



ANNUAL REPORT 2017



Norwegian
Centre of
Excellence

NOTES FROM THE DIRECTOR

Centre for Intervention Science in Maternal and Child Health (CISMAC) is now finishing a successful first five years of cutting-edge and high quality intervention research. Our work is at the heart of our university's Global Challenges thematic area¹ and in line with our government's development and research strategy².

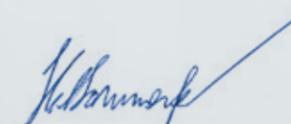
During this period, we initiated ten randomized controlled trials to evaluate promising maternal, newborn and child health interventions. Some of these trials are approaching completion, and new studies will soon start.

CISMAC engages early with low- and middle-income country (LMIC) health authorities as well as with the World Health Organization to effectively translate research results into policy and practice. This is in coherence with Norway's research strategy for the Foreign Service and NORAD, which emphasizes that overseas development activities should be more informed by evidence and that research-based knowledge should be used extensively by decision makers³. Norwegian development policy is aligned with the Sustainable Development Goals, with two of its thematic priority areas being education and health⁴. By generating a scientific basis for decision-making in these areas, our findings can be used to increase the health and development returns of Norway's substantial investments.

All our projects include significant capacity-strengthening activities, in our four Norwegian partner institutions as well as in LMIC research organizations. Furthermore, we invest in expanding the linkages among our partners and engage our PhD students and younger researchers in face-to-face meetings and courses as well as in monthly web-based seminars.

Most of CISMAC's studies are randomized controlled trials, which is the epidemiologic method considered to yield the most valid estimates of effect. They will also yield statistically precise effect measures because they include many study participants and follow up over 90% of them. To enhance the generalizability of our findings, CISMAC researchers gather information about local health systems and family care seeking and practices, and carefully describe the contexts where the interventions are implemented. We use qualitative methods to develop the interventions and describe their acceptability, and include process evaluation during study implementation. This generates the context-related information needed to implement the interventions elsewhere if the trials show they are effective. In short, we design and implement our studies to provide a solid basis for evidence-based decision-making.

In addition to classic cost-effectiveness analyses, which measure costs incurred by health systems, we also estimate out-of-pocket expenditures for health services and transportation, as well as income loss to families. These expenses may result in catastrophic expenditures for health care, where marginalized families are brutally thrust into overt poverty. By applying an equity lens^{5,6}, our research will provide evidence about whether the interventions can contribute to equitable improvements in maternal, newborn and child health and development.



*Halvor Sommerfelt,
Director, CISMAC*

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LETTER FROM CISMAC'S MANAGEMENT

CISMAC was established five years ago to pursue a vision of equitable improvements in maternal, newborn and child health and development in low- and middle-income countries (LMICs). Our primary contribution is high-quality research focused on the interventions we believe to be the most effective in promoting such improvements.

Maternal conditions, newborn and child illness and malnutrition are the leading causes of high disease burden and compromised child development in LMICs. The lifetime risk of maternal death in CISMAC partner countries is between 45 and 200 times higher than in Norway, and a child's risk of dying is between 20 and 35 times greater. Young age at pregnancy amplifies these dangers, and babies born with low birth weight have an increased probability of severe illness, death or disability.

Although there has been an impressive drop in child mortality since 1990, nearly six million children under 5 years of age still die every year. Almost all of these deaths are in LMICs, and nearly half of them are caused by infections, primarily pneumonia, diarrhea and sepsis. The 2.6 million annual newborn deaths, i.e. deaths among babies less than one month of age, are primarily the consequences of prematurity, complications around the time of birth and severe infections. It is sad to acknowledge that, in contrast to famines, war, and ravaging epidemics, these deaths are all but invisible; they rarely hit the headlines of big media. To this must be added the often-forgotten 2.5 million stillbirths. Regrettably, the prevention of the latter was neither among the Millennium Development Goals nor the current Sustainable Development Goals.

Contrary to common belief, many stillbirths can be prevented and neonatal survival can be substantially enhanced with interventions that are known to us, and which do not need sophisticated equipment. Ensuring that

reproductive health services, including the choice to use contraceptives, are available to more young women, and providing expanded and equitable health services across the continuum of care from pregnancy, around the time of birth and during the first month of life will significantly enhance women's health, newborn survival and child growth and development.

An underlying problem is that the coverage of many of these interventions remains low and highly inequitable, and progress in reducing mortality, particularly among newborns, is disappointingly slow. In countries where a considerable part of health services are private or where public services are not free, caring for illnesses in pregnant women and children can result in catastrophic health expenditures for families. This is compounded by the agony of severe illness, death or the developmental disability of one's own child.

Research on equitable delivery strategies of known interventions that can be applied at scale is an important priority for CISMAC. There are also some promising new interventions whose efficacy and effectiveness need to be established before they can be implemented at scale. An increasing body of evidence indicates that the remarkable improvement in child survival from 1990 to the present is due not only to general economic growth, but that it also follows specific biomedical interventions. It also shows that such gains were most pronounced when these interventions were brought quickly and equitably to scale. Vaccination programs and other programs for the prevention and early

treatment of diarrhea, pneumonia, malaria and sepsis and promotion of child nutrition are excellent examples of successful interventions. Such programs also promote children's physical and cognitive development, which by virtue of increasing human capital, result in more stable societies and further economic growth and development. In places where such successful programs are implemented in parallel with strengthened education services, especially for girls, the positive effects in terms of survival and development can be remarkable. Intervention and implementation research in these areas is sorely needed and will contribute vitally to national and global efforts to improve maternal, newborn and child health and child development.

CISMAC research evaluates interventions delivered during the preconception period, in pregnancy, around the time of birth, in infancy and in early childhood. We examine a number of interventions that we expect will, if rolled out equitably, benefit girls, women, mothers and children. Bridging several disciplines, we run a large school-randomized trial in Zambia ("RISE") that uses economic

incentives and education on sexual and reproductive health to empower girls to remain in school and support their right to decide when they shall have children. Similarly, we have recently engaged with the Norwegian School of Economics to support the "Girl Power" project in Tanzania. This trial investigates whether two different empowerment strategies, i) information about reproductive health, gender equality and rights and ii) entrepreneurship training, can reduce the risk of early childbearing.

Our studies generate results of high scientific quality that can be used to guide policy and develop strategies to enhance maternal, newborn and child health, survival and development. As an integral part of our work, we strengthen technical research competence and skills in Norway and in our partner countries. Recognizing the Norwegian authorities' emphasis on evidence-based decision-making and on strengthening capacity in low- and middle-income countries, it is our hope that our work will make an important contribution to the focus and efficiency of Norway's Overseas Development Cooperation.



Halvor Sommerfelt,
Director



Ingvild F. Sandøy,
Deputy Director



José Martínez,
Scientific Coordinator



Maharaj K. Bhan, Chair,
Technical Advisory Group



Ane Straume,
Head of Administration

NOTES FROM THE DEAN

CISMAC's research is at the heart of the University of Bergen's Global Challenges Strategy and plays a pivotal role in our university's focus on cutting-edge global health and development research, both in terms of the issues addressed and the quality of the science.



Over the past five years, CISMAC has set up several studies of high quality to address priority research questions and to strengthen already existing and establish new partnerships in Norway and with research institutions in low- and middle-income countries (LMICs).

CISMAC has also created excellent opportunities for PhD and postdoctoral fellows to participate in the meticulous and systematic design, planning and implementation activities that are required to conduct high quality intervention research. CISMAC also gives postdoctoral fellows and other young researchers an opportunity to lead studies or study subcomponents, under the guidance of leading experts in the field.

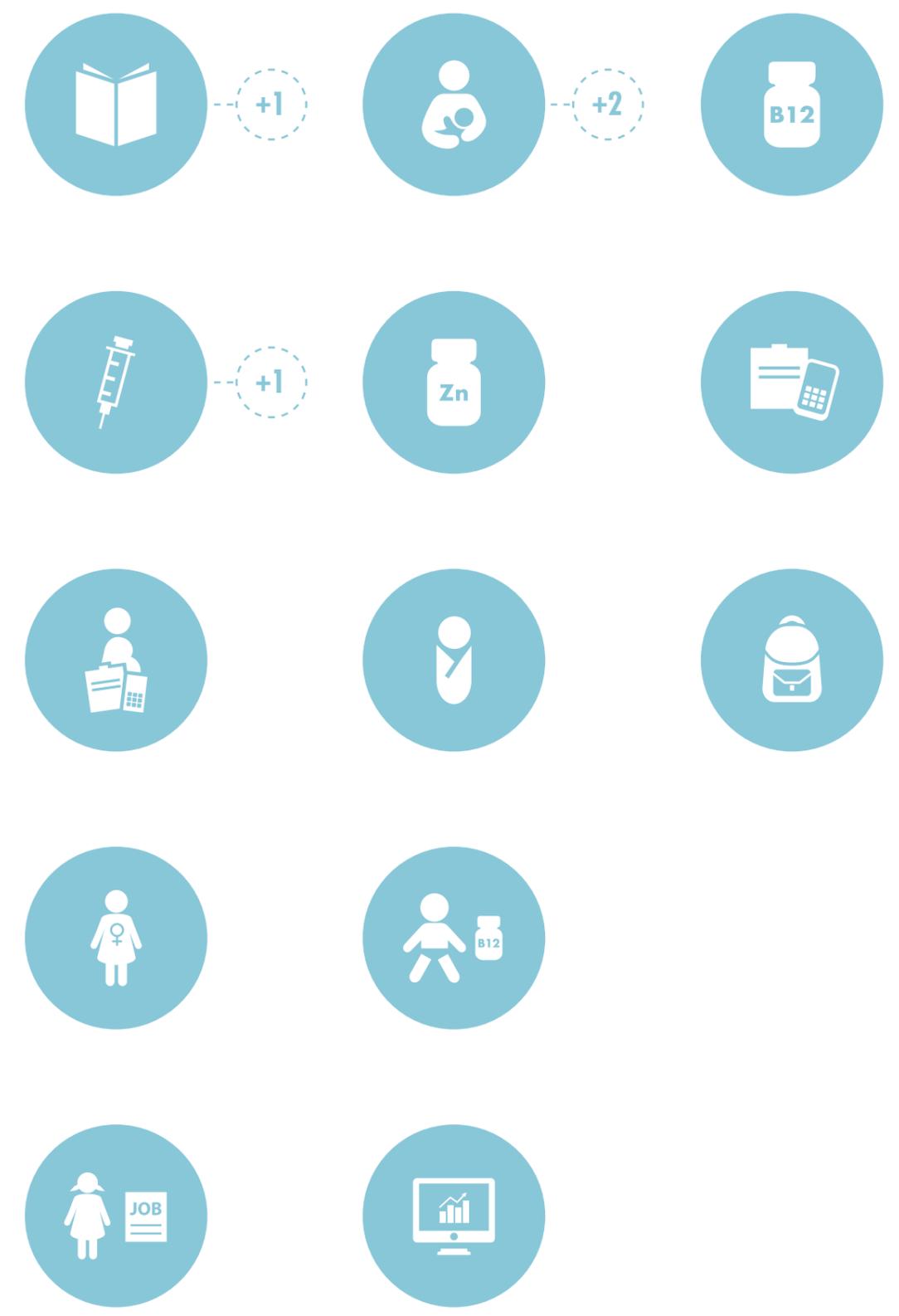
The Medical faculty is very pleased that CISMAC thus is creating conducive conditions and environments for these junior researchers to become independent and experienced scientists. The plans for a more structured research training for PhD and postdoctoral fellows within intervention and implementation science is likely to further contribute to this, and the courses that will be offered will also benefit other PhD and postdoctoral fellows at the University of Bergen, in the other Norwegian institutions and also very importantly in CISMAC'S LMIC partner countries. These activities, coupled with CISMAC's demonstrated ability to publish in high-impact journals, show that CISMAC is continuing to make remarkable contributions to our University and will continue to do so in the years to come.

*Per Bakke,
Dean, Faculty of Medicine, University of Bergen
and Chair of the CISMAC Board*





RESEARCH PROJECTS



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 seventh grade girls from 157 rural schools are enrolled in the 5-year study.



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

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 10 000 LBW babies to evaluate its impact on survival in newborns.



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

B₁₂ in Pregnancy

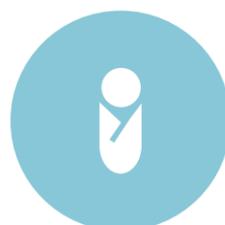
Worldwide, vitamin B₁₂ deficiency is common, affecting people of all ages. It can lead to a wide variety of health problems and can, without prompt treatment, result in permanent damage. In this study, we measure the effect of giving daily oral vitamin B₁₂ supplements to pregnant women and during a 6-month 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

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

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, Tor A. Strand

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 CISMACH, 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

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, rather than as soon as possible after birth, 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 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

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

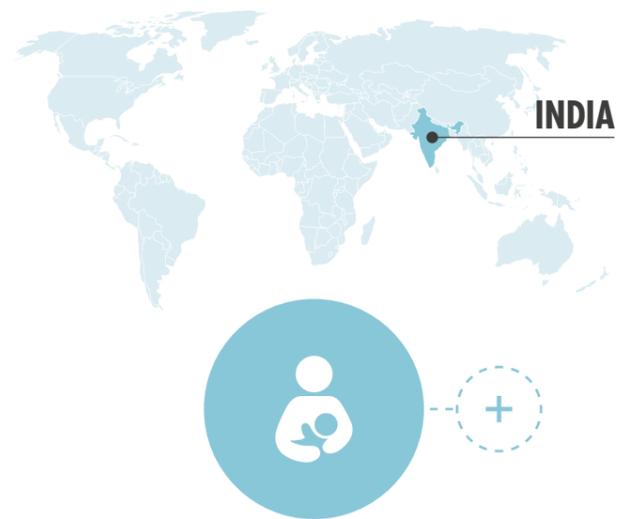
This three-year project examines global and national policy discourses surrounding fertility control and abortion, as well as local practices and moralities related to these issues among adolescents in Ethiopia, Zambia and Tanzania. The dynamics between the law, policies and access to fertility control 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

OUR NEW RESEARCH PROJECTS

In 2017 CISMALC substantially expanded its research portfolio. We are proud to present 3 new projects as well as 4 important spin-off studies which serve to extend the scope and the reach of our ongoing activities. ▶



Biological Effects of cKMC

Effect of community initiated Kangaroo Mother Care in low birth weight infants on infant breast milk intake, gut inflammation, maternal depressive symptoms and stress

This study investigates the mechanistic pathways involved in community initiated Kangaroo Mother Care (cKMC) and is a sub-study of CISMAC's cKMC trial. The study aims to explore biological and physiological pathways underlying the cKMC intervention that potentially improves survival and growth in low birth weight (LBW) infants.

By employing innovative scientific methods, the study will assess the impact of cKMC on the volume of infant breast milk intake in LBW babies, ma-

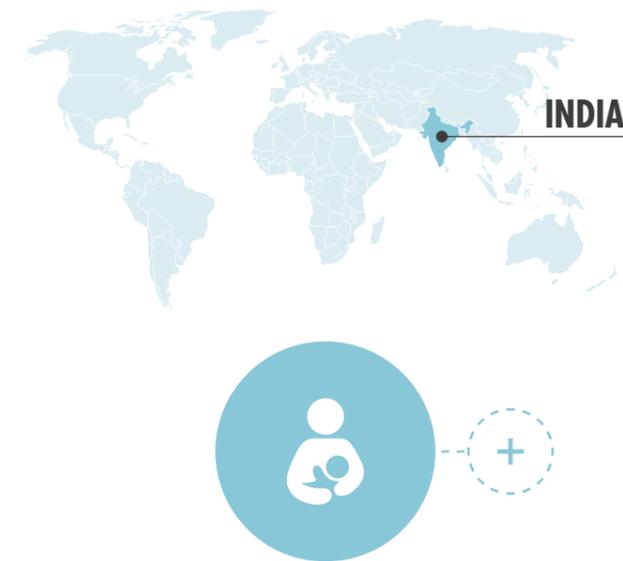
ternal postpartum depressive symptoms and stress, and infant gut inflammation. The results will fill in critical knowledge gaps linking biological mechanisms to the primary trial's clinical outcomes.

Many intervention trials do not incorporate assessments of the mechanistic pathways involved, which may cause difficulties in explaining the clinical success or failure of the intervention, and limit its scientific value. This study represents a step forward in intervention research by linking findings from a

large intervention trial with mechanistic studies. The approach could potentially be a model for adding scientific value to other public health trials currently only measuring clinical outcomes.

In addition to its inherent scientific value, a better understanding of the biological pathways involved in cKMC will enable this intervention to be more attractive to pediatricians and policy makers, and may thereby help to promote it.

Principal Investigator: Bireswar Sinha, Society for Applied Studies, India / Co-Principal Investigator: Nita Bhandari, Society for Applied Studies, India / Co-Principal Investigator: Halvor Sommerfelt, University of Bergen, Norway



Poverty and Equity cKMC

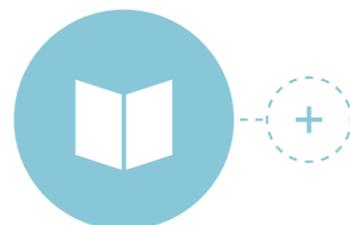
Community initiated Kangaroo Mother Care for low birth weight infants: a poverty and equity impact evaluation

Embedded in the ongoing trial, which estimates the survival benefits of promoting Kangaroo Mother Care at home (cKMC) to low birth weight (LBW) babies, this study will use the concentration index to estimate whether socioeconomic inequality in neonatal and early infant survival is more pronounced in the intervention

or in the control groups. Further, this extension of the trial will estimate the household out-of-pocket expenses for illnesses that may be prevented by cKMC. It will also assess the extent to which out-of-pocket expenses for health care contribute to household impoverishment. Should cKMC prove effective in enhancing equity

in child survival and in substantially reducing family expenditures, possibly even preventing catastrophic health expenditures, the findings of this added study could be of critical importance for scaling up Kangaroo Mother Care in India, as well as in other countries where many babies are born with LBW.

Principal Investigator: Sarmila Mazumder, Society for Applied Studies, India / Principal Investigator: Kjell Arne Johansson, University of Bergen, Norway



Cost-Benefit RISE

Cost-benefit and extended cost-effectiveness analysis of a comprehensive adolescent pregnancy prevention program in Zambia

This study builds on CISMAC's randomized controlled trial RISE. It seeks to examine the short- and long-term monetary benefits of providing cash support to adolescent girls and their guardians / parents, as well as community dialogue about delaying pregnancy and childbearing to an older age. The project has the potential to generate benefits that would span across different sectors including health, education, as well as both personal and community economies.

Adolescent pregnancies are associated with an increased risk of significant out-of-pocket health expenditures for the family as a consequence of additional health complications for the mothers and their babies. If the interventions can delay childbearing to an appropriate age, it may well also result in reduced costs for health care and increased economic benefits from higher levels of education and higher productivity. This study compares the cost of the program to the social

benefits resulting from reduced rates of adolescent births and the associated complications. The cost-benefit analysis will make it possible to determine to what extent the benefits of the RISE interventions outweigh their costs. The project will generate valuable information that can be used to guide future, large-scale implementations of similar programs in other areas of Zambia as well as other low- and middle-income countries.

Principal Investigator: Patrick Musonda, University of Zambia, Zambia / Principal Investigator: Ingvild Fossgard Sandøy, University of Bergen, Norway / Study Lead: Amani Thomas Mori, University of Bergen, Norway



EcoTime BCG

Economic evaluation of the timing of BCG-vaccination in HIV-exposed babies

The Bacillus Calmette-Guérin (BCG) vaccine protects children against primary tuberculosis, but it might also have positive health effects beyond that, so called non-specific effects (NSEs). It is unclear if such NSEs are also seen in children born to HIV-1 positive women, i.e. HIV-1 exposed infants, and if these effects depend on the timing when the vaccine is given. An ongoing randomized controlled trial in Uganda is currently assessing effects of enforcing BCG on the day of birth versus giving it at 14 weeks of age on the risk of severe illness (a

proxy for serious clinical infection) in HIV-1 exposed infants.

Besides these possible clinical benefits, it is important to estimate the cost-effectiveness of these two different vaccination schedules. The analysis in this add-on study will include household costs already being collected in CISMAC's Trial "Early Versus Late BCG Vaccination in HIV-1 exposed infants", and will expand the information by collecting data on health provider costs. Provider costs encompass both the intervention costs related to

ensuring timely BCG vaccination, as well as costs of managing the illnesses that the vaccine may prevent through the NSEs. We will use statistical approaches to estimate cost implications for the children from birth up until 5 years of age, and decision modelling to compare the cost-effectiveness of the two vaccination strategies.

The study findings can be used to inform stakeholders involved in the development of appropriate child vaccination schedules.

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



Child B₁₂ Follow-up

The effect of vitamin B₁₂ supplementation on growth and neurodevelopment in Nepali children after one and two years - extended follow up

Vitamin B₁₂ is involved in the metabolism of every cell and has a key role in the functioning of our nervous system. Vitamin B₁₂ deficiency is one of the most common micronutrient deficiencies worldwide and can occur at all ages. An association between vitamin B₁₂ deficiency with neurodevelopment and child growth has been reported with potentially irreversible impairments. It is therefore important to study if an improvement in vitamin B₁₂ status in children also improves developmental outcomes, and which populations potentially benefit the most.

The first 1 000 days of life represents a particular vulnerable period for neurodevelopment and growth. The timing of a nutritional deficiency during this period may have differing effects on different functions and areas of the nervous system. It is thus important to study at which age supplementation might result in improved functioning on different sub-scales of development and to assess if effects persist after the end of supplementation.

This study is a follow-up of an ongoing randomized placebo-controlled trial.

In total, 600 Nepalese children were enrolled at age 6-11 months, and half of them received 2µg of vitamin B₁₂ supplementation daily for 1 year. The trial aims to assess improvements in neurodevelopment and growth after one and two years. It will provide information expanding on that being provided by the CISMACH study on vitamin B₁₂ supplementation during pregnancy. These studies combined will be the most comprehensive study on the effects of vitamin B₁₂ supplementation throughout the most vulnerable period of life.

Principal Investigator: Tor Strand, University of Bergen/Innlandet Hospital Trust, Norway / Co-Principal Investigator: Laxman Shrestha, Tribhuvan University, Nepal / Co-Principal Investigator: Prakash S Shrestha, Tribhuvan University, Nepal



CCF instead of RCT?

Case-control studies with follow-up: An efficient and ethically justifiable alternative to the randomized control trial?

Randomized controlled trials (RCTs) are often seen as the gold standard of epidemiological studies, both to identify causality and test intervention effects, and to develop and tailor health programs. In many situations, actively allocating people to an intervention that is likely not to be beneficial is often ethically unjustified or politically impossible. Further, RCTs are often costly and difficult to implement.

This study aims to evaluate whether a case-control with follow-up (CCF) design may be an efficient alternative to an RCT or a case-control (CC) study when estimating the association between an intervention and a rare outcome. The CC and CCF studies will be undertaken in parallel with our RCT on umbilical cord stump care in newborns in Uganda, the Chlorhexidine Trial. For the CCF study, we will as-

semble and follow a cohort comprised of a disproportionately large number of newborns who have a relatively high risk of developing severe illness, and then compensate for this biased inclusion during analyses. The method should be more efficient than regular cohort studies and RCTs since fewer newborns need to be followed in order to capture the same number of severe illness episodes.

Principal Investigator: Victoria Nankabirwa, Makerere University, Uganda / Co-Principal Investigator: Hans Steinsland, University of Bergen, Norway



Girl Power

Economic Empowerment of young women in Tanzania

Early pregnancies, low level of education and income, as well as heavy household duties are common characteristics of young girls in low- and middle-income countries, and they often represent important infringements on the empowerment of girls and women. One conventional response to such circumstances is the introduction of reproductive health programs that aim to provide relevant health information. Appraisals of such policy responses have found improvement in knowledge and attitudes among girls, but less effects on behavior. This may be partly because decisions that lead to child bearing are also influenced by economic op-

portunities. In an environment where there are few jobs, early marriage and childbearing may be rational choices for young women. Better job opportunities may allow young girls to make decisions to postpone childbearing.

CISMAC supports an ongoing study undertaken by the Centre of Excellence FAIR at the Norwegian School of Economics and Chr. Michelsen Institute called "Girl's Economic Empowerment: A randomized experiment in Tanzanian schools". This study recruited 3 483 girls in 2013 from 80 schools located in four regions of Tanzania. The schools were randomly assigned to

four groups: provision of reproductive health information, entrepreneurship training, reproductive health information and entrepreneurship training combined, and no intervention. The trial investigates whether provision of reproductive health information and entrepreneurship training for young women influences decisions related to childbearing and economic activities. With support from CISMAC, the team has been able to complete a last round of follow-up interviews up to 4.5 years after recruitment, and is now starting the analysis of this important data.



RESEARCH PROJECTS BY COUNTRY



LEARNING OPPORTUNITIES

MAXIMIZING THE USE OF EXISTING DATA

Producing valuable research findings does not only depend on new data collection. Important information can also be produced from reviews of published information and analyses of existing data to address new research questions.

Systematic Reviews

Reviews of existing research information provide valuable answers to many questions. Systematic reviews are crucial for the development of health guidelines. Not only do they summarize what we know, but they assess the strength of the evidence. They can also help us refine our research questions, making them more focused, and allowing us to concentrate specifically on what is not yet known as well as highlighting important methodological issues learned from previous attempts to address similar questions.

Strengthening Skills

When conceptualizing new studies, CISMAC encourages its researchers to examine existing information using systematic reviews. In response, CISMAC scientists have already produced such reviews. Sometimes, this can represent a considerable challenge as the study questions have not yet been addressed by existing reviews and some teams have yet to develop adequate skills for conducting their own. Acknowledging this, CISMAC has engaged with the Norwegian satellite of the Cochrane Effective Practice and Organisation of Care (EPOC) Review Group⁷ at our ▶

FACTS

SYSTEMATIC REVIEWS

What is a systematic review?

- “A review of a clearly formulated question that uses systematic and explicit methods to identify, select, and critically appraise relevant research, and to collect and analyze data from the studies that are included in the review.” *Cochrane Handbook*

Why do we need systematic reviews?

- The achievement of health and others goals is more likely to be realized through well-informed health policies
 - Poorly-informed decisions in the health sector may lead to:
 - effective and cheap interventions not being implemented
 - services that are not effective or efficient
 - inequities within health systems, including services failing to reach those most in need
 - health indicators not being reached
- Simon Lewin, Cochrane Effective Practice and Organization of Care Review Group*

CISMAC has put in place an initiative to stimulate the utilization of existing data to address new research questions



Research nurse Jackie Komugisha and study participants interacting at Kitebi clinic for the Chlorhexidine trial in Kampala, Uganda.

Partner institution the Norwegian Institute of Public Health in Oslo to strengthen our skills in conducting systematic reviews concerning priority health systems questions.

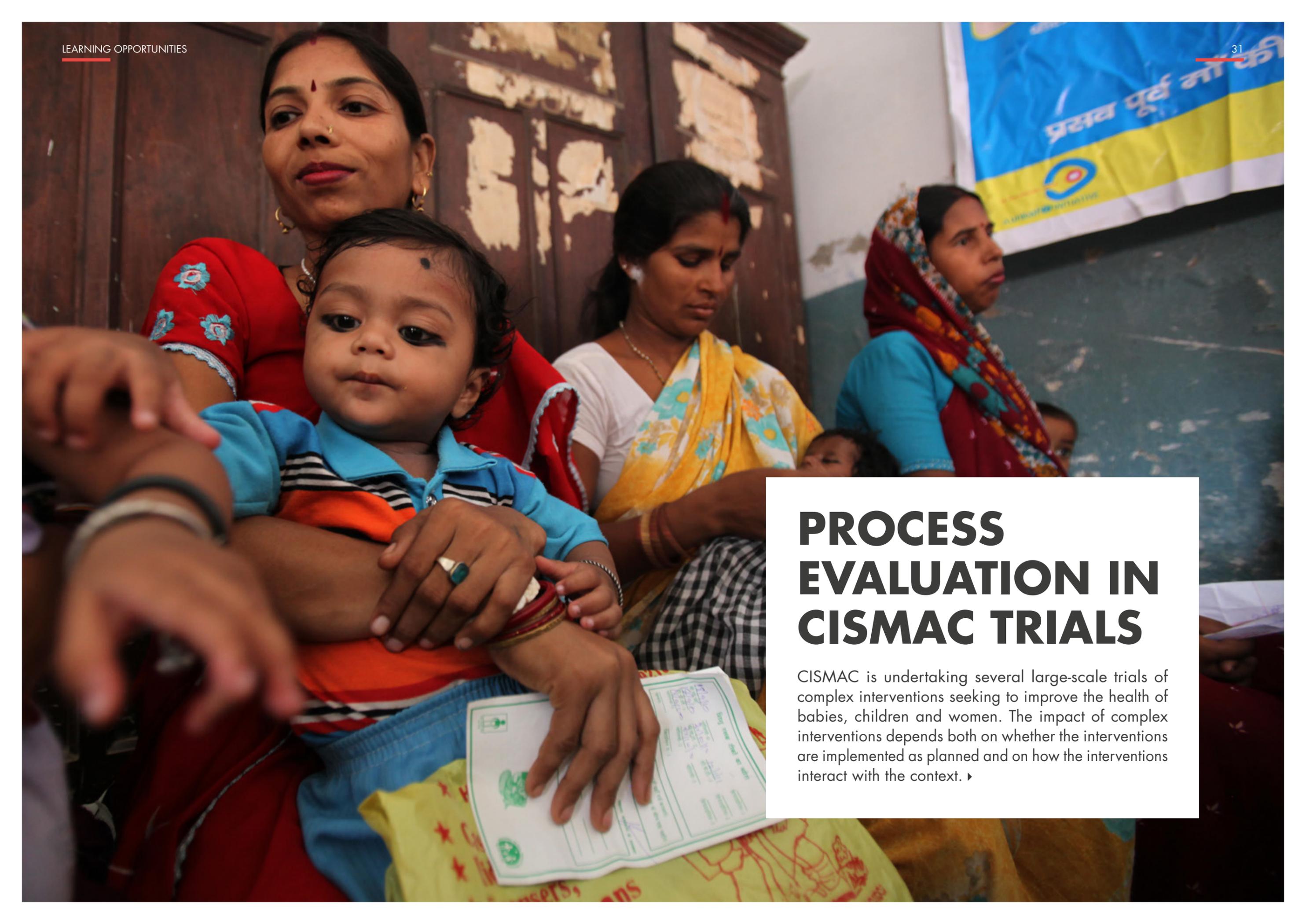
Data sets rich in important information have accumulated over the years in our partner institutions, as analyses of completed research findings first focus on the primary objectives of the studies. Funding for the production of papers through research proposals is usually restricted to one or two main papers. By the time they are completed, researchers have often engaged in new projects with other funding.

Publication Grants

Recognizing the value of these reserves of high quality data in our partner institutions, CISMAC has put in place an initiative to stimulate the utilization of existing data to address new research questions.

Acknowledging that such work requires motivation and resources, we announced competitive grants to support the development of publications addressing important questions. We selected proposals based on the relevance of the research question, quality of data and analysis plan, qualifications of the research team, and likelihood of publication in a peer-reviewed journal. The grants were given to young researchers, thereby also contributing to capacity strengthening and career development.

Five proposals were selected for support in 2016. They included topics such as “whether vitamin-D deficiency predicts infections, growth, or neurodevelopment in young children”, “Mid Upper Arm Circumference as a predictor of risk of death in children in an urban slum setting in North India”, “immunization practices in low birthweight infants” and whether “maternal low stature predicts poor linear growth in low birth weight babies”. They led to the completion of 4 important papers published in peer-reviewed scientific journals.^{8,9,10,11} The effectiveness of this initiative, which was much appreciated by our partners, encourages us to continue to announce this kind of grants. •



PROCESS EVALUATION IN CISMAC TRIALS

CISMAC is undertaking several large-scale trials of complex interventions seeking to improve the health of babies, children and women. The impact of complex interventions depends both on whether the interventions are implemented as planned and on how the interventions interact with the context. ▶

Thus, the effectiveness may be dependent upon factors such as socio-economic conditions, policy environment and target population. A process evaluation that considers both the fidelity (*whether the implementation was delivered as intended*) and quality (*how it is implemented*) increases our ability to interpret findings. If an intervention is found to be effective, findings from the process evaluation can indicate the likely causal mechanisms and facilitate the scale-up of the interventions in other populations. Conversely, if the studied intervention does not lead to the expected effects, information about fidelity and quality will make it possible to distinguish between poor implementation and an ineffective intervention.

The RISE project in Zambia and the cKMC study in India are two of our intervention studies that include detailed process evaluations.

Process evaluation and RISE

CISMAC's RISE project is a complex social intervention that combines multiple, synergistic components. One intervention arm offers economic support consisting of unconditional cash transfer to adolescent girls and their guardians and payment of school fees. The second arm combines the economic support with youth clubs that provide life-skills and sexuality education as well as community dialogue meetings on girls' empowerment, the benefits of education and the risks of early childbearing.

Various types of data are collected as part of the process evaluation, including:

- Structured observations during youth clubs and community meetings
- School and youth club attendance data
- In-depth interviews with teachers and community health workers involved in delivering the intervention
- Individual and group interviews with participants and parents

We use the information actively to improve both the fidelity and quality of the implementation. An example is the use of a quality assessment tool when monitoring meetings and then giving feedback to teachers and community health workers on their performance. Regular meetings with parents and interviews with the RISE participants have also allowed the researchers to discover when the economic support does not reach the intended beneficiaries and enables them to intervene to rectify this.

Good intervention fidelity

The preliminary findings indicate that the fidelity to the planned intervention, that is the study team's ability to deliver the intervention components as planned, is high. Girls and parents express great satisfaction with the economic support and inquire about the continuation and possible expansion of the program. While there have been some variations in the way the youth clubs and community

meetings have been carried out, the teachers and community health workers have expressed overall satisfaction with the training and support materials they have received.

Process evaluation and cKMC

Study leaders initially undertook process evaluation in CISMAC's large cKMC project in India with the aim to understand whether the intervention was being implemented as planned, to identify the barriers and facilitators to effective implementation and use the lessons learnt to improve the intervention package and delivery strategy. The process evaluation team, comprising of senior study staff members, observes the study-appointed KMC community supervisors and community workers when accompanying them during some of their home visits. They use an observation checklist that includes details about the interaction of study community supervisors and community workers with the

mother and family members. Data collected includes the workers' ability to assess compliance to the intervention, counseling skills, technical skills to demonstrate appropriate breastfeeding and skin-to-skin care, aptitude in resolving problems, alertness and responsiveness to the mother, baby and family, asking questions to document understanding and learn whether the mothers and their families are satisfied. In addition, they observe and document other aspects such as the interaction of the family members with the mother, family support to the mother, physical ambience and home environment, mothers' condition and caring practices for the baby. The team provides information to the study coordinator and intervention workers in the form of a descriptive report.

Intervention fidelity and quality

The preliminary findings from the process evaluation reveal that the fidelity to the planned implementation of the intervention activities is high. The intervention delivery team is well prepared in both technical and effective counseling skills. With time and experience, the team has gained the required expertise to resolve barriers and provide feasible solutions for effective practice of KMC. Ways to deal with barriers and possible solutions are updated in the counseling guide used by the team.

Interesting observations

The compliance with KMC is higher than expected. The most compelling reason for the high compliance seems to be the emotional bonding and the feeling of closeness that the mothers experience when they place the baby on their chest.

The fathers and grandparents also report similar experiences. Visible benefits motivate families to practice KMC, such as babies becoming more active and playful, feeding better, sleeping more peacefully, their skin looking smoother and their faces glowing.

FACTS

Process Evaluation

- A way of documenting how a study is implemented
- Helps us understand how our results are achieved
- Helps us recognize challenges in the implementation of a study and what can be done to overcome them
- Enables us to interpret our findings and whether our conclusions are likely to apply also in other contexts, and what adaptations may in that case be required

Families often give examples from their daily lives that the intervention workers use to encourage other families to promote the practice of KMC. For example, to illustrate why keeping a weak and small baby on the mother's chest is a good practice, families cited the example of a newly made clay pot becoming stronger when kept in a furnace, or the ripening of a raw fruit when kept covered with a husk.

The importance of process evaluation

The process evaluation has helped us to implement the interventions studied in the RISE and cKMC projects with higher quality. Although the assessment of the impact of the interventions will have to wait until the completion of the trials, the information from the process evaluations is encouraging. When the findings from the impact assessment become available, the process evaluation will help us interpret our findings and determine whether our conclusions may also apply in other contexts. •

FACTS & FIGURES

THE CISMAC ADMINISTRATION



Ane Straume
Administrative leader

Straume has a Master in Anthropology and is currently working on a PhD in Medical Anthropology focusing on health and healthcare in the Pacific through the University of Bergen. Straume has been a member of the administrative team of CISMAC since November 2016. In 2017 she was employed as Project Manager for CISMAC and is leading the administrations work.



Marte E. S. Haaland
Project administration

Haaland has a Master in Anthropology from UiB. Before returning to Norway Haaland worked as an administrative and consular officer at the Norwegian Embassy in Buenos Aires. She has been a member of the administrative team of CISMAC since 2013 and Administrative Leader from 2016-2017. In 2017 Haaland began a PhD in Anthropology but still assists the administration.



Ingvild Hope
Project administration

Hope has been a member of CISMACs administrative team since the work on CISMAC first began. She has a Master in Science of Religion from the University of Bergen. Hope has previously worked for several years at faculty for Humanities and Philosophy before moving to the department of Medicine and Dentistry and is currently Advisor at the Centre for International health at UiB.



Filiz Ipek
Economy

Ipek has a Master in Business Administration from the University of Istanbul. Ipek worked as a Managing Partner in the private sector for many years before taking a position at UiB. She is currently a Senior Executive Officer at the Centre for International Health and is part of the CISMAC financial team together with Vikøren. Ipek is in charge of overall management of CISMAC budgets and finances.



Solfrid Vikøren
Economy

Vikøren has a degree in Managerial Economics from the Norwegian School of Economics. She has more than 30 years of experience managing finances for projects at UiB. Vikøren is employed as a Senior Executive Officer at the Centre for International Health, UiB. Vikøren is currently in charge of financial management and support of projects in the CISMAC portfolio.



Elinor Bartle
Web & communication

Initially educated and trained as a high-school math and science teacher, with work experience in Canada and the US, Bartle has been working as an Academic English specialist in Japan and France (where she trained at INRA and passed the French civil service exam). Since moving to Norway in 1998, she has also been working with Science Communication.



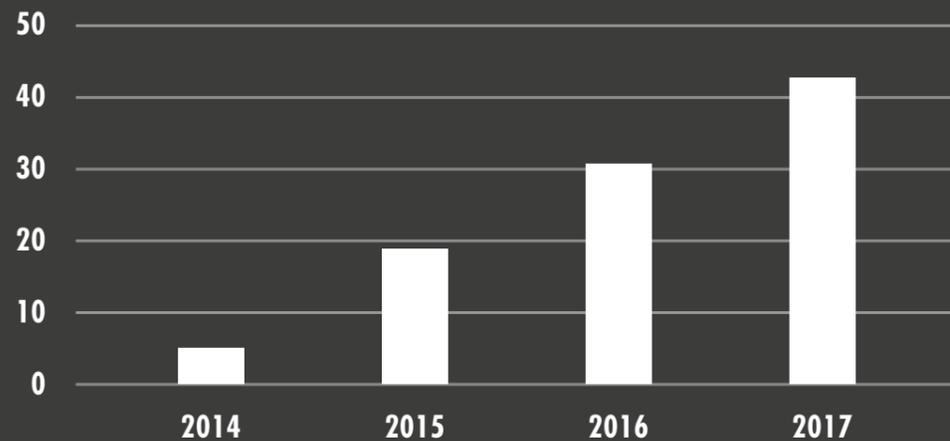
Gunhild Koldal
Web & communication

Koldal has a cand.mag. degree in English from University of Bergen. She works in the administration at Centre for International Health with research administration and web presence, including CISMAC webpages. She has previously worked for many years with course administration in the Norwegian Medical Association.

GENDER DISTRIBUTION PRINCIPAL INVESTIGATORS



SCIENTIFIC PUBLICATIONS, 2014–2017



SELECTED HIGHLIGHTS 2017

This year we saw the initiation of 7 new research projects. Three of these are stand-alone studies, whereas 4 are projects that have emanated from our larger, ongoing trials.



In 2017, CISMAC had publications in high level journals such as *BMJ*, *BMJ Global health*, *BMJ Open*, *Vaccine* and *The American Journal of Clinical Nutrition*.

CISMAC researchers had multiple presentations at international conferences, among other at the 2017 GLOBVAC conference with a session dedicated to our studies on e-Registries in Palestine and Bangladesh as well as a keynote presentation by CISMAC Director Halvor Sommerfelt and PI of CISMAC's BCG and Chlorhexidine studies, Victoria Nankabirwa.



One of our publications from research on vitamin B₁₂ in Nepal with researcher Ingrid Kvestad as the first author became widely discussed in the global news, also in *The Guardian*.

In 2017, CISMAC and the 12 other Centre of Excellence-III teams were evaluated as part of the Research Council of Norway's midway assessment process. Our progress and annual reports along with our future plans were submitted by March, and this was followed up with a meeting in Bergen with the independent evaluation committee, members of the Research Council of Norway's secretariat for the Centre of Excellence scheme as well as Principal Investigators from all of our studies flown in from 6 different countries and core staff from the CISMAC management.



At CISMAC we emphasize the importance of sharing our research questions and methods and have focused on publishing our study protocols fostering quality and transparency. In 2017 we have published 6 protocols for our ongoing CISMAC trials.

November marked the launch of monthly interactive CISMAC webinars, where also others scientists are invited to participate. The webinar series is part of the newly established CIH-CISMAC Research School (www.uib.no/en/rs/ih).

LIST OF SCIENTIFIC PUBLICATIONS

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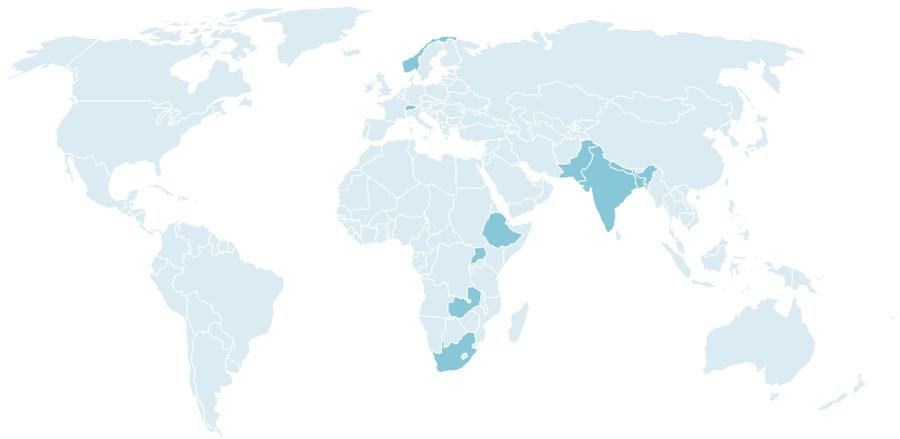
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TOWARDS A BRIGHTER FUTURE FOR MOTHERS AND CHILDREN

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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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