An integrated parenting, nutrition and malaria prevention package to improve nutrition and child development in infants and pre-school children:

Impact evaluation of a randomized controlled trial in southern Mali

Endline Report for World Bank Strategic Impact Evaluation Fund

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Save the Children

in collaboration with:

LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

MALARIA RESEARCH & TRAINING CENTER BAMAKO, MALI

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ACRONYMS

DNP	Direction Nationale de Pedagogie
ECD	Early Childhood Development
GCP	Good Clinical Practice
HSKT	Head Shoulders Knees and Toes test
IDELA	International Development and Early Learning Assessment
INRSP	Institut National de Recherche en Sante Publique
IOE	Institute of Education
LSHTM	London School of Hygiene and Tropical Medicine
MNP	Micronutrient Powders
MoH	Ministry of Health
MRTC	Malaria Research and Training Center
PNLP	Programme National de Lutte Contre le Paludisme
RAN	Rapid Automated Naming test
SMC	Seasonal Malaria Chemoprevention

INTRODUCTION

I. BACKGROUND TO THE PROJECT

Proper nutrition, especially from conception to age two, and early childhood stimulation play a critical role in the process of brain formation and development.[1] Children born in sub-Saharan Africa face increased risks of under nutrition and infectious disease in early childhood, increasing stunting and impacting ultimately on educational achievement. In addition to deficits in health and nutrition, household poverty leads to an impoverished environment in which children are deprived of early cognitive and non-cognitive stimulation. Low levels of child development are associated with lower school participation and performance, lower earning capacity, and perpetuate the intergenerational transmission of poverty. Early childhood is a time of rapid growth and development, and interventions during this period could yield substantial benefits across several developmental areas: physical, cognitive, linguistic and socio-emotional. Evidence on how to effectively tackle the underlying causes of undernutrition and improve child development through integrated interventions, that combine disease control, improved nutrition and cognitive stimulation in early childhood in sub-Saharan Africa and other low income settings is lacking.[2-4]

Early child development (ECD) programming is gaining momentum across Africa, and community-based ECD programs in disadvantaged rural settings are being established in a number of countries, including Mali. Attendance at rural ECD centers has been found to significantly improve core dimensions of children's development and school readiness, including cognitive and problem-solving abilities, fine-motor skills and socio-emotional and behavioral outcomes, and lead to significantly increased primary school enrollment at the appropriate age.[5] However, impacts on communication and language development were found to be more limited, thought in part to be due to the fact that many children arrived at ECD centers with severe delays in physical growth and vocabulary development. This finding highlights the need to expand ECD programmes to include health, nutrition and early stimulation interventions starting much earlier in life.

Iron is important in brain function,[6] and interventions that reduce iron-deficiency and anemia can improve cognitive function and learning.[7-9] Vitamin and mineral deficiencies frequently occur simultaneously, and their combined effects during the critical period from preconception to 23 months of age may be associated with increased neonatal mortality and morbidity, as well as irreversible adverse physical and cognitive outcomes.[10] In countries where diets are predominantly plant based, the amounts of key micronutrients to meet the recommended nutrient intakes of preschool children is usually insufficient and the cost of including animal-source foods to the diet to cover the nutrient gap is often prohibitive to the lowest income groups who most need it. Another major cause of anemia is malaria.[11] Whilst the deleterious effect of cerebral malaria through brain damage and long-term learning impairments is well recognized,[12-18] there is increasing evidence that asymptomatic malaria infections can also affect cognitive performance.[19-21] This necessitates a multipronged approach to combat the combined effects of undernutrition, anaemia and malaria in early childhood.

Preschools and ECD programs offer a new opportunity to mobilize communities and reach children under five years, both those attending the center and younger children (0-2 years), with key health and nutrition services. Although access to preschools in Africa is still limited, ECD programming is gaining momentum and political commitment to improve coverage has increased tremendously in the past decade. As access increases, so will the capacity of preschools to improve coverage of health and nutrition services to under five children. Combining health and nutritional interventions with early childhood development interventions may be synergistic in helping children to grow stronger, physically and mentally, and to be better prepared for entry into school.[4]

Healthy children may also gain more from the mental stimulation and early learning opportunities offered through ECD programs and parenting interventions during pre-school years.

In 2013, Save the Children and national partners in Mali intoduced an integrated parenting, nutrition and malaria prevention package in villages with community pre-schools in southern Mali. The aim of the programme is to reduce the incidence of clinical malaria, the prevalence of anemia and stunting, and improve cognitive development in children under 5 years by combining two newly recommended nutrition and malaria interventions in early childhood: home fortification with micronutrient powders[10] and seasonal malaria chemoprevention.[22] The programme which targets all children in the community is delivered through the pre-existing infrastructure of community-based Early Childhood Development (ECD) centers, previously established in the study area by Save the Children.

There have been no previous studies examining the combined impact of these two newly recommended malaria and nutrition interventions in early childhood. In addition, whilst each disease control and nutritional intervention has previously been shown to bring substantial gains in child survival and physical growth, the benefits for cognitive and linguistic development are comparatively unknown. Most intervention trials typically focus either on health or educational outcomes, rarely both. The impact of an integrated package of ECD, malaria and nutrition interventions on a child's physical and cognitive development over the first 5-6 years of life, and learning as children transition into school has not previously been examined. This study aimed to address this key gap in knowledge, whilst providing evidence of the operational feasibility and cost-effectiveness of the approach.

II. CONTEXT and JUSTIFICATION

An estimated 273 million (43%) preschool children worldwide have anaemia,[23] a largely invisible condition with irreversible adverse physical and cognitive effects that lead to lifelong consequences for health, productivity and economic growth. Iron deficiency is thought to be the most common cause of anaemia globally, althouth other conditions such as folate, vitamin B12 and vitamin A deficiencies, chronic inflammation, parasitic infections such as malaria, hookworm and schistosomiasis, and inherited causes can all cause anaemia. Anemia is multi-causal, and though individual interventions to combat anaemia can each bring significant gains, greater impact can be expected when interventions are combined, and could yield additional benefits for education by increasing the capacity of children to learn.

Mali is one of the least developed countries in the world, ranked 175th out of 187 on the Human Development Index, with some of the highest rates of anemia and malaria in the world. Sikasso, located in the south of Mali, is considered the bread basket of the country, yet it is the region with the highest levels of malnutrition: 45% of children under 5y are stunted, 16% wasted, and 88% are anemic. It is also the zone where the prevalence of malaria is highest according to a recent national survey on malaria and anaemia by the Ministry of Health.[24] Malaria accounts for 51% of all under five outpatient visits and is the primary cause of morbidity and mortality in Mali.[25] The combined effects of anemia and malaria in this age group have a devastating effect on children's health, development, education and longer term productivity. Hookworm, the main intestinal worm present in this part of the country, is already taken care of by annual deworming to all preschool and school age, alongside vitamin A which also has been shown to reduce the risk of anemia. Access to malaria treatment in remote communities has improved significantly in the past decade with the scale up of Integrated Community Case Management, which the Malian government endorsed following studies conducted by Save the Children in Sikasso region.[26] Although access to

malaria diagnosis and treatment is more accessible than ever before, it does not prevent clinical attacks of malaria or address asymptomatic malaria. Preventive approaches such as insecticide treated nets and the newly recommended approach of seasonal malaria chemoprevention are thus vital in reducing the risk of malaria in early childhood. Following the WHO policy recommendation in 2012,[22] the Mali government approved a national plan to roll out seasonal malaria chemoprevention to 9 districts in 2013, 47 in 2014 and the entire country in 2015. From a nutrition perspective, the Mali government has strong nutrition strategies, policies, and committees in place, and government health services have been equipped to conduct regular growth monitoring and promotion (GMP) and nutritional rehabilitation of malnourished children through its network of community health centers, agents and volunteers. Nonetheless, coverage remains patchy and incomplete. Identifying effective community approaches to decrease the incidence of malnutrition through improved feeding practices and micronutrient supplementation is thus equally vital in combating the combined effects of malaria, anemia, and undernutrition in early childhood.

Although preschool education has existed for decades in Mali, until very recently it was only accessible to wealthier urban communities and access to preschool education of any form was still very low in 2008 (4.2%). Nonetheless, there is strong commitment from the Malian government to improve education for all, including preschool education. A national ECD policy was validated in 2011 promoting a holistic and integrated, rights-based and interactive approach to preschool education in Mali.[27] It emphasizes a multisectoral approach across Ministries and strong community participation and ownership. A Directorate for Pre-school and Special Education is in place, and a national ECD task force established. The policy aims to increase preschool education to 15% by 2020 and reach 100% first grade enrollment by 2015, through increasing access to community-based ECD centers (CDPE; Centres de Development de la Petite Enfance) and promoting parenting education to increase use of essential health services and improve parenting practices.[28]

The development of preschools and ECD programs in Mali offer new opportunities to mobilize communities and parents, to reach children under five years, both those who attend the center as well as younger siblings (0-2 years), with key health and nutrition services.

What lead to the current work in southern Mali?

Save the Children's prior programs to improve children's health in primary schools and ECD centers in Mali
Save the Children has been working in Mali since 1987 supporting health and education programs, through community capacity and systems strengthening; and has gained both national and international recognition for their efforts to improve community health, through the establishment of Community Health Centers (CSCom) and integrated Community Case Management.[26] From an education perspective, Save the Children pioneered the community schools approach and supported scale up to the entire Sikasso region which increased the school enrolment rate from 20% to 80%. Community schools are now an integral part of Mali's national educational system. Save the Children uses a six-step approach to community mobilization called the Community Action Cycle which ensures community ownership, local relevance and promotes long term sustainability. Save the Children has well established relationships with the Malian government, particularly the Ministries of Health and Education, at national, regional and local level.

Save the Children has also been the leading agency supporting School Health and Nutrition programming for nearly 20 years providing a model for School health programming in Mali and contributing to the development and validation of the national School Health policy. Two previous randomized control trials have been conducted in schools, both with our long standing research partner the INRSP, to evaluate the impact of intermittent iron supplementation combined with deworming and vitamin supplementation,[29] and more recently an innovative malaria control

strategy in collaboration with LSHTM, INSRP, and Sorbonne University, which evaluated the impact of school-based promotion and distribution of insecticide treated nets, supplemented by intermittent parasite clearance (a single treatment given to all school children at the beginning of the school year).[21] The results showed that children treated for malaria at the end of the malaria transmission season in December will remain largely parasite free and less likely to be anemic until the end of the school year in May. Treated children also scored significantly higher on a sustained attention task suggesting improved cognitive function. Based on these findings, we postulated that seasonal malaria chemoprevention recommended for children under five might similarly prevent anemia and improve cognitive function and learning in early childhood. These previous studies in schools thus paved the way for the current study in ECD centers in terms of providing a similar model of the potential health and cognitive benefits that could arise from a similar intervention in younger children, establishing working relationships with relevant academic and government partners in Mali and outside), and from an advocacy perspective by highlighting the need to address malaria, undernutrition and anemia to support both health and educational goals.

In 2008, Save the Children launched its Early Childhood Care and Development program, and by 2013 there were 75 community preschools in Sikasso and Yorosso cercle. Save the Children is one of the leading agencies supporting ECD programming in Mali and has played a key role in supporting the development and harmonization of the national ECD policy for Mali, through technical validation in advocating for the integration of ECD in the national education policy and financing of workshops to support the process. Save the Children has similarly had an instrumental role in the newly-developed national parenting education program.

Policy relevance and national interest in the research

The Government of Mali is committed to reducing poverty and improving the welfare of its people. Malnutrution and malaria are two of the top health priorities for the Ministry of Health. The national health policy aims to reduce malnutrition and micronutrient deficiencies, including anemia through improved nutrition and health practices and strategies to control micronutrient deficiencies. From a malaria perspective, the national malaria control policy's overall objective is to reduce the morbidity and mortality by achieving universal coverage of Long Lasting Insecticide-treated Nets (LLINs) and malaria treatment, and through community based interventions to bring prevention, diagnosis and treatment closer to the household. Home fortification with micronutrient powders and seasonal malaria chemoprevention are two new interventions which the Malian government is hoping to scale up nationwide.

The Ministry of Education (Ministere de l'Education, de l'Alphabetisation et de la Promotion des Langues Nationales) approved a new policy on Early Childhood Development in May 2011, promoting a holistic and integrated, rights-based and interactive approach to preschool education in Mali.[27] The policy emphasizes a multisectoral approach across Ministries and strong community participation and ownership. The policy focuses on three age groups: 0-3yrs, 3-5yrs and 6-8yrs and highlights the need to address the health and nutritional needs of children as well as educational development.

Project history :

An initial study of an integrated package of interventions in pre-school children, combining seasonal malaria chemoprevention (SMC) and home fortification with micronutient powders (MNP), was conducted in 2013-2014 in 90 villages in the administrative cercles of Sikasso and Yorosso. The aim of this first study, which was funded by the UBS Optimus Foundation and Save the Children, was to evaluate the immediate short-term impact of the package of interventions on the health and development of children aged 3 and 5 years after 12 months of intervention. In 2013, 60 villages with ECD centers were randomly allocated to one of two groups: intervention or

control. Children in villages in the intervention arm received SMC and home fortification with MNPs; children in villages in the control arm received neither intervention. A third comparison group of 30 villages without ECD centres (not randomised) were selected to evaluate the ECD program. In May 2014, surveys were carried out to compare nutritional status (anaemia, height and weight), the prevalence of malaria and child development indicators in the three groups. The survey showed a significant reduction in the prevalence of malaria parasitaemia, but no effect on anaemia or cognitive function, after one year of the intervention.[30] After the surveys in 2014, seasonal malaria chemoprevention was extended to include all 90 villages in the trial, as part of the national scale up by the Ministry of Health. Save the Children has continued to work to identify and implement improvements in the nutritional component of the intervention, and children in the original 30 intervention villages have continued to receive MNPs annually for the last 3 years. In October 2015, parenting education, including cognitive stimulation of children, was also added to the ECD programme in the intervention and control arms (villages with ECD centers), targetting all parents of children aged 0-5 years in the community.

The funding from the World Bank Strategic Impact Evaluation Fund (SIEF) enabled the extension of the study to evaluate the impact of the interventions on health, nutrition and child development over the longer-term. Thus, a second survey was conducted in May 2016, involving the same children as examined in 2014, to evaluate the impact of the health interventions (SMC+MNPs), together with the ECD parenting program, after three consecutive years of implementation. The second phase of the study is based on the design of the original cluster-randomized control trial used in the first phase, and was carried out in the same 60 communities with ECD centers in Southern Mali to examine impact on malaria, anemia, growth, cognitive function (attention), and early educational outcomes (cognitive-linguistic literacy and numeracy-related foundation knowledge and skills), allowing the "added value" of home-fortification program using MNPs compared to SMC+parenting intervention alone to be assessed. The study also assesses the cost and feasibility of using community-based ECD centers as the main platform for delivering health and nutrition services to children under five. Parallel to the randomised trial of MNPs, the same battery of cognitive tests was used to assess children in the third comparison group of 30 villages without ECD centers (non-randomised) to evaluate the impact of the ECD and parenting program on child development.

The SIEF-funded evaluation of the study, named Projet "Jigifa" which means "to fulfil hope" [combler des espoirs], was conducted in partnership with the London School of Hygiene and Tropical Medicine (LSHTM), UK; the National Institute of Public Health (INRSP), Malaria Research and Training Centre (MRTC), University of Bamako, National Directorate of Health (DNS), National Directorate of Pedagogy (DPN), National Directorate of Preschool and Special Education (DNEPS), National Malaria Control Program (PNLP), and Institut Polythechnique Rural de Formation et de Recherche Appliquee (IPR/IFRA) in Mali; University of Leeds, UK; Michigan State University, USA; and Sorbonne University, France A full list of the research partners can be found in Annex IV.

METHODS

III. THE INTERVENTIONS

Two new WHO-recommended interventions were implemented: (i) home fortification with micronutrient powders,[10] and (ii) seasonal malaria chemoprevention,[22] using community-based Early Childhood Care and Development (ECD) centers as the main platform for delivery to reach all children between 3-59 months resident in the community.

These two health-specific interventions were supplemented by (iii) a community-based educational intervention to promote parenting practices that support good health, nutrition, emotional and intellectual development of young children.

1) Home fortification with micronutrient powders (MNPs)

Vitamin and mineral deficiencies frequently occur simultaneously, and their combined effects during the critical period from preconception to 23 months of age may be associated with increased neonatal mortality and morbidity, as well as irreversible adverse physical and cognitive outcomes that lead to unfavorable lifelong consequences for health, productivity and economic growth.[10] Nutritional risk factors, including underweight, suboptimal breastfeeding, and vitamin and mineral deficiencies, particularly vitamin A, iron or zinc deficiency, are responsible for 3.9 million deaths (35% of total deaths) and 144 million disability-adjusted life years (DALYs) (33% of total DALYs) in children less than 5 years of age.[10] Micronutrient interventions, particularly vitamin A and zinc supplements for children, and fortification of foods with iron and iodine, are among the most cost-effective global efforts for health improvement and were identified as one of the best investments for advancing global welfare at the 2012 Copenhagen Consensus.

WHO now recommends home fortification of foods with multiple micronutrient powders to improve iron status and reduce anemia among infants and children 6-23 months where the prevalence of anemia in children under 2 years or under 5 years is 20% or higher.[10] Although good evidence exists showing the impact of micronutrient supplementation on health outcomes, there is little evidence of impact on developmental outcomes and school performance in preschool children.[31-33] Furthermore, no study has been carried out in the sub-region, nor in areas of high malaria transmission such as Sikasso. Although the use of micronutrient powders is generally well accepted, adherence is variable and depends on a strong community mobilization strategy to improve compliance.

2) Seasonal Malaria Chemoprevention (SMC) :

Seasonal malaria chemoprevention is a new approach recommended by the World Health Organization in 2012 which dramatically reduces the incidence of clinical malaria in children, preventing approximately 75-87% of all malaria episodes.[34-36] There is also evidence that this approach prevents anemia, hospital admissions, and all-cause mortality.[34] SMC is recommended in the Sahel region of Africa, where malaria transmission is highly seasonal and the majority of clinical malaria cases occur within a single four-month period.[22] SMC is an intermittent preventive treatment given to all children, irrespective of whether they show symptoms of malaria, to prevent the incidence of clinical malaria during the months of peak transmission. The antimalarial drug combination used is sulfadoxine-pyrimethamine, combined with amodiaquine given over 3 days. WHO recommends a maximum of four rounds of SMC treatment to all children aged 3-59 months, once per month during the peak malaria transmission season. The treatment is administered by local community health agents trained by the Ministry of Health.

Seasonal malaria chemoprevention is an important new malaria control initiative in the sub-region, with potential for major gains in child survival, and is currently being taken to scale in Mali and a number of other countries, across the Sahel region. Apart from this study, no other research to date has evaluated the longer-term impact of SMC,[37] nor the impact of SMC combined with a nutritional intervention. Initial trials focused on immediate health outcomes, and none examined whether there are any additional benefits for cognitive development during early childhood.

3) Early Childhood Development

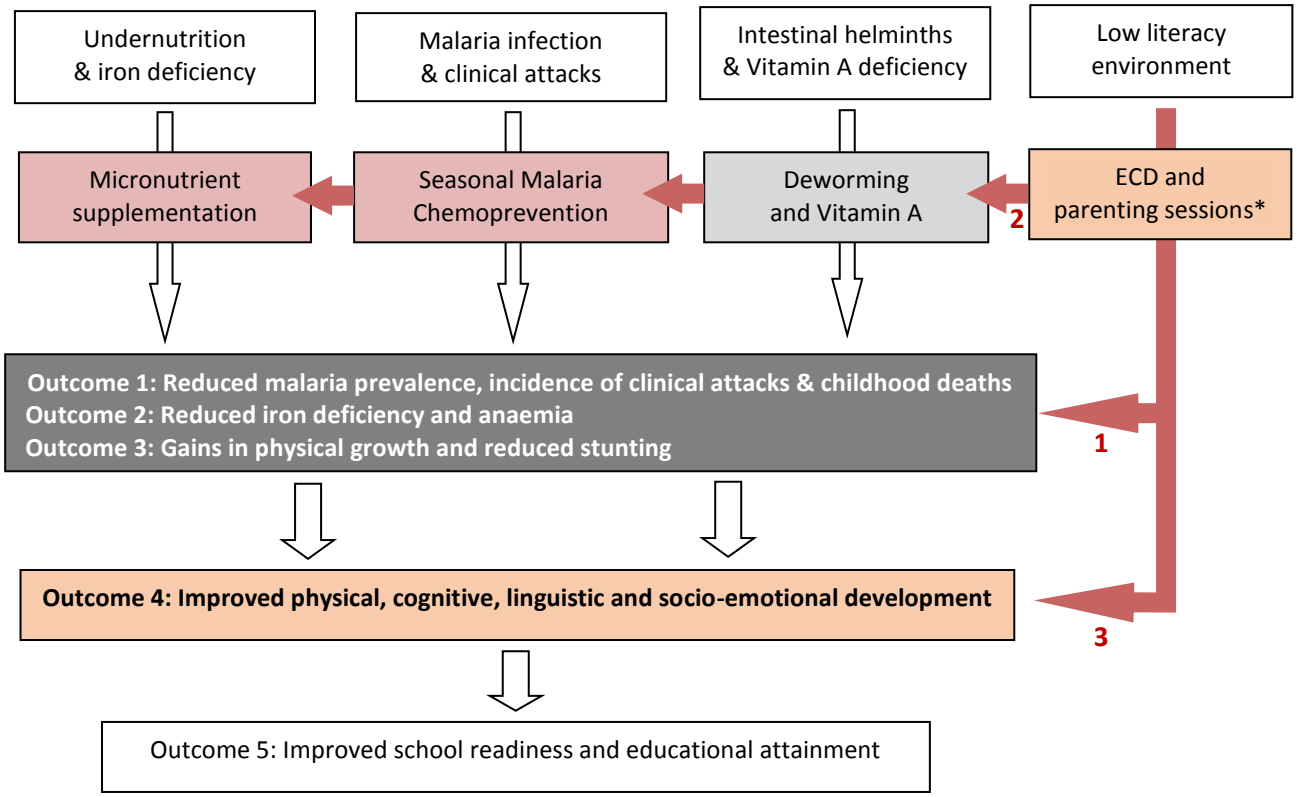
The MNPs and SMC were provided within the context of an existing Early Childhood Care and Development (ECD) program which by 2013 had reached 75 communities in the communes of Sikasso and Yorosso. The aim of the ECD program is to stimulate learning and creativity through the provision of an enriched environment within ECD centers, and activities designed to boost language and communication skills; awareness of basic mathematical concepts, simple reasoning and problem solving; physical, intellectual and socialization skills; in preparation for later school enrollment. Save the Children works with the training department of the National Directorate of Preschool Education (DNEPS) and Sikasso school inspectors (Conseillers CAP - Centre d'Apprentissage Pedagogique) to recruit and train voluntary mother educators (mères éducatrices) to run the ECD center supported by an ECD Management Committee. Adult literacy groups have been created in every ECD community to improve mothers' literacy and parenting practices.

Since October 2015, monthly parenting education sessions, using the tools developed for a national parenting education programme, have been introduced in all ECD communities targeting all parents with children under 5 years in communities with ECD centers. These sessions focus on health, nutrition, and early literacy, including how the home environment can be enriched for learning, caregiving practices, parent-child interaction, and child rights. Sessions are usually organised on a weekly basis to coincide with vaccination and antenatal clinic days (four sessions per month) and each session focuses on a specific theme. The topics of the sessions are usually selected by the parents.

IV. RESEARCH HYPOTHESIS

Home fortification with micronutrients and seasonal malaria chemoprevention and, combined with ECD programming and parental education will help a) reduce the incidence of clinical malaria, the prevalence of anemia and stunting amongst children less than five years and b) improve cognitive development and school readiness (see Figure 1)

Figure 1.**Hypothesised causal pathway:**



Note: The red boxes are addressed through the project and grey boxes through existing government programs (child health days).

* Since parenting sessions include messages on child nutrition practices, as well as how the home environment can be enriched for learning, and parent-child interaction, this intervention has potential to influence a number of points in the causal chain: through (1) improved parental knowledge of good nutrition practices; improved nutritional intake of children; (2) increased uptake/compliance of the three health interventions listed above; as well as (3) improved cognitive-linguistic stimulation of children and socio-emotional development.

V. OBJECTIVES

Overall Aim:
To evaluate the long-term impact and incremental cost-effectiveness of micronutrient supplementation (MNP), when combined with seasonal malaria chemoprevention (SMC) and early stimulation, delivered through community preschools and parenting sessions, on the health and cognitive development of children during the first five years of life.

Primary objectives :

1. To compare prevalence of anaemia [primary biomedical endpoint], prevalence of iron deficiency, and mean haemoglobin concentration between children resident in villages receiving MNP intervention combined with SMC and children resident in villages receiving SMC only, after three years of implementation
2. To compare prevalence of stunting, wasting, and underweight between children resident in intervention and control villages, after three years of implementation
3. To compare impact on child development at 3 years, 5 years and 7 years through assessment of cognitive foundation skills for learning [primary developmental endpoint], language skills and other aspects of school readiness in children in intervention, ECD control villages and non-ECD communities (without ECD and parenting education)
4. To estimate the incremental costs and cost-effectiveness of adding micronutrient supplementation to current practice (seasonal malaria chemoprevention) in ECD and non-ECD communities

Secondary objectives:

5. To assess the effectiveness and feasibility of using ECD centres as a community platform to deliver micronutrient supplementation, including levels of coverage achieved and equity of the approach.
6. To compare the proportion of children progressing to primary school at the appropriate age (before 6 years of age) in October each year in intervention, ECD control villages and non-ECD communities.
7. To examine the effect of the parenting intervention on intermediate outcomes, such as parenting practices and home environment, to support health, nutrition and cognitive development.

VI. STUDY AREA AND POPULATION

The study was undertaken in the administrative cercles of Sikasso and Yorosso in the region of Sikasso, the southern-most region of Mali, which has the highest rainfall and largest agricultural production. It is often called the bread basket of Mali, yet, it is also the region with the highest levels of malnutrition: 40**%** of children under 5y are stunted, 13% wasted, and 85% are anemic. It is also the region with one the highest burden of malaria with 62% of children 6-59 months infected, compared to 52% country wide.[24]

Sikasso cercle is 15,000 km^2 with a population of close to 800,000. It is home to the second largest city in Mali, Sikasso which has rapidly grown in recent years with immigration from Ivory Coast and Burkina Faso. Yorosso cercle is just 5,500 km^2. The main ethnic groups include the Senoufo, Samago and Bambara with a local economy primarily based on farming (cotton, potatoes, mango, millet and tubercules). Primary school enrolment was 59% in 2016.

Save the Children's child sponsorship programme in Mali has been running since 1987; the programme has been operating in Sikasso cercle since 2007 and in Yorosso cercle since 2008. The child sponsorship scheme is a long-term funding source which supports five programme areas: early childhood development, basic education, school health and nutrition, adolescent sexual and reproductive health, and livelihood. Save the Children's theory of change is to work in partnership with government, academia and civil society to build evidence and use this evidence to advocate for and support scale up. The sponsorship programme now reaches 40 communes with 92,241 children in Sikasso and Yorosso cercles, with the ECD programme reaching 75 communities.

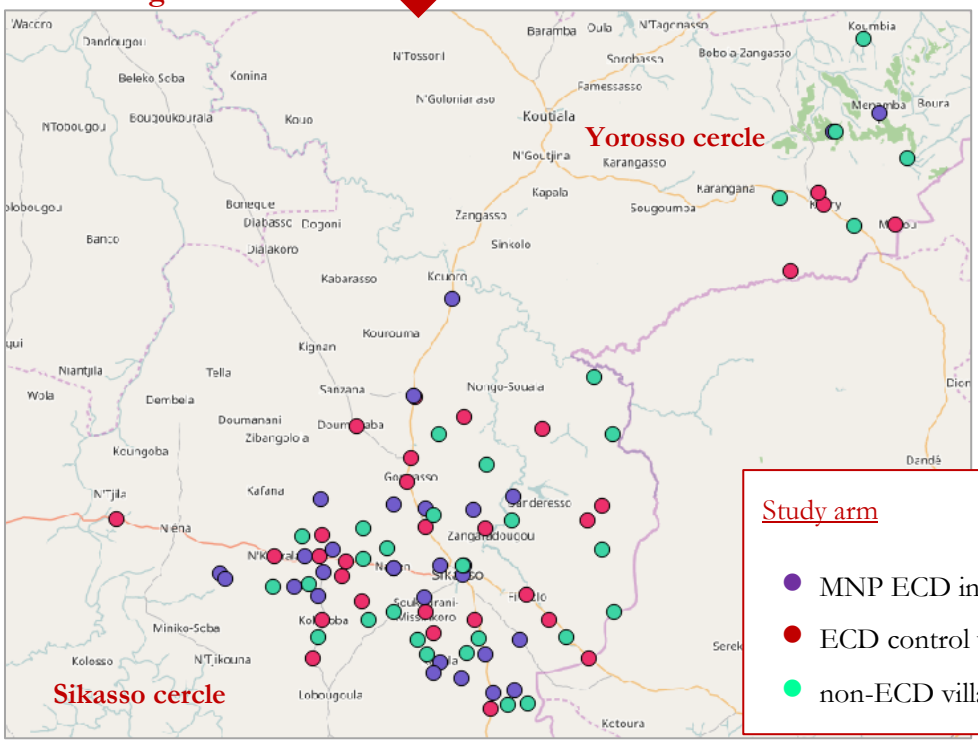
Target beneficiary population for the intervention:

Established community and/or ECD infrastructure was used to deliver the malaria, nutrition and parenting interventions to all children resident in the community, including children not enrolled in an ECD program. The target population for the interventions thus comprised all children aged 3 months to 5 years, who were resident in the 90 communities that consented to participate in the study in Sikasso and Yorosso cercles in southern Mali (Figure 2).

- All children within this age group living in the 30 communities with ECD centers that implemented the MNP intervention (intervention arm) were eligible to receive the micronutrient powders.
- Seasonal malaria chemoprevention (SMC) and the parenting program are both national policies in the process of being scaled up by the Government of Mali. SMC has therefore been implemented in all 90 communities (all three arms) since August 2014, and the parenting intervention implemented in the 60 communities with an ECD centre (intervention arm and ECD control group) since October 2015.

Figure 2. **Location of study villages in Sikasso Region, southern Mali**

Sikasso Region



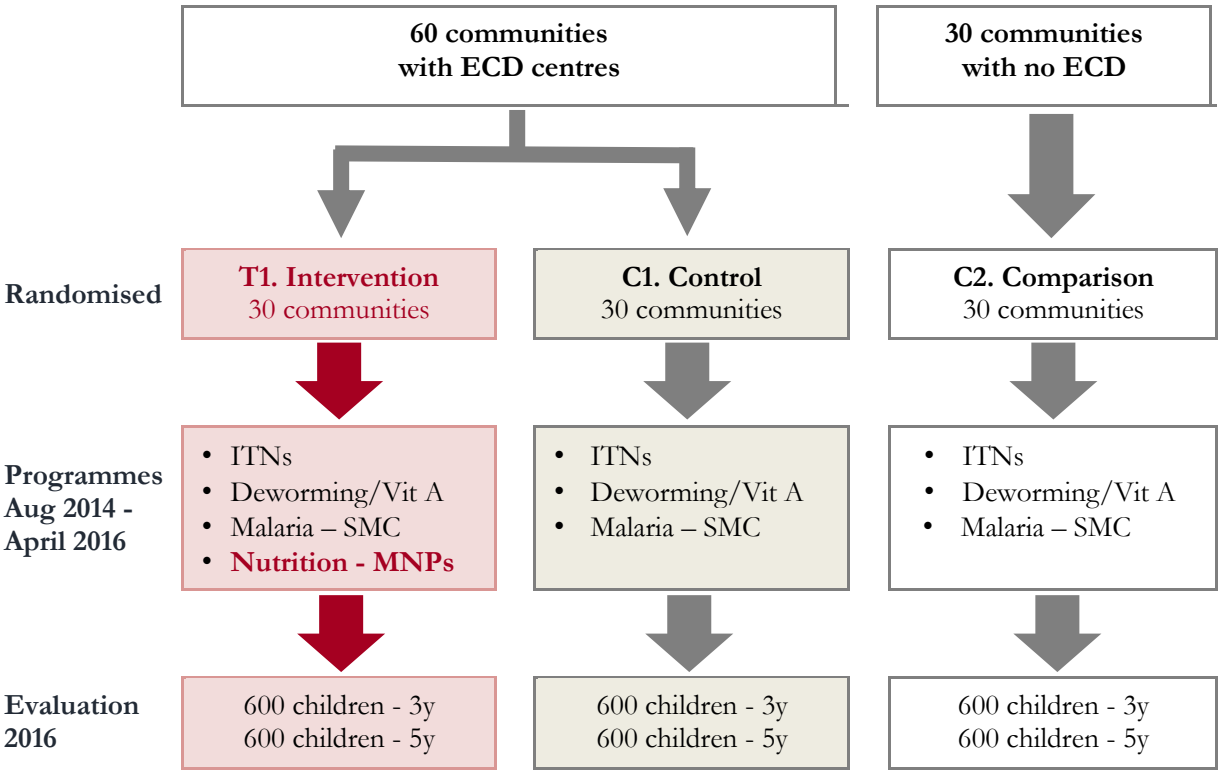
VII. IMPACT EVALUATION DESIGN

Trial Design

This was an open label, cluster randomized, controlled trial to investigate the health and educational outcomes of seasonal malaria chemoprevention (SMC) and micronutrient supplementation (MNP) delivered through Early Childhood Development (ECD) centers in 90 communities in southern Mali. The aim of the study is to evaluate the effectiveness of these interventions in improving the health and development of children under the age of five years.

The overall study comprises three arms: two randomized arms and one additional non-randomized comparison arm, as summarized in figure 3 below.

Figure 3. **Treatment and comparison groups, and intervention(s) received by each group**



- The two randomized arms comprise children resident in 60 rural communities with functional ECD centers in the cercles of Sikasso and Yorosso. Of these 60 villages, 30 were randomly allocated in 2013 to receive the full package of interventions, including micronutrient supplementation [intervention group, T1], and 30 were randomized to the current practice control group [ECD control group, C1]. Thus, by May 2016, children resident in intervention villages had received MNPs for 3 consecutive years.
- At the same time, a third group of 30 non-ECD communities were also recruited into the study and used to evaluate the impact of the ECD parenting program [non-ECD comparison group, C2].

All groups have received seasonal malaria chemoprevention, deworming and vitamin A, in accordance with national policy (current practice).

The interventions that each group received are summarized in Table 1 below.

Table 1. **Summary of interventions by study arm: 2014-2016**

T1. Intervention group	• **Home fortification with micronutrient powders** • **ECD centers and parenting education** • Seasonal malaria chemoprevention • Deworming and vitamin A (by the government)
C1. ECD control group (current practice)	• **ECD Centers and parenting education** • Seasonal malaria chemoprevention • Deworming and vitamin A (by the government)
C2. Non-ECD comparison group (current practice)	• Seasonal malaria chemoprevention • Deworming and Vitamin A only

T1 vs C1: **The main focus of the impact evaluation is the statistical comparison of trial endpoints between the two randomized arms of the trial**.
Randomised allocation of communities with ECD centres to arms T1 (intervention) and C1 (ECD control group C1, current practice arm) generates a random comparison group to serve as the counterfactual, helps prevent selection bias and minimizes risks of confounding between intervention and control group.[38] Randomisation ensures that these communities are comparable in all respects except for the intervention of interest (MNP) in order to evaluate the impact of adding MNP to the minimal intervention package of SMC and parenting in ECD communities. The results are generalisable to communities with an ECD centre.

Note: This report presents the statistical findings from the SIEF-funded comparison of biomedical and cognitive outcomes at endline in these two randomised arms (T1 vs C1)

Evaluation of outcomes in children living in non-ECD comparison communities (C2) permits the following additional research question to be addressed:

C1 vs C2: The inclusion of the non-ECD comparison group also provides an additional opportunity to examine the effectiveness of the new parenting intervention as it is rolled out. The comparison of arms C1 vs C2 (ECD control vs non-ECD comparison group), enables us to evaluate the impact of the ECD program and parenting intervention on intermediate outcomes, compared to villages without an ECD program, to help inform development of the program. The focus of this evaluation will be a comparison of intermediate outcomes, such as home literacy environment, parent-child interactions, and nutrition and health related behaviours, measured through a parent questionnaire. Nutrition and cognitive outcomes will also be examined, but as this is a new program and the size of the effects may be smaller than between T1 vs C1 above, the trial may not be powered to detect statistical significance. Furthermore, since communities without ECD centres were not randomly assigned to this additional comparison group and may differ systematically from communities with ECD centres, any conclusions drawn should take this into account.

Note: These findings are therefore not included here, but will be reported elsewhere.

Allocation rule for treatment and comparison groups:
In 2013, 60 rural communities with functional ECD centers were randomly allocated to the intervention or ECD control arm, using a computer-generated random list. The unit of randomization was the village, with all children aged between 3 months-5 years resident in participating communities eligible to receive the interventions.

The additional 30 communities for the non-ECD comparison arm were selected randomly from amongst communities that met the following inclusion criteria: 1) no ECD centre; and 2) no plans to establish an ECD centre in that community in the next 2-3 years.

Sample population for the evaluation:
For the purposes of assessing the impact of the interventions, children were assessed for biomedical outcomes and performance in tests of cognitive function and school-readiness at the end of the intervention period. For the assessment, a random sample of children aged 3 years, and a second sample of children around the age of starting school (5-6 years) were selected from each community participating in the trial.

The random sample comprised a cohort of 40 children per village: 20 children aged 3 years recruited in May 2014 who would thus be around the age of starting school (5-6 years) by the time of the endline evaluation in 2016; with an additional cohort of 20 children born in January-July 2013 recruited in February 2015 who would be around 3 years of age by the time of the evaluation in 2016 (total sample 40 children per village).

Table 2. **Age cohorts (intervention communities)**

Age at baseline in May 2014	**Age at endline in May 2016**	**Period of exposure to interventions**
1 year old	3 years	Received three years of treatment from age 3 months - 2 years of age during 2013-2016. This cohort of children will have received the interventions since birth, within first 1000 days of life.
3 years	5 years (prior to school entry)	Received three years of treatment from age 2-4 years during 2013-2016

Outcome data were collected through cross-sectional surveys in May 2016 in a random sample of children resident in intervention and control communities, according to the following eligibility criteria:

Inclusion criteria
a. All children in the study communities who were previously randomly selected and enrolled in the surveys in 2013 and who are still resident in the same village in 2016. This sample comprised children who were aged 1 year and 3 years in 2014 (see table 2 above).
b. In villages where losses-to-followup meant it was not possible to trace sufficient number of children from the original sample to meet the required sample size per cluster, additional children were recruited in 2016. New recruits were selected at random from the list of children resident in the village at the time of the original census in 2013. All new recruits had thus been resident in the village and exposed to the interventions throughout the 3 preceding years.

Exclusion criteria
a. Parent/guardian did not wish their children to participate in the survey

VIII. DATA COLLECTION AND INDICATORS

The following outcomes were measured in May 2016:

Impact on nutritional status:	• Prevalence of stunting, wasting and underweight • Prevalence of anaemia (Hb<11g/dL); mean Hb • Prevalence of iron deficiency
Other impacts on health:	• Prevalence of asymptomatic malaria parasitaemia
Impact on child development:	• Cognitive and linguistic development (with a focus on cognitive foundation skills for literacy and verbal fluency) • School readiness (awareness of print, linguistic and mathematical concepts; physical and socio-emotional development) – measured in children aged 5 years

a. Measurement of biomedical outcomes

Data on nutritional status and other health outcomes were collected in June-July 2016 at the end of the ECD school year. These surveys were time to coincide with the end of the dry season and the start of the rains, and the beginning of the next malaria transmission season – and thus measure the maximum impact on anaemia that would be expected to be achieved by the interventions.

Weights were measured using an electronic scale; and height measured using a stadiometer. Height-for-Age, Weight-for-Age and Weight-for-Height Z scores (HAZ, WAZ and WHZ) were computed with reference to WHO standard population using Anthro (version 3.2.2, 2011). The prevalence of stunting and underweight were defined as a height-for-age less than -2 SD from median of WHO reference population, and weight-for-age less than -2 SD from median of WHO reference population, respectively. Acute malnutrition in five-year olds was defined as BMI-for-age less than -2 SD from median of WHO reference population, and in three year olds as weight-for-height less than -2 SD from median of WHO reference population.

A finger prick blood sample was obtained from each child surveyed to assess infection by malaria parasites and prevalence of anaemia. Haemoglobin (Hb) concentration was measured using a portable Hemocue® photometer; quality control was carried out daily using a standard microcuvette or control blood sample of known Hb concentration. Complementary biomedical analyses were undertaken using a Hitachi Cobas c311 machine to measure serum ferritin, C-reactive protein (CRP), acid glycoprotein (AGP) and soluble transferrin receptor (sTfR). The procedure for the collection and analysis of blood was as follows : A 250-600µl capillary sample was collected from the finger of each child ; of which 16 µl of blood was used to prepare thick and thin blood films to measure malaria parasite density; 20 µl to measure haemoglobin concentration and the remaining 200 µl placed in a microcontainer and transported in a coolbox (2-8ºC) to the laboratory in Sikasso. The samples were centrifuged for >10 minutes at 6,000-15,000g to produce 125-350 µl of plasma and frozen at -20 ºC before transport to Bamako, where the samples were stored at -80 ºC until biomedical analysis to measure serum ferritin, CRP, AGP and sTfR. Malaria infection was measured through examination of thick and thin blood films, stained with 10% Giemsa for 10-15 minutes. The number of asexual malaria parasites/µl blood was estimated against 200 leucocytes, counted using light microscopy. Malaria infection status was defined as the presence of trophozoites and/or schizonts of any species in a thick blood film examined at x100 magnification.

Slides were declared negative after examination of 100 high-power fields. All blood slides were examined twice by two experienced research technicians. Any discrepancies between the first two results were subject to a third independent reading, blinded to the results of any prior readings.

We did not use placebo tablets, but precautions were taken to blind evaluators to the intervention status of communities. Measurement of study outcomes were undertaken using standardized tests by independent field teams unaware of which communities have received the intervention. Slide microscopy was likewise performed by technicians blinded to the intervention status of communities, and data analyzed in London by research staff blinded to intervention status of communities.

The primary endpoint is the prevalence of anemia, defined as a haemoglobin (Hb) concentration <110g/L. Secondary health outcomes include: prevalence of moderate-to-severe anaemia, defined as a haemoglobin (Hb) concentration <110g/L; prevalence of stunting, underweight and acute malnutrition; and haemoglobin concentration in g/dL. Summaries of the following additional health outcomes by study arm will be reported, but no statistical test for an intervention effect will be performed: height-for-age z score (SD from median of WHO reference population); weight-for-age z score; BMI-for-age z score; weight-for-height z score (measured in three year olds only); prevalence of malaria infection (presence of trophozoites and/or schizonts of any species); malaria parasite density (intensity/μL of trophozoites and/or schizonts) and malaria infectivity (presence of gametocytes of any species).

b. Measurement of cognitive outcomes and indicators of school readiness

Cognitive-linguistic literacy and numeracy-related foundation knowledge and skills were assessed in children aged 3 and 5 years at endline in May 2016 in intervention and control communities, to provide data on the impact of the malaria and nutritional interventions on cognitive development at the time that children transition into and out of the ECD center to primary school.

A battery of tests was developed for each age to assess cognitive-linguistic literacy and numeracy-related foundation knowledge and skills in children aged 3 and 5 years; adapted from existing tests which have previously been used in children of the same age. All instruments were adapted for local language and culture, and pre-tested in Mali to confirm their developmental appropriateness for the age group to be tested (see Annex III for further details). The same tests were used in 2014 and 2016. Children were assessed individually by trained assessors using a standard set of instructions; with assessments conducted in the child's mother tongue.

- In older children (aged 5 years), assessments of child development focussed on cognitive-linguistic skills known to predict the ease with which children acquire literacy and numeracy skills at school.[39-48] The assessment battery included tests of cognitive skills known to be precursors of early literacy skills in alphabetic writing systems, assessed using the rapid automatised naming (RAN) task[39-43] and expressive vocabulary. To explore the evidence for previously reported associations between health and nutrition interventions and improved outcomes in cognitive function, the assessment battery also included the head-shoulders-knees-toes (HSKT) task to assess executive function,[46-47] and the digit span test, as a measure of verbal short-term memory.[49-51]
- Among 5 year old children, other core dimensions of school readiness were also assessed using a subset of tasks from an early version of the International Development and Early Learning Assessment (IDELA) tool developed by Save the Children to examine differences in early literacy and numeracy skills (concepts about print, oral comprehension, letter and number recognition, basic number concepts); fine and gross motor skills; and socio-emotional

development. IDELA was compiled using multiple sources and existing validated tools, including the Early Development Instrument, East Asia-Pacific Scales of Child Development, Ages and Stages Questionnaire, Denver Scale, Early Learning Development Standards from a number of countries, and other tools previously used by Save the Children country offices to measure school readiness. Task items were selected with an eye to feasibility, cultural and program relevance, and adapted, tested and adapted again in a variety of settings to ensure appropriateness for a developing country context. The selection of measures was also informed by research evidence on early childhood development, knowledge and skills known to predict subsequent education outcomes.[52-54]

- In younger children (aged 3 years) assessments focussed on developmental milestones, including gross and fine motor skills, cognitive and spoken language development using a small subset of the tasks from the cognitive battery and IDELA used with the 5 year olds (adapted for younger age).
- In all age groups, a caregiver questionnaire was used to capture data on the home literacy environment. This questionnaire drew primarily on the Multiple Indicator Cluster Survey (developed by UNICEF) but included additional dimensions and questions that match Save the Children's programmatic focus and specific questions on SMC and MNPs (see annex VI).

The cognitive battery used for 5-year old children is summarised in Table 3 below.

Table 3. **Cognitive battery (including IDELA Tests) administered**
A description of each test can be found in Box I below.

Expressive vocabulary (number of words) – from IDELA
Rapid automated naming time (seconds)
Digit span (maximum digit span**)**
Mixed instructions (number correct) – from IDELA
Heads, shoulders, knees and toes (total score)
Listening comprehension (max 8 correct) – from IDELA, locally adapted
Letter recognition (max 20 correct) – from IDELA
Number recognition (max 20 correct) – from IDELA

Box 1. **Description of cognitive and child development assessments**

Expressive vocabulary (number of words) *(from SC's IDELA, locally adapted)*
This task is a measure of expressive oral language, but as a measure of verbal fluency, it is also recognised to tap executive function skills. In this task children were asked to verbally produce words which belonged to a predefined category. The first practice category was 'names of clothes, things people wear'. There were two test categories. The first category was 'food' ('name some things you can eat that you can buy from market'). The second category was 'animals'. The child was given 60 seconds for each category and the assessor recorded the child's spoken responses. The score was the total number of words produced that belonged to the category (not including repetitions). An overall total score was calculated by summing the scores for the two test categories.

Rapid Automated Naming (RAN) – objects *(locally adapted to use culturally appropriate images)*
Children were asked to name a series of pictured objects (animals) in a grid comprising 4 rows of 6 objects each (24 objects in total). This format for the RAN task with a reduced set of items relative to the paradigm traditionally used with school age children, has previously been found to be reliable for children in the target age, all be it in other country contexts (e.g., Lei et al. 2011; Pan et al. 2011). They initially completed a familiarisation task, where they simply had to name each object. If they did not know the name of the object on the first practice trial, they were given feedback and told the correct name. On the second practice trial, if they failed to name any of the practice items the test was discontinued. The total time (sec) taken to name the 24 pictures was recorded. Children repeated a second trial, and the total score was the average time (sec) across the two trials. Naming errors (including non-responses) were also recorded.

Forwards Digit Span
In this measure of verbal short-term memory (or working memory) children were presented auditorally with lists of digits, gradually increasing in length, and were required to repeat list in the same order. Children started with a list length of 2 digits (e.g., '3-1'; span 2) and were given a set of 4 trials at this length (pausing for one second in between each digit in a sequence). If they were correct on at least 1 out of the 4 trials, they continued to the next list length of 3 digits (e.g., '2-5-1'; span 3). The test was discontinued after children made errors on ALL 4 trials for a set. Children obtained a credit of 0.5 for each correct trial to calculate the maximum list length (or span) for the task. A set of 4 practice trials was completed with feedback if incorrect. The instructions and the list of numbers were presented in the child's local (maternal) language. Span scores were calculated and used in the data analyses.

Mixed instructions *(from SC IDELA)*
This measure of behavioural inhibition (executive function) is from Save the Children's IDELA. Children had to inhibit their natural inclination to follow motor/hand actions ('tap on the table' or 'clap your hands'), and do the opposite action to the adult. The number of times that the child correctly responded to the instructions for six trials (max 6 – 1 point per trial) was recorded, and performed the opposite action to the adult. Practice trials required the child to repeat the game with feedback 3 times, to make sure they understood the instructions.

Head, Toes, Knees and Shoulders (HTKS) task
(adapted from Burrage et al., 2008; Cameron & McClelland, 2011)
In this measure of behavioural inhibition the child was first asked to touch their head and then their toes. Once it had been established that they could perform this action they were instructed to do the opposite of what the examiner said (e.g. touch their toes if asked to touch their head and vice versa). The child had four opportunities to practice this, with up to 3 re-explanations of the directions. They then completed a block of 10 test trials with no feedback. If the child was able to successfully inhibit on 5/10 trials they went on to complete a further block of harder trials. For these trials, additional commands to touch their shoulders and knees were added and the child was reminded to do the opposite of what the examiner said (e.g. touch their shoulders if asked to touch their knees and vice versa). After four practice trials the child completed 10 further test trials involving all these two commands in a predetermined, pseudorandom order. Each correct response received 2 points, self-corrected responses (partial inhibitions; where the child moved towards the incorrect, intuitive response but demonstrated the correct final response) received 1 point and incorrect responses received 0 points (max score = 40).

Oral comprehension *(adapted from IDELA version)*
Children listened to a short story read aloud by the field officer in their local language, and were then required to answer short questions about the story (presented in spoken form). Children

were asked 8 questions in total – 7 questions each worth 1 point, and one question worth 2 points (max. score 9). However, due to a technical error for one item (#7) where large proportion of children were recorded with an erroneous response, data for this item was removed from the analysis, resulting in a possible maximum score of 8 on the test.

Letter identification *(from SC IDELA)*
Children were shown a grid containing 20 common letters and asked to say the name of each letter. Each letter correctly named was given 1 point.

Number identification *(from SC IDELA)*
Children were shown a grid containing 20 numbers. They were asked to say the name of each number in the grid, with each correctly named number given 1 point. The score for each child was the number correct out of a possible score of 20.

General Procedure
Two sets of assessments were programmed in ODK and uploaded onto a smartphone for each field worker to use: (i) the assessment battery for the 5 year olds, which included the cognitive tests described above, as well as the IDELA assessment items for the 5 year olds, and (ii) a shorter set of cognitive assessments and IDELA items for the 3 year olds. All instructions for the set of cognitive and IDELA tests were translated into French-Bambara, French-Shenara, French-Mamara. The instructions in French were administration instructions for the assessor, but all communication with the child, including the instructions the child received, was in one of the local languages (Bambara, Shenara or Mamara) to correspond with the child's mother tongue. The language used in the assessments was typically also the same as the language used in the local ECD center, which used the most commonly spoken language in the village for instruction. As the villages usually comprise people of the same ethnic group there is generally only one language spoken in each village. Thus, the chance that a child was not familiar with the language used by the assessor, whilst possible, should have been quite small. Each assessor was also equipped with a set of laminated stimuli cards for the cognitive and IDELA tests, plus stop watches, notepad and pencils, stickers for rewarding children, and a cloth bag.

Background information was recorded at the start of each assessment, including a unique ID code, the child's age, village of residence, and other identifying information and the maternal language used in the home. All field officers had knowledge (spoken and receptive) of Bambara and approximately half of the field officers had additional knowledge and experience using Shenara. A smaller group of field officers were also fluent in Mamara - the common local language used in Yorosso district, together with Bambara.

At the end of the assessment for each child, field workers recorded any important observations or field notes for subsequent data cleaning. For example, if the child was unwell or if they struggled to maintain attention when completing the tasks during the assessment session.

Measurement of cognitive outcomes were undertaken using standardized tests by independent field teams unaware of which communities have received the intervention, and data analyzed in London by research staff blinded to intervention status of communities.

Training of Field Officers to administer cognitive and child development assessments
The 32 field officers who would administer the cognitive and IDELA assessments received training over a one week period in Sikasso a few weeks preceding the start of the field work. Half of the

field officers (15/32) were teachers, educational advisors or school inspectors working for the Ministry of Education regional education government offices; and had substantial prior experience working with children in education settings, and using education based assessments of academic skills.

Training on administering the cognitive and IDELA assessments was provided by two members of the research team from Save the Children, experienced in literacy assessments and electronic data collection on smartphones using the ODK software; with additional training support provided by two research staff from LSHTM (Project PI and data manager). Field officers received three days training in the Sikasso office, first with paper versions of the assessments, and then role playing using the tablets to administer and record the responses. They then completed two days of training in the field - one day on the administration of the cognitive assessments for the 3-year olds and one day on the administration of the cognitive assessments in 3 year olds, in villages which were not participating in the trial. Members of the core team (LSHTM research staff, Save the Children trainers and project manager) observed the field officers during training at the office and in the field, providing feedback when appropriate. Briefing sessions took place at the end of each session, with the opportunity for the local field workers to ask questions and comment on the assessment tools, contributing to the adaptation of these assessment tools for use in the Malian context and with children of the target age.

Collection of data on school and household covariates:

A structured parental questionnaire was administered in May 2016 to capture data on educational, socio-economic and home literacy environment for each child selected for inclusion in the evaluation surveys.

IX. STATISTICAL ANALYSIS

The primary analysis was an intention-to-treat (ITT) analysis performed on data taken from a cross sectional follow-up surveys in May-July 2016. Data were analysed according to the study arm communities were randomised to, irrespective of whether the intervention was implemented in the community or not and the degree of coverage achieved, whereby outcome data from all children surveyed was included in the analysis, regardless of whether they received the intervention or not. The ITT approach provides an estimate of the impact of the interventions which most closely approximates the true effectiveness that would be achieved under routine operational conditions.

Statistical methods

Methods appropriate to cluster-randomized trials were used.[55] It was expected that due to the randomization process that there will be few differences in baseline characteristics between study arms, nonetheless all factors considered important prognostic factors with the potential to be highly correlated with the outcome were pre-specified and adjusted for in the analysis. The demographic and other household characteristics of children are compared to check for imbalances between study arms, and to confirm whether the randomization process was effective. No significance tests were performed to test for differences between groups at baseline, as this is not recommended.[55] Child characteristics compared include the following: mean age, sex, language spoken in the home, maternal and paternal education/literacy, presence of reading materials in the home, presence of games/toys in the home, household socio-economic characteristics and use of a mosquito net, and whether child is enrolled in ECD centre. Descriptive statistics for continuous variables include the number of observations, mean and standard deviation (or median and interquartile range as appropriate). Categorical variables are presented as numbers and percentages.

All trial outcomes were measured at child level. Therefore, wherever possible, statistical analysis was performed at child level and accounts for clustering of children within communities by including a random effect of school in mixed effect models (or other appropriate statistical method). If, due to the nature of the data, it was not possible to perform the analysis at child level, statistical analysis was performed at the community level using appropriate statistical methods for cluster level summaries.

All analyses account for the nature of the distribution of the outcome (for example, continuous outcomes are analysed using linear regression and binary outcomes are analysed using logistic regression) and reported using appropriate measures of effect and 95% CIs. Additional methods are used to analyse continuous measures which are not normally distributed (for example, 95% CI will be estimated using the bootstrap method). To minimise statistical concerns of multiplicity/multiple comparisons, no more than 10 outcomes (including the primary outcome) are considered for formal statistical testing at the 5% level. The number of secondary outcomes that will be tested for significant differences between arms is thus small and no formal adjustment for multiple comparisons will be made.

Unadjusted and adjusted results are presented for all analyses. Covariates for inclusion in adjusted analyses were specified *a priori*. For health outcomes, this included the following covariates: sex, language spoken in the home, maternal literacy, household socioeconomic status, and malaria infection status at endline. For adjusted analyses of cognitive/educational outcomes the following covariates were specified *a priori*: sex, language spoken in the home, maternal literacy, household socioeconomic status, and whether the child was enrolled in an ECD centre. A number of measures were also collected to assess levels of exposure (compliance and intensity) to the interventions.

Age groups

As mentioned above, the study was powered to answer the research questions separately for children around the age of entry to an ECD centre (approximately three years) and around the age

of starting school (approximately five years). Statistical analyses were thus performed separately on data from children in the three-year and five-year age groups.

Although both age groups are of equal interest, uncertainties relating to the validity of the cognitive outcomes for three year olds (arising from inherent difficulties of working with very young children, such their natural shyness with unfamiliar adults and limited communication skills at this age), means that analysis of the cognitive outcomes for this age group will be regarded as exploratory in nature and p-values and 95% confidence intervals should be interpreted with due caution. Outcomes and statistical methods will be identical to those used for the analyses on the five-year olds.

X. SAMPLE SIZE

Power analysis was undertaken for a comparison of two arms, taking account of clustering by community.[55] Survey data on biomedical and cognitive outcomes collected in 2014 were used to check the original sample size assumptions in the Technical Proposal, including prevalence of primary outcomes, intraclass correlation (ICC) and number of children recruited into the two age cohorts per cluster.

- Prevalence of anaemia at baseline amongst 3-year old children was found to be 61.6% and 64.0% in the intervention and control arms respectively (p=0.618) and 53.8% and 51.9% respectively amongst 5-year old children (p=0.582). The observed ICC for anaemia endpoint at baseline was 0.08 in 3-year old children and 0.06 in 5-year old children, confirming the lowest ICC assumption used in sample size calculations to be correct.
- Observed ICC for cognitive outcomes was 0.09, ranging from 0.05 to 0.16 for individual tasks within the cognitive battery. This was consistent with the ICC assumption used in original sample size calculations.

Based on the observed ICC, power calculations were undertaken to confirm the sample size required for the endline surveys. The results of these calculations are shown in Tables 4a and 4b.

Sample size estimation for health outcomes

Sample size estimation for health outcomes focused on the percentage of children who are anemic. Approximately 20-25 children per cluster were recruited into each age cohort in 2013. Power calculations for anaemia were undertaken for three alternative scenarios at endline: (i) to allow for the possibility of up to 20% loss to follow up (due to outmigration, child death or non-participation of children enrolled in 2014) between 2014 and 2016, power calculations were performed for a sample size at endline of 16 children per cluster; as well as for (ii) a smaller cluster size of 14 children sampled per village, under a scenario of a higher loss to follow-up of 30%, and (iii) unequal clusters, to allow for the possibility for variation in losses to follow-up between villages, where cluster size is the mean number of children sampled.

Table 4a. **Sample Size Calculation for Anemia (primary endpoint)**

	Original Scenario 2		**Original Scenario 1**		**Revised scenario A**		**Revised scenario B**	
	80% power		**80% power**		**80% power**		**80% power**	
Assumptions	**Equal clusters**	**Unequal clusters**	**Equal clusters**	**Unequal clusters**	**Equal clusters**	**Unequal clusters**	**Equal clusters**	**Unequal clusters**
Number of clusters per arm	30		30		30		30	
Cluster size	20		16		14		14	
Intra-cluster correlation	0.08		0.08		0.08 (3 year olds)		0.06 (5 year olds)	
Significance level (α)	0.05		0.05		0.05		0.05	
Total sample size in each age cohort	1,200		960		840		840	
Prevalence (control)	50%		50%		50%		50%	
Detectable prevalence (intervention)	**37.2%**	37.0%	**36.6%**	36.5%	36.2%	36.1%	37.1%	37.0%
Minimum detectable reduction in prevalence	**25.6%**	26.0%	**26.8%**	27.0%	27.6%	27.8%	25.8%	26.0%

Thus, assuming a conservative prevalence of 50% in the control group and an intraclass correlation (ICC) of 0.08, a sample size of 30 communities per arm with 14-20 children sampled per community, will under all of these scenarios provide 80% power to detect a reduction in anemia of at least 28% at 5% level of significance.

Sample size estimation for cognitive outcomes

Power calculations for cognitive outcomes also explored: (i) a smaller cluster size of 14 children sampled per village, for example resulting from a higher than expected loss to follow-up of 30%; (ii) statistical analysis of differences between arms which does not adjust for baseline - a scenario which allows for the possibility to increase the sample size to compensate for losses to follow-up by increased recruitment of new children for whom no baseline data would be available. Power calculations are also shown for (iii) effect of unequal clusters, to allow for the possibility for variation in losses to follow-up between villages, where cluster size is the mean number of children sampled.

Table 4b. **Sample Size Calculation for Cognition Outcomes**

	Original Scenario 2	**Scenario 2 Not adjusting for baseline**		**Original Scenario 1**	**Scenario 1 Not adjusting for baseline**		**Revised scenario Adjusting for baseline**	
	80% power	**80% power**		**80% power**	**80% power**		**80% power**	
Assumptions	**Equal clusters**	**Equal clusters**	**Unequal clusters**	**Equal clusters**	**Equal clusters**	**Unequal clusters**	**Equal clusters**	**Unequal clusters**
Number of clusters per arm	30	30		30	30		30	
Cluster size	20	20		16	16		14	
Intra-cluster correlation	0.10	0.10		0.10	0.10		0.10	
Significance level (α)	0.05	0.05		0.05	0.05		0.05	
Total sample size in each age cohort	1,200	1,200		960	960		840	
Correlation with baseline values	25%	n/a		25%	n/a		25%	
Minimum Detectable Effect (Standardised Effect Size)	**0.27 SD**	0.28 SD	0.28 SD	**0.28 SD**	0.29 SD	0.295 SD	0.29 SD	0.29 SD

Thus, for cognitive-linguistic skills, a sample size of 30 communities per arm with 14-20 children in each age cohort sampled per community will provide 80% power to detect an effect size between 0.27-0.29 at 5% level of significance, assuming an (ICC) of 0.10 and individual, household and community-level factors account for at least 25% of variation in cognitive foundation skills. **Whilst for a similar sample size of 30 communities per arm with 14-20 children sampled per community and ICC of 0.10, a statistical analysis which does not adjust for baseline will provide 80% power to detect an effect size between 0.28-0.30 at 5% level of significance.**

In addition to the reviewing the sample size requirements, field procedures for the endline surveys 2016 were revised with the aim to reduce the ICC further and thus increase power - through the provision of clearer guidelines and improvements to the training of assessors in order standardize administration of the tasks, prior to implementation of the endline surveys. Particular attention was paid to improving the administration of tasks which had the highest ICCs at baseline.

All analyses will be according to intention-to-treat, and all children will be included in the analysis irrespective of whether they actually received the intervention or not. This approach provides a realistic estimate of the intervention effect in randomized trials, as the level of take up is taken into account in the analysis. As ITT recognizes that take up may be less than 100%, the power calculations and MDE do not need to be adjusted for take-up rates.

Sampling procedures

The target population for the interventions comprised all children aged 3 months to 5 years, who were resident in the 90 study communities in Sikasso and Yorosso cercles. To identify the number of target beneficiaries, a complete census of all children of eligible age was carried out in the 90 study villages in August 2013. The first monthly round of SMC treatment was given in mid-October 2013, and MNP distributions commenced in early 2014. The census listing from 2013 thus defined the population of children who will have received the interventions since 2013; and was used as the sampling frame of children in whom the impact after three years of implementation of the interventions was evaluated.

For each age group examined in the first round of surveys in 2014, a random sample of children was drawn from all children listed in the census for each community participating in the trial, according to the following age criteria:

	Date of Birth, or Age in August 2013	Age group in May 2014	Age group in May 2016
(i)	Born between 1 Jan 2013 – 30 June 2013; or aged <1 year in census (DOB not known)	1 years	3 years
(ii)	Born between 1 May 2010 – 30 April 2011; or aged 2 years in census (DOB not known)	3 years	5 years
(iii)	Born between 1 Oct 2008 – 31 July 2009[a]; or aged 4 years in census (DOB not known)	5 years	N/A

[a] Due to decreasing size of population with age, the age range for eligibility was expanded in older children in order to sample a sufficient number of children in smaller villages.

All children previously randomly selected and enrolled in the study were, if still resident in the village and present on the day of the survey, re-surveyed in May 2016:

- A random sample of 20 children aged 3y recruited from each village in May 2014, generating a cohort of 600 children who would be aged 5y in 2016.
- A third cohort of 20 children born before July 2013 recruited from each village in February 2015, generating a cohort of 600 children who would be aged 3y in May 2016.

Note: In villages where losses-to-followup meant it was not possible to trace sufficient number of children from the original sample to meet the required sample size per cluster, additional children were recruited in 2016. New recruits were selected at random from the list of children resident in the village at the time of the original census in 2013. All new recruits had thus been resident in the village and exposed to the interventions throughout the three preceding years.

In this way, the sample at endline in May 2016 comprised a cohort of up to 600 children aged 3y and 600 children aged 5y at endline in each arm:

T1 **Intervention group** **(with ECD)**	**C1** **ECD control group** **(with ECD)**	**C2** **Comparison group** **(without ECD)**
30 communities, 60 randomly selected children in each community: (20 children aged 3y; 20 children aged 5y)	30 communities, 60 randomly selected children in each community: (20 children aged 3y; 20 children aged 5y)	30 communities, 60 randomly selected children in each community: (20 children aged 3y; 20 children aged 5y)

XI. PROCESS EVALUATION

Process evaluation

Ongoing data was collected by Save the Children agents to monitor the MNP distributions. These data included:

Measures of program delivery by implementing agency:

- Number of communities trained, number of persons trained per community
- Number of children who received MNPs per community per round
- Number of MNP sachets distributed per community per round
- Number of empty MNP sachets returned per community
- Topics covered during the distributions

Measures of village -level participation in:

- Number of MNP distributions implemented per year and number of sachets distributed
- Number of children who received the MNPs

Measures of household-level participation and parenting practices:

- Nutrition and hygiene practices at household level:
  - including participation in nutrition and stimulation education sessions; number of meals child has per day; quality of child's diet; frequency and correct use of MNPs
- Cognitive stimulation at household level:
  - including participation in nutrition and stimulation education sessions; availability of reading materials and toys in the home; type of activities/games played by child; frequency and type of parent-child interaction; ECD centre enrollment

Methods of data collection:

Routine program monitoring data were examined, including logs of training sessions held by Save the Children; community-led activities realized in each community; MNP and SMC distribution registers; and attendance. These data were validated through parental questionnaires in a random sample of households.

Evaluation of the implementation process and acceptability of the interventions

Coverage of each of the interventions (MNP and ECD) achieved, was assessed as part of the structured questionnaire interviews with parents. Questionnaire surveys with parents were also used to capture data on acceptability of the interventions, equity of coverage, and characteristics of children who do and did not receive the interventions. The parental questionnaire also captured data on home literacy environment, adult-child interaction, and nutrition practices.

XII. COST ANALYSIS

The cost analysis was conducted from a service provider perspective, using a one year time horizon. There were five strategies that were delivered by two different providers. Seasonal malaria chemoprevention, deworming, vitamin A supplementation were all delivered by the Ministry of Health; we did not capture the cost of these strategies in this cost analysis. Hence the cost analysis concerned only micronutrient supplementation and early child development program delivered by Save the Chiildren. The ECD program encompassed health parental education and preschool provision for children.

The ECD program started since 2013 and was ongoing until 2016. While the micronutrient program activities covered only a period of 4 months from January to April in 2016, the salary expenditures started in 2015. Although the impact of health prevention and pre-school programs can spread over a long time period, in this study we aimed to capture the short term effects of supplementation with micronutrients on children nutritional and health status (stunting, wasting and underweight, anemia, iron deficiency, malaria prevalence) and parental education and ECD program on cognitive development and school readiness. Furthermore, the health interventions (seasonal malaria chemoprevention and micronutrient supplementation) are carried out for a defined period of time each year and repeated annually – incurring recurrent costs annually. For the purpose of comparison between the two programs (MNP and ECD) the time horizon was thus fixed at 1 year.

Costing model and reference documents

The cost analysis was performed using the ***Standardized ECD Costing Tool (SECT)*** developed by Cornerstone Economic Research (http://www.cornerstonesa.net/) under the contract of World Bank and the Center for Universal Education at Brookings Institute. A user manual is provided for guidance in utilization of the tool: ECD Manual to the Costing Template Draft v.3, January 2016. Additional advice was provided by Conrad Barberton. A Brookings Report on the standardized tool used across several countries is available online.
https://www.brookings.edu/wp-content/uploads/2017/09/standardized-ecd-costing-tool.pdf.

Below are the costing model descriptions provided by Cornerstone Economic Research (*see italicized text throughout this section*).

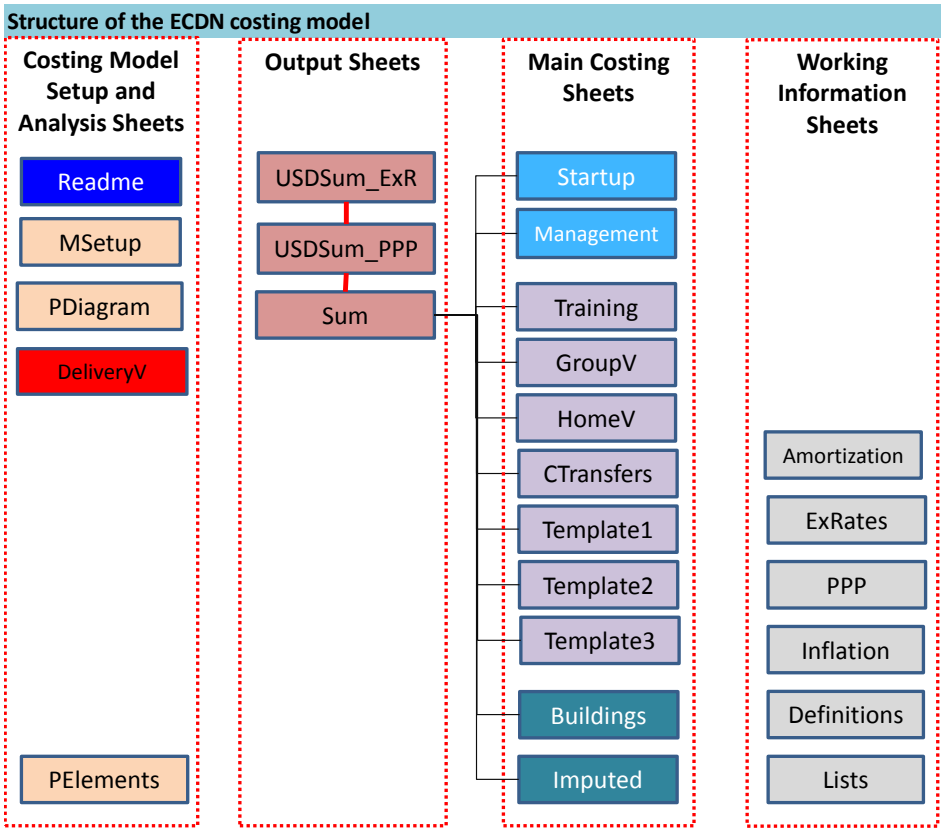
SECT attempts to address the challenges of comparability and the availability of data varies by type of intervention by providing a single tool that offers methodological consistency to costing. ECD programs, which can be used across the full range of interventions, balancing flexibility and rigor. The utility of SECT is twofold. On the one hand, standardized and accurate cost data can strengthen the case for investment by enabling more precise cost-benefit and cost-effectiveness analysis. On the other hand, such data can lead to more informed or better investments by improving the efficiency of administration, so that actual and expected expenditures are better aligned, investments are made in the most cost-effective interventions, and cost and quality trade-offs can be analyzed. In addition to an existing list of common ECD interventions, users can edit the tool to suit their individual needs. The tool can be used to analyze data as ECD line items across different interventions (for example, to track personnel costs), or can be broken down by activity. Unit costs can be calculated by entering beneficiary numbers, and scale-up costs can be estimated as well.

The quality of cost estimates is directly dependent on the quality of the costing assumptions and the quality of data used. The validity of the results must be seen in the context of these two factors.

Structure of the costing model

The SECT model is organized in several costing sections (for more details see Figure 4 below). Only those relevant to the project cost analysis carried out in Mali were provided here.

Figure 4. **Structure of the SECT ECDN costing model template**



SECT Guidance:

The SECT model consists of four groups of: Costing model setup and Analysis sheets, output sheets, Main costing sheets and Working information sheets. The costing work done in the Main Costing Sheets is fed through the Output sheets, where it is summarised. Some of the Working information sheets feed through to the Output sheets to convert the summary results into real values and values in US dollars.

- *Start-up: Most government programs will need to incur a range of costs to get the program going. For instance, the money spent on designing and piloting the program. There may also be some consulting and research costs that must be incurred at the start of the program. Most startup costs should be amortised over more than one year, since they represent an up-front investment in the program.*
- *Management: Successful programs must be managed properly. Program management incurs a cost and this cost must be estimated in the costing model.The cost of management is usually shared across all components of a program; i.e. it is difficult to attribute the cost of management to individual components of a program. As this cost is not linked to individual activities or events it should be costed separately and in quite a different way to how other aspects of ECD programs are costed. The template provides for management to be costed as a stand-alone item. All management costs that are applicable to more than one component of the program should be costed fully here. Management costs that can be attributed directly to a specific component of the program should be costed in the relevant part.*
- *Program activities: In the template there are several categories for costing program activities. These are: (i) Trainings – the purpose of this is to cost the training of trainers, i.e. carers in ECD centres. However it can also be used to cost training of other stakeholders involved; (ii) Group meetings – the cost of community group*

meetings and/or community consultation should be costed in this cost category. The activities costed here may range from small group meetings to large awareness campaigns; (iii) Home visits – this sheet is provided for costing home visiting. The cost of staff, provisions given to beneficiaries, the cost and travel are examples of the costs that should be captured in this category. Home visits include health checks on children, educating mothers about childcare at home and so on; (iv) It is also possible to add other cost activities that are not reflected above.

- *Buildings: Various different types of buildings and building works will be required in an ECD program. In this section it is costed various types of building activities such as: (i) Building new buildings: Thought needs to be given to whether the building is completed in one year or whether the costing should be spread over more than one year. If it is estimated that the building will take two years to build enter 0.5 in each of the years in which the building takes place and enter the full price of the building in the 'Nominal Unit Price'. Remember to include costs such as design and excavation in addition to other building costs; (ii) Renovations or upgrades: a variety of small building works may be required. The cost of building works should be amortised over a long period of time.*

Intervention Costs : Costing in Mali*:*

- Start-up: In the current analysis exercise we were not able to differentiate the cost for designing and piloting the program from the remaining costs.
- Management: For MNPs, the program management costs included salary, benefits and administrative supplies. A coordinator and two community development agents were directly involved as salaried workers in the micronutrient program. These workers also benefited monthly payments for communication. The shared administrative costs were determined according the percentage of utilization in individual input or activity. These costs included the fees for use of office building and storerooms, building security, electricity, water supply, telephonic communication, internet, air-conditioning, office building maintenance and disinfestation supplies. The capital inputs were a laptop, printer-scanner and other facilities such desks and chairs.
- For ECD program, only those activities from 2015 to 2016 were included in this cost analysis. The management and administration included the following inputs: rent of office and storage space, telephonic communication, internet, water supply, air-conditioning, working meeting, vehicles, transportation, security, accommodation and other local facilities.
- Buildings: Only for ECD program, buildings were built or renewed.

Outputs of Cost Analysis

- *The outputs of the SECT unit cost analysis will show what each unit of delivery costs or what the average cost of providing services to each beneficiary is. These average costs or unit costs are very useful for comparing program costs across programs – and in understanding the efficiency and cost effectiveness of programs, and different modalities of delivery.*
- *Amortisation: The SECT allows for costs to be amortised over a period of time. This period of time can range from one year to 40 years. The amortisation period determines the number of years over which a cost is spread. The amortised values show what costs are actually accrued in each year. The amortised values are very useful when conducting unit cost analyses as the amortised costs give a much more realistic unit cost than the unit cost based on a cash analysis will show especially in the first few years of a program's existence.*
- *Average costs: The average unit cost is what it costs on average for one unit to be produced. It is the total cost divided by the total units produced. As an example – a home visiting program costs USD 100 000 per year and reaches 1 000 children. The average cost of reaching a child is 100 000/1 000 = USD 100. The actual cost of reaching a specific child may be higher than the actual cost of reaching another specific child, but we can expect that on average, reaching all children will cost USD 100. Understanding the average cost is useful as one can compare average costs over time to check for efficiency gains. It also helps in planning –*

if we know that the average cost is USD 100 per child we can use that to estimate the resources required to reach a certain number of children.

- *Sensitivity Analysis: SECT enables sensitivity analysis. According to the cost data structure in the current cost exercise, sensitivity analysis have been done manually.*

Analysis of Mali cost data:

- Amortisation: The costs of all capital goods were annualized according their respective life span. An amortisation of 40 years was set for new buildings; 5 years for initial trainings and materials such internet connection, telephonic equipment; 3 years for the cost of trainings of trainers and ECD centre supplies such wood equipment, bags for assistants.
- Average costs: First, the total cost by input category was calculated. Then using the relevant inputs for either management or intervention deliveries, the respective total costs were calculated. Finally the total cost of each program (MNPs and ECD) was calculated by adding total costs of program delivery and management. The unit cost is the ratio of total cost to the number of beneficiaries in each program. The numbers of beneficiaries used in the analysis were 24,091 and 11,012 for MNPs and ECD respectively.
- Sensitivity analysis**:** Univariate sensitivity analysis was carried out to test the robustness of the conclusions of the cost analysis to variations in the costs and to determine how changes in some categories could affect the total cost. These analyses can be used to recognize and take account of the level of uncertainty associated with relevant parameters used in the calculation of costs, as well as potential future fluctuations in price. Univariate sensitivity analysis was performed for variation in micronutrient prices (± 25%); salary levels of direct personnel and other personnel of Save the Children involved in *Projet Jigifa* (-30%,+10%); and transport costs (±50%).

Intervention Costs : Methods of data collection in Mali

Note: The cost survey covered only Early Childhood Development and home fortification with micronutrient powders strategies. This is appropriate since seasonal malaria chemoprevention and deworming strategies were implemented in all study groups.

Cost data were obtained from the financial records of Save the Children in Bamako and Sikasso, supplemented by field surveys, where necessary. Cost data were collected for the 12-month period January 2016 to February 2017.

The cost data collection and analysis was undertaken by Hamidou Niangaly, an economist based at the MRTC, University of Bamako, Mali, under the supervision of Dr Josselin Thuilliez, CNRS/Centre d'Economie, Sorbonne University, France. The costing exercise used the template described above provided by SIEF (in partnership with the Brookings Institute), who contracted Cornerstone Economic Research to help with activity, provide guidance and help understanding the SIEF/Brookings template.

The process of data collection was organized following a top-down approach, from project coordination to the financial management. An inventory was made of all inputs required for the implementation of the project; and costs calculated using an ingredients approach which identifies all the inputs, their quantity and value.[56] Resources used were identified through direct observation as well as interviews with the project co-ordinators and other persons involved in the implementation of the interventions.

The costing aimed to capture data on 5 categories of costs : (i) Personnel costs including salaries, allowances, and benefits (housing, subsistence, medical insurance, life insurance, pension contrbutions, payments to participants, incentives etc). (ii) Costs of supplies, including cost of equipment and consumables required to deliver the interventions. These include the treatments (MNPs), education supplies (registers, pens), printing and other supplies. (iii) Capital costs include durable goods such as buildings, vehicles. For materials not purchased soley for this project, the portion used by the project was estimed for each item. For example, for vehicles the number of kilometers used to support project activities was calculated. (iv) All costs associated with running a vehicle were also included, such as cost of servicing, fuel, oil, and tyres. (v) Office costs associated with administrative support to the project, logistics, electricity, telephone, security, cleaning etc were also included.

Data were collected at different levels of cost resources in order to capture all activities and actions that were generating a cost during the implementation of the project. Four levels of costs resources were identified, including co-ordination, logistics, administration and financial service units. All of these units were visited to collect data in collaboration with the head of each unit.

- *Project coordination unit*. With the research coordinator of Project *Jigifa* and ECD programme manager in Sikasso, the activities and actions linked to the implementation of the MNP and ECD interventions were listed. The costs incurred for the co-ordination of these interventions were also recorded.
- *Finances*. Information on the direct costs incurred by the project activities were archived in this unit. The financial manager provided data on all the expenditures linked to the implementation of the MNP and ECD interventions. For frontline personnel salary and benefit (insurance, communication), data were collected from the financial management office in Bamako.
- *Logistic*. This administrative unit is in charge of managing the procurement of MNPs and other materials for the intervention programs, equipment, storage and transportation including the contracted supply transportation. The type and quantity of each item used by the MNP and ECD interventions were recorded. For the vehicles (car, motorcycle) - pruchased under different projects - the make, serial numbers and distances travelled to support the implementation of the MNP and ECD interventions were recorded to enable the project-related share of these vehicles' utilization, fuel consumption and other running costs to be calculated.
- *Administration*. In this unit, the administrative indirect costs such as electricity, water, building, security, renting, office cleaning and recurrent office supplies, were collected.

Cost analysis

The analysis was conducted from a service provider perspective, using a time horizon of 1 year.

Data were entered using a specific costing database for ECD programs developed in MS Excel software, by Cornerstone Economic Research department (http://www.cornerstonesa.net/), as described above. The database was designed to automatically generate the total and unitary costs in local currency XOF and in USD. Cost data were initially recorded in the local currency West African Francs (XOF); results of the cost analysis are expressed in XOF and USD 2012 (average exchange rate of 2015; 1 USD= 591.45 XOF)

Costs were classified according the classical economic evaluation costing model in management-administration and intervention-supply categories. The management-administration costs included the direct and indirect costs of the personnel salary payment and benefits (assurance, telephonic communication), resources for coordination administration (laptop, printer, office phone, etc.), office building facilities and supplies (renting, cleaning, security, internet, electricity, water, conditioned air, personnel, shipment, etc.), purchased vehicles and share of number of purchased

vehicle utilizations, working meeting, accommodation, travel. Intervention costs encompassed the costs of direct activities and resources used for the delivery of the interventions. These included the intervention products (micronutrient powders), training, monitoring, equipment (motorcycles, manual, register, etc.), transportation, salary of front-line personnel etc.

The costs of research and evaluation are excluded in this analysis, since government would not be expected to have the perspective to evaluate the impact of the program.

Program beneficiaries
The direct beneficiaries are children in the age range of 6 to 59 months in the MNP intervention, and 2-5 years for ECD interventions.

Total and unit costs

- Initially the total cost by input category was calculated. Then using the relevant inputs for either management or intervention deliveries the respective total costs were calculated. Finally, the total cost of each program (ECD and MNPs) was calculated by adding total costs of program delivery and management.
- The unit cost is the ratio of total cost to the number of beneficiaries in each program.

Annualization and amortization period
There are differences in timing related to when costs of certain inputs are incurred and when they are used over the lifetime of a program. For resources whose lifespans or benefits is 1 year or more and activities such initial training whose effects spread beyond one year were annualized. The values of annualization depend to the duration period of amortization of a given item. Therefore, for capital inputs, one year amortized costs were used for both ECD and MNPs programs.

Sensitivity analysis
Univariate sensitivity analysis was carried out to test the robustness of the conclusions of the cost analysis to variations in the costs and to determine how changes in some categories could affect the total cost. These analyses can be used to recognize and take account of the level of uncertainty associated with relevant parameters used in the calculation of costs, as well as potential future fluctuations in price. Univariate sensitivity analysis was performed for variation in micronutrient prices (± 25%); salary levels of direct personnel and other personnel of Save the Children involved in Project *Jigifa* (-30%,+10%); and transport costs (±50%).

XIII. ETHICAL CONSIDERATIONS

Ethical clearance

Ethical clearance for the original cluster randomized trial of MNPs+SMC in the 90 study villages in 2013-2014 was granted in Mali by the Ministry of Health, Comite Ethique de l'INRSP on 23 July 2013 [reference no. 06/13/INRSP-CE] and the UK by the LSHTM Ethics Committee on 16 August 2013 [ethics ref. 6489].

From August 2014, seasonal malaria chemoprevention was rolled out across all 90 villages in keeping with the change in national policy. In contrast, the MNP intervention continued to be implemented and developed further in the 30 intervention villages on an experimental basis but was not extended to the other study villages pending evidence of impact. Ethical clearance for a second evaluation after three years of implementation, through a series of cross-sectional endline surveys in May-June 2016, was obtained in Mali by the Ministry of Health, Comite Ethique de l'INRSP on 4 April 2016 [reference no. 06/13/INRSP-CE] and the UK by the LSHTM Ethics Committee on 10 May 2016 [ethics reference 11335] (See Annex V).

Informed consent

At the beginning of the randomised trial in July 2013, community meetings were held with community leaders and parents to explain the purpose of the study and to obtain informed consent from the community to participate in the trial. Community meetings were repeated in May 2014 (phase 1) to obtain informed consent from the parents of each child selected to participate in the evaluation surveys and recruited into one of the three age cohorts. The information sheet for the evaluation survey at the end of phase 1 also mentioned the possibility that the same children would be re-examined again in 2016.

Prior to the surveys in 2016 (phase 2), community meetings were repeated with community leaders and parents to explain the purpose of the study and the procedures to be followed, the risks and benefits of participation, including right to refuse or withdraw from the trial without penalty. At the start of each assessment session, children were asked for their verbal agreement to participate in the assessments. Cognitive or child development (IDELA) data was not collected for any children who refused consent.

Patient safety

It is recognized that improved iron status can, in some circumstances, increase the risk of malaria, and combining effective malaria control with micronutrient supplementation is important to minimize this risk.[33] For this reason, micronutrient supplementation (which contains iron) does not start until after the end of the malaria transmission season, and children do not receive the micronutrient supplements at the same time as they receive SMC. We thus believe that the intervention approach used should mitigate any concern. Use of an insecticide-treated net is a further important preventive measure, and in May 2012 the Ministry of Health undertook free community distribution of insecticide-treated nets throughout Sikasso region. Surveys conducted by Save the Children showed that this resulted in high levels of ITN ownership and use, with 92% of children reporting sleeping under an ITN in August 2012. In addition, Save the Children continues to be instrumental in promoting net use through school and community-led initiatives in the area. The existing use of ITNs, coupled with provision of seasonal malaria chemoprevention, should substantially reduce the risk of malaria infection in the study area.

Dosages followed WHO recommendations for home fortification for micronutrient powders. Evaluation of the intervention required the collection of finger-prick blood samples from children, which can cause a temporary discomfort at time of pricking. To minimize this discomfort,

hemoglobin and serum ferritin was measured and malaria slide prepared from same finger-prick blood samples, using sterile procedures. Children found with severe anemia (Hb<5g/dl) were taken to a health facility for urgent clinical assessment; and moderate anemia (Hb<8g/dl) treated with 30-days daily iron, and referred for follow-up.

Other ethical considerations

- To safeguard child rights, all project staff and survey team members were oriented on, and signed, Save the Children's child safety policy
- The research was conducted in accordance with the Ethics Principals for Research and Evaluation established by the United Kingdom's Department for International Development (DfID), which have been adopted by SIEF. The research staff were trained in current international standards for research ethics and principles of good clinical practice (GCP).

RESULTS

XIV. IMPLEMENTATION AND UPTAKE OF THE INTERVENTIONS

Project history: Development of the interventions and implementation timeline

A series of participatory workshops were held in Mali at key points during the project to drive the research and implementation forward and permit deeper discussion and interchange with the research and implementation teams.

(i) In April 2012, an initial multisector workshop was held in Sikasso to develop strategies for strengthening the health and nutrition elements of Save the Children's ECD program. The workshop included Save the Children program health and education staff, Sikasso regional health and educational authorities, Dr Sian Clarke from the LSHTM and Save the Children USA technical advisors in School Health and Nutrition and ECD, pulling together experience from a range of programs including maternal and child health and nutrition, Early Childhood Development, Basic Education, Livelihoods, Child Protection and School health and Nutrition. Malaria and malnutrition were identified as the two top health problems facing children under five years in the region and improving access to malaria and nutritional services through ECD centers a priority.

(ii) In January 2013, a second meeting was held at the National Malaria Control Program (PNLP) Office with representatives from the INRSP, MRTC, LSHTM and Save the Children to share the preliminary findings from the recently concluded trial on malaria control in schools and discuss proposed interventions in younger children using the infrastructure of pre-schools. The Director of the PNLP confirmed their wish to scale up seasonal malaria chemoprevention (SMC) in Mali, starting with Sikasso region and encouraged Save the Children to support the scale up of SMC in Sikasso and Yorosso cercles. All partners agreed that a trial of the proposed interventions in pre-school children would be valuable and help advance Mali's malaria and nutrition strategy.

(iii) These consultations were followed by a series of individual meetings with national partners (INRSP, MRTC, DPN, PNLP, DNS) to present the proposed research study and gather recommendations, and culminated in a research proposal that was submitted to the UBS Optimus Foundation.

(iv) Funding for the MNP+SMC trial was awarded by UBS Optimus Foundation, and recruitment of communities into the study started in July 2013. A complete census of all children of eligible age was carried out in the 90 stidy villages in August 2013, and the first monthly round of SMC treatment was given in mid-October 2013.

(v) On 30 September 2013, a Concept Note was submitted to the World Bank SIEF programme to seek funding to support the evaluation of the intervention of the longer-term, with the aim of examining impact after three consecutive years of implementation. The outline application was successful and $25,000 seed-funding was awarded in February 2014 for LSHTM to prepare a full technical proposal.

(vi) A meeting of research partners was held in Bamako on 4th April 2014 bringing together the Institut National de Recherche en Santé Publique (INRSP), the Direction Nationale de la Santé (DNS), the Malaria Research and Training Center (MRTC) from the University of Bamako, the Institut Polytechnique Rurale (IPR), la Direction Nationale de Pédagogie (DNP) and Save the Children to review the status of the UBS-funded study and gather recommendations. Individual meetings were also held throughout the project with specific partners, with INRSP acting as the lead partner and focal point for the study.

(vii) The impact of the intervention package on malaria, nutrition and cognitive outcomes after the first 12 months of implementation was evaluated through cross-sectional surveys in May-June 2014, with the funding from UBS Optimus Foundation.

(viii) Additional funding was also obtained from Sight and Life to support a qualitatiave evaluation of the use of MNPs, undertaken in January 2015 by the University of British Columbia. Findings from this study were used to identify modifications to improve the nutritional intervention and training materials in the following year(s), and target messages suited to the local context and feeding practices.[57]

(ix) In October 2014, SMC was scaled up to all communities in Sikasso and Yorosso cercles, including the 90 study communities. Unicef was responsible for SMC in Yorosso cercle and the government for SMC in Sikasso cercle. Save the Children provided funding and technical support to the government in Sikasso cercle to make sure SMC was conducted.

(x) On 5th February 2015, a multidisciplinary investigator workshop was held at the INRSP in Bamako to discuss preliminary research findings from the evaluation after the first 12 months of implementation, lessons learnt, and agree on next steps. A meeting with the donors, UBS Optimus Foundation and Sight and Life was also held at Save the Children in Zurich on 17th March 2015 to present and discuss the preliminary results of the evaluation.

(xi) The Full Technical proposal for the impact evaluation of the programme after 3 years of implementation was submitted to the World Bank SIEF in 31st May 2014, revised following WB technical review and resubmitted on 10th November 2014. The application was finally approved for funding in December 2014. However, the Contract was only signed in December 2015 and the first tranche of funding (10% of total award, including the seed funding for writing the proposal awarded in 2014) was not received until February 2016, just 2 months before the scheduled start of the endline survey. This meant that Save the Children and LSHTM had to pre-fund several key activities, including salary costs for key investigators, staff recruitment, contracts with national partners, community sensitization, etc.; capacity to oversee the intervention and prepare for the endline was very limited. This in part affected the timing of the endline survey which stretched into the high malaria transmission season, potentially affecting the ability of the surveys to measure the full impact of the intervention on anaemia.

(xii) A series of individual meetings were held in 2015-2016 with national partners (INRSP, DPN, PNLP, DNS) to present the proposed research study, gather recommendations and finalise plans for the implementation of the interventions. Additional meetings were held with INSRP (the partner responsible for the biomedical surveys at endline) to finalise the research procedures, timetable and logistics for the endline surveys.

(xiii) The research protocol for the endline evaluation was shared with all partners before submission to the ethical review board. Ethical approval for the endline surveys was received from Ministry of Health in Mali on 4 April 2016 and the Research Ethics Committee at LSHTM, UK on 10 May 2016.

(xiv) Regular monthly meetings were convened in Bamako to update national partners on the progress of the study; share experiences and challenges encountered whilst implementing the interventions in Sikasso; and to trouble-shoot, identify solutions and ways to improve implementation of the intervention and surveys collectively. Meetings commenced in November 2015, and continued until August 2016 shortly after the last of the endline surveys.

(xv) Endline surveys commenced on 20 April 2016 with community meetings to inform parents and reaffirm consent, and all three survey waves (parenting, cognitive and biomedical) were completed by 02 August 2016. The parenting and cognitive surveys to measure impact on household environment and parenting practices, as well as impacts on cognitive performance and child development, were organized by Save the Children, in collaboration with Académie d'enseignement de Sikasso et Koutiala, Les Centres d'animation Pédagogiques de Sikasso et

de Yorosso, les Districts sanitaires de Sikasso et Yorosso, ainsi que le Bureau National Catholique pour l'Enfance à Sikasso. Technical support in the development of the parenting questionnaire and training of assessors in electronic data capture was provided by LSHTM. Technical support in the development and implementation of cognitive assessments in young children, training of assessors, and electronic data capture was provided by LSHTM, University of Leeds, and University of Michigan and DPN, Mali. The biomedical surveys to measure impact on nutritional outcomes were organized by INSRP, and the blood samples collected were examined in the laboratories of INSRP in Bamako, with additional technical advice provided by LSHTM and University of Wageningen.

Target beneficiary population for the intervention:

Established community and/or ECD infrastructure was used to deliver the malaria, nutrition and parenting interventions to all children resident in the community, including children not enrolled in an ECD program. The target population for the interventions thus comprised all children aged 3 months to 5 years, who were resident in the 90 communities that consented to participate in the trial (community consent for the intervention) in Sikasso and Yorosso cercles in southern Mali. All children within this age group living in the 30 communities with ECD centers that implemented the MNP intervention (intervention arm) were eligible to receive the micronutrient powders.

Seasonal malaria chemoprevention [current practice 1 (SMC)] and the parenting program [current practice 2 (parent)] are both national policies in the process of being scaled up by the Government of Mali. SMC has therefore been implemented in all 90 communities (all three arms) since August 2014, and the parenting intervention implemented in the 60 communities with an ECD centre (intervention arm and ECD control group) since October 2015.

Thus by May 2016, the three groups of villages will have received the following interventions :

Table 5. **Interventions received in villages in each arm and timing of evaluation surveys**

Interventions	T1 : Intervention group (30 villages)	C1 : ECD control group (30 villages)	C2: Non-ECD control (30 villages)	Funding
Phase 1 pilot Oct 2013 – Apr 2014	Treatment 1 (MNP) + Treatment 2 (SMC)	0 0	0 0	
May/July 2014	Evaluation of phase 1: combined impact of SMC + MNPs Baseline cross-sectional surveys for phase 2			UBS/SC
	Seasonal malaria chemoprevention - scaled up to all 90 villages (as per national policy)			
Phase 2 Aug 2014 – Apr 2015	Treatment 1 (MNP) + Current practice 1 (SMC)	0 + Current practice 1 (SMC)	0 + Current practice 1 (SMC)	
October 2015	*National policy and guidelines for parenting programs – introduced into all villages with ECD centers*			
Phase 2 Aug 2015 – Apr 2016	Treatment 1 (MNP) + Current practice 1 (SMC) + Current practice 2 (parent)	0 + Current practice 1 (SMC) + Current practice 2 (parent)	0 + Current practice 1 (SMC) 0	
May/July 2016	Evaluation of phase 2: cross-sectional surveys to evaluate additional impact of MNPs in a population of children receiving SMC			SIEF/SC

At the time of the evaluation in May-July 2016, all children in the target age group should thus have received SMC for at least two years, equating to a total of approximately 30,000 beneficaries in 90 communities. Appoximately 10,000 should also have received MNPs, and 20,000 children were also exposed to the ECD program to support child development (including parenting education).

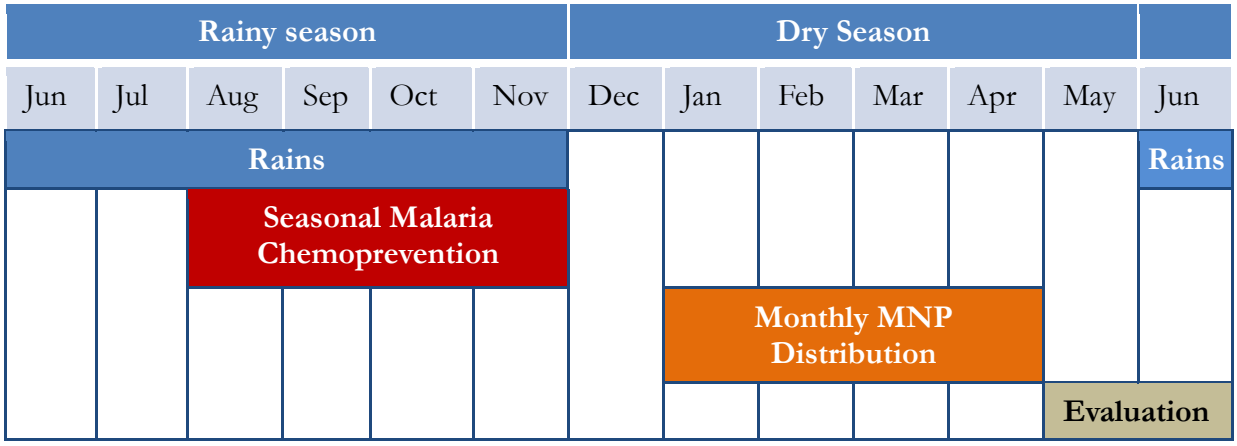
Implementation of the interventions

Home fortification with Micronutrient Powders

Since 2014, all children aged 6-59 months in the 30 intervention communities were targeted to receive a sachet of micronutrient powders (MNPs) daily for four consecutive months, between January andApril following SMC, during the dry season when malaria transmission is at its lowest (see Figure 5). Mothers were given a box of 30 MNP sachets per child (6-59m) every month on return of the previous' months empty sachets. MNPs were to be added by the mother (or prime carer) to the child's meal each day.

The World Health Organisation recommends 90 MNP sachets containing 10 to 12.5 mg of elemental iron to be given to children 6-23 months over a 6 month period where the prevalence of anemia is 20% or higher[1]. Under this project, 120 MNP sachets containing 10mg of iron were given to each child over a shorter 4-month period to avoid provision of iron-containing supplements during the malaria transmission season (which ends in December and starts again in May-June). Given the high prevalence of anemia in the study area, the increased number of MNP sachets provided, building on the health benefits of SMC provided in the preceding months, this 4-month regimen would be expected to reduce iron deficiency anemia.

Figure 5. **Timing of the malaria and nutrition interventions**



The MNPs were donated by Sight and Life (Mixme, DSM Nutritional products) and Unicef (see Annex I). The sachets used in 2014 and 2015 were donated by Sight and Life, and contained 400 mcg vitamin A, 5mcg vitamin D, 5 mg vitamin E, 0.5mg of vitamins B1, B2, B6, 0.9 mcg vitamin B12, 6mg niacinamide, 150mcg folate, 30 mg vitamin C, 10 mg iron, 4.1 mg zinc, 0.56 mg copper, 17mcg selenium and 90 mcg iodine. The sachets used in 2015 were donated by Unicef, and contained the same amounts of all micronutrients. (https://www.unicef.org/supply/files/ANNEX_3_-_Tech_specs_S1580201_S0000225.pdf).

Distribution of MNPs and supporting interventions at village-level

Micronutrient powders were distributed to caregivers through village nutrition groups (Groupes de Soutien aux Activites Nutrition, GSAN), a multisectoral group of people including the ECD center teachers (monitrices), the community midwife (matrone), the community health agent, women leaders and two committed men (approx. 8 people in total). All children aged 6-59m (including both enrolled and non-enrolled in the ECD center) were targeted. Mothers of all children resident in the village were mobilised by the GSAN members and village leaders to attend the distribution sessions using informal communication through networks of mothers and aunties

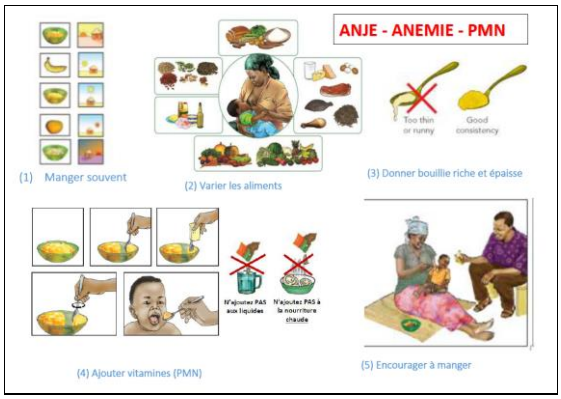
[1] http://www.who.int/elena/titles/micronutrientpowder_infants/en/

("tantines"), vaccination days, post-natal consultations, village fairs and other gatherings. The monthly MNP distributions were accompanied by informational sessions for parents, and used as an opportunity to teach parents about essential hygiene practices, nutrition and child stimulation and early learning. Each informational session included a cooking demonstration, to show parents how nutritious and age-appropriate meals could be prepared using local foods, supplied by the parents, including how and when to add MNPs. Informational sessions were open to all to attend, and included mothers, fathers and other caregivers.

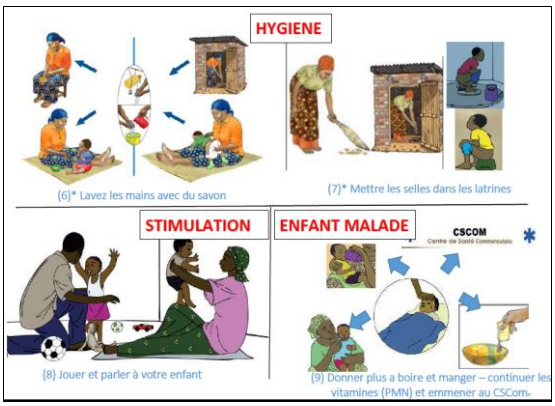
Prior to the distribution, GSAN members were trained on Infant and Young Child Feeding (IYCF), stimulation and hygiene concepts, how to organise a cooking demonstration, distribute MNPs and teach mothers about nutrition, stimulation and hygiene at the same time (See separate training manual and materials). A cascade training approach was adopted, starting with a training of trainers. Training level 1): Save the children staff and Nutrition and ECD focal ports from the Ministry of health and education at national level trained a multi-sector regional team which included the Nutrition and ECD focal points from Sikasso health and education office (Chargé de Nutrition du Centre de santé de reference, le Point focal Nutrition du Centre de sante de reference de Sikasso, Chargé de la Petite Enfance de l'Academie de Sikasso, la Chargé de la Petite Enfance du Centre Animation Pedagogique de Sikasso); local health agents (Directeur Technique du Centre -DTC) and education advisors (Conseiller Academique Pedagogique-CAP) from each commune. Training level 2): Regional teams then trained the GSAN over 3 days. The GSAN training utilised a training module developed by Save the Children with support from the Micronutrient Project, University of British Columbia in 2015. The training manual drew on findings from a qualitative evalution of the micronutrient powder distribution conducted in phase 1 to identify the main vehicle and target messages to the local context,[58] as well as national guidelines for IYCF and MNP distribution developed by Save the Children

The GSAN organized cooking demonstrations approximately once per month in each neighborhood to teach mothers and grandmothers how to enrich their child's porridge with nutritious local foods and how to add the MNPs to the food (see photos overleaf). Depending on the size of the village, it typically took up to 3-days to reach all neighbourhoods. A special emphasis was put on ensuring that the child consumed the whole sachet by giving it to him with a small amount of food in his own cup. The mother practiced adding the sachets to the food prepared at the cooking demonstration and feeding it to their child. They also used this opportunity as food was being prepared to discuss hygiene, stimulation and what to do with the sick child, using a set of visual aids (see Annex II with Key Messages and Figure 6 below).

Figure 6. **Visual aid of key messages used in informational meetings with parents**



Page 1



Page 2

Nutritional intervention – Cooking demonstrations and MNP distributions in villages

1. *Village meetings attended by mothers and other caregivers of young children were held monthly: Jan–Apr each year*

2. *ECD facilitator and women leaders demonstrate how to prepare nutritious meals for young children*

3. *ECD facilitator explains to mothers what the MNPs are for, and the value of using them every day*

4. *ECD facilitator demonstrates how to add the MNPs to child's food each day*

5. *ECD faciltator explains importance of giving the MNPs to each child individually and checking that she/he consumes the whole portion*

6. *ECD facilitator distributes a month's supply of MNPs for each child*

Mother holds up a sachet of MNPs

Mothers were given a box of 30 sachets of MNPs (one month's worth) for each child. The MNPs were then added to children's meals, usually to the morning porridge (bouillie) by the main caregiver every day over the course of the following month. A new box of 30 sachets was given to the mothers every month on distribution days. Empty sachets were collected once a week by the GSAN committee members and returned to the ECD center to monitor the number of MNP sachets that were being used.

Seasonal Malaria Chemoprevention

In 2013, all children aged 3-59 months in the 30 intervention villages received seasonal malaria chemoprevention treatments (SMC), co-ordinated by Save the Children through the ECD Centers. There were two levels of training in 2013. The first level was done by the National Malaria Control Program SMC focal point and the Save the Children project coordinator , using a training manual developed by Medecins sans Frontieres for SMC in Mali[58] to train district and community-level health agents; the second level of training targeted the ECD Center facilitators in the 90 study villages, and was done by the district and community level health agents.

Since October 2014, the SMC intervention was extended to all 90 villages enrolled in the study. From 2014, SMC treatments were organized by the Ministry of Health in Sikasso cercle and by Unicef in Yorosso cercle; and distributed by government health agents (Directeur Technique de Centre), through the combination of fixed-point distribution and mobile teams to reach any outlying hamlets, in accordance with the standard national guidelines and procedures recommended by PNLP. In villages with ECD centres, the ECD staff might also be involved sometimes and given the drugs to distribute to the children under their care. In Sikasso cercle in 2014, SMC coverage was delayed and patchy with no training provided. To address this issue, Save the Children provided additional financial and technical support to the MoH in Sikasso cercle from 2015 to ensure SMC was fully implemented.

Treatments were carried out between August and December each year, and intended to reach all children aged 3-59 months resident in the 90 study communities. The first dose of the 3-day treatment was given at a fixed point in the community by trained district and community level health agents, supported by village volunteers and ECD Center staff (see photos below). In common with previous studies, the 2nd and 3rd doses were given to parents for administration at home.

Malaria intervention – Seasonal malaria chemoprevention distributions in villages

Checking age eligibility *SMC treatment supervised by DTC* *Observation post-treatment*

Early Childhood Care and Development (ECD)

The above package of interventions was provided within the context of an existing ECD program which aims to stimulate learning and creativity through ECD centers which target children aged 3-5 years and parenting education sessions which target parents of all children aged 0-8 years in the community. The ECD centers are designed to boost language and communication skills in children; awareness of basic mathematical concepts, simple reasoning and problem solving; physical, intellectual and socialization skills; in preparation for later school enrolment. The language used in the ECD center is the most commonly used language in the village. The three main languages spoken in the 60 ECD study villages are Bambara, Shenara or Mamara and generally only one of these languages is spoken in a village. In line with the national ECD policy, the program also promotes parenting education to increase use of essential health services and improve parenting practices. [24,25] Adult literacy groups have also been created in every ECD community to improve parents' literacy. Save the Children works with the department of the National Directorate of Preschool and Specialized Education (DNEPS) and Sikasso school inspectors (Conseillers CAP-Centre d'Apprentissage Pedagogique) to train voluntary mother educators or ECD Center facilitators (monitrices) from the community to run the ECD center supported by an ECD Management Committee.

ECD class in session in Sikasso, Mali, attended by children aged 3-6 years from local village

Development and implementation of the Parenting Programme

In 2012, Save the Children worked with the Ministry of Education, Unicef, Born Fonden, Plan Mali et Aga Khan to develop a national parenting education framework and strategy to build parents, capacity to care and stimulate their children from birth through to primary school. A pictorial flipchart was produced and piloted by Born Fonden in 2014. Save the Children and other partners began rolling the parenting education programme in their project areas from 2015.

Save the Children's ECD programme staff were responsible for the roll-out and implementation of the community-based parenting intervention in ECD villages in the study area, in collaboration with local partners in the Centres d'Animation Pédagogiques and l'Académie d'Enseignement de Sikasso.

In the 60 study communities with an ECD center, ECD monitrices received a 5-day training to organize monthly parenting educational sessions targeting all parents of children aged 0-8 years, using a nationally-approved set of visual aids (Boîte d'Images) to promote a healthy, protective and stimulating home environment with positive parent-child interactions for infants and young children, whether they attend an ECD center or not.

Key themes covered in the parenting program include:

- Health of the child (includes child vaccination, medical care, physical and mental health)
- Nutrition (includes breastfeeding and weaning)
- Water, sanitation and hygiene practices (WASH)
- Stages of child development
- Cognitive stimulation and early learning activities
- Child protection

In recognition of local practices of care, shared responsibility and informal adoptive relationships within extended families, informational meetings are inclusive of all carers – including mothers, fathers, grandmothers, other family members and guardians. The sessions are participative, using the visual aids to prompt discussion with group participants on each topic (see photo below). The particular topics to be discussed at each session are chosen by parents, using a community-directed approach to reflect local priorities in the implementation of the programme.

Informational session for parents on child development and good parenting practices, being conducted by local ECD facilitator from the village pre-school

Fidelity of implementation and uptake of the interventions

Implementation

The number of SMC and MNP distributions held in each village are summarized in Tables 6a-6c. In summary,

- Between January and May 2014, four monthly rounds of MNP distributions were achieved in all the 30 MNP intervention villages, and a total 10,861 children aged 6-59 months received MNPs, under the UBS Optimus funded evaluation.
- In 2015, it was only possible to achieve one round of distribution of MNPs in Sikasso cercle because the MNPs available were expiring in March 2015 and no new products had been received from Unicef. SC's capacity to monitor MNP uptake, identify and support communities with lower MNP coverage was limited due to a shortage of field staff between the UBS Optimus funded phase 1 study and the World Bank funded phase 2 study
- In Yorosso, MNPs were distributed monthly between October 2014 and October 2015. These distributions were organised by another NGO called ASDAP with financing from Unicef, and were carried out in all villages (control and intervention). Children aged 6-23 months were eligible, and received one MNP sachet daily for the 12-month period. Children older than 23 months did not receive the MNPs.
- During the same period, another NGO called MPDL (also financed by Unicef) distributed MNPs in parts of Sikasso cercle, but as none of the Project *Jigifa* study villages were included in this program there was no contamination of the study design.
- In 2016, four rounds of distribution were successively conducted in all 30 MNP intervention communities between February and May 2016; reaching a total of 8,028 children in round 1; 9,598 in round 2; 11,107 in round 3; and 11,741 in round 4.

Coverage achieved

The coverage and acceptability of the intervention(s) were evaluated through a cross-sectional interview survey with parents conducted in May 2016. Overall findings for each of the intervention(s) are summarized by arm in Table 7. Additional information on variation in coverage between villages can be found in Tables 6a-6c.

Home fortification with Micronutrient Powders

The coverage achieved in terms of proportion of children who received MNPs in 2016 was determined by parental recall of use of MNPs, measured during the questionnaire survey with parents undertaken in May 2016 shortly after the last MNP distribution. Almost 80% of parents in the MNP intervention villages reported that they had given their child MNPs and 85% of those giving MNPs to their child had given them 4-7 times in the preceding seven days (Table 7). Although reported coverage of the MNP intervention exceeded 80% in more than half of the villages (17/30), there was some variation in the coverage between villages, which ranged from 38% to 97% (Table 6a); suggestive of some differential uptake and acceptability of the intervention and/or variation in implementation between communities. Despite the high coverage reported in the parent survey, the increase in numbers of children reached from the first to the 4th distribution from 8,028 to 11,741 in the routine M&E records for Jan-April 2016 (described above) suggests a proportion of children reported as receiving MNPs may not have received the MNPs for the full four-month period.

A sizeable proportion of parents surveyed in the non-intervention ECD control and non-ECD comparison villages (approximately 20%) also reporting having added MNPs to their child's food. Whilst this may partly be due to erroneous reports arising from recall error and/or social desirability bias in parental report (a shortcoming of this method of measurement); these data could also be a

Table 7. **Coverage and acceptability of the interventions, determined through interviews with parents**

	Intervention	Control	Comparison
Interventions	**MNP + Parenting**	**Parenting**	**None**
Number of villages surveyed	30 villages	30 villages	30 villages
SMC Coverage[a]			
No. (%) children reported to have received malaria tablets the previous year (2015)	1101/1137 96.8%	978/1073 87.2%	846/923 91.7%
MNP Coverage			
No. (%) parents who reported ever having added MNPs to their child's food	910/1163 78.3%	202/1120 18.0%	207/950 21.8%
MNP Acceptability			
Amongst parents who reported giving MNPs: No. (%) parents who had given MNPs on at least 4 days in the last week	772/910 84.8%	134/202 65.3%	165/207 79.7%
No. (%) parents who reported that their child liked to eat the food with the MNPs added	857/908 94.4%	183/202 90.6%	198/207 95.7%
No. (%) parents who reported rarely/never having difficulties with giving MNPs to their child	835/904 92.4%	178/200 89.0%	196/207 94.7%
No. (%) parents who would want to give their child MNPs again the following year	891/910 97.9%	198/200 99.0%	202/207 97.6%
Parenting coverage[b]			
No. (%) parents who reported participating in a community meeting where they learned about child nutrition or cognitive stimulation	496/1119 44.3%	374/1034 36.2%	335/910 36.8%

Notes: [a] SMC: All children aged <5 years in the 90 study villages should have received SMC in 2015 as part of the national government programme; [b]Parenting: responses might include participation in an information session organized in association with the MNP distributions, as well as those organized as part of the ECD parenting intervention. Both programs relayed key messages about child nutrition, parent-child interactions, cognitive stimulation and early learning.

result of the MNP distributions carried out by other NGOs during the last three years (as described above), since the question asked was simply: "Have you ever added these [shown sachet of MNPs] to your child's food?" or leakage of the intervention beyond the 30 intended intervention villages. Indeed a higher proportion of parents surveyed in Yorosso where MNPs were distributed between Oct 2014-Oct 2015 reported use of MNPs than in Sikasso (68% vs 36% overall). Within the control arms, the proportion of children reported to have been given MNPs in the ECD control and non-ECD comparison villages in Yorosso was 49% and 71% respectively, compared to 14% and 9% in the control arms in Sikasso. This is a potential concern for the study since use of MNPs in children in the control villages has the potential to reduce differences in nutritional status between the two experimental arms, and thus the capacity of the trial to demonstrate an impact of the MNP intervention. Nonetheless, since Unicef MNP distributions only targeted children 6-24 months, only lasted for 12 months in 2014-15 and did not continue in 2016, this might have limited impact on nutritional status when measured six months later in June-July 2016, and may not necessarily be a major concern for the study. Furthermore, although study outcomes in some of the younger children in Yorosso may be affected, due to the limited age range of the children targetted by the other programs, study outcomes in the older cohort of children aged 5 years in 2016 should be completely unaffected.

Acceptability
Amongst those that reported giving MNPs to their child, acceptability of the intervention was generally high (Table 7). Few parents had encountered problems in giving MNPs to their child, with 92% reporting no difficulty. Over 90% of parents reported that their child like the food with the MNPs added, and 98% of parents would want to give their child MNPs again.

Most parents (91%) reported noticing changes in their child since giving them the MNPs. The most frequent changes mentioned included: child had increased appetite (65%); was less sick (50%); more active (38%) and more naughty than usual (14%). Negative changes were noted much less frequently, such as child being more sick (mentioned by 5% of parents); less active (5%); vomiting (5%); diarrhoea (3%); black-coloured stools (2%); and fever/respiratory illness (1%).

Seasonal Malaria Chemoprevention

Implementation
In 2013, prior to the baseline survey, two rounds of SMC were conducted by Save the Children in the 30 MNP intervention villages with 9,983 children treated in round 1 in October and 8,339 in round 2 in November.[59] In 2014, two rounds of SMC were carried out in all of the 90 study villages, with round 1 given in October and round 2 in November. Financial limitations in 2014 severely constrained the quality of implementation of the government-run SMC campaign, such that the following year, additional financial support was provided by Save the Children child sponsorship funding and by Unicef to strengthen the implementation of SMC in Sikasso and Yorosso Cercles, respectively. Save the Children staff from Project *Jigifa* also provided technical support in the training of DTCs, and in supervision of the SMC distributions. In 2015, 2 rounds of SMC were carried out in all 90 villages, with round 1 given in October and round 2 in November. Thus by May 2016, children in the MNP intervention group had received 3 years of SMC in 2013-2015 and children in the ECD control and non-ECD comparison groups had received 2 years of SMC in 2014-2015.

Coverage
The coverage achieved in terms of proportion of children who received SMC was determined by parental recall of treatments received in the previous year in August-December 2015, measured during the questionnaire survey with parents undertaken in May 2016. Reported coverage of SMC in 2015 exceeded 90% in all three study arms, with the highest coverage seen in the MNP intervention arm, where 96.8% of caregivers reported that their child had received malaria tablets in 2015 (Table 7). Reported coverage differed slightly between villages (ranging from 60% to 100%); although only 9 of the 90 villages reported <80% coverage (see Tables 6a, 6b and 6c for coverage data in MNP intervention, ECD control, and non-ECD comparison villages respectively).

Table 6a. **Implementation of the interventions by village (30 intervention villages)**

		Seasonal Malaria Chemoprevention					Micronutrient distribution and Informational Sessions for Parents					ECD Parenting	% parents reported attending information session(s)
Commune	Village	ECD trained - SMC	No. of rounds SMC achieved Aug-Dec per annum 2013	2014	2015	% children reported receiving SMC in 2015	GSAN trained - MNP	No. of rounds MNP achieved Jan-Apr per annum 2014	2015	2016	% children reported receiving MNPs	ECD monitrices trained -parenting	
Cercle: SIKASSO													
Kapala	Kapala	Yes	2	2	2	94.1	Yes	4	1	4	58.8	Yes	26.5
Kapala	Niagansoba	Yes	2	2	2	100	Yes	4	1	4	83.3	Yes	47.6
Kapolondougou	Fantéréla	Yes	2	2	2	94.9	Yes	4	1	4	92.3	Yes	43.6
Kapolondougou	Molasso	Yes	2	2	2	97.6	Yes	4	1	4	95.1	Yes	61.0
Kapolondougou	Tiagala	Yes	2	2	2	87.2	Yes	4	1	4	87.2	Yes	41.0
Zanferebougou	Zanferebougou	Yes	2	2	2	97.4	Yes	4	1	4	97.4	Yes	50.0
Gongasso	Noyaradougou	Yes	2	2	2	97.1	Yes	4	1	4	82.4	Yes	29.4
Doumanaba	Boro	Yes	2	2	2	82.9	Yes	4	1	4	82.9	Yes	29.3
Doumanaba	Niaradougou	Yes	2	2	2	84.4	Yes	4	1	4	93.8	Yes	40.6
Natien	Natien	Yes	2	2	2	97.1	Yes	4	1	4	55.9	Yes	2.9
Natien	Tamba	Yes	2	2	2	86.5	Yes	4	1	4	54.1	Yes	21.6
Farakala	Ifola	Yes	2	2	2	97.5	Yes	4	1	4	97.5	Yes	60.0
Kolokoba	Niantanso	Yes	2	2	2	97.6	Yes	4	1	4	92.9	Yes	66.7
Missirikoro	Missirikoro	Yes	2	2	2	100	Yes	4	1	4	72.1	Yes	9.3
Kaboïla	Mandela	Yes	2	2	2	95.5	Yes	4	1	4	61.4	Yes	25.0
Kaboïla	N'Dallé	Yes	2	2	2	95.1	Yes	4	1	4	92.7	Yes	46.3
Kaboila	Fachoribougou	Yes	2	2	2	84.1	Yes	4	1	4	59.1	Yes	34.1
Kaboila	Bemabougou	Yes	2	2	2	100	Yes	4	1	4	82.1	Yes	51.3
Pimperna	Zérélaba	Yes	2	2	2	92.7	Yes	4	1	4	61.0	Yes	24.4
Pimperna	Diassa-Deni	Yes	2	2	2	100	Yes	4	1	4	88.1	Yes	59.5
Kléla	Zerelani 1	Yes	2	2	2	90.2	Yes	4	1	4	65.9	Yes	41.5
Kouoro	Kouoro Barrage	Yes	2	2	2	94.1	Yes	4	1	4	61.8	Yes	11.8
Niena	Ouekorobougou	Yes	2	2	2	91.9	Yes	4	1	4	67.6	Yes	56.8
Niena	Banzana	Yes	2	2	2	94.4	Yes	4	1	4	72.2	Yes	58.3

Niena	Sirakoroba	Yes	2	2	2	93.8	Yes	4	1	4	90.6	Yes	65.6
Danderesso	Zoumayere	Yes	2	2	2	95.1	Yes	4	1	4	97.6	Yes	42.7
Diomaténé	M'pegnesso	Yes	2	2	2	94.6	Yes	4	1	4	37.8	Yes	29.7
Cercle: YOROSSO													
Koumbia	Koumbia	Yes	2	2	2	97.4	Yes	7	10	4	89.8	Yes	46.2
Koury	N'Gouélé	Yes	2	2	2	100	Yes	7	10	4	74.4	Yes	59.0
Ménamba 1	Ménamba 1	Yes	2	2	2	100	Yes	7	10	4	95.2	Yes	85.7

Table 6b. **Implementation of the interventions by village (30 ECD control villages)**

n/a = not applicable

		Seasonal Malaria Chemoprevention					**Micronutrient distribution and Informational Sessions for Parents**					**ECD Parenting**	**% parents reported attending information session(s)**
Commune	**Village**	ECD trained - SMC	No. of rounds SMC achieved Aug-Dec per annum			**% children reported receiving SMC in 2015**	GSAN trained - MNP	No. of rounds MNP achieved Jan-Apr per annum			**% children reported receiving MNPs**	ECD monitrices trained -parenting	
			2013	2014	2015			2014	2015	2016			
Cercle: SIKASSO													
Finkolo AC	Finkolo	n/a	0	2	2	92.1	n/a	n/a	n/a	n/a	18.4	Yes	42.1
Finkolo AC	Farako	n/a	0	2	2	95.0	n/a	n/a	n/a	n/a	7.5	Yes	40.0
Finkolo	Hérémakono	n/a	0	2	2	100	n/a	n/a	n/a	n/a	14.7	Yes	11.8
Kapala	Tarakasso	n/a	0	2	2	95.2	n/a	n/a	n/a	n/a	4.8	Yes	35.7
Kapolondougou	N'Kourala	n/a	0	2	2	81.6	n/a	n/a	n/a	n/a	15.8	Yes	50.0
Gongasso	Gongasso	n/a	0	2	2	93.6	n/a	n/a	n/a	n/a	12.9	Yes	29.0
Gongasso	Tabarako	n/a	0	2	2	90.0	n/a	n/a	n/a	n/a	7.5	Yes	15.0
Doumanaba	Doumanaba	n/a	0	2	2	86.5	n/a	n/a	n/a	n/a	24.3	Yes	10.8
Doumanaba	Fonsébougou	n/a	0	2	2	87.8	n/a	n/a	n/a	n/a	7.3	Yes	31.7
Natien	Sopie	n/a	0	2	2	81.4	n/a	n/a	n/a	n/a	0	Yes	16.3
Farakala	Farakala	n/a	0	2	2	87.2	n/a	n/a	n/a	n/a	15.4	Yes	23.1
Farakala	Kandiadougou	n/a	0	2	2	78.1	n/a	n/a	n/a	n/a	46.3	Yes	36.6
Farakala	Gniriwani	n/a	0	2	2	83.3	n/a	n/a	n/a	n/a	55.6	Yes	55.6
Kolokoba	Kolokoba	n/a	0	2	2	82.5	n/a	n/a	n/a	n/a	4.9	Yes	53.7
Kolokoba	Bowara	n/a	0	2	2	78.1	n/a	n/a	n/a	n/a	2.4	Yes	48.8

Sokourani-Missirikoro	Sokourani-Missirikoro	n/a	0	2	2	93.8	n/a	n/a	n/a	n/a	0	Yes	6.3
Kaboïla	Ouahibéra	n/a	0	2	2	100	n/a	n/a	n/a	n/a	2.7	Yes	27.0
Kaboila	Kaboila	n/a	0	2	2	100	n/a	n/a	n/a	n/a	4.6	Yes	18.6
Pimperna	Pimperna	n/a	0	2	2	97.4	n/a	n/a	n/a	n/a	2.6	Yes	18.4
Klela	Kong-Kala	n/a	0	2	2	89.7	n/a	n/a	n/a	n/a	2.6	Yes	43.6
Klela	Klela	n/a	0	2	2	82.4	n/a	n/a	n/a	n/a	5.9	Yes	47.1
Kafouziéla	Kafouziéla	n/a	0	2	2	86.5	n/a	n/a	n/a	n/a	18.9	Yes	10.8
Niena	Dougoukolobougou	n/a	0	2	2	88.1	n/a	n/a	n/a	n/a	4.8	Yes	35.7
Danderesso	Warasso	n/a	0	2	2	70.0	n/a	n/a	n/a	n/a	30.0	Yes	10.0
Danderesso	Nebadougou	n/a	0	2	2	79.5	n/a	n/a	n/a	n/a	18.0	Yes	12.8
Dandéresso	Bambougou	n/a	0	2	2	78.4	n/a	n/a	n/a	n/a	46.0	Yes	46.0
Cercle: YOROSSO													
Koury	Koury	n/a	0	2	2	80.1	n/a	3	10	0	25.0	Yes	66.7
Koury	Diaramana	n/a	0	2	2	80.0	n/a	3	10	0	56.7	Yes	36.7
Ménaba	Yacrissoun	n/a	0	2	2	95.6	n/a	3	10	0	64.4	Yes	77.8
Mahou	Mahou	n/a	0	2	2	79.3	n/a	3	10	0	48.3	Yes	48.3

Table 6c. **Implementation of the interventions by village (30 non-ECD comparison villages)**

n/a = not applicable

		Seasonal Malaria Chemoprevention					**Micronutrient distribution and Informational Sessions for Parents**					**ECD Parenting**	**% parents reported attending information session(s)**
Commune	**Village**	ECD trained - SMC	No. of rounds SMC achieved Aug-Dec per annum			**% children reported receiving SMC in 2015**	GSAN trained - MNP	No. of rounds MNP achieved Jan-Apr per annum			**% children reported receiving MNPs**	ECD monitrices trained -parenting	
			2013	2014	2015			2014	2015	2016			
Cercle: SIKASSO													
Danderesso	Bandieresso	n/a	0	2	2	97.1	n/a	n/a	n/a	n/a	45.7	n/a	34.3
Danderesso	Diassaba	n/a	0	2	2	91.3	n/a	n/a	n/a	n/a	4.4	n/a	10.9
Danderesso	Niaradougou	n/a	0	2	2	86.5	n/a	n/a	n/a	n/a	18.9	n/a	32.4
Danderesso	Seydoubougou	n/a	0	2	2	59.5	n/a	n/a	n/a	n/a	7.1	n/a	9.5

Finkolo	Kouloukan	n/a	0	2	2	84.4	n/a	n/a	n/a	n/a	0	n/a	9.4
Finkolo	Sanakoro	n/a	0	2	2	84.6	n/a	n/a	n/a	n/a	0	n/a	18.0
Kaboila	Doniena	n/a	0	2	2	93.0	n/a	n/a	n/a	n/a	2.3	n/a	20.9
Kaboila	Niankorobougou	n/a	0	2	2	94.3	n/a	n/a	n/a	n/a	5.7	n/a	45.7
Kaboila	Zangabougou	n/a	0	2	2	97.0	n/a	n/a	n/a	n/a	0	n/a	27.3
Kapala	Ngoulokouna	n/a	0	2	2	92.3	n/a	n/a	n/a	n/a	11.5	n/a	46.2
Kapala	Sanasso	n/a	0	2	2	100	n/a	n/a	n/a	n/a	11.8	n/a	47.1
Kapolondougou	Montonbougou	n/a	0	2	2	83.3	n/a	n/a	n/a	n/a	0	n/a	66.7
Kapolondougou	Ntiosso	n/a	0	2	2	85.2	n/a	n/a	n/a	n/a	3.7	n/a	77.8
Kapolondougou	Sintani	n/a	0	2	2	88.9	n/a	n/a	n/a	n/a	61.1	n/a	83.3
Klela	Dougoumousso	n/a	0	2	2	93.2	n/a	n/a	n/a	n/a	6.8	n/a	30.0
Klela	Tourmadie	n/a	0	2	2	100	n/a	n/a	n/a	n/a	0	n/a	10.0
Kolokoba	Dosansso	n/a	0	2	2	89.7	n/a	n/a	n/a	n/a	0	n/a	48.7
Kolokoba	Gondaga	n/a	0	2	2	78.8	n/a	n/a	n/a	n/a	3.0	n/a	51.5
Missirikoro	Faboulasso	n/a	0	2	2	86.5	n/a	n/a	n/a	n/a	0	n/a	2.7
Natien	Farga	n/a	0	2	2	90.9	n/a	n/a	n/a	n/a	27.3	n/a	36.4
Natien	Kena	n/a	0	2	2	76.7	n/a	n/a	n/a	n/a	3.3	n/a	3.3
Natien	Pitagalasso	n/a	0	2	2	86.7	n/a	n/a	n/a	n/a	6.7	n/a	23.3
Natien	Zierodougou	n/a	0	2	2	78.6	n/a	n/a	n/a	n/a	0	n/a	57.1
Pimperna	Sidaribougou	n/a	0	2	2	96.8	n/a	n/a	n/a	n/a	16.1	n/a	25.8
Sokourani-Missirikoro	Zerela	n/a	0	2	2	94.7	n/a	n/a	n/a	n/a	15.8	n/a	15.8
Cercle: YOROSSO													
Koumbia	Ouyasso	n/a	0	2	2	95.4	n/a	3	10	0	79.1	n/a	76.7
Koumbia	Tebere	n/a	0	2	2	93.3	n/a	3	10	0	66.7	n/a	46.7
Koury	Founa	n/a	0	2	2	88.4	n/a	3	10	0	60.5	n/a	46.5
Mahou	Nafarola	n/a	0	2	2	92.1	n/a	3	10	0	71.1	n/a	60.5
Menaba 1	Niessoumana	n/a	0	2	2	83.3	n/a	3	10	0	80.0	n/a	56.7

Early Childhood Care and Development (ECD)

ECD centres operate under the supervision of the Headteacher of the local primary school, but are almost entirely community managed and funded. Enrolment in the ECD center varies between 15-150 children, depending on the size of the village and the level of parental engagement Enrolment in ECD center is voluntary, and thus levels of participation will reflect the importance that local parents place on the value of the center, the number of children of eligible within the age bracket, and the means at their disposal. The cost of ECD attendance is set by the community and varies between villages, but is usually around 500 FCFA (0.90 USD) per child per month. Activities at the ECD include the initiation of pre-school children into a familiarity with letters, numbers, counting games and early maths, as well as a variety of games.

Table 8. **ECD Enrolment in the two age cohorts**

Proportion reported to be currently enrolled in an ECD centre in 2016	**MNP Intervention**	**ECD Control**	**Non-ECD Comparison**
Children aged 3-years	238/583 (41.5%)	139/553 (25.4%)	4/463 (0.9%)
Children aged 5-years	323/590 (55.0%)	273/573 (47.9%)	9/493 (1.8%)

Enrolment of children in ECD

Amongst the 60 ECD study villages, 33.2% of 3 year olds and 51.2% of 5 year olds were reported to be enrolled in an ECD center. Rates of reported ECD enrolment were higher in the MNP intervention villages than in the other ECD control villages, for reasons unknown; less than 2% of children in the non-ECD comparison villages were reported to be enrolled in an ECD centre (Table 8). There was however large variation in the proportion of children enrolled between the villages, which varied from 14-94% in the MNP intervention villages, and 5-74% in ECD control villages. Whilst the variation in coverage of ECD enrolment between villages may partly reflect differences in the level of engagement and means of parents, it will also be strongly affected by differences in village size and the capacity of an ECD centre, which can place a finite limit on enrolment in larger communities.

Participation in informational sessions for parents

In recognition that not all children of eligible age (3-5 years) are enrolled in ECD and in order to also reach parents with younger children, the parenting and nutritional interventions are not limited to the parents of children enrolled in ECD but instead are organized as community-based meetings open to all caregivers of young children aged 0-8 years living in the local community. In recognition of local practices of care, shared responsibility and informal adoptive relationships within extended families, this includes all carers of young children – including mothers, fathers, grandmothers, other family members and guardians.

Participation in nutrition or stimulation education sessions for parents, and thus exposure to key messages of the nutrition, welfare and cognitive development of young children, was determined by parental recall of attendance of a community meeting where they learned about child nutrition or cognitive stimulation, measured during the questionnaire survey with parents undertaken in May 2016. Overall, 37.3% of caregivers interviewed reported attending one or more informational meeting(s): 44.3%, 36.2% and 36.8% of caregivers in the MNP intervention villages, ECD control villages and non-ECD comparison villages respectively (Table 7). It is important to note that both the MNP intervention and the ECD parenting program relayed key messages about child nutrition, parent-child interactions, cognitive stimulation and early learning. Therefore parental responses to

this question might refer to participation in an information session organized in association with the MNP distributions, as well as those organized as part of the ECD parenting intervention.

The proportion of caregivers reporting attending an informational meeting for parents varied considerably between villages, ranging from 3% to 86% amongst MNP intervention villages (Tables 6a, 6b and 6c). A similar range in coverage was seen in the other two study arms. That less than 50% of caregivers interviewed in many ECD villages reported attending an informational meeting could be indicative of low uptake of the intervention, but could also partly reflect the range of respondents that were interviewed and their role in child care. On the other hand, the high proportion of respondents who reported attending an informational meeting in non-ECD villages is somewhat surprising, but may be due to the fact that most interventions aimed at improving child health and development (including those organized by government and NGOs other than Save the Children) also typically involve community meetings. The key IYCF messages on nutrition and child health are also common to many programmes.

When asked about the three most important things that they learnt during the sessions, the most common topics recalled by caregivers who reported having attended a community informational session were: hygiene (mentioned by 85%); appropriate kinds of food to give to children (60%); need to take malnourished children to health facility, CSCom (37%); how to cook enriched foods for children (33%); how to add MNPs to food (16%); how best to stimulate/support cognitive development of the child (16%); and not to hit/slap children (6%). Responses were similar across all three arms. That so many parents recalled messaging on hygiene (85%) is possible confirmation that the parents may be recalling one or more of a multitude of educational interventions targeted at parents in which community informational meetings were held. It may also indicate that this was the topic that had had most resonance for them. As the responses cannot necessarily be assumed to be attributable to either of the interventions under study, the findings should therefore be treated with caution. Furthermore, as the parents themselves selected the topics to be discussed at the ECD parenting sessions, the relative frequency of each topic may also be a reflection of local priorities, with hygiene and health accorded more importance than nutrition, and a lesser priortity placed also on parent-child interaction, cognitive stimulation, and play. Interestingly, only 6% of the parents recalled messaging about child disciplinary actions – suggesting either that this topic was rarely discussed or that it is made little impression on the parents, when it was.

XV. INTERMEDIATE OUTCOMES

Parenting practices, including child nutrition, were examined through a cross-sectional interview survey with parents or other caregivers conducted in May 2016. A structured questionnaire was used to capture data on the meals the child had consumed the previous day, as well as adult-child interactions during the previous seven days (Annex VI). The parental questionnaire also captured data on household socio-economic status, parental education, home literacy environment and enrolment in ECD.

The frequency of specific nutritional and parenting practices reported at endline are summarized by arm in Tables 9 and 10 below. Since informational sessions for parents on child nutrition and cognitive stimulation had been carried out in both ECD arms, no formal statistical comparisons were performed.

Reported nutrition and child feeding practices

Almost all children had consumed cereals/grains, fats/oils and fruit the previous day, with little difference between the three groups of villages (all more than 95%, Table 9). Consumption of protein-rich foods was less common - with approximately 70% of children reported to have consumed either red meat, poultry or fish the previous day – and similar across the three groups. More than 60% were also reported to have consumed beans and nuts. Consumption of milk and eggs was generally low; 34% and <20% respectively. Other food items, such as root vegetables (including cassava, potatoes and yams), and other vegetables were less common, eaten by less than 25% overall. Consumption of palm oil, which is rich in Vitamin A, was also uncommon.

Table 9. **Reported nutrition and child feeding practices by study arm**

	MNP Intervention (30 villages)	**ECD Control** (30 villages)
Interventions	**MNP + Parenting**	**Parenting**
Nutritional practices		
Proportion of parents who reported that in the day prior to the survey: Child had eaten at least 4 times in previous day [all snacks and meals] (%)	67.4	66.1
Child had consumed cereals and grains (%)	99.7	99.5
Child had consumed root vegetables [cassava, potatoes, yams] (%)	26.2	23.6
Child had consumed beans and nuts (%)	67.0	61.1
Child had consumed other vegetables (%)	23.5	20.6
Child had consumed fruit (%)	96.2	96.0
Child had consumed meat, poultry or fish (%)	68.2	71.5
Child had consumed milk (%)	36.9	32.1
Child had consumed eggs (%)	18.6	18.8
Child had consumed palm oil (%)	12.9	9.9
Child had consumed other fats and oils (%)	93.9	94.7

Nevertheless, reported consumption of root vegetables, beans and nuts, other vegetables, milk, and palm oil was generally slightly higher for children living in the MNP intervention group than amongst children living in the ECD control, indicating that children in these villages may have

received a slightly more diverse diet. For example, 67% of children in MNP intervention villages ate beans and nuts compared to 61% in the ECD control group; 37% had consumed milk vs 32%, and 13% had consumed palm oil vs. 10% respectively.

Although both groups of ECD villages organised parent information sessions which included key messages on child nutrition, cooking demonstrations were only held in MNP intervention villages. The marginally higher dietary diversity seen in MNP intervention villages could indicate that cooking demonstrations were a useful addition to the informational meetings (both in terms of providing practical examples based on locally available foodstuffs and re-inforcing verbal messaging), and/or that there had been greater focus on child nutrition during the information sessions in these villages (frequency and intensity of communication), however it is not possible to fully separate these two effects.

Home environment and reported parenting practices

Data was captured on the home literacy environment and different types of adult-child interactions that took place within households, including interactions with older children and adult family members as well as parent-child interactions during the past week (Table 10).

Table 10. **Home environment and reported parenting practices by study arm**

	MNP Intervention (30 villages)	**ECD Control** (30 villages)
Interventions	MNP + Parenting	Parenting
Home literacy environment		
Mean number of reading materials in home (SD)	1.95 (1.99)	1.79 (1.94)
Mean number of toys and other play items in home (SD)	3.76 (1.41)	3.69 (1.35)
Parent-Child Interaction		
Proportion reporting that in the last week a parent or other family member had: - Played with child (%)	95.2	95.0
- Hugged or showed affection to child (%)	92.9	92.5
- Taken child on visit outside the home (%)	77.1	80.2
- Sung song or lullaby to the child (%)	75.3	72.7
- Named objects for the child (%)	63.8	64.0
- Told stories to the child (%)	59.3	55.4
- Shown or taught something new to child (%)	53.0	46.7
- Played counting game or taught numbers (%)	51.2	48.0
- Read or looked at books with child (%)	36.1	31.1
- Drawn something for /with child (%)	34.9	30.6
- Taught alphabet or letters to child (%)	34.6	29.5
Mean number of different stimulating parent-child activities in past seven days [max 11] (SD)	6.82 (2.89)	6.54 (2.78)
- Smacked child for misbehaving (%)	90.7	91.2
- Hit child for misbehaving (%)	79.6	79.8
- Criticized or shouted at child (%)	84.3	85.1

The mean number of reading materials (which included items such as story books for children, school text books, newspapers, and religious books) was 1.95 and 1.79 in MNP intervention and ECD control villages respectively. Parents also reported that their child played with a variety of items, including items such as homemade toys, household items and found objects, as well as shop-bought toys and games. The mean number of different reported play items was 3.76 and 3.69 in MNP intervention and ECD control villages, respectively.

Certain types of positive parent-child interaction were very common in all households and villages. This included hugging or showing affection, and playing with the child, with both behaviors reported by over 90% of caregivers interviewed. Activities such as taking the child on visits outside the home and singing songs to the child were also commonly reported by more than 70% of parents in both arms. However, more intentional educational activities, such as naming things for the child, telling stories, showing the child something new, or playing counting games, were generally less common – with between 47% to 64% of parents reporting these activities in the last week. Furthermore, only around a third of parents reported that someone in the family had read or looked at books, drawn something, or taught alphabetic letters with/to the child within the last week. As seen for nutrional practices above, the data again indicate a tendency for some of these latter educational parent-child interactions to be slightly more common in ECD villages that had also received the MNP interventions than in the ECD control villages, perhaps as a result of more informational meetings arising from each of the two interventions, or due to greater levels of parental participation associated with the MNP distributions.

In contrast, it is also important to note the high prevalence of corporal punishment, with 91% of caregivers in both arms reporting having spanked the child for misbehaving within the last week, and 80% reported hitting the child. Criticising or shouting at the child was also common, reported by 84% and 85% of caregivers in the MNP intervention and ECD control villages respectively.

Discussion

In summary, the data on intermediate outcomes are indicative of a slight difference between the two arms across a broad range of parenting behaviours. These included differences in the reported diet of children living in MNP intervention villages compared to children living in other ECD villages. There are number of possible reasons for the reported dietary difference amongst ECD villages. First, although all informational sessions for parents included key messages on child nutrition, these sessions had been held in MNP intervention villages for the three previous years (ever since January 2014) compared to just one year for the ECD control villages (since Oct 2015).

Second, the informational sessions in MNP villages also included cooking demonstrations. These could have been useful in re-inforcing the verbal messaging of the informational meetings and in providing practical examples based on locally available foodstuffs, thus helping parents to see the desired behavioural changes as achievable. Third, the existence of MNPs may have led to a heightened awareness of nutrition amongst both parents and facilitators, resulting in a greater focus on child nutrition during the information sessions in these villages, both in terms of the frequency and intensity of messaging around nutrition. In other respects, the content of the messaging around nutrition was similar, being consistent with national Infant and Young Child Feeding (IYCF) guidelines, and would not account for the differences seen. Nevertheless, despite the overall trend, it should also be acknowledged that the differences between the two groups were not marked (generally less than five percentage points). All nutrition programmes in Mali include similar IYCF messages, and thus parents in all villages should have been exposed to these ideas at some point, whether through this specific intervention, other nutrition-specific programmes implemented by Mali government and NGOs, or routine interactions with local health providers and district officials. Whilst the uniformity of messaging from a wide variety of sources could dilute the

measurable effect of the parenting interventions, it is equally possible that the influence of the intervention is boosted by the fact that it reinforces other pre-existing messaging.

Slight differences were also seen in the home environment and reported adult-child interactions that support child development and early learning in MNP villages, compared to ECD control villages. Reported adult-child interactions were measured just six months after the launch of the national parenting programme in ECD control villages, in contrast to the MNP intervention which began in 2014. As a result, caregivers in MNP villages had been been exposed to messaging about child development for longer, and could have attended more informational meetings arising from each of the two interventions. Furthermore, it is possible that there were higher levels of parental participation associated with the MNP distributions.

In contrast, practices such as corporal punishment were extremely common in both arms, and indicates that these behaviours could be deeply entrenched as a societal norm. Indeed, these data suggest this aspect of parenting might be have been accorded low priority in the local culture, and that since the topic focus of each session was determined by the parents, is it quite conceivable that disciplinary practices were rarely discussed. Equally, if the topic was raised, it is possible the message content would not have been as fully appreciated by parents as other aspects of the programme. Qualitative research focusing on adult-child disciplinary interactions might be useful to inform how future ECD programming in this area could be improved.

An inherent limitation of using questionnaire surveys to collect data on behavior amongst parents that have been exposed to information on parenting practices, is that parental reports may be subject to a social desirability bias. In other words, parents that have attended parenting session(s) may be more inclined to report a behavior or other household attribute which they have been told is good for child development, but that does not necessarily correspond with the everyday reality of that child's life or the frequency the behaviour actually occurs with the home. The only way to confirm that the reported positive behaviours have truly occurred is through direct observation, a time consuming and costly technique which was not undertaken in this study. Nonetheless, at minimum we can be confident that the reported practices do provide confirmatory evidence that parents have received and readily recall the messages - an essential first step in behavioral change. Improved parental knowledge and appreciation of the practical steps that can be taken to support child development can only be beneficial, and pave the way to improving the nutrition, health and cognitive development of the young children in their care. The impact of the interventions on these biomedical outcomes is examined in the next section.

XVI. IMPACT ON BIOMEDICAL OUTCOMES

a. Characteristics of children surveyed in the cohort aged 5 years

Data on household characteristics were collected by a structured questionnaire interview with the child's parent or guardian. The characteristics of children in the 5 years old age-cohort that were surveyed in the MNP intervention and ECD control villages are shown in Table 11 (overleaf). In both arms, the vast majority of the children surveyed lived in households where either Bambara or Shenara was the principal language spoken in the home. The main source of income was subsistence agriculture, and levels of parental education were generally low: only 20.2% of fathers and 16.4% of mothers had attended school. Four in every 10 parents interviewed reported that their child's diet in the last 4 weeks had been limited by lack of financial resources, with 6.7% saying their child had sometimes gone to bed hungry due to a lack of food. Approximately half the children resident in villages with an ECD centre were currently enrolled in ECD: 55.0% of the children surveyed in intervention villages and 47.9% of children in ECD control villages.

Characteristics of children surveyed in ECD villages (Age 5 cohort)
The household characteristics of children surveyed in the intervention arm were generally similar to those of children in the ECD control arm, with very few differences seen in most of parameters examined. Mothers of children surveyed in the intervention villages are slightly younger and more literate than mothers in the ECD control arm, but this difference is only marginally significant ($p=0.046$ and $p=0.048$ respectively).

In terms of exposure to the interventions,

- Villages in both arms received malaria prevention interventions in accordance with national malaria control programme strategy: universal distribution of ITNs since 2011 and SMC since 2014. Coverage of seasonal malaria chemoprevention during previous rainy season, as well as use of mosquito bednets, was high in both groups. Nevertheless, children in the MNP intervention villages were more frequently reported to have received SMC in 2015 (97.6% vs 92.2%, $p<0.001$) and to have slept under a mosquito net the night before the survey (93.0% vs 87.2%, $p=0.074$). This difference may reflect the fact that in addition to the specific nutritional messaging, informational sessions in MNP villages also discussed the health of children in general, including prevention and treatment of malaria.
- MNPs had been distributed in MNP intervention villages since 2014. According to parent recall, 79.6% of children in the MNP intervention arm had been receiving micronutrient powders added to their food. As discussed in the previous section, MNP distributions had also been carried out by other NGOs in some of the ECD control and non-ECD comparison villages during the intervention period, which may account for why 21% of children in the ECD control arm were also reported to have received MNPs.

In conclusion, the randomisation process appears to have been effective in ensuring that the two groups of 5-year olds (intervention and ECD control) were comparable in terms of background characteristics. Nevetheless, there appear to be differences in how the malaria prevention intervention were implemented in the two arms, as well as some contamination of the experimental design as a result of MNP distributions in villages in the control arm.

Table 11. **Characteristics of 5-year old children in each study arm evaluated in July 2016, after three years of the intervention**

	Intervention	ECD control	
Five year olds	**(N = 590)**	**(N = 573)**	
Child and household characteristics[3]	Proportion	Proportion	*p*-value
Sex – N (%) - Male - Female	 306 (52.1%) 282 (48.0%)	 308 (54.1%) 261 (45.9%)	0.477
Principal language spoken in the home – - Bambara - Shenara - Mamara - French - Other	 207 (35.1%) 295 (50.1%) 35 (5.9%) 0 (0%) 52 (8.8%)	 180 (31.5%) 291 (50.9%) 30 (5.2%) 2 (0.4%) 69 (12.1%)	0.925
Number of siblings – Mean (SD)	6.86 (4.28)	6.96 (3.81)	0.633
Mother's age in years – Mean (SD)	30.32 (7.07)	31.07 (6.99)	**0.046**
Father's age in years – Mean (SD)	41.32 (10.77)	42.31 (10.37)	0.156
Maternal literacy -– N (%) - Not Literate - Literate	 478 (81.6%) 108 (18.4%)	 484 (86.4%) 76 (13.6%)	**0.048**
Mother's education – N (%) - Did not attend school - Attended school	 481 (81.9%) 106 (18.1%)	 460 (81.4%) 105 (18.6%)	0.800
Paternal literacy -– N (%) - Not Literate - Literate	 382 (66.4%) 193 (33.6%)	 376 (67.1%) 184 (32.9%)	0.893
Father's education – N (%) - Did not attend school - Attended school	 468 (80.6%) 113 (19.5%)	 433 (77.1%) 129 (22.9%)	0.286
Source of household revenue – N (%) - Subsistence agriculture - Other income	 551 (93.7%) 37 (6.3%)	 518 (90.6%) 54 (9.4%)	0.236
House construction (roof) – N (%) - Thatch or earth (banco) - Zinc sheet, tile, concrete	 39 (6.6%) 550 (93.4%)	 42 (7.3%) 530 (92.7%)	0.548
House construction (walls) – N (%) - Earth (banco) or none - Fired bricks or concrete	 565 (96.9%) 20 (3.4%)	 540 (94.9%) 29 (5.1%)	0.398
House construction (floor) – N (%) - Earth (banco) - Tiles or concrete	 384 (65.2%) 205 (34.8%)	 366 (64.0%) 206 (36.0%)	0.869
Principal source of lighting– N (%) - Lantern, torch, candle etc - Solar panel/Electricity	 100 (17.0%) 488 (83.0%)	 103 (18.0%) 449 (82.0%)	0.822
Diet limited by lack of financial resources in last 4 weeks – N (%)	215 (37.1%)	199 (35.5%)	0.615
Child ever went to bed hungry due to lack of food in last 4 weeks – N (%)	43 (7.3%)	29 (5.1%)	0.318
Child slept under mosquito net previous night – N (%)	547 (93.0%)	497 (87.2%)	0.074
Child received malaria tablets (SMC) in 2015 – N (%)	563 (97.6%)	505 (92.2%)	**0.001**
Child enrolled in ECD centre – N (%)	323 (55.0%)	273 (47.9%)	0.171
Child ever given MNPs – N (%)	460 (79.6%)	112 (21.2%)	-

b. Characteristics of children surveyed in the cohort aged 3 years

The characteristics of children in the 3 years old age-cohort that were surveyed in the MNP intervention and ECD control villages are shown in Table 12 (overleaf). As was seen in the older cohort, the vast majority of 3-year old children in all three arms lived in households where either Bambara or Shenara was the principal language spoken in the home. The main source of income was subsistence agriculture, and levels of parental education were generally low: only 20.8% of fathers and 18.9% of mothers had attended school. Four in every 10 parents interviewed reported that their child's diet in the last 4 weeks had been limited by lack of financial resources, with 8.1% saying their child had sometimes gone to bed hungry due to a lack of food.

Characteristics of children surveyed in ECD villages (Age 3 cohort)
The household characteristics of 3-year children surveyed in the MNP intervention arm were similar to those of children in the ECD control arm, with few differences seen across all of the parameters examined. A slightly lower proportion of the mothers and fathers of children surveyed in the intervention villages had attended school than parents in the ECD control arm, but these differences were small and did not reach statistical significance (mothers: 19.6% vs 24.8% and fathers: 25.0% vs 21.7%, p=0.067 and p=0.451 respectively). Despite a consistent tendency towards inferior house structure and other socioeconomic indicators in the intervention arm, no marked differences in socioeconomic status were observed.

In terms of exposure to the interventions,

- Villages in both arms received malaria prevention interventions in accordance with national malaria control programme strategy: universal distribution of ITNs since 2011 and SMC in all villages since 2014. Over 90% of 3-year children were reported to have received seasonal malaria chemoprevention during previous rainy season in 2015. The proportion of children reported to have slept under a mosquito net the night before the survey was also high and similar in both groups. However, as also seen in the older cohort, 3-year children in the MNP intervention villages were more frequently reported to have received SMC (96.1% vs 90.1%, p=0.006). As previously discussed this probably reflects general health messaging during the informational sessions, including prevention and treatment of malaria, in MNP intervention villages.
- MNPs had been distributed in MNP intervention villages since 2014. According to parental recall, 81% of children in the MNP intervention arm had been receiving micronutrient powders added to their food. As also seen in the older cohort, 17.6% of children in the ECD control arm were also reported to have received MNPs.
- Less than half of the 3-year old children resident in villages with an ECD centre attended ECD, but this was much more common in intervention villages than control villages, with respectively 41.5% and 25.4% of children currently enrolled in an ECD programme (p=0.006).

In conclusion, the randomisation process appears to have been effective in ensuring that the two groups of 3-year olds (intervention and ECD control) were comparable in terms of background characteristics. Nevetheless, there appear to be differences in how the malaria prevention intervention were implemented in the two arms (affecting both the 3-year old and 5-year old cohort), as well as some contamination of the experimental design as a result of MNP distributions in villages in the control arm.

Table 12. **Characteristics of 3-year old children in each study arm evaluated in July 2016, after three years of the intervention**

	Intervention	ECD control	
Three year olds	**(N = 583)**	**(N = 553)**	
Child and household characteristics[3]	Proportion	Proportion	*p*-value
Sex – N (%) - Male - Female	 282 (48.7%) 297 (51.3%)	 294 (53.2%) 259 (46.8%)	0.169
Principal language spoken in the home – - Bambara - Shenara - Mamara - French - Other	 201 (34.9%) 289 (50.2%) 37 (6.4%) 1 (0.2%) 48 (8.3%)	 187 (34.0%) 266 (48.4%) 25 (4.6%) 1 (0.2%) 71 (12.9%)	0.882
Number of siblings – Mean (SD)	6.54 (3.99)	6.43 (4.02)	0.545
Mother's age in years – Mean (SD)	28.85 (7.11)	28.82 (6.76)	0.803
Father's age in years – Mean (SD)	39.69 (10.57)	39.57 (10.00)	0.893
Maternal literacy -– N (%) - Not Literate - Literate	 476 (83.7%) 93 (16.3%)	 445 (81.5%) 101 (18.5%)	0.403
Mother's education – N (%) - Did not attend school - Attended school	 460 (80.4%) 112 (19.6%)	 413 (75.2%) 136 (24.8%)	0.067
Paternal literacy -– N (%) - Not Literate - Literate	 362 (63.8%) 205 (36.2%)	 365 (67.6%) 175 (32.4%)	0.417
Father's education – N (%) - Did not attend school - Attended school	 447 (78.3%) 124 (21.7%)	 405 (75.0%) 135 (25.0%)	0.451
Source of household revenue – N (%) - Subsistence agriculture - Other income	 545 (94.8%) 30 (5.2%)	 506 (92.2%) 43 (7.8%)	0.125
House construction (roof) – N (%) - Thatch or earth (banco) - Zinc sheet, tile, concrete	 41 (7.1%) 534 (92.9%)	 36 (6.6%) 513 (93.4%)	0.812
House construction (walls) – N (%) - Earth (banco) or none - Fired bricks or concrete	 549 (95.8%) 24 (4.2%)	 500 (92.4%) 41 (7.6%)	0.077
House construction (floor) – N (%) - Earth (banco) - Tiles or concrete	 373 (64.8%) 203 (35.3%)	 313 (56.9%) 237 (43.1%)	0.164
Principal source of lighting– N (%) - Lantern, torch, candle etc - Solar panel/Electricity	 111 (19.3%) 465 (80.7%)	 112 (20.4%) 438 (79.6%)	0.698
Diet limited by lack of financial resources in last 4 weeks – N (%)	223 (39.5%)	199 (36.7%)	0.506
Child ever went to bed hungry due to lack of food in last 4 weeks – N (%)	48 (8.4%)	36 (6.6%)	0.420
Child slept under mosquito net previous night – N (%)	528 (92.2%)	489 (89.4%)	0.378
Child received malaria tablets (SMC) in 2015 – N (%)	537 (96.1%)	473 (90.1%)	**0.006**
Child enrolled in ECD centre – N (%)	238 (41.5%)	139 (25.4%)	**0.006**
Child ever given MNPs – N (%)	451 (81.0%)	89 (17.6%)	-

c. Effect of MNP intervention on biomedical outcomes in children aged 5 years

A similar number of five-year old children were surveyed in the two groups of ECD villages in the endline surveys conducted in July 2016 to assess biomedical outcomes after three years of intervention: 590 children in the 30 ECD villages that had received the MNP intervention and 573 children in the 30 ECD control villages. The ECD control villages had not received the MNP intervention in the preceding years – and thus should be representative of the outcomes that would have been expected in the intervention group in the absence of intervention (counterfactual). As ECD villages were randomly allocated to the intervention or control arm, the characteristics of the two groups of ECD villages and the children surveyed in these arms would be expected to be similar.

Data on biomedical outcomes measured in children aged five years in July 2016, after three years of implementation of the MNP intervention, in the two randomised groups of ECD villages (MNP intervention and ECD control) are summarised in Table 13 (overleaf).

Effect of the MNP intervention on anaemia

Anaemia was highly prevalent in the study population with more than 50% of children in the age 5 cohort having a haemoglobin (Hb) concentration <11.0 g/dL. In contrast, moderate-to-severe anaemia (Hb<10.0 g/dL) was less common, around 22% in both groups; showing that anaemia though highly prevalent was relatively mild in more half of the cases recorded. No difference was observed in the prevalence of anaemia in 5-year old children living in intervention villages after three years of implementation of the MNP intervention compared to children living in ECD villages that had been randomised to the control arm (no intervention): 51.3% vs 53.0% respectively; adjusted odds ratio 0.90 (95% CI 0.60-1.35); p=0.607. The prevalence of severe-to-moderate anaemia in the two arms was comparable: 22.1% vs 22.7% respectively; adjusted odds ratio 0.94 (95% CI 0.64-1.40); p=0.770.

Mean Hb concentration was also remarkably similar across the two arms: 10.80 and 10.78 g/dL in the MNP intervention and ECD control arm respectively. Nonetheless, serum ferritin in children in the MNP interevention villages was slightly higher than among children in the ECD control villages: 90.0 and 74.4 μg/dL in the MNP intervention and ECD control arm respectively, a significant increase of +15.6 μg/dL, p=0.002.

Measures of malaria infection (another common cause of anaemia in the study area) were also similar between the two study arms, indicating that the apparent lack of effect of the MNP intervention on anaemia was not due to any difference in malaria risk. Indeed, findings of the fully adjusted analysis (which controlled for sex, malaria infection status of child, language spoken in the home, maternal literacy and wealth quintile) were similar to the results of the unadjusted analysis.

Effect of the MNP intervention on other nutritional outcomes

The chronic effects of poor nutrition in early childhood were manifest in the high proportion of children who were stunted and underweight at age five years. Overall, one in every five children in the age 5 cohort were stunted (height more than 2 SD below the age-specific mean in the WHO standard population), and a similar proportion of children were underweight (weight more than 2 SD below the age-specific mean in the WHO standard population). In contrast, the prevalence of acute malnutrition, measured according to body mass index for age, did not exceed 8% prevalence in any of the groups examined.

Table 13. **Effect of the MNP intervention on health outcomes in five-year-old children evaluated in July 2016, after three years of the intervention**

	Summary statistics		Intervention Effect for Intervention vs ECD control			
Five year olds	**Intervention (N = 530)** % (n / N)	**ECD control (N = 551)** % (n / N)	Crude Odds ratio 95% CI	p value	Adjusted Odds ratio[2] 95% CI	p value
Anaemia: Hb <11g/dL (primary outcome)	**51.3% (272 / 530)**	**53.0% (292 / 551)**	**0.91 0.60 to 1.38**	**0.643**	**0.90 0.60 to 1.35**	**0.607**
Moderate-to-severe anaemia: Hb <10g/dL	22.1% (117 / 530)	22.7% (125 / 551)	0.95 0.63 to 1.45	0.826	0.94 0.64 to 1.40	0.770
Stunting	21.8% (115 / 528)	22.2% (121 / 546)	1.00 0.65 to 1.53	0.998	0.84 0.54 to 1.30	0.422
Underweight	21.8% (115 / 528)	18.5% (101 / 546)	1.24 0.87 to 1.77	0.230	1.01 0.72 to 1.42	0.934
Acute malnutrition	7.0% (37 / 528)	7.9% (43 / 546)	0.88 0.55 to 1.40	0.591	0.84 0.51 to 1.37	0.478
Malaria infection[1] (presence of trophozoites and/or sporozoites, all species)	37.4% (198 / 529)	38.6% (212 / 549)	n/a	n/a	n/a	n/a
Malaria infectivity[1] (presence of gametocytes, all species)	17.0% (90 / 529)	17.9% (98 / 549)	n/a	n/a	n/a	n/a
	Mean (SD)	Mean (SD)	Difference 95% CI	p value	Difference[2] 95% CI	p value
Haemoglobin (g/dL)	10.80 (1.31)	10.78 (1.27)	0.02 -0.23 to 0.27	0.884	0.02 -0.21 to 0.25	0.869
Serum ferritin (geometric mean, µg/L)	90.02 (2.16)	74.44 (2.03)	0.18 0.05 to 0.31	**0.006**	0.18 0.07 to 0.30	**0.002**
Height-for-age Z-score[1] (SD)	-1.11 (1.43)	-0.99 (1.39)	n/a	n/a	n/a	n/a
Weight-for-age Z-score[1] (SD)	-1.15 (1.10)	-1.12 (1.08)	n/a	n/a	n/a	n/a
BMI-for-age Z-score[1] (SD)	-0.62 (0.91)	-0.70 (0.96)	n/a	n/a	n/a	n/a
Malaria parasite density[1] (geometric mean, parasites/µL)	1224.15 (11.94)	982.40 (6.05)	n/a	n/a	n/a	n/a

***Notes**: Weight for height is not assessed in five year olds. [1]Differences in additional outcomes between arms were not subject to statistical tests.[2] Fully adjusted analyses control for sex, malaria infection status of child, language spoken in the home, maternal literacy and wealth quintile. All analyses account for clustering within villages.*

None of the growth indices showed any sign of improvement when measured in children in intervention villages after three years of MNP distributions compared to children living in ECD villages that had been randomised to the control arm (no intervention). The prevalence of stunting was essentially the same in the two arms: 21.8% vs 22.2% respectively; adjusted odds ratio 0.84 (95% CI 0.54-1.30); p=0.422. The proportion underweight was also similar: 21.8% vs 18.5% respectively; adjusted odds ratio 1.01 (95% CI 0.72-1.42); p=0.934. Neither was there any evidence of an effect on the prevalance of acute malnutrition: 7.0% vs 7.9% respectively; adjusted odds ratio 0.84 (95% CI 0.51-1.37); p=0.478. Similarly, mean z-scores for height-for-age, weight-for-age, and BMI-for-age in the age-5 cohort were virtually identical across the two arms.

d. Effect of MNP intervention on biomedical outcomes in children aged 3 years

A comparable number of three-year old children were examined for biomedical outcomes in each of the two groups of villages in July 2016: 583 children in the 30 ECD villages that had received the MNP intervention, and 553 children in the 30 ECD control villages. Data on biomedical outcomes measured in children aged three years in July 2016 in the two randomised groups of ECD villages (MNP intervention and ECD control) are summarised in Table 14. Children in the intervention villages will have been eligible to receive MNPs from age 6-months onwards, and thus should have received MNPs every year of their life ever since weaning.

In comparison to the older age cohort aged 5-years in 2016, the prevalence of anaemia was higher in the younger age cohort, with almost 60% of children aged 3-years being anaemic in both arms. Moderate-to-severe anaemia (Hb<10.0 g/dL) was also more slightly more common than observed in older children. In contrast, the prevalence of malaria in 3-year olds was lower than that in the older children. The prevalence of stunting was similar in the two groups, although the prevalence of underweight was slightly lower in the younger children.

Effect of the MNP intervention on anaemia

Anaemia was highly prevalent; more than 57% of children in the age 3 cohort had a haemoglobin (Hb) concentration <11.0 g/dL. However, as also seen in older children, the prevalence of moderate-to-severe anaemia (Hb<10.0 g/dL) was much lower, indicating that anaemia was relatively mild in more half of the cases recorded.

There was a negligible and non-significant difference seen in the prevalence of anaemia in children aged 3-years living in MNP intervention villages compared to children resident in ECD villages that had been randomised to the control arm (no intervention): 57.6% vs 60.1% respectively; adjusted odds ratio 0.84 (95% CI 0.59-1.21); p=0.352. Similarly, the prevalence of severe-to-moderate anaemia was slightly lower amongst children in the intervention arm: 27.1% vs 31.3% respectively; adjusted odds ratio 0.70 (95% CI 0.47-1.04); p=0.081. Mean Hb concentration was similar across the two arms: 10.59 and 10.44 g/dL in the MNP intervention and ECD control arm respectively. Serum ferritin levels were also similar: 71.5 and 69.4 μg/dL in the MNP intervention and ECD control arm respectively, an increase of just +2.1 μg/dL, p=0.771.

Measures of malaria infection (another common cause of anaemia in the study area) in the younger group of children were similar between the two study arms, again indicating that the apparent lack of effect of the MNP intervention on anaemia was not due to any difference in malaria risk. Results of the fully adjusted analysis were similar to those of the unadjusted analysis.

Effect of the MNP intervention on other nutritional outcomes

The chronic effects of poor nutrition in early childhood were manifest in the high proportion of children who were stunted and underweight at age three years. Overall, one in every five children was stunted by age 3 years, and between 13.4%-15% of children were underweight. In contrast, the prevalence of acute malnutrition, measured according to weight for height, did not exceed 5% prevalence in any of the groups examined.

None of the growth indices showed any sign of improvement when measured in three-year children in intervention villages after three years of MNP distributions compared to children living in ECD villages that had been randomised to the control arm (no intervention). The prevalence of stunting was similar in the two arms: 25.2% vs 22.6% respectively; adjusted odds ratio 1.13 (95% CI 0.69-

Table 14. **Effect of the MNP intervention on health outcomes in three-year old children evaluated in July 2016, after three years of the intervention**

	Summary statistics		Intervention Effect for Intervention vs ECD control			
	Intervention	**ECD control**	Crude Odds ratio 95% CI	p value	Adjusted Odds ratio[2] 95% CI	p value
Three year olds	**(N = 538)**	**(N = 514)**				
	% (n / N)	% (n / N)				
Anaemia: Hb <11g/dL (primary outcome)	**57.6% (310 / 538)**	**60.1% (309 / 514)**	**0.89 0.63 to 1.26**	**0.517**	**0.84 0.59 to 1.21**	**0.352**
Moderate-to-severe anaemia: Hb <10g/dL	27.1% (146 / 538)	31.3% (161 / 514)	0.80 0.52 to 1.21	0.283	0.70 0.47 to 1.04	0.081
Stunting	25.2% (131 / 519)	22.6% (113 / 500)	1.16 0.72 to 1.88	0.547	1.13 0.69 to 1.84	0.634
Underweight	15.0% (78 / 519)	13.4% (67 / 500)	1.14 0.73 to 1.76	0.564	1.07 0.68 to 1.69	0.753
Acute malnutrition	4.2% (22 / 519)	4.8% (24 / 500)	0.87 0.46 to 1.64	0.666	0.83 0.44 to 1.59	0.580
Malaria infection[1] (presence of trophozoites and/or sporozoites, all species)	29.0% (155 / 534)	26.5% (136 / 513)	n/a	n/a	n/a	n/a
Malaria infectivity[1] (presence of gametocytes, all species)	11.2% (60 / 534)	12.3% (63 / 513)	n/a	n/a	n/a	n/a
	Mean (SD)	Mean (SD)	Difference 95% CI	p value	Difference[2] 95% CI	p value
Haemoglobin (g/dL)	10.59 (1.38)	10.44 (1.46)	0.15 -0.10 to 0.40	0.243	0.19 -0.54 to 0.43	0.129
Serum ferritin (geometric mean, µg/L)	71.52 (2.14)	69.41 (2.25)	0.03 -0.11 to 0.17	**0.663**	0.02 -0.12 to 0.16	**0.771**
Height-for-age Z-score[1] (SD)	-0.89 (1.67)	-1.02 (1.38)	n/a	n/a	n/a	n/a
Weight-for-age Z-score[1] (SD)	-0.82 (1.17)	-0.92 (1.02)	n/a	n/a	n/a	n/a
Weight-for-height Z-score[1] (SD)	-0.44 (0.91)	-0.48 (0.97)	n/a	n/a	n/a	n/a
BMI-for-age Z-score[1] (SD)	-0.35 (0.92)	-0.40 (0.98)	n/a	n/a	n/a	n/a
Malaria parasite density[1] (geometric mean, parasites/µL)	497.70 (15.49)	992.27 (14.15)	n/a	n/a	n/a	n/a

***Notes**: [1]Differences in additional outcomes between arms were not subject to statistical tests. [2] Fully adjusted analyses control for sex, malaria infection status of child, language spoken in the home, maternal literacy and wealth quintile. All analyses account for clustering within villages.*

1.84); p=0.634. The proportion underweight was also similar: 15.0% vs 13.4% respectively; adjusted odds ratio 1.07 (95% CI 0.68-1.69); p=0.753. Neither was there any evidence of an effect on the prevalance of acute malnutrition: 4.2% vs 4.8% respectively; p=0.580. Likewise, there were no marked differences seen between the two arms in mean z-scores for height-for-age, weight-for-age, weight-for-height, and BMI-for-age in the age-3 cohort.

XVII. IMPACT ON COGNITIVE FUNCTION

a. Effect of MNP intervention on cognitive outcomes and school-readiness in children aged 5 years

A similar number of five-year old children were surveyed in the two groups of ECD villages in the endline surveys conducted in July 2016 to assess cognitive outcomes and school-readiness after three years of intervention: 474 children in the 30 ECD villages that had received the MNP intervention and 497 children in the 30 ECD control villages. There was a smaller number of children of eligible age in the 30 non-ECD villages, and only 287 children were surveyed in this arm.

No differences were observed in performance in tasks designed to assess cognitive-linguistic literacy-related foundation skills among children aged 5-years living in intervention villages after three years of implementation of the MNP intervention, compared to children living in ECD villages which had been randomised to the control arm and who had not received the MNP intervention (Table 15). Indeed, test scores were remarkably similar across both groups for every test performed, which had been selected to assess skills such as sustained attention, working memory, and self-regulation of behaviour (visual search, digit span, RAN, mixed instructions, HSKT) – key cognitive foundation skills for development and academic progress in early literacy and numeracy. Performance in tasks which also assessed linguistic skills (expressive vocabulary, RAN) likewise were almost identical across the two groups of children tested.

Table 15. **Effect of the MNP intervention on cognitive outcomes in five-year old children evaluated in May-June 2016, after three years of the intervention**

	Summary statistics		Intervention Effect[1] MNP Intervention vs ECD control	
	Intervention	ECD control		
Five year olds	**(N = 474)**	**(N = 497)**	Crude Difference bootstrap 95% CI	Adjusted Difference[2] bootstrap 95% CI
	Mean (SD)	Mean (SD)		
Visual search (number correct, max 33)	26.9 (7.1)	26.7 (7.1)	0.27 -1.16 to 1.78	0.07 -1.26 to 1.45
Visual search (number of errors)	2.5 (5.2)	2.4 (4.6)	0.07 -0.56 to 0.66	-0.06 -0.69 to 0.61
Mixed instructions (number correct, max 6)	5.6 (1.0)	5.5 (1.1)	0.05 -0.10 to 0.19	0.05 -0.10 to 0.20
Heads, shoulders, knees and toes [HSKT] (total score)	26.4 (12.2)	27.7 (12.0)	-1.34 -3.09 to 0.37	-1.26 -3.08 to 0.67
Digit span	2.7 (0.76)	2.8 (0.83)	-0.09 -0.22 to 0.04	-0.07 -0.22 to 0.06
Expressive vocabulary (number of words - total across 2 categories)	8.9 (3.2)	8.8 (3.4)	-0.01 -0.76 to 0.64	0.07 -0.65 to 0.70
Rapid automated naming time [RAN] (seconds; total across 2 trials)	136.5 (61.3)	137.3 (56.8)	-0.61 -11.53 to 10.49	-2.32 -13.47 to 9.36

***Notes**: [1]Data were analysed using linear mixed models with a random effect of village to account for clustering within community. Since the outcome data was not normally distributed, the bootstrap method was used (2,000 replications) and bias corrected, bootstrap 95% confidence intervals are reported. [2]Fully adjusted analyses control for sex, language spoken in the home, enrolment in ECD, maternal literacy, wealth quintile.*

b. Effect of MNP intervention on cognitive outcomes in children aged 3 years

A similar number of three-year old children were surveyed in the two groups of ECD villages in the endline surveys conducted in July 2016 to assess cognitive outcomes and school-readiness after three years of intervention: 474 children in the 30 ECD villages that had received the MNP intervention and 497 children in the 30 ECD control villages. There was a smaller number of children of eligible age in the 30 non-ECD villages, and only 287 children were surveyed in this arm.

As was observed for the older children, performance in tasks designed to assess cognitive-linguistic foundation skills in children aged 3-years (including sustained attention, working memory, self-regulation of behaviour, and linguistic skills) likewise did not differ between children living in intervention villages where MNPs had been distributed for the last 3 years, and children of similar age living in ECD control villages that had not received the MNP intervention (Table 16).

Table 16: **Effect of the MNP intervention on cognitive outcomes in three-year old children evaluated in May-June 2016, after three years of the intervention**

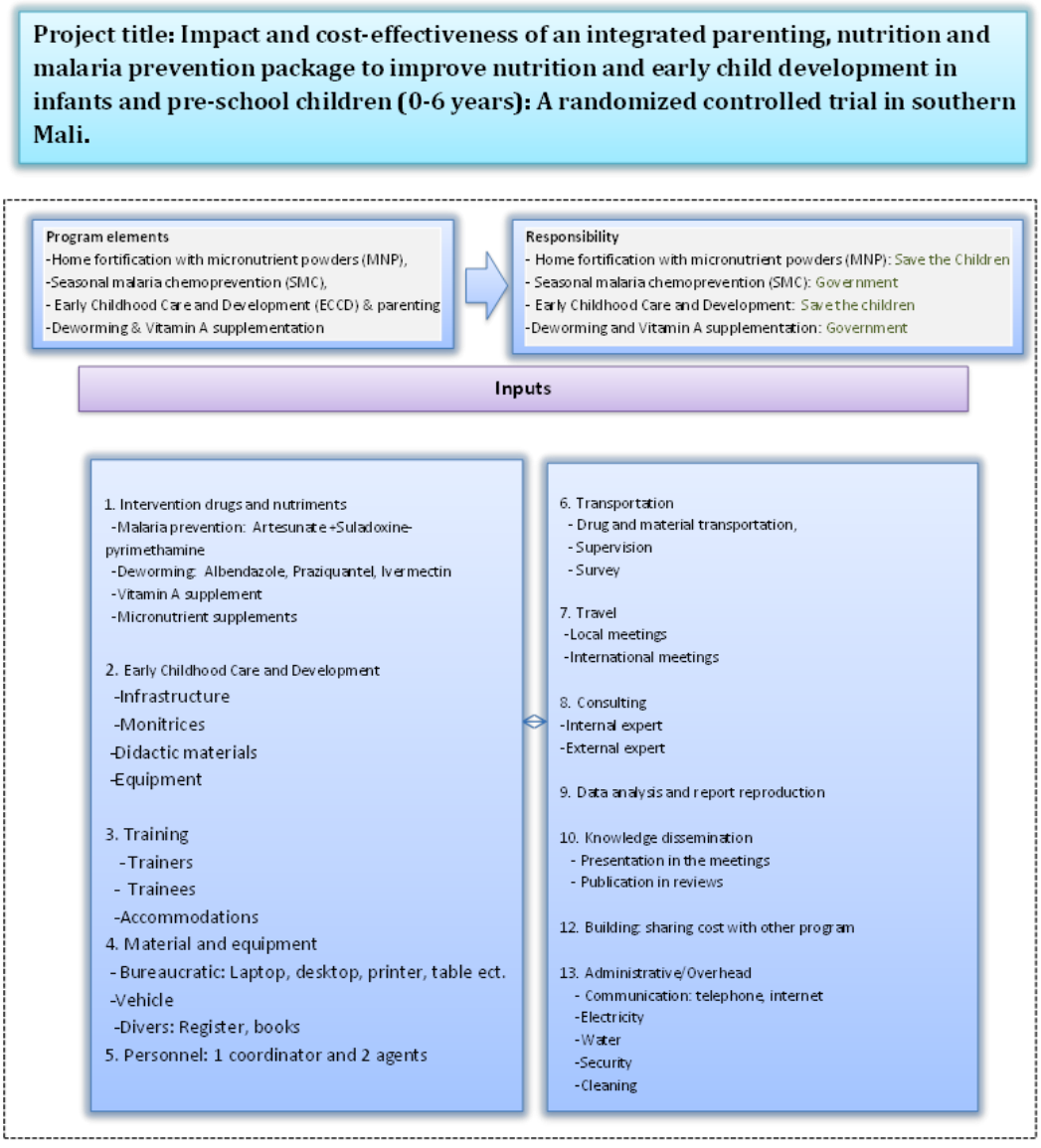
	Summary statistics		Intervention Effect [1] MNP Intervention vs ECD control	
	Intervention	ECD control		
Three year olds	**(N = 474)**	**(N = 497)**	Crude Difference bootstrap 95% CI	Adjusted Difference[2] bootstrap 95% CI
	Mean (SD)	Mean (SD)		
Visual search (number correct, max 33)	22.5 (9.5)	21.9 (8.6)	0.78 -1.14 to 2.70	0.22 -1.72 to 2.14
Visual search (number of errors)	3.5 (4.5)	3.8 (4.8)	-0.35 -1.00 to 0.34	-0.20 -0.87 to 0.45
Expressive vocabulary (number of words - total across 2 categories)	7.3 (3.1)	6.7 (2.9)	0.60 -0.03 to 1.21	0.51 -0.09 to 1.16
Rapid automated naming time [RAN] (seconds; total across 2 trials)	118.2 (58.2)	118.4 (58.8)	-0.93 -13.0 to 9.9	0.31 -11.91 to 12.07

***Notes**: Digit span, mixed instructions and head, shoulders, knees and toes tasks were not administered to the three year old children. [1]Data were analysed using linear mixed models with a random effect of village to account for clustering within community. Since the outcome data was not normally distributed, the bootstrap method was used (2,000 replications) and bias corrected, bootstrap 95% confidence intervals are reported. [2]Fully adjusted analyses control for sex, language spoken in the home, enrolment in ECD, maternal literacy, wealth quintile.*

XVIII. COST ANALYSIS

The analysis has been conducted from a service provider perspective, using a time horizon of 1 year. There were five strategies that were delivered by two different providers. Seasonal malaria chemoprevention, deworming, vitamin A supplementation were all delivered by the Ministry of Health: we did not capture the cost of these strategies in this cost analysis. Hence the cost analysis concerned only micronutrient supplementation and early child development program delivered by Save the Chiildren. The ECD program encompassed parental education and preschool provision for children. The program diagram used for the analysis is given below (Figure 7).

Figure 7. **Program Diagram used in Costing**



The ECD program started since 2013 and was ongoing until 2016. While the micronutrient program activities covered only a period of 4 months from January to April in 2016, the salary expenditures started in 2015. Although the impact of health prevention and pre-school programs can spread over a long time period, in this study we aimed to capture the short term effects of supplementation with micronutrients on children nutritional and health status (stunting, wasting and underweight, anemia, iron deficiency, malaria prevalence) and parental education and ECD

program on cognitive development and school readiness. For the purpose of comparison between the two programs the time horizon was thus fixed at 1 year.

The costs of research and evaluation are excluded in this analysis, since government would not be expected to have the perspective to evaluate the impact of the program.

Beneficiaries

The direct beneficiaries are children in the age range of 6 to 59 months in the MNP intervention, and 2-5 years for ECD interventions.

- The MNPs were delivered during 4 months from January to April 2016. A total of 24,091 boxes of MNPs were distributed in 2016; 7728, 6472, 5839 and 4052 boxes in January, February, March and April 2016 respectively. One box contains 30 daily doses to cover 1 month of supplementation for one child.
- The ECD intervention included support to 60 ECD centers and parenting education. From 2015 to 2016, there were a total of 11,012 children enrolled in these 60 ECD centers participating in *Projet Jigifa*

Costs

Costs were classified according the classical economic evaluation costing model in management-administration and intervention-supply categories. The management-administration costs included the direct and indirect costs of the personnel salary payment and benefits (assurance, telephonic communication), resources for coordination administration (laptop, printer, office phone, etc.), office building facilities and supplies (renting, cleaning, security, internet, electricity, water, conditioned air, personnel, shipment, etc.), purchased vehicles and share of number of purchased vehicle utilizations, working meeting, accommodation, travel. Intervention costs encompassed the costs of direct activities and resources used for the delivery of the interventions. These included the intervention products (micronutrient powders), training, monitoring, equipment (motorcycles, manual, register, etc.), transportation, salary of front-line personnel etc.

Initially the total cost by input category was calculated. Then using the relevant inputs for either management or intervention deliveries the respective total costs were calculated. Finally the total cost of each program (ECD and MNPs) was calculated by adding total costs of program delivery and management. The unit cost is the ratio of total cost to the number of beneficiaries in each program. The numbers of beneficiaries used in the analysis were 24,091 and 11,012 for MNPs and ECD respectively.

Cost data were initially recorded in the local currency West African Francs (XOF); results of the cost analysis are expressed in XOF and USD 2012 (average exchange rate of 2015; 1 USD= 591.45 XOF)

Total costs

The total annual costs of the MNPs and ECD programs in 2015/16 were 171,082 USD (101,816,352 XOF) and 851,904 USD (474,088,317 XOF) respectively (Table 17). These include both financial and economic costs. The management cost component accounted for the largest portion of the total costs for MNPs program with 58.1%; whilst for the ECD program the costs of intervention delivery accounted for the largest proportion, representing 85.1% of the total cost.

Unit costs

A total of 7728, 6472, 5839 and 4052 children were supplemented by MNPs in January, February, March and April respectively in 2016; making a total of 24,091 monthly child-supplements distributed. In 2015/2016, there were 10,112 children enrolled in the 60 ECD preschool centers.

Table 17. **Total and unit costs for MNPs and ECD programs, broken down by the share of management and intervention costs of the total costs**

	MNPs					ECD				
	Manangement		Intervention		total	Manangement		Intervention		total
Total costs		%total		%total			%total		%total	
in USD	98,891	57.8	72,191	42.2	171,082	125,225	17.2	726,679	85.3	851,904
in XOF	59,119,139	58.1	42,697,214	41.9	101,816,352	70,458,123	17.5	403,630,195	85.1	474,088,317
Cost per child										
in USD	4	57.1	3	42.9	7	12	14.3	72	85.7	84
in XOF	2,454	58.1	1,772	41.9	4,226	6,968	14.9	39,916	85.1	46,884

Notes: USD: Unated State Dollar, XOF: F CFA, MNPS: Micronutrient powders, ECD: Early Children Care Development, %total: the percentation of the corresponding total

The total cost per child for the MNP intervention was therefore estimated as 7 USD (4,226 XOF) per child supplemented and the cost per child for the ECD program was 84 USD (46,884 XOF) per child enrolled in ECD.

Sensitivity analysis

Tables 18 and 19 provide a breakdown of the costs by item, the cost share of each item within the total cost, and the analysis of time uncertainty variation of costs (sensitivity analysis) for the MNP supplementation and ECD program respectively. The main limitation of the costing surveys was that costs were collected from archived expenditures in financial, logistic and administrative units. There was limited detail available for some items and other costs were aggregated, making it impossible to capture individual cost for all items.

MNP supplementation program:

The cost of the MNPs program was driven by the costs of the intervention itself representing 50.4% of the total cost of the intervention delivery only, followed by the cost of training that represented 44.3% of the total cost (Table 18a). Regarding MNPs management, the cost was primarily driven by the personnel cost, with a 71.1% cost-share (Table 18b). Since the price of micronutrient powders could fluctuate over the time, the results of the sensitivity analysis showed that a variation in the price of MNPs between +25% and -25% would result in an increase of the total costs of MPN program intervention delivery by 7.1% (77,537 USD; 45,859,157 XOF) or decrease by 7.1% (66,845 USD; 39,535,270 XOF) respectively. In the same way, a variation in transport costs by ±50% due for example to an increase in fuel price, could change the total cost of MNPs delivery by ±1.6% (Table 18a). Whilst an increase in salaries of 10%, would increase the total cost of MNPs program management by 86,159 USD (12.87%, Table 18b).

ECD program:

For the ECD program, the total cost of intervention delivery was driven by personnel costs and the cost of training: 33.3% and 24.8% respectively (Table 19a). While the management cost of the ECD program was driven by the costs of transportation (41.0%) and office and store supply (15.4%, Table 19b).

In conclusion,

The cost per child of ECD program was higher than the cost of the MNPs program.

- Cost of the MNP intervention was 7 USD (4,226 XOF) per child supplemented
- Cost of the ECD program was 84 USD (46,884 XOF) per child enrolled in ECD per annum.

For both programs, the costs of training, transportation and personnel were the more costly items of expenditure.

Itemised costing and results of univariate sensitivity analyses for the MNP intervention

Table 18a. **MNP intervention delivery cost, cost share of each item and sensitivity analysis**

	Cost (XOF)	Cost (USD)	%total.dass	%total.interv	(Trsprt ±50% XOF)	(Trsprt ±50% USD)	MNPs (±25% XOF)	MNPs (±25% USD)
Training costs	-	-	-	-	-	-	-	-
Trainee paiement	3318100	5610	16.89	-	3318100	5610	3318100	5610
Trainer paiement	3030220	5123	15.43	-	3030220	5123	3030220	5123
Foods	2160000	3652	11.0	-	2160000	3652	2160000	3652
Supervision	63830	108	0.32	-	63830	108	63830	108
Transport	335780	568	1.71	-	503670	852	335780	568
Hall renting	150000	254	0.76	-	150000	254	150000	254
Anthropometric training	10582100	17892	53.88	-	10582100	17892	10582100	17892
Total	*19640030*	*33207*	*100*	*44.3*	*19807920*	*33490*	*19640030*	*33207*
Equipment	-	-	-	-	-	-	-	-
Monitoring material	61667	104	7.93	-	61667	104	61667	104
Register	20000	34	4.29	-	20000	34	20000	34
Motors	662500	1120	56.78	-	662500	1120	662500	1120
Total training	*744167*	*1258*	*100*	*5.3*	*744167*	*1258*	*744167*	*1258*
Intervention	-	-	-	-	-	-	-	-
Micronutriment powder	12647775	21384	56.68	-	12647775	21384	15809719	26730
MNP distribuor paiement	7290000	12326	32.67	-	7290000	12326	7290000	12326
Transport	1088862	1841	4.88	-	1633293	2762	1088862	1841
Supervision	1220740	2064	5.47	-	1220740	2064	1220740	2064
External expertise	65640	111	0.29	-	65640	111	65640	111
Total intervention	*22313017*	37726	100	50.4	22857448	38646	25474961	43072
Total	*42697214*	*72191*	-	*100*	*43409535*	*73395*	45859157	77537
Sensitivity	-	-	-	-	*1.6*	*1.6*	7.1	7.1

Table 18b: **MNPs management cost, cost share of each item and sensitivity analysis**

Salary and benefits	Cost (XOF)	Cost (USD)	%total.dass	%total.interv	Salary (-30% XOF)	Salary (+10% XOF)	Salary (-30% USD)	Salary (+10% USD)
Salary	25100688	42439	59.7	-	17570482	27610757	29707	46683
Insurance	16000000	27052	38.1	-	16000000	16000000	27052	27052
Telephonic communication	928000	1569	2.2	-	928000	928000	1569	1569
Total personnel	*42028688*	71060	100	71.1	34498482	44538757	58329	75304
Micronutrient Fortification Administration	-	-	-	-	-	-	-	-
Labtop	163989	277	26.0	-	163989	163989	277	277
Printer-scaner	107460	182	17.1	-	107460	107460	182	182
Office phone	83700	142	13.3	-	83700	83700	142	142
Office table	200000	338	31.7	-	200000	200000	338	338
Chair	75000	127	11.9	-	75000	75000	127	127
Total direct administration	*630149*	*1065*	100	*1.1*	*630149*	*630149*	*1065*	*1065*
Housing	2161440	3654	14.2	-	2161440	2161440	3654	3654
Security	6657248	11256	43.7	-	6657248	6657248	11256	11256
Building cleaning and management	1777680	3006	11.7	-	1777680	1777680	3006	3006
Water	95184	161	0.6	-	95184	95184	161	161
Electricity	2162000	3655	14.2	-	2162000	2162000	3655	3655
Internet	667024	1128	4.4	-	667024	667024	1128	1128
Phone	265248	448	1.7	-	265248	265248	448	448
Conditionned air	412362	697	2.7	-	412362	412362	697	697
Insecitide	280000	473	1.8	-	280000	280000	473	473
Vehicule utilization	768200	1299	5.0	-	768200	768200	1299	1299
Total indirect administration	*15246386*	25778	100	25.8	15246386	15246386	25778	25778
Travel and accommodation	-	-	-	-	-	-	-	-
Accommodation	140000	237	24.0	-	140000	140000	237	237
Travel	443766	750	76.0	-	443766	443766	750	750
Total travel and accommodation	*583766*	987	100	1.0	583766	583766	987	987
All total	*59119139*	*98891*	-	-	*50958783*	*60999058*	*86159*	*103135*
Sensitivity analysis	-	-	-	-	*13.8*	*-3.2*	*12.9*	*-4.3*

DISCUSSION

In conclusion, in both age groups examined, the nutritional intervention had no impact in reducing the prevalence of anaemia in pre-school children living in intervention villages where community-led programs of home fortification with micronutrient powders had been implemented. Neither was there any evidence of improvement in other nutritional indices after three years of implementation of the MNP intervention. Nor any indication that the intervention improved cognitive performance.

Losses to follow-up were approximately 20% amongst the two age groups of children recruited at baseline in 2013, and resampling was carried out to improve statistical power at endline. Under these circumstances, bias due to differential losses could be a potential concern. However, there was no circumstantial evidence to suggest that differential attrition had occurred between the two study arms: the interventions were reported to have been well received and popular with both parents and children; there were no documented refusals or withdrawal of consent; and losses to follow-up were mainly due to outmigration, and thus can be assumed to be missing at random. Furthermore, the characteristics of the children examined at endline in 2016 were well balanced across the intervention and control arm.

The risk of randomization failure is increased in cluster-randomisation trials with a small number of clusters, but we did not find any evidence of imbalance in the characteristics of the children surveyed between the two randomized arms. Nonetheless, there was an imbalance between the arms with respect to the proportion that reported receiving malaria preventive treatment in 2015; as well as differences in ECD enrolment. This suggests that increased parental engagement through the MNP intervention may have increased the likelihood of attendance on the days of SMC distribution, as well as the likelihood that a child attends an ECD center throughout the year – though we cannot know for certain. Since malaria can also cause anaemia, increased exposure to seasonal malaria chemoprevention in the intervention arm would make it hard to conclude that any reduction in anaemia was due to the MNPs alone. However, since there was no observed difference in anaemia between the two groups, this is not a particular concern in this study. Indeed, results of the adjusted analysis of the impact of the MNP intervention anaemia which controlled for individual child-level differences in malaria infection status, confirmed that this imbalance cannot explain the null effect.

All children resident in the community were eligible to receive micronutrients, and thus ECD enrolment did not determine access to the intervention. The data were therefore analysed according to intention-to-treat, which includes all children irrespective of whether they received the micronutrient intervention or not. However, participation in ECD classes could affect how well a child performs in tests of cognition and school-readiness (independently of the nutritional intervention), and could be important confounder with respect to cognitive outcomes. Analyses of cognitive outcomes were therefore adjusted for ECD enrolment.

In summary, the effect estimates for the impact on biomedical and cognitive oucomes generated by the adjusted analyses were similar to the unadjusted results, and did not substantially alter our conclusions. Thus, from the statistical evidence, combined with the remarkable similarity of outcome measures between groups as well as the consistency across all outcomes measured, we can be confident that the null findings are not due to sampling bias or confounding.

Effect on biomedical outcomes

Anaemia was highly prevalent in the study population, with more than 50% of children in the age 5 cohort, and almost 60% of children in the age 3 cohort having a haemoglobin (Hb) concentration

<11.0 g/dL. Although a deficit in micronutrients, particularly iron deficiency, is thought to be the most common cause of anaemia globally; other conditions such as chronic inflammation, parasitic infections such as malaria, hookworm and schistosomiasis, and inherited causes can also cause anaemia. The specific causes for the high prevalence of anaemia amongst children in Sikasso Region are unknown, though all the risk factors listed above are present. Thus, whilst the MNP intervention was designed to specifically address undernutrition, it was implemented as part of a broader context of public health interventions to combat malaria and intestinal helminths (including regular deworming campaigns, insecticide-treated nets, and seasonal malaria chemoprevention); in anticipation that the combination of these multiple interventions could be instrumental in reducing the overall prevalence of anaemia. Within this context, it is important to recognise that the occurrence of other major causes of anaemia can also make it more difficult to demonstrate a substantial impact of intervention on the overall prevalence of anaemia.

All possible explanations for this null finding need to be examined – starting with whether the intervention was delivered and implemented as fully as was originally intended. Surveys with parents at the end of the study indicate that the intervention was acceptable and that uptake of MNPs was high, and thus we can be confident that the lack of impact was not due to low uptake and acceptability of the intervention. The qualitative evaluation at the end of the trial reinforced the findings from the quantitative results from the parental surveys which showed high demand for the MNPs and perceived benefits to children. More than 75% of parents reported that their child had received the micronutrient powders in 2016. Nonetheless, we cannot know whether these children received the micronutrient powders every year, nor whether they received them on a daily basis throughout the full four-month period as intended, nor whether the powders were administered correctly in the home. Neither do we know whether the food vehicle to which the MNPs were added and/or other elements of the child's diet might have limited the bioavailability of the micronutrients; for example foods high in phytates are known to inhibit absorption of iron. Whilst the significant increase in serum ferritin observed in five-year children living in MNP villages compared to children living in non-intervention villages may be indicative that use of MNPs did result in an improvement in iron status; the lack of data on markers of inflammation in these children prevents a firm conclusion to be drawn. No difference in serum ferritin was seen amongst three-year old children. For maximal impact, timely procurement and disbursement of micronutrient powders to communities is also critical, and implementation was affected by delays in the receipt of donations from donors in 2014 and 2015. As a consequence, only one round of MNP distribution (one month supply) was carried out in 2015, instead of four rounds as intended. Use of MNP stock which was close to expiry date also led to concerns and non-compliance amongst some target communities. Although all four rounds of monthly MNP distributions were achieved in 2014 and 2016, the low coverage in 2015 reduces the possibility for cumulative gains to accumulate year-on-year, thus potentially limiting the overall impact of the intervention.

Considering the high background prevalence of anaemia, it is also possible that more than four months of daily supplementation each year is needed. The World Health Organisation recommends 90 MNP sachets with 10 to 12.5 mg of elemental iron to be given to children 6-23 months over a 6-month period where the prevalence of anemia is 20% or higher. In this study, 120 MNP sachets containing 10mg of iron were given to each child over a shorter 4-month period to avoid the malaria transmission season (which ends in December and starts in May-June). Bearing in mind that SMC to reduce malaria-related anaemia was provided before the MNP supplementation to clear the child from malaria parasites, as well as the increased number of sachets given, this regimen would have been expected to reduce iron deficiency anemia and improve the child's nutritional status. Furthermore, previous research in the same region of Sikasso amongst school age children found that weekly iron supplementation alone prevented anaemia. We are

therefore confident that the regimen provided should have been sufficient to reduce and prevent anemia in children, and alternative explanations for the lack of effect are more likely.

The lack of impact on nutritional indices, such as stunting and underweight, within the context of this study, is not entirely unexpected. Stunting is an indicator of overall child health and wellbeing in infancy and early childhood, and like anaemia also influenced by a multitude of factors, of which micronutrient deficiencies are but one. Given that we did not see an effect of the MNP intervention on anemia, the likelihood that impacts would be seen in preventing stunting and other more distal outcomes is even more remote. Furthermore, impacts on stunting and chronic malnutrition, may only become apparent after repeated years of continuous exposure to the interventions, starting early in life. It is possible that the older cohort of children (aged 5 years in 2016) may have started receiving the interventions too late to observe reversals of the chronic effects of undernutrition in early childhood.

Unlike the previous studies in schoolchildren in Sikasso, we did not see any impact of the multi-pronged interventions on anaemia or cognition.[21,29] In part, this difference between the trials may reflect epidemiological differences between the target age groups, and the relative importance of malaria as a cause of anaemia compared to other risks in these two age groups. This possibility is supported by the fact that the prevalence of malaria was considerably lower in five-year olds than that previously recorded amongst older school-age children in Sikasso (39% vs 78% in both control groups respectively), yet the prevalence of anaemia was higher (53% vs 35%). In both studies, health outcomes were measured in the month of June at the end of the school year. The difference between the two studies could also reflect differences in the design of the interventions. Seasonal malaria chemoprevention in under-fives is a strategy targeted at preventing clinical attacks and is thus given during the peak months of malaria transmission, with the last treatment given in the month of November. In southern Mali, where the rainy season extends over six months, malaria transmission may persist for longer and treated children may have become re-infected during the month of December. In contrast, the approach previously used in schools included an antimalarial treatment given in December and thus may have been more effective in ensuring that children remained parasite-free during the ensuing dry season, and thereby more effective in permitting haematological recovery following the end of the malaria transmission season. To increase the effectiveness of seasonal malaria chemoprevention in preventing anaemia in young children it could therefore be useful to include an additional round of treatment in the month of December to clear residual infections at the end of the transmission season.

Recent reports have also highlighted the importance of recurrent gut infections and the consequent malabsorbtion of nutrients as a major cause of chronic undernutrition in young children.[60] Though the MNP distribution sessions did include simple messaging on handwashing, it is possible that more extensive approaches to improve hygiene in children's homes, schools and the surrounding environment, are also required in order to see a major impact on anaemia and growth.

Thus, although the timing of the MNP distributions could have been improved, we consider that changes in the other interventions discussed above are likely to be equally important in increasing the overall effectiveness of the programme in improving biomedical outcomes. These include: (i) increased attention to the types of foods that children are eating, both in terms of improving nutritional content and reducing any foods which inhibit iron absorption; (ii) adding a malaria parasite clearance treatment round in December to reduce asymptomatic parasite carriage, a chronic cause of anaemia, and (iii) focus on preventive strategies to reduce the incidence of gastrointestinal tract infections in young children. Repeated intestinal infections may be an additional important contributory cause of undernutrition. Thus, even if delivery of the MNP intervention and child's diet were to be improved, through inhibiting uptake of nutrients from the

gut, these infections could remain a critical limiting factor on the effects of micronutrient supplementation and other interventions to improve nutritional intake.

Effect on cognitive and child development outcomes

Given the lack of impact on anaemia and child growth indices in children examined after three consecutive years of implementation of the health interventions, it is perhaps not surprising that no differences were observed in their performance in tests of cognitive function and school readiness. Nonetheless, the possibility of limitations in the methodology used and ability to detect important functional differences, need also to be considered. Few studies have examined cognitive outcomes in young children, and whether the tests used provide a sensitive measure of the effect of the intervention on cognitive performance is less certain. Finally, we need also to consider if an evaluation after three years is too soon to witness an effect of the intervention on developmental outcomes. Previous evidence that long term effects of intervention programmes as children develop has been reported in the literature, where short-term effects were initially absent.[61-63] This finding does not therefore preclude the possibility that impacts of the intervention on cognition, language and learning might be observed if children were followed up over a longer period of time.

Whilst it was not realistic to evaluate impacts on literacy (the top learning goal) before children enter primary school, the tests selected for inclusion in the battery aimed to measure a variety of cognitive foundation skills essential for early progress in literacy. For example, performance in the RAN tasks has been shown to be highly predictive of early literacy across a variety of language and cultural settings. Nevertheless, measurement of cognitive function in young children in any setting is challenging. The concept and process of testing itself will have been unfamiliar to children, and testing in a low-literacy environment where children may be unfamiliar with looking at pictures or other visual stimuli on an everyday basis adds further complexity to the task. A particular challenge in our study was the multilingual environment in southern Mali, with over 15 different ethnic groups recorded within our study population. Thus, although the research team included cognitive assessors from the three main ethnic groups in the region (Shenara, Bambara, and Shenara), it may not always have been possible to communicate with all the children in their mother tongue. The accent or dialect of the individual assessor could also have been unfamiliar to the child. The data generated by cognitive testing inevitably suffers some inherent limitations as a consequence, which needs to be considered.

On the whole, a number of the tests in the cognitive assessments for the 3-year old and 5-year old agegroups showed reasonable sensitivity to tap individual variation within the sample, and were appropriate for age group, although there were some ceiling and floor effects at the extremes of the distributions for some tests.

The absence of a specific measure of sustained attention in the final set of assessment tools for the 5 year olds could be seen as a limitation of the study, and may account for the absence of observed effects of the intervention on cognition. However, it is important to note that previous assessment tools used to measure sustained attention in the literature, also draw heavily on working memory skills and oral language, hence it is difficult to be certain that the interventions used with samples of older children had a specific impact on sustained attention, or if this was mediated by working memory or oral language skills. Hence, very few of these cognitive measures can be described as pure measures of components of attention (e.g., sustained, selective, executive function). For example, when we piloted the pencil-tapping task with five-year old children as a test of sustained attention, the children consistently struggled with this task due to its working memory demands and/or inability to inhibit their responses. Other measures of auditory sustained attention (e.g. Score or Code Transmission subtests from the TEA-Ch) also place demands on a child's working memory, verbal language and number skills. Observed differences across groups in performance

on such tasks may be wholly or partially mediated by the working memory constraints when undertaking the task.

We have yet to examine the possible effects of the intervention on other outcome measures included in the IDELA school readiness assessment, such as motor skills, socio-emotional development. Some other interventions targeting health and nutrition have been reported to impact on these early child development outcomes,[64,65] and thus could be of additional relevance to this study.

We need also to consider the effect of missing data from the cognitive assessments, as we cannot rule out the possibility that the missing data is from the most vulnerable children (e.g. poorest health, lowest SES, least amount of stimulation in the home, most likely to be non-enrolled in the ECD centre), who may have been unable to complete the cognitive assessments on the day of the field work in their village for a variety of reasons (e.g. child unwell on the day; other socio-economic factors affecting participation or consenting), but may be the children most likely to benefit from the intervention.[62]

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ANNEXES

ANNEX I. MICRONUTRIENT POWDERS USED

The micronutrient powders donated by Sight and Life (Mixme, DSM Nutritional products) and used in 2014 and 2015:

The micronutrient powders donated by Unicef and used in 2016:

ANNEX II. INTERVENTION - KEY MESSAGES

The following document was used by members of the GSAN as guidance for the organisation and conduct of informational meetings held at community-level with the parents of young children.

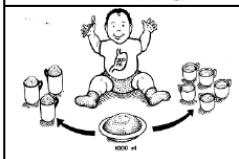
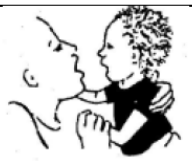
Bien nourri
Propre
Stimulé
+ Vitamines

Préparation :

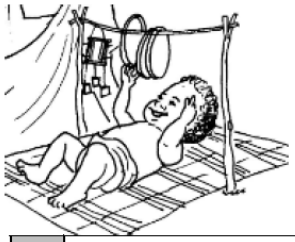
1. Jouets : Objets de la maison + CDPE
2. Aliments : femmes apportent
3. Ustensiles cuisine : bois, casserole,…
4. Poudres Micronutriments (PMN)
5. Cartes conseils, fiches de suivi

Aide-mémoire pour Groupes de Soutien des Activités Nutritionnelles (GSAN)

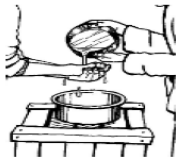
10 Etapes d'une démonstration culinaire

Avant de cuisiner		**Etape 1 : Bienvenue** - ***Objectifs :*** « Nous allons apprendre comment nourrir, stimuler et prévenir les maladies pour leur santé et éducation » - ***Prétest :*** questions sur thèmes (oui/non avec signes de la main)
		**Etape 2 : ANJE et anémie** - ***Démonstration*** : avec sacs de 1000ml et 200ml - ***Questions***: Consistance, Quantité, Variété, alimentation Active - ***L'anémie*** : Comment reconnaitre ? Quels aliments préviennent l'anémie ? - ***Présentation des aliments*** (démonstration) et les 5 étoiles
Preparation repas		**Etape 3 : Démonstration culinaire** - ***Lavage de mains*** : GSAN démontrent et demande à quels autres moments ? 4 moments clés. Les bénévoles se lavent les mains aussi (avant préparation repas) - ***Démonstration culinaire :*** préparation d'un repas sain et équilibré qui doit être mélangé avec PMN - ***Questions et explication*** (pendant démonstration) : o Variété : Insister sur 3e (produit animal) et 4e étoile (fruits/ légumes) o Hygiène : aliments propres et frais, espace et ustensiles propres
Pendant la cuisson		**Etape 4 : Jouez** - ***Questions:*** Qu'est ce qui fait rire votre enfant ? Comment apprend-il? Jouez, parlez, écoutez et encouragez votre enfant et il apprendra à parler, lire et écrire plus vite - ***Démonstration et pratique*:** des jeux avec et sans objets de la maison. C'est la Pause !
		**Etape 5 : L'enfant malade** - ***Questions:*** Quelles maladies votre enfant a le plus souvent ? Est-ce qu'il peut grandir et apprendre quand il est malade ? Que faire quand il est malade ? - ***Démonstration :*** bouteille/gourde/sac avec trou dessous pour montrer déshydratation et besoin de plus de liquide. - ***Questions :*** Qu'est-ce que l'enfant malade a besoin d'autre ? Plus de liquide, un repas de plus, encouragement et aller au CSCom.

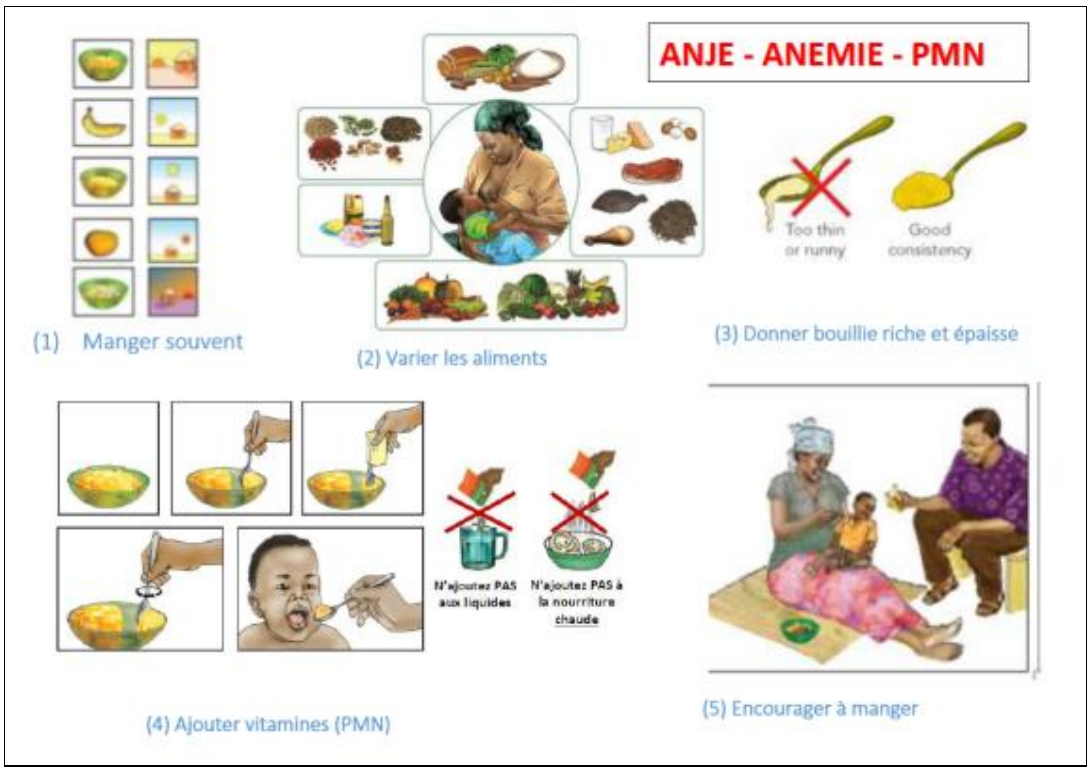
Note: ANJE=Alimentation du Nourrisson et Jeune Enfant



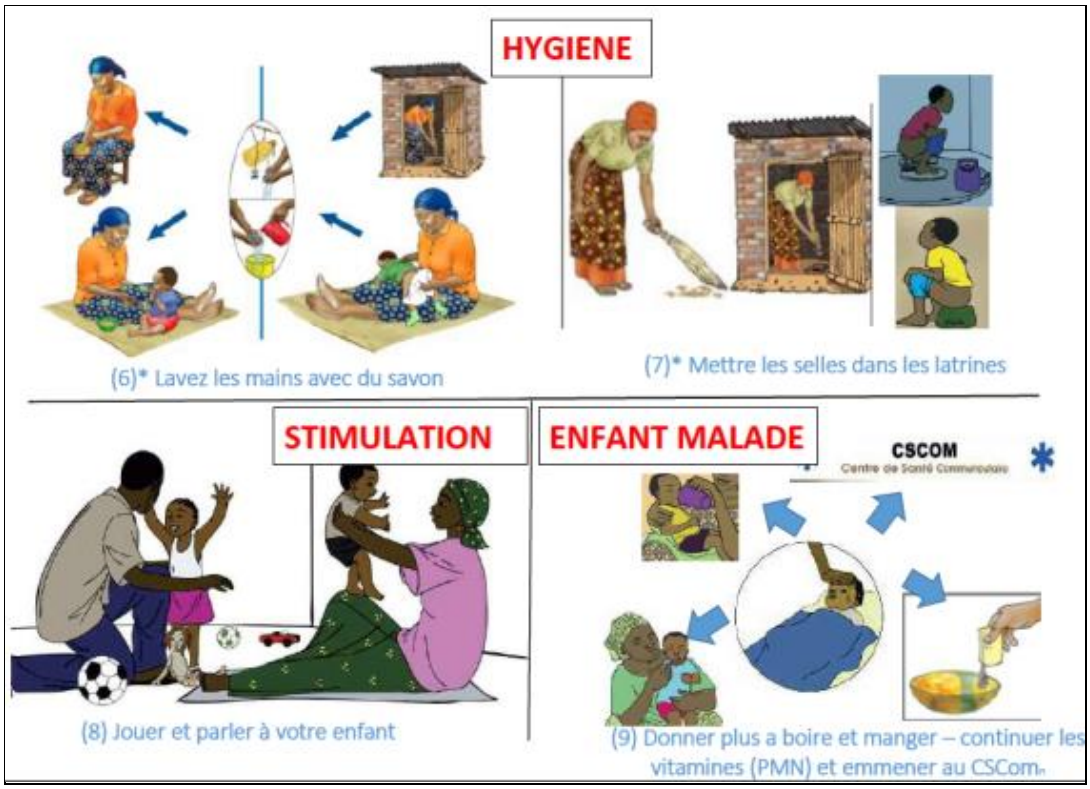
Bien nourris
Propre
Stimulé
+ Vitamines

Pendant la cuisson		**Etape 6 : Vitamines (PMN)** - ***Présentation PMN*** (pendant que le repas cuit), montrez le sachet et parlez des bienfaits sur sante (anémie) et développement de l'enfant. - ***Utilisation*** : 1 par jour par enfant ; secouer le sachet avant ouverture ; ajouter à toute nourriture à consistance épaisse, aliments mous, semi-solides ou en purée (fruits, pommes de terre, patates, courge, etc.) ; séparer petite quantité, mélanger et donner avant le reste; - ***Ne pas ajouter à:*** Tô, sauce de Tô, café, thé, autres aliments chauds ou liquides, liquides, aliments solides - ***Effets secondaires :*** selles molles (4-5 jours), constipation passagère, selles de couleur noire - ***Enfant Malade*** : Continuez à donner PMN, allez au CSCom. PMN n'est pas un médicament
On se Lave les mains et On mange !		**Etape 7 : Lavage de mains (Hygiène)** - ***Démonstration (par bénévoles):*** Lavage des mains avec du savon – eau courante, frotter, cendre ok - ***Question*** : A quels autres moments faut-il se laver les mains ? 4 moments clés : avant préparer repas, avant manger, après latrines, après nettoyage selles- Souvent ! - ***Pratique (toutes les mères et leurs enfants) :*** tous se lavent les mains et lavent les mains de leurs enfants -
		**Etape 8 : On mange et on ajoute PMN** - ***Distribution PMN:*** Servir le repas dans les bols et pendant que la nourriture refroidit sur une natte propre, distribuer les PMN aux mères ; - ***Ajout des PMN :*** chaque mère ajoute PMN - séparer et mélanger - ***On mange :*** Mamans goûtent la nourriture mélangée avec PMN, donne l'aliment avec PMN aux enfants et encouragent l'enfant
Apres le repas		**Etape 9 : Restitution** (pendant moment calme) - ***Discussion :*** Qu'avez-vous appris aujourd'hui ? Qu'allez-vous faire à la maison ? rappel des concepts ANJE, anémie, hygiène, stimulation et PMN et adaptation au quotidien - ***Voisines s'entraident :*** Les femmes se regroupent en 4-5 voisines/amies pour s'entraider et se soutenir, avec 1 membre GSAN pour les superviser - ***Promesses*** : Dans leurs petits groupes, elles font des promesses « Je vais parler à mon enfant quand je cuisine…. »
		**Etape 10 : Au revoir et musique** - ***En musique !*** Commencer un rythme avec objets/jouets et encourager les femmes et les enfants à rajouter un rythme et du chant - ***Créer une Chanson 'PMN'*** ou sur autres thèmes du jour

And the following pictorial visual aid was utilised by GSAN to convey nine key messages during the informational meetings with parents:



Page 1



Page 2

ANNEX III. Adapting the cognitive and child development assessments for use in Mali

Phase 1 (November 2013, Senegal)
Development of the cognitive battery for use in Mali was undertaken by Dr Yvonne Griffiths, University of Leeds, UK; in consultation with the PI from LSHTM, Save the Children Technical Advisors and senior programme staff from Mali. Due to the political and travel constraints prevailing at the time, the initial piloting was carried out in two rural villages in Kedougou, southern Senegal; an area with an environment, language and culture that was not dissimilar to Sikasso. The aim of the initial phase of piloting was to trial existing cognitive tests reported in the literature as important foundations for the development of key academic skills (early literacy and numeracy). In the absence of a strong evidence base on longitudinal predictors of early literacy development in low income countries (see Nag et al., 2014 DfID report for a recent review), the selection of measures was informed by the large body of research on the foundations of early literacy and numeracy development in children from med-high income countries. Recent meta-analyses of research investigating an association between cognitive skills and health or nutrition status in low income countries report equivocal results (Best et al. 2011; Kristjansson et al. 2007; Eilander et al. 2010; Mc Ewan, P.J. 2014), and unfortunately, studies included in these reviews have used a wide range of cognitive measures, including measures of working memory (e.g., digit span), nonverbal ability, visual or auditory attention (e.g., sustained attention; selective attention; executive function), verbal IQ. Most have been with school age children. Measures of attention (also referred to in the literature as executive function skills) were included in the current set of cognitive assessments, in an attempt to replicate previous findings reporting a significant impact of improved health on cognition (attention) in school age children (Clarke et al. 2008, Clarke et al. 2017), with a younger sample of preschool children. Furthermore, there is now a growing body of evidence recognizing the importance of self-regulation of behavior (executive function) as one key component of school readiness, and a longitudinal predictor of education outcomes in numeracy (Burrage *et al., 2008*), and to a lesser degree, in literacy.

The set of tests that were piloted included: letter identification*, number identification*, expressive vocabulary*, listening comprehension*, syllable counting (phonological awareness), rapid automated naming test [RAN] (colours and objects), and pencil tapping task (executive function / sustained attention) (* donates tasks within Save the Children's IDELA battery). The pencil tapping task was observed to be too cognitively and conceptually challenging for most pupils in this age range, and was dropped from the piloting quite early on. A small amount of data from a few children was collected for two additional tasks which have previously been used in the literature with children under 5 years of age in high income country contexts: a) red apples visual search task, and b) the go-no-go puppet task. The research team had concerns about the feasibility of administering the puppet go-no-task in a survey context, as it relied on two people – one to administer the task, and the other to record the response.

Pilot phase 2 (January 2014, Mali) -
A primary aim of this pilot phase was to trial the cognitive assessments using Google Nexus tablets with Tangerine software, to minimize the time demands on data entry, scoring and cleaning. The set of tests included a subset of tasks used in the previous pilot phase in Senegal, following modifications to the administration instructions, stimuli, procedures and record sheets: Expressive vocabulary, Rapid naming (objects), Red Apples Search task, Digit span (forwards and backwards), Oral Comprehension (adapted from the IDELA), letter and number identification (both from the IDELA). After the second pilot, it was decided not to include the red apples visual search task in the final set of tests due to children's unfamiliarity with the visual image and verbal concept of 'apples'. It was not possible to fully adapt and validate this task to incorporate a different set of images more appropriate to the local context within the time constraints and limited resources

remaining for piloting work. An alternative visual search task, the Mosquitoes and Balloons task was introduced in place of the Red apples search task. This test had previously been used with success in studies with older children in Mali by Josselin Thuilliez. Following piloting with 3-5 year old children, it was included in the test battery, with some adaptations for use with the younger age group (e.g., larger images printed onto an A3 sheet, and children pointing to the visual target and the assessor noting the response).

Approximately 10 SC members from the Sikasso field office were trained to use the Google Nexus tablets to collect data for an assessment of young children's cognitive abilities. After office and field training, assessors from the Sikasso office reported comfort and ease when using the tablets and Tangerine software. Overall, the output from the Tablets was complete and cleanly recorded, allowing the team to review pilot data from each day immediately after returning from the schools, for early detection of problems with the assessment tools.

In addition, results of the pilot showed that the cognitive tests captured variation in 5- and 6- year old children's abilities in the villages participating in the pilot. Five subtests were administered to all children with the goal of determining whether the instructions were understood by assessors and children, and whether the tasks captured individual variation in children's cognitive abilities. Forty-four children aged between 5-6 years of age completed some or all of the assessment tasks to see how well subtests were functioning. All test instructions and stimuli were translated from English, into French, and then into Bambara.

Pilot phase 3 (April 2014, Mali) -
Further fine tuning of the tasks and instructions for assessors were made during the 2-week orientation, training and field testing with the assessors recruited to carry out the first round of cognitive surveys in 2014. This allowed for improvements in the clarity and understanding of instructions; standardization of administration of the tasks across the group; and tips to help ease of administration of the battery of tests with young children in the field, including considerations of local culture and language, and administration of the tests to large numbers of children on the same day.

Cognitive surveys at baseline (May 2014, Mali) -
Based on the findings from these pilots, the final battery of tasks was developed for use in the cross-sectional surveys in 2014, test instructions were translated into French, Bambara, Mamara and Shenara and loaded onto Tangerine software. The team of assessors was recruited to include native speakers of Bambara, Shenara and Mamara, to ensure the tests were administered to all children in their maternal language. The most common maternal language used by children in the sample was Bambara, followed by Shenara and Mamara (Yorosso District). However, due to a shortage of trained assessors who were fluent in Shenara, the evaluation team had some concerns with the degree to which all children were able to receive the tests in their maternal language. Where this was not possible, teachers or mothers supported the translation during test administration. Data collection in the field was carried out using a set of laminated pictorial sheets to visually present the tasks to children accompanied by verbal explanation given by the assessors. The Google Nexus tablets were used by assessors to standardize the instructions delivered to each child, and to record the childs responses in the tasks.

Review of cognitive data and methods prior to endline surveys (April 2016, Mali) –
The cognitive and school-readiness tasks used at baseline were reviewed by Prof Michael Boivin, Michigan State University, USA; in consultation with Dr Yvonne Griffiths from Leeds University, Siân Clarke, the PI from LSHTM and the field team in Mali. As an internationally-recognised expert in cognition and child development, who was not involved in the development of the battery, Prof

Boivin was well placed to provide an independent assessment of the tool and provide additional recommendations prior to the endline survey. His review confirmed that the range and content of the tests were appropriate for a large-scale survey in children of this age; all key domains were assessed and there were no major omissions in the battery. Challenges experienced by the field team at baseline were primarily related to the difficulties of testing young children (especially those aged 3 years) as the children were often shy and reluctant to talk to an unknown adult, which both increased the time it took to complete each assessment and resulted in missing data; as well as a limited number of assessors fluent in Shenara. Prof Boivin confirmed that these challenges are common when testing young children, and thus were not unusual. Several recommendations were made to help overcome this challenge and improve the administration of the battery during the endline surveys in 2016, whilst maintaining consistency and comparability with the battery whuch was used in 2014. This included changes to the sequence in which tests were administered and the inclusion of additional ice-breaker activities to help amuse and relax the child during the tests. It was recommended to drop four items from the SRA battery that were too difficult or culturally inappropriate, as evidenced by floor-effects in the data, and thus took a long time to administer. The importance of administering the tests in the child's mother tongue by an assessor of the same ethnic group and the advantages this brings in terms of creating a better rapport between the assessor and the child, improving the child's responses and decreasing time needed to complete the assessment, was also stressed. In light of the review, some minor adjustments were made to the test battery prior to its use in 2016, with the aim to reduce the time it takes to administer the batteries, reduce the amount of missing data and improve the reliability of responses, especially amongst the youngest age group.

ANNEX IV. RESEARCH TEAM

The study was conducted in partnership with the National Institute of Public Health (INRSP), the Ministry of Health, the National Directorate of Health (DNS), the National Directorate of Pedagogy (DPN), the National Directorate of Preschool and Special Education (DNEPS) in Mali, the London School of Hygiene and Tropical Medicine (LSHTM), University College London, and University of Leeds in the UK, Michigan State University, USA and Sorbonne University, France. A full list of the partners is shown in the table below.

Implementation Team

Development and implementation of the interventions was conducted by Save the Children in Mali: **Dr Niélé Hawa Diarra**, Project manager and **Philippe Thera**, ECD Program Manager, supported by Yahia Dicko, Kalifa Sidibe and Modibo Bamadio who provided expertise in monitoring and evaluation, research methods and data management. Technical support was provided by **Natalie Roschnik**, Nutrition and Child Development Advisor, Bonita Birungi, ECD Senior Specialist and Sara Poehlman, Senior Director for Early Childhood Development for Save the Children USA. Technical guidance on seasonal malaria chemoprevention was provided by Dr Alassane Dicko, Malaria Research and Training Cente (MRTC), University of Bamako; Medicins sans Frontieres (MSF); and staff from the National Malaria Control Program (PNLP) in Mali. Dr Judy Mclean, Kathy Ho and Fatou Diarrassouba from the University of British Columbia provided additional support to develop the MNP training package and conduct the formative qualitative studies in 2014. Advice on development of the nutrition intervention was also provided by staff from the Nutrition Division, Ministry of Health, Mali; Dr Moctar Coulibaly, senior nutritionist from the INRSP and IPR/IFRA; and Klaus Kremer, Sight and Life.

Impact Evaluation Team

The impact evaluation was led by **Dr Sian Clarke** (Prinicipal Investigator), an Associate Professor in Epidemiology at LSHTM, heading an international multidisciplinary team who provided technical support and guidance in research methods in clinical trials, nutrition, child development and economics. Sian Clarke has over 20 years experience in conducting public health research in developing countries, including randomized controlled intervention trials. A major focus of her recent work has been the impact of malaria control in school-aged children on health and education outcomes, one of which was in the current study area in Sikasso region with Save the Children. Sian Clarke had overall responsibility for the design of the trial and conduct of the impact evaluation, and worked closely with the co-PI from Save the Children, **Natalie Roschnik**, with shared responsibility for management of the impact evaluation. The co-PI from Save the Children was the main focal point for SIEF over the duration of the project and facilitated links between program implementation and evaluation, and national level policy and advocacy efforts across the disciplines. Statistical analysis of the data was performed by an independent statistician, Rebecca Jones, based at UCL, Univeresty of London, UK; with extensive prior experience in analysis of cluster-randomized trials and cognitive data.

In Mali, the biomedical research team was led by **Dr Moussa Sacko** (co-investigator), Head of Department of Diagnostic and Biomedical Research at the National Institute of Public Health Research (INRSP), Ministry of Health, Mali and focal point to the PNLP regarding malaria case management and member of WHO working group on the M&E of Neglected Tropical Diseases. Dr Sacko has over 20 years experience in the conduct of biomedical surveys and has supported a number of rigorous research studies, including previous evaluations of Save the Children's School Health and Nutrition program and malaria in schools trial conducted in 2011-2012, demographic health surveys, and other studies on quality of antenatal care, malaria, and other neglected tropical diseases. Moussa Sacko was assisted by Renion Saye, PhamD and PhD candidate in Epidemiology.

In Mali, the research was supported by senior researchers from the INRSP, IPR/IFRA and DNS including Dr Moctar Coulibaly, senior nutritionist from the INRSP and IPR/IFRA. Additional expertise in the biochemical analysis and interpretation of results, including serum ferritin and inflammatory markers, was provided Dr Hans Verhoef, LSHTM, UK and Wageningen University, The Netherlands.

Dr Yvonne Griffiths (co-investigator), Associate Professor in Psychology & Special Education from the School of Education, University of Leeds, UK (previously based in the Department of Psychology and Human Development at UCL Institute of Education until 2015), was responsible for the evaluation of impact on cognitive foundation skills and educational outcomes, and development of specialist measurement instruments. Additional relevant expertise in the fields of cognition, child development, and school readiness assessments was provided by Dr Michael Boivin of Michigan State University, USA and Lauren Pisani of Save the Children, as well as Mme Maria Sangaré, Director of Pre-School Education, Ministry of Education and Dr Bonaventure Maiga, the Director of DPN and lead researcher on preschool education in Mali.

Expertise in economic analyses was provided by **Dr Josselin Thuilliez** (co-investigator), an economist based at CNRS and Centre d'économie de la Sorbonne in France. He obtained his PhD in economics at the University of Paris 1 and has worked with the Malaria Research and Training Centre (MRTC) in Bamako on several studies since 2007. The cost data collection and analysis was carried out by Hamidou Niangaly, a Malian PhD student at the University of Bamako, previously trained at the University of Paris and working under the supervision of Dr Thuilliez.

The impact evaluation team, thus comprised experienced researchers across a broad range of expertise drawn from the University of London, University of Leeds, Michigan State University and University of Bamako, and research institutes within the Ministry of Health and Ministry of Education in Mali, many of whom have a substantial track record in the conduct of intervention trials and international peer-reviewed publications. The involvement of research partners from the Direction Nationale du Préscolaire et de l'Education Spéciale, Ministry of Education and Ministry of Health will ensure that the research objectives and outputs from the evaluation have relevance for national policy and programming and that results are reflected in national strategies and plans.

Planning and coordination

The planning and conduct of all evaluation activities was undertaken jointly in close collaboration between researchers in London and in Mali, working together in equal partnership. Experienced researchers both from the UK and Mali, all of whom have a substantial track record in the conduct of intervention trials and international peer-reviewed publications, provided academic guidance and research capacity strengthening to the implementation partners in Mali. An advisory group, involving senior staff from the Ministry of Health and Ministry of Education and other key stakeholders was created to guide the research and situate results in the context of current national policy discourse. This allowed for continuous interchange and knowledge transfer in research skills and techniques, whilst grounding the research in the local context, to reflect national priorities and operational realities.

Ministry staff from both national and regional levels were also involved both in the training and orientation of ECD facilitators with regard to the interventions and in the training of surveyors to evaluate health and education outcomes. The involvement of national and regional staff from the health and education directorates in all stages of research planning and evaluation activities will increase understanding of the research process by local authorities, and promote ownership and interest in the results of the research.

National partners

- The Ministries of Health and Education, specifically the National Malaria Control Program (PNLP), Division of Nutrition and National Directorate of Health (DNS), the National Directorate for preschool and specialised education (DNESPS) the National Directorate of Economie Solidaire (NDES) and members of the national task for on ECD
- Major donors, technical and implementing agencies within Mali: The President Malaria Initiative, USAID, the World Bank, Unicef, WHO, Medecins Sans Frontieres, Helen Keller International, Borne Fonden, Plan Mali and Aga Khan Foundation

Local government offices and Community representatives

- The Sikasso Regional Directorate of Health and Education, Education Academy and Reference Hospital Directors
- The Mairies, district and community health centers and pedagogical advisors (school inspectors)
- School Management Committees, Community health volunteers, mothers groups and teachers and other community associations

1) Save the Children

Exécution des interventions, Coordination de l'évaluation, Liaison Banque Mondiale, Gestion du Grant SIEF,

Nom	**Responsibilité**
Hawa Diarra, Chargée de recherche Projet *Jigifa*	Point focal de l'étude Point focal Banque Mondiale et SCUK Supervision ADC suivi et supervision Gestion données de suivi et documentation progs Coordination et communication partenaires (national et international) Gestion du budget du projet Gestion des contrats nationaux Coordination de l'enquête de finale Gestion des données de l'enquête Elaboration et soumission du protocole de recherche
ADCs : Mamadou Sissoko et Worokia Kayentao	Point focal pour les communautés, communication de l'étude Participation aux formations des interventions Suivi et supervision des interventions (Inc. collecte de données de suivi sur ODK Smart phone) – PMN, CPSe et ECD Rapport et résolution de problèmes (communautaire) Documentation des succès, défis
Yahia Dicko, Coordinateur ASRH	Supervision de l'équipe étude Résolution de problèmes Revue des outils de suivi et documents Point focal pour discussion CPSe
Dr Seybou Diarra School Health and Nutrition Manager	Qualité et exécution des interventions Organisation des formations CPSe et Nutrition Gestion du budget des interventions CPSe et Nutrition Résolution de problèmes Représentant de l'étude national (SHN, PNLP)
Philippe Thera ECD Coordinator	Qualité et exécution des interventions ECD (CDPE et éducation parentale) Représentant de l'étude aux partenaires ECD Revue documents (rapports etc)

	Revue/revision outils IDELA + Cognitif Formation IDELA+ Cognitif
Kalifa Sidibe Charge M&E, Spon	Coordination d'activities d'evaluation SIEF avec autres études Spon (LB et IDELA) Gestion du système de collecte données suivi/supervision ODK Gestion/analyse des données de suivi Soutien pour gestion des données enquête
Bamadio Modibo, Conseiller Senior, M&E	Revue du plan d'enquête Revue des questionnaires Revue des contrats et TOR Revue des documents SIEF (deliverables) Participation a la formation des enquêteurs
Souleymane Toure,	Résolution de problèmes Représentant de l'étude (Spon HO et SCI) Appui en gestion du Grant et contrats nationaux
Khady Ndeye Fall, Grant Manager	Gestion du Grant Gestion des contrats nationaux (INRSP etc) Rapports financier
Nitasha Kulashreshtha, Project Officer, SC UK	Gestion du grant Gestion des contrats internationaux (LSHTM, UCL, Sorbonne)
Natalie Roschnik, Nutrition & Child Development Advisor	Point focal SCUK et Banque Mondiale Qualité des interventions MNP et CPSe Contrats internationaux (LSHTM, Sorbonne, UCL) Revue des documents (deliverables) Dissémination Publication Représentation
Lauren Pisani, Senior Specialist, Education Research	Révision IDELA et Cognitif Formation IDELA et cognitive Analyses exploratoires des données ECD/Sante/Cognitif
Sarah Poehlman, Senior Director ECD	Qualité des interventions ECD (Ed parental et CDPE) Revue des documents (Deliverables) Interprétation des résultats ECD

2) Partenaires Recherche Nationaux

INRSP	Dr Moussa Sacko Senior research scientist; Senior Lecturer in Medical Parasitology (USTTB)	Chercheur Principal National Point focal partenaires nationaux Revue et soumission protocole au comité éthique Enquête biomédicale Nettoyage données biomédicales Coordination enquête biomédicale Revue documents (Rapport etc.) Dissémination Liaison politique nationale
INRSP	Dr Renion Saye	Enquête biomédicale Nettoyage données biomédicales

	Assistant de recherche, parasitologiste	Coordination enquête biomédicale Revue documents (Rapport etc.) Dissémination
DNEPS	Mme Coulibaly Maria Sangaré, Directrice Nationale de l'éducation préscolaire et spéciale	Revue protocole recherche Revue questionnaire IDELA et Cognitif Participation formation IDELA/Cognitif Revue rapport et interprétation Dissémination résultats Liaison politique ECD
IPR-IFRA, Katibougou, Mali	Dr Moctar Coulibaly Nutritionist; Senior Lecturer in Food, Technology and Nutrition	Revue protocole recherche Revue rapport résultat et interprétation Dissémination
DNS/DN	Dr Seybou Guindo, Chef Division Nutrition	Revue protocole recherche Revue rapport résultat et interprétation Dissémination Liaison politique nutrition
PNLP	Dr Diakalidia Koné, Directeur	Représentant CPSe et politique nationale lutte contre le paludisme

3) Partenaires Internationaux Recherche

London School of Hygiene and Tropical Medicine (LSHTM), Royaume-Uni	Dr Sian Clarke Senior lecturer in malaria research & control,	Principal Investigateur, responsable de l'évaluation Point Focal chercheurs internationaux Révision outils de collectes (Suivi et enquêtes) Planification de l'enquête (avec Hawa) Formation des enquêteurs Contrôle de qualité enquete Gestion et analyse des résultats Rapports pour Banque Mondiale Dissémination
	Sham Lal, etudiant Doctoral	Gestion de données de base Micro catalogue des données (site BM) Préparation et coordination enquête Codification questionnaire et gestion des tablettes Analyse résultats
	Louise Abela	Nettoyage données de base Préparation et coordination enquête
University College London (UCL), Royaume-Uni	Rebecca Jones, statisticienne	Analyses statistiques Tableau de résultats pour rapport
L'Universite de Leeds, Royaume-Uni	Dr Yvonne Griffiths	Revue des résultats Cognitifs base et recommandations

	Lecturer in Psychology & Special Education,	Revue des documents (Protocole, rapports SIEF) Interprétation des résultats
Centre d'Economie, Université de Sorbonne, Paris, France	Dr Josselin Thuilliez	Protocole analyse de cout Analyse et rapport de cout et efficacité Econométrique
	Hamidou Niangaly, etudiant Doctoral	Collecte de données des couts Analyse des données

Autres Collaborateurs

MRTC	Dr Alassane Dicko, Professor of Public Health and Research Program Director	Conseiller CPSe Revue protocole recherche Revue et interprétation résultats Liaison politique CPSe
Ministère de l'éducation	Dr Bonaventure Maiga	Revue protocole recherche Revue questionnaire IDELA et Cognitif Participation formation
DNS /DRS Koulikoro	Dr Diahara Traoré	Revue rapport résultat et interprétation Dissémination Liaison politique Paludisme
University of British Columbia, Micronutrient Project	Dr Judy Mclean, Directeur	Experte Poudre Micronutriment et nutrition Evaluation qualitative (revue et interprétation résultats Revue et interprétation résultats
	Dr Fatou Diarrassouba, Chercheuse	Evaluation qualitative (design, exécution, analyse et rapport) Recommandations
Michigan State University	Dr Michael Boivin, Professor of Psychiatry and Neurology & Ophthalmology	Conseiller tests cognitifs Revue et interprétation résultats cognitifs de base et recommandations enquête finale Revue plan d'analyse Revue résultats et interprétation
LSHTM/ Wageningen University, The Netherlands	Dr Hans Verhoef, Nutrition and Malaria	Développement de sous études pour comprendre cause de l'anémie Revue et interprétation des résultats
Sight and Life	Klaus Kraemer, Directeur	Conseiller en PMN

ANNEX V. ETHICS APPROVALS

MINISTERE DE LA SANTE
ET DE L'HYGIENE PUBLIQUE
-=-=-=-=-=-=-
INSTITUT NATIONAL DE RECHERCHE
EN SANTE PUBLIQUE (INRSP)
BP 1771 / Tel 20 21 43 20/20 21 42 31
-=-=-=-=-=-=-
COMITE D'ETHIQUE DE L'INRSP
BP 1771/ Tél : 66 76 63 37 / 76 18 72 60
- Bamako
-=-=-=-=-=-=-

REPUBLIQUE DU MALI
Un Peuple – Un But – Une Foi
-=-=-=-=-=-=-

Bamako, le 04 avril 2016

Madame la Présidente du Comité d'Ethique

A

Docteur Moussa SACKO
Principal Investigateur de l'étude

Objet : ***Réponse à votre saisine du 01 avril 2016***

Suite à votre lettre ci-dessus citée en objet sollicitant l'amendement du protocole d'étude intitulé «***Chimioprévention du paludisme saisonnier et supplémentation intermittente en micronutriments à base communautaire à travers les établissements préscolaires : Evaluation des résultats sanitaires et éducatifs dans les cercles de Sikasso et Yorosso »*** , nous en prenons acte des modifications.

Par la présente, nous donnons notre accord pour la poursuite de l'étude conformément aux amendements proposés ; toutes autres modifications intervenant dans l'exécution dudit Protocole doivent être portées à la connaissance du Comité d'Ethique dans un délai de 15 jours.

Vous en souhaitant bonne réception, veuillez agréer Docteur SACKO, l'assurance de notre salutation distinguée.

Ampliations :
Membres/CE.....10
Archives/CE.....1
Save the Children USA/UBS optimus Suisse... 1

P/LE PRESIDENT DU COMITE D'ETHIQUE/P.I
LA VICE-PRESIDENTE,

INSTITUT NATIONAL DE RECHERCHE EN SANTE PUBLIQUE (I.N.R.S.P.) Comité d'Ethique LE PRESIDENT

Madame SIDIBE Diaba CAMARA

London School of Hygiene & Tropical Medicine
Keppel Street, London WC1E 7HT
United Kingdom
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Observational / Interventions Research Ethics Committee

Dr Sian Clarke
Senior Lecturer
Department of Disease Control (DCD)
LSHTM

10 May 2016

Dear Dr Sian Clarke ,

Study Title: Impact of an integrated parenting, nutrition and malaria intervention to improve nutrition and child development in pre-school children: Impact evaluation of a randomised controlled trial in S Mali

LSHTM ethics ref: 11335

Thank you for your application for the above research, which has now been considered by the Interventions Committee.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Conditions of the favourable opinion

Approval is dependent on local ethical approval having been received, where relevant.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document Type	File Name	Date	Version
Information Sheet	Fiche _Information parentale_Mali_CPS_SMC_240414-FINALE	24/04/2014	final in french
Information Sheet	Fiche _consentement parentale_Mali CPS_SMC_240414-FINALE	24/04/2014	final in french
Information Sheet	Fiche _Information parentale_Mali_CPS_SMC 240414_english	24/04/2014	final in english
Information Sheet	Fiche _consentement parentale_Mali CPS_SMC_240414_English	24/04/2014	final in english
Investigator CV	CV Josselin Thuilliez 2014	01/08/2014	1
Investigator CV	Rebecca Jones CV - 2015	01/09/2015	1
Investigator CV	Sian Clarke CV 2016	31/01/2016	1
Investigator CV	CV_Natalie Roschnik 2016	31/01/2016	1
Investigator CV	CV_Moussa Sacko 2016	31/01/2016	1
Investigator CV	CV_Yvonne Griffiths 2016	31/01/2016	1
Protocol / Proposal	Protocole de recherche SIEF_English_final 310316	31/03/2016	final for ethics_eng

After ethical review

The Chief Investigator (CI) or delegate is responsible for informing the ethics committee of any subsequent changes to the application. These must be submitted to the Committee for review using an Amendment form. Amendments must not be initiated before receipt of written favourable opinion from the committee.

The CI or delegate is also required to notify the ethics committee of any protocol violations and/or Suspected Unexpected Serious Adverse Reactions (SUSARs) which occur during the project by submitting a Serious Adverse Event form.

An annual report should be submitted to the committee using an Annual Report form on the anniversary of the approval of the study during the lifetime of the study.

At the end of the study, the CI or delegate must notify the committee using an End of Study form.

All aforementioned forms are available on the ethics online applications website and can only be submitted to the committee via the website at: http://leo.lshtm.ac.uk

Additional information is available at: www.lshtm.ac.uk/ethics

Yours sincerely,

Professor John DH Porter
Chair

ethics@lshtm.ac.uk
https://www.lshtm.ac.uk/ethics/

Save the Children

Child ID_____

QUESTIONNAIRE FOR CAREGIVERS

Instruction: *The interview should conducted with the* **primary caregiver of child**. *If the primary caregiver is absent from the village, the interview can be conducted with another adult member of the same household, provided they are in regular daily contact with the child. Where no suitable informant can be identified, the household will need to be revisited at a later time.*

Hello. My name is _____. I work for Save the Children. I would like to ask you some questions as part of an evaluation of our early childhood program. The goal of this evaluation is to improve the education, health and nutrition services that are being provided to your child. Any information that you give me will remain strictly confidential. This information will be used to better orientate the actions that Save the Children is implementing in your area. The interview will take about 1 hour. Participation in this survey is voluntary and you are free to decide if you accept to interviewed or not. You may also refuse to answer some questions. I would be very grateful if you could provide me with as much information as possible and in all sincerity.

Can we begin? |___| **1**=Agreed |___| **2**= Refused interview (**END**)

	QUESTIONS	RESPONSES
01	Time interview started	|___|___| hour |___|___| min
02	Questionnaire number	|___|___|___|___|
03	Date of interview	|___|___ / ___|___ / 2016
04	Name of interviewer	

A. Identifying Information

06	Cercle	
07	Commune	
A1.	Village name	
Ask the following questions to check you have the right child, before confirming the child's ID number		
A3.	**What is your child's name?**	
A4.	**What is the sex of your child?**	❒ Girl ❒ Boy
B1.	**What is the mother's full name?**	
B5.	**What is the father's full name?**	
A2	ID number of child	
N1 new	Is this the correct child?	❒ Yes (1) ❒ No (0) *Interviewer to confirm that all the identifying information (mother, father, age, sex etc) matches the child ID*
A5.	*If DOB is missing, ask:* **What is the Date of Birth of the child?**	Year:_____ Month_____ Day_____
N2 new	**Is child still resident in village in 2016?**	❒ Yes (1) ❒ No (0) ❒ Don't know (9)
N3 new	*If no,* **What has happened to the child?**	❒ Child has died/passed away (1) ❒ Child and family have left the village permanently (2) ❒ Child adopted by someone living in another village (3) ❒ Child currently lives elsewhere, but may come back (4) ❒ Child has gone away for school (5) ❒ Other reason (6) Specify (6A):_____

1

A7.	What is your full name?	
A8.	How are you related to the child?	❒ Mother (1) ❒ Grandmother (4) ❒ Father (2) ❒ Grandfather (5) ❒ Guardian (3) ❒ Other caregiver (6) Specify (6A):_____
N4 new	*If respondent is not the mother or father, ask* Are you the main person responsible for the welfare of this child?	❒ Yes (1) ❒ No (0) ❒ Don't know (9)
N5 new	Is interview being done in child's home?	❒ Yes (1) ❒ No (0) ❒ Don't know (9)
N6 new	***If yes***, record GPS co-ordinates	

B. Family Background

B2.	What is the mother's age?	|__|__| years ❒ Don't know (9)
N7 New	Has the mother ever attended school?	❒ Yes (1) ❒ No (0) ❒ Don't know (9)
B3.	***If yes,*** What is the highest level of education that the mother has completed?	|_____| ❒ Don't know (9) 0 = None 1 = Primary – dropped out 2 = Primary –completed 3 = Fondamental– dropped out 4 = Fondamental – completed 5 = Secondary 6 = Superieur (Uni/Higher Education)
B4.	Can the mother read?	❒ Yes (1) ❒ No (0) ❒ Don't know (9)
B6.	What is the father's age?	|__|__| years ❒ Don't know (9)
N8 new	Has the father ever attended school?	❒ Yes (1) ❒ No (0) ❒ Don't know (9)
B7.	*If yes,* What is the highest level of education that the father has completed?	|_____| ❒ Don't know (9) 0 = None 1 = Primary – dropped out 2 = Primary –completed 3 = Fondamental– dropped out 4 = Fondamental – completed 5 = Secondary 6 = Superieur (Uni/Higher Education)
B8.	Can the father read?	❒ Yes (1) ❒ No (0) ❒ Don't know (9)
	If Yes, B8(A) Which languages? *Tick all that apply*	❒ Bambara ❒ Shenara ❒ Mamara ❒ French ❒ Don't know (9) ❒ Other (specify) _____
B10.	What is the main language spoken at home? *Tick one response only*	❒ Bambara ❒ Shenera ❒ Mamara ❒ French ❒ Don't know (9) ❒Other (specify) _____

B11.	What other languages are spoken at home? *Tick all that apply*	❒ Bambara ❒ Shenera ❒ Mamara ❒ French ❒ Don't know (9) ❒Other (specify) _____	
B12.	Does your child recognize or speak any words in French?	❒ Yes (1)	❒ No (0) ❒ Don't know (9)
I1	How many children does the mother have at present? (including this child)	|__|__| children	❒ Don't know (9)
B9.	How many children does the father have, in total (include children of co-wives)?	|__|__| children	❒ Don't know (9)
If the respondent is not the mother or father of the child, go directly to question I8.			
I2	How many children, in total, would you like to have?		
I4	If there was a method of contraception available at no cost, how many children would you like to have?		
I8	Do you have any children already in school? *If no, go to question I13*	❒ Yes (1)	❒ No (0) ❒ Don't know (9)
I9	*If yes,* How many?	|__|__| children	
I10	*If yes,* Are they in primary or secondary school? *Tick all that apply*		❒ Primary (1) ❒ Secondary (2)
I11	*If has children in primary school,* How much do you pay in total each year to educate one child at primary school (including enrollment fees, pens, books, and other expenses)?		
I12	*If has children in secondary school,* How much do you pay in total each year to educate one child at secondary school (including enrollment fees, pens, books, and other expenses)?		
I13	Would you like to educate this child when they reach the age to begin primary school?	❒ Yes (1)	❒ No (0) ❒ Don't know (9)
I14	*If yes,* How much are you willing to pay each year for the education of this child?		
I15	*If no,* How much money would you need each year to be able to educate this child?		
B13.	Do you expect that your child will complete primary school?	❒ Yes (1)	❒ No (0) ❒ Don't know (9)
B14.	Do you expect your child will complete secondary school?	❒ Yes (1)	❒ No (0) ❒ Don't know (9)

C. Home and Literacy and Math Background

C1.	Do you have any of these types of reading materials available in your home?			
	a. Storybooks / picture books for young children?	❒ Yes (1)	❒ No (0)	❒ Don't know (9)
	b. Textbooks?	❒ Yes (1)	❒ No (0)	❒ Don't know (9)
	c. Newspapers / Magazines?	❒ Yes (1)	❒ No (0)	❒ Don't know (9)
	d. Booklets / pamphlets?	❒ Yes (1)	❒ No (0)	❒ Don't know (9)
	e. Religious books?	❒ Yes (1)	❒ No (0)	❒ Don't know (9)
	f. Coloring books?	❒ Yes (1)	❒ No (0)	❒ Don't know (9)
	g. Comics?	❒ Yes (1)	❒ No (0)	❒ Don't know (9)
	f. Others (specify)? _____	❒ Yes (1)		
C2.	I am interested in knowing about the things that your child plays with when s/he is at home. Does she play with:			
	a. Homemade toys, such as stuffed dolls, cars, or other toys made at home?	❒ Yes (1)	❒ No (0)	❒ Don't know (9)
	c. Toys bought from a shop or manufactured toys (plastic toys)?	❒ Yes (1)	❒ No (0)	❒ Don't know (9)
	d. Household objects, such as bowls or pots?	❒ Yes (1)	❒ No (0)	❒ Don't know (9)
	e. Objects found outside, such as sticks, rocks, animal bones or leaves?	❒ Yes (1)	❒ No (0)	❒ Don't know (9)
	f. Materials for drawing or materials for writing?	❒ Yes (1)	❒ No (0)	❒ Don't know (9)
	g. Puzzles/brain teazers?	❒ Yes (1)	❒ No (0)	❒ Don't know (9)
	h. Toys that teach about colors, shapes, numbers or sizes?	❒ Yes (1)	❒ No (0)	❒ Don't know (9)
	i. Toys that teach about letters (such as alphabet games, wooden letters)?	❒ Yes (1)	❒ No (0)	❒ Don't know (9)
	j. Others (specify) _____	❒ Yes (1)	*If yes, specify* _____	

C3. In the past 7 days, did you, or another adult in the family, or a schoolchild, engage in the following types of activities with <<insert child's name>>?
Note: ask "who?" if the answer is "yes". – tick as many as appropriate

NB: For EACH question 1=Yes; 2=No; 9=Don't know	Mother	Father	Grand-mother	Grand father	Other Adult	Older child
a. Read books or look at pictures books with child?						
b. Told stories to the child?						
c. Sung songs to or with the child, including lullabies?						
d. Took the child outside the home? (For example, to the market, visit relatives)						
e. Played with the child?						

	f. Named objects for or with the child?						
	g. Drew things for or with the child?						
	h. Showed or taught your child something new, like a new word, or taught child how to do something?						
	i. Taught alphabet or encouraged child to learn letters? To learn to write words?						
	j. Played a counting game or taught numbers to the child?						
	k. Hugged or showed affection to your child?						
	l. Spanked your child for misbehaving?						
	m. Hit your child for misbehaving?						
	n. Criticized or shouted at your child?						

D. ECCD Experience

D1.	Is your child currently enrolled at a preschool or any other early learning program?	❒ Yes (1) ❒ No (0) ❒ Don't know(9)
Note: If the child is not enrolled at a preschool, ask question "D2", and then move to Section E. *Family socioeconomic background*; if the child is enrolled, ask questions "D3 to D8", and then move to the next section; if the respondent doesn't know whether the child is enrolled, move directly to the next section E.		
D2.	*If no,* Why is your child not enrolled at a preschool? *Let parent respond freely and tick as many options as appropriate.* *Prompt:* Any other reasons?	❒ Child is still too young (0) ❒ There is no preschool near our home (1) ❒ Not interested; Did not want to enroll him/her (2) ❒ Children only have fun there (3) ❒ I have no means to pay the fees (4) ❒ Not enough space at CDPE (5) ❒ Child is already at primary school (6) ❒ Other (8): specify _____ ❒ Don't know (9)
IF CHILD IS NOT ENROLLED IN PRESCHOOL, PROCEED DIRECTLY TO NEXT SECTION (SOCIOECONOMIC BACKGROUND). IF CHILD IS ENROLLED IN A PRESCHOOL, ASK QUESTIONS D4 and D6		
D4.	*If yes,* How long has your child been in this preschool/program?	❒ First year in program (0) ❒ Second year in program (1) ❒ Third year in program (2) ❒ Don't know (9)
D6.	In the last week, how many days did he/she go to ECCD?	❒ Daily (1) ❒ 3 to 4 days a week (2) ❒ Once or twice a week (3) ❒ Less than once a week (4)

E. Family Socioeconomic Background

E1.	What kind of roof does your house have?	❒ Thatch (1) ❒ Cement (4) ❒ Mud/Terre battue (2) ❒ Tiles (5) ❒ Metal sheets (3) ❒ Don't know (9) ❒ Other (8) (specify) _____
E2.	What kind of walls does your house have?	❒ Mud (1) ❒ Wood (5) ❒ Mud Bricks (2) ❒ Cement (6) ❒ Fired Bricks (3) ❒ Don't know (9) ❒ Bamboo (4) ❒ Other (8) (specify) _____
E3.	What kind of floor does your house have?	❒ Soil (1) ❒ Tiles (3) ❒ Cement (2) ❒ Don't know (9) ❒ Other (8) (specify) _____
E4.	What is the main source of lighting in your home?	❒ Firelight/candles (1) ❒ Solar panel (5) ❒ Pocket torch (2) ❒ Mains electricity (6) ❒ Paraffin lamp (3) ❒ Chinese wall torch (7) ❒ Hurricane lamp (4) ❒ Don't know (9) ❒ Other (8) (specify) _____
E5.	Does anyone in your household own a:	
	a. Radio?	❒ Yes (1) ❒ No (0) ❒ Don't know (9)
	b. Television?	❒ Yes (1) ❒ No (0) ❒ Don't know (9)
	c. Motorcycle?	❒ Yes (1) ❒ No (0) ❒ Don't know (9)
	d. Motor vehicle (car/tractor/lorry)?	❒ Yes (1) ❒ No (0) ❒ Don't know (9)
	e. Mobile phone?	❒ Yes (1) ❒ No (0) ❒ Don't know (9)
	f. Solar panel?	❒ Yes (1) ❒ No (0) ❒ Don't know (9)
	g. Cows?	❒ Yes (1) ❒ No (0) ❒ Don't know (9)
	h. Goats / Sheep?	❒ Yes (1) ❒ No (0) ❒ Don't know (9)
	i. Horse / Donkey?	❒ Yes (1) ❒ No (0) ❒ Don't know (9)
	j. Cart?	❒ Yes (1) ❒ No (0) ❒ Don't know (9)
E6.	What is the household's main source of livelihood?	❒ Subsistence agriculture (1) ❒ Cash crops (2) ❒ Petty trading (3) ❒ Own business/Self-employed (4) ❒ Salaried employment (5) ❒ Other (8) (specify)_____ ❒ Don't know (9)
E7.	During the past 7 days, did the mother of the child do any kind of paid work?	❒ Yes (1) ❒ No (0) ❒ Don't know (9)
E8.	During the past7 days, did the father of the child do any kind of paid work?	❒ Yes (1) ❒ No (0) ❒ Don't know (9)

F. Nutrition and Micronutrient Powders

N9 new	How many times did your child eat a meal or snack yesterday?	❒ 5 times per day (5) ❒ 4 times per day (4) ❒ 3 times per day (3) ❒ 2 times per day (2) ❒ Less than 2 times per day (1)
G2	Did your child eat any of the following foods yesterday?	
	a. Grains: millet, sorghum, maize, rice	❒ Yes (1) ❒ No (0) ❒ Don't know (9)
	b. Roots: cassava, potato, yam	❒ Yes (1) ❒No (0) ❒ Don't know (9)
	c. Beans and nuts (arachides)	❒ Yes (1) ❒ No (0) ❒ Don't know (9)
	d. Other vegetables	❒ Yes (1) ❒ No (0) ❒ Don't know (9)
	e. Fruit	❒ Yes (1) ❒ No (0) ❒ Don't know (9)
	f. Meat, Poultry or Fish	❒ Yes (1) ❒ No (0) ❒ Don't know (9)
	g. Milk	❒ Yes (1) ❒ No (0) ❒ Don't know (9)
	h. Eggs	❒ Yes (1) ❒ No (0) ❒ Don't know (9)
	i. Palm oil	❒ Yes (1) ❒ No (0) ❒ Don't know (9)
	j. Other oils and fats	❒ Yes (1) ❒ No (0) ❒ Don't know (9)
N10 New	In the past four weeks, did your child ever have to eat a limited variety of foods due to a lack of resources?	❒ Yes (1) ❒ No (0) ❒ Don't know (9)
N11 new	In the past four weeks, did your child ever go to sleep at night hungry because there was not enough food?	❒ Yes (1) ❒ No (0) ❒ Don't know (9)
G3	When do you usually wash your hands? *Prompt:* Are there any other times? *Tick all that are mentioned*	❒ Before preparing food (1) ❒ Before breastfeeding or feeding a child (3) ❒ Before eating (6) ❒ After eating (2) ❒ After contact with faeces (cleaning baby faeces) (4) ❒ After using the latrine (5) ❒ Other (8): specify _____ ❒ Don't know/can't describe (9)
N12 new	Have you participated in any sessions about feeding your child or about playing with or stimulating your child?	❒ Yes (1) ❒ No (0) ❒ Don't know (9)
	If yes, N13 (A) What were the three most important things you learnt during those sessions? *Prompt:* Anything else? *Tick all that are mentioned*	❒ Hygiene practices (1) ❒ How to identify a malnourished child (2) ❒ Take a malnourished child to CSCOM for treatment (3) ❒ Kinds of food that are important for health of child (4) ❒ How to cook enriched meals (To or bouillie) (5) ❒ How to add MNP sachets to child's food (6) ❒ How to wean young children (7) ❒ How to play/talk/stimulate child (10) ❒ Not to hit/slap a child (11) ❒ Other: (8) specify _____ ❒ Don't know/Can't describe (9)
N13 new	Have you ever shared or discussed what you learnt with anyone else living in this village (same village as you)?	❒ Yes (1) ❒ No (0) ❒ Don't know (9)

N14 new	Have you ever shared or discussed what you learnt with anyone else in living in another village?	❒ Yes (1) ❒ No (0) ❒ Don't know (9)
G5	*Show the MNP sachet:* Have you ever added these to your child's food?	❒ Yes (1) ❒ No (0) ❒ Don't know (9)
	IF NO OR DON'T KNOW, PROCEED DIRECT TO SECTION H. ACTIVITY LEVELS ***IF YES, CONTINUE WITH QUESTIONS G6-14 BELOW.***	
G6	On how many days in the last 7 days, were these sachets added to your child's food?	❒ Never (0) ❒ Every day (1) ❒ 4-6 times per week (1) ❒ 2-3 times per week (2) ❒ Once per week (3) ❒ Don't know (9)
G7	The days when the sachet was not added to your child's food, what were the reasons? *Prompt:* Any other reasons? *Tick/List all reasons*	❒ This never happened; I gave the sachets every day (0) ❒ Child was away from home (1) ❒ I did not give sachet when my child was sick (2) ❒ Child became ill after taking MNPs and I stopped giving the sachets (3) ❒ No more sachets to give / I run out of sachets (4) ❒ I forgot to add the sachet (5) ❒ Others prepared the meal and child did not get MNPs (6) ❒ I did not have the right kind of food to add the MNPs to (7) ❒ Preparing a separate meal for child took too much time (10) ❒ Adding the MNPs to the food took too much time (11) ❒ The MNPs changed the colour or taste of the food (12) ❒ Child did not like/refused the food with MNPs added (13) ❒ I do not understand why I should give the sachets (14) ❒ I do not understand how I should give the sachets (15) ❒ My child does not need these MNP sachets (16) ❒ Other: (8) specify _____ ❒ Don't know/No reason (9)
N15 New	Does your child like to eat the food with the sachet added?	❒ Yes (1) ❒ No (0) ❒ Don't know (9)
G8	To what kind of food/type of meals do you add the MNPs to? *Prompt:* Anything else? *Tick/list all meals*	❒ Bouillie (1) ❒ Tô (2) ❒ Bean puree (3) ❒ Drinks/liquids (4) ❒ Hot food (5) ❒ Other foods: (8) specify _____ ❒ Don't know (9)
G10	To what kind of foods should the MNPs NOT be added to? *Prompt:* Anything else? *Tick/list all meals*	❒ Hot food (1) ❒ Liquid food (2) ❒ Tô (3) ❒ Bouillie (4) ❒ Other foods: (8) specify _____ ❒ Don't know (9)

G11	On the whole, do you think that giving your child the MNPs was difficult to do?	❒ It was never/rarely difficult ❒ Sometimes difficult ❒ Often difficult ❒ Always difficult
G12	Have you noticed any changes in your child since you began giving him/her MNPs?	❒ Yes (1) ❒ No (0) ❒ Don't know (9)
	If yes, ask 12(A) What changes have you noticed? *Prompt:* Anything else? *Tick/list all changes*	❒ Child was more sick than normal (0) ❒ Child had fever and/or respiratory illnesses (10) ❒ Child sometimes vomited (11) ❒ Child sometimes had diarrhea (12) ❒ Child had black stools (13) ❒ Child was less sick than normal (1) ❒ Child's appetite increased (2) ❒ Child is more naughty (3) ❒ Child is more active/energetic (4) ❒ Child is less active/energetic (5) ❒ Other: (8) specify _____ ❒ Don't know/can't describe (9)
	If any illness is mentioned, ask: 13(B) Did you need to take the child for medical treatment at the CSCom or elsewhere? Si maladie, a-t-elle nécessité une consultation médicale au centre de santé ?	❒ Yes (1) ❒ No (0) ❒ Don't know (9)
G14	Do you want to give your child MNPs again, when the distribution starts again next year?	❒ Yes (1) ❒ No (0) ❒ Don't know (9)

G. Malaria prevention and health

F5.	Does your child sleep usually under a bed net?	❒ Yes (1) ❒ No (0) - *Go to question F8* ❒ Don't know (9)
F6.	Did your child sleep under a bed net last night?	❒ Yes (1) ❒ No (0) ❒ Don't know (9)
F8.	Did your child receive any tablets to protect them against malaria last year (2015)?	❒ Yes (1) ❒ No (0) ❒ Don't know (9)
	If yes, F8(A) How many times did they receive the tablets?	❒ One time / one month (1) ❒ Two times / two months (2) ❒ Three times / three months (3) ❒ Other (8) specify _____ ❒ Don't know (9)

H. Activity Levels

I now want to ask you some questions relating to the health and behaviour of your child

F3	Has your child been sick at any time in the last two weeks?	❒ Yes (1) ❒ No (0) ❒ Don't know (9)
	If yes, 3(A) Describe your child's illness(es) *Prompt:* Anything else? *Tick all that are mentioned*	❒ Malaria (1) ❒ Fever (2) ❒ Respiratory infection / cough (3) ❒ Vomitting (4) ❒ Diarrhoea (5) ❒ Abdominal pain (6) ❒ Abscess or skin infection (7) ❒ Other (8) à préciser: _____ ❒ Don't know/can't describe (9)
H1	In the last 7 days, how often has your child been well enough to play with other children or adults?	❒ Never/rarely well enough to play (0) ❒ Sometimes well enough to play (1) ❒ Often well enough to play (2) ❒ Always well enough to play (3) ❒ Don't know (9)
H2	In the last 7 days, how well has your child been sleeping?	❒ Never/rarely sleeps well (0) ❒ Sometimes sleeping well (1) ❒ Often sleeps well (2) ❒ Always sleeps well (3) ❒ Don't know (9)
H3	In the last 7 days, how often has your child been active/energetic?	❒ Never/rarely active/energetic (0) ❒ Sometimes active/energetic (1) ❒ Often active/energetic (2) ❒ Always active/energetic (3) ❒ Don't know (9)

We have reached the end of the interview.
Thank you for your time

ANNEX VII. Biomedical Survey - Questionnaire

Enquête biomédicale Sikasso 2016

Save the Children

FICHE D'ENQUETE PARASITOLOGIQUE, CLINIQUE ET NUTRITIONNELLE, CPSe-MicroNut, SIEF, SIKASSO 2016

No	QUESTIONS	MODALITÉS DE REPONSES	PASSER A ⇐
0.1	Date de l'enquête	/_____/_____/ 2016	
0.2	Numéro de l'enfant	/____/____/____/____/____/____/____/____/	
0.3	Nom de l'enfant	_____	
0.4	Sexe	Garçon 1 Fille 2	
0.5	Age de l'enfant	/_____/ ans	
0.6	Cercle	_____	
0.7	Commune	_____	
0.8	Village	_____	
0.9	Prénoms du Père/Tuteur de l'enfant	_____	
0.10	Prénom et Nom de la mère	_____	
0.14	Déparasité en 2016 (vermifuge)		

DONNEES NUTRITIONELLES ET PARASITOLOGIQUES

Poids (Kg) 1e mesure	Poids (Kg) 2e mesure	Taille (Cm) 1e mesure	Taille (Cm) 2e mesure	Perimetre branchial	Taux Hb (g/dl)

TDR (0= Positif ; 0= négatif) /____/

Goutte épaisse (0= Positif ; 0= négatif) /____/

Si Positif : Densité parasitaire .....

Espece et stade parasitaire .....

1

DONNEES CLINIQUES

(0=Absence ou négatif ; 1= présence ou positif)

TETE

1. Cheveux: Existe-il des poux ou des oeufs? !__!
2. Cuir chevelu: La teigne? !__!
3. Ganglions cervical? !__!

YEUX

4. Conjonctivite? !__! 5. Pâleur conjonctivale? !__!

OREILLES

6. Y a-t-il du pus dans les conduits auditifs externes? !__!
7. Y a-t-il un gonflement retro-auriculaire? !__!
8. Douleurs à la mobilisation du pavillon auriculaire? !__!

BOUCHES, OREILLES, GORGE

9. Stomatite (aphtes)? !__! 10. Amygdales? !__! ***1** = Normal; **2** = Elargi*
11. Carie dentaire? !__! 12. Saignement genvical? !__!
13. Avulsion dentaire? !__! 14. Gonflement des glandes parodiennes? !__!

PEAU

15. Gale? !__! 16. Dermatose? !__!
17. Hygiène des ongles? !__! 18. Plaie nettoyée (en traitement)? !__!
19. Plaie surinfectée? !__! 20. Cicatrice BCG (avant bras)? !__!

ABDOMINALE

21. Splenomegalie? !__! 22. Hépatomegalie? !__!
23. Hernie anguinale? !__! 24. Hernie Ombilicale? !__!
25. Douleur abdominale à la palpitation? !__!
26. Pli de déshydratation abdominale? !__!
27. Adenopathies axillaires? !__! 28. Adenopathies Inguinales? !__!

Goitre*		Cécité Nocturne	

*Goitre: 1 = Absence de nodule
1 = Oui
2 = Nodule palpable mais invisible
3 = Nodule visible

*Cécité Nocturne:
2 = Non

Autres Observations/ Commentaires .....

.....

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REMERCIEZ L'ELEVE, C'EST FINI

2

ANNEX VII. Supplementary Table S1

Sample attrition between 2014 and 2016: comparison of characteristics of 3-year old children recruited in 2014

Of the 1,577 children aged 3 years at the time of the surveys in 2014, a total of 1,437 (91%) were successfully contacted and re-surveyed in 2016. Data on household characteristics were collected through a questionnaire interview with the child's primary caregiver in May 2014, with parental interviews conducted for 1,221 (77.4%) of the 3-year old children examined in the biomedical and/or cognitive surveys in June/July 2014.

There were no marked differences between the characteristics of the 3-year old children that were re-surveyed in 2016 (now aged 5 years old) and those that were lost-to-follow-up (see table below). Most children lived in homes with walls made from earth (banco), however a slightly larger proportion of children lost-to-follow-up lived in homes with walls made from fired bricks or plastered with cement: 7.8% vs 3.1%, p=0.007. Though a similar tendency can be seen in some of the other socio-economic parameters recorded, these differences were generally slight and none reached statistical significance.

In summary, these data provide evidence that there was no participation bias in the sample of 3-year old children successfully re-surveyed in 2016 at age 5 years.

	Re-surveyed in 2016	**Lost to follow-up**	
Three year olds in 2014	**N = 1437**	**N = 140**	
Child characteristics	Proportion	Proportion	*p*-value
Sex – N (%) - Male - Female	 759 (52.8%) 678 (47.2%)	 75 (53.6%) 65 (46.4%)	0.835
Parent questionnaire completed in 2014	**N = 1118 (78%)**	**N = 103 (74%)**	
Household characteristics	Proportion	Proportion	*p*-value
Principal language spoken in the home – - Bambara - Shenara - Mamara - French - Other	 384 (37.8%) 483 (47.5%) 111 (10.9%) 13 (1.3%) 25 (2.5%)	 34 (36.6%) 45 (48.4%) 11 (11.8%) 1 (1.1%) 2 (2.2%)	0.994
Maternal literacy – N (%) - Not Literate - Literate	 833 (87.8%) 116 (12.2%)	 78 (83.9%) 15 (16.1%)	0.270
Father's education – N (%) - Did not attend school - Attended school	 717 (76.7%) 218 (23.3%)	 68 (78.2%) 19 (21.8%)	0.448
Source of household revenue – N (%) - Subsistence agriculture - Other income	 1050 (93.9%) 68 (6.1%)	 95 (94.1%) 6 (5.9%)	0.952
House construction (roof) – N (%) - Thatch or earth (banco) - Zinc sheet, tile, concrete	 198 (20.8%) 753 (79.2%)	 16 (19.1%) 68 (80.9%)	0.651
House construction (walls) – N (%) - Earth (banco) or none - Fired bricks or concrete	 1083 (96.9%) 35 (3.1%)	 95 (92.2%) 8 (7.8%)	**0.007**

House construction (floor) – N (%) - Earth (banco) - Tiles or concrete	 853 (76.5%) 262 (23.5%)	 76 (74.5%) 26 (25.5%)	0.653
Principal source of lighting – N (%) - Lantern, torch, candle etc - Solar panel/Electricity	 362 (33.3%) 725 (66.7%)	 28 (28.3%) 71 (71.7%)	0.309
Wealth index (ownership of household assets) - 1st quartile (most poor) - 2nd quartile - 3rd quartile - 4th quartile (least poor)	 249 (24.7%) 236 (23.4%) 205 (20.4%) 317 (31.5%)	 17 (18.3%) 28 (30.1%) 18 (19.4%) 30 (32.3%)	0.372
Child enrolled in ECD centre in 2014* – N (%) - Yes - No	 158 (14.4%) 943 (85.7%)	 13 (12.6%) 90 (87.4%)	0.178

*Note: This cohort of children were aged 3 years in 2014, and few are enrolled in an ECD centre by this age.

Additional notes:

- Data are not presented for children aged 5 years at the time of the survey in 2014, as these children were not re-surveyed in 2016.
- Neither are data available for the youngest cohort (aged <1 year at the start of the trial; aged 3 years in 2016) since parental interviews, biomedical and cognitive surveys were not carried out in this age group in 2014.