-initiated kangaroo mother care: a randomized controlled trial.** Int J Equity Health. 2021; 20: 263. <https://doi.org/10.1186/s12939-021-01605-0>

Choudhary, T. S., S. Mazumder, O. A. Haaland, S. Taneja, R. Bahl, J. Martinez, M. K. Bhan, O. F. Norheim, H. Sommerfelt H, N. Bhandari, K. A. Johansson KA. 2022. **Effect of kangaroo mother care initiated in community settings on financial risk protection of low-income households: a randomised controlled trial in Haryana, India.** BMJ Glob Health 2022 Nov;7(11):e010000. <https://doi.org/10.1136/bmjgh-2022-010000>

Mazumder, S., R. P. Upadhyay, Z. Hill, S. Taneja, B. Dube, J. Kaur, M. Shekhar, R. Ghosh, S. Bisht, J. C. Martinez, R. Bahl, H. Sommerfelt, and N. Bhandari. 2018. **Kangaroo mother care: using formative research to design an acceptable community intervention.** BMC Public Health. 18:307. <https://doi.org/10.1186/s12889-018-5197-z>

Mazumder, S., S. Taneja, S. K. Dalpath, R. Gupta, B. Dube, B. Sinha, K. Bhatia, S. Yoshida, O. F. Norheim, R. Bahl, H. Sommerfelt, N. Bhandari, and J. Martinez. 2017. **Impact of community-initiated Kangaroo Mother Care on survival of low birth weight infants: study protocol for a randomized controlled trial.** Trials. Doi: [10.1186/s13063-017-1991-7](https://doi.org/10.1186/s13063-017-1991-7)

Mazumder S., S. Taneja, B. Dube, K. Bhatia, R. Ghosh, M. Shekhar, B. Sinha, R. Bahl, J. Martinez, M. K. Bhan, H. Sommerfelt, and N. Bhandari. 2019. **Effect of community-initiated kangaroo mother care on survival of infants with low birth-weight: a randomized controlled trial.** The Lancet. 394: 1724–36. [https://doi.org/10.1016/S0140-6736\(19\)32223-8](https://doi.org/10.1016/S0140-6736(19)32223-8)

Sinha, B., H. Sommerfelt, P. Ashorn, S. Mazumder, S. Taneja, D. More, R. Bahl, and N. Bhandari. 2021. **Effect of community-initiated kangaroo mother care on postpartum depressive symptoms and stress among mothers of low-birth-weight infants.** Jama Netw. Open. 4(4):e216040. doi:[10.1001/jamanetworkopen.2021.6040](https://doi.org/10.1001/jamanetworkopen.2021.6040)

Kangaroo mother care in the press

Forskning.no: [Flere spedbarn overlever når de holdes tett inntil mor. Øyeblikkelig hudkontakt etter fødsel er den nye gullstandarden for premature](#)

Science Daily: [Kangaroo mother care reduces infant mortality](#)

The Hindu: [Kangaroo mother care improves infant survival](#)

Tidsskrift for Den norske legeforening: [Nyfødtomsorg som redder liv](#)

VG: [Norsk forskningsfunn: Flere babyer overlever når de holdes tett inntil mor](#)



Young Indian woman holding her baby, desert village, India.
Credit: hadynyah | iStock

Dr. Bireshwar Sinha's PhD dissertation:

“Effect of kangaroo mother care in low birth weight infants on breastfeeding performance, gut function, and maternal depressive symptoms in low middle income populations in the Indian subcontinent”

In his [doctoral dissertation](#), Dr. Bireshwar Sinha presents studies in which he and his team at the [Society for Applied Studies](#) estimated the effect of promoting home-based kangaroo mother care (KMC) in low birthweight (LBW) infants on breastfeeding, biomarkers of gut function, and maternal postpartum depressive symptoms.

Knowledge of the wide range of benefits of KMC is lacking among health care workers, mothers, and community members. Generating and disseminating such knowledge can contribute to its promotion and practice.



Bireshwar Sinha. Photo: Yvonne Muthiani.

The findings of Dr. Sinha's PhD studies shed new light on KMC.

Dr. Sinha explains: “Despite WHO's recommendations, KMC is not much practiced in low-income countries. Beyond the prevention of hypothermia in infants, the ways in which KMC works to prevent infant deaths is not clearly understood. Knowledge on the wide range of benefits of KMC is lacking among health care practitioners and communities. Moreover, the potential benefits of KMC to mothers is unclear, which is often a barrier to its promotion and practice”.

Research evidence aligns with WHO recommendations

In the above-mentioned randomized controlled trial, the research team showed that promotion and support of KMC in the community can reduce the risk of LBW babies dying with 30% during the first month and with 25% during the first half year of life. As an extension of and partly embedded in this large trial, Dr. Sinha designed his doctoral studies to address knowledge gaps related to the possible biological pathways through which KMC can operate to improve survival.

In his studies, Dr. Sinha exploited the randomized controlled design, and found that the promotion and support



Biresh surrounded by his supervisors (Profs. Per Ashorn and Halvor Sommerfelt to his left), opponent (Prof. Liisa Lehtonen and SAS-Director Dr. Nita Bhandari to his right) and the Society for Applied Studies (SAS) family. Photo: Yvonne Muthiani.

of KMC in LBW infants substantially improves effective breastfeeding and reduces the risk of maternal postpartum depressive symptoms. He also found no measurable effect of KMC on certain biomarkers of infant gut function. “However, this area of research is still not fully understood and needs further research”, he adds.

The evidence from my studies is in support of KMC having the potential to ameliorate the difficulties associated with breastfeeding LBW babies [...]

“The findings of my investigations align with the WHO's 2022 recommendations, and support the promotion of KMC among LBW infants in public health programs in low- and middle-income settings in India and other South Asian countries,” Sinha says.

In India, the caregivers of these vulnerable infants often visit primary health care centers or local physicians to seek medical help for difficulties in latching, sucking, nipple-

related problems, and poor breastfeeding. In addition, in the Indian subcontinent, almost 1 in 5 women suffer from postpartum depression that needs clinical attention.

“The evidence from my studies is in support of KMC having the potential to ameliorate the difficulties associated with breastfeeding LBW babies, at the same time preventing maternal depressive symptoms in the postpartum period in some mothers”, Dr. Sinha explains.

Dr. Sinha is from India. He was initially registered as a PhD student at the University of Bergen and then transferred to Tampere University in Finland where he defended his thesis in November 2023 with Professor Liisa Lehtonen from the University of Turku as his opponent. His supervisors were Professor Per Ashorn (Tampere University) and Halvor Sommerfelt (University of Bergen). Tampere University awarded his thesis and defense not only with a distinction but also hailed it as the best clinical PhD thesis in its Faculty of Medicine and Health Technology in 2023. CISMACH congratulates Dr. Sinha!

Dr. Sinha works as a Scientist at the Society for Applied Studies and holds a Clinical and Public Health Research Fellowship from the Indian Department of Biotechnology - Wellcome Trust India Alliance.

RESEARCH PROJECTS



COMAC

Uganda faced several waves of the COVID-19 pandemic. A high urban population density and extensive and necessary social interaction along with challenging hygienic conditions represented major impediments to the country’s battle against COVID-19. COMAC contributes to describe the spread and impact of the COVID-19 pandemic on vulnerable groups in Uganda. The project has a particular focus on HIV-1 positive women and their babies.



Principal Investigators: Victoria Nankabirwa and Halvor Sommerfelt

RISE

In Zambia, approximately one third of young girls in rural areas have given birth by the age of 18. Adolescent pregnancies pose significant risks to both mothers and their babies. The Research Initiative to Support the Empowerment of girls (RISE) estimates the effect of interventions that include economic support, education and reproductive health programmes on early childbearing in rural Zambia. Nearly 5 000 grade seven girls from 157 rural schools were enrolled in the 5-year study.



Principal Investigator: Ingvild Fossgard Sandøy | Co-Principal Investigator: Patrick Musonda

Cost-Benefit RISE

Adolescent pregnancy is one of the greatest development challenges facing low- and middle-income countries, not only because it represents a danger to mother and child, but also because of its profound social and economic consequences. This economic evaluation investigates the short- and long-term costs per unit health and non-health gain of providing cash support to adolescent girls and their guardians / parents, as well as community dialogue to delay pregnancy and childbearing to an appropriate age in CISMACH’s RISE trial.

Principal Investigators: Ingvild Sandøy, Patrick Musonda | Study Lead: Amani Thomas Mori

B₁₂ in Pregnancy

Worldwide, vitamin B₁₂ deficiency is common, affecting people of all ages. It can lead to a wide variety of health problems. In this study, we estimated the effect of giving daily oral vitamin B₁₂ supplements to pregnant women until they had given birth and for a 6-month period thereafter on the neurodevelopment and growth of their children. We found that such supplementation did not affect their infants’ growth or development, which is in support of current recommendations of not providing such supplements even in populations in whom vitamin B₁₂ deficiency is common.



Principal Investigators: Tor A Strand, Ram Krishna Chandyo, Laxman Prasad Shrestha

Child B₁₂ Follow-up

Vitamin B₁₂ deficiency is common and can occur at all ages. This study follows up children who participated in a placebo-controlled randomized trial in Nepal, assessing effects on child growth and neurodevelopment, one and two years beyond supplementation with vitamin B₁₂ to infants. Children who were supplemented with vitamin B₁₂ in infancy had a substantially improved vitamin B₁₂ status. However, there were no effects of vitamin B₁₂ on any of the neurodevelopmental outcomes measured up to 4 years after the end of supplementation. The results from our study do not support widespread vitamin B₁₂ supplementation in young children.



Principal Investigator: Tor Strand | Co-Principal Investigators: Laxman Shrestha, Prakash S Shrestha

cKMC

Nearly 80% of infant deaths occur in babies born with low birth weight (LBW). According to hospital-studies, up to 40% of these deaths could be prevented with Kangaroo Mother Care (KMC), where the baby is kept for several hours every day on the mother’s chest, giving them warmth and access to life-saving breast milk. Almost all evaluations of KMC have been carried out in health facilities. This study evaluated KMC initiated in the homes, also called community-initiated KMC (cKMC). The study took place in India, where over one quarter of babies are born with LBW, and included 8 402 LBW babies. Promotion of and support for cKMC increased the survival chances of infants with 25%.



Principal Investigators: Sarmila Mazumder, Sunita Taneja | Co-Principal Investigator: Halvor Sommerfelt

Biological effects of cKMC

Training mothers in community-initiated Kangaroo Mother Care (cKMC) is an effective way to reduce mortality and morbidity of low birth weight babies. This sub-study of CISMACH’s main cKMC trial, and investigated pathways with which cKMC can improve infant health and survival.

Principal Investigator: Bireshwar Sinha | Co-Principal Investigators: Nita Bhandari, Halvor Sommerfelt

Poverty and Equity cKMC

As an extension of the completed trial on the survival benefits of promoting Kangaroo Mother Care at home to low birth weight babies (cKMC), this equity study evaluated the impact on fairness outcomes such as survival benefits for the poorest vs. the less poor and the prevention of catastrophic health care expenditures among the poor in two districts in North India.

Principal Investigators: Sarmila Mazumder, Kjell Arne Johansson, Tarun Shankar Choudhary

Zinc-Sepsis

Severe infections, including sepsis and severe pneumonia, contribute to almost one quarter of the deaths in infants up to two months of age. Widely accessible and very cheap, we previously showed that a daily dose of zinc given to young infants under antibiotic treatment for “clinical severe infection” increased the success of treatment by 43%. These encouraging results prompted us to do a much larger study in almost 4 000 infants under two months of age to estimate the efficacy of the treatment to prevent death. The study involved hospitals in Nepal and India and its findings are soon to be published.



Principal Investigators: Nitya Wadhwa | Co-Principal Investigator: Tor A Strand

Zinc Equity

Low-cost health care interventions that prevent impoverishment and catastrophic health expenditures can be valuable national health initiatives. Zinc Equity is a sub-study of the ongoing zinc-sepsis trial. It evaluates the health and economic consequences for families of zinc given as an adjunct to standard treatment in young infants hospitalized with “clinical severe infection”. Zinc may shorten the length of stay and the demand for expensive intensive care for these infants. The study will provide information about socio-economic inequalities in infant deaths, cost-effectiveness and financial risk protection.

Principal Investigators: Nitya Wadhwa, Kjell Arne Johansson
Co-Principal Investigator: Debjani Ram Purakayastha

eRegistry and care

The Norwegian Institute of Public Health and the World Health Organization have developed a framework and series of tool kits to make it easier for low- and middle-income countries to improve their collection and use of health information to the benefit of women’s and children’s health. This study assessed the benefits of this type of programme in improving the quality of care in rural Bangladesh.



Principal Investigator: J. Frederik Frøen | Co-Principal Investigator: Anisur Rahman

eRegQual

eRegistries are designed to increase the availability and timely use of routine maternal and child health (MCH) data. The Palestinian National Institute of Public Health, in close collaboration with the Ministry of Health in Palestine, has rolled out an MCH eRegistry. With support from CISMACH, the Norwegian Institute of Public Health carried out a randomized controlled trials with 120 health center clusters in Palestine and assessed how the eRegistry and its interactive checklists and clinical decision support can improve the quality of antenatal care.



Principal Investigator: J. Frederik Frøen | Co-Principal Investigator: Buthaina Ghanem

BCG

The Bacillus Calmette-Guérin (BCG) vaccine may have non-specific effects in infants, with protection beyond its ability to prevent tuberculosis (TB). In addition, some evidence suggests that giving BCG later in infancy may enhance its effects. This may be particularly important for HIV-1 exposed infants, i.e. those whose mothers have HIV-1 infection. This study randomized 4 500 HIV-1 exposed Ugandan infants to receive BCG either within 24 hours of being born or at 14 weeks of age. The field part of the study will be completed in 2024 and its findings may impact policies concerning timing of BCG administration in HIV-1 exposed babies.



Principal Investigator: Victoria Nankabirwa | Co-Principal Investigator: Halvor Sommerfelt

BCG Immunology

The BCG immunology study is a sub-study of the larger BCG trial. The study seeks to provide additional information of the optimal timing of BCG vaccination among HIV-1 exposed infants. Concretely, the substudy will describe possible immunological mechanisms of any non-specific effects of BCG. The results may also be important for upcoming studies of new vaccines against tuberculosis.

Principal Investigators: Kurt Hanevik, Victoria Nankabirwa

EcoTime BCG

This study evaluates and compares the cost-effectiveness of giving the BCG vaccine to Ugandan HIV-1-exposed babies at birth or at 14 weeks of age. Combined with possible treatment benefits assessed in the main study, the cost implications of the two vaccination strategies will generate information important for vaccine programme development and implementation.

Principal Investigator: Victoria Nankabirwa | Co-Principal Investigator: Bjarne Robbestad
Master student: Stephe Kabanda

Chlorhexidine

Infection of the umbilical cord stump (omphalitis) can lead to life threatening illness in the first 28 days of life. The risk of omphalitis is high in low- and middle-income countries. This now completed trial took place in Uganda and involved nearly 5 000 babies of mothers who were not infected with HIV-1. It assesses the effect of a single cleansing of the umbilical cord stump with an antiseptic solution of 4% chlorhexidine in birth facilities on the risk of omphalitis and severe newborn infections.



Principal Investigator: Victoria Nankabirwa | Co-Principal Investigator: Halvor Sommerfelt

SCALE-8

More than 250 million children living in low- and middle-income countries do not achieve their full development potential. This study followed a previous project assessing the effectiveness, feasibility and cost of integrated early stimulation and nutrition interventions delivered by a government community-based health service in Pakistan. It re-enrolled children at 8 years of age from 80 population clusters to determine which beneficial effects may have endured to school age. The study will identify risks and protective factors that influence outcomes and will inform the development of improved interventions for child development.



Principal Investigator: Muneera A Rasheed | Co-Principal Investigator: Tor A. Strand

SAFEZT

This three-year project examined global and national policy discourses surrounding fertility control and abortion, as well as local practices and moralities related to these issues among adolescents in Ethiopia, Zambia and Tanzania. The dynamics between the law, policies and access to fertility control and safe abortion services differ between these countries. The project generated comparative knowledge of the interplay between policy, legislation and socio-cultural conditions framing girls’ and women’s reproductive choices.



Principal Investigator: Astrid Blystad | Co-Principal Investigator: Getnet Tadele

CCF instead of RCT?

This study evaluates whether a novel observational epidemiological study design, the case-control with follow-up (CCF), could be an efficient alternative to randomized controlled trials (RCTs), case-control (CC) studies and cohort studies for investigating the association between exposures and rare outcomes. To find out, we did a CCF and a CC study in parallel with the recently completed RCT in Uganda that measures the association between cleansing of the umbilical cord stump with chlorhexidine on the day of birth and the risk of subsequent severe illness in the newborns.



Principal Investigator: Victoria Nankabirwa | Co-Principal Investigator: Hans Steinsland

Girl Power

Lack of reproductive health information and lack of economic opportunities may contribute to a high proportion of girls in low- and middle-income countries becoming pregnant at a young age. This study investigated how reproductive health information and entrepreneurship training affect the decision-making of girls when it comes to postponing pregnancy and engaging in economic activities. More than 3 400 female Tanzanian high school pupils from 80 schools across four regions of Tanzania were included in this cluster randomized controlled trial.



Principal Investigator: Bertil Tungodden

The CAP trial

Low dietary intake of calcium increases the risk of pre-eclampsia and eclampsia, which are serious hypertensive disorders in pregnancy that are dangerous for mother and baby. Although calcium supplementation is recommended by WHO from 20 weeks of pregnancy, no research has evaluated whether starting it before pregnancy can reduce the risk among women with previous pre-eclampsia. This multi-center randomized trial in South Africa, Argentina and Zimbabwe estimated the effect of calcium supplementation before and in the first half of pregnancy on the risk of re-current pre-eclampsia.



Principal Investigator: Justus Hofmeyer

NeoSupra

Globally, many babies are born too exhausted to breathe spontaneously after birth. Such babies need immediate assistance – otherwise they die. At Mulago Hospital, Kampala, Uganda, we conducted a randomized controlled trial to see if the use of a supraglottic airway device instead of a facemask, which is commonly used for assisted ventilation, can reduce the risk of dying or brain damage in newborns who did not breathe after birth. The now published results are important for low- and middle-resourced settings where many such deaths occur.



Principal Investigators: Thorkild Tylleskär, Josaphat Byamugisha

Small babies

Babies who are born preterm or at term but small-for-gestational age face high risks of death, of growth failure and of neurodevelopmental deficits in infancy and later in life. The identification of interventions to promote their early catch-up growth and reduce health and development risks is a research priority for scientists and public health policy makers. Responding to this need, CISMAC supports a large on-going randomized controlled trial in India to assess the impact of an integrated health, nutrition, early child stimulation and responsive care intervention package on growth and neurodevelopment in these vulnerable babies.



Principal Investigators: Ranadip Chowdhury, Tor Strand

MATRISET

Significant weaknesses have been documented in reporting routines and data flow in maternal death reporting, compromising the quality of global maternal mortality data. Under-reporting has been linked to a complexity of social, legal and political factors, including pressure to meet global maternal health goals. The MATRISET project (Research Council of Norway 2021-26) is an interdisciplinary initiative that explores institutional reporting routines, legal frameworks and accountability processes in maternal death surveillance in Ethiopia and Tanzania.



Principal Investigators: Astrid Blystad | Co-Principal investigators: Getnet Tadele (Ethiopia), Ali Said (Tanzania)



Uganda, location, Africa. Credit: Pernille Bering | Colourbox

BUILDING FOR THE FUTURE



From Josephine's PhD defense. Photo: Thorkild Tylleskär.

Our PhD candidates 2023

We are pleased and proud that four of our PhD candidates defended their PhD degrees in 2023.



Hanne Keyser Hegdahl defended her PhD thesis "Young women's sexual and reproductive health behaviour, beliefs and risks in a sub-Saharan African setting" on the 5th June 2023 from the University of Bergen.



Josephine Tumuhamy defended her thesis on the 26th of October 2023 for the PhD degree from the University of Bergen with the dissertation "Vaginal Colonization and Neonatal Infections in Central Uganda: Etiology, Antimicrobial Resistance and Associated Factors"



Ravi Prakash Upadhyay defended his thesis on the 28th of September 2023 for the PhD-degree from the University of Bergen with the dissertation "Nutrition, growth and neurodevelopment in children from low resource settings in India"



Bireshwar Sinha defended his thesis on the 10th of November 2023 for his doctorate at Tampere University in Finland with the dissertation "Effect of Kangaroo Mother Care in Low Birth Weight Infants on Breastfeeding Performance, Gut Function, and Maternal Depressive Symptoms in Low Middle Income Populations in the Indian Subcontinent"



Participants, Prof. Håkon K. Gjessing (teacher, in the back, partly against dark brown wall), co-ordinator Dr. Victoria Nankabirwa (in the front obliquely to the right of Håkon) and co-facilitators after having survived the statistics course at Makerere University.

Fundamental concepts in medical statistics with applications to randomized controlled trials

CISMAC worked with partners to hold an intermediate level course in Medical Statistics by Prof. Håkon K. Gjessing in the middle of June 2023 at [Mulago Guest House](#) in Kampala, Uganda.

It was arranged by [Makerere University School of Public Health](#) in collaboration with the [Centre for Fertility and Health](#) at the Norwegian Institute of Public Health, and was also supported by the [HKDir-funded NORPART](#) project “Improving Health Professional Education and capacity in Experimental epidemiology – (HePEd) which is coordinated by the [Department of Education](#) at UiB’s Faculty of Psychology.

The course was hosted by the [Makerere University’s School of Public Health](#) with [Dr. Victoria Nankabirwa](#) as its co-ordinator.

Faculty

[Håkon K. Gjessing](#), PhD, is a Principal Investigator at the [Centre for Fertility and Health](#), a Norwegian Research Council Center of Excellence at the [Norwegian Institute](#)

COURSE COLLABORATORS



Makerere University
College of Health Sciences
SCHOOL OF PUBLIC HEALTH





[of Public Health](#), and an adjunct Professor of Biostatistics at the [Department of Global Public Health and Primary Care, University of Bergen](#).

Co-facilitators in the course were [Ronald Senyonga](#), [Hans Steinsland](#), [Ramachandran Thiruvengadam](#) and [Ayushi Na](#).

The course was attended by almost 30 graduates and researchers from Uganda, India, Nepal and Norway. Ahead of the course, they had made themselves familiar with the topics covered in “Medical Statistics: A Textbook for the Health Sciences”, by Walter, Campbell, and Machin and ensured that they had practical experience with analyzing medical research data and using statistical software, a prerequisite for fully exploiting the course’s learning opportunities.

Prof. Gjessing briefly recapitulated some basic statistical topics and proceeded to introduce several important techniques for analyzing clinical and epidemiologic data. His lectures further introduced key statistical concepts, while the co-facilitators organized analysis exercises using the Stata® software.

The course covered different statistical aspects of relevance to randomized controlled trials (RCTs). At the end of the course, the participants were expected to be able to:

- recognize situations where linear, binomial, and Poisson regression models are appropriate.
- know how to interpret effect measures estimated by these models.
- be familiar with survival and other time-to-event data, be aware of challenges related to censoring, and know how to analyze such data using survival analysis techniques.
- be familiar with basic principles of RCTs and how to analyze such data, as well as avoiding common pitfalls.
- have a basic understanding of sample size calculations to achieve sufficient statistical precision and power in a study.
- apply useful Stata® techniques such as weighting and robust standard errors.

The participants were very content with the course. The teaching material can be accessed on Prof. Gjessing’s [course web page](#). The video of the lectures can be accessed by contacting Mr. Ivan Mutyaba ([imutyaba@musph.ac.ug](#)).



Halvor Sommerfelt (left) and Victoria Nankabirwa (right) in Kampala June 2023. Photo: Håkon K. Gjessing.

Tel: +256 754524705) at the Makerere School of Public Health or CISMAC attn. Iselin Henriksen Kvamme ([Iselin.Kvamme@uib.no](#)) or Ane Straume ([ane.straume@uib.no](#)).

Prof. Gjessing is set to hold a follow-up course on Advanced statistics in 2025 in Nepal or India under CISMAC’s new “EpiCap” initiative (please see NOTE FROM THE MANAGEMENT). Among many other topics relevant to analytic epidemiology, it will cover aspects such as problems with multiple testing and p-value hacking, weighting (frequency weights, sampling weights), and how to estimate and interpret robust standard errors, handle simple correlated data situations from e.g. cluster-randomization or family data and from repeated measurements in the same individuals.



Håkon K. Gjessing, PhD, is a Principal Investigator at the Centre for Fertility and Health, Norwegian Institute of Public Health.

BERGEN CENTRE FOR ETHICS AND PRIORITY SETTING IN HEALTH

– A new Centre of Excellence

At the end of 2022, the Research Council of Norway granted the [Bergen Centre for Ethics and Priority Setting in Health](#) (BCEPS) status as a Centre of Excellence (CoE). BCEPS was launched in September 2023 and had its [official opening](#) on the 8th of January 2024.

Photo: Eivind Senneset



Ole Frithjof Norheim is the Director of the new centre, Ingvild Fossgard Sandøy its Deputy Director. The new CoE will partly build on the work of CISMAL.

Tough priorities are inevitable in the health services of all countries. These choices create winners and losers, even as budgets gradually increase. Determining whether priorities are fair requires ethical judgment and medical and economic evaluation. BCEPS aims to develop new methods and a new ethical framework for efficient and fair distribution. The centre will study the impact of different priorities on the level and distribution of health and income over time and develop new methods for the economic evaluation of health interventions. BCEPS also leads the Disease Control Priorities Project ([DCP4](#)) which will publish relevant evidence and new recommendations on prioritization. In addition, the centre will conduct epidemiological studies to measure the effect of interventions to reduce inequalities in health.

In addition to conducting high quality research within medical ethics, health economics and epidemiology, BCEPS will organize courses for students and researchers and actively engage with decision-makers nationally and internationally to share and discuss the findings and recommendations emerging from its work.



MANAGEMENT & PUBLICATIONS

CISMAC MANAGEMENT AND ADMINISTRATION



Halvor Sommerfelt
Director



Ingvild F Sandøy
Deputy Director



Jose Martinez
Scientific Coordinator



Ane Straume
Administrative Leader



Filiz Ipek
Economy



Anne Berit Kolmanskog
Project administration



Gunhild Koldal
Project administration



Ricky Heggheim
Web and communication

LIST OF SCIENTIFIC PUBLICATIONS IN 2023

Arach, A. A. O., Nakasujja, N., Rujumba, J., Mukunya, D., Odongkara, B., Musaba, M. W., ... & Kiguli, J. (2023). **Cultural beliefs and practices on perinatal death: a qualitative study among the Lango community in Northern Uganda.** BMC Pregnancy and Childbirth, 23(1), 1-12.

Blom-Bakke, Kjersti Mørkrid; Ghanem, Buthaina; Abbas, Eati-mad; Khader, Khadija Abu; Ward, Itimad Abu; Ataallah, Am-jad; Baniode, Mohammad; Bogale, Binyam; Hijaz, Taghreed; Frost, Kimberly; Frost, Michael James; Isbeih, Mervett; Issawi, Sally; Nazzal, Zaher A.S.; O'Donnell, Brian; Papadopoulou, Eleni Zoumpoulia; Qaddomi, Sharif; Rabah, Yousef; Rose, Christopher James; Venkateswaran, Mahima; Frøen, Jahn Frederik (2023) **Quality improvement dashboard for health-care providers and targeted client communication to pregnant women to improve timely attendance and quality of antenatal care: A multi-arm cluster randomized trial** (the eRegCom trial) Oxford Open Digital Health

Briend, A., Myatt, M., Berkley, J. A., Black, R. E., Boyd, E., Garenne, M., ... & Khara, T. (2023). **Prognostic value of different anthropometric indices over different measurement intervals to predict mortality in 6–59-month-old children.** Public health nutrition, 1-12.

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Chandyo RK, Kvestad I, Ulak M, Ranjitkar S, Hysing M, Shrestha M, Schwinger C, McCann A, Ueland PM, Basnet S, Shrestha L,Strand TA. **The effect of vitamin B₁₂ supplementation during pregnancy on infant growth and development in Nepal: a communitybased, double-blind, randomised, placebo-controlled trial.** Lancet. 2023 May 6;401(10387):1508-1517. doi: 10.1016/S0140-6736(23)00346-X. Epub 2023 Apr 6. PMID: 37031691.

Jadaun, A. S., Dalpath, S. K., Trikha, S., Upadhyay, R. P., Bhandari, N., Punia, J. S., ... & Mazumder, S. (2023). **Government-led initiative increased the effective use of Kangaroo Mother Care in a region of North India.** Acta Paediatrica, 112, 6-14.

Kvestad, I., Silpakar, J. S., Hysing, M., Ranjitkar, S., Strand, T. A., Schwinger, C., ... & Ulak, M. (2023). **The reliability and predictive ability of the Test of Infant Motor Performance (TIMP) in a community-based study in Bhaktapur, Nepal.** Infant Behavior and Development, 70, 101809.

Loha, E. (2023). **Association between Livestock Ownership and Malaria Incidence in South-Central Ethiopia: A Cohort Study.** The American Journal of Tropical Medicine and Hy-giene, 1(aop).

Manapurath, R., Strand, T. A., Chowdhury, R., Kvestad, I., Yajnik, C. S., Bhandari, N., & Taneja, S. (2023). **Daily Folic Acid and/or Vitamin B₁₂ Supplementation Between 6 and 30 Months of Age and Cardiometabolic Risk Markers After 6–7 Years: A Follow-Up of a Randomized Controlled Trial.** The Journal of Nutrition, 153(5), 1493-1501.

Rasheed, M. A., Kvestad, I., Shaheen, F., Memon, U., & Strand, T. A. (2023). **The predictive validity of Bayley Scales of Infant and Toddler Development-III at 2 years for later gen-eral abilities: Findings from a rural, disadvantaged cohort in Pakistan.** PLOS Global Public Health, 3(1), e0001485.

Rebnord, T., Mmbaga, B. T., Sandøy, I. F., Lie, R. T., Mchome, B., Mahande, M. J., & Daltveit, A. K. (2023). **Time trends in perinatal outcomes among HIV-positive pregnant women in Northern Tanzania: A registry-based study.** Plos one, 18(8), e0289740.

Rim, S., Sakkestad, S. T., Zhou, F., Gullaksen, S. E., Skavland, J., Chauhan, S. K., ... & Hanevik, K. (2023). **Dynamics of circulating lymphocytes responding to human experimental enterotoxigenic Escherichia coli infection.** European Journal of Immunology, 2250254.

Ulak, M., Kvestad, I., Chandyo, R. K., Ranjitkar, S., Hysing, M., Schwinger, C., ... & Strand, T. A. (2023). **The effect of infant vitamin B₁₂ supplementation on neurodevelopment: a follow-up of a randomised placebo-controlled trial in Nepal.** British Journal of Nutrition, 129(1), 41-48.

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Vedøy, O. B., Steinsland, H., Sakkestad, S. T., Sommerfelt, H., & Hanevik, K. (2023). **Strong Association between Diarrhea and Concentration of Enterotoxigenic Escherichia coli Strain TW10722 in Stools of Experimentally Infected Volunteers.** Pathogens, 12(2), 283.

BOOK CHAPTER:

Unnithan, M., De Zordo, S., Blystad, A., & Moland, K. (2023). Anthropology of abortion. **A Companion to the Anthropology of Reproductive Medicine and Technology**, 349-364.

Content:
Ane Straume, Halvor Sommerfelt, Ingvild E. Sandøy, Iselin Henriksen Kvamme, Jose Martines, Ricky Heggheim, Tor A. Strand

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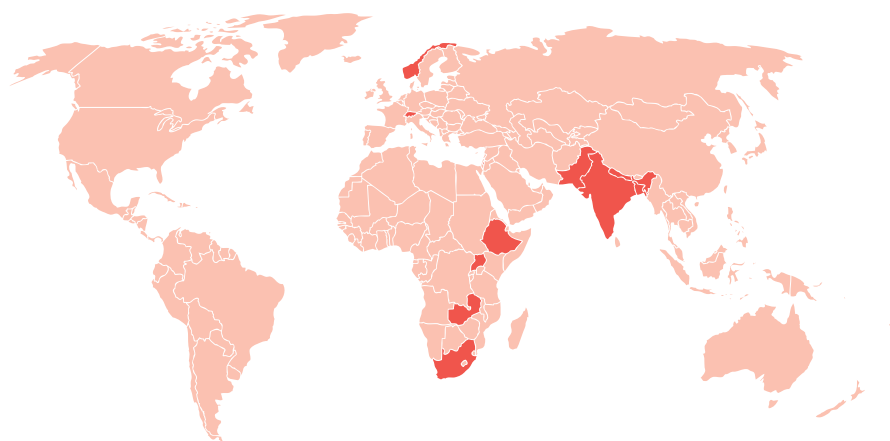
Photo this page:
Young Woman from Borana tribe, southern Ethiopia, Africa
Credit: hadynyah | iStock





Panoramic image, sunrise at Murchison Falls National Park, Uganda.
Credit: Alexander Ludwig | Colourbox

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TOWARDS A BRIGHTER FUTURE FOR MOTHERS AND CHILDREN

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CENTRE FOR INTERVENTION SCIENCE IN MATERNAL AND CHILD HEALTH (CISMAC)

is anchored at the Centre for International Health (CIH), IGS, University of Bergen, Norway. CISMAC is a consortium of CIH and research institutions in Ethiopia, India, Nepal, South Africa, Uganda, Zambia, Pakistan, Bangladesh and Palestine. The consortium also includes Chr. Michelsen Institute, the Norwegian Institute of Public Health, Innlandet Hospital Trust and the World Health Organization.

Email: cismac@uib.no