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Operations Research on a Multiple Micronutrient Powder Programme in Cambodia

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Abstract

Background

To tackle the problem of anaemia in infants aged 6-24 months home-fortification of complementary (weaning) foods with multiple micronutrient powder (MNP) was recommended by the World Health Organisation in 2011. The Cambodian Ministry of Health is currently in the process of scaling-up an MNP programme, which at present is implemented in two provinces.

Objective

To document the current functioning of the Cambodian MNP programme and investigate community perceptions of MNP in relation to this, in order that recommendations may be made before national scale-up.

Methods

Qualitative and quantitative monitoring of MNP delivery channels, provider knowledge, coverage estimates and community perceptions was carried out. This enabled exploration of community perceptions of MNP and the distal factors that relate to these. Data sources included; semi-structured interviews with programme managers, health staff and village health volunteers; focus group discussions with caregivers of infants who had been using MNP; and a quantitative questionnaire administered to caregivers of infants of the target age range.

Results

Community perceptions of MNP were mainly positive, though there were some complaints of a metallic taste leading to difficulty in feeding the food mixed with MNP. Community perceptions were related to delivery method, provider knowledge and quality of service provision.

Conclusions

This study highlighted the need for; effective training on expected benefits and side-effects, a regular supply of micronutrient powder, the possible importance of starting the micronutrient powder at six months, and the role of trust and value in continued use of micronutrient powder.

Acknowledgements

Academic

Project Development: The idea for a project in Cambodia came from my having lived in Cambodia previously. I contacted my eventual local supervisor at UNICEF, Mr Joel Conkle, by email and outlined my wish to undertake a summer project. He suggested a few topics that would be useful for UNICEF and he thought suitable for a summer project. Together we decided to look at community perceptions on micronutrient powders. Initially we also planned to do operations research on zinc for the treatment of diarrhoea, but it turned out that the programme was not in an advanced enough state to do this when I arrived in Cambodia.

I found my main academic supervisor, Dr Sophie Hawkesworth after these initial stages. During our 3 or 4 meetings throughout the year and numerous email exchanges she helped me refine the research question and provided general advice and support during the planning stages.

Main Research Work: During my time as an intern at UNICEF Cambodia, I was working as part of a small team on the community perceptions of MNP project. In addition to myself, the team comprised Mr Conkle, Dr Un SamOeum and Dr Ung KimHeang. The qualitative sampling strategy was informed by the UNICEF members of the team, in terms of selecting areas to visit. I suggested looking at not only the perceptions of the community members, but also the volunteers and health centre staff in the same areas, and provincial health department staff, to allow more triangulation of data.

With input from my local supervisor Mr Conkle, I produced the focus group topic guides. I worked alone planning the data collection and analysis of the qualitative data. I contributed towards development of the quantitative questionnaire, though this was produced by Mr Conkle. I entered the data and worked alone on the analysis of the quantitative aspects which are presented in this report. During the field work, I was accompanied by Dr Un SamOeum for both weeks, and also Dr Ung KimHeang for one week. They provided support in terms of translation and data collection for the quantitative aspects. Mr Un SamOeum was the main facilitator for the qualitative data collection.

Writing Up: Dr Sophie Hawkesworth gave me advice regarding the overall structure of the report during email exchanges, and also read two drafts. Her comments on the drafts were mainly around areas that could be cut or expanded on, and in particular she helped me to clarify the discussion.

I would like to thank both of my supervisors for their excellent support and guidance during this project.

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In particular I would like to thank LSHTM for covering my medical insurance for my time in Cambodia and the School Trust Fund for financing my return flights, without which my

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List of Abbreviations

WHO: World Health Organisation
IYCF: Infant and Young Child Feeding
MNP: Micro-nutrient Powder
DMT-1: Divalent metal transporter 1
CDHS: Cambodia Demographic Health Survey
GFC: Good Food for Children Study
S.Rieng: Svay Rieng province
K.Speu: Kompong Speu province
PI: Principal Investigator
HC: Health Centre
VHV: Village Health Volunteer
UNICEF: United Nations Children Fund
O.D: Occupational District
PHD: Provincial Health Department
FGD: Focus Group Discussion
P-Value: Probability value
SRS: Simple random sampling

Introduction

Nutritional Challenges in Infants

Growth is at its most rapid in humans up to the age of two years (1). This represents a unique nutritional challenge, in that nutrient requirements are proportionally the highest, but food volumes consumed are the lowest during our lives. For example, at age six months the iron stores that the infant had at birth can no longer be recycled to support the escalating demands of growth (2). Breast-milk has a low iron content and thus beyond six months can no longer fulfil the role of complete nutrition (2).

Complementary feeding

“Complementary food” refers to the initial foods that are given to the infant under two years of age, alongside breast-milk (3). Due to the nutritional demands of meeting high growth rates with low gastric capacity, complementary foods should be nutrient dense, with increasing amounts of energy and fat as breast-milk intake declines and the infant’s energy requirements increase (3, 4). Particular “problem nutrients,” are iron, zinc and Vitamin B6 (see figure 1 for comparative iron requirements) (4). Ideal sources of these micronutrients are organ meats or other animal foods (5, 6).

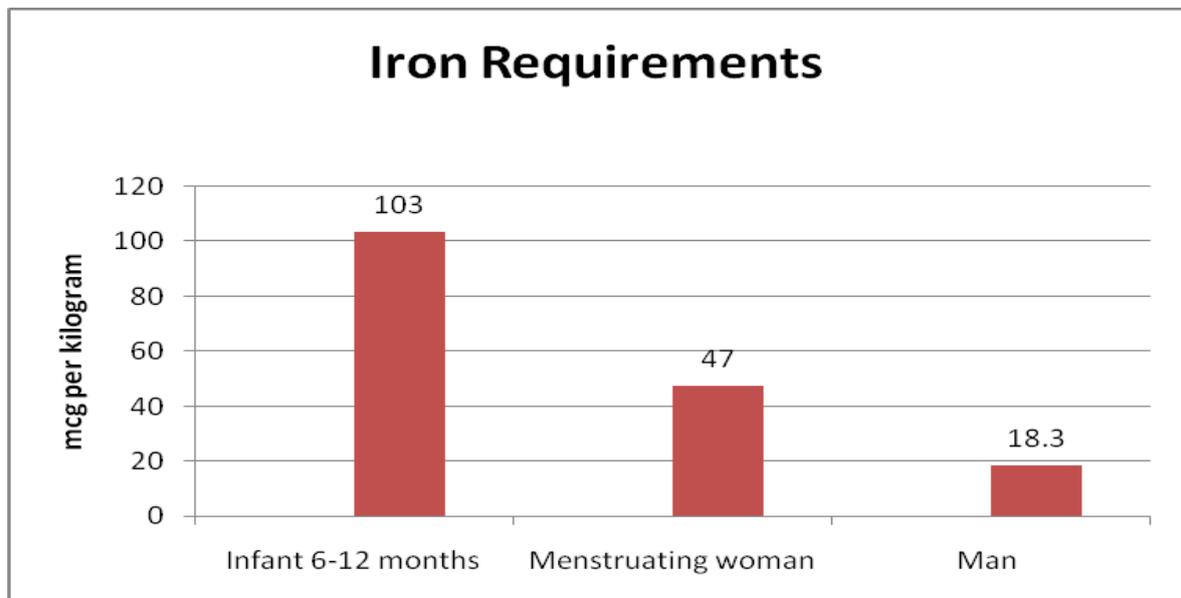


Figure 1 Proportional iron requirements, in micrograms per kilogram (10% bio-availability)(7)

Consequences of Poor Complementary Feeding Practices

Animal foods are often not given to young infants due to economic or cultural factors, or lack of knowledge. The World Health Organisation (WHO) 2001 guideline outlines essential characteristics of appropriate complementary feeding (timing, frequency, amount, variety of food groups, and care practices) (3).

When complementary feeding does not meet these criteria, there can be immediate and long-term consequences. Due to the very high iron requirements in infants aged 6-24 months, many infants in this age group become anaemic (defined as haemoglobin concentration of <110 g/dl) (8). The first two years of life are critical for neuro-development, and iron deficiency and anaemia in infancy has been consistently associated with poorer mental and motor capacity in children and which can, in turn, result in reduced earning potential in adulthood (9, 10).

Growth faltering often also occurs during the period of complementary feeding, due to inadequate nutritional intake, compounded by the effect of recurrent infections. Short term inadequate nutritional intake can lead to wasting (weight-for-height Z score < -2), whilst longer-term nutritional inadequacy leads to stunting (height-for-age Z score < -2) (11).

Severe wasting (weight-for-height Z score of < -3) carries increased odds for mortality of 9.7 (95% C.I 5.2-17.9), whilst severe stunting (height-for-age Z score of < -3) is associated with 4.1 (95% C.I 2.6-6.4) increased odds of mortality (12).

Stunting has largely been shown to be irreversible after three years and long term consequences include increased peri-natal infant mortality due to cephalo-pevic disproportion and obstructed labour, decreased work capacity, and poorer school performance and intellectual capacity (13-17).

Good complementary feeding practices provide an opportunity to catch-up on growth failure due to intra-uterine growth restriction and low-birth weight. If catch-up growth

occurs later than the period of complementary feeding, it may be associated with higher risks of diabetes, hypertension and cardiovascular disease (18).

Interventions for Complementary Feeding

Infant and Young Child Feeding (IYCF) education with or without food supplements

Maternal education on appropriate IYCF with or without provision of foods in food secure populations has been shown to increase weight and length of infants under two years, with the best results seen when education focuses on the need to increase animal foods in the infant's diet (5, 19). In food insecure populations, provision of calorie and protein containing foods or supplements has been shown to be effective at increasing growth (5, 14, 19, 20).

Multiple Micronutrients

The term "Multiple Micronutrients" refers to any combination of (at least) iron, zinc and vitamin A (21). In addition to iron, folate and B12; deficiencies of vitamins A and C can also contribute to the aetiology of anaemia. Stunting and anaemia are often seen together in populations and individuals, which may be confounding due to poverty restricting consumption of animal foods. Animal foods are rich in both iron and zinc, which contribute to anaemia and stunting, respectively. There may also be specific pathways linking iron and growth, involving transferrin and insulin-like growth factor binding protein 3 (IGFBP-3) (22). Zinc may also play an active role in erythropoiesis or haemoglobin synthesis (23, 24). Therefore, in order to see the largest benefit in children with multiple deficiencies in terms of growth and anaemia, all deficiencies must be corrected. This is one of the main advantages of giving multiple nutrients together.

Micronutrient Fortification

Iron-fortification rather than supplementation became more of an urgent requirement following a 2006 randomised-trial in Tanzania. This trial found that in children supplemented with iron and folate, there was a 16% increase in serious adverse events and deaths, mainly due to cerebral malaria (25). It is thought that excess iron in the circulation may lead to increased susceptibility to infectious disease (26, 27) . Therefore iron-fortification was recommended by the WHO as an alternative to supplementation in malaria endemic areas and increasing attention has been focused on an effective way to fortify foods with iron (28).

Home Fortification

Mass fortification of staple foods is the most cost effective method of micro-nutrient fortification. However, when the level of micronutrient added must be within safe limits for the whole population, the small volumes involved in complementary feeding mean that it is not possible to meet the nutrient requirements of the infant by this method alone (29, 30). Home fortification provides a unique and targeted solution for the high nutrient requirements of infants.

Various carriers for the micro-nutrients used in home fortification have been proposed, including; crushable tablets (“Nutritabs”), a powder mix (“Sprinkles”, or micronutrient powder (MNP)), or formulations that also contain some energy and protein, e.g. lipid based spreads (“Nutributter”), or soy based formulations (20, 31).

Evidence for Efficacy of Home Fortification

A 2009 systematic review and meta-analysis of eight efficacy trials and three programme evaluations pooled the evidence for home fortification of complementary foods, focusing on anaemia as the outcome of interest (31).

The main outcomes were that home fortification;

- **Reduced the risk of iron deficiency: RR¹ 0.44** (95% C.I 0.22 -0.86).
- **Reduced the risk of anaemia: RR 0.54** (95% C.I 0.54 – 0.64)
- **Was as effective as iron drops at reducing anaemia: RR 1.04** (95% C.I 0.76 – 1.41)

This review established that fortification of complementary foods was a feasible alternative to iron drops for the treatment and prevention of anaemia in infants (31). Various different methods of fortification were included in the meta-analysis, but the majority of studies used micronutrient powders (MNP).

Evidence for Efficacy of MNP

Anaemia

A 2011 Cochrane systematic review of eight efficacy trials evaluated MNP alone (rather than crushable tablets or spreads). This is the highest level of evidence regarding efficacy of MNP's (21).

The main outcome measures were that MNP's:

- **Reduced the risk of anaemia: RR¹ 0.69** (95% C.I 0.60-0.78). (21)
- **Reduced the risk of iron deficiency: RR 0.49** (95% C.I 0.35-0.67). (21)
- **Was as effective as daily iron drops at reducing anaemia: RR 0.89*** (95% 0.58-1.39)(21)

* The estimate comparing MNP to daily iron drops comes from just one trial and thus should be interpreted with caution.

¹ Relative Risk

Other Micro-nutrients and Effects on Morbidity and Growth

A recent systematic review of vitamin A supplementation trials has shown that in children aged six months to five years, supplementation can reduce all cause mortality by 24%, with rate ratio of 0.76 (95% C.I 0.69-0.83) (32). Therefore MNP containing Vitamin A could contribute to lower rates of morbidity and mortality.

The deleterious effect of zinc deficiency on growth is so well established that stunting prevalence within a population is used as the indirect method of assessing population zinc status (33). Supplementation with zinc alone has previously been shown to have a marked effect on linear growth in a meta-analysis of randomised trials (n=2637) (34).

However, at present the effect of MNP on plasma zinc, vitamin A levels, and effects on morbidity and growth are unclear (21, 31). In part because the trials have not been designed, or powered to assess those outcomes.

In addition zinc status is notoriously difficult to assess, because plasma zinc levels show wide diurnal variation, are reduced during infection, and fall when the child is growing well, because zinc is incorporated into new tissue (35, 36). Absorption of zinc may also be inhibited by dietary factors such as phytates in the complementary food (37).

The Cochrane review (of the efficacy of MNP) contained only two studies (combined sample size of 304 children) that looked at growth, with the intervention lasting either six or 12 months (21). Six months may be too short to see any effect on growth, or a much larger sample size may be needed to detect the small growth changes that would occur in this time frame.

A further area of controversy relating to giving multiple micro-nutrients together is that divalent ions contained in the powder mix (Fe^{2+} Zn^{2+}) may compete for the same transporter in the gut ('DMT-1') (38, 39). However, studies have shown that when given alongside foods, zinc absorption is not inhibited, such that there may be an alternative absorption pathway involving binding to ligands present in the food (40, 41). A tracer study

found that 10mg zinc reduced iron absorption, whereas 5mg did not. Therefore, 5mg is the usual dose recommended for MNP (42).

2011 WHO recommendation: Micronutrient Powders

The WHO released a “strong recommendation” for in-home fortification of complementary foods for infants aged 6-23 months, with multiple micronutrient powders (MNP’s) in order to improve iron status and reduce anaemia (6).

The suggested composition of the sachets is;

- Iron: 12.5mg , as ferrous-fumarate
- Vitamin A: 300 mcg retinol
- Zinc: 5 mg, as zinc-gluconate.
- Other micro-nutrients at currently recommended doses for the target population.

At present the WHO recommends “a minimum intervention period of two months, followed by a period of three to four off supplementation, so that the use of micronutrient powders is started every six months” (6).

Reported acceptability of MNP

MNP have been shown to be acceptable to caregivers and children in a wide variety of settings (43-47). Adherence rates in trials in developing countries have generally been high (31). MNP does not have the strong metallic taste of standard iron drops due to lipid encapsulation of the iron particles, is reportedly easier to use and does not stain the teeth which may result in higher compliance (31, 46).

Cambodian Context

In Cambodia, 40% of children under the age of five years are stunted, 11% are wasted, and 55% have anaemia (figure 2) (48). With reference to WHO standards, these rates are “very high” for stunting, “high” for wasting, and represent a “severe public health problem” for anaemia (8, 11).

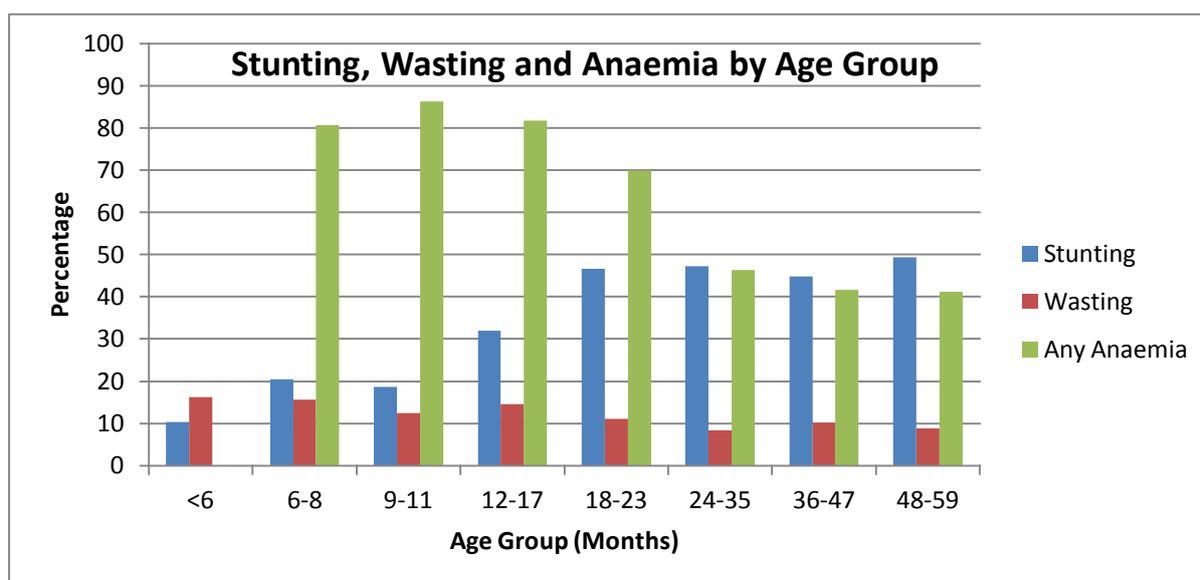


Figure 2 Nutritional Status of Children under 5 Years, (CDHS 2010). Stunting (Height-for-age < -2 Z-scores), Wasting (Weight-for-height < -2 Z scores), Anaemia (Haemoglobin < 110 g/dl) (48).

In the 2010 Cambodian Demographic Health Survey (CDHS) only 24% of children aged 6-23 months had met the minimum standard for all three Infant and Young Child Feeding (IYCF) practices (48). The main problem is lack of dietary diversity, with only 37% of children consuming the minimum number of food groups recommended for this age range, and only 42% of infants aged 6-8 months having consumed animal products in the last 24 hours (48). This undoubtedly contributes to the highest anaemia rates in any age group, with 86.2% of Cambodian children aged 9-11 months classified as anaemic (2010 CDHS)(48).

This lack of dietary diversity is partly due to cultural factors, such as fears that the child will choke if meat or vegetables are added to the traditional complementary food, a thin rice-porridge called “*bobor*” (49). Poverty is also a factor, with 11% of the population classified

as food insecure, rising to 18% during the lean season, according to the last Food Security and Vulnerability Analysis (50) .

A high prevalence (>50%) of genetic haemoglobin-disorders (mainly Hb E trait and alpha-thalassaemia trait) in Cambodia is well documented (51, 52). It is therefore important to refer to research specific to the Cambodian context as well as estimates of efficacy of MNP from international literature.

Three randomised trials of home fortification for the treatment/prevention of anaemia in Cambodia have been carried out (see figure 3 for summary). One individually-randomised, high quality triple blinded trial with clear allocation concealment (CESVI), and two cluster randomised trials, one of which “Good Food for Children” (GFC) was an effectiveness trial for MNP distribution via government health services (53-55). The cluster-randomised trials (GFC and GTZ) suffered from unclear allocation concealment, and lack of placebo control in the case of the GFC study.

<i>Details</i>	<i>Study</i>		
	<i>"GTZ" (54)</i>	<i>"CESVI" (53)</i>	<i>"GFC" (55)</i>
Date	2004	2004	2008
Duration of Intervention	20.5 weeks	12 mo	6 mo
Sample size (number of children analysed at endline)	250 (231)	204 (191)	1071/3112 Subsample selected for bio-chemistry (1014 actually analysed)
Inclusion Criteria	Children 6-24 Mo	Children 6 months	6-7 month old infants
Exclusion Criteria	Severely anaemic	Severely anaemic	Severely anaemic
Intervention	FoodLET containing either Fe/folate or Fe/folate/MN. Twice weekly	MNP or Fe/folate powder daily	MNP daily + IYCF education
Control group	Placebo	Placebo	IYCF education
Randomisation	Cluster	Individual	Cluster
Allocation concealment	Unclear	Yes	Unclear
Blinding	Double blind	Triple blinded	No
Intention-to-treat	Yes	Yes	Yes
Baseline prevalence of anaemia (Hb < 110 g/L)	74.4%	78%	84%
Outcome measures: 1)Risk difference in anaemia compared to control	20.8% (95% C.I unavailable)	35% (95% C.I unavailable)	20.6% (95% C.I 9.4-30.2)
2)Zinc status	N/A	N/A	Mean difference 0.44 micromol/L (95% C.I 0.04-0.83). No difference in prevalence of zn deficiency (Zn<9.9 micromol/L)
3)Anthropometry	No difference	No difference	No difference

Figure 3 Table of Key Characteristics of Cambodian trials of Home-fortification.

In summary the three trials of home fortification in Cambodia have produced risk differences in anaemia compared to control of between 20.6 -35%, even with the high levels

of genetic haemoglobinopathies. The children with abnormal haemoglobin saw reductions in anaemia of the same magnitude, but with lower end-of-trial haemoglobin levels.

MNP Programme

The Cambodian Ministry of Health is in the process of scaling-up an MNP supplementation programme for infants 6-24 months of age. Following the GFC effectiveness trial in Svay Rieng province in 2008, implementation started in S.Rieng, in 2010, and expanded to Kompong Speu province in September 2011 (55).

Rationale for Operations Research on Community Perceptions of MNP

There has not been any evaluation of community perceptions of MNP and function of the programme, without the extra support and incentives offered by the previous effectiveness trial (GFC). It is important to understand these to allow resolution of any problems before the impact evaluation and national scale-up.

Study Aim

This study aimed to investigate current community perceptions and uptake of the MNP programme in two provinces in Cambodia, and the factors affecting these, including service delivery methods and staff knowledge.

Objectives

- 1) To report on current functioning of the MNP programme, with reference to procedures outlined in the Cambodia Micronutrient Policy 2012.
- 2) To investigate and record community perceptions of the MNP programme, both in the original study area for the GFC trial and in the areas where implementation has been more recent.

- 3) To report on key themes in perceptions, and the operational factors which influence them, in order to propose recommendations for action before national scale-up of the MNP programme.

Structure of the MNP Programme in Cambodia as Outlined in the 2012 Micronutrient Policy

Cambodian government health-centre (HC) staff aim to visit every village in their catchment area once a month for outreach activities. These include treatment of minor illness, health and nutrition education and immunisations.

The MNP is intended to be distributed via this monthly outreach service. Caregivers are either expected to come to the outreach meeting in the village and collect the MNP sachets for the month, or the Village Health Volunteer (VHV), should collect the MNP to distribute to the caregivers who cannot access the outreach sessions.

Until the programme is scaled-up the VHV's and the HC outreach are the only source of counseling for the correct use of MNP, and its benefits and side effects. A mass media campaign around MNP is planned to coincide with national scale-up.

As shown below, the caregivers are instructed to use up 15 sachets within one month, as opposed to every day. This schedule has been shown to have better adherence and therefore haematological outcomes than a daily schedule (56).

<i>Target Group</i>	<i>Dose</i>	<i>Frequency</i>	<i>Duration</i>
Children 6-24 months	10mg Iron 10mg Zinc, 400 mcg Retinol, 12 other micronutrients	15 sachets per month	18 months maximum (not over 24 months of age)

Figure 4 Dosing schedule for MNP in Cambodia

Instructions for use

- Add the sachet to the food when it has cooled down, and feed within 30 minutes.
- Do not mix the powder with liquid.
- Possible side-effects that should be expected are diarrhoea, dark stools and constipation. These should subside in a few days to a few weeks.
- In case of side-effects, the sachet can be divided into 2-3 meals instead of one (57) .

Ethical Approval

Ethical approval was granted by London School of Hygiene and Tropical Medicine Ethics Committee. Local ethical approval was not required as the research was undertaken as part of monitoring of an ongoing programme. Informed consent was gained from all participants in the study, and all data was anonymised (see appendix 1 and 2).

Methods

This study utilises a mixed-methods approach, combining both quantitative and qualitative elements in order to describe and explain current programme delivery, community perceptions and uptake of MNP. The author of this report was the principal investigator (PI), who carried out the work as part of an internship with UNICEF Cambodia, between 18/6/12-18/8/12.

Qualitative Research Approach

My approach to the qualitative data collection and analysis is based in the subtle-realist epistemology (58-60). This approach assumes that we can only know reality from our own perspective, therefore attaining a definite “truth” is impossible, but is a goal that all research should strive for.

As seen from the realist tradition, the task of the researcher is to remain objective and provide a transparent methodological account (61). Realists have developed a variety of alternatives to the concept of “validity”, as used in positivist inquiry, as outlined below (61-63).

I will use the first person when discussing the qualitative analysis, to aid reflexivity and allow the reader to see how I decided to interpret and report the data.

As a guide for ensuring quality in both the methods and interpretation of the qualitative data, I referred to Lincoln and Guba’s criteria for rigour in qualitative research, which have been compared to positivist criteria as shown below (64-67):

<i>Positivist</i>	<i>Subtle-realist</i>	<i>Methods proposed to ensure quality</i>	<i>Methods used in this study</i>
Internal Validity	Credibility: Addresses the issue of “fit” between responders views and the researchers interpretation of them	Prolonged engagement in the field, member checks, peer debriefing, audit trails	The PI has lived in Cambodia for nearly 4 years. Peer debriefing carried out with assistant researcher and translator after each FGD / interview and after analysis.
External Validity	Transferability: Generalisability of inquiry.	Thick description of setting and / or participants	Facilitated by field notes and reported in methods.
Reliability	Dependability: Inquirers are responsible for ensuring that the process of research is logical, traceable and clearly documented.	Audit trail – documentation of data, methods and interpretive decisions taken.	Stages of analysis documented in methods section, plus audit in appendix
Objectivity	Confirmability: Establishing that data and interpretations come not from the researchers imagination, but from the data.	Audit and Reflexivity	Peer review, audit trail, and field notes

Figure 4 Table of Criteria for Rigour in Qualitative Work, as proposed by Lincoln and Guba (66, 67)

Within the O.D, health-centers (HC) were selected based on advice from staff at the Provincial Health Departments (PHD), with the aim of including a variety of high and low coverage HC's (although exact figures were not available for HC level). Villages were selected based on being either close to (e.g. <5Km) or remote from (e.g. >10km) the HC

In Svay-Rieng province, two HCs were included in each O.D, in order to allow more of a comparison between GFC and non GFC areas. In Kompong-Speu only 1 HC was included in each O.D.

Thick Description of Setting and Participants

Fieldwork was carried out between 23/07/2012 and 02/08/2012 which is the rainy season in Cambodia. The villages were rural and the majority of the houses lacked electricity, toilets or running water. The main occupation is small-scale rice farming – at this time of year the rice is transplanted, meaning that a lot of mothers were working in the fields.

Increasingly women are leaving the rice fields to find employment in garment factories and this scenario was common in visited villages. In this situation the caregiver was defined as the person who “usually feeds the child”.

Health-centres were situated on dirt roads between villages, and this is where the interviews with HC staff were conducted.

Houses in rural Cambodia are typically raised on stilts to protect them from flooding, and the area under the house is used for receiving visitors. The FGD's and interviews with VHV's were normally held with everyone sitting on the bamboo platform under the house of the VHV, or in the village meeting place.

<i>Province</i>	<i>O.D</i>	<i>Health -centre</i>	<i>Village</i>
Svay-Rieng	Svay-Rieng O.D (high coverage). Previous GFC study	Chumlor	Jeeah-Srusay (Remote) Tajeeay (close)
		Svay Rumpeah	Kampot-Touk (Remote) Kanchayt (close)
	Chiphu O.D (low coverage)	Porpet	Tropeang-Chak (Remote) Svay Pha-Em (close)
		Samley Svay-Tayean	Samley-Kangchung (remote) Svay-Tayean (close)
Kompong-Speu	Kompong-Speu O.D (high coverage)	Talat	Doung (remote) Krang-Po (close)
	Udong O.D (low coverage)	Omlaing	Preik (remote) Tomneab (close)
Total	4 O.D's	6 Health-centre's	12 villages

Figure 6 Table Showing Geographic Sampling

Groups of Participants and Method

- 1) Semi-structured interviews with staff at National and Provincial level, in order to involve key stakeholders in study design, and to document current implementation and existing thoughts on community perceptions. Present were; PI and translator, and for the interview with the National Nutrition Programme, the Nutrition Specialist from UNICEF.
- 2) Semi-structured interviews with staff involved in the distribution of and education on MNP. PI and translator were accompanied by the part-time Nutrition Focal Point

staff member from the Provincial Health Department, though they did not participate in interviews.

- 3) Focus group discussions (FGD's) conducted with caregivers of children who were using the MNP or are in the target group but were not using MNP. After the FGD participants were given soap to compensate them for their time. Present were; P.I. and translator.
- 4) Individual questionnaire interviews conducted with caregivers to obtain quantitative estimates of side-effects and usual delivery channels. The sampling strategy was "take-all" eligible caregivers who were available in the village. There were no refusals.

Triangulation of data from different participants and areas allowed a comprehensive picture to emerge of the current community perceptions of the MNP programme, and the distal operational factors that relate to these.

<i>Method</i>	<i>Number Conducted</i>	<i>Number of Participants</i>	<i>Type of participant</i>
Semi-Structured Interview of National Nutrition Programme	1	3	National Nutrition Programme Directors.
Semi-structured interview of Provincial Health Department Staff (1 in S.Rieng Province and 1 in K.Speu Province).	2	4	Provincial Health Directors (2), Nutrition Focal Point (2).
Semi-Structured Interviews of Health-center (HC) Staff	6	13	Secondary nurses, HC Chief's, Midwives.
Semi-Structured interviews with VHV's	12	12	Village Health Volunteers
FGD with Caregivers of Children 6 to 24 months	12	60 Average of 5 participants, (range 3-9)	48 mothers, 11 grandmothers, 1 father
Administered Questionnaire to caregivers of children who were: currently using MNP, had recently stopped using MNP (within 3 months), or were in the target age group but were not using MNP		161	130 mothers, 27 grandparents, 3 fathers, 1 aunt / uncle

Figure 7 Summary of Data Collection Methods

Steps Taken to Reduce Bias

Selection Bias

Due to logistical constraints, it was not possible to select a random sample for the questionnaires. Within the villages, the VHV and HC staff collected most of the caregivers for the FGD's and questionnaires after our arrival in the village.

In order to try and reduce the selection bias inherent in this process, after conducting the FGD and interview with VHV, the team then split up to seek out more caregivers who were in the village but who had not attended the site of the FGD, or had not been selected by the VHV.

Information Bias

Persons involved in the fieldwork were given a half-day orientation on the discussion guides for semi-structured interviews and FGD's, and the quantitative questionnaire. This focused on keeping questions as open as possible, in order to reduce information bias.

In addition, we strived to administer the questionnaires in as private a location as possible, and away from the VHV / HC staff and PHD staff. FGD's were carried out while the PHD staff, HC staff, and VHV collected all caregivers in the village for the quantitative interview, in order to allow the caregivers to speak freely without the VHV and H.C staff overhearing.

Raw Data Collection

Interview and Focus Group Topic Guides

Interview and FGD topic guides were produced to structure the discussions (appendix 3). Open-ended questions were followed by probing points to ensure that the major areas of interest were covered. Questions were designed to elicit the information in a non-leading way. Areas of interest were developed by; review of international literature and consultation with programme managers.

Quantitative Questionnaire

The questionnaire was designed by UNICEF (See appendix 4) and consisted of 14 questions, relating to: care-giver relationship, age at starting MNP, location of receiving MNP, personnel received from, number of sachets used per week, past / current side effects, or reasons for stopping MNP.

Audio Recording

All Interviews and FGD's were recorded on a digital Mp3 Dictaphone (Sony IC Recorder ICD-UX513F). The purpose of this was to allow clarification of points at a later date if things were missed during simultaneous translation and transcription.

Field Journal and Transcription

I took detailed field notes during the interviews and discussions. The field notes comprised of three main parts:

- 1) Hand written detailed transcription of simultaneous translation provided by UNICEF staff member.
- 2) Contextualisation of the data; details on setting, interview dynamic and pre-conceptions of P.I. and translator, and sources of bias. This was used to aid interpretation and analysis, by providing thick description and reflexivity around the effect we had on the answers we were given, and the "credibility of the account" (66).
- 3) Notes on emerging themes and hypotheses, and further questions to add to the interviews and FGD's.

See appendix 5 for sample of field notes.

Analysis

Qualitative

Framework-analysis was used for qualitative data, which involves creating tables whereby themes can be examined both within and between cases (68). Themes were either pre-conceived based on the background literature or areas of interest brought up by programme managers, or were generated by the data.

1) Familiarisation with Hand Written Transcripts

Every evening after the day's field work I read through and summarised the main themes and points of each transcript and added them to the Framework-analysis table (see below).

2) Construction of Detailed Framework Tables

I organised cases (either FGD or individual interview) in rows, and themes across columns. This generated two tables, one for FGD's with caregivers, and one for interviews with service delivery staff / VHV's. The final size of the tables was 12r x 20c for FGD's, and 20r x 16c for interviews (sample in appendix 6). At this level, the unit of analysis for the FGD's is the group and the majority view was recorded in each cell. If there was disagreement within the group I recorded the number agreeing with the view as x/y participants.

3) Construction of Summary Framework

I condensed the large tables down into groupings, pooling the FGD's and interviews, so that there were three groups for comparison (sample in appendix 7). The decision of how to group the cases was informed by the data, and was itself part of the analysis. The most natural groupings within the data became obvious as Svay Rieng O.D, Chiphu O.D and Kompong Speu province taken as a whole. Community perceptions and programme delivery were fairly homogenous within, and heterogeneous between these three groups.

- 1) Svay Rieng O.D (4 FGD's, 6 interviews). S.Rieng OD was the area that was included in the 2008 GFC effectiveness trial, and the area that has most experience of using MNP. The MNP programme started in 2010.
- 2) Chiphu O.D (4FGD's and 6 interviews). This area started the MNP programme in 2010 at the same time as S.Rieng O.D but was never part of the effectiveness trial.

3) K.Speu province (four FGDs and six interviews). The MNP programme started here in September 2011.

At this level, I recorded themes as coming up in x/6 interviews, and x/4 focus groups. I then pooled and summarised the final tally's for each theme for each group as being discussed in x/18 interviews with HC staff / VHV's and x/12 FGD's (where there was no clear majority view, this is highlighted in the results).

3) Mapping and Interpretation

Cross comparison of community perceptions, staff perceptions, staff knowledge and programme delivery allowed identification of patterns and links between and within grouped areas, using triangulation of staff interviews and FGD's with caregivers.

4) Peer Review

To ensure that the analysis and interpretation was a close reflection of the data, I discussed the preliminary results with the facilitator / translator for the qualitative data collection.

5) Provision of Audit Trail

Included as appendices (5-7) is a sample of analysis, to allow the reader to evaluate for themselves the credibility, dependability and confirmability of my account (66, 67).

Quantitative

Data was initially entered into a Microsoft Excel spreadsheet by the P.I and then analysed using STATA 12. Tests of association using Pearson's chi-squared were carried out using the geographic area as the exposure, and outcomes were summarised as proportions in each area. For test-for-trend analysis (binary outcomes only), the areas were classified as going from the better performing area of S.Rieng O.D = 1, then Chiphu O.D = 2, followed by K.Speu = 3 as the poorest performing area, which was the impression given by the qualitative data. In each case the null hypothesis was that there was no association between the geographic area and the outcome of interest.

Results

Quantitative: Coverage and Service Provision

Flow Diagram of Total Sample

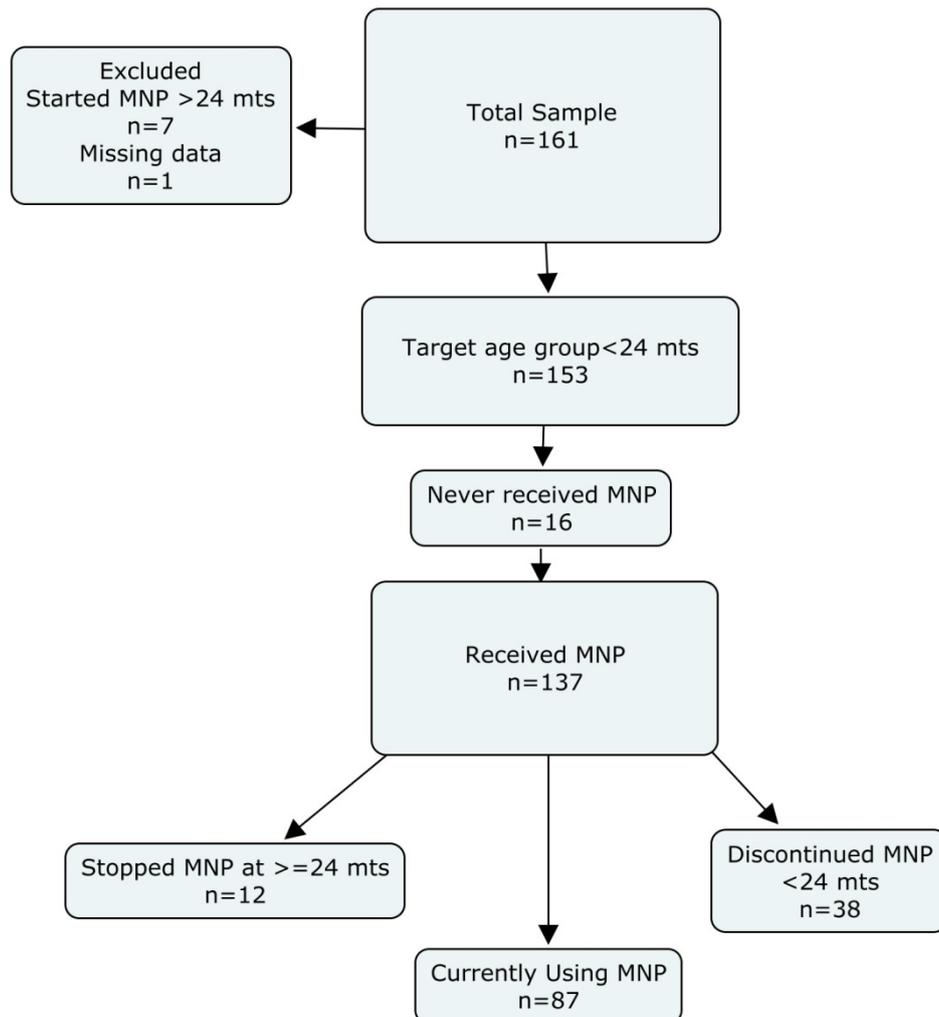


Figure 8 Flow Diagram of Participants (Quantitative Sample)

Disaggregated Coverage

Although 90% of the children in the sample who were of the target age group had received MNP, when disaggregating the data, some important differences emerge.

In the previous GFC study area of S.Rieng O.D, all of the children sampled had received the MNP (figure 9). In Chiphu O.D, the district adjacent to the study area in the same province, nearly all had received MNP (95.8%), In K.Speu province coverage of target children sampled is lower (72%) (figure 6). With a probability, or P-value of <0.0001, there is very strong evidence that the differences found in coverage rates between the areas are not due to chance.

	S.Rieng O.D (GFC)	Chiphu O.D (non-GFC)	K.Speu province	Total	P-Value Chi² test for trend
Received <24 mts	55 (100%)	46 (95.8%)	36 (72%)	137 (89.5%)	
Never Received <24 mts	0	2 (4.2%)	14 (28%)	16 (10.5%)	
Total	55 (100%)	48 (100%)	50 (100%)	153 (100%)	P <0.0001 X ² = 21.34

Figure 9 Table: Disaggregated coverage estimates. Showing increasing likelihood of target children not receiving MNP, from S.Rieng O.D to Chiphu O.D, to K.Speu.

Continued Use

There is very strong evidence of an association between area of residence and the proportion of children in the sample who have dropped-out of the programme early (chi squared test for trend, $P < 0.0001$). Of those children sampled who received the MNP, in the previous GFC area (S.Rieng O.D), 94.6% of children are currently using MNP, or have recently graduated from the programme (within three months). In the non-study area (Chiphu) 76.1% of children are either current users of have recently graduated from the programme, with 23.9% of children discontinuing MNP before the age of 24 months. In K.Speu province however, there is a much larger early drop-out rate of 66.7% (figure 10).

	S.Rieng O.D	Chiphu O.D	K.Speu	Total	P-Value Chi² test for trend
Currently using MNP or stopped ≥ 24mts	52 (94.6%)	35 (76.1%)	12 (33.3%)	99 (72.3%)	
Stopped MNP ≤23 mts	3 (5.4%)	11 (23.9%)	24 (66.7%)	38 (27.7%)	
Total	55 (100%)	46 (100%)	36 (100%)	137 (100%)	$P < 0.0001$ $\chi^2 = 38.68$

Figure 10 Table: Disaggregated early drop-out rates. Showing trend for increasing early drop-out going from; S.Rieng O.D, to Chiphu O.D, to K.Speu

Service Provision

Personnel

In the Cambodian Micronutrient Policy 2012, the proposed pathway for delivery of the MNP is via HC outreach meetings, held in the village. The VHV is then responsible for supplying the MNP to any caregivers who are unable to attend the HC outreach, in what is termed “mop-up.”

In both the previous GFC study area and the non-study area of Svay Rieng province (Chiphu), it seems that this is indeed what is happening, with around half of caregivers reporting they received the last MNP supply from HC staff and around half from VHV’s. In K.Speu province however, the service is overwhelmingly provided by VHV’s, (97.2%), with very little involvement from H.C staff (figure 11). There is very strong evidence that this a true difference (P-value of < 0.0001).

	S.Rieng O.D	Chiphu O.D	K.Speu	Total	P-Value Chi ² test for Trend
H.C Staff	29 (52.7%)	17 (37%)	1 (2.8%)	47 (34.3%)	
VHV	26 (47.3%)	29 (63%)	35(97.2%)	90 (65.7%)	
Total	55 (100%)	46 (100%)	36 (100%)	137(100%)	P < 0.0001 χ ² = 23.00

Figure 11 Table: Disaggregated service provision by personnel. Showing increasing involvement of volunteers going from S.Rieng O.D, to Chiphu O.D, to K.Speu.

Location of MNP Delivery

The location of MNP delivery is split along provincial lines, rather than GFC study versus non-GFC study area. In S.Rieng O.D, the majority of caregivers reported receiving the MNP at their own home (60%), followed by Health Centre outreach (25.5%). No caregiver reported going to collect the MNP from the house of the VHV (figure 12). The pattern is similar in the non-GFC study area of Chiphu, with the most common place of delivery being the caregivers own home (47.8%), followed by HC outreach (34.8%). However there is more collection by caregivers of the MNP from the house of the VHV (17.4%).

In K.Speu the majority of caregivers reported having collected the last MNP supply from the house of the VHV (66.7%). There is some delivery to the caregivers house by the VHV (19.4%), but hardly any involvement from HC staff, with only one person having reported receiving MNP from HC outreach (figure 12).

	S.Rieng O.D	Chiphu O.D	K.Speu	Total	P-Value Chi ²
Health Centre	8 (14.6%)	0	0	8 (5.8%)	
H.C Outreach	14 (25.5%)	16 (34.8%)	1 (2.8%)	31 (22.6%)	
VHV House	0	8 (17.4%)	24 (66.7%)	32 (23.4%)	
Own House	33 (60%)	22 (47.8%)	7 (19.4%)	62 (45.3%)	
Village Meeting	0	0	4 (11.1%)	4 (2.9%)	
Total	55 (100%)	46 (100%)	36 (100%)	137 (100%)	P <0.001 X ² = 82.84

Figure 12 Table: Disaggregated service delivery, by location. In S.Rieng "outreach" and "own home" are the most common, whereas in Chiphu O.D and K.Speu there is increasing tendency for collecting MNP form the house of the VHV.

Age at Enrolment

There is very strong evidence of a trend of decreasing percentage of children who started MNP at the target of six months of age, going from almost all in S.Rieng, to around half in Chiphu and 40% in K.Speu (P-value <0.0001) (figure 13). This reflects quality of service provision and the efficiency of the HC staff and volunteers at identifying children in each village of the target age group.

	S.Rieng O.D	Chiphu O.D	K.Speu	Total	P-Value Chi ² Test for Trend
Received MNP at 6 months	53 (96.3%)	25 (55.6%)	15 (41.7%)	93 (68.4%)	
Received MNP after 6 months	2 (3.6%)	20 (44.4%)	21 (58.3%)	43 (31.6%)	
Total	55 (100%)	45 (100%)	36 (100%)	136² (100%)	< 0.0001 X ² = 35.25

Figure 13 Table: Disaggregated age at enrollment. Showing trend of decreasing likelihood of starting at 6 months, going from S.Rieng, to Chiphu O.D, to K.Speu.

² Denominator is 136 not 137 because of missing data for start date

Side-effects

The proportion of *current-users* with any side effects (excluding taste) was 23 infants/87, which gives an estimate of percentage of children experiencing side effects of 26.4% (95% C.I 17.1-35.7%).

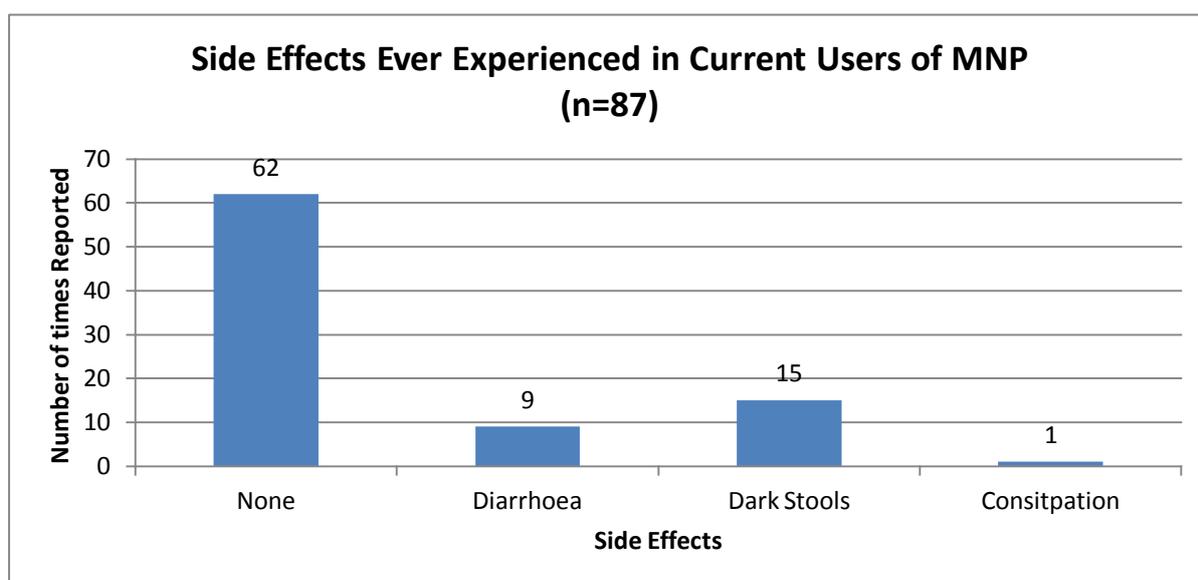


Figure 14 Graph to show side-effects ever experienced in current users.

Reasons for Discontinuing MNP before 24 months

In *ever-users* the number of children who experienced any side-effects or difficulties in using MNP (including those who stopped due to diarrhoea or taste), was 41/137 or 29.9 % (95% C.I 22.2-37.6)

As can be seen from figure 15, the major reasons caregivers gave for stopping MNP early were; no supply, taste objections from the child, and diarrhoea. However, the questionnaire allowed caregivers to give multiple reasons, and some of them overlap.

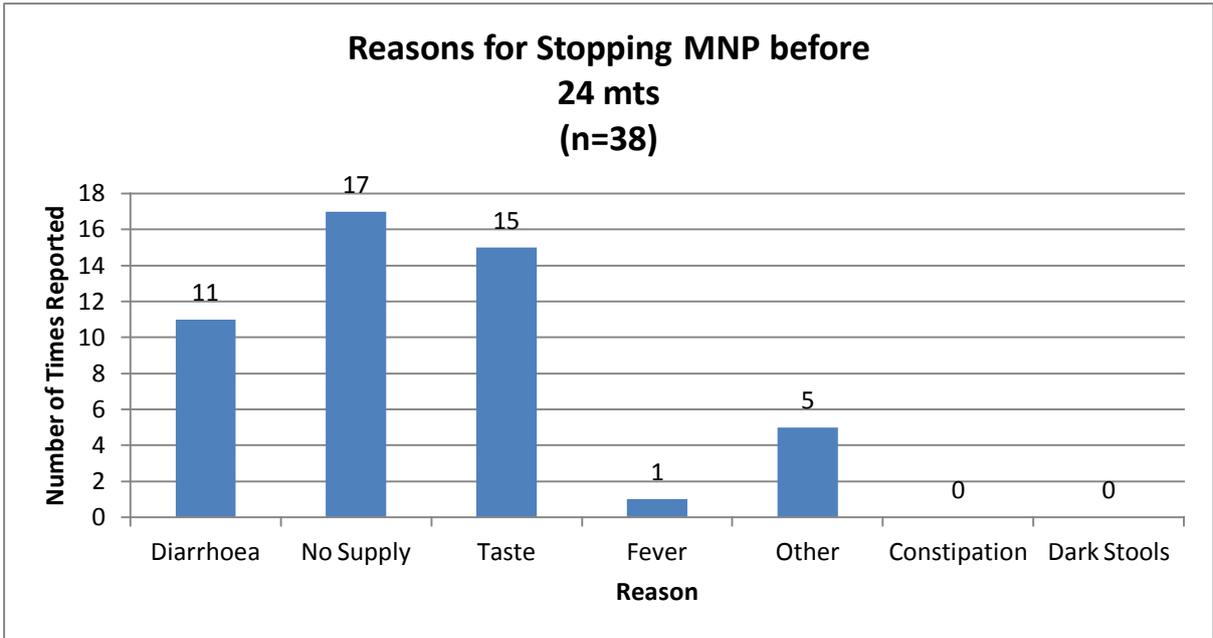


Figure 15 Graph to show reasons for discontinuation of MNP.

The connections between the reasons can be better seen in a Venn diagram, as below. When presented in this way, taste as a sole reason for stopping MNP becomes more prominent and “no supply” less so. Most of the “no supply” responses were from one village in K.Speu where the VHV refused to collect any more MNP due to initial complaints of diarrhoea.

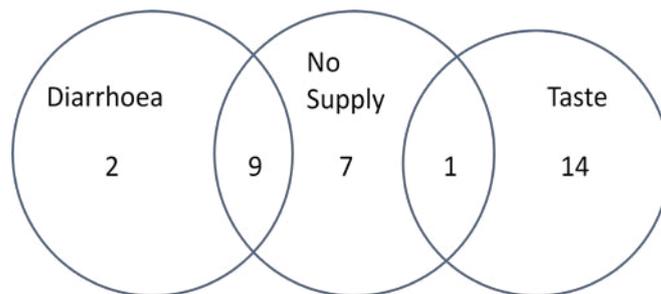


Figure 16 Venn diagram showing reasons for early discontinuation of MNP

Qualitative

Community perceptions on MNP were noticeably more positive in the previous GFC study area of S.Rieng O.D. In addition, the HC staff and VHV's were more knowledgeable on expected benefits and side effects of MNP, and how to minimise side effects.

Benefits

The most commonly reported "reasons to use the MNP" by caregivers were; "good growth or gaining weight" (8/12 FGD's), for "good health" (7/12 FGD), to "reduce sickness" (5/12 FGD) and to "improve appetite" (2/12 FGD).

The main benefits of MNP "seen in their own children" were; "good growth or gaining weight" (6/12), child becoming "more active or having more energy" (3/12), and "fresh" or "bright" (3/12) skin.

Side-effects

The main problem reported by caregivers and staff was that the children did not want to eat the food with MNP added, due to a "metallic", or "sour" taste. (7/12 FGD's and 15/18 interviews with VHV's and H.C staff). Complaints around taste seemed to be much more a problem in Chiphu O.D and K.Speu, than S.Rieng O.D.

The next most commonly reported side effect in FGD's with caregivers was diarrhoea (4/12 FGD's). It seemed that the diarrhoea was just for the first few days. In villages where the majority of caregivers were continuing to use the MNP (10/12), they reported that there were no ongoing problems with diarrhoea. Black stools were mentioned in only (2/12) FGD's, and did not appear to be a big cause for concern.

Methods of Use and Dealing with Side-effects

The usual method of feeding the MNP was either with rice, or rice-porridge "*bobor*." Nearly all caregivers knew that the MNP must be added to the food after it had cooled down.

When caregivers were asked how they dealt with any problems they encountered with using the MNP, the most common response was splitting the sachets into more meals (8/12) in order to try to dilute the taste (this was more common in S.Rieng O.D). However, in Chiphu and K.Speu caregivers had tried mixing the MNP with water, again to overcome the taste objections (3/8).

Factors influencing Community Perceptions and Adherence: Triangulation of Qualitative and Quantitative Data

Several operational factors interact to influence community perceptions and adherence to MNP. These are explored in the following section and represented in figure 17.

Knowledge of HC Staff and VHV's

HC staff and VHV's were more knowledgeable about expected benefits and side effects in S.Rieng O.D. The caregivers themselves also provided more "reasons to use the MNP" during the FGD's in S.Rieng O.D, so it appears the knowledge had filtered into the community. Thus in S.Rieng the caregivers have more incentive to overcome objections from the child around taste, because they have more knowledge on the reasons for giving the MNP.

In Chiphu O.D and K.Speu, when interviewing VHV's and HC staff, "the child might not want to eat the MNP" was the most commonly reported side effect remembered from training (6/12 interviews), with the only other reported side effect remembered from training being fever (1/12), which is actually not an established side-effect. Diarrhoea was only mentioned twice as a possible side-effect, and both of these were in S.Rieng O.D.

In K.Speu especially, there was very little knowledge on expected side effects, with "none" (5/6) the most common response, and the only other response being the "child might not want to eat" (1/6). The majority of quantitative cases of "diarrhoea and no supply" come from one remote village in K.Speu, where the VHV did not feel he "had the capacity" to advise caregivers on the diarrhoea, and needed more support from HC staff. Except for this

village, diarrhoea was not the major cause of stopping using the MNP. The other village that had stopped using MNP consistently was also in K.Speu and this was due to complaints about the taste.

In S.Rieng O.D there was more knowledge on strategies to cope with side-effects, such as splitting the sachets into smaller amounts, and around half of the mothers were dividing the MNP into two or more meals. In Chiphu and K.Speu, only a minority of mothers were doing this. In K.Speu, the original training for HC staff and VHV's recommended using one sachet in one meal, but this was amended to splitting the sachet if experiencing side effects three or four months after implementation.

One of the staff at the PHD in K.Speu said that some HC staff were "afraid" to advise splitting the sachet in case they get in trouble when there are spot checks from the national level.

Method of Supply

In S.Rieng and Chiphu O.D, the HC staff usually deliver the MNP each month via village outreach. This is the procedure outlined in the 2012 Micronutrient Policy for Cambodia. In K.Speu, the VHV must go and collect the MNP when they are at the HC for other meetings, because the MNP programme does not refund travel costs. This means that sometimes when they attend those meetings, the MNP supply for that month has not arrived yet.

As the VHV said, he has to attend meetings at least three times a month at the HC, and "I should be able to collect the MNP whenever I am going, not wait until the deadline, because then I might not be able to go." In K.Speu, the method of supply results in higher opportunity costs for the unpaid VHV's.

Diarrhoea is an established side effect of using the MNP, but normally only for the first week, also in (4/12) FGD's the caregivers mentioned that the child accepted MNP more easily with longer use. If the supply is irregular (more of a danger if distribution relies on the unpaid VHV collecting the MNP from the HC, especially in remote areas), then interruptions

will result in the caregivers having to overcome these barriers all over again. For behaviour to become habitual, for example, remembering to add MNP to a child's food, a regular supply is essential.

Delivery Personnel, Trust and Value

The HC staff themselves provided the MNP during community outreach meetings in the village in S.Rieng province. In K.Speu, the usual delivery method was the VHV collecting the MNP when they attended meetings at the HC, and then the VHV distributes at the village level. In (2/4) FGD in S.Rieng O.D the theme of trusting the HC staff and relying on their advice came up. For example, one mother said that, although she herself wasn't too clear on the good effects of the MNP, she "believes the health workers when they say to use it," and that was why she continued to use it.

One grandmother said in S.Rieng O.D, although she had heard of some families whose child doesn't want to eat because of the taste, "we have to try every day." So it seems that although the community in S.Rieng also faced some difficulties with feeding the MNP due to the taste, they value the MNP more because it comes from a trusted source, and they are better informed on the benefits.

Starting at six months

In S.Rieng O.D, nearly all of the children had started using the MNP at six months, as intended. In Chiphu O.D 46% of children had started after 6 months and in K.Speu province, 60% had started late. This may impact on the acceptability of the taste of the MNP to the child, with more objections if the MNP is introduced as the child is getting older and has already become accustomed to the taste of complementary food without MNP. The view that getting the children to accept the MNP was harder if they started older was reported in one interview with a secondary nurse and in two caregiver FGD's.

Ability of the Carer to Care

In many of the interviews (7/18) with VHV's and HC staff, when asked about factors influencing use of MNP, the interviewee's brought up the theme of "care". They talked about how some caregivers may not "try hard" to push the children to eat the food with the MNP, or even "leave the child to eat alone", especially when the mothers are working in factories and the child is left with the grandmother. They stated that the grandmother might have two or three children to look after, and as one HC staff from S.Rieng stated "the older generation don't see why they should use the MNP as they have raised many children before [without it]." In one FGD in Chiphu, a grandmother echoed this theme by saying that "when we mix the MNP, the child doesn't want to eat the food", and that they could not sit and encourage the child because they are "busy with daily living"

Although the sample size for grandmothers is very small, the limited quantitative data does not provide any evidence of a true difference in adherence rates dependent on caregiver relationship, as can be seen from the overlapping confidence intervals. With 71.4% (95% C.I 54.3-88.5) of children cared for by grandmothers (n=27) continuing with MNP, as opposed to 60% (95% C.I 51.5-68.5) of children cared for by mothers (n=130).

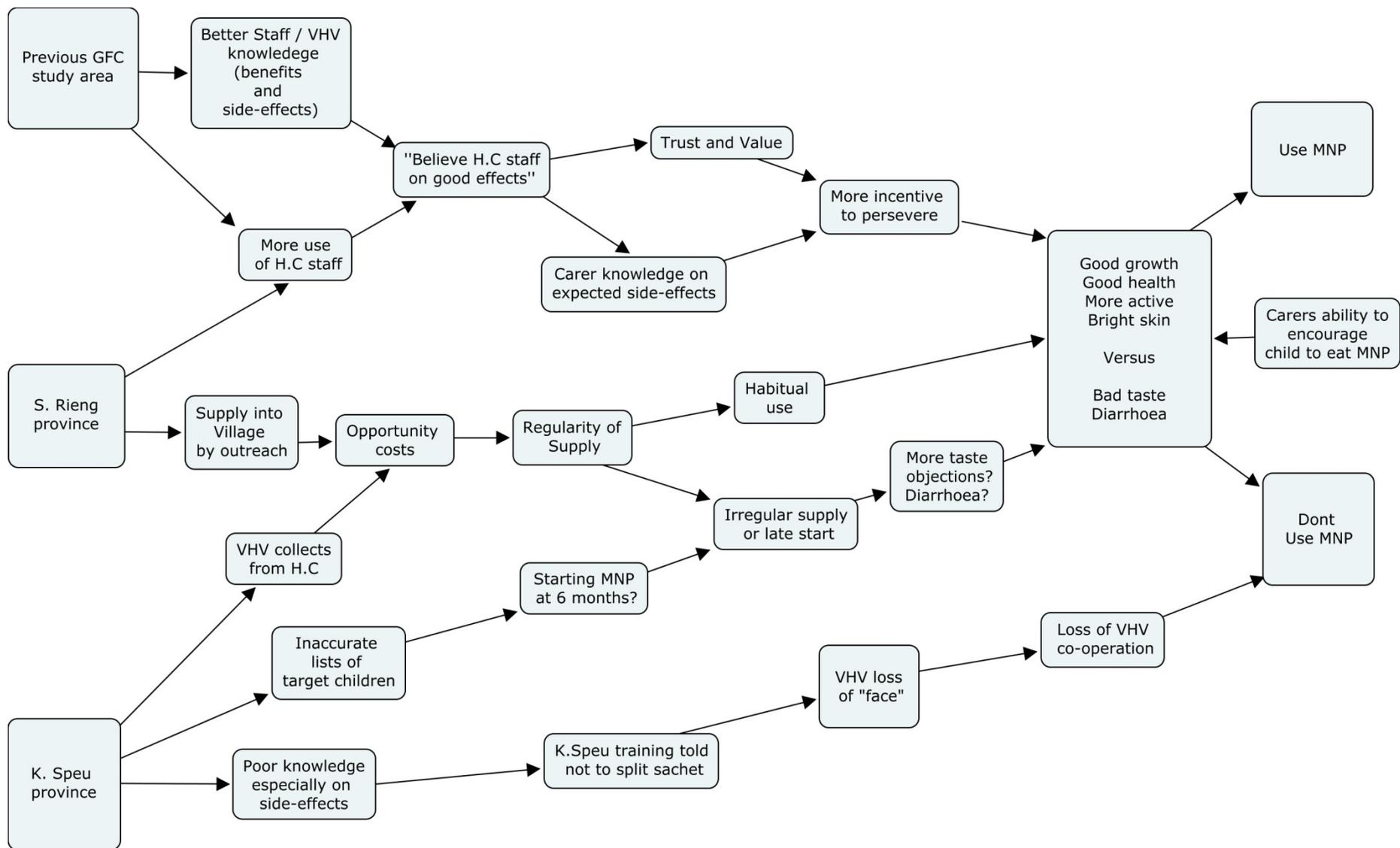


Figure 17 Diagram of distal factors relating to caregiver decision to use MNP.

Discussion

This study aimed to report on current functioning and community perceptions of the MNP programme, without the incentives offered by the GFC effectiveness-trial (55). The findings show that the legacy of the trial has resulted in higher levels of knowledge amongst staff, volunteers and caregivers around benefits and side-effects of MNP. This has then translated into higher adherence rates and more positive community perceptions in the previous study area, compared to the non-study areas.

In addition, there is a provincial level split in mode of delivery and personnel involved in delivery, with S.Rieng province utilising HC outreach and staff more than VHV's. In K.Speu the majority of the service delivery is coming from volunteers. This is contributing to lower initial coverage rates, a more disrupted supply of MNP, lower trust and value and thus poorer community perceptions and adherence rates.

The WHO guidelines on the use of MNP state that programme managers "should select the most appropriate delivery platform with the aim of reaching the most disadvantaged populations". Community based distribution has been identified as one of the best ways to reach people in rural areas when resources are limited (69). In the present Cambodian context, as the results from the current study show, this will be best implemented via HC outreach delivering the MNP to the VHV in the village. Integrating new products into existing services has been shown to be one of the best ways of increasing acceptance, and is often more cost effective (70).

Alternative delivery channels in other settings (Niger, Bangladesh and Kenya) have been to involve private vendors and social marketing (45, 71, 72). The best mode of delivery into the community will be context specific, but must consider the importance of the trust and value of MNP in the eyes of the community, as highlighted by this study and previous work exploring low uptake of MNP in a refugee camp (73).

The Cochrane review of MNP reports that more evidence is needed on the most appropriate arrangements for use (daily or intermittently) and effective delivery methods for the intervention (21). The WHO guidelines recommend a minimum of two months of MNP, starting every 6 months (meaning that some children will be older than six months when the six monthly distribution comes around) (6). At present MNP supplementation in Cambodia is continuous for 18 months, starting at six months of age. Intermittent regimens may have the capacity to provide protection

from anaemia for around six months (55, 56, 74). However, MNP may have the potential to address other nutritional problems if the duration of supplementation is long enough.

This study has highlighted operational factors that may need to be considered when choosing an intermittent or continuous regimen. Specifically; the possible lower acceptability of the taste if MNP is started after six months of age, and the possibility that a disrupted supply may mean the care-giver and infant may have to overcome diarrhoea and taste objections on multiple occasions. These factors may lend support to a continuous regime, although this may be associated with higher costs.

The main benefits of MNP “seen in their own children” in this study were; “good growth or gaining weight”, child becoming “more active or having more energy”, and “fresh” or “bright” skin. Although published reports of community perceptions of MNP are rather limited, this is the first study to report on any comments regarding the improved appearance of skin. Positive effects noted in other settings by caregivers include; improvement in children’s appetite, or weight gain, increased energy or strength, and increased interaction with other children, or play (45, 75, 76).

Problems with MNP reported by caregivers in the international literature include darker stools and some mild diarrhoea (21, 45, 53, 57, 72,). Diarrhoea was reported in this study, but the major problem was the taste, with 36.8% (95% C.I 21.5-52.1) of the caregivers who discontinued MNP, doing so solely because of taste objections. There have been no reports in the literature of recurrent complaints of a metallic taste and refusal to eat food with MNP. One study did report that 16% of children objected to taking MNP (77). In the CESVI trial in Cambodia, no caregiver reported any change in the organoleptic properties of the food, and only 3% discontinued MNP (53).

A metallic taste may be caused when the soy-lipid coating around the encapsulated iron particles melts, if the temperature of the food is above 60 °C (57). However, when questioned on the use of MNP, nearly all caregivers and all VHV’s knew that the MNP must be added to the food after it had cooled down. There may, however be issue’s with subjective interpretations of “cooled down”. Alternatively this may be a “nocebo” effect, as warnings on taste were the main “side-effects from training” mentioned in Chipu and K.Speu, but not in S.Rieng.

An alternative possibility could be that the current Cambodian MNP mixture contains 10mg of zinc rather than the 5mg recommended by WHO (though this will change in October 2012). The extra

zinc may be causing an excessively metallic taste. When 10mg of zinc is given as a liquid supplement for the treatment of diarrhoea, a metallic taste and vomiting are the most commonly reported side effects (78, 79). Interestingly, the study where 16% of infants objected to MNP also used 10mg zinc (77).

Mixing the MNP with water is not recommended, because studies have shown that zinc absorption is inhibited by iron unless there is food present (38, 40). If no food is given at the same time as the MNP, then zinc absorption will be reduced, as well as the absorption of the fat soluble vitamins (38, 40).

MNP can offer part of the short-term solution to anaemia in infants, especially in countries with endemic malaria. However to increase sustainability and tackle stunting and wasting, this must also be combined with interventions to increase macro-nutrient availability at the household level, IYCF education focusing on animal foods, and hygiene and sanitation measures to reduce disease burden.

Strengths

Living in Cambodia for four years and speaking reasonable Khmer provided “prolonged engagement”, afforded me greater cultural understanding, interaction with participants and more accurate translation and interpretation of the results. This increases the “credibility” of the analysis, in addition to the process of “peer de-briefing” to check agreement on findings (66).

Simultaneous translation allowed a flexible approach whereby emerging themes and concepts were explored in an iterative fashion, and ambiguous points clarified at the time. It also allowed a more diverse sample to be obtained by reducing the time required for transcription.

Utilising data from several different sources, i.e. national, provincial, health centre and village levels, allowed triangulation to increase the accuracy of the picture that was emerging. In the same way, having the quantitative data provided an opportunity to clarify and test hypotheses that were generated by the qualitative data.

Limitations

The main limitation to the study was the sampling for the quantitative aspects, both in terms of estimated sample size and sampling strategy.

A sample size calculation could have been carried out based on the precision of the estimate required for the proportion of children experiencing any side effects, if that was the main aim of the study. For instance, using our estimate of 30% of children ever experiencing any unwanted effects, and accepting a confidence interval of 10%, using the following formula;

$$n = \frac{3.48 \times 30 \times (100-30)}{5^2} = 292 \text{ children required.}$$

This could then be increased by 10% to account for non-response to give a target sample of 321.

There will inherently be selection bias operating due to the VHV collecting caregivers for interview. This has probably resulted in an underestimation of side-effects and an overestimation of coverage. The non-random sampling strategy means that the 95% confidence limits around estimates for proportions must be treated with caution.

A self-weighting sample could be used to provide a more valid estimation of coverage/side-effects. This could be done by simple random sampling (SRS) of villages (clusters), and then the individual children could be selected by constant proportion from within each village (by SRS). This would have necessitated accurate lists of target children.

Alternatively, villages could have been listed with population size and chosen using a sampling interval to give a “probability proportional to size” weighting. The second stage of selecting children could then have been done by SRS to give a constant number, using lists of children, or a “random walk” through the village. The random walk method would, however take a long time to find enough children of the target age. If a sampling strategy other than SRS was used, the clustering would need to be accounted for by using the expected design effect (DEFF).

The present study was not planned to provide an accurate an estimate of side-effects, merely to give a “snap-shot” as an aide to the qualitative data. Due to time constraints, it was not possible to aim for such a large sample size, or to find target children using random walk methods (accurate lists of target children were not available).

Selection bias may have affected the qualitative results if the VHV preferentially invited those caregivers who were using the MNP well. Participants may have been influenced by the presence of the local health staff, other members of the community, or a “*barang*,” or foreigner, which may have contributed to non-differential courtesy bias, thus affecting the validity of the results.

The qualitative data-analysis was carried out using hand written transcripts from an in-field translator. Although this provided benefits in terms of flexibility of questioning, some of the detail of the speech will inevitably have been lost. Having the recordings fully transcribed and translated would perhaps give further insights into the subtleties of phrasing and meaning.

Recommendations

Cambodia Specific

1. Health-centre staff should deliver the MNP into the villages via community outreach, and any families not present should have the MNP delivered to their house by the VHV's, as opposed to the VHV collecting the MNP from the HC and storing at their house. This model places less burden upon unpaid volunteers, and translates into increased trust and value within the community.

2. HC staff and VHV's should have further training on expected side-effects, and how to deal with them, specifically around splitting the sachets and ensuring the MNP is not added to the food whilst it is too hot.
3. Caregivers should be advised not to give the MNP with water unless accompanied with a meal.
4. Behaviour change counselling and education on MNP should aim to target Grandmothers in addition to mothers.

General

1. Regular availability of MNP at the local level is a key determinant of use. This points towards community based distribution, either via existing health-services or social marketing.
2. Due to the nature of MNP as a non-food supplement, provider credibility and knowledge is especially important if the community is to trust and value the MNP.

Further Research

Cambodia

1. Only two staff reported anaemia as a “reason to use MNP”. Further research could explore community understanding of anaemia, in order to provide more specific counselling on the benefits of MNP, other than the general “for good health.”
2. When the MNP mixture changes in October to the 5mg zinc formulation, it would be interesting to re-evaluate perceptions of the “metallic taste.” If this persists, direct observation could be used to check the temperatures of the food when the MNP is added.

General

1. Further research exploring the advantages and disadvantages of continuous versus intermittent supplementation is warranted, considering implications for acceptability, wastage, habituation and impact on anaemia rates.

Conclusion

This study used both qualitative and quantitative methods to seek to understand community perceptions of micronutrient powder and the role that delivery methods and personnel counselling may have on these perceptions. This study has highlighted the need for; effective training on expected benefits and side-effects, a regular supply of micronutrient powder, the possible importance of starting the micronutrient powder at six months, and the role of trust and value in continued use of micronutrient powder. These findings may be applied to other resource poor settings.

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Appendix 1: Information Sheet

Information Sheet for Multi-Micronutrient Powder Programme Monitoring

Focus Group Discussions

Version 2

PROGRAM BACKGROUND

Joint program between the Ministry of Health, Cambodia and UNICEF Cambodia to provide Multiple Micronutrient Powder (Sprinkles) to enrich the foods given to infants aged 6-24 months of age. Currently the program is operational in Svay Rieng and Kompong Speu provinces.

Purpose of the research

In order to understand how the programs are running, and any problems with delivery and use of the multiple micronutrient powder it is necessary to consult with both the staff involved in program delivery, and the intended beneficiaries.

What does the research mean for you?

The research aims to inform the organizers of the program so that they are aware of any problems that you are having in your local area, both to improve service delivery for you and to improve the program before it is scaled up nationally.

What is required if I take part?

If you decide that you want to contribute to the research, you will be asked to participate in a discussion group along with 4 others, to talk about:

- Good points and bad points about the Sprinkles programme
- How you use the Sprinkles
- If you would ever buy the Sprinkles
- Important foods for young children

The discussion will be recorded so that the researchers can analyse it later to see what the important issues are.

Your real name will not be used.

Will this affect my healthcare?

Your name will not be used in the discussions and none of the things you say will be associated with you. Your personal healthcare and that of your child will not be affected by anything that you say. The staff at the health centre will not be aware of what you say in the discussions.

How long will it take?

The discussions will take no longer than 60 minutes.

Consent Process

If you have any questions now please ask.

If you decide to take part, you will be asked to sign or thumbprint a form to say that you have understood everything in this information sheet and that you have been able to ask any questions that you have. If you decide to take part but then change your mind, you can withdraw at any time without giving a reason.

Further questions?

If you have any further questions about the study please contact:

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Principal investigator

XXXXXXXXXXXXXXXXXXXXXXXXXX

Msc Public Health Nutrition student,
London School of Hygiene and Tropical Medicine.

Provider Interviews

Version 2

PROGRAM BACKGROUND

Joint program between the Ministry of Health, Cambodia and UNICEF Cambodia to provide Multiple Micronutrient Powder (MNP) to enrich the foods given to infants aged 6-24 months of age. Currently the program is operational in Svay Rieng and Kompong Speu provinces.

Purpose of the monitoring

In order to understand how the program is running, and any problems with delivery and use of the multiple micronutrient powder, it is necessary to consult with both the staff involved in program delivery, and the intended beneficiaries.

What does the monitoring mean for you?

The research aims to inform the organizers of the program so that they are aware of any problems that are occurring, in order to rectify these.

What is required if I take part?

If you decide that you want to contribute to the programme monitoring, you will be asked to participate in an interview to talk about;

- What you understand to be the aims of the Sprinkles programme
- How you perceive the Sprinkles program is running currently.
- Any barriers to effective implementation of the Sprinkles programme
- Extra workload caused by the Sprinkles programme
- Any problems that you are having in sourcing or supplying the Sprinkles sachets

The interview will be recorded so that the researchers can analyse it later to see what the important issues are. Your real name will not be used.

Will this affect my work?

Your name will not be used in the interviews and none of the things you say will be associated with you. The report will not include any direct quotations from you that would identify you.

How long will it take?

The interview will take no longer than 30 minutes.

Consent Process

If you have any questions now please ask.

If you decide to take part, you will be asked to sign or thumbprint a form to say that you have understood everything in this information sheet and that you have been able to ask any questions that you have. If you decide to take part but then change your mind, you can withdraw at any time without giving a reason.

Further questions?

If you have any further questions about the study please contact:

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Principal investigator

XXXXXXXXXXXXXXXXXXXXXXXXXXXX

Msc Public Health Nutrition student,
London School of Hygiene and Tropical Medicine.

Appendix 2: Consent Forms

Consent form for Multiple Micronutrient Powder Programme Monitoring

Focus Group Discussions

The information sheet has been read to me and I understand it / I have read and understood the information sheet.

I understand what participation in the discussion means for me.

I understand that the information I give in the course of this discussion will remain confidential. I understand that I am free to take part in the study or refuse, and that I can withdraw myself from the discussion at any time, and without giving any reason. Deciding not to take part or to withdraw from the discussion will not affect the care that I or any of my family are normally entitled to.

I have had a chance to ask questions and have them answered.

Signature or thumb print of volunteer: _____

This form has been read by / I have read the above to _____
(write name of volunteer)

in a language that he/she understands. I believe that he/she has understood what I explained and has freely agreed to take part in the study.

Signature of field worker: _____

Name of field worker: _____

Date: |_|_| / |_|_| / |_|_|_|_|

Consent form for Multiple Micronutrient Powder Programme Monitoring

Provider Interviews

The information sheet has been read to me and I understand it / I have read and understood the information sheet.

I understand what participation in the interview means for me.

I understand that the information I give in the course of this interview will remain confidential. I understand that I am free to take part in the interview or refuse, and that I can withdraw myself from the discussion at any time, and without giving any reason. Deciding not to take part or to withdraw from the interview will not have any consequences for me in my work.

I have had a chance to ask questions and have them answered.

Signature or thumb print of interviewee: _____

This form has been read by / I have read the above to _____
(write name of interviewee)

in a language that he/she understands. I believe that he/she has understood what I explained and has freely agreed to take part in the study.

Signature of field worker: _____

Name of field worker: _____

Date: |__|__| / |__|__| / |__|__|__|__|

Appendix 3: Focus Group Discussion Topic Guides

Provider Interview Topic Guide

1) National Nutrition Programme / Provincial Health Departments

Attitudes to Programme Delivery

1) How do you feel the programme is working currently?

Probing questions;

- How is the supply chain currently working?
- What about workload within the health centre's?
- How is the demand for the MNP – from the health centre level?
- What have you heard about community perceptions of MNP from the field?

2) Can you think of anything in particular that would improve the programme delivery for the future?

Probing questions;

- Anything that could improve the supply of the MNP to the families?
- Any way to increase demand for the MNP from the families?

Provider Interview Topic Guide

2) Health Centre Staff / VHSG's

Knowledge about the intended benefits and side effects of MNP

1) In your eyes, what is the aim of the MNP (Sprinkles) programme?

Probing questions;

- a) Do they know of any specific health problems that the MNP aim to treat or prevent?
- b) Do they know of any other ways to treat or prevent these health problems? For example, specific foods?
- c) Do they feel that these health problems are a concern in Cambodia?
- d) Do they know why the current target population is children under 2 years?

2) What reasons for using the MNP do you give to the caregivers?

Probing questions;

- a) What were the benefits for the child that they have been told about in training?
- b) Do they feel that they have had adequate training on the benefits of MNP?

3) Are there any unwanted effects of the MNP that they warn the caregivers to expect?

Probing questions;

- a) What were the side effects that they were told about in training?
- b) Do they feel that they have had adequate training on side effects of MNP?

Perceived factors influencing demand within the community

1) What factors determine if the caregivers will use the MNP?

Probing questions;

- In general, do the caregivers know about the MNP?
- Can all of the caregivers that want to use the MNP, access them?
- Are there any extra costs associated with using the MNP for the families?
(E.g. Increased appetite? Separate bowls for the child's food? Cost of collecting the MNP from the health centre?)
- Have the care takers talked about any good effects of the MNP on their child?
- Have the caregivers talked about any bad effects of the MNP on their child?

Attitudes to Programme Delivery

1) What could be done to increase the use of MNP within the target group?

Probing questions;

- Ways to increase demand for the MNP from the families?
- Ways to increase availability of MNP at the community level?

Focus Group Topic Guide

3) Caregivers

1) Overall, what is your opinion about the Sprinkles?

- Allow the group to set the priority areas for discussion. Ask if participants other than the speaker agree with the speaker. Only move to following questions if conversation stops.

Preparation and Compliance

1) How do / did you use MNP?

Probing points;

- Who eats MNP? [youngest child, all children, mother, whole family, neighbours]
- What food or drink do you use MNP with?
- When do you use MNP? [before / after cooking, in the pan or in the bowl? hot or cold food?]
- Do you always use the whole sachet?
- How long after mixing MNP do you wait before feeding the child?

2) Has MNP changed the way that you prepare food?

3) Has MNP changed the way that you feed your child?

4) Does adding MNP have any effect on the food?

Probing points;

- How does the MNP affect the taste, smell, appearance and texture of the food?
- Does MNP affect how much your child eats?

Communication, Access and Value

1) How do you get the MNP?

2) What have you heard about MNP from other people?

probing points;

- What have you heard about MNP from health workers or volunteers about MNP? [reasons for giving, how to prepare, positive and negative side-effects, how to cope with side-effects?]
- What have you heard from friends or family members about MNP?

3) How important is it for a child to eat MNP?

Probing points;

- What reason do you believe is important for giving MNP to your child?

- At what age is MNP most important?
- If you had to guess, how much one sachet cost in the pharmacy, how much would you guess?

Community Perceptions of benefits and side-effects

- 1) Are there any changes for your children that you have noticed because of using the MNP?

Probing points;

- Have you noticed any difference when your child goes to the bathroom? [increased / decreased diarrhoea, dark stools, constipation]
- Have you noticed any difference in the behaviour of your child?
- Have you noticed any difference in the physical appearance of your child?
- Have you noticed any change in the health of your child?

- 2) Have any of the changes that you noticed started or stopped at a specific time?

- 3) What did you do after you noticed any of the negative changes?

Probing points;

- Stop using MNP? Reduce the amount? Go to health centre?

Closing Question

- 1) Is there anything else they feel is important for us to know about the MNP programme?

**MNP QUANTITATIVE MONITORING
JULY 2012**

11	Province	Province Code [S. Rieng 1 ; K. Speu 2]	<input type="checkbox"/> <input type="checkbox"/>
12	District	District Code [Good Food 1 ; other 0]	<input type="checkbox"/> <input type="checkbox"/>
13	Health Center	Health Center [High 1 ; low 0]	<input type="checkbox"/> <input type="checkbox"/>
14	Village	Village Code [remote 1 ; close 0]	<input type="checkbox"/> <input type="checkbox"/>
15	Name of Respondent Name of child 6-24 months		
16	Has your household been identified as poor through the identification of Poor Households process conducted by village representatives, and been placed on the List of Poor Households or received an Equity Card or Priority Access Card?	Yes No	1 0
17	What is your relationship to (Name)?	Mother Father Grandparent Brother/Sister Aunt/uncle Other (specify):	1 2 3 4 5 6
18	How old were you at your last birthday?	Age (completed years)	<input type="checkbox"/> <input type="checkbox"/>

Appendix 4: Quantitative questionnaire

1	After [name] was born, Have you ever received micronutrient powder like this? <i>Show micronutrient powder</i>			Yes No	1 0----	Probe why and write on back. End survey.
2	How old was your child when you first received micronutrient powder? <i>Write age in months</i>					
3	The last time you received micronutrient powder, who did you receive it from?			Health center staff VHV Other _____	1 2 3	
4	The last time you received micronutrient powder, where did you receive it?			Health center Outreach site Home of VHV Own home Other _____	1 2 3 4 5	
5	In the last 7 days was (name) given micronutrient powder like this? <i>Show micronutrient powder</i>			Yes No	1---- 0----	Go to Q. 8 Go to Q. 6
6	How old was (name) when you stopped giving micronutrient powder? <i>Write age in months</i>					
7	Why did your child stop eating micronutrient powder? <i>Circle all that apply. Probe, but do not read</i>	A B C D E F G	Child doesn't like taste or smell Did not receive MNP More diarrhea More sickness other than diarrhea Dark stools Constipation Other		-----	End interview
8	Over the last 7 days how many sachets has					

	your child eaten?				
	Write number				
9	Did your child ever experience any of these effects as a result of eating micronutrient powder? <i>Read and circle all that apply</i>	A B C D E	More diarrhea More sickness other than diarrhea Dark stools Constipation Other _____		
10	Does your child currently experience any of these effects as a result of eating micronutrient powder? <i>Read and circle all that apply</i>	A B C D E	More diarrhea More sickness other than diarrhea Dark stools Constipation Other _____		

①

FGD

Krong Po Village

30/7/12. 4-5 km from

MC

higher Coverage.

OD K. Spau.

0:00

6 women all mothers. ^{Maise of}
VHV.

all using currently
except 1 who has stopped
b/c over age.

general opinion.

good to have powder b/c

good health & make children
gaining even. Prevent from
sickness, make children
grow faster.

make cleverer. (yes believe).

at the beginning difficult to
eat but keep trying &
can eat.

0:05

Side effect - there is
some bad smell on
the 1st day.

but after that no
problem.

4/6 can eat well.

CAMPAC

Appendix 5: Sample of Field Notes

Appendix 6: Detailed Framework Analysis Example

This is a small sample from a 10 x A4 Framework that was taped together to allow cross comparisons. The following page has the horizontal extension that matches this section.

	A	B	C	D	E	F	
1	Date	O.D / H.C	Village	Location	Mixture Participants	General opinion	Child
2	25/7/12	S RIENG / CHUMLOR	JEEAH SRUSAY, 5KM FROM VIETNAMESE BORDER	TEA SHOP ①	6 YOUNGER WOMEN, ONE GRANDMOTHER	GOOD FOR HEALTH, LESS SICK, INCREASE APPETITE. GRANDCHILDREN EAT WELL	6/7 CHILDREN VERY M... PACKET
3	OVERFLOW	S RIENG / CHUMLOR	JEEAH SRUSAY, REMOTE, GFC, HIGH COVERAGE				
4	24/7/12	S RIENG / CHUMLOR	TA JEEAY GFC, HIGH COVERAGE. CLOSE	VHV HOUSE ②	2 GRANDMOTHER REST YOUNG	HEALTHIER STRONGER, CLEVERER	SOMETIM
5	24/7/12	S RIENG / SVAY RUMPEAH	KANCHAYT. CLOSE, GFC, HIGH COVERAGE	VHV / CHIEF HOUSE ③	1 GRANDMOTHER 2 MOTHER	GOOD HEALTH. PHYSICAL GROWTH, GOOD GROWTH AND CLEVER. FEEL THE PROGRAMME IS GOOD. DONT KNOW ABOUT OTHERS OPINION BUT ONLY THAT EVERYONE COMES TO COLLECT SUPPLY	WHEN FI... NOW MI
6	25/7/12	S RIENG / SVAY RUMPEAH	KAMPOT TOUK, GFC, HIGH COVERAGE	VHV HOUSE ④	4 MOTHERS, 1 GRANDMOTHER	HEALTHIER, MORE CLEVER 1/4. GAINED MORE WT 2/4. GOOD HEALTH 1/4 GOOD APPETITE 1/4. GRANDMOTHER KNOWS SOME FAMILIES WHOSE CHILD CANNOT EAT	FIRST TIN
7	25/7/12	CHIPHU / PORPET HC	SVAY PLEA EM. NOT GFC, NOT HIGH COVERAGE. CLOSE	VHV HOUSE ①	4 MOTHERS 1 FATHER	GOOD, GOOD FOR HEALTH	DOESN'T TO TRICK WILL NOT TRY A SM BOWL.
8	25/7/12	CHIPHU / PORPET HC	TROPEANG CHAK	VHV HOUSE ②	9 ALTOGETHER INCLUDING 2 GRANDMOTHERS	SOME CHILDREN GET VOMITING WHEN EATING BUT SOME CHILDREN EAT WELL 1/9 HER CHILD LIKES TO EAT VERY MUCH	MOST OF GET THEM A METAL
9	25/7/12	CHIPHU / SVAY TAYEAN HC	SVAY TAYEAN VILL, CLOSE	VHV HOUSE ③	4 GRANDMOTHERS AND 2 MOTHERS	4/7 NOT REG USERS B/C CHILD DOESNT WANT TO EAT. MNP CAN PROVIDE GOOD HEALTH	MOST M EAT, 1/7 SACEHT
10	27/7/12	CHIPHU / SAMLAY SVAY TAYEAN HV	SOMLAY KANG CHUNG, FAR	VHV HOUSE ④	6 ALL MOTHERS	GOOD, GOOD FOR HEALTH. DIDINT SAY MUCH ABOUT THIS	MOST MI 1/6 CHILD IN GOOD CANNOT DIARRHO
11	30/7/12	K.SPEU / TALAT HC. THIS HC COVERS 51 VILL AGES. NEAR. HIGHER COV	GRANG PO VILL NEAR. 4-5KM. 13 TARGET CHILDREN. LIST INCOMPLETE	VHV HOUSE ①	6 ALL MOTHERS	ALL USING CURRENTLY. GOOD TO HAVE POWDER B/C GOOD HEALTH, MAKE CHILDREN GROWING WELL, CLEVERER. AT THE BEGINNING DIFFICULT TO EAT BUT KEEP TRYING AND NOW CAN ETA	SOME BA THAT NG JUST FIN BUT STILL
12	31/7/12	K.SPEU / TALAT HC. NEAR HIGHER COV	DOUNG VILL FAR, 20KM FROM HC.	VILLAGE MEETING PLACE ②	NO FGD B/C NO MOTHERS USING B/C VHV DID NOT TAKE ANY MORE AFTER THE FIRST TIME	DIARRHOEA AND NO SUPPORT FROM HC, VHV DID NOT WANT TO TAKE ANY MORE	
13	1/8/12	UDONG OD. OMLAING HC PREIK VILL	PHSIX VILL FAR 17KM.	VHV HOUSE ③	FGD ALL MOTHERS. 4 INITIALLY THEN 5 LATER	CLEVERER, REDUCED SICKNESS. MNP IS GOOD B/C HELPS WITH PHYSICAL GROWTH OF THE CHILD	3/4 CAN SO WELL SACHET
14	1/8/12	UDONG. OMLAING HC.	TUMNEAUP VILL, CLOSE 6KM.	VHV HOUSE ④	4 MOTHERS	THEY KNOW IT IS A POWDER TO MIX WITH THE RICE TO MAKE THE CHILDREN HEALTHY	ONLY O WATER DOESNT

Handwritten notes:

- Row 3: Overflow
- Row 4: overflow from
- Row 11: 1 bad - one good one bad
- Row 12: 2 bad

Second page, detailed framework analysis sample;

Children's Opinion	Method of use. Who eats / what food / when mixed / when fed / keep sachet?	Changed preparation?	Any effects?
6/7 CHILDREN LIKE TO EAT IT. ONE CHILD LIKES VERY MUCH AND WANTS TO EAT FROM THE PACKET	1 NOT SHARING. ALL MIX WHEN FOOD HAS COOLED DOWN. USE WITH RICE OR BOBOR. 2/7 MOTHERS HAVE TRIED TO MAKE THE SPECIAL BOBOR. ONE ONLY FOR 1 WEEK. ONE WHEN CHILD VERY SMALL, ALSO DID WITH PREVIOUS CHILD TOO. 2/7 SPLIT SACHET.	NO. CHILDREN EAT EITHER THE SAME OR MORE, NOT LESS	LITTLE BIT OF... NOT MUCH 7/7 DARKER IF LEFT WITH SOY SAUCE
<i>above</i>	2		
SOMETIMES REFUSE BUT ENCOURAGE TO EAT	3 EAT IMMEDIATELY B/C FLIES, KEEP SEALED WITH BAND AND KEEP WELL,		
WHEN FIRST STARTED CHILD REFUSED 1/1. NOW MIXES WITH DESSERT. 2/3 NO PROBS	4 BOBOR WITH MEAT OR PLAIN OR RICE. MIX WHEN FOOD IS COLD 7/7 USE ONE SACHET ONE TIME. FEED STRAIGHT AWAY. NO CHANGE IN FOOD PREP	NO	COLOUR AND... CHILD EATS SAME
FIRST TIME USED DIDN'T LIKE IT BUT NOW OK	5 MIX STRAIGHT AWAY. NO CHANGE TO FOOD PREP. 2/3 USE IN 1 MEAL. 1/3 USE IN 2 MEALS. BOBOR / FAMILY FOOD	NO	NOT SURE ABOUT
DOESN'T WANT TO EAT. EVEN WHEN THEY TRY TO TRICK, BY MIXING IN 2 BOWLS, THE CHILD WILL NOT EAT THE ONE WITH MNP. EVEN IF TRY A SMALL AMOUNT, CANNOT FINISH THE BOWL.	6 MIX WITH FOOD WHEN COOLED DOWN, EAT STRAIGHT AWAY	NO	DARKER COLOUR TASTE, NO CHANGE
MOST OF THE CHILDREN 8/9 IT IS DIFFICULT TO GET THEM TO EAT IT. THE MOTHERS SAY IT HAS A METAL TASTE	7	CHILD EATS LESS IF GIVING MNP	RED COLOUR, TA
	8 MIX STRAIGHT AWAY. NO CHANGE TO FOOD PREP. MIX COLD. ALL USE ONE SACHET PER TIME, NO ONE HAS TRIED TO SPLIT THE SACHET. IF MIX COLD GET A REDDISH COLOUR	CHILDREN EAT LESS WITH MNP	PURPLE COLOUR REDDISH COLOUR METAL TASTE
MOST MOTHERS SAY CHILD DOESN'T WANT TO EAT, 1/7 THE CHILD EATS WELL. SHE SPLITS THE SACHET	9 ONLY ADD TO FOOD NOT WATER. ADD COLD, TO BOBOR, MOST USE ONE SACHET ONE MEAL, EXCEPT FOR THE LADY WHOSE CHILD EATS WELL. SHE SPLITS	THE WOMEN WHO SAID THE CHILD DOESN'T WANT TO EAT ALL SAID THEY LEAVE THE CHILD TO EAT BY ITSELF B/C THEY ARE BUSY WITH RAISING PIGS ETC (GRANDMOTHERS) 2/7 SAID THIS	HAVE NEVER TRIED... CHANGES COLOUR COLOUR.
MOST MOTHERS SAY DIFFICULT TO FEED 5/6. 1/6 CHILD DOESN'T NOTICE AND HER CHILD IS IN GOOD HEALTH. 2/6 HAVE STOPPED B/C CANNOT GET TO EAT IT. 1/6 STOPPED B/C HIS DIARRHOEA	10 WITH BOBOR AND RICE 3/6 ADD TO HOT FOOD. ONLY ONE SAID ADD WHEN COOLED DOWN. 1/6 SHARES WITH ELDER SISTER	NO BUT 6/6 SAY CHILD EATS LESS WITH MNP ADDED	4/6 SAY CHANGED DARKER, BAD TASTE HAVE TASTED IT
SOME BAD SMELL ON 1ST DAY BUT AFTER THAT NO PROBLEM 4/6 CAN EAT WELL. 1/6 JUST FINISHED B/C OLD AGE. 1/6 DIFFICULT BUT STILL CAN EAT	11 ADD TO WHIRE BOBOR (RICE SALT WATER). ADD WHEN COOLED DOWN. 3/6 ONE SACHET 1 TIME. 3/6 SPLITTING 2 TIMES. ADD WHEN COLD	NO. EATING MORE AFTER USING	CHANGES COLOUR YELLOWISH.
3/4 CAN EAT WELL. THE ONE WHO DOESN'T EAT SO WELL DID NOT KNOW ABOUT SPLITTING SACHET. THE OTHERS ALL SPLIT	12		
ONLY ONE IS STILL USING, SHE MIXES IT WITH WATER B/C IF SHE MIXES WITH RICE THE BABY DOESN'T EAT. NO OTHER SIDE EFFECTS.	13 BOBOR OR RICE, ADD WHEN COLD. NOT SHARING. 1 USES ALL IN 1 MEAL, 3 USE BY SPLITTING INTO 2 OR MORE. WHEN MIXED FOOD TURNS YELLOW / BLUE. SOME DISAGREEMENT ABOUT THE COLOUR. 2/4 PREPARE SP BOBOR, 2 ARE TOO BUSY	NO. 2/4 EATS MORE, 1/4 EATS NORMAL, 1/4 EATS LESS	METALLIC TASTE BLUE COLOUR
	14 NO ONE IN THIS FGD IS USING CONSISTENTLY, JUST TRIED A FEW SACHETS AND FOUND DIFFICULT TO GET THE CHILD TO EAT IT SO THEY STOPPED. THEY HAVE NOT HEARD ANY OTHER BAD EFFECTS. NOT CLEAR ON BENEFITS		

Appendix 7: Summary Framework Analysis Example

The above framework analyses were then condensed down into the summary framework analysis, show below. This is an example for the focus group discussions with caregivers. The process was repeated for the provider interviews.

Summary of FGD's

FGD's

O.D / Province	General opinion	Childs Reaction	Method	Effects on Food?	Distribution
Svay Rieng: Total 4 FGD = 16 women incl 5 grandmothers	good health 3/4, less sick 4/4, good growth / gain wt 2/4, appetite 2/4, can eat well 1/4	like v.much 1/4, refused / <u>difficult at 1st but better</u> now 3/4	mixing cold 3/4, bobor or rice 4/4, most mixing in 1 meal, but quite a lot splitting sachet 1/4	a little change in taste 1/4, metallic taste 2/4, darker 3/4, not sure on taste 1/4	HC outreach or house by house from VHV
summary	all positive points	seems to be harder at first	splitting, mixing cold	not very much complaint on the taste	easy access for mothers and they seem to respond well to something being given from HC
Chiphu: Total 4 FGD = 26 incl 6 grandmothers and 1 father.	good health 3/4, vomiting but some can eat well 1/4, only half using b/c dont want to eat 1/4	doesn't want to eat / difficult to feed 4/4, in each FGD btw 1-4 mothers whose child can eat well (usually the minority)	mix cold 2/4, in one FGD half say mix hot 1/4, seems like the children who can eat well, their mothers split the sachet	child eats less if MNP added 4/4, metal taste 3/4, colour: red 1/4, red if cold, purple if hot 1/4, yellow 1/4, darker 1/4	VHV house, sometimes outreach 2/4, VHV goes to HC then distributes 2/4
summary	know abt good for health but not very positive experiences for themselves all currently using 1/4 - good, good health, cleverer, growing well, difficult at first but ok now. cleverer, less sick, growth 1/4, 2/4 not using consistently - one b/c diarrhoea and VHV wanted	main problem is dont want to eat bad smell / didn't want to eat at first, then mostly can eat 1/4, mainly eating well, splitting sachets 1/4, stopped b/c no supply 1/4, only one mother continuing - by mixing w water 1/4	eat better if split sachet? some uncertainty for the first time abt cold / hot	child eating less b/c taste. mentioned in these groups that it requires more effort for caretaker if add mnp "tired to push the child to eat", and "busy raising pigs and with daily living"	not so easy access, less involvement from HC staff
K.Speu: Total 4 FGD = 30 - all motehrs	1/4 villages seemed to be doing well. In this village more knowledge on good effects	village doing well, talk abt harder to eat at first, but then OK, and splitting sachets	half split sachet, half use in 1 time 1/4, add cold 1/4, not using consistently or mixing w water 2/4	darker 1/4, metallic taste 1/4, disagreement on colour, yellow or blue 1/4,	collect form VHV house 2/4, not currently using consistently 2/4
Summary				<i>Taste 7/12</i>	2 villages not using consistently, one b/c complaints on diarrhoea, one b/c mothers dont collect from his house b/c cannot eta



**Combined Academic, Risk assessment
and Ethics (CARE) approval form for
MSc Project Reports**

**This form must be completed electronically. For detailed guidance, please refer to the
Project Handbook for your course.*

SECTION 1 – STUDENT AND COURSE INFORMATION

MSc DETAILS AND DEADLINES (deadlines to be communicated by Course Director)

Academic Year	2011-12
MSc course (and stream, where applicable)	Public health Nutrition
Deadline for Supervisor approval	
Deadline for Course Director approval	27/02/12
Deadline for submission to Ethics Committee	Friday 23 March 2012
Target for approved form to be passed to TSO	Friday 11 May 2012

STUDENT AND SUPERVISOR DETAILS (to be completed by student)

Full name of student	105857
Student email address	
Year of study (part-time students only)	<input type="checkbox"/> First Year
Supervisor name	Sophie Hawkesworth
Supervisor email address	Sophie.hawkesworth@lshtm.ac.uk
Supervisor institution/organisation	LSHTM
Supervisor status (at time of this version of the form being completed)	<input checked="" type="checkbox"/> Confirmed
Name of personal tutor (where Supervisor is still to be identified)	

SECTION 2 – APPROVAL AND SUBMISSION STATUS

***Students please note:** It is a requirement of your LSHTM degree that you obtain all required approvals before beginning your project work. Your Supervisor and Course Director must specifically give Risk Assessment approval. Ethics approval must also be obtained where necessary (answers in Section 5 will help determine if this is required or not).

STUDENT DECLARATION (to be completed for all projects)

I agree to conduct my project on the basis set out in this form, and to consult staff (initially, my Supervisor) if making any subsequent changes – especially any that would affect the information given with respect to ethics approval.	<input checked="" type="checkbox"/>
I agree to comply with the relevant safety requirements, and will submit a separate request for LSHTM travel insurance where relevant.	<input checked="" type="checkbox"/>

**Where seeking ethics approval for a study involving human subjects, please also attach copies of any information sheets, consent forms, and other relevant documents.*

Date of declaration	15/02/12
---------------------	----------

Please save the electronic file of this CARE form in the format

“[MSc title]_[Year of Submission]_[Surname]_[Forename]_CARE”

You will also be required to submit a copy of this CARE form with your final written-up project. This should be anonymised, i.e. with your name and email address removed.

STAFF APPROVAL	
<p>*Staff please note: Sections 3 and 4 of the form should be completed by the student before you give approval. Rather than 'sign' this form, you should email the student and explicitly confirm approval, e.g. stating "In my role as supervisor, I approve the attached form". The student is then responsible for updating the form and passing it on to any other staff.</p> <p>However if you would answer 'no' to any of the 'Yes/No' questions below, or disagree with any of the statements given, or have any other concerns, then you should not give approval. Instead, please contact the student immediately to inform them of your concerns and discuss changes which they may need to make before you may be willing to give approval.</p> <p>Please also be aware that in the exceptional case of a request to undertake a project in a country or region to which the Foreign & Commonwealth Office advise against travel, the student would need to fill out a separate form which will then need further School-level approval by the Safety Manager and Secretary & Registrar.</p>	

SUPERVISOR'S APPROVAL (required for all projects – this approval should be given first)	
Supervisor has agreed that Section 3 of this form is a reasonable summary of the proposed project.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Supervisor has agreed that responses in Section 4 of this form address the main risks connected with a project of this nature.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Supervisor has agreed that responses in Section 5 of this form correctly indicate whether or not ethics approval will be required.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Name of Supervisor (if not yet identified, personal tutor or Course Director should approve)	Sophie Hawkesworth
Date of approval	23 rd March 2012

COURSE DIRECTOR'S APPROVAL (required for all projects – should follow Supervisor approval)	
Course Director has agreed that the proposed project's academic content, set out at Section 3 of this form, is suitable for this MSc.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Course Director has agreed that responses in Section 4 of this form address the main risks connected with a project of this nature.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Name of Course Director (or nominee)	Claire Schofield
Date of approval	April 5 th 2012

FACULTY SAFETY SUPERVISOR'S APPROVAL (only required if project involves working with pathogenic organisms, human blood or radiochemicals – should follow Supervisor approval)	
Faculty Safety Supervisor has agreed that the proposed project, as set out in this form and particularly Section 4, may proceed.	<input type="checkbox"/> Yes <input type="checkbox"/> No
Name of Faculty Safety Supervisor (or nominee)	
Date of approval	

ETHICS APPROVAL (required for all projects involving human subjects or human data, except for public domain data that cannot enable the identification of living people – NB that Supervisor approval must have been received before the application is submitted to the Ethics Committee)	
The Ethics Committee has approved the project proposal set out on this form.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Date of approval	6/6/12
Ethics Committee application number assigned	011/388

SECTION 3 – APPLICATION FOR ACADEMIC APPROVAL

**All students should complete all sub-sections (3.1, 3.2 and 3.3). If particular questions are not applicable to you then please write 'N/A'.*

3.1 PROJECT OUTLINE (should not normally exceed 750 words total)

Proposed project title: (should not normally exceed 20 words)

Operations research of micronutrient interventions in children under 5 years in Cambodia.

Proposed project type:

**See course-specific section of Project Handbook for details of project types permitted for each MSc. Be aware that restrictions may apply for individual courses.*

Field Research

Proposed project length:

**For almost all students, this will be 'Standard'. Extended projects are only available for MSc IID; they have a different schedule and allow a slightly greater word count.*

Standard

Background: (about 200 words)

**Indicate why this topic is of interest or relevance.*

**If the project involves work with a specific organisation please give details.*

**Please give any other details specifically relevant for consideration by the Ethics Committee, e.g. related to purpose.*

Undernutrition in Cambodia is a major public health issue, with national rates of stunting and wasting at 40% and 11% respectively.(1) Malnutrition is the end result of complex underlying social and environmental problems that mediate their effects via recurrent infection and inadequate intake of foods of appropriate quality.

Diarrhoeal disease is a major contributor to the malnutrition-infection cycle, due to detrimental effects on the absorptive architecture of the gut, reduced appetite, and nutrient loss in the stools. Diarrhoea prevalence in children under 5 years was reported as 15% in the 2010 Cambodia Demographic Health Survey.(1)

Inadequate quantity and quality of complementary foods for children aged 6-24 months is another important cause of malnutrition in this age group resulting in high rates of stunting, wasting and anaemia.

Micronutrient interventions such as **Multiple Micronutrient Powders (MNP)** for home fortification of complementary foods, and **zinc supplementation** for the treatment of acute diarrhoea are simple and cost effective ways of tackling two of the biggest contributors to malnutrition in children under 5 years.

Zinc supplementation as part of treatment of diarrhoea has been shown to shorten the duration of acute diarrhoeal episodes.(2)The WHO (World Health Organisation) and Unicef (United Nations Children's Fund) issued a joint statement in 2004 that zinc should be included as part of the treatment of acute diarrhoea.(3) However, the challenge for both interventions is ensuring high coverage, due to low utilisation of health services in Cambodia. Only 59% of children reported as having had diarrhoea in the preceding 2 weeks in the 2010 Cambodia Demographic Health Survey had sought advice or treatment at a health facility, and only 2.4% had taken zinc supplements, as recommended by

the WHO. In 2011 the Cambodian government allowed community based distribution of MNP sachets and zinc treatment for diarrhoea for the first time. Unicef Cambodia, in association with the Ministry of Health, have implemented a **Micro-Nutrient Powder** (MNP) supplementation programme in 2 provinces (Svay Rieng started in 2010, and Kompong Speu in 2011). This initial programme is serving as a pilot for possible national coverage. In Kompong Speu province in 2010, 42.1% of children under 5 years were stunted, 10.2% wasted and 53% were suffering from anaemia.(1) In Svay Rieng province, 31.2% were stunted, 12.2% wasted, and 65.5% were anaemic, which is the highest under 5's anaemia prevalence of any province in Cambodia.(1) An anaemia prevalence above 40% is classified as a severe public health problem by the WHO.(4)

A recent meta-analysis of 8 clinical trials of MNP for home fortification (which included one carried out in Cambodia), concluded that micronutrient home fortification reduced the relative risk of anaemia by 0.69 (C.I 0.60-0.78), and iron deficiency by 0.49 (C.I 0.35-0.67) (5). The accumulated evidence for efficacy has resulted in the WHO issuing a strong recommendation that "home fortification of foods with MNP is recommended to improve iron status and reduce anaemia among infants and children 6-23 months of age".(6)

The MNP powders are distributed via government village health workers providing outreach, and volunteers within the community. The target group is all children in the selected provinces, and the schedule is that the children should be receiving MNP with their complementary food from 6-23 months, with one single use sachet per day. Initial estimates from Unicef suggest that at present, 60% of the target population is receiving the MNP (approximately 30,000 children).

MNP's appear to be well tolerated by infants and acceptable to families, but there is little data on adherence and effectiveness in a programmatic rather than research setting. Cost, ease of delivery and distribution and the impact of using MNP on overall infant and young child feeding (IYCF) practices and behaviour have not been evaluated in Cambodia.

This project aims to report on barriers to effective distribution and utilisation of both the MNP sachets and zinc supplements in the provinces of Kompong Speu and Svay Rieng in order to address bottlenecks and improve coverage prior to nationwide scale-up of the interventions..

Hypothesis: (about 30 words, where applicable)

N/A

Overall aim of project: (about 30 words)

To evaluate Unicef's MNP and zinc micronutrient programs in Svay Rieng and Kompong Speu provinces, with regard to both product delivery and uptake by families.

Specific objectives of project: (about 70 words)

Part One: To conduct operations research on the first stage of Unicef / Ministry of Health Cambodia's MNP programme.

Specifically to:

- 1) Assess the impact of support from local government on in-home

fortification supply by comparing programme operations in health centres with and without commune (local government) support.

- 2) Assess demand and compliance with in-home fortification by determining from the target families that have received / not received MNP sachets, their understanding of MNP use, perceived barriers to using the MNP, beliefs around the effects of use, and self-reported compliance.

Part Two: To conduct operations research on the use of zinc supplements for the treatment of diarrhoea.

Specifically to:

- 1) Review national data from the Cambodian Demographic Health Survey and Unicef's bottleneck analysis.
- 2) Identify barriers to utilisation of zinc supplements, including attitudes and knowledge of health care staff, community outreach volunteers and target families.

Proposed methods: (about 200 words)

Please summarise methods, and include **any relevant details for consideration by the Ethics Committee such as numbers of participants and procedures to be performed.*

- 1) Qualitative and quantitative assessment of the impact of support from local government health services on in-home fortification and Zinc supplementation:

Qualitative:

Key informant semi-structured interviews will be conducted with local government health centre staff / community outreach volunteers to ascertain how they perceive the programme and any problems with the delivery of MNP / zinc supplements. Supply chain issues and workload will be investigated. Varying grades of staff will be selected for interview to provide multiple points of view from different hierarchical levels, in order to triangulate results and identify bottlenecks.

Quantitative:

I will be using data from the Cambodian Demographic Health Survey and Unicef's Bottleneck Analysis to aid the quantitative evaluation of supply for both products.

For zinc treatment of diarrhoea I will also be looking at Health Information System data to carry out a quantitative trend analysis on what treatments are being prescribed at the local level.

- 2) Qualitative and semi-quantitative assessment of demand and compliance with in-home fortification and Zinc supplementation.

Focus group discussions (FGD's) and semi-structured interviews will be used to assess reported: compliance, acceptability, side effects, ease of use, adherence to guidelines on hygienic preparation of complementary foods and beliefs regarding the benefits / side effects of the MNP and zinc supplements. Barriers to use and any problems with obtaining the MNP / zinc will be investigated. In addition any further suggestions that the families have to improve the

programme delivery will be sought.

A purposive sampling strategy(7) for the focus group's and interviews will be used to maximise the representation of different demographic backgrounds, with particular reference to: rural, urban, affluent or poor – this may be assessed by a proxy measure such as type of house (e.g. brick, wood, bamboo). Other demographic characteristics of interest would be; number of children in the family, ethnicity (e.g. Khmer, Cham Muslim, Vietnamese). The aim will be to ensure that all subgroups within the target population will be represented.

Ongoing analysis of the data will mean that as theories and concepts emerge, it may be deemed necessary to include further groups of participants, to test theories or explore deviant cases, which is an element of grounded theory known as theoretical sampling.(7) Final numbers of participants will depend to some extent on the results of the initial discussions and interviews. If the stage is reached whereby no new ideas or concepts are being generated, (“theoretical saturation”) there is little reason to continue conducting more interviews or focus groups, and this will be evaluated continuously.

It has been suggested that theoretical saturation point is often reached after interviewing approximately 20 people in the same “category”. (7) However, the aim of this study is not an exhaustive account that reaches theoretical saturation point, but a good account of “what is going on”, with the generation of specific answers to the areas of interest posed above. Therefore it may be reasonable to include only 10 participants per category. For the focus group discussions the categories may be thought of as broadly: Rural, urban, affluent, poor. Within these broad categories the aim will be to include the varying ethnic groups. This would give an estimate of 40-50 participants in the focus groups, made up of care-givers of the targeted children.

For the semi-structured interviews with the local government health centre staff and community volunteers involved in distribution of the MNP and zinc, the sampling strategy will be more based on convenience sampling and an upper limit of 20 interviews should be adequate, although as above, the final numbers will depend on the outcomes of the initial interviews, with continuous evaluation of themes possibly indicating areas that require further study.

The location of the focus group discussions will be important in order to maximise the attendance of hard to reach groups, this may mean that in practice that some of the families who are further from the health centres (for example) may not be able to attend the group discussions and it may be necessary to arrange household visits for semi-structured interviews instead.

I will be responsible for designing the interview and focus group topic guides, providing orientation to the Cambodian staff that will be conducting the interviews and FGD's, and analysing the transcripts, which will be translated into English.

Framework analysis(8) will be carried out on the transcripts to allow interpretation of key themes and cross-comparison of themes within and between cases. This method is suited to policy and practice-orientated research, when there are clear questions that need to be answered in advance.

References: (max 150 words)

**List any key references which will shape the project, including for methods to be used.*

It should not normally be necessary to quote more than 5 references.

1. National Institute of Statistics, Directorate General for Health, Macro I. Cambodia Demographic and Health Survey 2010. Phnom Penh, Cambodia and Calverton, Maryland USA: 2011.
2. Lazzarini M, Ronfani L. Oral zinc for treating diarrhoea in children. Cochrane Database of Systematic Reviews. 2008(3):CD005436.
3. WHO / UNICEF Joint statement. Clinical Management of Acute Diarrhoea. 2004.
4. Iron deficiency: Assessment, prevention and control: A guide for Programme Managers. Geneva: World Health Organisation, 2001.
5. De-Regil LM, Suchdev PS, Vist GE, Walleser S, Pena-Rosas JP. Home fortification of foods with multiple micronutrient powders for health and nutrition in children under two years of age. Cochrane Database Syst Rev. 2011;9:CD008959. Epub 2011/09/09.
6. Organisation WH. Guideline: Use of Multiple Micronutrient Powders for Home Fortification of Foods Consumed by Infants and Children 6-23 Months of Age. Geneva: 2011.
7. Judith Green, Thorogood N. Qualitative Methods for Health Research. Second Edition ed: SAGE Publications; 2009.
8. Ritchie J, L S. "Qualitative data analysis for applied policy research" by Jane Ritchie and Liz Spencer in A. Bryman and R.G. Burgess [eds] "Analysing qualitative data". Bryman A, R.G B, editors 1994 1993.

Prior work: (only where relevant; max 100 words)

**Indicate any previous work you have done related to this project topic, including student work, professional work, or publications.*

No prior work

3.2 FEASIBILITY (about 100 words total – but can write more or write less if appropriate)

What could stop this project from succeeding, or prevent you from achieving your objectives?

**Please indicate any aspects of your proposed approach which could potentially experience difficulties, e.g. delays with permissions, data collection or storage problems, lack of sufficient comparable information, etc. You may also wish to mention any wider matters which could affect your project, e.g. civil unrest, natural disasters, transport availability.*

Lack of availability of health centre / ministry of health / Unicef staff for interviews could be a problem. Technical problems with recording of interviews or travel disruptions due to the rainy season affecting roads. Heavy rain may also mean families are less willing to come for focus group discussions / interviews. Kompong Speu province is about 2 hours by car from Phnom Penh, and Svay Rieng province is about 3 hours drive.

What alternative plans do you have in case you encounter any of the potential problems you have identified?

Secondary analysis of infant and young child feeding practices in relation to growth outcomes of children aged 6-24 months, taking into account the impact of water and sanitation variables. Using the Cambodia Demographic Health

Survey 2010.

3.3 DATA SOURCES, INTELLECTUAL PROPERTY AND PERMISSIONS

If you expect to use existing data, how will you obtain it?

**Indicate who holds the data, who specifically you will contact, and by when. Any contact so far, especially anything confirmed in writing, should be mentioned.*

I have been granted access to the Cambodia Demographic Health Survey 2010 data files.

If you expect to use any public domain data, please give further details.

**Make clear who owns the data and how you will gain access (giving a link if possible). Public domain data must be available to any member of the public, without any restrictions or requirement for special permission, and must not enable the identification of living people.*

As above.

Will any specific data rights permissions or usage limitations be required regarding data to be used or collected in the project?

If 'Yes', please describe further. **Remember that local ethics or research governance requirements (see Section 5.2) may entail specific data rights limitations.*

Yes

No

Will any copyright agreements or intellectual property rights (IPR) agreements be required regarding data to be used or collected in the project?

**Please tick all boxes that apply, and attach copies of any forms/agreements (even if in draft).*

- No specific IPR, copyright or permissions issues should apply to this project (student retains copyright and a claim to related IPR)
- IPR to be retained by LSHTM (specific LSHTM form to be completed)
- Copyright to be transferred to LSHTM (specific LSHTM form to be completed)
- IPR, copyright or other agreements/permissions required with external parties/organisations

Please give any further relevant details about IPR, copyright or other permissions.

SECTION 4 – APPLICATION FOR RISK ASSESSMENT APPROVAL

**All students should answer all questions in sub-section 4.1; this will make clear which of the subsequent sub-sections you need to complete.*

Ensuring safety during project work is the responsibility of each individual student, and not of LSHTM or LSHTM staff. **Please see the Project Handbook for further guidance.*

4.1 TYPE OF RISK (to be completed by all students)

Where will the project be carried out? (please tick all that apply)

**Note that work away from LSHTM or outside the UK means any form of work for your project, not just primary data collection. Some courses may have specific restrictions on this.*

X **Some work will take place outside the UK that is not at my personal residence**
 [If so, both sections 4.2 and 4.3 on 'Work away from LSHTM' and 'Work outside the UK' must be completed]

Will the project involve working with or handling any of the following materials?

Pathogenic organisms No
Human blood No
Radiochemicals No
 [If 'Yes' to any of the above, Sections 4.4 and 4.5 must be completed]

Are any other potentially hazardous activities likely to be carried out during the project?

No
 [If 'Yes', Section 4.5 must be completed]

Do any special requirements (e.g. disability-related issues) or other concerns need to be taken into account for either you as a student, study participants or colleagues?

No
 [If 'Yes', Section 4.6 must be completed]

4.2 WORK AWAY FROM LSHTM (to be completed if any work will be done away from LSHTM, other than at your home or at libraries elsewhere in the UK)

Will the project be based in an established hospital, college, research institute, NGO headquarters, field station or other institutional site? If 'Yes', please give the name and location of the site(s); describe approximately what proportions of your project will be spent there; and state name and role of person who has confirmed willingness to support you at each site (indicating extent of correspondence, especially what they have confirmed in writing). Yes

UNICEF
 No. 11, 75th Street
 Srachark Quartier
 Phnom-Penh, State of Cambodia, P.O Box 176.
 Phnompenh@unicef.org
 I will be in Cambodia for approximately 2 months – July and August. I will be an intern with Unicef for the duration of the project.

Will you have an 'external supervisor', co-supervisor or other main advisor, or be working with any specific organisation(s), during your work away from LSHTM? If 'Yes', please indicate the name, role, contact details, and level of support that any such external advisors are expected to provide, and give details about any organisations you will be working with. Yes

– Nutrition Specialist at Unicef. xxxxx@unicef.org +855 (0)23 426 214
 Ext: 155

Will the project involve personal visits, interviews or interactions with people in their homes, workplaces, community settings or similar? If 'Yes', please give details, including approximately what proportion of your project this will involve. Yes

The project will involve focus group discussions with members of the public at

venues such as health centres, and interviews with health centre staff and ministry of health staff at their workplaces. There may be the need for some one to one interviews of general public if there are problems with accessing certain groups (e.g. rural populations), and they cannot attend focus group discussions. The data collection component will involve approximately 25% of my project time

Will the project involve lone/isolated work or significant travel? If 'Yes', please give details, including approximately what proportion of your project this will involve, and state how you can be contacted while working or travelling.

Yes
 No

The project will not involve any lone work, but there will be some travel to the provinces selected. For Kompong Speu this is approximately 2 hours from Phnom Penh, and Svay Rieng is approximately 3 hours from Phnom Penh. I will be accompanied by Cambodian national Unicef staff to act as translators and focus group leaders.

What arrangements are proposed for contact with your main supervisor while you are away from LSHTM? Indicate expected ease and frequency of contact, and communication methods to be used.

Email and Skype, approximately once a week.

Please tick to confirm: I have read the [LSHTM Code of Practice on off-site work](#).

4.3 WORK OUTSIDE THE UK (to be completed if any work will be done outside the UK)

What form of project work will be undertaken outside the UK? (please tick all that apply)

- Work at my family home or personal residence only
 - Work at an established hospital, college, research institute, NGO headquarters, field station or other institutional site
 - Work away from my personal residence or an established site
- *Note that for either the second or third options, you should also have completed Section 4.2.*

Name the country/countries and region(s) in which work will be undertaken:

Country or countries: Cambodia **Region(s) :** Phnom Penh, Svay Rieng and Kompong Speu

Do the Foreign & Commonwealth Office's (FCO) Travel Advice Notices (www.fco.gov.uk/en/travelling-and-living-overseas/travel-advice-by-country) advise against travel to the regions(s), country or countries involved?

Yes
 No

**Note that if 'Yes', the School will not normally permit such travel for project work. In exceptional circumstances only, requests may be considered by the Safety Committee and require approval by the Safety Manager and Secretary & Registrar.*

Please tick to confirm: I will seek specific travel health advice before any international travel as part of my project.

**Free travel health advice is available, along with anti-malarials, vaccinations and medication, from the School's approved providers – please see details in the project handbook.*

Please tick to confirm: I understand that travel insurance is required when travelling internationally for project purposes.

**Free LSHTM travel insurance can be applied for using a separate form – provided the travel is for location-specific*

	<i>project purposes.</i>
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4.4 WORK WITH HAZARDOUS SUBSTANCES (to be completed if the project involves any work with pathogenic organisms, human blood or radiochemicals – NB that this will require approval by the Faculty Safety Supervisor)

Name the organism or organisms to be used:

--

Identify all potential routes of infection:

--

Name the radiochemical or radiochemicals to be used:

--

List laboratories where work with pathogens or radioisotopes will be carried out:

--

List disinfectants to be used, and describe arrangements for disposal of used material:

--

Will or might Health Surveillance be required for you or any staff working with you? If 'Yes', please give details.

Yes
 No

--

4.5 PRECAUTIONS AGAINST HAZARDS (to be completed if any potentially hazardous activities are likely to be carried out during the project. Refer to Project Handbook and School safety documentation for further information. Faculty Safety Supervisor's approval may be further requested where felt appropriate by project Supervisor.)

Indicate any procedures, activities or aspects of the proposed project which may entail hazards (including work with hazardous substances as per Section 4.4, or anything else relevant). Please set distinct hazards out separately, in a numbered list.

- 1) Travel by car in Cambodia

Indicate the precautions you will take to prevent or mitigate such potential hazards. Please number these to refer to the specific hazards identified in the preceding question.

- 1) I will ensure that there are seatbelts provided in any vehicles that I travel in and will make sure that the driver does not drive too fast. I speak intermediate level Khmer, having lived in Cambodia previously for 3 ½ years.

4.6 SPECIAL REQUIREMENTS (to be completed if the project involves any special requirements, e.g. disability-related issues, or other concerns that need to be taken into account for either you as a student, study participants or colleagues)

What special requirements or concerns need to be taken into account?

--

Do these need to be considered in planning arrangements?

If 'Yes', please give details.

Yes
 No

--

Do these impact on supervision arrangements? If 'Yes', please give details.	<input type="checkbox"/> Yes <input type="checkbox"/> No
Does the project location need to be considered in relation to these? If 'Yes', please give details.	<input type="checkbox"/> Yes <input type="checkbox"/> No
Do arrangements for access to specialist medical treatment need to be considered? If 'Yes', please give details.	<input type="checkbox"/> Yes <input type="checkbox"/> No

SECTION 5 – APPLICATION FOR ETHICS APPROVAL

All students should **answer all questions in sub-sections 5.1 and 5.2. Answers to 5.1 will make clear whether approval by the LSHTM Ethics Committee is necessary, and which later sub-sections you may need to complete. Section 5.2 covers any external approvals required.*

Further detailed guidance about completing this section, and what to do next if formal LSHTM ethics approval is required, is given in **Chapter 6 of your Project Handbook.*

NB that supervisor approval must be obtained **before an application is submitted to the Ethics Committee.*

5.1 SCOPE OF STUDY (to be completed by all students)

Which of the following applies to your project? (please tick one option only)

**Note – the term 'human data' includes any documentary data, datasets or biological samples.*

Project does not involve any human subjects or any human data. [If so, formal LSHTM ethics approval is not required and you do not need to complete Sections 5.3 or 5.4]

Project involves human data, but all this human data is fully in the public domain. [If so, formal LSHTM ethics approval is not required and you do not need to complete Sections 5.3 or 5.4]

**Public domain human data must be: available to any member of the public without special permission; to which access is not restricted in any way; and which does not enable the identification of living people, either directly or by linking to other data.*

Project involves some non-public-domain human data, all of which was previously collected in another study or studies. [If so, formal LSHTM ethics approval is required and Section 5.3 must be completed]

Project involves some additional collection of data, further to an ongoing or previously completed study or studies. [If so, formal LSHTM ethics approval is required and Section 5.4 must be completed]

Project is a completely new study which will involve human subjects or human data. [If so, formal LSHTM ethics approval is required and Section 5.4 must be completed]

5.2 LOCAL ETHICS APPROVAL OR RESEARCH GOVERNANCE APPROVAL (to be completed by all students)

**As well as approval from the LSHTM Ethics Committee, projects may require specific*

approval from other involved or responsible bodies. For example, in the UK you may need specific authorisation to work in an NHS facility, or to work with vulnerable groups such as patients or children. Outside the UK a wide range of requirements may apply e.g. from local or national Ethics Committees, government departments etc. **Students must investigate all potential local approval required for your project work. Failure to check or gain any necessary external approval may invalidate LSHTM approval.**

Is local approval required for the work being done (whether this approval is still to be obtained, or has already been granted)?

Yes
 No

**This should include any forms of ethics approval, research governance approval or other specific permissions that may apply.*

If 'Yes', give details of local approval to be obtained (this must be in place before commencing fieldwork) or which has already been granted.

**Please name all bodies whose approval is required, or indicate where work is expected to take place using permissions already granted for a 'parent' project. Where approval has already been granted, quote approval reference numbers and if possible give web links to documents.*

If 'No', explain why formal local approval is not required, and describe any less formal permissions, invitations or support you are being given for this work.

**If you will be working away from LSHTM with human subjects or human data, but cannot identify a local Ethics Committee or believe that no formal approval is required, then please give details and explain what you have done to check this. In such cases, if you do not have formal approval you should always demonstrate appropriate local support, such as correspondence with local government officials or an involved Non-Governmental Organisation.*

The project represents operational research as part of Unicef Cambodia's programme monitoring activities, in association with the Ministry of Health. The MNP and zinc programmes are already implemented, and the focus group discussions and interviews described above relate solely to the evaluation of programme delivery commissioned by Unicef. I have explicitly asked my supervisor in Cambodia about the need for local ethics approval and his response is as follows;

"As both diarrhoea treatment and multiple micronutrients are currently implemented as government programmes, and bearing in mind that the proposed operations research does not include additional interventions, invasive procedures, or sensitive information, ethical approval should not be required. The work that we will be doing is part of ongoing monitoring of the programmes."

I will take every care to ensure that the participants are giving fully informed consent before being included in the study (as outlined further in the attached information sheets and consent forms) and that they do not feel under any pressure to participate. All qualitative data will be anonymised. The data that I am using for the quantitative aspect of the project, Health Information System and Cambodian Demographic Health Data are all anonymised, and are freely available for routine government monitoring.

**If any specific data rights permissions or usage limitations will be required regarding data to be used or collected in the project (e.g. as a result of local ethics or research governance requirements), this should be spelt out in Section 3.3 earlier.*

5.3 PROJECTS USING ONLY PREVIOUSLY-COLLECTED HUMAN DATA (to be completed if project involves non-public-domain human data, datasets or biological

samples previously collected in another study or studies; if collecting any new data, complete Section 5.4 instead)

Summary of purpose and methods of the original study or studies: (max 100 words)

Give details of all approvals under which the original study or studies took place:

**Please quote names of Ethics Committees and approval reference numbers (required if previous approval was from LSHTM); if possible give web link to original study application.*

Proposed study: Ensure that the project outline given in Section 3.1 states the purpose, methods and procedures of the new work to be done in your project, and describes how this builds on the previous study or studies (for which participants will already have been recruited, data or samples collected, and procedures performed). Do not reproduce here.

Will your analyses be for purposes not covered by the original application detailed above? If 'Yes', indicate how you will obtain (i) permission to use the data from the principal investigator responsible for each original study; and (ii) retrospective consent, where appropriate, from the participants in each original study.

Yes
 No

Does the project involve analysis of documentary information and/or data already collected from or about human subjects? If 'Yes', specify analyses briefly.

Yes
 No

Does the project involve laboratory analysis of human biological samples already collected, or new or additional analysis of stored samples? If 'Yes', specify the laboratory analyses or tests to be performed.

Yes
 No

Specify how confidentiality will be maintained. Where data will be anonymised, specify how this will be done. When small numbers are involved, indicate how possible identification of individuals will be avoided.

State how your data will be stored and what will be done with it at the end of the study.

5.4 PROJECTS COLLECTING ANY NEW HUMAN DATA (to be completed if project involves collection of human data, datasets or human biological samples – either as a completely new study, or collecting additional data further to an ongoing or previously completed study)

Proposed study: Ensure that the project outline given in Section 3.1 contains sufficient detail (inc. purpose, methods, procedures for both new data collection and any work building on previous studies), so as to allow the Ethics Committee to make an informed decision without reference to other documents. Do not reproduce here.

<p>Is your project an intervention study?</p> <p>For LSHTM ethics approval purposes, 'interventional studies' include all trials based on random allocation of interventions, and also non-randomised interventions where participants or groups of participants are given treatments (of whatever nature) that they would not otherwise be receiving in the ordinary course of events and which are allocated by the investigators.</p>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
<p>Will any human biological samples be collected? If 'Yes', specify details.</p>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
<p>Will any human biological material be stored at LSHTM for more than 24 hours? If 'Yes', specify which samples and how and where they will be stored.</p> <p><i>*Further guidance is given at http://intra.lshtm.ac.uk/support/research/humantissueact.html</i></p>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
<p>Specify the number - with scientific justification for sample size – age, gender, source and method of recruiting subjects for the study.</p>	
<p>The sample size will not exceed 60 participants. This upper limit has been derived from the literature regarding focus group discussions and interviews, where it is proposed that after speaking to 20 people in each in 'category', there are usually no more new ideas generated to analyse (saturation point). Due to the type of questions I will be asking (relatively closed ended), I feel that a sample that provides around 10 participants per 'category' will provide sufficient data to allow a good analysis of what is happening, without necessarily reaching saturation point. The sample will be purposefully planned to comprise of the following "categories" of participants</p> <p>Ministry of health staff involved in programme delivery. Sample size: maximum 10 individuals. Convenience sampling will be used to select participants for interview initially, which then may lead onto a more purposive sampling strategy as important themes and ideas develop which require further investigation. The objective of these interviews is to gain an insight into the attitudes of the ministry of health staff at the national level to the MNP and Zinc programmes, and any barriers to implementing the programmes, including workload and supply chain issues.</p> <p>Health centre staff and community out-reach volunteers involved in product distribution. Sample size: maximum 10 individuals. Again, convenience sampling will be used initially, which may become more purposive based on the results of the initial interviews. The objective of these interviews is to understand any barriers to MNP / zinc delivery at the local level, such as perceived extra work load and supply problems. Staff knowledge regarding hygienic use of MNP's, expected benefits and possible side effects of zinc and MNP will be investigated.</p> <p>Care-givers of children from the target population. Sample size: subdivided to include participants who are representative of urban (10), rural (10) and wealthy (10), poor (10) (maximum). Basic demographic indicators will be recorded for each participant, this will be recorded privately. Focus group discussions comprising approximately 5 individuals, which will last approximately 60 minutes. The objectives of these discussions will be to see if the care-givers are experiencing any barriers to using the MNP, knowledge regarding use of MNP and infant and young child feeding practices in general, and any</p>	

suggestions that the participants have for ways to improve uptake of MNP. The sample will be drawn from volunteers attending the participating health centres, and if possible some structured interviews will be conducted with individuals away from the health centres to try and capture a differing perspective from families that may not have access to the health centres. This method may also be used if after analysing the demographic characteristics of the groups, some groups are under-represented.

State the location and likely duration of new or additional human data collection, and the extent to which this will be carried out by you alone, or in collaboration with others, or by others.

The location of data collection will be:

- Phnom Penh – Unicef offices and Ministry of Health.
- Svay Rieng and Kompong Speu - interviews with health workers and community outreach volunteers will be conducted at the participating health centres.
- Svay Rieng and Kompong Speu – Focus group discussions in health centres or in another suitable location such as a community gathering place. To gain data which includes target families who are further away from the health centres, it may be necessary to conduct one to one interviews in people's homes.

The duration of the interviews will be not more than 30 minutes, and the focus group discussions will be approximately 60 minutes.

I will be collaborating with a Unicef staff member who will facilitate the interviews and focus groups.

State the potential distress, discomfort or hazards, and their likelihood, to which research subjects may be exposed (these may include physical, biological and/or psychological hazards). What precautions are being taken to control and modify these hazards?

The subjects will not be exposed to any psychological stress, except for perhaps feeling embarrassed to speak in front of others. This will be limited by explaining the aims of study clearly and by obtaining fully informed consent from each interview participant. It will be made clear that in no way does the operations research have any effect on the individual's health treatment or ability to receive the MNP sachets or zinc treatment. Please see attached information sheets and consent forms.

Specify how confidentiality will be maintained. Where data will be anonymised, specify how this will be done. When small numbers are involved, indicate how possible identification of individuals will be avoided.

Confidentiality will be maintained by asking the participants to choose a name that they would like to be assigned to their voice for the recordings, which is not their actual name. When analysing the data, I will not present any quotes from staff members that may by inference be traceable to them. No names will be used in the final report.

State how your data will be stored and what will be done with it at the end of the study.

The data will be stored on audio recordings and the analysis will be carried out at the head office of Unicef Cambodia. The audio recordings will be wiped at the end of the study. The written transcripts will be anonymised, broken up and coded into themes for analysis. The themes will be stored and some excerpts from the transcripts may be included in the final report to illustrate key points or

to provide an example of how the analysis was carried out, but the full written transcripts will be destroyed after the analysis stage.	
State the manner in which consent will be obtained from subjects.	
<ul style="list-style-type: none"> - Written consent is normally required. Where not possible, explain why and confirm that a record of those giving verbal consent will be kept. - Where appropriate, please state if and how the information and consent form will be translated into local language(s). 	
Written consent will be obtained prior to interviews or focus group discussions. The consent form will be translated into Khmer. In addition a full verbal explanation will be provided, which will include the same information as the written form. If the participants cannot sign their name, a thumb print will be used. The explanation will cover the aims of the research, and the fact that data will be anonymised, will not affect access to health care or be reported back to Unicef / Ministry of Health staff in a way that is traceable to individuals. It will also be made clear that there is no obligation to be interviewed or participate in the focus group discussions. Please see attached information and consent forms.	
Please tick to confirm:	<input checked="" type="checkbox"/> I have attached copies of the information sheet(s), consent form(s), and other relevant documents related to work with human subjects.
As well as collecting new data, will your project also make use of any human data or biological samples collected in a previous study or studies? If 'Yes', summarise the purpose and methods of the original study or studies – for which participants will already have been recruited, data or samples collected, and procedures performed. (max 100 words)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Data from the Cambodian Demographic Health Survey 2010. This is all anonymised and freely available online. Health Information Systems monitoring data – anonymised data regarding incidence of disease and treatments offered, no data regarding individuals.	
Give details of all approvals under which the <u>original study or studies</u> took place:	
<i>*Please quote names of Ethics Committees and approval reference numbers (required if previous approval was from LSHTM); if possible give web link to original study application.</i>	
Routine government statistics collected to inform health policy at national level.	
Will your analyses be for purposes <u>not covered</u> by the original ethics approval detailed above? If 'Yes', indicate how you will obtain (i) permission to use the data from the principal investigator responsible for each original study; and (ii) retrospective consent, where appropriate, from the participants in each original study.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

Confirmation of LSHTM ethical approval:

“I have reviewed your project on behalf of the Ethics committee. I confirm your project is approved, on the understanding you have permission from the local UNICEF office.”