

ANNUAL REPORT 2016



Norwegian
Centre of
Excellence



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NOTES FROM THE DIRECTOR

Although child mortality is decreasing in most low and middle income countries, a staggering 6 million children under five years of age and approximately 300 thousand mothers die every year, mainly in these countries. Most of these children die from common and preventable diseases that should be affordable to treat. The illnesses or events that kill women during pregnancy or childbirth could likewise be mitigated by relatively simple means.

On this backdrop of what has been called *the unfinished agenda*, researchers at the Centre for International Health at the University of Bergen and its collaborating institutions, most of them in developing countries, and the World Health Organisation (WHO), developed a conceptual framework and a portfolio of study ideas when they in 2011 conceived the Centre for Intervention Science in Maternal and Child Health (CISMACH). Our overarching aim is to do cutting edge research to develop and evaluate interventions that can equitably reduce the number of maternal and child deaths, and foster child development.

Preparing for a randomized controlled trial (RCT) entails a lot of work, consulting with stakeholders, writing detailed protocols and standard operating procedures, making the questionnaires, seeking ethical and government approvals, and recruiting and training the study staff. One and a half year ago, CISMACH was already running an RCT in India, which examines if Kangaroo Mother Care, where low birth weight babies are wrapped to the mother's chest, could substantially enhance the baby's chances of survival. Over the last year, CISMACH scientists launched 8 large randomised controlled trials, which are also described in this report.

We have procured substantial additional resources from several funding agencies. We have participated in extensive consultations, with both national authorities in the countries we work and with the WHO, to develop strategies for research as well as new guidelines for treatment and prevention of important health problems.

CISMACH addresses topics that rarely reach the big media headlines; we address the silent "chronic disasters" such as girls becoming pregnant before their bodies and minds are ready for it, instead of remaining in school; women dying in childbirth, stillbirths due to malpresentation discovered too late, and newborns dying of sepsis. These important, persistent, invisible, unnecessary and unacceptable disasters are the focus of our science.

CISMACH's major tasks are to keep its focus on these non-fashionable illnesses because they are so common, maintain high scientific quality, support our partner institutions' zeal of capacity strengthening, and contribute to translate findings into policy and guidelines. While we present our trial findings in percent efficacy with 95% confidence intervals, we should remember that each figure in our tables and each number in our regression analyses represent adolescent girls, mothers or children with hopes, feelings and dreams just as we all have. It is our hope that our science will save maternal and child lives, foster their development and thereby their opportunities to support their families and build healthy societies.

Bergen, 20th of February 2017

Halvor Sommerfelt
Director CISMACH

LETTER FROM CISMAC’S MANAGEMENT

CISMAC envisions a world where mothers, newborns and children in low- and middle-income countries are healthier, and where children can develop to their full potential.

Attaining this vision requires actions along the life course, starting before conception through pregnancy, childbirth, infancy and childhood and adolescence. We explore promising interventions, ranging from improvements in the treatment of very sick newborns to preventive approaches that empower adolescent girls to remain in school and postpone childbearing. The CISMAC consortium provides a unique platform for conducting cutting-edge research while simultaneously strengthening research capacity and fostering a strong network of partners.

CISMAC’s network spans institutions in Norway and in low- and middle-income countries, plus members of the international scientific community. This strong partnership is a valuable asset for generating ideas, and for developing, supporting and conducting relevant front-line research. Original members in 2013 included research institutions in Ethiopia, India, Nepal, Uganda, South Africa and Zambia, the Chr. Michelsen Institute, the Norwegian Institute of Public Health and the World Health Organization. The consortium subsequently expanded by including the Aga Khan University in Pakistan and Innlandet Hospital Trust in Norway. In addition, the Norwegian Institute of Public Health implements their CISMAC studies with the ICDDR,B in Bangladesh and the Palestinian National Institute of Public Health.

Since its initiation, CISMAC has engaged in 10 projects to improve maternal health, pregnancy outcomes, newborn survival and child development. The studies, predominantly randomized controlled trials, employ rigorous methods for implementation and for capturing data. They have large sample sizes to ensure high statistical precision, and have very low attrition, which reduces the risk of selection bias. Our studies address questions that are among the top global priorities in maternal, neonatal and child health. To be selected as CISMAC studies, they must also be relevant for national programmes, and the interventions must have the potential for substantial impact on morbidity, mortality, or growth and development. Examples of the questions we ask are: Will zinc given in addition to antibiotics reduce the number of deaths caused by clinical severe infection

in young infants? Is Kangaroo Mother Care safe when it is initiated in the community? Can it substantially increase the survival of low birth weight babies as is observed when it is initiated in hospitals? Among HIV-1 exposed infants, does BCG vaccination reduce the risk of severe clinical infection early in infancy? Can a single application of chlorhexidine on the umbilical cord stump reduce the risk of clinical severe infection in newborns? These are the first and, to our knowledge, the only ongoing trials to adequately examine the efficacy of these interventions in improving survival or reducing the risk or consequences of severe infection. The findings of the trials will strengthen the evidence base for new maternal, neonatal and child health policies and practices.

CISMAC studies also contribute to understanding the mechanisms that underlie intervention effects. For this we have included sub-studies in the Kangaroo Mother Care trial and in the trials on treating or preventing clinical severe infection. These sub-studies are being carried out by our PhD students, thus contributing to the CISMAC objective of strengthening research capacity. Similarly the involvement of medical anthropologists and behavioural economists improves our understanding of how behavioural interventions may affect people’s preferences and norms and how these in turn may influence the effectiveness of the studied interventions.

As a key part of CISMAC’s Cooperative Governance approach, study topics are developed into proposals and study protocols under the leadership of Project Management Teams, composed of Norwegian and low- and middle-income country scientists, with support from CISMAC centrally. The proposals are reviewed by leading international experts who assess them against a set of pre-defined criteria including originality, adequacy of design, suitability of methodology, feasibility within time proposed, and potential value to the field of knowledge.

Intervention trials are time-intensive, and require a substantial level of understanding of the study population and of suitable delivery mechanisms. This implies a process of

interacting with stakeholders at various levels, and formative research to adequately tailor the intervention and its delivery to the specific setting. As part of the preparations for trials on community Kangaroo Mother Care in India and prevention of adolescent childbearing in Zambia, we conducted extensive formative research. The findings revealed important lessons about the acceptability of and adherence to the planned interventions. This information will be critical if these interventions are scaled up into national health and educational programmes.

The core competence of CISMAC in conducting randomized controlled trials has been strengthened through CISMAC-led workshops and courses, and by the recruitment of PhD and postdoctoral fellows. Since 2013, CISMAC has held three protocol development workshops that, in addition to producing strong study protocols, provide a forum for junior and senior scientists to exchange experiences. Our course on cluster-randomized trials in June 2016 attracted both junior and senior scientists wanting to further advance their understanding of this study design.

The growing number of peer-reviewed papers generated – from five in 2014 to 30 in 2016 – reflects CISMAC’s expanding scientific production. Because all CISMAC studies are still ongoing, papers focus on methodology, protocols and the results of relevant formative research. We have also published important findings from secondary analysis of earlier studies and systematic reviews on priority topics. By participating in the production of three influential series in *The Lancet*, on stillbirths (1) newborn health (2) and breastfeeding (3), we have played a part in setting the global agenda for research and programming. In addition, we have

contributed to public debate on issues within our remit, and engaged in dissemination activities such as popular science presentations and feature articles in newspapers.

In its second five-year term, CISMAC will focus on completing ongoing trials, on implementing a new set of innovative studies to address recently identified research priorities, and on establishing mechanisms to ensure that the consortium continues to carry out high quality research beyond the end of the grant in 2023.

As the first studies are now well underway and their quality is being assured through rigorous, yet supportive, monitoring mechanisms, we have engaged with new partners and other funding sources to develop several new projects, which we will initiate over the next couple of years.

CISMAC’s network will continue to evolve. We promote strong teams in diverse settings who are capable of conducting research on priority topics, ensuring excellence in implementation, and translating findings into policy and action. CISMAC fosters sustainability by expanding sources of financial support to projects, enhancing skills in critical thinking and idea generation, and strengthening research methods, data analysis and scientific writing. CISMAC aims to develop a critical mass of researchers in Norway and in each of the low and middle income country partner institutions. They will, supported by a variety of funders, collaborate with each other as sustainable Groups of Excellence beyond the end of the targeted support from the Research Council of Norway and the University of Bergen.

Bergen, 15th of February 2017



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Halvor Sommerfelt,
Director



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BETTER HEALTH FOR ALL

Better health for all is the vision of the Norwegian Institute of Public Health, NIPH; this includes contributing to better health globally.

The social mission of NIPH is to produce, summarise and communicate knowledge in order to contribute to successful public health interventions and good quality health and care services. In this way, the NIPH will contribute to better health in Norway and better health globally. In order to achieve its goals NIPH collaborates extensively with universities, other institutes, organisations and governments in Norway and internationally. NIPH is an active partner in CISMAC both through extensive research collaboration and by participation in its Board.

CISMAC is solidly based in the mainstream of Norway's research agenda, and is specifically mentioned in the 2012-2013 White paper on research (4). Further, its focus is congruent with our government's intention to "Continue and refine [Norway's] efforts in the sphere of global health, especially women's and children's health" and in agreement with its intention to "Take a leading role globally in the efforts to ensure education for all", especially of girls (5). Thus, the CISMAC study in Zambia that examines the possible health benefits of cash transfers and community dialogue to keep adolescent girls in school is an example of how CISMAC contributes to generate evidence that is central to the Norwe-

Improving the continuum of care from pregnancy, during birth and of the newborn can thus substantially reduce child mortality.

gian overseas development agenda. Furthermore, CISMAC's core scientific approach, that of randomized controlled trials, is in line with our governments dedication to "carry out systematic evaluations [of development cooperation activities] towards performance...". Finally, CISMAC's emphasis on capacity strengthening and knowledge transfer is also in line with our government's policy statement pertaining to Development.

Infectious diseases, preterm birth complications and neonatal encephalopathy due to birth asphyxia and trauma are among the ten most important causes of healthy life year loss in sub-Saharan Africa and South Asia (6). In low and middle income countries (LMICs) 45% of child deaths occur in the first month of life, almost half of these neonatal deaths occur on the day they are born. Better identification of complications in pregnancy and better birth care will not only enhance the survival of these live born babies and improve maternal health; it will also substantially cut down the number of stillbirths, currently at a staggering annual of 2.7 million and not even counted in the statistics on child mortality (6). Improving the continuum of care from pregnancy, during birth and of the newborn can thus substantially reduce child mortality

and is likely to lead to better cognitive development and growth of children. In the long term, such strategies may contribute to improving the life expectancy and general health status of the population at large.

CISMAC evaluates new or improved interventions, which, if shown to be effective, could substantially improve maternal health and newborn and child survival, health and development. The mentioned study in Zambia is an example of how CISMAC contributes to generate evidence on measures to improve the health of both women and their children. The studies in Palestine and Bangladesh on the use of electronic registries with decision support in antenatal care and around the time of delivery are likely to improve detection and prognosis of complicated pregnancies. In India, where 25% of newborns have low birth weight, the large trial on community-based Kangaroo mother care for low birth weight babies, examines a promising low-cost intervention for this vulnerable group. Overall, the centre's focus on women's and children's health gives it a central place among Norwegian efforts to contribute to increased knowledge about and possible solutions to the world's major challenges. CISMAC's close engagement with the World Health Organization (WHO) and with LMIC governments throughout the development and implementation of its studies is key to ensure translation of study results to policy and practice.

Norway has through its sustained support to the WHO played an important role in promoting maternal and child health and survival in LMICs and also provides substantial financial support to GAVI – The Vaccine Alliance, which contributes to vaccinate over 500 million infants against important infections and prevents millions of deaths. Norway is also committed to other initiatives to prevent disease and promoting health for women and children like the *Global Fund to Fight AIDS, Tuberculosis and Malaria* and the recently established *Global financing facility in support of every woman every child*. The health of women and children is also central in agenda of the Sustainable Development Goals.



The Research Council of Norway's GLOBVAC programme makes serious investments in research on maternal and child health in LMICs. As pointed out in the recently published mid-term evaluation of GLOBVAC, the program has been instrumental in the creation of CISMAC (7). It is my expectation that CISMAC, by virtue of its excellent research and capacity strengthening activities, will contribute to the sort of solid evidence that will also be required to more effectively target Norwegian overseas development cooperation, both with respect to health and education of girls.

Oslo, 25th of February, 2017

Camilla Stoltenberg, Director General,
Norwegian Institute of Public Health

CISMAC
HIGHLIGHTS

2013

2014

2015

2016

Establishment of international consortium



First CISMAC Symposium

Operationalization of CISMAC's procedures for management and study support

Agreement with CMI for support on health and behavioural economics

First meeting of SSAC

Engagement on Global priorities for New-born Health Research

Engagement on Global priorities for diarrheal diseases research

Participation in Lancet Series on improving newborn health

Formative research India (cKMC) and Zambia (RISE)



Launching of CISMAC Strategic Directions

Recruitment of participants started in Community-initiated KMC study, India



Studies funded in Bangladesh, Zambia, India, Palestine

Expansion of Outreach activities: Bergen Summer Research School, Visjon 2030 Conference, popular press (Bergens Tidende), Website, University of Bergen Strategy

Recruitment of participants started in CISMAC trials: in Zambia (RISE) and Uganda (BCG and Chlorhexidine studies)



New study funded in Pakistan

International course on Cluster Randomized Trials held in Bergen, led by Prof Allan Donner

Workshop for methods' papers preparation held in Bergen for all CISMAC trials

Courses in trials methodology and epidemiologic analysis held in Kampala and New Delhi

International Symposium on Equity research held in Boston

Participation in 2 Lancet series identifying priorities and intervention guidance on promotion of breastfeeding and prevention of stillbirths

Further expansion of outreach activities: Increased media coverage in Norway and in our partner countries, Popular Science presentation at the Christie conference 2016

SETTING THE GLOBAL RESEARCH AGENDA



CISMAC researchers have made significant contributions to setting the global research agenda for maternal, newborn and child health.

CISMAC's Scientific coordinator José C. Martines provided crucial input to the rigorous WHO process of identifying research priorities for newborn health beyond 2015, and he and CISMAC researcher Justus Hofmeyr from the University of Fort Hare participated in the analogous process of identifying research priorities for maternal and perinatal health. These two activities led to publications in three influential journals: *The Lancet* (2), *the Journal of Global Health* (8) and *Reproductive Health* (9).

In 2014 José C. Martines and Halvor Sommerfelt, CISMAC's Director, were part of an expert group convened jointly by WHO and the Bill & Melinda Gates Foundation who met in Geneva to define priorities for research on the treatment of child diarrhea. José C. Martines and Nita

Bhandari from the Society for Applied Studies co-authored a paper on the benefits and costs of promoting breastfeeding, part of the 2016 *Lancet* series on breastfeeding that also identified priorities for research (10). The significance of these initiatives is described in the Societal impact section of this report.

Also in 2016, Frederik Frøen from the Norwegian Institute of Public Health played a central role in developing the *Lancet* series "Ending Preventable Stillbirths", and authored the series' papers on stillbirth rates and on progress towards ending preventable stillbirths (1).

CISMAC involvement on the global research agenda continues. Tasked by the WHO Initiative for Vaccine Research, Victoria Nankabirwa from the University of Bergen and Makerere University and Halvor Sommerfelt ordinate the development of a generic protocol for estimating the additional non-specific effects of BCG vaccination. This protocol is intended for use in a large multi-country randomized trial to examine whether BCG given on the day of birth could enhance infant survival.



SOCIETAL IMPACT

The societal impact of CISMAC’s work extends from global to local levels. Our research activities aim to produce evidence that can be acted upon to improve maternal, neonatal and child health (MNCH). Working in collaboration with fellow scientists we aim to have a range of effects on society and social groupings, from informing advocacy and health policy decisions at global and national levels to engaging communities in improving practices. At the international level, we bring expertise to efforts that define priorities for research and programmes. At country level, CISMAC uses its presence to engage policy-makers in discussions on how best to use research-based evidence to inform the selection of priority interventions. ▶

Promoting investments in MNCH

CISMAC was involved in developing three crucial Lancet series. CISMAC’s contributions to define global research priorities for MNCH (see preceding section) include actions to promote investments in MNCH programmes and policies. The most salient was its participation in developing a set of three series published in The Lancet (Ending preventable stillbirths (6), Every newborn (11), Breastfeeding (3). All three were accompanied by strong dissemination activities, aiming to increase the exposure of policy makers and other stakeholders to the key messages. Some of those messages are:

- Substandard care contributes to 20-30% of all stillbirths.
- There are large equity gaps in stillbirth rates between richer and poorer women, in LMICs and in high-income countries alike.
- Increasing the availability of data is required to attain a coverage of interventions that will prevent stillbirths.
- Strong leadership in promoting healthy pregnancies and conditions that ensure live births is needed worldwide to reduce the risk of stillbirth.
- The last ten years have seen progress in formulating policy for newborn health but investment and large-scale implementation have been limited and need to be accelerated.
- Faster progress in improving newborn health will require better coordination of partners, actions and technical support at global and country levels, increased domestic investment and access to supplies as well as better monitoring data.
- Accountability will be required at all levels, from communities to the global level, to achieve impact on newborn health and mortality.

- Breastfeeding provides major short- and long-term health, economic and environmental advantages to children, women, and society.
- Not being breastfed may be associated with lower individual performance on intelligence tests with substantial economic losses for families and countries. Further, breastfeeding protects infants and women from common and serious illnesses and increasing its prevalence would translate substantial health care cost savings.
- Effective interventions to promote breastfeeding exist. Breastfeeding can be increased rapidly if these interventions are delivered through multiple channels.

The use of research results for improving health is paramount for CISMAC. Ensuring that scientific results contribute to formulating policy and programmes is one of CISMAC’s principal markers of success and of societal impact. Acknowledging that this process is potentially lengthy, we take deliberate actions to shorten the time from research output to programme action, thereby facilitating impact.

Communication – a powerful ally

We get policy makers on board from early on – when defining the study questions, planning the studies, and preparing to analyse and interpret study findings. In Zambia, the intervention components in the RISE project were developed in consultation with the Ministry of Education, the Ministry of Community Development, Mother and Child Health, and local stakeholders. In addition, four ministries (Education, Chiefs and Traditional Affairs, Gender, and Health) are represented on the project’s advisory board. Engaging the local community has also been important to gain support for introducing measures to empower adolescent girls to stay in school and postpone childbearing. In Uganda, the

State Minister for Public Health and other representatives from the Ministry of Health were involved in the discussions when CISMAC scientists conceptualized and planned the trial to explore possible additional benefits of BCG. The State Government of Haryana in India was engaged in conceptualizing our Kangaroo Mother Care (KMC) trial, and participated in discussions with our partner Society for Applied Studies and WHO on how coverage with KMC might be increased to make it available to over 80% of low birth weight babies. The Palestinian authorities are currently involved in supporting intervention delivery in our trial on electronic registries to improve quality of maternal and child health care.

Creating demand for research findings and engaging influential agents such as professional associations and authorities reduce obstacles to using scientific evidence for policy. We anticipate the types of questions that may arise when initiating programmatic actions. To enable us to respond adequately to them, we are collecting information on the costs, processes of implementation, implementation needs, impact on health equity and possible strategies for scale-up of interventions.

Finally, we participate in policy-making bodies and meetings at both national and global levels to take advantage of the opportunities they create for sharing and discussing our findings, understanding concerns and clarifying the interpretation of results, and enhancing our impact.

Societal impact globally and at home

In Norway, CISMAC engages with policy makers in the areas of overseas development, research and education. In the 2012-2013 White paper on research and higher education, CISMAC was specifically mentioned as an example of international research cooperation (4). In 2015, CISMAC participated in the “Visjon 2030” conference where the Norwegian ministries of Foreign Affairs, Health and Education requested innovations that could

contribute to attaining the Sustainable Development Goals (SDGs) for health and education. The conference provided the ministries with guidance for Norway’s participation in the final negotiations on the SDGs.

Globally, CISMAC works closely with WHO and supports the organization’s efforts to promote research, summarize evidence and develop guidelines for improved MNCH. This collaboration has included: the preparation of systematic reviews such as the one on

the benefits of exclusive breastfeeding and its timely initiation, participation in meetings to review the evidence behind policy recommendations for MNCH and promoting, and providing guidance on specific research efforts to address critical knowledge gaps. CISMAC also supports GAVI’s important efforts to vaccinate children in LMICs against pneumococcal disease through Halvor Sommerfelt’s contribution to the Independent Assessment Committee of its Advance Market Commitment (12). •

We get
policy makers
involved from
early on.

INTERVIEW WITH THE DEPUTY DIRECTOR OF CISMAL

Ingvild Fossgard Sandøy has always had a desire to use her education to do something meaningful and to help others. Now she leads the Zambian based project RISE, aiming to reduce teenage pregnancies.

Can empowerment of girls reduce adolescent childbearing?

“It makes an impression on you to see how, often due to poverty, girls as young as 12 to 14 years of age become pregnant and have babies, while they are still children themselves,” says Ingvild Fossgard Sandøy. She goes on to say, “In many parts of Africa it is typical that the family receives a bride-price in the form of money or cattle from the husband and his family when he marries their daughter, and many poor parents marry off their daughters at an early stage in order to supplement their family’s income.”

Ingvild Sandøy has been working in Southern Africa for many years, evaluating the effects of home-based HIV testing and other sexual and reproductive health challenges in low-income countries. She currently leads the CISMAL project “RISE - Research Initiative to Support the Empowerment of girls”, carried out with co-Principal Investigator Patrick Musonda from the University of Zambia. Working with them is an interdisciplinary team of researchers from the University of Bergen, the University of Zambia, the Chr. Michelsen Institute and the Norwegian School of Economics. In the autumn of 2015, this project was awarded a prestigious GLOBVAC grant of NOK 25 million (almost 3 mill US \$) from the Research Council of Norway.

Teenage pregnancies carry a high risk to mother and child

“Early pregnancy represents a serious health risk for both the girls themselves and the children they are carrying. Many children and young people in Zambia grow up in tough conditions and if they drop out of school, there is

a particularly high risk of them marrying or becoming pregnant at an early age” says Ingvild Sandøy. In Zambia, it is estimated that as many as 35% of girls from rural areas have given birth to at least one child by the age of 18. “When a girl becomes pregnant before she turns 18, there

When a girl becomes pregnant before she turns 18, there is a greater risk of the baby being premature or of low birth weight.

is a greater risk of the baby being premature or of low birth weight, or both. These children have an increased risk of experiencing complications, disease and even death. The girls themselves are also at an increased risk. Pregnancy and illegal abortion are the most common causes of death among adolescent girls in poor countries. In Zambia, as in many other countries, rural girls and girls who have dropped out of school are at greater risk of becoming pregnant at a young age,” Ingvild Sandøy explains. The project aims to increase the proportion of girls who complete

junior secondary school and to reduce the number of teenage pregnancies. ▶

FACTS

Ingvild Fossgard Sandøy

- Born: 1977
- PI, RISE study
- MD (2002) and PhD (2008) from University of Bergen
- Did her PhD research on HIV epidemiology in Zambia
- Is currently Professor at UiB and Deputy Director of CISMAL

Financial support to families can help keep girls in school

As part of the project, a package of support measures are being implemented to help girls remain in or return to school, and to assist those who are not able to return to school by helping them to delay becoming pregnant. One of the problems in Zambia is that the country only has a limited number of available places at secondary school level, and not everyone can be given the opportunity to attend.

“It has been shown that dropping out of school and early pregnancy are associated with poverty, so we would like to see whether it helps if girls and their parents are provided with financial support. The money can be used to cover school-related expenses or other necessary items,” Ingvild Sandøy says.

Community dialogue may create an enabling environment

The GLOBVAC financing will also enable the project to test any additional positive effects of engaging in dialogue meetings in the local communities. The dialogues are intended to start a discussion in the local community about how education, and postponement of marriage and pregnancy, may benefit girls and their future children. They will also increase knowledge about the use of contraceptive methods. Our hope is that this will promote supportive beliefs and norms that will make it possible and more attractive for girls to delay marriage and pregnancy until they are more physically and cognitively mature.

Clarifying myths and improving knowledge supports better health

Sandøy highlights that “On paper, Zambia has a comprehensive school curriculum for sexual and reproductive health, but the practical implementation is often something completely different. Teachers mostly talk about sexual abstinence. There is a lack of knowledge about modern contraception. For example, there is a wide-spread myth that you can become infertile if you use hormonal contraception before you have had children.” She goes on to clarify, “The long-term goal is, of course, to promote young girls’ health and enhance their opportunities; this will have positive ramifications for their families in the future.”

FACTS

RISE – Research Initiative to Support the Empowerment of girls

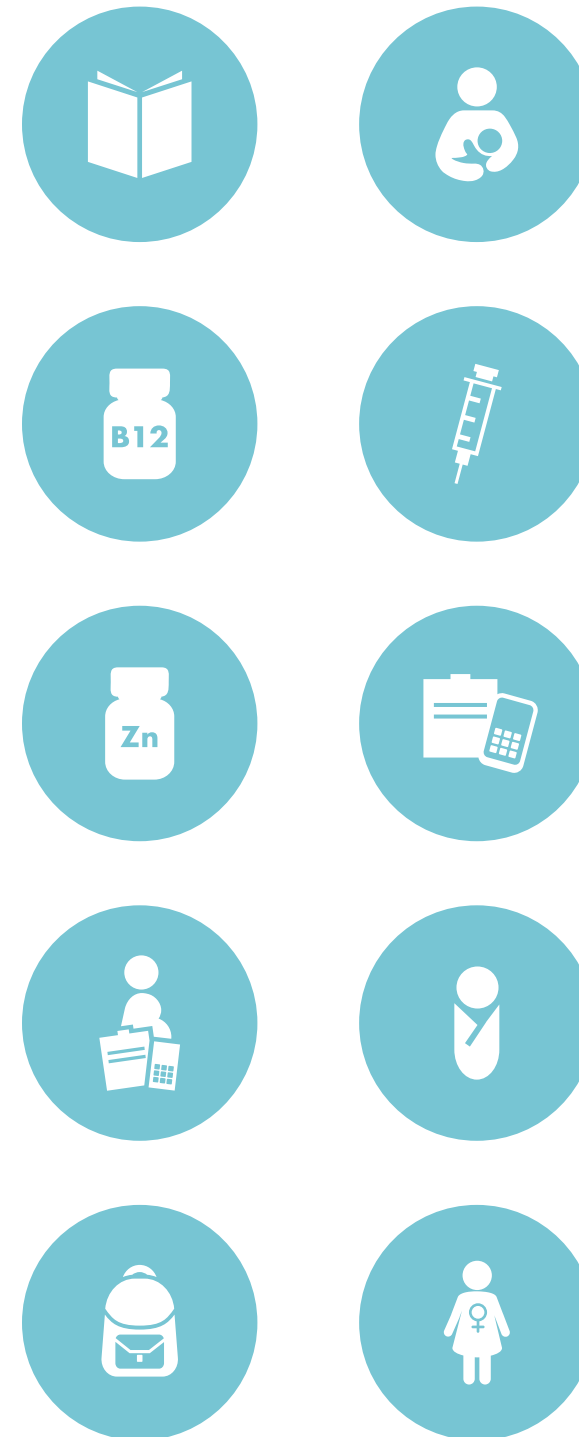
- The trial is set to last from March 2016 to December 2020
- The trial has 3 study arms: Control, economic support and combination of economic support and community dialogue
- 4900 girls of about 14 years of age participate in the trial
- The girls are enrolled in 157 schools in 12 different study districts
- The girls will be followed up for 4.5 years
- The researchers are primarily interested in the effects on the proportion of girls giving birth before age 18, and the proportion of girls who complete grade 9

Meaningful and useful research

Ingvild Sandøy has always had a desire to use her education to do something meaningful and to help others. She says, “It is incredibly exciting to learn new things, to have the opportunity to immerse myself in what I’m interested in. In one way, it is like being an eternal student. With the high quality scientific projects we carry out in CISMAC, our work can actually contribute to improved health for girls, women and children,” and emphasizes “I consider it extremely meaningful to study measures that can enhance education and improve health and opportunities in countries where people live more challenging lives than we do. The greater the challenges, the greater the potential for improvements.” •



RESEARCH GROUPS WITH RESEARCH LEADERS





RISE

Research Initiative to Support the Empowerment of girls

Adolescent pregnancies pose a risk to young mothers and their babies. In Zambia, 35% of young girls in rural areas have given birth by the age of 18. Poverty, low secondary school enrolment, myths and community norms regarding contraceptive use all contribute to early childbearing. The Research Initiative to Support the Empowerment of girls (RISE) aims to measure the effect on early childbearing rates in a rural Zambian context of (1) economic support to girls and their families, and (2) combining economic support with a community intervention to enhance knowledge about sexual and reproductive health and supportive community norms.

The trial has three arms, and the clusters are rural schools in twelve districts. The participants are girls who were enrolled in grade 7. The target sample size was 4,900 girls and 157 schools. Recruitment took place March-July and randomization was conducted in July 2016. The intervention period is from September 2016 to November 2018. In one intervention arm, girls and their guardians are offered economic support in the form of cash transfers and payment of school fees. In the second intervention arm, economic support is combined with community dialogue including youth club meetings (covering a sexual and reproductive health curriculum) and community meetings. The girls will be interviewed every six

months, with the final interview taking place 4.5 years after recruitment. We will measure to what extent the interventions increase the proportion of girls who complete grade 9 and reduce the proportion that give birth before reaching the age of 18. Of 164 schools invited to participate in the project, 157 were included and had 5,107 eligible girls of whom 4,922 assented. Thus, a very high proportion of invited schools, guardians and girls participate in our study. The findings of this trial will be highly relevant for education programmes for adolescents and for reproductive health programs in Zambia and in similar contexts.

PROJECT MANAGEMENT TEAM

PRINCIPAL INVESTIGATOR



INGVILD FOSSGARD SANDØY is a medical doctor from Norway, and her PhD was on HIV epidemiology in Zambia. She has been involved in a number of research projects on HIV and other sexually transmitted infections in Eastern and Southern Africa, including a cluster randomized trial on home-based HIV testing in rural Zambia, and an intervention study on the effects of targeting HIV prevention and condom distribution at high risk places in Zambia. She is a Professor at the Department of Global Public Health and Primary Care at the University of Bergen, and the Deputy director of CISMAC.

CO-PRINCIPAL INVESTIGATOR



PATRICK MUSONDA specializes in Medical Statistics and has been teaching and doing research at higher learning institutions, including the Institute of Child Health (London) and the University of Zambia, for 15 years. He has a PhD in Medical Statistics from the Open University (UK) and a Master of Science in Medical Statistics from the London School of Hygiene and Tropical Medicine. He has co-authored over 50 research papers published in peer-reviewed journals and published a book on statistical methodology. He has an academic interest in statistical modelling of observational data and in modelling adverse outcomes using a case series approach. Musonda is currently a postdoctoral fellow at CISMAC and the Co-Principal Investigator of RISE.

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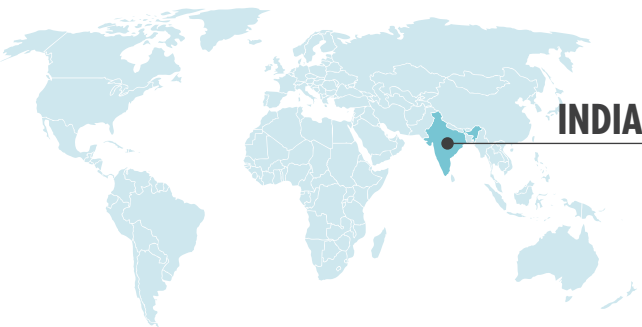
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cKMC

Impact of promoting Community initiated Kangaroo Mother Care with support for low birth weight infants in India

Babies that are born small (also called low birth weight babies), many of whom are born too early, make up nearly 80% of infant deaths. More than 75% of these deaths could be prevented even without access to intensive care. Providing low birth weight babies the necessary care in the community could make a major contribution to enhancing neonatal and early infant survival. This is particularly salient in India, where over one quarter of infants are born with low birth weight.

Most interventions to promote Kangaroo Mother Care (KMC) have been carried out in health facilities. This study, developed in collaboration with the WHO, aims to evaluate an intervention package based on the promotion of community initiated KMC (cKMC). The first completed stage designed and developed the intervention package and pilot tested it for feasibility and acceptability among mothers of low birth weight babies. The ongoing second stage is a randomized

controlled trial of 10,500 low birth weight babies in Haryana, India, which ascertains the impact of community initiated KMC on survival of low birth weight infants during the neonatal period and in the first 6 month of life. A sub study among the first 550 children also assess for psycho-motor development. Furthermore, the bond between mother and baby is evaluated, as well as rates of maternal depression. The state government of Haryana, India, is a partner in this effort.

PROJECT MANAGEMENT TEAM

PRINCIPAL INVESTIGATORS



SARMILA MAZUMDER is a community health researcher and her main research interests are child health and nutrition with a focus on changing care practices and finding optimal ways to sustainably improve child feeding practices, including micronutrient intake. She has extensive experience in evaluating mortality, hospitalization and morbidity in intervention trials and implementation research. She is involved with the design, implementation and analyses of several community-based research studies, primarily randomized controlled trials, programme evaluations and scaling-up studies. She has experience in quantitative and qualitative research methods and the use of modern software for analysis. Mazumder is currently Senior Scientist and Deputy Director at Centre for Health Research and Development at Society for Applied Studies, New Delhi, India.



SUNITA TANEJA is a community health researcher with vast experience in child health, nutrition and growth. Her research interests are child nutrition, micronutrient deficiencies and vaccine trials. She has extensive experience in design and analysis of interventions trials including individual and cluster randomized trials. She is involved in the design, implementation and coordination of community-based and regulatory trials, and she has experience in programme evaluation and scale-up of interventions as well as expertise in the coordination of data management of multicentre trials. Taneja is currently Senior Scientist and Deputy Director at Centre for Health Research and Development at Society for Applied Studies, New Delhi, India.

CO-PRINCIPAL INVESTIGATOR



HALVOR SOMMERFELT is Professor in epidemiology and global health at the University of Bergen, Director of CISMACH, and senior consultant at the Norwegian Institute of Public Health. Through international collaborative ventures with research groups in South Asia, sub-Saharan Africa, Europe and the U.S. he has participated in or coordinated front-line research aimed at improving management and prevention of important childhood illnesses and promoting childhood nutrition. Sommerfelt has (co-)authored more than 100 scientific papers, holds lectures at research institutions in Norway, elsewhere in Europe, India, South Africa, and the US, and he has organized international scientific meetings on maternal and child health and vaccination research. Sommerfelt is also member of the Independent Assessment Committee of Advance Market Commitment for vaccines.

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B₁₂ in pregnancy

Supplementation of vitamin B₁₂ in pregnancy and postpartum on growth and cognitive functioning in early childhood

Globally, vitamin B₁₂ deficiency is one of the most common micronutrient deficiencies. The only relevant source of vitamin B₁₂ is animal-source foods; in addition poor gut function may decrease absorption. Vitamin B₁₂ is crucial for normal cell division and differentiation, and necessary for the development and myelination of the central nervous system. Deficiency is also associated with impaired fetal and infant growth. In this randomized controlled trial we measure the effect of daily oral vitamin B₁₂ supplementation

to pregnant women on the neurodevelopment and growth of their children. This is an individually randomized double-blind placebo controlled trial in pregnant Nepalese women at risk of poor vitamin B₁₂ status. We will randomize 800 women in a 1:1 ratio as early as possible during pregnancy, and no later than in week 15. Enrolled women will receive 50 µg of vitamin B₁₂, or a placebo, daily until 6 months after birth.

The main outcomes of the study are neurodevelopment in children, measured at 6 and 12 months of age, and growth in children measured by weight and length at 12 months. The results of this study will inform revised dietary guidelines for South Asian women that can lead to improved pregnancy outcomes as well as improved child neurodevelopment and cognitive functioning.

PROJECT MANAGEMENT TEAM

PRINCIPAL INVESTIGATORS



SUDHA BASNET is a pediatrician with considerable clinical and research experience in child health in Nepal. Basnet has made significant contributions to the design, implementation, analyses and dissemination of two large randomized controlled trials (community based and hospital based) on zinc as adjunct treatment of pneumonia in young children. Basnet is currently a Postdoctoral fellow at the Centre for International Health/Department of Global Public Health and Primary Care, UiB and Associate Professor of Pediatrics, Tribhuvan University Institute of Medicine, Nepal.



LAXMAN PRASAD SHRESTHA is a medical doctor specializing in pediatrics with a degree from All India Institute of Medical Sciences, New Delhi. He is the principal investigator and co-principal investigator of multiple studies focusing on child health issues in Nepal, including pneumococcal vaccination, zinc supplementation, enteric infections, Hib vaccination, community newborn health and health networks. Shrestha has co-authored a wide range of research papers published in peer-reviewed journals. Shrestha is currently Professor and Head of Department of Paediatrics at Thribhuvan University Teaching Hospital, Kathmandu, Nepal.



TOR A STRAND has a longstanding research interest in immunity, infection and nutrition. His work has focused on zinc, B vitamins and vitamin D and common childhood infections such as diarrhea and pneumonia. He has undertaken clinical trials of micronutrient supplementation to prevent diarrheal and respiratory infections, as well as studies on the aetiology, natural history and risk factors of pneumonia and severe bacterial illnesses. Micronutrient deficiencies, inflammation and infections are all risk factors for poor neurodevelopment and growth in young children, and these are the focus of many of his ongoing studies. He is a research professor at Innlandet Hospital Trust, University of Bergen, and Innlandet University of Applied Sciences.

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BCG

Early versus late BCG vaccination in HIV-1 exposed infants

The Bacillus Calmette–Guérin (BCG) vaccine may have beneficial, so-called non-specific effects, i.e. it may protect babies from serious infections and death, a protection beyond its ability to protect them against tuberculosis (TB). However, most of the studies that indicate that BCG may have such additional non-specific effects are observational in nature and are fraught with controversy. This makes it difficult to ascertain from them whether the babies who get BCG are truly less prone to severe illness because they received the vaccine or because they had a lower risk of severe illness for other

reasons. Moreover, a different set of studies indicates that giving BCG later in infancy, for example at 10 weeks of age, may enhance immune responses against the vaccine and perhaps even to non-mycobacterial antigens. This may even enhance any non-specific effects of BCG. This enhanced immunity by a deferred BCG vaccine would be particularly useful among HIV-1 exposed (HE) children who show signs of impaired immunity in early infancy and in whom the appropriate timing of BCG vaccination that maximizes protection is uncertain.

This study randomizes 2,200 HE Ugandan infants to receive BCG within 24 hours of being born or at 14 weeks of age. Our main study outcomes are severe illness in the first 14 weeks of life and several immunological responses to mycobacterial and non-mycobacterial antigens. The trial is conducted in three health centers in or close to Kampala. A well-timed BCG vaccination could have important additional effects in HE infants. This study could inform the development of programmatically appropriate timing of BCG vaccination for HE infants.

PROJECT MANAGEMENT TEAM

PRINCIPAL INVESTIGATOR



VICTORIA NANKABIRWA is a senior lecturer in the Department of Epidemiology & Biostatistics, School of Public Health, Makerere University and a researcher at the Center for International Health, University of Bergen. She holds a doctorate degree (PhD) from the University of Bergen. In the past, she has worked at the Norwegian Institute of Public Health (NIPH) as a researcher, at ICAP, Columbia University, New York as an analyst, at Nsambya hospital as a medical doctor and at Mulago national referral hospital. Her research and interests lie in the fields of maternal and child health, perinatal epidemiology, vaccination, core epidemiologic methods, randomized controlled trials and implementation research.

CO-PRINCIPAL INVESTIGATOR



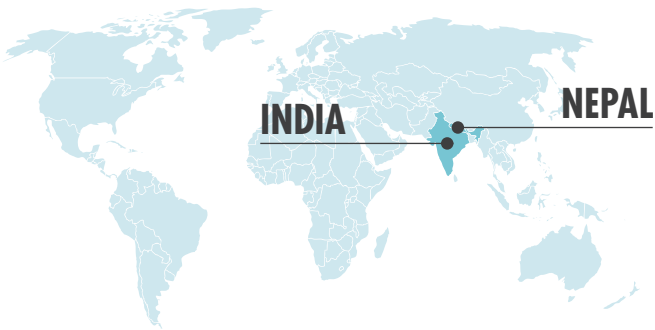
HALVOR SOMMERFELT is Professor in epidemiology and global health at the University of Bergen, Director of CISMAT, and senior consultant at the Norwegian Institute of Public Health. Through international collaborative ventures with research groups in South Asia, sub-Saharan Africa, Europe and the U.S. he has participated in or coordinated front-line research aimed at improving management and prevention of important childhood illnesses and promoting childhood nutrition. Sommerfelt has (co-)authored more than 100 scientific papers, holds lectures at research institutions in Norway, elsewhere in Europe, India, South Africa, and the US, and he has organized international scientific meetings on maternal and child health and vaccination research. Sommerfelt is also member of the Independent Assessment Committee of Advance Market Commitment for vaccines.

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Zinc-sepsis

Zinc as an adjunct for the treatment of clinical serious infection in young infants

Severe infections, including sepsis and severe pneumonia, contribute to almost one quarter of the deaths in infants up to two months of age. This is despite available – although not always accessible – antibiotic therapy, and the problem is likely to be aggravated as antibiotic resistance continues to spread. In a recent randomized controlled trial in India, which was anchored at the Translational Health Science and Technology Institute (THSTI), CISMAC researchers found that a daily dose of zinc given to infants aged 7 to 120 days under antibiotic treatment for

probable serious bacterial infection increased the success of treatment by 43%. The trial was not powered to estimate the effect of zinc on their risk of dying. With collateral funding from RCN’s GLOBVAC programme, we are now undertaking a much larger trial, this time in infants younger than two months of age, also with clinically suspected sepsis. Enrolling 4.140 children, this trial is powered to estimate the efficacy of zinc to improve survival rates when it is given in addition to antibiotics. The trial is being undertaken in three hospitals in Nepal and four hospitals in New

Delhi with CISMAC partners THSTI in India and the Institute of Medicine, Tribhuvan University in Nepal.

Being used routinely for treatment of children with diarrhoea, zinc is widely accessible; it is also very cheap. Should the adjunct zinc treatment prove to be effective in increasing the survival chances of these vulnerable babies, our study will provide important evidence for improving the treatment guidelines for sepsis, thereby contributing to enhanced survival of young infants in LMIC.

PROJECT MANAGEMENT TEAM

PRINCIPAL INVESTIGATORS



SUDHA BASNET is a pediatrician with considerable clinical and research experience in child health in Nepal. Basnet has made significant contributions to the design, implementation, analyses and dissemination of two large randomized controlled trials (community based and hospital based) on zinc as adjunct treatment of pneumonia in young children. Basnet is currently a Postdoctoral fellow at the Centre for International Health/Department of Global Public Health and Primary Care, UiB and Associate Professor of Pediatrics, Tribhuvan University Institute of Medicine, Nepal.



NITYA WADHWA is a Scientist at the Paediatric Biology Centre at the Translational Health Science and Technology Institute (THSTI), Faridabad, India. Wadhwa transitioned from a clinical career to research in 2005. In her initial five years as a clinical researcher, she was involved in implementing hypothesis-driven studies that evaluated interventions directed at commonly-occurring infections in children in India. In 2010 she joined the Paediatric Biology Centre at THSTI as a Clinical Investigator, leading a multicenter study of immune profiling in cord blood. Since then she has collaborated with the biologists at THSTI on several projects aimed at understanding the development and maturation of the neonatal and infant immune system.



TOR A STRAND has a longstanding research interest in immunity, infection and nutrition. His work has focused on zinc, B vitamins and vitamin D and common childhood infections such as diarrhea and pneumonia. He has undertaken clinical trials of micronutrient supplementation to prevent diarrheal and respiratory infections, as well as studies on the aetiology, natural history and risk factors of pneumonia and severe bacterial illnesses. Micronutrient deficiencies, inflammation and infections are all risk factors for poor neurodevelopment and growth in young children, and these are the focus of many of his ongoing studies. He is a research professor at Innlandet Hospital Trust, University of Bergen, and Innlandet University of Applied Sciences.

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eRegistry and care

eRegistries: Strengthening the extension of reproductive maternal, newborn and child health services in Bangladesh

Bangladesh has made great progress in reducing maternal and child mortality over the last decade. Still, major gaps remain in the quality of care for mothers and children, particularly in rural areas. The ICDDR,B a research institution with a 50-year history of improving the quality of maternal and child health services, is working with the Ministry of Health to expand quality improvement approaches to government-run facilities in order to demonstrate the benefits.

Electronic health registries, sometimes called eRegistries, for women and children gather information on their health, and on essential care being provided across the continuum of care from the community to the health facility. Using the opportunities of electronic communication, such tools can contribute to the quality of care, share information across the various levels of care provision, and empower women and families.

Together, 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 the collection and use of health information to benefit women's and children's health. The present study builds on this framework to be the first of its kind to assess the benefits of this type of programme in improving the quality of care in rural Bangladesh.

PROJECT MANAGEMENT TEAM

PRINCIPAL INVESTIGATOR



J. FREDERIK FRØEN is the current Head of Research and former Director of the Department of International Health as well as the head of the reproductive, maternal and child health team at the Norwegian Institute of Public Health. He was a co-founder and former chair of the International Stillbirth Alliance, as well as an executive committee member and lead author of both the Lancet Stillbirth series (2011) and the Lancet Ending Preventable Stillbirths series (2016). He is a former Fulbright visiting professor of maternal-fetal medicine at Brigham and Women's Hospital, Boston, USA and visiting lecturer in obstetrics at Harvard Medical School. He received PhDs in pediatrics and obstetrics from the University of Oslo.

CO-PRINCIPAL INVESTIGATOR



ANISUR RAHMAN is a medical doctor who obtained his PhD from Uppsala University, Sweden and has been working as Head of the Matlab Health Research Centre of International Centre for Diarrhoeal Disease Research, Bangladesh. Rahman has more than 25 years of experience as a clinician and public health researcher. His main areas of research are arsenic exposure and reproductive health, preterm and stillbirth issues, quality of care during the pregnancy, delivery and post-partum periods, and implementation research related to improving perinatal health. He leads several projects funded by the Bill & Melinda Gates Foundation, by Globvac, Norway, by Uppsala University and by USAID.

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eRegistry support

eRegistries: Electronic registries with interactive checklist and clinical decision support to improve quality of antenatal care in Palestine

Better data on health status and quality of healthcare are crucial to address bottlenecks in achieving universal health coverage and producing better policies for health. eRegistries are designed to increase the availability and timely use of routine maternal and child health (MCH) data, as data is consistently captured and the eRegistries are strategically designed to inform decision-making. They therefore enable care providers to perform interventions based on the client's actual health needs, and allow for better-informed

planning. Thus, eRegistries serve the dual purpose of patient management and public health monitoring. The Palestinian National Institute of Public Health (PNIPH)/WHO is, in close collaboration with the Ministry of Health in Palestine, currently rolling out a nationwide MCH eRegistry. The national implementation of the MCH eRegistry includes cluster randomized controlled trials led by the Norwegian Institute of Public Health, designed and monitored in collaboration with

CISMAC. The first ongoing trial will assess if the MCH eRegistry with interactive checklists and clinical decision support can improve the quality of antenatal care. The trial includes 120 health centres (clusters). The US Institute of Medicine's domains of quality of care, namely: safety, effectiveness, patient-centeredness, timeliness, efficiency and equity will be used to evaluate quality of care.

PROJECT MANAGEMENT TEAM

PRINCIPAL INVESTIGATOR



J. FREDERIK FRØEN is the current Head of Research and former Director of the Department of International Health as well as the head of the reproductive, maternal and child health team at the Norwegian Institute of Public Health. He was a co-founder and former chair of the International Stillbirth Alliance, as well as an executive committee member and lead author of both the Lancet Stillbirth series (2011) and the Lancet Ending Preventable Stillbirths series (2016). He is a former Fulbright visiting professor of maternal-fetal medicine at Brigham and Women's Hospital, Boston, USA and visiting lecturer in obstetrics at Harvard Medical School. He received PhDs in pediatrics and obstetrics from the University of Oslo.

CO-PRINCIPAL INVESTIGATOR



BUTHAINA GHANEM has more than 23 years of professional working experience in managing different health programs mainly in the areas of Public Health, Epidemiology, International Health Regulations and Reproductive Health. She worked in MOH Palestine between 1993 til 2001, then joined WHO Emergency Coordination office in Pakistan followed by WHO Afghanistan office as a public health officer. In 2003 she joined WHO Iraq as an Epidemiologist for almost ten years, before joining WHO Jordan as coordinator for the health facility assessment conducted to study the burden on Jordan health system due to the Syrian crisis. Currently Ghanem serves as team leader for the MCH e-Registry at World Health Organization office/ Palestinian National Institute of Public Health.

RESEARCHERS

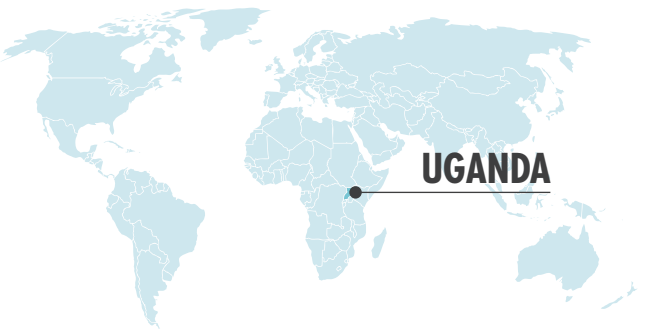
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Chlorhexidine

The use of Chlorhexidine to disinfect the umbilical cord stump to prevent newborn infections

Ninety-eight percent of the approximately 2.7 million deaths in the first 28 days of life occur in low and middle income countries (LMICs), yearly. A third of them are associated with infections and this proportion rises in areas where at least half of the births occur at home like Uganda. Infection of the umbilical cord stump (omphalitis) is a major contributor to these infections. The umbilical cord is cut after birth and the remaining cord stump generally dries and falls off within 5-15 days. Before it detaches, the stump provides dead tissue, and acts as an easy entry point for micro-organisms into the newborn. Several interventions have been recommended to combat newborn infections including full body skin cleansing with antiseptics

like chlorhexidine, hand washing with soap and water and use of clean birth kits. But the effects of these interventions on the incidence of infection and death in newborns are unclear. Of the applications that could be used to lower the risk of newborn infections and death through appropriate cord care in LMICs, chlorhexidine application shows the most promise. The World Health Organization (WHO), recognizing the importance of cord care, recommends chlorhexidine for babies born at home but not for those born at health facilities in LMICs. For these children, WHO recommends dry cord care (applying nothing to the cord but washing it with clean water when it is soiled) which is

questionable given the lack of proper evidence. Moreover, there are substantial challenges in achieving appropriate hygienic practices within facilities and children born in these facilities are quickly discharged into the same community conditions as children born at home. This trial will therefore assess the effect of a single washing of the umbilical cord stump with 4% chlorhexidine in facility settings on omphalitis and severe infections. The trial enrolls 4,760 children. Receiving the bulk of its funding from the Research Council of Norway's GLOBVAC program, it will be undertaken by researchers at the Makerere University, College of Health Sciences and the Center for International Health, University of Bergen.

PROJECT MANAGEMENT TEAM

PRINCIPAL INVESTIGATOR



VICTORIA NANKABIRWA is a senior lecturer in the Department of Epidemiology & Biostatistics, School of Public Health, Makerere University and a researcher at the Center for International Health, University of Bergen. She holds a doctorate degree (PhD) from the University of Bergen. In the past, she has worked at the Norwegian Institute of Public Health (NIPH) as a researcher, at ICAP, Columbia University, New York as an analyst, at Nsambya hospital as a medical doctor and at Mulago national referral hospital. Her research and interests lie in the fields of maternal and child health, perinatal epidemiology, vaccination, core epidemiologic methods, randomized controlled trials and implementation research.

CO-PRINCIPAL INVESTIGATOR



HALVOR SOMMERFELT is Professor in epidemiology and global health at the University of Bergen, Director of CISMACH, and senior consultant at the Norwegian Institute of Public Health. Through international collaborative ventures with research groups in South Asia, sub-Saharan Africa, Europe and the U.S. he has participated in or coordinated front-line research aimed at improving management and prevention of important childhood illnesses and promoting childhood nutrition. Sommerfelt has (co-)authored more than 100 scientific papers, holds lectures at research institutions in Norway, elsewhere in Europe, India, South Africa, and the US, and he has organized international scientific meetings on maternal and child health and vaccination research. Sommerfelt is also member of the Independent Assessment Committee of Advance Market Commitment for vaccines.

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SCALE-8

Stimulation of children and effects on learning and education at 8 years

The SCALE-8 study seeks to assess the impact of exposure to early responsive stimulation and nutrition interventions and their effect on learning, behaviour and growth later in life.

More than 250 million children living in low- and middle-income countries (LMICs) are not achieving their full development potential due to biological, psychosocial and environmental risks. These risks include inadequate stimulation, malnutrition, infectious illnesses, maternal depression and so-

cietal violence. The current study is a follow up to a previous project that assessed the effectiveness, feasibility and cost of integrated early stimulation and nutrition interventions in a government community-based health service. The initial study reported a significant impact on children's development at age 2 years (36). There is evidence that these gains were sustained at age 4 years although with smaller impact. On the other hand there is very limited evidence of the enduring effects on later life outcomes in LMICs.

The current study will re-enroll children in 80 population clusters at age 8 years to determine which beneficial effects on learning, behaviour and growth have endured to school age. These data will provide insights on whether there are any sustained benefits and whether any particular sub-group of children have benefited more or less from the exposure to early interventions. The data will also identify risks and protective factors that influence outcomes to inform the development of interventions.

PROJECT MANAGEMENT TEAM

PRINCIPAL INVESTIGATOR



MUNEERA A RASHEED is a clinical psychologist working with children with developmental and behavioural difficulties in Pakistan. Her research portfolio includes seven years of community-based research experience in the development, implementation and evaluation of interventions to promote children's early development in disadvantaged communities. Rasheed has also gained extensive experience in building capacity, and has trained more than 100 community-based child development assessors in six different countries: Armenia, Bosnia and Herzegovina, Pakistan, Rwanda and the United Republic of Tanzania. She is currently Senior Instructor at the Department of Paediatrics and Child Health, Aga Khan University, Karachi while simultaneously undertaking PhD studies at the University of Bergen, Norway.

CO-PRINCIPAL INVESTIGATOR



AISHA K YOUSAFZAI has extensive experience in evaluating early childhood interventions in low- and middle-income countries. She is currently the PI of a randomized controlled trial in Pakistan investigating the impacts of community youth leaders delivering early childhood care and learning interventions on a host of early childhood and community outcomes. Yousafzai serves on a number of international early childhood development committees including the Technical Advisory Group for the UNICEF Central and Eastern Europe/Commonwealth of Independent States Regional Office and the Advisory Group for the Early Learning Program of the World Bank. Yousafzai is an associate Professor of Global Health at the Department of Global Health and Population, Harvard T.H. Chan School of Public Health in Boston, USA.

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SAFEZT

Competing discourses impacting girls’ and women’s rights: Safe Abortion and Fertility control in Ethiopia, Zambia and Tanzania

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. Fertility control and safe abortion exemplify the controversies over sexual and reproductive health policies and the gendered socio-cultural and religious norms affecting girls’ and women’s rights. The dynamics between the law, policies and access to fertility control and safe abortion services differ between Ethiopia, Zambia and Tanzania. Although all three countries have ratified the major international

and regional conventions and protocols on the rights of women, including the Maputo Protocol on the Rights of Women in Africa, the laws regulating access to safe abortion services reflect differing legal histories. For example, judicially, abortion is legal in Zambia but illegal in Ethiopia and Tanzania. In practice, however, Ethiopia is the most liberal of the three countries in terms of legal provision of safe abortion services, and the case of Zambia shows that a liberal abortion law is not a sufficient condition to secure access to legal abortion. Hence, the association between the status of the law and access to safe abortion continues to be unclear, and

is a central question for comparison in this research project. Concretely, the project aims to generate comparative knowledge of the interplay between policy, legislation and socio-cultural conditions framing girls’ and women’s reproductive choices. Furthermore, it aims to explore adolescent girls’ struggles and agency to handle their fertility within the given legal, socio-economic and religious frames, and finally to examine men’s involvement in the reproductive arena with particular emphasis on the power dynamics between men and women pertaining to fertility control and abortion.

PROJECT MANAGEMENT TEAM

PRINCIPAL INVESTIGATOR



ASTRID BLYSTAD is professor in medical anthropology at the University of Bergen (UiB), Norway. Her research interests are in reproductive health with an empirical focus on adolescent sexual and reproductive health, childbirth and infant feeding practices, HIV, mother to child transmission of HIV, female genital cutting and pelvic floor disorders. Her work arises from more than 25 years of research in East Africa. Methodologically her research is grounded in the ethnographic tradition, and in recent years has evolved to combine this with other qualitative and quantitative methods (mixed methods designs). Her theoretical interests are located within socio-cultural theory, social constructivism, critical theory, gender theory, phenomenology and institutional ethnography. Blystad is principal investigator of several externally funded multidisciplinary research projects.

CO-PRINCIPAL INVESTIGATOR



GETNET TADELE is Associate Professor of medical sociology/anthropology at Addis Ababa University with more than two decades of research experience on child rights, adolescent health, sexual and reproductive health including HIV/AIDS, podoconiosis and aspirations of rural youth. His publications include numerous articles in prestigious journals and a number of chapters in internationally-published books. He has received a fellowships, academic grants and visiting professorships, and has taught and/or researched in Nigeria, Senegal, Netherlands, UK, US, Australia, New Zealand and Norway. He is a winner of Addis Ababa University’s 2015/16 “Distinguished Research Award”. He also received the 2016 People to People’s Community/Social service recognition award for his contribution to community development.

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STUDY PLANS
AND PROGRESS

TITLE IN ANNUAL REPORT	2013		2014				2015				2016				2017				2018				2019				2020				2021				2022				2023		
	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3
RISE: Research Initiative to Support the Empowerment of girls																																									
cKMC: Impact of promoting Community initiated Kangaroo Mother Care (cKMC) with support for low birth weight infants in India																																									
B12 in pregnancy: Supplementation of vitamin B12 in pregnancy and postpartum on growth and cognitive functioning in early childhood																																									
BCG: Early versus late BCG vaccination in HIV-1 exposed infants																																									
Zinc-sepsis: Zinc as an adjunct for the treatment of clinical serious infection in young infants																																									
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eRegistry and care: eRegistries: Strengthening the extension of reproductive maternal, newborn and child health (RMNCH) services in Bangladesh																																									
Chlorhexidine: The use of Chlorhexidine to disinfect the umbilical cord stump to prevent newborn infections																																									
SCALE-8: Stimulation of children and effects on learning and education at 8 years																																									
SAFEZT: Competing discourses impacting girls’ and women’s rights: Safe Abortion and Fertility control in Ethiopia, Zambia and Tanzania																																									

Development and finalization of protocol, Standard Operating Procedures, questionnaires, interview guides and other measurement instruments, ethical approvals, government permissions, consultation with and orientation of stakeholders, piloting, formative research, training study staff

Recruitment of participants, randomization, administration of interventions, follow-up or qualitative fieldwork

Analysis of data, main paper writing, dissemination

CISMAC RESEARCH

IMPROVING THE QUALITY OF HEALTH CARE SERVICES TO PREGNANT WOMEN

A health system's ability to respond and to monitor progress and accountability demands the active use of timely population-based individual level data. The current information flow based on aggregate reporting and sporadic surveys is often insufficient. The innovative system of eRegistries for maternal and child health (MCH) responds to these information needs.

The Sustainable Development Goals (SDGs) and the UN Secretary-General's Global Strategy for Women's, Children's and Adolescents' Health (2016-2030) have moved the focus beyond measuring simple counts of care contacts and mortality rates, to embrace a life course approach of universal access and universal health care coverage. This approach requires increased attention to both the continuity and the quality of care.

The health information ecosystem of eRegistries represents more than merely a technology change from aggregate to individual level data. It constitutes a shift in how health care providers simultaneously collect, report and use data. The introduction of eRegistries transforms health systems' typical separation of documenting health information for clinical care and the tardy and burdensome reporting of data into one single integrated and interactive data entry for all purposes at the point and time of care.

Global public goods building on global evidence-based recommendations

The generic eRegistries builds on WHO's recommended Essential Interventions, Commodities and Guidelines for Reproductive, Maternal, Newborn and Child Health (13). It is part of a framework developed by the NIPH, WHO, and partners, laying out the core components of eRegistries

for health priorities, health and health care provision indicators, functionalities, technologies, and ethical and privacy issues – adhering to the established global “Principles for Digital Development”. Implementation requires adaptation to local guidelines and interventions to fully match the needs of the users. The eRegistries build on open source systems supporting both stationary and mobile solutions, online as well as offline, incrementally developing global common goods where improvements made for a single setting facilitate implementation for others.

Interactive checklist and clinical decision support to care providers

Client information, entered at the point of care through an online system, creates a real-time registry of individuals. It becomes an eRegistry when this information is used interactively, both during and after client-provider interactions. The front line care providers are assisted with evidence-based guidelines, interactive checklists, and clinical decision support which respond immediately to the entered client information. If a care provider, for example, records that a pregnant woman has a low hemoglobin value (<12 g/dL), the MCH eRegistry will present the appropriate management plan (iron supplement and a new blood test after a fixed time interval). Easily modified and updated centrally, the eRegistry supports training and task shifting in emergencies or for implementing new guidelines for care. ▶

The eRegistry also enables electronic patient scheduling and priority-setting, follow-up, referrals and discharge notes between and across providers, as real-time information is available to different levels of the health care system. It eliminates time-consuming reporting, and generates aggregate statistics for supervisors and decision makers. Additional uses of information in the eRegistry can include automated performance feedback to health care providers and their supervisors, plus SMS-based appointment and care reminders and personalized health information for the client based on individual conditions and risks.

Similar studies in dissimilar settings

Electronic health information programmes have usually been investigated with weak study designs, and often involve only one vertical health information intervention, creating disruption in the information flow. More evidence is needed to support the implementation of eRegistries with decision support. As a response, two population-scaled cluster randomized controlled trials (cRCT) are being conducted by CISMAC partners in Palestine and Bangladesh. The studies will assess the effectiveness of an MCH eRegistry in improving the quality of care provided to pregnant women.

The cRCT in Palestine is embedded in the nationwide implementation of the MCH eRegistry, using the District Health Information System (DHIS2). It includes 120 clusters (primary health care clinics providing antenatal care), each enrolling a mean of 60 new pregnancies per year. The trial compares interactive checklists and clinical decision support within the MCH eRegistry with paper-based case notes. Adverse pregnancy outcomes and timely and appropriate screening and management of pregnancy complications are being examined.

It is unique to assess the effect of any electronic health information system, such as the MCH eRegistry, in such dissimilar large scale settings simultaneously.

The cRCT in Bangladesh, which is in its final stages of pre-implementation preparation, will be conducted in the rural Matlab sub-districts with a population of nearly 88,000 married women of reproductive age. The Bangladesh MCH eRegistry, using a DHIS2 android application, will be available to all front line health care workers providing antenatal, childbirth and postnatal care. The MCH eRegistry, including interactive checklists and clinical decision support, as well as information dissemination strategies such as SMS-messaging and performance feedback will be compared to a 'silent electronic registry' that has no interactive functionalities.

It is unique to assess the effect of any electronic health information system, such as the MCH eRegistry, in such dissimilar large scale settings simultaneously. Palestine has a relatively developed health care system where ultrasound examinations during pregnancy and advanced interventions are available, and the majority of women deliver in health care facilities. Bangladesh, on the other hand, has a high proportion of home deliveries, and the majority of health care providers

are capable of performing only a minimum of WHO's recommended essential interventions.

Individually and together, these two large studies aim to demonstrate the capacity of an MCH eRegistry to alter the existing patterns of quality of care provided during pregnancy, childbirth and beyond. They will develop the high-quality evidence needed to inform public health practitioners, researchers and governments as they collectively work towards achieving universal health coverage and meet the SDGs. •



ELECTRONIC REGISTRIES TO IMPROVE MATERNAL AND CHILD HEALTHCARE IN PALESTINE

Antenatal care provides a platform for important health care functions, including health promotion, screening and diagnosis, and disease prevention. The eRegistries Initiative is dedicated to increasing the availability and timely use of routine maternal and child health data. Each specific eRegistry should be customized to fit the local context and needs.

The following interview with Mahima Venkateswaran describes an ongoing experience in Palestine of design and implementation of an MCH electronic registry and the comparison of its use to that of the existing paper-based system.

What are the main goals of the study?

We are working to improve quality of care for women during pregnancy, childbirth and the post-partum period.

What are the potential findings of this study?

Quality care must be timely and appropriate, but both of these features are hard to measure. Our new interactive and electronic registry allows us to do just that, by tracking a woman from early pregnancy to after childbirth. With this register we can see when she has been screened for different conditions by a health worker. We will measure health outcomes of the women enrolled in the study, and compare the proportion in the intervention and control groups who enter labor with an unidentified risk. The women in the intervention group will have been followed up during pregnancy in a health clinic that uses the interactive electronic registry. The women in the control group are followed up during pregnancy in a health clinic using the standard paper based system. By the end of the year we will have a registry for all the pregnancies in the study area, and for the first time we will be able to compare the information recorded through the electronic and paper-based systems. This will tell us the effects of having an electronic system with its different functionalities.

What is the time frame of this study?

The implementation phase of this study is 16 months, with eight months each for recruitment, which started recently, and for follow-up of participants.

How was the study set up?

The intervention that we are testing in this study grew out of an initiative from Palestinian and Norwegian stakeholders. In 2014-2015, a series of meetings were held with medical doctors, midwives, the Palestinian Ministry of Health and health clinic staff, who discussed the guidelines for antenatal, postnatal and newborn care and made suggestions ▶

FACTS

Mahima Venkateswaran

- Born: 1986
- From: Chennai, India
- Study coordinator, eRegQual Study
- Educational Background: Medicine- PSG Institute of Medical Sciences and Research, The Tamil Nadu Dr MGR Medical University, MSc (Global Health) - Maastricht University, the Netherlands



for updates and improvements. Once the revised guidelines were approved, the study team translated them into algorithms, indicators and interactive checklists that were built into the electronic registry that care providers in primary healthcare clinics are now using. This process took longer than expected and was important to ensure the relevance of the study.

It was important that the indicators and checklists were coded into the system in a way that made it understandable and easy to use for the health care workers. A series of user evaluations, including pilot testing in five health clinics, gave us the feedback needed to improve the software. Today we have a process for receiving and addressing continuous feedback from the health care workers that use it.

How is the study organized?

When the software was rolled out, our colleagues in Palestine trained 340 care providers from all 67 study clinics plus health care providers in the referral clinics and representatives from the Ministry of Health. Two field implementers provide technical support to the health care workers using the electronic registry. Dedicated Ministry of Health staff provide assistance regarding computers and internet connectivity. Four trained midwives are entering the data from the paper files in the control group health clinics into our database, while the electronic registry does so automatically. Anonymization contributes to secure handling of confidential data.

What are some of the challenges of setting up this study? Any specific challenges due to the location and context of this study?

Logistics is quite challenging. The distances between the clinics are not very far, but it can take two hours to travel 20 km due to check points and other obstacles. Many of our necessary tasks take longer than expected.

We have focused on strengthening capacity and encouraging ownership in Palestine, so that the Palestinian National

Institute of Public Health (PNIPH) will be able to use and maintain the electronic registry after the study is finished. Sometimes this means that processes take longer, but it is still important to us. Today the PNIPH has complete control of the software, how to design and deploy it and how to define who can access what data. All registry-related activities are also managed in accordance with detailed Standard Operating Procedures.

What has been the most challenging part of setting up this study?

Getting all the infrastructure in place has been difficult. The intervention requires all health clinics to have computers and internet. We had originally planned to use tablets with 3G to access the electronic registry, but this was impossible since 3G coverage in Palestine is blocked. This meant we had to ensure that internet cables were rolled out to the health clinics.

We also needed to map out the entire health system. Knowing the number of clinics in the study area was not enough, we needed to have better information on the number of pregnancies per year, how the referral system works, and how many women

give birth in public hospitals, in NGO clinics and in private hospitals. Right now the team in Palestine is compiling data from 2015 on birth outcomes from a number of clinics to give us a baseline to compare with.

What has been the most rewarding part of setting up this study?

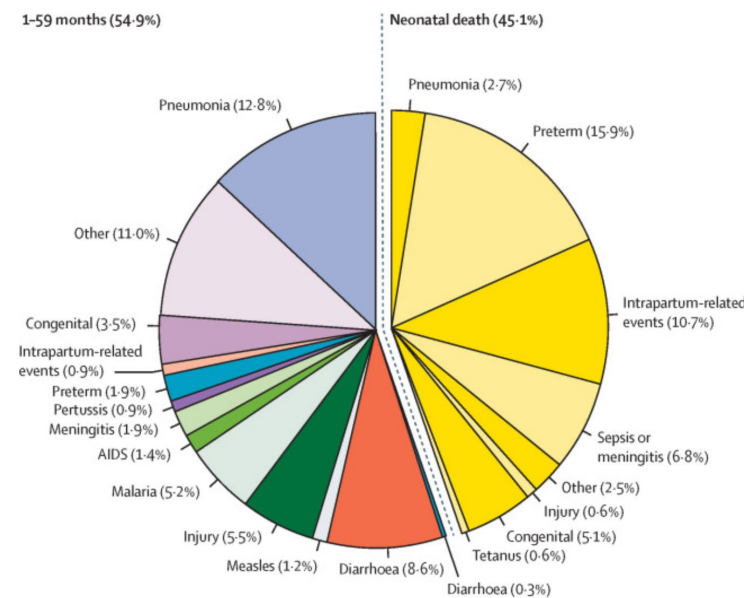
The logistical challenges we faced in setting up the study are the same faced by women giving birth in Palestine. Many times they don't reach the clinics because they have to pass through checkpoints or other barriers. What I like about this study is that although these challenges are difficult and severely complicates our work, we choose to acknowledge them and focus on how we can optimize the services and our research despite the very difficult context. •

PREVENTING AND TREATING SEVERE INFECTIONS IN INFANCY – ENHANCING CHILD SURVIVAL



Nearly half of children who die before they reach 5 years of age succumb within the first month of life (15). This means an estimated 2.7 million newborn deaths every year, 98% of which are in low- and middle-income countries.

Most newborn and child deaths occur in Africa and South Asia, and a disproportionate number occur among those who are born small. Severe infections, including sepsis and severe pneumonia, contribute to almost one quarter of the deaths in infants up to two months of age. This is despite effective – but often not accessible – antibiotic therapy, and mortality due to severe infections is likely to be aggravated as antibiotic resistance continues to spread. There is a need to develop better interventions to prevent infections and to improve treatment strategies. CISMAC is engaged in very ambitious randomized controlled trials with excellent research teams in India, Nepal and Uganda to explore effective means of preventing and treating these infections. ▶



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Zinc in the treatment of severe infection

In a recent randomized controlled trial in three tertiary hospitals in New Delhi, CISMAC researchers found that for infants aged 7 to 120 days under antibiotic treatment for probable serious bacterial infection, a daily dose of zinc increased the success of treatment by 43% (16). This study was the first to report on the efficacy of zinc in the treatment of probable serious bacterial infection in infants. Interestingly, the babies experienced a similar relative reduction in the risk of dying, but the study was too small for us to be confident about the efficacy estimate for case fatality.

Policies and guidelines are most strongly influenced by evidence of improved survival. To estimate the degree to which adjunct zinc therapy may increase the chance of surviving, CISMAC works with the Institute of Medicine at Tribhuvan University, the Translational Health Science and Technology Institute and the Innlandet Hospital Trust to undertake a very large randomized clinical trial in seven hospitals in India and Nepal. Pooling resources with the Research Council of Norway’s GLOBVAC programme, more than 4,000 young infants admitted with clinical severe infection (a diagnosis very similar to that of probable serious bacterial infection) are being randomized to receive either zinc or placebo in addition to antibiotics. If the findings are similar to what we found in the previous smaller trial in India, we will provide critical evidence towards revising treatment recommendations for low-resource settings

in South Asia and elsewhere. This would improve infant survival and may also contribute to limit the spread of antibiotic resistance.

Kangaroo Mother Care initiated at home

Babies that are born small (also called low birth weight babies), many of whom are born too early, make up a disproportionate number of infant deaths. Worldwide, approximately 15% of babies are of low birth weight, while in India this reaches nearly 25%. These babies carry a substantially increased risk of breathing problems, hypothermia and severe infections. It has been shown in hospital settings that if a mother keeps such a vulnerable baby in skin-to-skin contact between her breasts for several hours every day and feeds her or him nothing but breastmilk, the baby has a much better chance of surviving.

In addition to meeting the need for warmth, this practice of Kangaroo Mother Care may also protect the small baby from infection. In CISMAC’s very large trial of 10,500 low birth weight babies in India, the team at the Society for Applied Studies explores the extent to which this intervention can enhance survival when instituted in the home (17). In addition, a CISMAC PhD student will use this opportunity to explore whether Kangaroo Mother Care reduces the risk of clinical severe infection, and whether

any such reduced risk could be explained by changes in the volume or composition of breast milk.

Protective effects of BCG vaccination

Although the HIV-1 incidence is on the decline in many sub-Saharan African countries, including Uganda, the prevalence of HIV-1 infection among adults is more stable or on the rise due to reduced HIV-related mortality. Those babies born to mothers who are infected with the virus are referred to as HIV-1-exposed and, even if not infected with the virus themselves, are at an increased risk of common illnesses such as sepsis, pneumonia and diarrhea. These illnesses also tend to be more severe in HIV-1 exposed babies. Studies in West Africa indicate that the BCG vaccine, when given in infancy, may do more than protect against childhood tuberculosis. However, the available literature on the additional so called non-specific effects is mostly from observational studies, and is fraught with controversy, including criticism of methodological weaknesses and geographic limitations. CISMAC scientists previously undertook a cohort study in Uganda showing substantially lower mortality among children 1 month to 5 years of age who received BCG compared to those who did not (18). Because it is possible that health personnel withheld BCG from neonates who were sick, they chose to exclude the findings in babies 4 weeks or younger. In fact, they found that unvaccinated neonates were more likely to die than those who had received BCG (unpublished data), again similar to the findings of the West Africa studies. However, because of the above-mentioned possibility of reverse causality and because observational studies may for other reasons yield confounded measures of association, we argue that the question of whether BCG offers such additional effects could only be addressed by randomized controlled trials. We share this view with WHO, a view which is in line with a recent literature review (19). It is well established that BCG can induce modulation of the immune system; it is, for example, used to treat bladder cancer, and there are studies showing that in HIV-1-exposed as well as -unexposed babies, BCG may modify immune responsiveness to non-mycobacterial antigens as well. Our ongoing trial of 2,200 HIV-1-exposed babies in Uganda explores whether giving BCG on the day of birth rather than at 14 weeks of age leads to a reduced risk of severe illness (20).

The CISMAC scientists responsible for this study have been tasked by the WHO department of Immunization, Vaccines and Biologicals to coordinate the development

of a generic protocol for a much larger multi-site trial to estimate additional effects that BCG may have in reducing the risk of infant death. These studies will also provide an opportunity for advanced immunological research to elucidate the immunobiological mechanisms behind any clinical effects.

Preventing infections with chlorhexidine

Interventions recommended during or shortly after delivery to prevent serious infections in newborns include hand-washing with soap and water by birth attendants, use of clean birth kits, and full body skin cleansing of babies with antiseptics such as chlorhexidine. But the effects of these interventions on the risk of serious infection and death in neonates have varied, and two systematic reviews did not arrive at firm conclusions. Because an infected umbilical cord stump may progress to become a severe and generalized infection, it would seem logical that cleaning the stump with an antiseptic would reduce the risk of severe illness. WHO now recommends that in areas with high neonatal mortality, chlorhexidine be applied to the umbilical cord stump of babies born at home. The evidence for such a strategy rests primarily on findings from trials in Asia and has recently been put into question because two very large randomized trials in Zambia and Zanzibar failed to show any increase in neonatal survival(21, 22).

For babies born in health facilities, dry cord care is recommended, as there is not enough evidence to decide that antiseptic treatment in health facilities reduces the risk of clinical severe infection and enhances neonatal survival. Again with collateral funding from the GLOBVAC program, the School of Public Health at Makerere University works with CISMAC to undertake a trial estimating the efficacy of a single chlorhexidine application to the umbilical cord stump on the risk of severe illness in babies born in three health centres in and close to Kampala (23).

Summing up, sepsis (diagnosed clinically as probable serious bacterial infection, clinical severe infection or severe illness), is one of the main killers of young infants. In addition to providing an abundance of solid data, these CISMAC trials will make important contributions to the evidence required to inform policies and guidelines and ultimately improve infant health and survival. •

PROMOTING CHILD DEVELOPMENT

The SCALE-8 project in Pakistan examines the impact of early nutrition and stimulation interventions on school-age children.

SCALE-8 is a longitudinal study that looks at how early stimulation of children in rural Pakistan may affect their development, learning and behaviour when they reach 8 years of age. It is a longitudinal follow up study of a cohort of children who were enrolled in an early stimulation and nutrition intervention trial in the first 2 years of life.

“The early stimulation intervention had significant benefits on children’s cognitive, language and motor development at 2 years of age. In SCALE-8, we would like to learn whether the exposure to these early interventions has had any benefits to child development, learning and behaviour at age 8 years. “We want to investigate what factors contribute

to any sustained impacts of early interventions, as well as factors that might mitigate the earlier benefits to children’s development”, says Muneera A. Rasheed, PI of the project.

Protect children against developmental risks

More than 250 million children living in low- and middle-income countries are unable to achieve their development potential due to biological, psychosocial and environmental threats. These include inadequate stimulation, malnutrition, infectious diseases, maternal depression and societal violence.



Data collector following up participant in the STAR-project, a predecessor to the CISMAC Scale-8 study.

“These threats are particularly harmful in the first 2 to 3 years of life, when the brain is developing rapidly and establishing pathways for healthy sensory-motor, cognitive-language and social-emotional development,” says Aisha K. Yousafzai, co-PI of SCALE-8. “We can protect children against these threats and support their healthy development by providing interventions to improve health, nutrition and stimulation in these early years.”

A unique opportunity

In the last 30 years, a consistent body of evidence has demonstrated the effectiveness of early stimulation interventions on children’s early cognition. Only one study from a low- and middle-income country, Jamaica, followed an early stimulation intervention cohort into adulthood. SCALE-8

provides an important opportunity to add to the evidence of the effect of early interventions later in childhood.

“It is critical to gain better understanding of impact of early stimulation interventions on the life course for children growing up in highly impoverished settings and to identify how to strengthen early interventions or provide booster interventions at other strategic points in the child’s life,” says Rasheed.

“Given the growth of evidence on brain and behaviour development, there is an opportunity to identify constructs that can help us understand child development more comprehensively and its potential impact on adult health, learning and behaviour”, Yousafzai adds.

UPDATES FROM THE FIELD

Sandra Nublime has always had a special interest in caring for newborns and their mothers. Now she is working as a study nurse on CISMAC's BCG study in Uganda.

Please tell us a little about yourself

I am a registered nurse with a three-year diploma in nursing. I have always had a special interest in caring for newborns and their mothers.

Why did you apply for the job as a research nurse in the BCG -study?

Before starting to work here, I was a research assistant on a small project. I liked that a lot, and I got interested in working with research. In that project, we collected data by looking at patient files. In this job, I get to be part of a project where I also can interact with the participants. Here I get to combine my interest in research work with face-to-face interaction.

Please describe your activities during a normal day in the study clinic

The mothers we recruit for this study are HIV positive and recruited through cooperation with the elimination-of-mother-to-child-transmission (EMTCT) clinic. After the recruitment interview, we do not see the mother again until she comes to give birth at the maternity ward in the Mukono Health Centre next door. On a normal day, when we get to the clinic we check whether a recruited mother gave birth during the night. We have to check right away, because normally the baby gets the BCG vaccine right after birth, and we are testing when it is best to give it, on the day of birth or later on. We advise the mother to come to our study clinic next door for the first interview. After checking for mothers in the ward, we calibrate the scales for weighing the babies. Then we look through the list of participants who will come for follow-up during the day.

Our participants are used to coming early in the morning, so the mornings are quite busy. They come back for follow-up visits with their babies 9 times during the baby's first year of life.

In addition to the follow-up visits, we often have recruitment visits. We know that the EMTCT clinic sees new patients on Tuesdays, Wednesdays and Fridays, so on these days they may send us a mother. Some days we can get as many as eight expecting mothers for recruitment.

We are always two nurses at work. It would be very difficult to do this work alone. It is also nice to feel that I am part of

a larger team. Once a week we get a report from the study coordinator. She gives us feedback on our work from the previous week. This helps us to improve and to keep up the quality of our work.

What do you do to ensure that the mothers bring their babies to the follow up visits?

If a mother has not come by two o'clock on the day her visit is scheduled, we give her a call to confirm. Maybe she just forgot or maybe she has a problem that makes it difficult for her to come. Most of our participants call us in advance if they cannot come as expected. If the mother doesn't come, and we can't get hold of her on the phone, we send a tracer to go to her house and look for her to see if something is wrong. Almost all of our participants come to the follow-up visits. They know that coming to us is good for their baby.

What is the most rewarding part of working at the clinic?

For me there is a feeling of attachment with the mothers. They come to see us many times and we build trust with them. We listen to what they have to say, and sometimes we are able to help just by listening to them. That is very rewarding.

FACTS

Sandra Nablime

- Born: 1990
- From: Kampala, Uganda
- Nurse in the study: Early versus late BCG vaccination in HIV-1 exposed infants
- Educational Background: Registered nurse with diploma in nursing. Finished nursing education in 2012.



A photograph of a family of four in a rural setting. A woman in a pink sari and headscarf holds a young girl in a red shirt. A man in a light blue shirt holds a young boy in a light blue shirt. They are standing in front of a structure made of mud and wood, with a black tarp covering the roof. The background is slightly blurred, showing more of the structure and some foliage.

SOCIAL SCIENCE IN HEALTH RESEARCH ›

CISMAC does not only aim to develop and test the delivery of interventions to improve maternal, neonatal and child health (MNCH), but also engages in research to generate knowledge about socio-cultural contexts within which MNCH problems arise.

This is crucial, both for understanding the socio-economic roots of a problem, developing future interventions tailored to specific contexts, and for possible scale-up of an intervention. By carrying out studies using explorative qualitative methods and informed by social science theory, CISMAC aims to identify and understand risk factors that may be modified to foster MNCH.

Qualitative formative studies in randomized controlled trials

Qualitative research and social science perspectives are vital in the planning of complex health interventions where the aim is to alter social practices. CISMAC's RISE study examines whether economic support and community dialogue can affect the age of first birth for Zambian girls. The intervention was developed after two phases of comprehensive formative research, conducted to generate in-depth knowledge of complex local contexts. The first phase served to inform the choice of intervention and the second to assess the acceptability of the suggested intervention components. The community initiated Kangaroo Mother Care study (cKMC) is another example of an intervention aiming to change a social practice, in this case related to newborn care in

India. The formative research undertaken in this study found that a joint family system where the extended family live together, and the practice of seclusion and bed rest for mother and baby in the post-partum period, facilitated the practice of cKMC.

Socio-political determinants of health

SAFEZT ("Competing discourses impacting girls' and women's rights: Safe Abortion and Fertility control in Ethiopia, Zambia and Tanzania") is the most recent study to be included in CISMAC. This study aims to explore policies, legislation and the socio-cultural conditions that surround, interact with and affect attitudes and access to fertility control and safe abortion for women and girls. Through a comparative analysis, this study aims to identify possible risk factors for unsafe abortions, with a particular focus on exploring the articulations between women's access to fertility control and safe abortions, and the three countries' legislation. While Ethiopia and Tanzania have laws prohibiting induced abortion, Zambian law allows induced abortion on many grounds. Nevertheless, in terms of provision of legal and safe abortion services, it is Ethiopia that

is the most liberal of these three countries while in Zambia access to safe abortion is very difficult. The SAFEZT team explores what other factors than legislation plays important roles in affecting attitudes towards and access to safe abortions.

The SAFEZT study highlights how health challenges cannot be understood in isolation from the context within which they exist. The health status and challenges of a population are heavily influenced by multiple factors such as history, economics and politics. If the aim is to find and suggest measures that may improve the health status of a given part of the population, context-

tual factors need to be understood and taken into consideration.

By employing social science theories and qualitative methods CISMAC projects such as SAFEZT aim to shed light on these complex and challenging issues. For SAFEZT this includes understanding what shapes individual decision making in relation to reproductive health, and how new interventions to improve maternal and child health may need to be adapted to specific contexts. The findings from SAFEZT may also serve to inform future studies on interventions that can reduce the number of unsafe abortions. •



Principal Investigator Victoria Nankabirwa and CISMAC Director Halvor Sommerfelt.

RESEARCH COLLABORATION AND INTERNATIONAL COLLABORATION

The mission of CISMAC is to create and support a sustainable global network of institutions and individuals who carry out high-quality research, aiming to develop and test the delivery of interventions to improve MNCH in low- and middle-income countries (LMICs).

As asserted in our strategy (24), CISMAC uses its network – that spans institutions in Norway and in LMICs, plus members of the international scientific community – to enhance the quantity and quality of evidence on interventions that MNCH and that reduce inequities in LMICs, by:

- conducting and supporting cutting-edge research
- creating mechanisms for sustained and expanded collaboration
- strengthening research capacity and leadership
- influencing policy and programme action

En route to become a sustainable international consortium of institutions, CISMAC prioritizes strengthening research capacity in partner institutions. The integration of capacity strengthening, research and institutional commitment represents a unique opportunity for interaction among institutions, researchers and international agencies at home and abroad. The resulting mix of competencies and geographic focus provides the expertise and infrastructure to carry out studies on a large scale that would be beyond the reach of any single research group.

Given its composition, CISMAC is able to facilitate studies in multiple contexts, particularly in sub-Saharan Africa and South Asia, the regions with the highest burden of maternal and child ill health. The close relationship with WHO provides CISMAC with access to an expanded international network of experts and health policy-makers who can provide technical resources, research questions of global priority, and an understanding of needs for guideline development and opportunities for policy-dialogue.

Scientific collaboration across research groups at home and abroad is at the very heart of CISMAC's remit. Our current core network consists of institutions in seven LMICs (Ethiopia, India, Nepal, Pakistan, South Africa, Uganda and Zambia), the Centre for International Health and the Chr. Michelsen Institute in Bergen, Innlandet Hospital Trust in Lillehammer and the Norwegian Institute of Public Health in Oslo with its sister institution, the Palestinian National Institute of Public Health in Palestine, and the ICDDR, B in Bangladesh. Our consortium works closely with three WHO departments: Maternal, Newborn, Child and Adolescent Health, Reproductive Health and Research, and Immunization, Vaccines and Biologicals.

The CISMAC Strategic and Scientific Advisory Committee brings additional perspectives, including from the World Bank and from the Bill & Melinda Gates Foundation. This extended network represents a strong partnership for generating ideas, and for developing, supporting and conducting our intervention studies. The collaboration has grown in relation to the numbers and types of studies with which CISMAC is involved. The network continues to evolve in the interest of developing teams in diverse settings capable of conducting research on priority topics, ensuring excellence in implementation, generating scientific output and contributing to the translation of scientific findings into policy, guidelines and programme action.

The extensive collaboration between Norwegian, LMIC and WHO scientists is concretized during the phases of conceiving, planning (developing protocols, standard operating procedures and study instruments) and conducting research, followed by analysis and report/manuscript preparation. All our studies involve at least one LMIC entity (the implementing institution) and one or two Norwegian

institutions. One of our studies, the trial estimating the efficacy of zinc as adjunct therapy in clinical severe infection (see page 30) is undertaken in India and Nepal, thereby intensifying the previously established collaboration between the CISMAC partner institutions in these two countries.

All our studies are led by a Project Management Team comprised of key researchers from both the LMIC and Norwegian partner institutions. Several of the studies also engage senior faculty members from other institutions and countries, both as advisors and collaborators to the studies as well as supervisors and mentors for younger scientists. For example, Professor David Murdoch from the University of Otago, New Zealand, is engaged in our trial on chlorhexidine for preventing severe infection in Ugandan newborns. Similarly, professors Mihai Netea from the Radboud Institute for Molecular Life Sciences, the Netherlands and Stephen Cose from the London School of Hygiene and Tropical Medicine, UK and the Medical MRC/UVRI Uganda Research Unit on AIDS in Uganda, are involved in two CISMAC trials.

Beyond the collaborative scientific and training activities, CISMAC management works with all teams and draws on international experts from WHO and elsewhere as members of the Data Safety Monitoring Board for each study.

By operating as a virtual centre (as opposed to a geographically localized research entity) the CISMAC consortium encounters opportunities for extensive international collaboration and synergies. In addition to using electronic and web based channels for most study-related communication and even project meetings, CISMAC arranges face-to-face meetings as needed. This includes annual workshops to discuss specific topics, such as for prioritizing and selecting research projects (2013), working to develop and refine research protocols, ensuring excellence in study implementation and employing modern biostatistical procedures (2014), developing CISMAC's overriding strategy (24) (2015), and protocol finalization and instrument development plus inclusion of cross-cutting aspects such as health economy and equity impact analysis (2016). The 2016 workshop also

included a three-day course with Prof. Allan Donner from the Schulich School of Medicine and Dentistry on Cluster randomized trials (see the section on Research training, page 67, for further details)

As demonstrated by our publications (listed on page 92 in this report and on our webpage), virtually all articles produced with CISMAC support and/or co-authored by CISMAC scientists include authors from more than one research group. This strong reflection of CISMAC's international network will become increasingly apparent as the main papers emerging from our large trials are published, with authors from the LMIC and Norwegian institutions.

In addition, CISMAC has led to an increase in interdisciplinary research collaboration in Norway and LMIC partner institutions to explore and assess promising interventions in maternal and child health. Epidemiologists, obstetricians, pediatricians, medical anthropologists, economists, immunologists, and psychologists work closely together to design interventions and find out how they work. Some papers from this interdisciplinary work have been submitted to scientific journals, and more will come as the trials are being implemented. For example, the Global Health Priorities research group at UiB is involved in many of the CISMAC studies in order to measure equity and poverty impact. With CISMAC support and in collaboration with the Campbell and Cochrane Equity Methods Group, Bruyère Research Institute, the University of Ottawa and The Centre for Health Economics, University of York, the group also arranged a 2-day workshop "Incorporating equity indicators in randomized controlled trials" at Harvard Chan School of Public Health in Boston in September 2016. With participants from 14 countries, the seminar represented a culmination of several years of work and critical discussions, concluding an extensive set of publications, some of which have already been submitted to peer-reviewed scientific journals. One of the submitted papers was commissioned by the British Medical Journal and describes a suggestion for a concrete extension on equity relevant trials to the CONSORT statement (25).

RESEARCHERS BY COUNTRY OF ORIGIN



CAPACITY STRENGTHENING

RESEARCH TRAINING

CISMAC is dedicated to fostering the capacity of young researchers to conduct relevant and high quality research.

CISMAC contributes to doctoral and postdoctoral training by

- funding PhD and post-doctoral positions
- offering opportunities for hands-on participation in high quality randomized controlled trials
- providing mentorship
- holding workshops on specific topics (e.g. statistical analysis, modelling for health economic evaluation and qualitative research methods)
- establishing new courses and workshops open to PhD candidates in CISMAC projects as well as those at UiB

The first thesis defenses by CISMAC- associated PhD candidates took place in 2016. Sudha Basnet successfully defended her dissertation “Severe pneumonia in hospitalized young Nepalese children - Studies on the efficacy of oral zinc, respiratory viruses and prognostic determinants”, which was based on data from a randomized controlled trial on providing zinc supplements to children hospitalized with pneumonia. Richard Banda defended his thesis on risk factors for maternal death in his dissertation “Measuring maternal mortality in a context of deficient vital registration systems: use of population census in Zambia”. Currently, 14 PhD candidates are involved with CISMAC’s work. They are intensely involved in high quality front-line intervention science from trial conceptualization and implementation to completion and data analysis. Another two PhD candidates have been recruited and will enroll in the PhD programme before July 2017. Our PhD grants are announced internationally. In order to attract well-qualified applicants, we also share the advertisements with leading international research environments in the specific fields.

To date, eight postdoctoral fellows have been engaged in CISMAC studies. They have participated in CISMAC’s workshops where study design, research methods, research management and data analysis were discussed. The fellows gain research competence as PIs of projects or project sub-components, under the mentorship of senior scientific staff with extensive experience in intervention science.

Many of our PhD candidates are women. Since most are also from LMICs, we hope to contribute to close the gender gap among PhD-level scientists in LMIC research institutions. Among our postdoctoral fellows, three of the eight are men.

In 2016, CISMAC organized a PhD- and post-doctoral-level course on cluster randomized trials, led by Allan Donner, a leading expert in the field (26). The success of and interest generated by this course has led CISMAC to plan a similar course every second year, taught by CISMAC scientists. In addition, CISMAC contributed to a PhD course in maternal and child health at the Bergen Summer Research School, and our scientists are responsible for a three-week intensive course in experimental epidemiology (27) at UiB. These activities pave the way for the creation of a CISMAC PhD track in implementation research, consisting of courses in observational epidemiology, experimental epidemiology, qualitative research methods, implementation science, applied economic evaluation and maternal and child health. The courses are being offered by one or more of the following CISMAC partners, with the participation of CISMAC staff: University of Bergen, Makerere University, University of Zambia, Tribhuvan University and Society for Applied Studies.

We intend to intensify this important capacity strengthening activity and we have received funding from NORPART (28) to support the travel of CISMAC staff, Masters students and PhD candidates between the University of Zambia and UiB. We will use CISMAC funds to facilitate similar efforts with the other institutions. Finally, we are planning an advanced course in epidemiologic study design, analysis and inference in 2018 for CISMAC scientists and teachers, to which we may also invite epidemiologists from other academic institutions. This course will be taught by epidemiologists Kenneth J. Rothman and Elizabeth E. Hatch, of Boston. Dr. Rothman, a world renowned scientist and teacher, is the author of two widely read epidemiology textbooks, and Dr. Hatch is an eminent investigator specializing in cancer and reproductive health epidemiology. Together they have taught courses in epidemiologic methods for a variety of international audiences.

IN THE FIELD TO REDUCE NEWBORN SEPSIS

Josephine Tumuhamyie is a Ugandan microbiologist who is taking her PhD at the University of Bergen. Her PhD research is nested into the CISMAC study on using chlorhexidine to prevent umbilical cord infections in Uganda.

What do you focus on in your PhD project?

I intend to describe the bacteria that colonize women in labour, and their patterns of antimicrobial resistance. I would also like to know if these bacteria are similar to those isolated from the umbilicus or blood of sick newborns. To do this, I will examine the association between maternal bacterial colonization and blood stream bacteria in babies with early onset neonatal sepsis. In addition, I will assess the role of multidrug-resistant bacteria in newborn sepsis and umbilical cord infections.

Why is your study important?

Women in labour colonized by pathogenic bacteria may predispose their babies to bacterial infection of the umbilicus, and of neonatal sepsis. Bacterial infections such as umbilical cord infections and neonatal sepsis are still common in sub-Saharan Africa and Uganda is no exception, accounting for a significant proportion of morbidity and mortality in the first month of life. Understanding the pathogens as well as their antibiotic resistance patterns is important in order to manage and treat these infections, potentially saving lives among mothers and babies.

Why do you think it is worthwhile to do the PhD in a CISMAC project?

CISMAC is a Centre of Excellence, which means that the research must be of the highest possible quality. Doing this PhD keeps me in check to critically think through my methodology as I collect my data, and not compromise the quality of my work. This experience has sharpened my understanding of the dynamics that come with clinical trials. One must pay attention to the smallest details that may have a big impact on study outcomes. I have also learned to appreciate how demanding it is to conduct high quality research in real life situations amidst diverse challenges that I as the researcher find it difficult to control.

What are the main lessons you have learned in the field?

You must have a keen “eye” to ensure that study procedures are being followed. This helps detect problems very early and hence allows you to address them immediately. In other words, you have to be alert and on the ground. ‘You’ve got to make things work out somehow. In the field, you learn to think creatively and must come up with quick solutions to solve small problems arising that may affect study outcomes.

CISMAC puts significant effort into strengthening local capacity. Why is this important?

Local capacity strengthening is key in equipping young researchers with knowledge and hands-on skills within their local contexts. This empowers them to conduct high quality research on interventions or strategies to deal with the needs identified in their communities.

FACTS

Josephine Tumuhamyie

- Born: 1987
- From Kampala, Uganda
- PhD Candidate, Chlorhexidine study
- Microbiologist with a Master’s degree in Immunology and Clinical Microbiology, Makerere University, Uganda
- Dr. Victoria Nankabirwa (PI of Chlorhexidine study) and Prof Halvor Sommerfelt (Co-PI) are her supervisors together with Prof James K Tumwine and Dr Freddie Bwanga



PRODUCING RESULTS

MOST IMPORTANT SCIENTIFIC RESULTS

This section summarizes the most important scientific findings produced by CISMAL researchers, and reflects formative research, analyses of existing data and systematic reviews. CISMAL trials, started in 2014, will begin to produce their main results in 2018.

MATERNAL HEALTH

Research Initiative to Support the Empowerment of Girls (RISE)

(Ongoing study - University of Zambia and University of Bergen)

Formative research indicated that early marriage and pregnancy are seen as means to achieve social and economic security in resource constrained settings in Zambia. Early pregnancy should be understood as more than a cultural phenomenon, and successful interventions need to consider dynamics profoundly embedded in social and economic structures. A trial is being conducted to examine whether economic support – alone or in combination with youth club meetings and community dialogue on the value of education, early marriage and childbearing – may reduce the risk of adolescent childbearing and increase completion of junior secondary school.

Breastfeeding and maternal health

(Completed systematic review and meta-analysis - SAS, India)

Breastfeeding for over 12 months was associated with reduced risks of breast cancer (26%) and ovarian cancer (37%) and type 2 diabetes (32%). Exclusive and predominant

breastfeeding were associated with longer duration of amenorrhea. Shorter duration of breastfeeding was associated with higher risk of postpartum depression (29).

Promotion of facility births and implication on health-seeking

(Completed CISMAL-supported analysis - University of Bergen and Centre Muraz, Burkina Faso)

Policies to increase the number of institutional births are being implemented worldwide. This study explored the promotion of facility birth care in Burkina Faso, and how this influenced health-seeking behaviour. The norm of institutional delivery has expanded beyond the recommendations of professional health workers to become a socially accepted ideal. Women faced verbal, economic and administrative sanctions if they did not attend services. For women with limited access to health facilities, the sanctions involved higher costs, led to social stigma and acted as additional barriers to seeking skilled birth attendance. The study shows how promotion of the global and national policy of skilled care for pregnancy and birth can have unintended outcomes (30). ▶

NEWBORN HEALTH

Promoting community-initiated Kangaroo Mother Care (cKMC)

(Ongoing study - SAS, India)

Formative research in Haryana, India indicated that most mothers in the community were able to identify small babies and many recognized their need for special care. KMC was a new concept, so discussions required showing photos and videos to explain the intervention. All respondents felt that KMC can be done if mothers know its benefits. Respondents expressed concerns about its duration, as mothers need time to rest. Mothers’ delayed return to household chores, and other family members sharing in giving skin-to-skin care could make it easier to adopt the practice. The observation that the baby’s health was improving was seen as a key motivation for mothers to adopt KMC. Household piloting conducted at the end of the formative research showed a high acceptability of KMC. Most mothers reported perceived benefits: their babies gained weight, looked healthy, were active and fell ill less frequently.

Effect of neonatal vitamin A supplementation on newborn and infant mortality

(Completed CISMAL-supported analysis - SAS, India)

A randomized placebo-controlled trial followed 45,000 newborns from the first days after birth to 12 months of age. Supplementation with 50,000 IU vitamin A within the first 72 hours of life was associated with a modest (10%) reduction in mortality as compared to supplementation at 6 months of age. Supplementation was safe and well tolerated, except for a small excess risk of transient bulging fontanelle (31).

Timing of breastfeeding initiation and exclusive breastfeeding, and effects on mortality

(Completed CISMAL-supported analysis - SAS, India)

Data were analysed from nearly 100,000 newborns participating in the above-mentioned vitamin A supplementation trial in India and in similar trials in Ghana and Tanzania. Compared with infants initiating breastfeeding within the first hour of life, neonatal mortality between enrolment and age 28 days was 40% higher in infants who started breastfeeding at 2–23 hours after birth, and 79% higher among those starting at 24–96 hours. Exclusive breastfeeding was associated with lower mortality during the first 6 months of life. The risk of death between 1 and 3 months of age was over 10 times higher among those who at 1 month of age were not breastfed, compared with those who were exclusively breastfed. Findings suggest that early initiation of breastfeeding reduces neonatal and early infant mortality, and confirm the importance of exclusive breastfeeding. Early initiation facilitates exclusive breastfeeding but may have survival benefits through additional mechanisms (32).

CHILD HEALTH

Effect of promoting the Integrated management of neonatal and childhood illness (IMNCI) strategy on treatment seeking

(Completed CISMAL-supported analysis - SAS, India)

A cluster randomized trial followed nearly 60,000 infants born in 18 population clusters from soon after birth to 12 months of age. Those born in intervention clusters received the IMNCI intervention (home visits by community health

workers, improved management of illness, and strengthening of health systems). Those in the control clusters received standard care. Implementation of the IMNCI strategy was associated with more timely treatment seeking from appropriate providers and lower morbidity, a likely explanation for reductions in mortality observed following implementation of the programme (33). In the intervention clusters, treatment was sought more often from an appropriate provider for severe neonatal illness, for local neonatal infection, for diarrhea and for pneumonia. Mothers in the intervention clusters reported fewer episodes of severe neonatal illness and lower prevalence of diarrhea and pneumonia. Infants in the intervention clusters were three times more likely to still be exclusively breastfed at 6 months of age.

Possible additional effects of BCG vaccination

(Completed CISMAL-supported analysis - Makerere University, Uganda)

Between 2006 and 2014, a birth cohort study by CISMAL scientists in Uganda showed substantially lower mortality among children 1 month to 5 years of age who had received BCG vaccination compared to those who had not (18). Because there is a possibility that health personnel withheld BCG from infants who were sick, the scientists chose not to include in the publication the findings concerning babies 4 weeks or younger. However, a second analysis shows that these neonates were less likely to die if they had received BCG. CISMAL’s ongoing trial on BCG vaccination is further exploring this issue.

Strategies to develop prognostic markers and improve treatment of serious bacterial infections

(Completed CISMAL-supported analysis of two studies - THSTI, India and Tribhuvan University, Nepal)

In the first study, conducted in Nepal among children 2-35 months of age hospitalized with pneumonia with lower chest indrawing, slower recovery was predicted by younger age, hypoxia on admission, radiographic findings of pneumonia, wasting or presence of danger signs (34). In the second study (35), conducted in India among babies 1 week to 4 months of age hospitalized with probable serious bacterial infection, slower recovery was predicted by having received formula milk before the onset of the illness, being underweight, lethargic or irritable, or having elevated CRP on admission. Additional analyses of data on the same severely ill infants in India, showed that giving zinc syrup in addition to antibiotics and supportive therapy resulted in a substantial reduction in the risk of treatment failure. In fact, there was an equally strong effect on the risk of dying, with zinc-treated babies showing a substantially reduced case fatality risk, although this effect was statistically imprecise. This study was completed prior to the establishment of CISMAL and formed the basis for CISMAL’s decision to undertake a much bigger trial to assess the effectiveness of the adjunct zinc therapy in improving survival. •

EXPLORING COMMUNITY INITIATED KANGAROO MOTHER CARE

This trial, set in India, aims to enrol 10,500 babies and their families to examine how community-initiated Kangaroo Mother Care (cKMC) may increase the survival and health of babies that are born with a low birth weight. Sarmila Mazumder was the Principal Investigator of the formative research phase of the cKMC project. She shares some of the insights obtained in the project.

Why is this study important?

So far, the experience and documented benefits of KMC come from hospital settings where it was initiated with the help of skilled health workers. We do not know whether the same benefits can be gained when KMC is initiated at home. This is particularly important for low- and middle-income countries with a higher proportion of babies who are born small (low birth weight babies), and where a large number are born at home. Even babies born in facilities are often discharged earlier than recommended. Obtaining evidence of the benefits of community initiated KMC is imperative for the decisions on promoting such care.

How did you determine what would be an acceptable and feasible way to deliver the intervention?

The intervention package and delivery strategy were developed based on extensive formative research. We used qualitative research methods such as in-depth interviews, focus group discussions and observations to explore community beliefs and perceptions. We identified missing links and gaps in information from previous studies. We collected new data around caring for low birth weight babies, familiarity with the concept of KMC, whether it could be initiated at home, the possible barriers and enabling factors, the best channels for delivering interventions and the specific messages and recommendations that would need to be promoted. A prototype intervention

was developed and piloted in homes to see whether this intervention was acceptable and feasible.

What has been the most challenging part of planning and conducting this trial?

We have run into several challenges. First, KMC itself can be difficult to practice. The extremes of weather conditions with heat and cold, no one to help with household chores if the mother is busy with KMC and lack of privacy in single-room dwellings are some of the common issues. This means that the families require strong motivation, counselling and support.

The positive experiences, satisfaction and happiness of the mothers and families have been very exciting.

Second, it can be challenging to have the families initiate KMC early enough. Our aim is that KMC should be initiated as soon as possible after birth. However, this is community-initiated KMC, so we need to wait until the mother and baby are discharged and come home. About 80% of deliveries take place in facilities, and the government programme recommends retaining the mother and new-born for at least 24 and preferably 48 hours after delivery. Given that, for this trial, KMC needs to be initiated within three days of birth, there is sometimes a rather small window during which we can enrol the baby and family. To ensure that this happens, evening enrolments beyond office hours were initiated. This is not always easy as it may be unsafe for women to work late in the evening in these communities. ▶

Lastly, the trial aims to enrol 10,500 low birth weight babies who live with their families among a population of about 1.3 million spread over 2,250 sq. km. Logistically this can be very challenging.

Can you briefly describe the most important results from the formative research?

The most important finding was that it is feasible for mothers of low birth weight babies to practice KMC. During the pilots KMC was given by 97% of mothers of low birth weight babies. The median duration of skin-to-skin contact was more than six hours over a 24-hour period, with 24% giving skin-to-skin contact for more than eight hours. The mothers preferred to give skin-to-skin contact lying on their backs, or partially lying down. Strong and persistent motivation, plus effective counselling skills involving other family members were also critical to initiate skin-to-skin contact and sustain it for prolonged periods. Since babies were small with poor sucking ability, breastfeeding support was crucial. Male members of the family were supportive, with many fathers happily giving skin-to-skin contact themselves. The joint family system, the cultural practice of separating the mother and baby from the rest of the family and ensuring bed rest in the postpartum period were also helpful.

What has been the most rewarding part of this research project?

The positive experiences, satisfaction and happiness of the mothers and families have been very exciting, encouraging and definitely the most rewarding aspect of conducting this study. Nearly all mothers, 90%, reported liking to practice KMC. Mothers shared that the babies became healthy and gained weight. They became active and did not remain limp, and they were able to breastfeed better and became stronger. Mothers also said that their babies looked good, skin dryness was reduced, and they became beautiful with glowing faces. Babies were more calm and slept peacefully. A few mothers said that the babies did not fall ill as often as other siblings who had had low birth weight. The active participation of fathers and grandmothers was an exhilarating experience. •

FACTS

Sarmila Mazumder

- Born: 1964
- PI of cKMC study
- Educational background in Community Health, Social Sciences and Epidemiology



FACTS

Community-initiated Kangaroo Mother Care-study

- Through good rapport between families and study teams, and rigorous follow-up by field-workers the trial has achieved more than 95% follow-up of babies until 6 months of age
- Kangaroo Mother Care consists of: Early and prolonged skin to skin Contact (SSC) and exclusive and frequent breastfeeding
- Within 3 days of birth, a Pregnancy Follow Up, Screening and Enrolment worker visits the households to weigh, screen and enrol the baby. A trained intervention delivery team is informed whenever an infant is assigned to the intervention group. Once the infant is enrolled, the follow-up team visits the family when the baby reaches 1, 3 and 6 months.
- At enrolment all contact phone numbers of the family are recorded. If the family does not have a telephone, the team asks for phone numbers of relatives and neighbours. If the family is not available during the follow-up period, the team tracks them through the contact numbers and make outstation visits to collect follow-up information.



CISMAC DISSEMINATION AND COMMUNICATION

In its role of carrying out intervention research that will inform policy and practice, and ultimately improve MNCH, CISMAC recognizes that communication and visibility are crucial for engaging stakeholders, for influencing health policy and for creating public interest about global maternal and child health issues.

In addition to publishing papers in peer-reviewed journals (see page 92) CISMAC researchers have presented their work in national and international conferences including for example the Congress of the World Association for Infant Mental Health, the European Society for Pediatric Infectious Diseases and the GLOBVAC conference. CISMAC researchers have also presented at meetings and conferences targeting the general public such as the Christie conference in Bergen. Participation at such events broadens the reach of CISMAC messages.

The consistent and close engagement of CISMAC with WHO and with government stakeholders allows the early communication of our research results and increases the probability that research findings will be translated into policy and practice. We invite you to read more about CISMAC's engagement with national and international stakeholder on page 13.

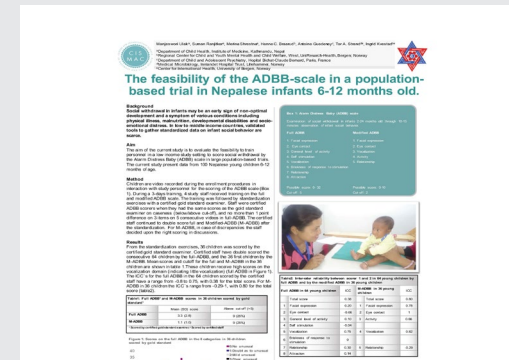
The CISMAC website www.cismac.org is an important communication tool by which CISMAC reaches both the general public and the scientific community; it provides general information about CISMAC, detailed information about the CISMAC studies as well as an updated overview of all CISMAC publications. It is also an information source for policy makers, stakeholders and interested journalists.

Along with social media, the general media is also crucial for reaching the public. It serves as a means of demonstrating the societal impact of CISMAC research, as well as the contributions of this research to finding solutions for major societal challenges. CISMAC has influenced public debate and is featured in general media coverage both in Norway and in our partner countries.

- 1) Poster presented by CISMAC researcher at the World Congress of the World Association for Infant Mental Health
- 2) Social media presence: Facebook post about the publication of Lancet paper in 2015
- 3) Feature article about progress of maternal and child health in Africa by CISMAC researchers in regional newspaper Bergens Tidende
- 4) Interview with CISMAC director about positive developments in maternal and child health in the specialized press magazine Bistandsaktuelt

- 5) Article about Kangaroo Mother Care made front page of regional newspaper - Interview with CISMAC researchers Maharaj K. Bhan and Rajiv Bahl
- 6) Article about Kangaroo Mother Care with CISMAC researchers replicated in 5 Norwegian newspapers, including national level newspaper Aftenposten
- 7) Article about CISMAC BCG-study in Daily Monitor – National newspaper in Uganda
- 8) Deputy director Ingvild Sandøy talks about the CISMAC-Rise study in Zambia at the Christie conference, where CISMAC also had a stand

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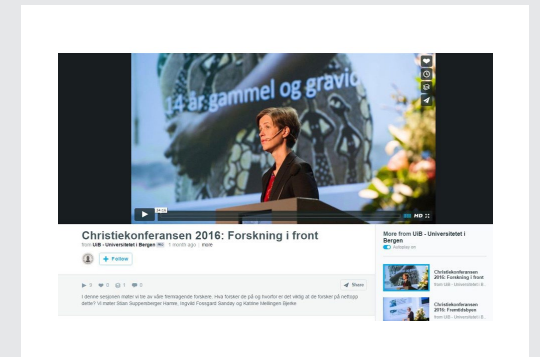
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CISMAC STAFF AND MANAGEMENT

THE CISMAC BOARD



Nina Langeland

Nina Langeland (Chair) is a medical doctor and specialist in internal medicine and infectious diseases. She holds a full professorship at the University of Bergen, and has since 2009 been the Dean of the Faculty of Medicine and Dentistry at the University of Bergen. Her scientific interest has been in clinical research, antimicrobial resistance and infections relevant for low-income countries. She has had the initiative and received funding to support specialist degrees in several medical specialties in Tanzania and Ethiopia. She has held several positions on behalf of Norwegian medical schools.



Wakgari Deressa

Wakgari Deressa has more than 15 years of research experience in malaria, HIV/AIDS, adolescent health risk behaviors, reproductive health, occupational health and major parasitic diseases. His focus is on community-based studies aimed at developing and evaluating interventions that can improve maternal health and child survival. He has been active member of different multidisciplinary collaborative research and capacity building projects particularly in partnership with UiB. Wakgari is currently Dean of the School of Public Health at Addis Ababa University in Ethiopia.



Anne Christine Johannessen

Anne Christine Johannessen is Vice Rector for International Affairs at the University of Bergen. She is professor in oral pathology and a senior consultant at Haukeland University Hospital. In her research, Johannessen has worked at the interface between medicine and dentistry and has focused on inflammatory diseases of the mouth and oral cancer, with special focus on developing countries. Johannessen is also affiliated to the Centre of Excellence "Centre for Cancer Biomarkers" at the University of Bergen.



Bente E. Moen

Bente E. Moen is the Director of the Centre for International Health, at the Department of Global Public Health and Primary Care, University of Bergen. She is a physician, with a PhD from 1991. She has been a professor in Occupational Medicine the past 19 years and has worked mainly in the area of occupational epidemiology and occupational exposure. The past 15 years, she has been involved in research and training collaboration with institutions in Low Income Countries in East Africa. She has written about 200 original papers in international journals and has been the editor of several books.



Ottar Mæstad

Ottar Mæstad is the Director of Chr. Michelsen Institute (CMI). Mæstad is an economist with a research background both in global health and in areas such as environment and energy, climate policy and international trade. Since 2004 he has been the leader of the global health research programme at CMI, focusing mainly on health service delivery - human resources, quality of health care, governance in the health sector, results-based financing, vaccination coverage – and more recently also on adolescent health / early marriage.



Shinjini Bhatnagar

Shinjini Bhatnagar is Professor and Dean of clinical research and Head of the Pediatric Biology Centre at THSTI, Faridabad, India. Bhatnagar specializes in the development of interventions for reducing neonatal and child morbidity and mortality. She has supervised 18 large double blind RCTs in the field of diarrheal diseases and infections in children aiming to facilitate evidence based recommendations in child health. Currently she is coordinating a multi-institutional and interdisciplinary program aiming to capture environmental, clinical and biological risk factors for preterm birth.

STRATEGIC AND SCIENTIFIC ADVISORY COMMITTEE (SSAC)



Mickey Chopra

Mickey Chopra is responsible for taking forward the World Bank’s work on optimizing efficient and equitable service delivery and models of care. Before joining the World Bank he was Chief of Health and Associate Director of Programmes at UNICEF, leading the agency’s work in maternal, newborn and child health, immunisation, and paediatric HIV/AIDS. Prior to his appointment to UNICEF, Dr. Chopra was the director of the Health Systems Research Group of the South Africa Medical Research Council. Dr. Chopra is a qualified medical doctor with degrees in Medical Sociology and Medicine from the University of Southampton, UK; a Masters Degree in Public Health from London School of Hygiene and Tropical Medicine; and PhD from Faculty of Medicine, Uppsala University. He has published over 150 peer-reviewed papers in global health and contributed to numerous book chapters concerned with international child health and nutrition.



Kåre Mølbak

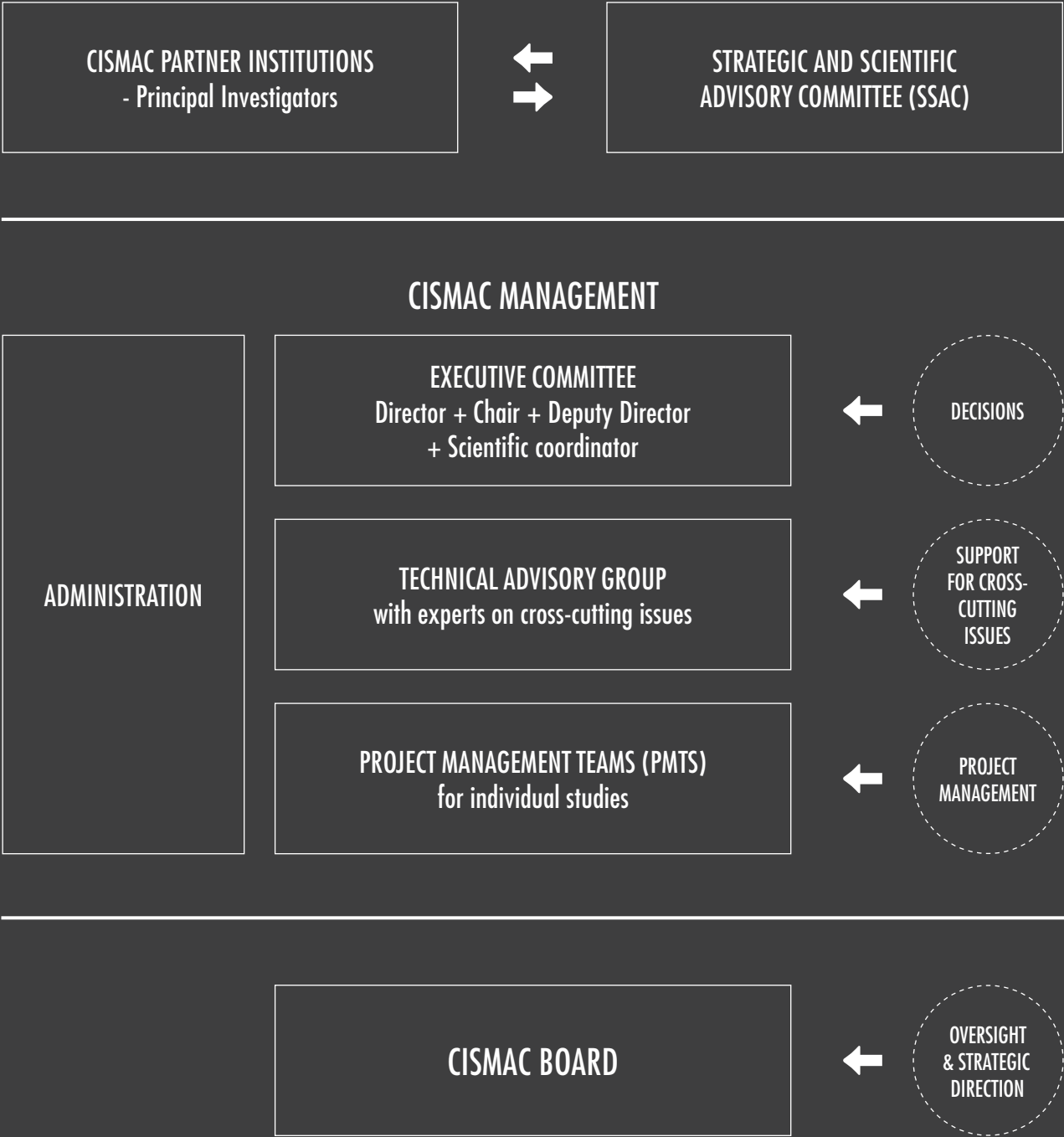
Kåre Mølbak is trained in clinical infectious diseases and has held research positions in connection with the Bandim health research project in Guinea Bissau and at several departments at Statens Serum Institut. At the present position, he works as State Epidemiologist for Infectious Diseases in Denmark. Particular areas of interest are control of infections, vaccinology, and emerging infections. He has also an interest in longitudinal studies of infectious diseases. Dr Mølbak has been the speaker at a number of international conferences, the organizer of international workshops, the coordinator of large WHO and EU funded research programmes, including DG-RESEARCH and DG-SANCO funded projects. Furthermore, Dr Mølbak chaired the group that prepared the Health Technology Assessment which resulted in the decision to introduce the HPV vaccine in the Danish childhood vaccination programme and the creation of the Danish vaccination registry. Dr Mølbak is member of the advisory forum of the European Centre for Disease Prevention and Control, ECDC, and participates in the European vaccinology consortium ADVANCE.



Ellen Piwoz

Ellen Piwoz joined the Bill & Melinda Gates Foundation in 2007 and currently leads the Nutrition Strategy Data, Analytics, and Evidence Initiative. In addition, she has shaped and managed a diverse portfolio of grants including research on healthy birth, growth, and development; testing new delivery models for improving maternal nutrition, breastfeeding, and complementary feeding at scale; costing and financing of interventions to achieve the 2025 World Health Assembly nutrition targets; and evidence syntheses and guidelines for use in policy and program decision-making. Prior to joining the foundation, Dr. Piwoz held adjunct faculty appointments in the Schools of Public Health at the Johns Hopkins University and the University of North Carolina, Chapel Hill. Dr. Piwoz has a Doctor of Science degree in Human Nutrition and a Master of Health Science degree in International Health from the Johns Hopkins University School of Public Health.

ORGANIZATION CHART OF THE CENTRE



As a research consortium, CISMAL employs a “Cooperative Governance” philosophy, taking the partners’ point of view into consideration when making important decisions. The CISMAL Management is based at the University of Bergen and comprises the Executive Committee, the Technical Advisory Group and the Administration Team. The Director and the Executive Committee carry out the daily management of CISMAL supported by the Administration team. Important decisions are taken to the CISMAL Board where the partners are represented on a rotatory basis. The Technical Advisory Group ensures a multidisciplinary perspective which is critically important for CISMAL. Once a year, the Strategic and Scientific Advisory Committee (see page 82) meets to review progress and advise on CISMAL’s strategic way-forward.

THE CISMAL ADMINISTRATION



Marte E. S. Haaland
Administrative leader

Haaland has a Master in Social 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 CISMAL since 2013 and is currently employed as Project Manager for CISMAL, leading the administrations work.



Ingvild Hope
Project Administrator

Hope has been a member of CISMALs administrative team since the work on CISMAL 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.



Ane Straume
Project Administrator

Straume has a Master in Social Anthropology from UiB. Since 2010 she has been affiliated with the department of Social Anthropology at UiB where she has been working and conducting a research project in the Pacific for her ongoing PhD in Medical Anthropology. She is currently employed as Senior Executive Officer supporting Haaland in the administrative work of CISMAL.



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 CISMAL financial team together with Vikøren. Ipek is in charge of overall management of CISMAL 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 and is part of the financial team of CISMAL. Vikøren is currently in charge of financial management and support of projects in the CISMAL portfolio.

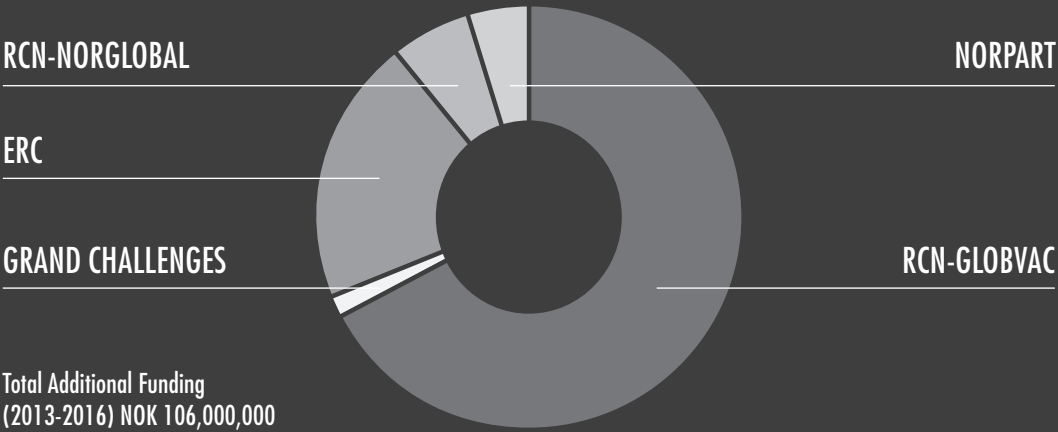


Therese M. Istad
Web & Communication

Istad has a bachelor in Visual Culture and a Master's degree in Media Studies from UiB. Istad has more than 10 years working experience at UiB where she has worked with research administration as well as communication and media since 2007. Since CISMAL was first started, Istad has been in charge of CISMALs web presence and communication work.

CISMAL NUMBERS

SOURCES OF ADDITIONAL FUNDING GENERATED



GENDER DISTRIBUTION PRINCIPAL INVESTIGATORS



CISMAC RESEARCHERS

Africanus, Polycarp

Institute of Social Work

Aggarwal, Kailash C.

Vardhman Mavhir Medical College

Ansari, Imran

Patan Academy of Health Sciences

Bahl, Rajiv

World Health Organization

Basnet, Srijana

Tribhuvan University

Basnet, Sudha

University of Tribhuvan,
University of Bergen

Bhandari, Nita

Society for Applied Studies,
University of Bergen

Bhatnagar, Shinjini

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2016

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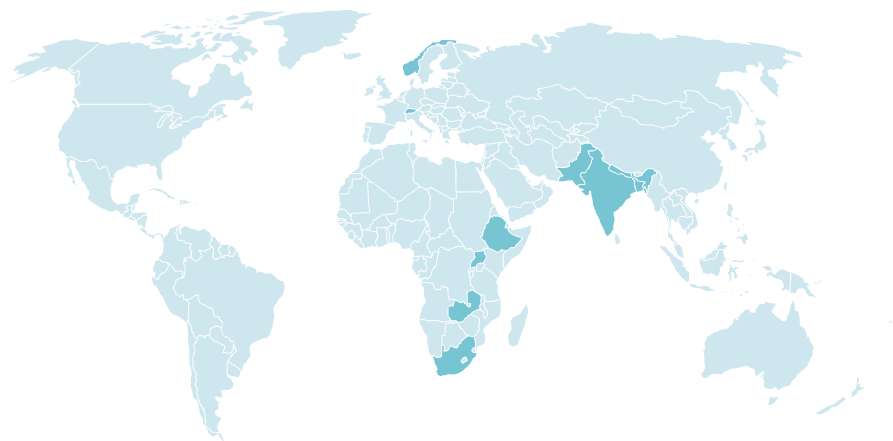
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