CENTRE FOR INTERVENTION SCIENCE IN MATERNAL AND CHILD HEALTH

CIS MAC

# ANNUAL REPORT 2018

UNIVERSITAS BERGENSIS

Norwegian Centre of Excellence

# CONTENTS



# FROM THE DIRECTOR AND DEPUTY DIRECTOR

CISMAC underwent a rigorous independent assessment by international experts in 2017, as part of the Research Council of Norway's mid-term evaluation of its 13 SFF-III centers. The Evaluation Committee concluded that our scientific and capacity strengthening activities, as well as our governance were of excellent quality. It also pointed out that our impact could be further enhanced by creating stronger horizontal linkages between our research teams, and by using a unifying strategic focus when selecting new studies. CISMAC not only appreciates the thorough evaluation but also fully endorses these two main recommendations, as well as the other very useful suggestions from the Committee. The suggestions included putting greater emphasis on implementation research and making greater efforts towards getting research findings into policy and practice (GRIPP), as well as further strengthening the research capacity in CISMAC's low- and middle-income country (LMIC) partner institutions.

**Strengthening capacity** is important in its own right, to foster maternal, neonatal, child and adolescent health (MNCH) research in LMIC, and to improve the sustainability of our CISMAC consortium, helping to extend it beyond 2023, when our core funding from the Research Council of Norway stops. A sustainable consortium enables our partners to continue to benefit from the pool of knowledge and skills we are building. It will also enable us to continue the front-line MNCH research activities in our countries.

So far, CISMAC has retained its original focus on randomized controlled trials of new MNCH interventions to estimate efficacy and on evaluating the delivery of efficacious interventions to measure effectiveness in real life settings. The Evaluation Committee's recommendations are an inspiration for us to put more emphasis on **implementation research**, and research linked to the **scale-up** of large programs to improve their effects and evaluate their impact.

**The political platform of Norway's new Government states that it will "Strengthen Norway's global health efforts, particularly in the areas of vaccines, child health and sexual and reproductive health and rights, including health education for girls and maternal and child health."**

## Representing Norwegian policy

The political platform of Norway's new Government states that it will "Strengthen Norway's global health efforts, particularly in the areas of vaccines, child health and sexual and reproductive health and rights, including health education for girls and maternal and child health." The 2017–2024 Research Strategy for Norway's Foreign Service and Norad emphasizes that its overseas development activities should to be more guided by research-based evidence and that continued support should be conditioned on *what is shown to actually work*. It also emphasizes the importance of strengthening partnerships with LMIC researchers and institutions, and their research capacity. Given the opportunity, and based on the suggestions from the mid-term Evaluation Committee, CISMAC can contribute effectively towards Norway's overseas development health goals and zeal to promote young girls' education in LMIC.

## Deep institutional roots

CISMAC would like to pay tribute to the **University of Bergen** (UiB) and its **Faculty of Medicine**. Over the last 3 decades, by securing faculty positions and administrative staff, UiB spearheaded Norwegian efforts in global health research and capacity strengthening, with a special focus on MNCH. The Centre for International Health was UiB's main instrument in this important activity. CISMAC receives substantial core support from the UiB. Thus, of its total 319 mNOK 10-year core funding base, UiB has committed 144 mNOK (45%), primarily in the form of PhD and post-doctoral fellowships, as well as time dedicated by permanent faculty members and administrative staff. This represents an impressive investment for a moderately sized university.

**The 2017–2024 Research Strategy for Norway's Foreign Service and Norad emphasizes that its overseas development activities should to be more guided by research-based evidence and that continued support should be conditioned on what is shown to actually work.**

## Ramifications of new funding models

Norway's universities, including the UiB, are undergoing a transition from being primarily funded by the Ministry of Education and Research directly, to being more and more reliant on external funding. Just a decade ago, external funds were mainly used to finance research projects, while researchers and their support staff were financed by the universities' core funding. This transition means that more resources, including those supporting university staff, must be derived from external sources, such as the Research Council of Norway, EU research programs and private foundations. Today, strong incentive mechanisms have been put in place to encourage researchers to procure external funding, and even the core support to each university department is in part determined by their researchers' ability to procure such funds.

## The uncertain future of global health research

The global health research portfolio in Norway expanded considerably during the period from 2005 to 2015, fueled by the substantial infusion of resources from the Research Council of Norway's GLOBVAC program. Now that this program is being dismantled, funding for global health research in Norway is uncertain, and may even dissipate, unless other funding mechanisms are found. The bulk of the funding towards global health research should, for obvious reasons, be spent in the LMIC themselves. Unfortunately, these expenditures are not counted when the Ministry of Education and Research gives incentives to the universities. If this principle trickles down to the departments with a large global health research portfolio, both the departments and this research will be at an economic disadvantage. Unless the universities are politically willing and economically capable of prioritizing global health research, the substantial Norwegian research and training capacity may wither.

Our Government reaffirms its commitment to support maternal, reproductive and child health research and capacity strengthening in LMIC. It states that it supports the goal of having Norway's overseas development investments be guided by research-based evidence on *what actually works*. We hope that our political leaders, together with universities and other research institutions, will explore economic mechanisms to consolidate and support Norway's significant global health research, enabling our country to consolidate its efforts to improve MNCH in LMIC, and to Sustainable Development Goal 3 – ensuring healthy lives and promote well-being for all.

Halvor Sommerfelt,
*Director, CISMAC*

Ingvild F. Sandøy
*Deputy Director, CISMAC*

# MEASURING EQUITY IMPACT IN RANDOMIZED CONTROLLED TRIALS

CISMAC aims to generate evidence on how to effectively and equitably improve maternal, neonatal and child health and development. This includes rapid translation of evidence generated by CISMAC into health program policy and action.

## Pervasive inequities

Health equity has many definitions, but is often defined as the absence of avoidable and unfair inequalities in health between individuals or groups in a population. Health inequalities are unfair when they are the result of an unjust distribution of socially controllable determinants of population health. Health financing is inequitable if patients have to pay high out-of-pocket expenditures for important services, sometimes being pushed into poverty. These types of inequities are pervasive in most low- and middle-income countries. Promoting health equity is a widely acknowledged health policy goal. There are well developed methods for measuring inequities in health and health service financing. Until recently, however, guidelines were lacking for how to report equity considerations in randomized controlled trials (RCTs).

## Including equity in RCTs

RCTs can provide very high quality evidence about the effects of interventions and the impact of programs. If the RCTs are well performed, the observed effects will not be influenced by known or even by unknown confounders. If designed properly, they can also generate evidence on equity and poverty impact. CISMAC aims to further this equity research agenda in two ways: by promoting guidelines, and by conducting equity relevant trials that can measure impact on equity, poverty and financial risk protection.

CISMAC recently collaborated with the Campbell and Cochrane Equity Methods Group and the University of York Centre for Health Economics to develop a CONSORT reporting guideline for better design and reporting of health equity relevant randomized trials. The process engaged potential users from high-, middle- and low-income countries, including knowledge users such as patients and methodologists. In a consensus meeting we discussed evidence for each recommendation based on results from empirical studies, reviews, key informant interviews and an online survey, aiming to improve clarity of reporting

## Opening up for new research questions

CISMAC has designed several of its ongoing RCTs, including the community-initiated KMC study, RISE, BCG, Chlorhexidine and the Zincsepsis trial, so that the impact on equity and poverty is measured and can be analyzed. Novel research questions have emerged: Will the new intervention increase, reduce, or be neutral with respect to health equity? Are some interventions better than others in improving gender equity?

Does the new intervention also protect against poverty? Method questions are also becoming increasingly important, for example: How should we estimate sample size for robust statistical analysis of intervention effects in sub-groups with unequal socioeconomic status? How can we best measure poverty in settings with an informal economy, by collecting data on assets, expenditures, or income?

As we write this, we are eagerly discussing methods questions and analyzing incoming data. Preliminary results suggest that we may get new knowledge about how RCTs can be used to effectively measure intervention impact on equity and financial risk. Although only a small piece of the bigger picture, this evidence can help policy makers make decisions concerning which new interventions to include in national health programs.

*Ole F. Norheim*

*Kjell Arne Johansson*

# RESEARCH INSIGHTS

# NEOSUPRA TRIAL

Preventable and unacceptable – annually, the number of newborns who die or suffer long-term negative consequences from not managing to breath at birth is around 1 million. Most of these deaths and injuries happen in poor countries. ▸

PhD candidate Susanna Höök with study participant in the NeoSupra trial in Uganda.

A team of CISMAC researchers, led by principal investigators, Profs. Josaphat Byamugisha (Makerere University) and Thorkild Tylleskär (UiB) are testing a simple tool that could help health personnel, particularly in low-resource areas, reduce these numbers. Two PhD candidates, Nicolas Jovo Pejovic and Susanna Myrnerts Höök, are centrally involved in the trial.

## Background

Paediatrician Susanna Höök explains the "golden minute": Within one minute of birth, Dr. Höök says, a baby should be breathing well. If not, it needs to be ventilated.

Paediatrician and neonatologist Nicolas Pejovic explains that the statistics are grim. Globally, approximately 650 000 live-born babies die of so-called intrapartum-related events; helping babies breathe immediately after birth could prevent many of these deaths. Moreover, many of the approximately 1 million intrapartum stillbirths (i.e. deaths during labour) are seemingly lifeless babies at delivery, but not actually dead; early resuscitation can rescue them. In addition, approximately 1 million babies that do not breathe by themselves at birth survive but develop neonatal encephalopathy, a condition involving disturbed neurological function that can develop in the first few days of a baby's life, and may have lasting negative neurological consequences. A vast (96%) majority of these deaths and injuries occur in low- and middle-income countries. Improving neonatal care in these countries is an important means to reach the UN's Sustainable Development Goal 3 of healthy lives for all (SDG-3.2).

## Developing a face mask alternative

Dr. Pejovic says that successful resuscitation could prevent a large proportion of these neonatal deaths and improve the outcomes for those neonates who survive intrapartum-related events. However, success depends on all birth attendants, including physicians, midwives and nurses, having sufficient knowledge and training required to perform neonatal resuscitation.

Currently, the standard response to a baby who does not breathe spontaneously after birth is to provide ventilation, first using a facemask and, if that is insufficient, intubation and, if necessary, prolonged ventilation support – all demanding a high standard of technology and technical competence. This response may be possible in places with advanced health care facilities manned by skilled health care personnel, but the techniques are difficult to master, and successful ventilation is not guaranteed. In addition, implementation of this response is an almost impossible challenge in low-resource settings where skilled medical staff attend less than half of infant deliveries and where the equipment for assisted ventilation is often not available.

## The NeoSupra Trial

Drs. Pejovic, Höök, Byamugisha and Tylleskär and their research team will use an alternative to facemask ventilation that we hope will provide better ventilation and will be easier to use. The uncuffed i-gel® laryngeal mask is a supraglottic airway device that provides effective positive pressure ventilation in newborns more effectively and without demanding the same high level of skills as conventional facemask ventilation. Like conventional facemask ventilation, it can, when required, be followed by intubation.

The researchers first undertook a pilot feasibility study with mannequins to assess whether the cuffless supraglottic airway device could be effectively used in low-resource settings. The results show that the device was more effective than the facemask in the mannequins. It was also more popular, as participants reported that it was easier and more satisfying to use. When tested in a second pilot with babies, the researchers found that the midwives rapidly learnt to use the device in newborns who did not breathe spontaneously. Although the study was too small to draw any conclusions, it seemed that the midwives were able to safely ventilate newborns, and those who were treated this way seemed to tolerate the procedure well. •


Newborn being monitored, Mulago Hospital, Uganda.


NeoSupra

## FACTS

**Study:** The NeoSupra trial

**Purpose:** To evaluate the efficacy of using the i-gel® supraglottic airway device compared with current standard of care, which is facemask ventilation.

The NeoSupra trial is a phase III, open-label, RCT, and the first large study comparing the two resuscitation methods. It is taking place in Mulago National Referral Hospital, Kampala, Uganda. The trial will last about 1 year and will have an estimated enrolment of 1 150 participants

# OVERCOMING RESEARCH CHALLENGES

Being a researcher can be considered as participating in a marathon obstacle course. It takes years of disciplined training and there are continual hurdles to overcome.

Like top athletes, researchers are driven by excellence. Almost every dimension of global health research has its challenges, so excellence does not come easy. It is multi-national; regulations differ between countries and institutions; one needs to transport equipment, specimens and people across borders, sometimes to inaccessible destinations.

CISMAC racks such challenges up a further two notches by both undertaking extremely large randomized controlled trials (RCTs) and by demanding very high levels of follow-up. This ensures that CISMAC's RCT findings are reliable and can be used to inform evidence-based policy to improve maternal and child health. Global health research demands extremely dedicated research leaders with hard-working and highly competent research teams.

## The Vitamin $B_{12}$ Intervention Studies

Typical examples of CISMAC RCTs are the vitamin $B_{12}$ intervention studies in Nepal, led by Prof. Tor Strand. Since 1998, Prof. Strand and colleagues have been investigating the effect of nutrient supplementation in early life on growth and cognitive development in children. The groundwork for the current trials were a number of earlier studies in Nepal, India, and Tanzania. Supplements of vitamin $B_{12}$ are cheap and they can potentially greatly enhance health, especially in children. Strand, in collaboration with partners at Tribhuvan University is now leading 2 CISMAC RCTs, studying the impact of vitamin $B_{12}$ supplementation.

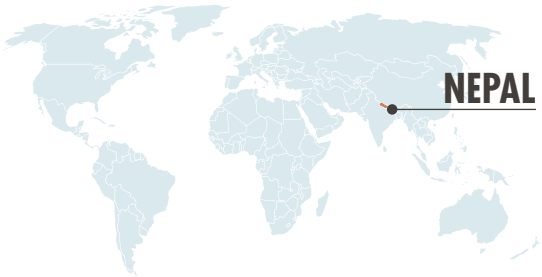
In the first study, 600 children between 6 and 11 months of age were given daily vitamin $B_{12}$ supplements for one year. This group of children is now being monitored in a follow-up study for an additional two years. In the other trial, 800 pregnant women are given daily vitamin $B_{12}$ supplements starting early in pregnancy until 6 months after they give birth. The main aim of both studies is to measure any effect that vitamin $B_{12}$ may have on the growth of the children and on their cognitive and neurological development.

## Catch-22

Mothers with low levels of vitamin $B_{12}$ will pass on small amounts of the vitamin to their babies during pregnancy and breastfeeding. WHO recommends a minimum of 6 months of exclusive breastfeeding. Prof. Strand's earlier studies in Nepal and India have shown that infants who are breastfed have substantially poorer vitamin $B_{12}$ status than those who are not.

The ongoing CISMAC-funded studies will not only guide nutritional recommendations during pregnancy, lactation and early childhood. They will also address the question of whether or not a biochemical profile reflecting poor vitamin $B_{12}$ status in children is a reason for concern. The findings from these projects can lead to new recommendations that can improve growth and learning worldwide or rebut the concern that breastfeeding reduces the supply of this essential nutrient. ▸

Researcher Manjeswori Ulak interacting with study participant at Siddhi Memorial Hospital in Bhaktapur, Nepal.





# $B_{12}$ in pregnancy

## FACTS

**Studies:** $B_{12}$ in Pregnancy and Child $B_{12}$ Follow-up

**Purpose:** To study the effect of vitamin $B_{12}$ supplementation on children's growth and cognitive development.

Vitamin $B_{12}$ is important for optimising growth and neurodevelopment in children. The main source of vitamin $B_{12}$ in the diet comes from animal products (meat, eggs, seafood, and dairy). Populations whose diet includes little or no animal products are particularly vulnerable to poor vitamin $B_{12}$ status.

## Research Challenges

Undertaking an RCT is challenging not only because of the logistics of dealing with many people – interaction with participants, regular visits to capture the outcomes, re-visiting if they are not available etc. In addition, scheduling follow-up visits may be complicated by the fact that many people move or travel. In order for the results of the study to be as accurate as possible, CISMAC research teams expend a great deal of effort to reach all participants at each follow-up visit.

The vitamin $B_{12}$ studies in Nepal underline how challenging this can be. In 2015, the study area was hit by a massive earthquake measuring 7.8 on the Richter scale, one of the worst natural disasters Nepal has ever seen. Despite the tragedy and the challenges of re-building, the research team worked very hard and managed to follow up on almost all of the children in our first study, missing only 4 % at the follow-up examination at two years of age. Now, in the follow-up study of these children, as the children are nearing 4 years of age, the dedicated efforts of the research team have ensured that the proportion being lost to follow-up is still less than 5%. However, the dedication needs to be matched by resources. Prof. Strand's team involves more than 30 people, most of whom have been working full-time for 4 years. The reward is the high quality of the results, which may impact the health and wellbeing of all Nepal's children, and may inform decisions on whether children in low- and middle-income countries should be supplemented with vitamin $B_{12}$. •

The research team of the Vitamin $B_{12}$ studies in Bhaktapur, Nepal.

# EMPOWERING GIRLS

Enabling girls to stay in school longer may be good for their health and their wellbeing. Becoming pregnant at a young age comes with higher risks and high costs both for the baby and for the mother.

Research has shown that in most countries across the world, girls who stop school early are also more likely to become pregnant at a young age. In the last decades, the proportion of children who enrol in primary school has increased considerably in many poor countries. However, the proportion that enrols at secondary level is much lower, particularly for girls. This is due to a range of factors such as there being fewer places at secondary schools, there are longer distances to these schools, there are higher fees, high academic requirements, and there is a cultural preference to support boys' education over that of girls. Early marriage or pregnancy are also a factor.

## Securing the future

In many poor societies, marrying off a girl may be regarded a better way to secure her future than sending her to school. In many African countries, the bride-price paid to the girl's family is an important source of income for poor families. In settings where access to cash is limited, another challenge is that many unmarried adolescent girls engage in sexual relationships. Even if this behaviour is not socially acceptable, the girls hope their boyfriends will give them gifts and money. When access to modern contraceptives is limited, this puts them at risk of getting pregnant. In Zambia, approximately 50% of girls never enrol in secondary school. At the age of 17, 36% of out-of-school girls in rural areas have started childbearing versus only 5% of those who are still in school.

## Keeping girls in School

The Zambian based CISMAC trial, named RISE (Research Initiative to Support the Empowerment of girls), is seeking to find out if supporting girls economically so that they can stay in school can reduce the risk of girls becoming pregnant too early.

In 2016, almost 5 000 girls from 157 schools in 12 rural districts in Zambia agreed to take part in the RISE study. Based on previous research, we already knew that economic support to girls and their families can increase school enrolment and attendance. In addition, studies in other countries have found that girls who receive such support are more likely to delay marriage and pregnancy. However, the effects of economic support may differ in various settings because other factors in addition to poverty may also be important barriers. Based on this knowledge, RISE aims to examine the effects of different kinds of support on grade 9 exam results and on early childbearing in young girls in rural Zambia.

**"All the time the pupils were in classes and this turned down the issues of absenteeism. The other effect is that pupils were able to perform well because they had a free mind, knowing that their school fees have been paid for. Those who were not in the project had times when they were not in class because they had to go and look for money."**

Mr Godfrey Mweemba, Head Teacher of Kayosha School

## Research for education and health policies

When the trial started in 2016, the schools were randomly assigned to one of 3 groups. In one group, the girls received writing materials and economic support in the form payment of school fees, monthly cash and an annual grant to their guardians to cover school-related and other expenses. In the second group, the girls were offered the same support, and in addition they were invited to youth club meetings focusing on sexual and reproductive health, and community meetings, which were on issues that are important for the welfare of young women. Finally, in the third group, the girls did not receive any special support apart from writing materials. The support packages were offered from September 2016 to November 2018. The results of the study have not yet been analysed as the participants will be followed up for another two years in order to assess the longer-term effects of the support. However, some teachers and girls have shared their own impressions of the impact the support has had. ▸

**"I sat for my grade 9 exams and passed to grade 10. Had it not been for the RISE project I wouldn't have managed to complete because my parents wouldn't have managed to pay all the school fees and this would have affected my school performance because my mind wasn't going to be free."**

Idah Nshinde, a RISE participant at Kayosha School in Chibombo district

Currently Idah is in grade 10, and she is looking forward to complete her secondary school with good results after which she wants to study medicine at the University of Zambia. She hopes this will enable her to help her parents and the community at Kayosha where she comes from.


RISE

## FACTS

**Study:** RISE: Research Initiative to Support the Empowerment of girls

**Purpose:** To measure the effect of interventions that include economic support, sexual and reproductive health education and community dialogue on rates of teenage pregnancies

In Zambia, 50% of girls never enrol in secondary school and 35% of girls from rural areas have given birth to at least one child by the age of 18. We know that early pregnancy creates higher risks for both mother and child, yet adolescents have limited access to modern contraceptives.

The RISE team is now hard at work on the final stages of the study. Currently, the team is collecting data on the results of the grade 9 exams for the participants. It is still unclear whether we will see a difference between the three groups in the proportion of participants who passed the exams. Data on the impact of the support on childbearing before age 18 will only be available at the end of 2020. The Zambian government has shown great interest in this study and the findings will be shared with them as soon as they are available. The RISE study will inform future education and health policies for young people in Zambian and elsewhere. •

**"They never lacked a thing. Their performance greatly improved also because the pupils seemed to have a free mind and were motivated by the support they were receiving. The RISE participants scored very well on the exams, and all the girls made it to grade 10. It really surprised us because this has never happened before in the history of the school. They even performed better than the boys! This time around, it was the girls' cut-off point that was raised higher than that of boys. I think it would be a good investment if the government decided to provide similar support to girls in grades 8 and 9 in Zambia because girls will be able to access and complete basic education. And it will help reduce early marriages and pregnancies."**

Mr Chingumbe, Head Teacher of Monze East School

# RESEARCH PROJECTS


+1
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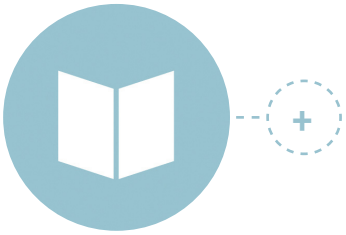
## RISE

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) aims to measure the effect of interventions that include economic support, education and reproductive health programs on early childbearing rates in rural Zambia. Nearly 5 000 7th grade girls from 157 rural schools are 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. It is a particular challenge in rural Zambia. This study investigates the short- and long-term benefits of providing cash support to adolescent girls and their guardians / parents, as well as community dialogue in CISMAC's RISE trial to delay pregnancy and childbearing to an appropriate age.



Principal Investigator: Ingvild Sandøy / Co-Principal Investigator: Patrick Musonda / Study Lead: Amani Thomas Mori

## $B_{12}$ in Pregnancy

Worldwide, vitamin $B_{12}$ deficiency is common, affecting people of all ages. It can lead to a wide variety of health problems and can, without prompt treatment, result in permanent damage. In this study, we measure the effect of giving daily oral vitamin $B_{12}$ supplements to pregnant women and during a 6-month period after they have given birth on the neurodevelopment and growth of their children. The results may help revise dietary guidelines for South Asian women, and could lead to improved pregnancy outcomes as well as improved child neurodevelopment.


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

## Child $B_{12}$ Follow-up

Vitamin $B_{12}$ deficiency is common and can occur at all ages. This study is a follow-up of 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. If persistent improvements in growth and development are found, results can guide international nutrition recommendations and potentially improve the well-being of many children.


Principal Investigators: Tor A Strand, Laxman Shrestha, Manjeswori Ulak

## 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 evaluates KMC initiated in the home, also called community-initiated KMC (cKMC). The study takes place in India, where over one quarter of babies are born with LBW, and includes over 8 000 LBW babies to evaluate its impact on survival in newborns.

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

## Biological effects of cKMC

Training mothers in community initiated Kangaroo Mother Care (cKMC) may be an effective way to reduce mortality and morbidity of low birth weight babies (LBW). The current study is a sub-study of CISMAC's main cKMC trial and seeks to investigate some of the biological pathways with which cKMC can improve infant health and survival.

Principal Investigator: Bireshwar Sinha / Co-Principal Investigators: Nita Bandahari, Halvor Sommerfelt

## Poverty and Equity cKMC

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

Principal Investigators: Sarmila Mazumder, Kjell Arne Johansson

## 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, a daily dose of zinc given to young infants under antibiotic treatment for probable serious bacterial infection was shown to increase the success of treatment by 43%. These encouraging results have prompted us to do a much larger study in over 4 000 infants under two months of age to estimate the efficacy of the treatment to prevent death. The study involves a hospital in Nepal and four hospitals in New Delhi, India.


Principal Investigators: Sudha Basnet, Nitya Wadhwa / Co-Principal Investigators: Shinjini Bhatnagar, Tor A Strand

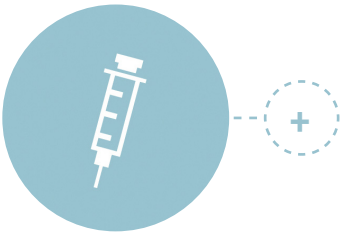
# BCG

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 children who have an increased risk of severe infections. This study randomizes 2 200 HIV-1 exposed Ugandan infants to either receive BCG either within 24 hours of being born or at 14 weeks of age. The results may impact policies concerning timing of BCG administration.

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

# EcoTime BCG

There is still uncertainty pertaining to when it is best to give the BCG vaccine to babies born to mothers infected with HIV. This study will evaluate and compare the cost-effectiveness of giving the BCG vaccine to Ugandan HIV-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 program development and implementation.



Principal Investigator: Victoria Nankabirwa / Co-Principal Investigator: Bjarne Robbestad / Master student: Steve Kabanda

# 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 is the first of its kind to assess the benefits of this type of program in improving the quality of care in rural Bangladesh where major gaps remain, despite the progress made in reducing maternal and child mortality over the last decade.

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

# eRegistry support

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, is currently rolling out a nationwide MCH eRegistry. With support from CISMAC, the Norwegian Institute of Public Health is carrying out randomized controlled trials with 120 health center clusters in Palestine to assess if 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

## 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 trial takes place in Uganda and involves nearly 5 000 babies of mothers who are not infected with HIV-1. It assesses the effect of a single washing 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 follows 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 has 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: Aisha K Yousafzai

## SAFEZT

This three-year project examines 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 aims to generate 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 will perform a CCF and a CC study in parallel with an ongoing RCT in Uganda that measures the association between cleaning 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 investigates 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 Tanzanian school girls drawn from 80 schools across four regions of Tanzania are involved 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 tested 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. The main findings of this important trial is due for publication in the Lancet in 2019.


Principal Investigator: Justus Hofmeyr

## 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 are conducting a randomized controlled trial to see if the use of a supraglottic airway device instead of a facemask, which is commonly used for ventilation, can reduce the risk of dying and of brain damage in newborns who do not breathe after birth. These results are important for low- and middle-resourced settings where many such deaths occur.

Principal Investigators: Thorkild Tylleskär, Josaphat Byamugisha

# BUILDING FOR THE FUTURE

# THE CISMAC RESEARCH TRAINING TRACK

In 2018, CISMAC launched its CISMAC Research Training Track for PhD and Postdoctoral fellows in intervention science. The initiative is part of CISMAC's vision to strengthen research capacity in maternal and child health in all CISMAC institutions and to train excellent researchers for the future.

Professor Stan Lemeshow and teaching assistant Remle Crowe with CISMAC participants during statistics course in Lillehammer.

Throughout the research training track, CISMAC supports PhD candidates and postdoctoral fellows so that they acquire appropriate knowledge about and skills in relevant research methods. There is much one needs to know to be able to undertake the planning, implementation and analysis of randomized controlled trials (RCTs) and implementation research.

Combined with opportunities to participate in high quality CISMAC trials, participation in the track supports CISMAC junior researchers becoming highly competent independent researchers, who are capable of initiating and leading trials, and implementation studies. All PhD and postdoctoral fellows associated with research groups running CISMAC projects are eligible to participate in the research training track. Through courses in randomized controlled trials and implementation research, the training track candidates receive high-quality, specialized training in the methodological skills required for excellent research. In addition, the candidates are encouraged to take elective courses to gain specific knowledge about the field of maternal and child health. This training will enable them to identify knowledge gaps and help them to identify future research directions.

As part of the CISMAC Research Training Track Initiative, CISMAC organizes a series of courses with international experts in their field. In 2018, CISMAC supported a course on 'Logistic Regression' held by Professor Stanley Lemeshow from Ohio State University. Professor Lemeshow is a highly renowned statistician and author of the most quoted book in medical statistics. The course took place at Innlandet Hospital Trust and was attended by researchers, PhDs and postdoctoral fellows from 9 CISMAC partner institutions. In 2019, CISMAC will support a course on 'Systematic Review and Meta-Analysis' taught by health systems researcher Simon Lewin, and a course on implementation research to be held at the Bergen Summer Research School. •

Participants at CISMAC meeting "Fostering linkages between CISMAC partner scientists"

.

Young researchers from CISMAC partners in India, Zambia and Oslo/Palestine during statistics course in Lillehamme.

Study area, Bhaktapur, Nepal.

# CISMAC'S POSTDOCTORAL FELLOWS

### Amani Mori
University of Bergen

Amani has a background in pharmaceutics and health economics from Tanzania and Norway. His main interests are economic evaluations, financing, costing and pricing of pharmaceuticals and other healthcare intervention strategies. He is a key person in the Cost-Benefit RISE study implemented in Zambia.

### Catherine Schwinger
University of Bergen

Catherine holds a PhD from the University of Bergen based on a thesis on the assessment of child growth. Her main research interests are child nutrition and interventions to prevent child undernutrition. She is involved in the Vitamin $B_{12}$ studies in Nepal.

### Fatema Khatun
Norwegian Institute of Public Health

Fatema is associated with the International Centre for Diarrhoeal Disease Research in Bangladesh (ICDDR,B). She has expertise in antimicrobials and infectious diseases and does research on health care system delivery in Bangladesh. She is involved in the eRegistry and Care study in Bangladesh.

### Ingrid Kvestad
University of Bergen

Ingrid is a clinical psychologist and currently employed at RKBU-Vest, NORCE Norwegian Research Center AS. Her main research interest is neurodevelopment and nutrition in young children both in Norway and in low- and middle-income countries. She is involved in the Vitamin $B_{12}$ studies in Nepal.

### Joar Svanemyr
University of Bergen and
Christian Michelsens Institute (CMI)

Joar is a sociologist and holds a PhD from the University of Oslo. His doctoral research focused on induced abortion and gender relations in Côte d'Ivoire. Specific areas of interest are child marriage, female genital mutilation and sexuality education. He is involved in the RISE study.

### Joseph Zulu
University of Zambia

Joseph holds a PhD in Public Health from Umeå University. He is currently employed at the School of Public Health, University of Zambia. His postdoctoral research is on the implementation of comprehensive sexuality education in Zambian schools within the SAFEZT study.

## Kjersti Mørkrid Blom-Bakke
Norwegian Institute of Public Health

Kjersti has a background in International Community Health and holds a PhD from the University in Oslo with a thesis on gestational diabetes in a multi-ethnic population in Norway. She is involved in the eRegistry Support study in Palestine.

## Mulumebet Zenebe
University of Addis Ababa

Mulumebet holds a PhD in sociology from the University of Tromsø (2006). She is currently employed at the Centre for Gender Studies, College of Development Studies at the University of Addis Ababa. Her postdoctoral research focuses on sexuality, fertility control and abortion among university students in Ethiopia within the SAFEZT study.

## Patrick Musonda
University of Bergen

Patrick is trained in medical statistics at the Open University (UK) and the London School of Hygiene and Tropical Medicine. He is currently employed at the School of Public Health at the University of Zambia and is Co-Principal Investigator for the RISE study.

## Richard Sambaiga
University of Dar es Salaam

Richard holds a PhD in Social Anthropology from the University of Basel. He is currently employed at the Department of Sociology and Anthropology at the University of Dar es Salaam. His postdoctoral research is on contemporary discourses on fertility control and abortion in Tanzania within the SAFEZT study.

## Sudha Basnet
University of Bergen

Sudha is a paediatrician with a PhD from the University of Bergen. Her main research is on treatment of childhood infections and she is currently employed as an Associate Professor at Tribhuvan University in Kathmandu. She is one of the Principal Investigators for the Zinc-Sepsis study in Nepal and India.

## Victoria Nankabirwa
University of Bergen

Victoria holds a PhD from the University of Bergen and has considerable research and clinical experience. Her main research is on perinatal epidemiology, vaccination, core epidemiologic methods, and implementation research. She is Principal Investigator for the following CISMAC studies: BCG, EcoTime BCG, Chlorhexidine, CCF instead of RCT.

# FACTS & FIGURES

# CISMAC MANAGEMENT AND ADMINISTRATION

**Halvor Sommerfelt**
Director

**Ingvild F Sandøy**
Deputy Director

**Jose Martines**
Scientific Coordinator

**Ane Straume**
Head of Administration
(Partial parental leave)

**Catherine Schwinger**
Head of Administration
(substitute)

**Filiz Ipek**
Economy

**Solfrid Vikøren**
Economy

**Carmeliza Rosario**
Project administration

**Ingvild Hope**
Project administration

**Marte E. S. Haaland**
Project administration

**Elinor Bartle**
Web & communication

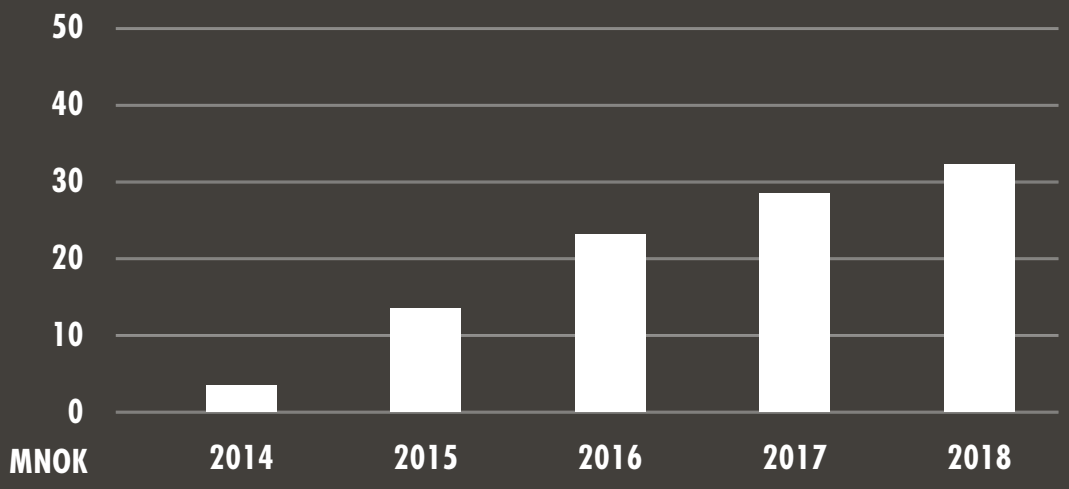
**Gunhild Koldal**
Web & communication

## GENDER DISTRIBUTION POSTDOCTORAL FELLOWS

58%

42%

## EXTERNAL FUNDING GENERATED BY CISMAC STUDIES (2014-2018)



# SELECTED HIGHLIGHTS 2018

The first large CISMAC study was completed in October 2018. The main analysis of the community-initiated Kangaroo Mother Care study (cKMC) was completed and its important findings will be published soon.

Many CISMAC studies reached major milestones: the eRegistry study in Palestine (eRegistry support) completed follow-up while the eRegistry study in Bangladesh (eRegistry and care) started to recruit participants. Several studies underwent interim analyses, and the RISE study completed the intervention phase and continues to follows up the more than 4900 participating adolescent girls.

CISMAC expanded its portfolio with one study: the NeoSupra trial, which is conducted in Uganda in newborns who don't breath immediately after birth. It assesses the effect of a new ventilation method to help them breathe.

2018 was an important year for CISMAC's efforts to support younger promising researchers. The Center supported a one-week course on logistic regression and a Bergen Summer Research School course on fair priority setting in global health, and launched the "CISMAC Research Training Track" for PhD students and postdoctoral fellows.

CISMAC has high demands on the quality of studies. In 2018 we have seen that this gives results. All of CISMAC's studies today can show an impressively high proportion of participants being followed-up. In the recently completed cKMC study, the investigators were able to follow up an incredible 99.9% of the 8400 participants!

**99.9 % FOLLOW-UP**

# LIST OF SCIENTIFIC PUBLICATIONS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PhD Thesis:

**Onarheim KH:** "*Priority to the newborn? Real-life priority setting and intra-household resource allocation for newborn health in Ethiopia".* University of Bergen. Available at: https://bora.uib.no/handle/1956/17619

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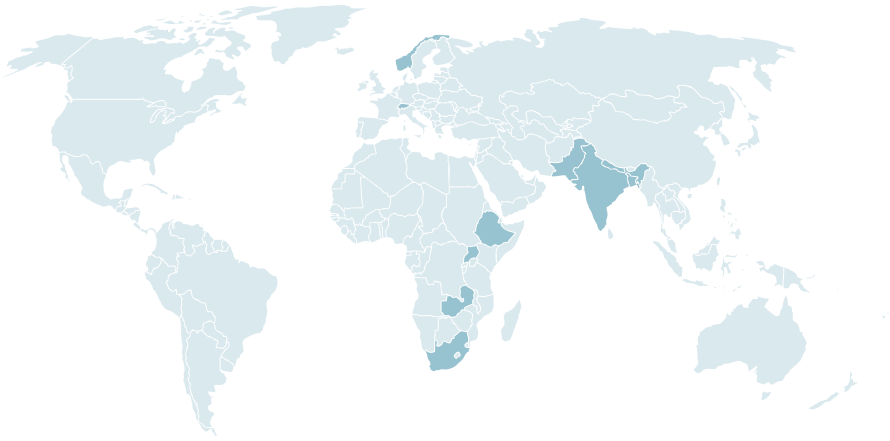

TOWARDS A BRIGHTER FUTURE FOR MOTHERS AND CHILDREN

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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.

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