

# **ENHANCING PREGNANCY OUTCOMES**

**A joint program of UNICEF PNG and the PNG National  
Department of Health, implemented by the  
PNG National Institute of Medical Research**

*CONSULTANT REPORT*

**SUMMARY AND INTERPRETATION OF THE  
RESEARCH AND EVALUATION FINDINGS**

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## Abbreviations

BMI	Body Mass Index
CHW	Community Health Workers
CI	Confidence intervals
CSS1	First cross-sectional survey – Oct – Dec 2006
CSS2	Second cross-sectional survey – Nov – Dec 2007
EPO	Enhancing Pregnancy Outcomes
HEO	Health Extension Officer
HIV	Human Immunodeficiency Virus
INT1, 2,3,4	Intervention surveys 1, 2, 3 and 4
LLG	Local Level Government
NDOH	National Department of Health, Papua New Guinea
Pf	Plasmodium falciparum
Pm	Plasmodium malariae
PNG	Papua New Guinea
Po	Plasmodium ovale
Pv	Plasmodium vivax
RR	Relative risk
UNICEF	United Nations Children's Fund
VBA	Village Birth Attendants
VHV	Village Health Volunteer
VLAP	Village Level Pregnancy Assistants
WHO	World Health Organisation
WRA	Women of Reproductive Age

## 1. Introduction

The Enhancing Pregnancy Outcomes (EPO) program has provided an opportunity to perform a true public health *effectiveness* study that examines the population effect of a community-based intervention for pregnant women, and women of reproductive age (WRA), delivered by a combination of village health volunteers (VHVs) and outreach by rural health workers. It tested this intervention under 'real-world' circumstances. Both the intervention and the research methodology were subject to the difficulties of operating in remote rural areas of Papua New Guinea (PNG).

This report was prepared from data collected during the course of the EPO program. The data entry and cross-checking was managed by IMR and files provided to the consultant. Further cleaning of the data, such as harmonising of identification numbers and handling of missing values, was carried out at Burnet, in consultation with IMR.

Mr Ali Kevin from IMR provided essential guidance and assistance in understanding and analysing both the research data and the operating environment, supported by Mr Namarola Lote and Ms Grace Pongua. Ms Sarah Sheridan, from Burnet, provided invaluable help in further cleaning and analysis of the data files. Others consulted, including Professor Peter Siba, the program director, provided valuable direction to this analysis and are listed in the annex.

## 2. Background

### 2.1 Setting

Papua New Guinea is a low-middle income, moderately indebted country with a GNP per capita of US\$ 800. One third of the estimated population of 5.95 million (from national census in 2000) is estimated to live at or below the poverty line and 83% live in rural areas. Illiteracy rates are high (29% of men, 44% of women). Papua New Guinea is culturally rich and diverse, with huge differences between and within provinces. Traditional tribal linkages remain powerful, with about 800 tribal groups. The churches are an important influence and provide many social sector services, including about 50% of rural health services.

The country has one of the most rugged terrains in the world. Central mountain ranges with sharp ridges and steep slopes reach altitudes over 4000 meters. Extensive marshes dominate the coastal areas. Vast areas are remote with difficult accessibility and only three percent of roads are paved. As a result of geography and limited roads, air transport is often the only mode of transport. In coastal areas, island and large river localities, sea transport is important. Transport infrastructure is inadequate and deteriorating.

Typically, inland villages consist of hamlets of 5-12 houses, (for example, population of up to 50 – 100 persons). There are some moderate-sized villages with populations of more than 2,000, although these represent the exception rather than the rule. The hamlets are frequently isolated by geographic constraints. It is believed that 80% of the population are living in "hard to reach" areas, impeding access to health services and resulting in prohibitive logistic and operational cost of health services.

Additional information on the setting, including the status of maternal health is contained in the original proposal “Enhancing Pregnancy Outcomes in Papua New Guinea” developed by all stakeholders, including the National Department of Health (NDOH), UNICEF Port Moresby and the PNG Institute of Medical Research, Goroka (IMR). Current indicators of maternal and infant health are tabled below, noting trends over the past five years.

**Table 1: Selection of current maternal and infant health data**

<i>Indicator</i>	<i>Measurement</i>	<i>5 year trend</i>
Estimated (2005) total population <sup>1</sup>	5,950,000	
Estimate of women of reproductive age (15 – 44 years) (2005) <sup>1</sup>	1,380,400	
Estimated births (est. CBR of 3.5%) (2005) <sup>2</sup>	208,250	
Infant mortality <sup>2</sup>	64/1,000	decreasing
Antenatal coverage (1 visit) (2003) <sup>3</sup>	57%	decreasing
Antenatal coverage (4 visits) (2003) <sup>3</sup>	26%	
Supervised delivery (village) (2003) <sup>3</sup>	3%	
Supervised delivery (health centre) (2003) <sup>3</sup>	32%	static
Tetanus toxoid coverage (of those attending ANC) (2003) <sup>3</sup>	88%	improving
LBW (% of HC supervised deliveries) (2003) <sup>3</sup>	9.8%	
Stillbirths (% of HC supervised deliveries only) (2003) <sup>3</sup>	3.0%	
Anaemia – n/a		
Maternal mortality (by ‘sisterhood method’, 1996) <sup>4</sup>	370/100,000	
Outreach clinics (per 1,000 children under 5) (2003) <sup>5</sup>	24.05	decreasing
Family Planning (couple years protection) (2003) <sup>5</sup>	90	decreasing
HIV in pregnancy (15-24 yo PMGH, 2003-Q1 2004) <sup>5</sup>	1.38%	increasing

*Data sources:*

1. National Census, 2000
2. Fertility and Mortality Indices and Trends in PNG, NSO April 2003
3. National Health Information System
4. Demographic and Health Survey, 1996
5. Annual Sector Review, 2004

Accessibility to services has diminished sharply in recent years as a result of inadequate staffing in remote static facilities, and a reduction in outreach activity. Consequently, child and pre-pregnancy services, and antenatal and obstetric services have become increasingly unavailable. Accessibility issues also escalate the cost and effort of providing health care to the point where meeting defined minimum standards for district level care is becoming increasingly difficult. The World Health Organization ranks the country as 149th in its responsiveness to the health needs of the people. As a result, there is the sense that with deepening poverty, the WHO ranking is slipping even further as the health system finds it progressively difficult to supervise and monitor health workers in ‘remote’ areas. It should be noted that  $\geq 80\%$  of all areas are ‘remote’.

This research project was carried out in two districts, one coastal (Maprik) and one island (Esa’ala). Communities in both districts suffered varying constraints relating to remoteness, poverty and low levels of education and both are endemic for malaria.

## **2.2 Rationale**

The original proposal also provided detailed information on the project rationale. This identified the full spectrum of intervention points required in order to improve pregnancy outcomes, including:

- The underpinning social and economic climate,
- Childhood,
- Pre-pregnancy,
- Pregnancy, and
- Intra-partum and post-partum.

The rationale described the potential benefit of community-based interventions delivered during the pregnancy period, including:

- Malaria prevention (through insecticide impregnated bed-nets) and intermittent treatment;
- Treatment with anti-helminthics;
- Screening for syphilis and referral for treatment if required
- Referral for screening for HIV infection
- Screening for anaemia
- Treatment with micronutrients

The rationale identified the high rates of anaemia, infection, low birth-weight, prematurity and maternal and newborn death in PNG in general, and the study districts in particular. There is a complex interaction between poor nutrition, malaria infection, helminth infection, syphilis and other infections as a cause of many of these problems, and anaemia in particular. Studies of micronutrient use identified their potential to reduce infection, anaemia and mortality and promote increased birth-weight. Studies of malaria in PNG identified the high rates of chloroquine resistance which diminish the efficacy of current policies for weekly chloroquine prophylaxis in pregnancy and identified the potential benefit of intermittent treatment with sulfadoxine-pyrimethamine, which is now a key component of national malaria treatment policy. Studies of soil-transmitted helminths (particularly hookworm and roundworm) identified the potential of a single treatment dose of albendazole.

There was a clear need to need to test a community-based approach in a way that would be transferable to other sites in PNG. This complemented other work in progress, including that of NDOH on safe motherhood and supervised delivery and the PNG National Micronutrient Survey 2005 conducted by NDOH, UPNG, UNICEF and CDC.

## **2.3 Program aim and expected achievements**

The project aim was based on the rationale, which identified important determinants of poor pregnancy outcomes, including maternal under-nutrition, malaria, syphilis and other infections, and a risk of exposure to HIV infection.

The aim, from the original proposals, is to ensure that a pregnant woman is in optimal health through her pregnancy to ensure that the infant is well nourished and free from congenital disease, and that the woman is resilient to potential hazards of late pregnancy and childbirth, as well as in the puerperal period.

The program was envisaged as a pilot intervention, so that the effectiveness of a targeted package of preventive and curative care in two district populations can be demonstrated. The results were expected to form the foundation of advocacy for expansion into other districts should benefit be realised. The expected short- and medium-term achievements of the pilot program were expected to be:

- A decrease in anaemia in pregnant women in the study districts;
- A decrease in the rate of low birth weight among babies born in the study districts
- A decrease in congenital syphilis
- A decrease in malaria morbidity and mortality

It was also anticipated that successful implementation of the project would clearly demonstrate what would be realistic logistics required to deliver multiple long-term interventions at the district level in PNG. The anticipated longer-term benefits in the study districts included:

- A decrease in infant mortality
- A decrease in maternal mortality
- Improved well being of women

The specific project objectives were as follows:

- To develop implementation processes and prepare with community for pilot study,
- To work with communities in providing preventive and curative support for women of reproductive age, and
- To evaluate the effectiveness of the interventions provided.

### 3. Methods

In this effectiveness study, the intervention was made available to all pregnant women. There were no control groups and no need for blinding of surveyors or treatment administrators. The study aimed to establish a baseline and then assess changes over time across the populations of pregnant women and women of child-bearing age in each district. This entailed a census to enumerate women of child-bearing age (both pregnant and non-pregnant), baseline and follow-up surveys either side of the intervention period, and regular surveys during the intervention period.

#### 3.1 Overview of field data collection and intervention

In short, the field work involved in the EPO program was:

1. Recruitment of staff, consultation and site selection	June – August 2006
2. Census of women of reproductive age (WRA)	August - September 2006
3. Baseline data collection through a cross-sectional survey of WRA, accompanied by distribution of bed nets	October – December 2006
4. Intervention and surveys of pregnant women <ul style="list-style-type: none"> <li>- Micronutrients for pregnant women and other WRA given continuously by VHVs</li> <li>- Four health team visits, at 10 week intervals to give malaria and worm treatment, bed nets and carry-out survey</li> <li>- Qualitative interviews with focus groups in each site</li> </ul>	1st round: February - March 2007 2nd round: April – June 2007 3rd round: July – August 2007 4th round: September - October 2007
5. Follow-up cross-sectional survey of WRA, accompanied by distribution of bed nets	November – December 2007

#### 3.2 Site selection and sample size calculation

Site selection aimed to cover two districts in contrasting locations which were both malaria endemic, and both with similar sized population:

- Maprik, in a northern coastal location in East Sepik Province, had an estimated population approximately 57,500 persons with an expected 13,340 WRA and a district total of 2,000 pregnancies per year.
- Esa'ala, in Milne Bay Province, a more isolated island district, had an estimated population of approximately 48,500 persons with an expected 11,200 WRA and a district total of 1,700 pregnancies per year

There was purposeful selection of 39 villages in each site, (from a total of approximately 160 villages in each site) based on a number of determinants:

- Local population seeking larger centres where possible and attempting to have each local-level government division given correct proportional representation;
- Access to a health facility and road or sea transport points;

- Maternal and infant health indicators and estimated number of women of reproductive age (based on projection from National Census 2000).

It should be noted that the intention was to include sites with access constraints, acknowledging that in these places delivery of health services will be more difficult. This aspect emerges clearly in the sections on limitations and general discussion at later points in this report.

In Esa'ala, villages were chosen in consultation with District Health Office and the Health Secretary for the United Church and directed towards villages with high numbers of maternal health morbidity and mortality. In Maprik villages were chosen in consultation with IMR staff who had a very good knowledge of the Maprik district. Because of the tight timeframe the logistical issues and access were quite a strong determinant for choosing a village.

The census of WRA aimed to enumerate 7,000 women across the two sites, which was intended to generate access to 500 to 700 deliveries, that is: 250 to 350 in each site. Within this, 1,000 WRA were accessed for cross-sectional surveys across the two sites. This was based on the power needed to detect changes in haemoglobin levels, derived from internal IMR consultations.

### **3.3 Surveys**

#### **3.3.1 Census**

Stakeholder meetings to provide information about the project and raise awareness of safe motherhood were conducted by the project team prior to conducting the census in each village. The census aimed for a comprehensive sample across all 39 villages and was carried out as a house-to-house survey, starting from the point furthest from the transport access and working backwards, attempting to cover every house. The census covered basic demographic data, including age, education, marital status and some information on experience of pregnancy and childbirth, as well as usage of bed nets.

#### **3.3.2 Cross-sectional surveys**

These were performed as baseline and follow-up to the intervention period and performed at equivalent seasons at a one year interval. The aim was that at least 500 WRA, both pregnant and non-pregnant, in each site were chosen for inclusion based on random selection within identification numbers from the census. Both surveys covered pregnancy status, experience of childbirth outcomes in the past, family planning, weight, height, haemoglobin, syphilis rapid tests (if pregnant), and blood slides for malaria.

Qualitative interviews and other mid-term assessments raised additional issues, which were included in the second cross-sectional survey. This was expanded to include acceptability and compliance with micronutrients, use of antenatal care, and attitudes to referral for testing or treatment, with regard to syphilis and HIV.

Cross-sectional surveys were accompanied by free distribution of insecticide-treated bed nets.

Health facility records were examined for information on deliveries over the 12 months prior to the intervention period. These were entered into the birth register database for future comparison with birth outcome information to be collected during the intervention.

A change to the protocol, approved by national ethics authorities, allowed collection of blood for assessment of measles and rubella antibodies as a separate study carried out by IMR and the Burnet Institute.

### **3.3.3 Intervention period – February to October 2007**

As noted above, health teams visited each village at approximately 10 week intervals for two purposes: firstly to deliver bed nets, antimalarials and antihelminthics, as well as support VHVs, as part of the intervention; and secondly to survey pregnant women.

The intervention surveys were conducted in four rounds and aimed for voluntary recruitment of as many pregnant women as possible in each village. These surveys covered stage of pregnancy, weight, height, haemoglobin, syphilis rapid test (if not already done), blood for malaria microscopy, a record of micronutrient, antimalarial and antihelminthic administration and a note on education regarding HIV testing.

Intermittent preventive therapy for malaria required that all pregnant women receive at least two courses of malaria treatment during the pregnancy. It is preferable that this is provided early in the pregnancy before or as soon as the baby starts moving (eg less than 20 weeks gestation) and in later pregnancy (eg 30 – 38 weeks gestation). The intervention study treatment regime consisted of administration of sulfadoxine-pyrimethamine in early pregnancy and sulfadoxine-pyrimethamine treatment at 30-38 weeks.

Each round of the survey attempted to follow women who had been pregnant in previous rounds, and also enrol women who were newly found to be pregnant. The surveys assessed

- stage of pregnancy,
- height and weight,
- visible pallor
- haemoglobin level,
- malaria slide,
- syphilis rapid test (if not already done)

Interventions were delivered at the time of the survey, providing women with antimalarial, albendazole (in line with dose protocol), bed-nets (if not already supplied or in use) and counselling regarding HIV testing, other needed referrals and general information on pregnancy. Micronutrients were also supplied to mothers and VHVs supporting treatment during the surveys. Survey records (see section 4.6) suggest high rates of delivery of interventions in each survey round.

During the intervention a register was maintained at each village that was intended to record all births, including delivery complications, outcomes for baby and mother and birth weight.

Qualitative interviews were carried out in the second half of the intervention period, with separate focus groups in each site. These were intended to investigate attitudes

towards the intervention and pregnancy in general. An overview of these findings is provided in the annex.

### **3.4 Description of the intervention**

A separate health and research team was formed in each site, led by a nurse or HEO, supported by CHWs. While these particular teams were well experienced, their level of training was similar that of many rural health workers, so that they could model a feasible form of outreach from most peripheral health facilities. As delivered, the intervention varied only slightly from that in the original proposal and comprised:

- An initial training of village health volunteers (here termed Village Level Pregnancy Assistants (VLPA)) in pregnancy care, data recording and the administration of micronutrient supplements.
- Arrangement for supplies (derived directly from UNICEF and transported to central health facilities of micronutrient supplements to be available to village health volunteers (VHVs) or village birth attendants (VBAs);
- Administration of micronutrients in the village, supervised by VHVs through weekly follow-up, on a daily basis to pregnant women and a weekly basis to WRA;
- Clinics held by the health and research team in each village at approximately 10 week intervals during which they:
  - o Completed survey tasks on all pregnant women
  - o Distributed bed nets
  - o Administered to pregnant women sulfadoxine-pyrimethamine (as Fansidar, bi-monthly) and albendazole (100mg after 14 weeks, and again after four months)
  - o Syphilis rapid test, and referral if positive, for newly recruited pregnant women
  - o Awareness of counselling and voluntary testing for HIV
- VHVs supported the regular clinics through encouragement of attendance and joining in treatment and survey tasks. The regular clinics also provided a point of referral of women to VHVs to continue micronutrient use.

The project aimed to distribute one family size 'long life' insecticide treated bednet to all pregnant women within the selected villages as part of the intervention. Women were identified on the basis of their responses during the census to questions regarding their ownership and use of bednets in the home. However, some distribution of bednets occurred prior to the intervention period which affected interpretation of related data.

### **3.5 Problems and limitations**

#### **3.5.1 External problems affecting the program**

There were many problems that affected the program, many of which were outside of the control of the health and research teams, and their directors. These were typical of the constraints that operate on any health development activity in PNG. The fact that external factors operated in this way helped ensure that the implementation and outcomes were attained under conditions that would be similar in other sites in PNG if this intervention were introduced as a routine part of the health system.

**Social and cultural tensions** arose at different times, including:

- Staff met with suspicion that they were labelling houses with spiritually harmful insignia such as “666”.
- Some villages did not participate due to lack of interest or understanding.
- Expectations that services would be always be accompanied by personal benefits, particularly in receiving free bed nets every survey. In Maprik a failure in bed net supply meant the fourth round of the intervention survey had very poor recruitment and had to be excluded from data analysis. There was conflict between community members, and with the health team, when such expectations could not be met.
- Conflicts related to national elections in 2007 delayed work in some sites and in one instance there were accusations of micronutrients being supplied as political favours to exclusive sections of the community.
- Well-founded fears around sea piracy hampered scheduling of work in Esa’ala.

**Difficult geography and weather conditions** affected work on a regular basis. Maprik was less affected as most villages could be accessed by road, but this was a particular problem in Esa’ala where access was by sea. Houses in many villages in Esa’ala were widely dispersed and often separated by bush, hills or waterways. In addition, many people choose to stay in huts by their fields, often a great distance from the village. This made comprehensive surveys difficult. Rough seas and high usage caused repeated problems with boat equipment, with some potentially life-threatening consequences at times. Extremes of weather and difficult logistics damaged a critical number of malaria slides in Esa’ala. Very strong wind conditions late in 2007 meant recruitment to the fourth round of the interventions surveys was very low and some travel for the second cross-sectional survey had to be diverted or delayed.

**Logistics** caused particular difficulties, as is often the case in PNG. As well as damage to malaria slides in Esa’ala, logistic difficulties also affected the supply of bed nets in both sites. An early supply to each province, earmarked for the EPO program, was distributed prior to program commencement and so was not available during surveys. Later supplies were delayed in delivery. This caused significant concerns around loss of community confidence, as the nets were promised during initial meetings. UNICEF purchased extra nets to help make up the mid-term short fall.

The EPO program placed **significant demands on VHVs**, especially with the inclusion of the need to record all birth outcomes in a birth register. This proved difficult for several reasons:

- it added an unfamiliar burden of work and in Esa’ala VHVs often found it difficult to travel to dispersed, difficult-to-reach hamlets;
- it required access to and correct use of a hanging weight scale, which was not guaranteed despite distribution of scales by the EPO program; and
- the study protocol required that the weight be taken within 24 hours of birth, which was difficult when access was poor and impossible when VHVs were not notified of a birth until several days after the event.

### 3.5.2 Limitations on the data and its analysis

The impact of these difficulties and problems meant that:

- Numbers in the fourth intervention survey were too low for it to be included in the analysis
- It was not possible to report malaria results from Esa'ala
- There was a slight drop in the numbers of villages in the second cross-sectional survey, but without any definite bias involved
- Not all births were recorded in the birth register and a lower proportion of births had weights and valid birth dates recorded. The exact bias in the missing data is unclear, but it is possible that births with poorer outcomes were less likely to be recorded, for a variety of reasons.

On detailed analysis, some issues related to the data themselves, became apparent:

- Age data was not available for women whose identification number was not found in original census, and this provided minor limitations on the testing of hypotheses, such as those for nutrition in young nulliparous women.
- There were significant differences between the pregnant proportions of the census and cross-sectional survey populations (census had 9% pregnant, cross-sectional surveys had 20+% pregnant). This may be due to some seasonality of births, but may also represent some failure of randomisation whereby there was increased voluntary recruitment of pregnant women into the cross-sectional surveys. It is also possible that the census under-reported pregnancy, especially if women in early pregnancy were asked the question within earshot of other community members. A rough estimate of the proportion of the population expected to be pregnant at any one time (based on national crude birth rates) falls between the census and the cross-sectional survey rates. The consultant has consulted on the potential bias this may introduce and believes that this does not invalidate the results.
- It was not practical to obtain full obstetric histories from women during the cross-sectional surveys, so that it is not possible to calculate mortality rates from these surveys, which had larger sample sizes. In the birth register, where some measure of live births was available, mortality could not be calculated to a meaningful degree, as numbers were too small. It is noted that the size of the research population was calculated with the aim of examining changes in haemoglobin, rather than mortality.
- Some measures used to calculate BMI were subject to error, particularly in the recording of heights, where paired analysis showed non-physiological variation in height in some cases, possibly more so in Maprik.

It is emphasised again, that these difficulties are common to health development and hence pilot interventions or effectiveness studies in PNG. The VHVs, health teams, and research directors overcame significant obstacles to both deliver the intervention and demonstrate its effectiveness in challenging rural environments.

## 4. Results

### 4.1 Approach to analysis of the data

Note that the time-frame of data collection, and the limitations on the data, including confounders, are discussed above in section three.

Databases were provided by IMR in both Excel and Stata. Cleaning of the data in both IMR and Burnet paid special attention to validating identification numbers and included activities such as:

- investigating duplicate or invalid numbers and tracing individuals by name and village to validate these (name and village were not used in any other analysis);
- identifying gross outliers or non-physiological data and either correcting these or removing them from the analysis; and
- investigating partially valid data, such as date with month but not day indicated, and either assigning a reasonable value or excluding them from analysis.

Analysis carried out below used Stata software and standard tests of statistical significance.

The census provided some data for analysis of women's general situation and was used as the reference point for identification numbers when consolidating other datasets. It also contained some information linked to identification numbers that was not available elsewhere, such as age. After the census there were two types of survey available: the cross-sectional surveys in late 2006 and late 2007 (CSS1 and CSS2) and intervention surveys (INT1, INT2, INT3 and INT4) from February to October 2007. As noted above, external problems in both Maprik and Esa'ala greatly affected recruitment to INT4 and so data from this survey was not able to be included in this analysis.

The combination of survey data, and consistent use of identification numbers, allowed for the comparison of populations as a whole, and also paired analyses to trace the progress of individual women. However, there was not a large overlap between the CSS1 baseline survey and the first intervention survey (INT1) in that only 22 women pregnant during CSS1 (in both districts) subsequently appeared in INT1, and only 15 women who were not pregnant during CSS1 subsequently became pregnant and then appeared in INT1. Subsequent INT surveys captured lesser numbers of women from CSS1. For this reason, this analysis treated the two cross-sectional survey populations as being largely independent of those of the intervention surveys. Paired analyses were carried out, where possible, within the two CSS and within the three INT datasets, but not between survey types. These were supplemented with unpaired comparisons across time periods, both for INT1, 2 and 3 and for CSS1 and CSS2.

The approach to analysis is organised around several different perspectives:

- 1) A descriptive "snapshot" of the health status of women, both pregnant and WRA in both districts. This used information that was collected only once, and derived from the census, CSS1 and the extra questions added to CSS2.
- 2) Changes observed in pregnant women during the intervention surveys.
- 3) Changes in WRA and pregnant women over the 12 months between CSS1 and CSS2 (noting that micronutrients were given to both pregnant women and WRA);

- 4) Information on maternal deaths, birth outcomes and birth weights before and during the intervention, available from analysis of the birth register; and
- 5) Information on how the intervention was implemented, available from intervention surveys and CSS2.

## 4.2 Description of women's health status

This section summarises the data that was only measured once from the census, baseline CSS1 and a few items that were asked only in the second CSS2.

### 4.2.1 Overview of women of reproductive age

The census is intended as the reference population of WRA from which subsequent study populations were derived. There was a target of 3,500 women per district, aiming to comprehensively cover the 39 selected villages. The number of women recruited to the census were 3,678 in Maprik and 3,761 in Esa'ala. Demographic data suggests the two districts are readily comparable. The cross-sectional surveys were intended to provide population snapshots prior to the intervention and one year later, following 10 months of intervention. In Maprik, CSS1 included 651 WRA from 39 villages and in Esa'ala 637 WRA from 35 villages.

**Table 2: Demographic information of women self-reported as being of reproductive age during the census**

	Age			Marital status			Education		
	Range (yrs)	Median (yrs)	Mean (yrs)	Married	Never married	Divorced, separated, widowed	No school	1-6 yrs	>7 yrs
Maprik	12-64	28	28.6	63.3%	31.8%	4.9%	33.6%	44.8%	21.6%
Esa'ala	13-58	28	28.8	69.9%	24.5%	5.9%	16.0%	56.8%	27.3%

The international WRA definition is women aged between 15 and 49 years of age. However, in the current study, women were identified as being of reproductive age if they reported menstrual periods, rather than basing this on uncertain age data. Analysis of the reported age data suggests only 1% of the study population in the census, across both districts fell outside this range, so this is not felt to bias the results. Most women reporting as 'never married' were younger in age. Information on bed net usage was collected in the census, but is reported below in section 4.4 as comparison with usage in CSS2. A high proportion of women had had at least one child, 65.3% in Maprik and 74.3% in Esa'ala, with the median number of children reported as 3 in both districts.

The age distribution of the CSSs was similar to that of the census. However, the proportion of women who identified themselves as pregnant during the census was less than that in the two cross-sectional surveys, as tabled below.

**Table 3: Proportion of women of reproductive age who were pregnant in Maprik and Esa'ala districts, as recorded during the census and cross-sectional surveys**

	<b>Census</b>	<b>CSS1</b>	<b>CSS2*</b>
Maprik	6.8%	23.7%	18.9%
Esa'ala	9.0%	25.4%	17.9%

\*excluding &lt;1% missing answers

Some of this difference may be seasonal (the census was mid-year and the CSS were at the end of the year) but this may also represent a bias in recruitment towards pregnant women in the CSS1 and CSS2 (see discussion in section 3.5). This is not likely to alter the interpretation of results. A rough calculation (based on national crude birth rates) of the expected proportion of women pregnant at any one time puts this at between 10 and 20%.

#### 4.2.2 Women's experience of childhood death

Women's experience of childhood death was captured by the census and CSS1 and 2. In the census, over 30% of women who had ever had a child (30.3% in Maprik and 30.8% in Esa'ala) reported having lost a child aged less than 5 years (with a median of 1 child lost). Rates obtained from cross-sectional surveys were similar: 33.2% in Maprik and 33.9% in Esa'ala in CSS1; and 31.5% in Maprik and 28.8% in Esa'ala in CSS2.

**Table 4: Age of death among reports of childhood death in the census**

<b>Time of child's death</b>	<b>Census</b>		<b>CSS2</b>	
	<b>Maprik</b>	<b>Esa'ala</b>	<b>Maprik</b>	<b>Esa'ala</b>
Still birth	41 (19.2%)	19 (10.3%)	41 (23.4%)	35 (36.5%)
Neonatal (under 1 month)	75 (35.2%)	93 (50.5%)	66 (37.7%)	34 (35.4%)
1 month up to 5 years	97 (45.5%)	72 (39.1%)	68 (38.9%)	27 (28.1%)
Total deaths reported	213 (100%)	184 (100%)	175 (100%)	96 (100%)

\*4 (1.8%) and 9 (4.6%) children in CSS1 and 7 (3.8%) and 28 (21.5%) in CSS2 between 5-18 years were reported to have died in Maprik and Esa'ala respectively. These were excluded from the analysis above.

The ages at which children were reported to have died are tabled above, and the proportions varied slightly between census and CSS. However it is clear that that a significant proportion of remembered deaths occurred in the neonatal period (35.2% in Maprik and 50.5% in Esa'ala). As noted in section 3.5, it is not possible to calculate mortality rates because the total number of live births is unknown.

#### 4.2.3 Syphilis in pregnant women

Syphilis was measured using a field using the Abott Determine rapid test for Syphilis<sup>1</sup>. Women testing positive were referred to the relevant health facility for treatment. The test was intended to be administered only to women who were

<sup>1</sup> This test provides 92 % sensitivity and a specificity of 95%, positive predictive value of 43% and negative predictive value of 99.6% as shown at the Port Moresby General hospital in 2003 (paper accepted for Publication in the PNG Medical Journal)

pregnant and who had not been tested previously, which is why numbers tested declined with subsequent surveys. Because of this, it was not feasible to attribute any changes over time in syphilis rates to direct effects of the intervention. Syphilis rates measured at different times during the study are presented here to provide a picture of the range of syphilis infection in these sites.

**Table 5: Syphilis rates among pregnant women recorded through the study period**

Survey	Maprik		Esa'ala	
	Number tested	Number (%) positive for syphilis	Number tested	Number (%) positive for syphilis
CSS1	130	7 (5.4%)	146	13 (8.9%)
INT 1	141	3 (2.1%)	129	9 (7.5%)
INT 2	72	0	113	4 (3.5%)
INT 3	15	0	62	3 (4.8%)
CSS 2	59	0	57	2 (2.9%)

For the reasons stated above, it is not possible to provide meaningful confidence intervals however the low numbers involved suggest the apparent decline may be an artefact of sampling.

#### 4.2.4 Antenatal care usage

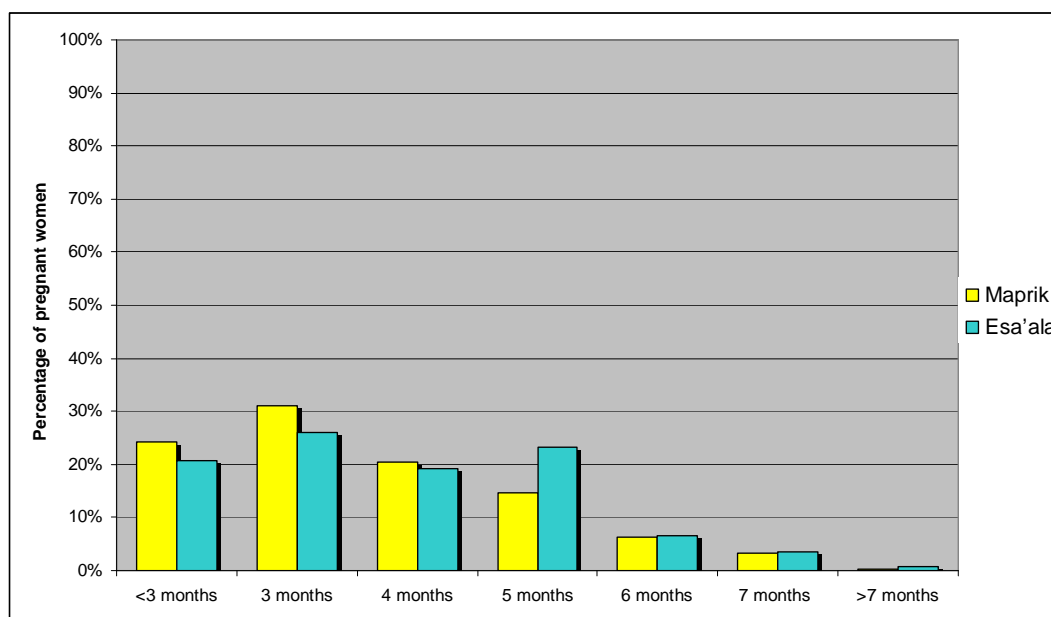
The second cross-sectional survey included questions on antenatal care for women who were currently pregnant or who had been pregnant in the past. These data are based on mothers' recall and reported practice, rather than observed rates. A high number of women reported using antenatal care at some stage in the last pregnancy: 90.6% (404 of 446) in Maprik, and 91% (305 of 335) in Esa'ala. Missing values were negligible. Of those reporting usage of antenatal care, the stage of pregnancy by which they attended is tabled below.

**Table 6: Stage of pregnancy reported as first antenatal care attendance in CSS2.**

Stage of pregnancy	Maprik		Esa'ala	
	Number (Percentage)	Cumulative percentage	Number (Percentage)	Cumulative percentage
<3 months	98 (23.9%)	23.9%	62 (20.6%)	20.6%
3 months	125 (31.1%)	55.0%	78 (25.9%)	46.8%
4 months	83 (20.7%)	75.6%	58 (19.3%)	65.8%
5 months	59 (14.7%)	90.3%	70 (23.3%)	89.0%
6 months	25 (6.2%)	96.5%	20 (6.6%)	95.7%
7 months	13 (3.2%)	99.8%	11 (3.7%)	99.3%
>7 months	1 (0.3%)	100%	2 (0.7%)	100%

\*two missing answers (0.5%) from Maprik and four (1.3%) from Esa'ala excluded from analysis

**Chart 1: Comparison between Maprik and Esa'ala districts of stage of pregnancy reported at first antenatal care attendance (CSS2)**



This data conflicts with the findings of the qualitative interviews, which reported most women as saying that they attended in the second or third trimester. It also conflicts with established National Health Information System data. It is possible that this represents a change of behaviour towards earlier consultation for ante-natal care as a result of the intervention. However, because of the conflicts with other data sources, this conclusion has not been drawn, nor incorporated into the discussion.

#### 4.2.5 Family planning usage

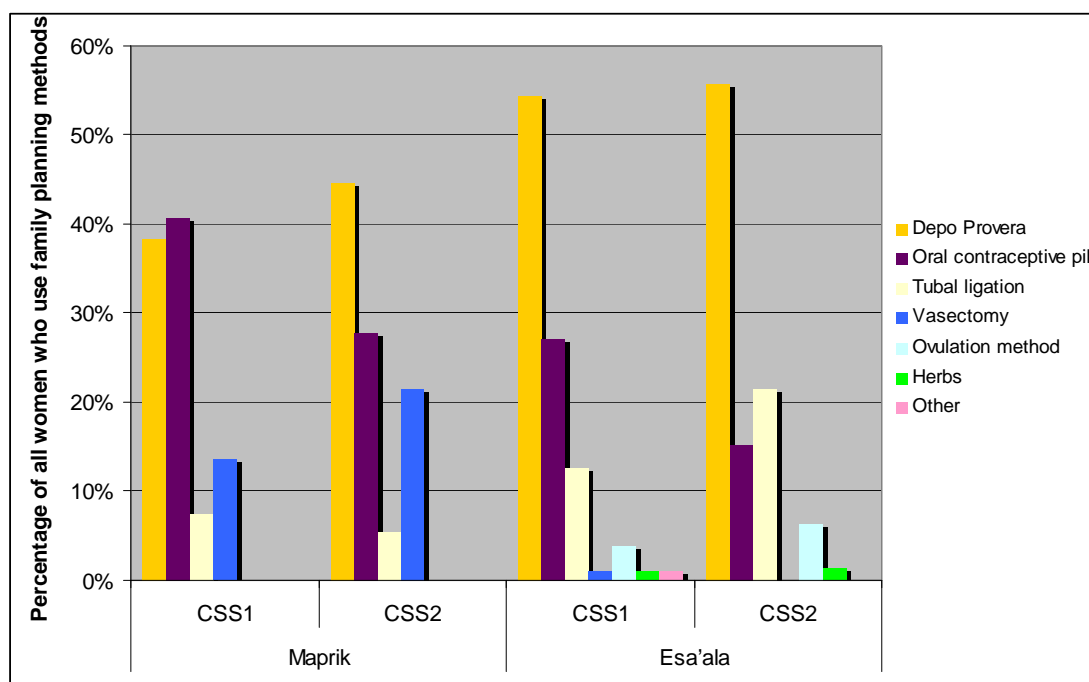
Because family planning was not an outcome directly targeted by the intervention, it is reported here as descriptive statistics. Both CSS1 and CSS2 asked women about their family planning usage. Rates are reported as proportions of women who were not currently pregnant. It can be assumed that most of these women are sexually active, because more than 75% have had children, although the exact proportion of sexually active women is not known.

**Table 7: Overall rates and types of family planning method used (CSS1 and 2)\***

	Maprik		Esa'ala	
	CSS1	CSS2	CSS1	CSS2
Overall rates (% of women surveyed)	16.6%	30.4%	23%	25%
<i>Type of family planning:</i>				
Depo Provera	31 (38.3%)	58 (44.6%)	56 (54.4%)	44 (55.7%)
Oral contraceptive pill	33 (40.7%)	36 (27.7%)	28 (27.2%)	12 (15.2%)
Tubal ligation	6 (7.4%)	7 (5.4%)	13 (12.6%)	17 (21.5%)
Vasectomy	11 (13.6%)	28 (21.5%)	1 (1.0%)	0 (0%)
Ovulation method	0 (0%)	0 (0%)	4 (3.9%)	5 (6.3%)
Herbs	0 (0%)	0 (0%)	1 (1.0%)	1 (1.3%)
Other		1 (0.7%)		0 (0%)
Total	81 (100%)	130 (100%)	103 (100%)	79 (100%)

\*2 (2.4%) and 6 (5.5%) of missing answers in CSS1 and 4 (3.0%) and 2 (2.5%) of missing answers in CSS 2 from Maprik and Esa'ala excluded from analysis

**Chart 2: Comparison of types of family planning method preferred for women who reported using family planning in CSS1 and 2**



There is a significant rise in proportion of WRA who report using family planning for Maprik (RR 1.84 (95% CI 1.44 – 2.35) p<0.001). There was no change in Esa'ala, in the proportions of WRA reporting use of family planning. The increase in usage in Maprik seems to relate to an increase in users of Depo-Provera and increased uptake of vasectomy. In Esa'ala the rates of oral contraceptive usage are lower than Maprik and the rates of vasectomy are very low.

#### 4.2.6 Baseline levels of malaria infection in Maprik

As noted above, malaria infection results are only available from Maprik. All women in Maprik were recorded as having a test taken for malaria in CSS1. These are based on blood slides collected at the time of the CSS1, stored and later examined under light microscopy. Results were available from 135 pregnant and 434 non-pregnant women, as tabled below.

**Table 8: Malaria parasite detection in WRA in Maprik in CSS1**

	Pregnant (n=135)		Non-pregnant (n=434)	
	Prevalence of infection rate (%)	High parasitaemia* Number (%)	Prevalence of infection rate (%)	High parasitaemia* Number (%)
Any species	56 (41.5%)	5 (3.7%)	159 (36.6%) <sup>‡</sup>	7 (1.6%)
<i>P falciparum</i> <sup>^</sup>	51 (37.8%)	5 (3.7%)	121 (27.9%)	5 (1.2%)
<i>P vivax</i> <sup>^</sup>	5 (3.7%)	0 (0%)	26 (5.9%)	1 (0.2%)
<i>P malariae</i> <sup>^</sup>	1 (0.7%)	0 (0%)	11 (2.5%)	1 (0.2%)
Pf and Pv	1 (0.7%)	0 (0%)	4 (0.9%)	0 (0%)
Pf and Pm	0 (0%)	-	2 (0.5)	0 (0%)

\*High level of parasitaemia defined as >5,000/μL for *P. falciparum*. High level of parasitaemia defined as >1,000/μL for other *Plasmodium* species (Michon et al, 2007)

<sup>‡</sup>7 records only recorded malaria “positive” without detail of malaria species

<sup>^</sup> Includes combined infections

This provides a picture of the burden of malaria among WRA prior to the intervention. Rates of parasitaemia were slightly higher among pregnant women, but the difference was not statistically significant. Small numbers of women had high levels of parasitaemia, defined in the same terms as other studies in PNG. 3.7% of pregnant infected women had a high level of parasitaemia compared to 1.6% of non pregnant women, however this difference was not significant (even when removing the 7 records where non-pregnant women were reported malaria positive but no density was provided).

#### 4.2.7 Baseline measures of BMI

The body mass index (mass in kilograms / [height in metres]<sup>2</sup>) was calculated for non-pregnant and pregnant women in the CSS1 sample. The data cleaning highlighted some errors in height measurement, such as large differences in height being recorded for the same woman in different surveys. These were common (but non-systematic) particularly in Maprik. Approximately 30% of the paired samples had differences in heights >2cm. Obvious errors were corrected to the lower of the two heights recorded. This indicates that there may be other inaccuracies in the BMI data and so this should be treated with caution. BMI data are not reported for pregnant women, as body mass increases during pregnancy and women in the sample group were at different stages of pregnancy, making comparisons inappropriate. Low BMI for non-pregnant women was defined as less than or equal to 18.5 kg/m<sup>2</sup>.

**Table 9: Comparison of mean baseline BMI of all non-pregnant and young nulliparous women of reproductive age in Maprik and Esa'ala districts (CSS1)**

	<i>Maprik mean BMI (95% CI)</i>	<i>Esa'ala mean BMI (95% CI)</i>	<i>Difference in means (Maprik – Esa'ala) (95% CI)</i>	<i>P-value</i>
All non-pregnant	22.76 (22.54 – 22.98) n=495	20.76 (20.55 – 20.96) n=475	2.01 (1.71 – 2.31)	<0.001
Young nulliparous (15-21 years)	23.16 (22.60 – 23.72) n=82	21.27 (20.68 – 21.84) n=56	1.89 (1.07 – 2.72)	<0.001

**Table 10: Comparison of the number and percentage of non-pregnant women with low BMI (BMI <18.5kg/m<sup>2</sup>) in Maprik and Esa'ala districts (CSS1)**

	<i>BMI ≥ 18.5 kg/m<sup>2</sup></i>	<i>&lt;18.5 kg/m<sup>2</sup> (low BMI)</i>
<i>Maprik</i>	485 (97.6%)	12 (2.4%)
<i>Esa'ala</i>	404 (85.1%)	71 (15.0%)

There were significant differences between Maprik and Esa'ala, with Maprik recording higher BMIs. The proportion women with low BMI (<18.5) in Maprik was significantly less than in Esa'ala. This difference may, however, be explained by differences in measurement technique. Given the likelihood of inaccurate height measurements, BMI was not incorporated further in analysis.

#### 4.2.8 Baseline measures of haemoglobin and anaemia

Haemoglobin levels were measured in the field using HemoCue photometer. Because they were the primary outcome measure they received particular scrutiny. The process of analysis suggests that the quality of this data is reliable and valid. Results were available for all but a few of WRA surveyed in CSS1.

Haemoglobin measures, here and in subsequent comparisons is presented as continuous and categorical variables, with most analyses producing similar changes for the two different types of variable.

Baseline mean haemoglobin levels for each district are tabled, and the districts compared. The left-hand column comprises sub-groups of WRA who could be potential targets of nutritional interventions.

**Table 11: Mean baseline haemoglobin comparing Maprik and Esa'ala (CSS1)**

	<i>Maprik mean Hb (95% CI)</i>	<i>Esa'ala mean Hb (95% CI)</i>	<i>Difference in means (Maprik – Esa'ala) (95% CI)</i>	<i>P-value</i>
All pregnant	8.74 (8.52 – 8.96) n=154	9.59 (9.37 – 9.81) n=162	-0.85 (-1.16 - -0.54)	p<0.001
Primiparous	7.69 (7.16 – 8.22) n=25	9.84 (9.16 – 10.52) n=31	-2.15 (-3.03 - -1.27)	p<0.001
All non-pregnant	10.36 (10.25 – 10.47) n=495	11.15 (11.02 – 11.27) n=473	-0.79 (-0.95 - -0.62)	p<0.001
Young nulliparous (15-21 years)	10.44 (10.16 – 10.72) n=82	11.48 (11.15 – 11.81) n=56	-1.04 (-1.47 - -0.61)	p<0.001

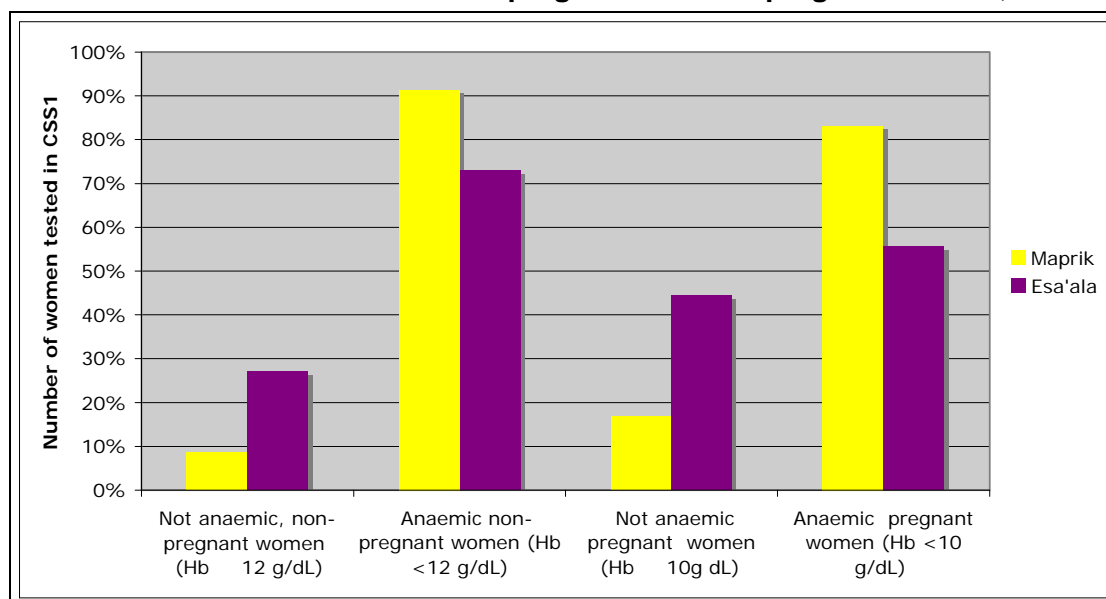
In all groups, mean haemoglobin levels were significantly lower in Maprik than in Esa'ala. Primipara had significantly lower haemoglobins than other pregnant women in Maprik.

Local cut-offs for anaemia were used in the categorical analysis. Later analyses include more categories, however the baseline analysis here terms anaemia as haemoglobin less than 12 g/dL in non-pregnant women and 10 g/dL in pregnant women. Comparisons between districts are tabled below.

**Table 12: Anaemia rates, baseline, in Maprik and Esa'ala**

<i>District</i>	<i>Haemoglobin (g/dL)</i>			
	<i>Non-pregnant women</i>		<i>Pregnant women</i>	
	<i>≥ 12</i>	<i>&lt;12</i>	<i>≥ 10</i>	<i>&lt;10</i>
Maprik	43 (8.7%)	452 (91.3%)	26 (16.9%)	128 (83.1%)
Esa'ala	128 (27.1%)	345 (72.9%)	72 (44.4%)	90 (55.6%)

**Chart 3: Baseline anaemia rates for pregnant and non-pregnant women, CSS1**



Very high rates of anaemia were found, with 91.3% (in Maprik) and 72.9% (in Esa'ala) of non-pregnant women having anaemia. Significantly more non-pregnant women in Maprik were anaemic (Hb<12) (RR 1.25; 95%CI 1.18 – 1.33; p<0.001) and significantly more pregnant women (Hb<10) (RR 1.50; 95%CI 1.28 – 1.75; p<0.001).

#### 4.2.9 Interaction between malaria and anaemia

Baseline haemoglobin levels, both as mean haemoglobin and as rates of anaemia, were stratified by rates of positivity for any malaria parasite and are tabled below. Stratification by women with malaria and high parasitaemia was not possible due to the small numbers involved.

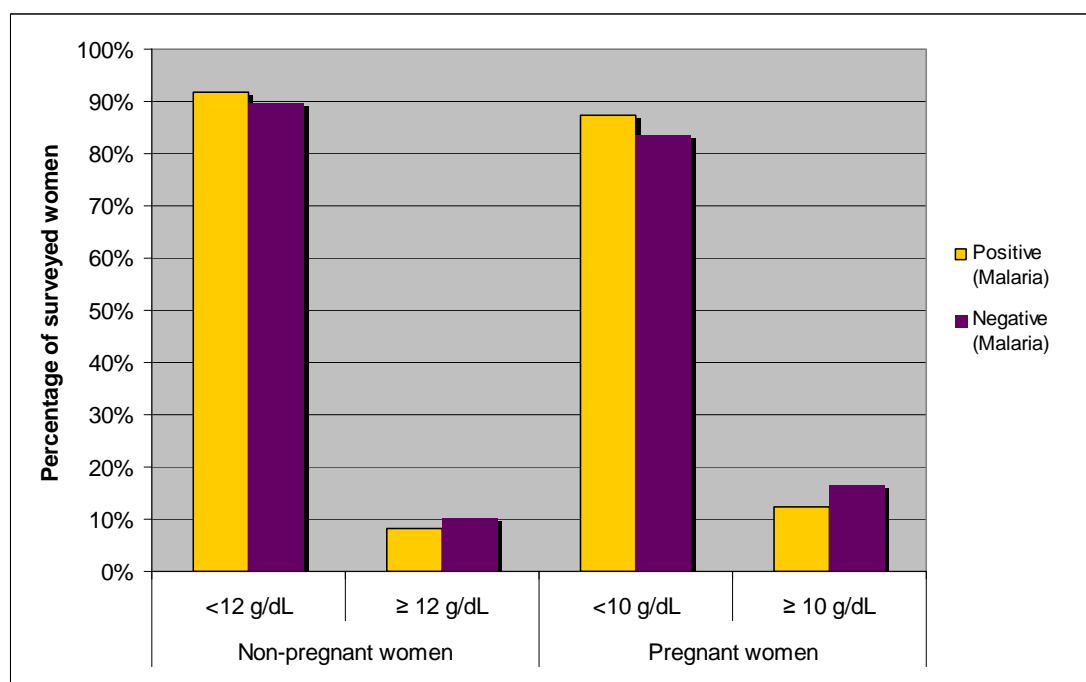
**Table 13: Malaria and haemoglobin in Maprik CSS1**

	No malaria infection Mean (95% CI) n	Malaria infection Mean (95% CI) n	Difference in means (95% CI)	P-value
All women	10.14 (9.99 – 10.30) n=352	9.73 (9.53 – 10.11) n=215	0.41 (0.16 – 0.66)	0.001
All non-pregnant	10.50 (10.36 – 10.65) n=273	10.18 (9.97 – 10.39) n=159	0.32 (0.07 – 0.58)	0.012
Pregnant	8.90 (8.58 – 9.21) n=79	8.45 (8.13 – 8.77) n=56	0.45 (-0.02 – 0.91)	0.058

**Table 14: Malaria and anaemia rates, Maprik CSS1**

Malarial infection	Haemoglobin (g/dL)			
	Non-pregnant women		Pregnant women	
	<12	≥ 12	<10	≥ 10
Positive	146 (91.8%)	13 (8.2%)	49 (87.5%)	7 (12.5%)
Negative	245 (89.7%)	28 (10.3%)	66 (83.5%)	13 (16.5%)

**Chart 4: Comparison of haemoglobin concentrations and malarial infection in pregnant and non-pregnant women of Maprik district (CSS1)**



Note: As outlined above, local cut-off haemoglobin levels were used to identify anaemic women, ie. haemoglobin less than 12 g/dL in non-pregnant women and less than 10 g/dL in pregnant women.

Mean haemoglobin levels were lower in those with malaria, attaining statistical significance for the group of all WRA and those who were not pregnant. When assessed using anaemia categories, women were not significantly more likely to be anaemic (Hb<12g/dL). (Non-pregnant: RR 1.02; 95% CI 0.96 – 1.09; p=0.477; pregnant: RR 1.05; 95% CI 0.91 – 1.20; p=0.524).

Thus, there was some association between lower haemoglobin levels and malaria infection, however the association was not sufficiently strong to explain all of the prevalence of anaemia in this group. This stratified analysis was repeated in subsequent surveys with similar results: that there was some association between anaemia and malaria, but that anaemia remained highly prevalent even when malaria was excluded from the analysis.

### 4.3 Intervention surveys among pregnant women

The intervention period attempted to follow as many pregnant women as possible through the intervention period. In addition to a village-based register of births (see

below), this involved four surveys (of which three can be analysed) at 10 week intervals.

### 4.3.1 Intervention survey participants

Pregnant women enrolled in each survey are tabled below. The numbers of women who were enrolled in each survey were very close to expected.

**Table 15: Enrolment of pregnant women in three intervention surveys**

	<i>Timing</i>	<i>Maprik</i>	<i>Esa'ala</i>
<i>INT 1</i>	February to early April	174	176
<i>INT 2</i>	April to early June	170	177
<i>INT 3</i>	June to early September (Maprik) early August (Esa'ala)	176	144

Some women appeared in more than one survey, and a few women appeared in all three. As noted above, both unpaired analyses and paired analyses have been performed to investigate changes. The unpaired analyses track change in the general population of pregnant women, hypothesising that there will be improvements in health status of this group as a whole, as the intervention progresses. The paired analyses consolidate changes in haemoglobin or anaemia rates for individual women, testing whether such changes achieve statistical significance. The paired analyses necessarily have smaller sample sizes, because they require women to appear in more than one survey.

The first intervention survey can be considered as a baseline for this group of pregnant women because:

- the first distribution of antimalarial was at this point, and
- micronutrient supplementation either started at this point (for many women) or only shortly prior to this point.

### 4.3.2 Changes in haemoglobin levels, anaemia rates and observed pallor

Overall, both paired and unpaired analyses showed an increase in haemoglobin and decrease in anaemia among pregnant women during the intervention period. This was most marked when comparing INT1 data with INT3. This was supported by the health team's observations of rates visible pallor among pregnant women.

### Haemoglobin levels

Changes in haemoglobin over the three intervention surveys are presented below.

**Table 16: Mean haemoglobin levels in three intervention surveys**

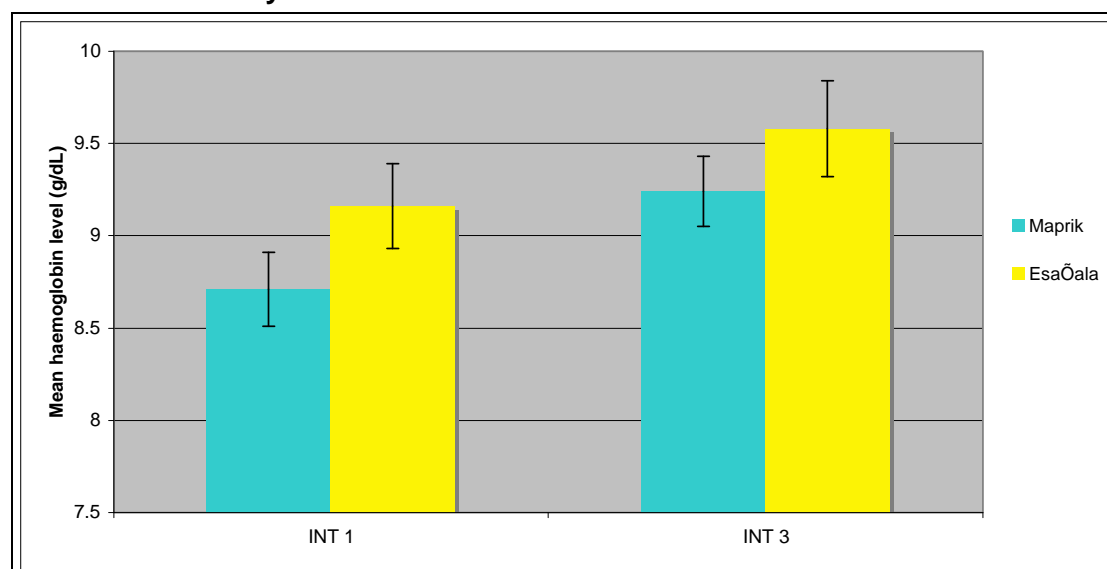
	Maprik			Esa'ala		
	Number of pregnant women	Mean Hb	95%CI	Number of pregnant women	Mean Hb	95%CI
INT 1	173	8.71	8.51 – 8.91	171	9.16	8.94 – 9.39
INT 2	169	9.05	8.86 – 9.24	174	9.35	9.04 – 9.46
INT 3	115	9.24	9.05 – 9.43	143	9.58	9.32 – 9.83

This shows a general increase over the period of the three surveys, and differences in these means were analysed for statistical significance, presented below. The most striking change is between the first (baseline) intervention survey and the third intervention survey, which took place between four and seven months later. This is tabled and charted below.

**Table 17: Unpaired comparison of mean haemoglobins in INT1 and INT 3**

	INT 1 Mean (95%CI)	INT 3 Mean (95%CI)	Mean difference INT3 - INT1 (95%CI)	P-value
Maprik	8.71 (8.51 – 8.91)	9.24 (9.05 – 9.43)	0.53 (0.24 – 0.81)	<0.001
Esa'ala	9.16 (8.94 – 9.39)	9.58 (9.32 – 9.83)	0.41 (0.07 – 0.75)	0.018

**Chart 5: Comparison of mean haemoglobin levels in the first and third intervention surveys**



When individual pregnant women were assessed across two surveys (that is, across approximately 10 week intervals), on average their haemoglobin levels were found to

increase. Paired analyses tested these increases across the three surveys for statistical significance, presented below.

**Table 18: Paired analysis of pregnant women with two haemoglobin measures**

	<i>Changes between:</i>	<i>Mean Haemoglobin and 95% CIs</i>		<i>Difference in means (95%CI)</i>	<i>P-value</i>
<i>Maprik</i>	INT1 and INT2 (n=80)	8.66 (8.35 – 8.96)	9.12 (8.85 – 9.39)	0.47 (0.21 – 0.73)	<0.001
	INT2 and INT3 (n=49)	8.88 (8.52 – 9.25)	9.42 (9.14 – 9.70)	0.53 (0.25 – 0.81)	<0.001
	INT 1 and INT 3 (n=23)	8.82 (8.16 – 9.47)	9.38 (8.91 – 9.86)	0.57 (-0.11 – 1.24)	0.095
<i>Esa'ala</i>	IN1 and INT 2 (n=58)	9.23 (8.84 – 9.62)	9.46 (9.11 – 9.81)	0.22 (-0.19 – 0.63)	0.278
	INT2 and INT3 (n=65)	9.22 (8.86 – 9.58)	9.99 (9.64 – 10.34)	0.77 (0.43 – 1.11)	<0.001
	INT1 and INT3 (n=28)	9.71 (9.20 – 10.23)	10.18 (9.67 – 10.68)	0.46 (-0.20 – 1.12)	0.164

There is a significant rise in haemoglobin among mothers who were measured twice. Although two of the individual survey comparisons in Esa'ala, and one of Maprik, do not reach statistical significance, Chi square for linear trend is significant in Esa'ala over the three intervention surveys (p=0.024), as it clearly is for Maprik as well.

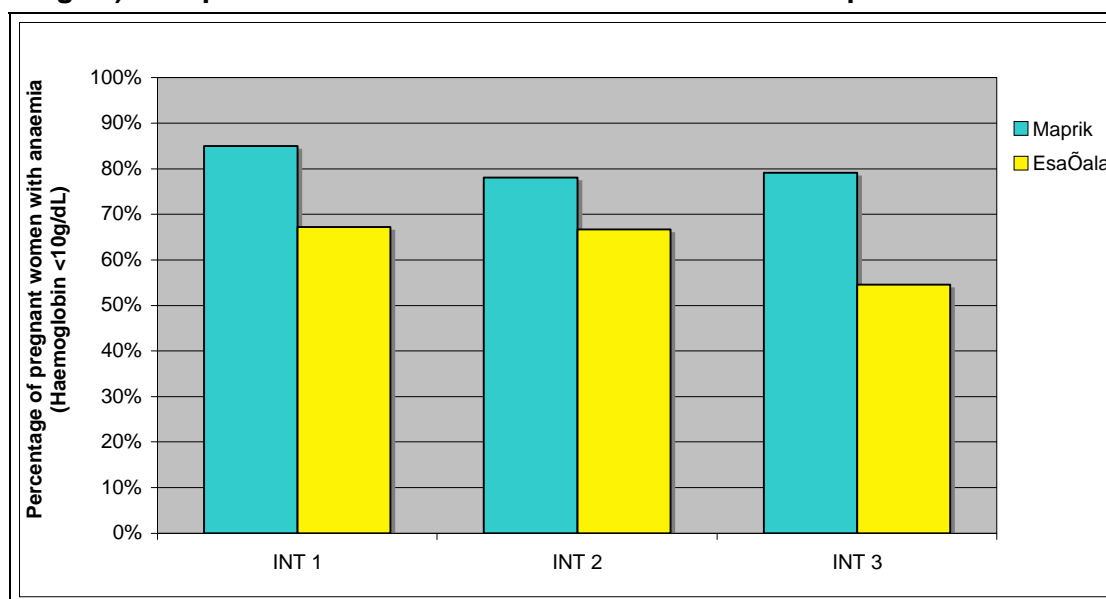
## Anaemia

Local categories were used to define anaemia and changes in proportions of populations with anaemia were examined across the three intervention surveys.

**Table 19: Anaemia rates during intervention surveys**

<i>District</i>	<i>Survey</i>	<i>Haemoglobin g/dL</i>		<i>Chi square for linear trend</i>	<i>RR for increase in non-anaemic women from INT1 to INT3</i>
		<i>Pregnant women</i>			
		<i>≥ 10</i>	<i>&lt;10</i>		
<i>Maprik</i>	INT 1	26 (15.0%)	147 (85.0%)	p=0.170	RR 1.39 95%CI 0.84 – 2.29 p=0.200
	INT 2	37 (21.9%)	132 (78.1%)		
	INT 3	24 (20.9%)	91 (79.1%)		
<i>Esa'ala</i>	INT 1	56 (32.7%)	115 (67.3%)	p=0.024	RR 1.39 95%CI 1.05 – 1.84; p=0.021
	INT 2	58 (33.3%)	116 (66.7%)		
	INT 3	65 (45.5%)	78 (54.5%)		

**Chart 6: Percentage of pregnant women with anaemia (haemoglobin concentration <10g/dL) in Maprik and Esa'ala districts across the intervention period**



There is a general trend that the proportion of pregnant women with anaemia (defined in PNG terms) decreases during the intervention. This is not statistically significant in Maprik, but is significant in Esa'ala.

The categories of anaemia were examined more closely to try to track changes in proportions of women with more severe forms of anaemia. These are tabled below:

**Table 20: Changes in categories of anaemia across three intervention surveys**

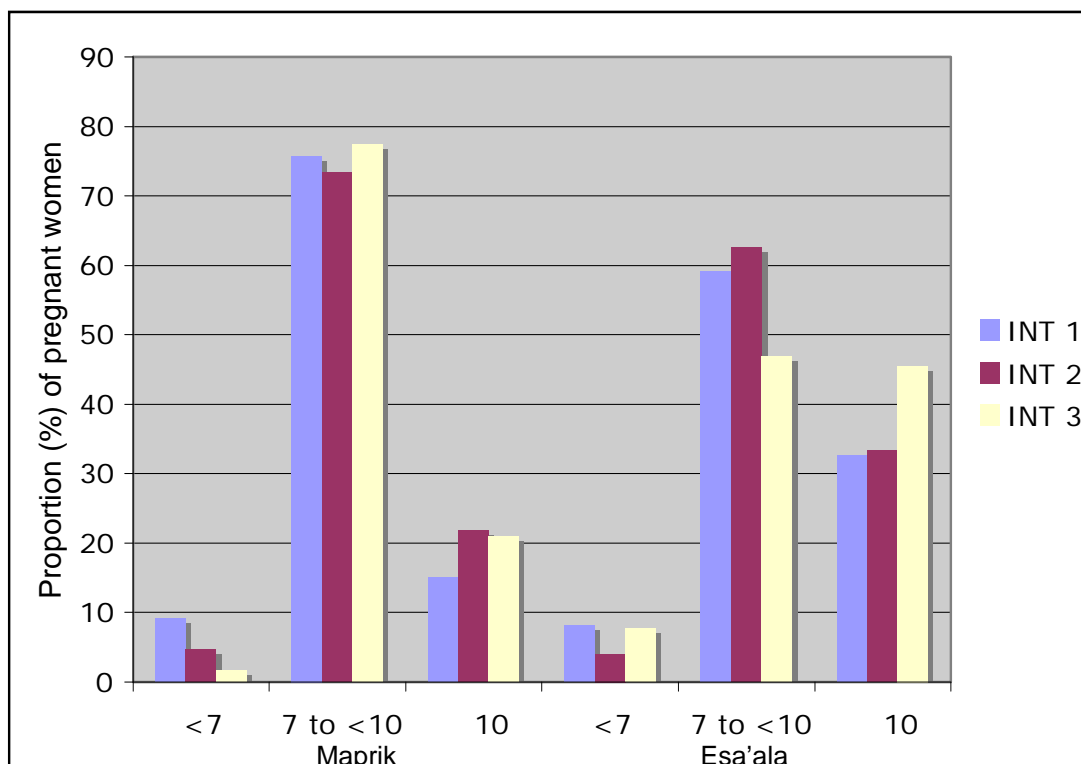
	Anaemia category by haemoglobin in g/dL	INT 1 Number (%)	INT 2 <sup>†</sup> Number (%)	INT 3 Number (%)
Maprik	<7	16 (9.2%)	8 (4.7%)	2 (1.7%)
	7 to <10	131 (75.7%)	124 (73.4%)	89 (77.4%)
	≥10	26 (15.0%)	37 (21.9%)	24 (20.9%)
Esa'ala	<7	14 (8.2%)	7 (4.0%)	11 (7.7%)
	7 to <10	101 (59.1%)	109 (62.6%)	67 (46.9%)
	≥10	56 (32.7%)	58 (33.3%)	65 (45.5%)

<sup>†</sup>1 (0.6%) missing answer excluded from Maprik analysis.

\*5 (2.8%) and 2 (1.1%) of missing answers from Int 1 and Int 2 respectively, excluded from Esa'ala analysis

This table, and the chart below, illustrate that anaemia improves, but in different patterns in each district. In Maprik the proportion of pregnant women with severe anaemia (<7) declines through the intervention period, but the proportion of women who shift from moderate anaemia to normal does not change greatly. In Esa'ala, the proportion with severe anaemia does not change greatly, but there is a greater rise in the proportions with moderate anaemia who improve.

**Chart 7: Proportion of pregnant women with various categories of anaemia during Intervention surveys**



**Visible pallor**

Women were assessed by the health team for visible pallor in each survey. This was a subjective measure, and potentially subject to observer error.

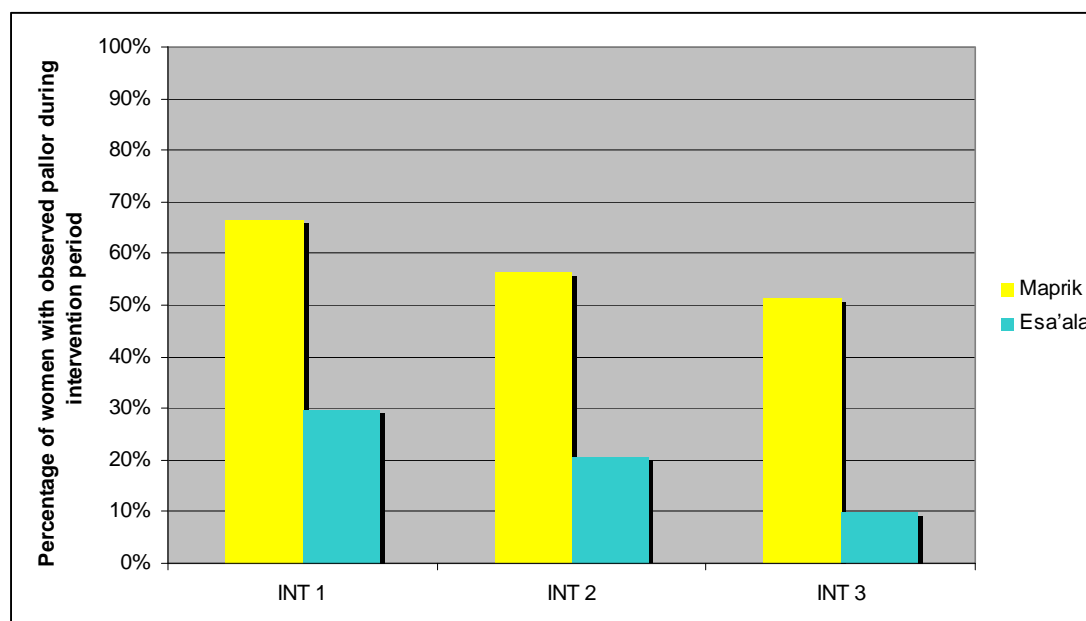
**Table 21: Changes in observed pallor over three intervention surveys**

	<i>INT 1</i>	<i>INT 2</i>	<i>INT 3</i>
<i>Maprik</i>	66.3%	56.3%	51.4%
<i>Esa'ala</i>	29.8%	20.6%	9.9%

Measured as a proportion of women surveyed, with missing values excluded.

This is provided as a chart, below:

**Chart 8: Comparison of the percentage of women with observed pallor in Maprik and Esa'ala districts over three intervention periods**



The trend supports the data on anaemia – suggesting a decrease in anaemia over the course of the intervention, however the observations in Esa'ala suggest a greater decline than that shown in the blood results.

### 4.3.3 Malaria in Maprik during the intervention period

Identification numbers were used to match malaria results to pregnant women in Maprik in the intervention surveys. Names and villages were also checked. Any malaria results that could not be matched to a survey identification numbers were dropped. This resulted in some decrease in the size of the study population, with the loss of 14 of 179 results from INT1, loss of 7 of 105 from INT2 and 23 of 109 in INT3.

### Changes in malaria infection across the three surveys

The rates of malaria changed over the three surveys. Intervention 1 survey can be considered as a baseline as women would not have received antimalarial treatment prior to this survey. The changes during the intervention period are tabled here. This data is also compared with that in the cross-sectional surveys, in section 4.4 below.

**Table 22: Malaria infection and severity of malaria infection across intervention surveys\***

Malaria species	Intervention 1 n=165 (February to April)		Intervention 2 n=98 (April to June)		Intervention 3 n=87 (June to September)	
	Any infection Number (%)	High parasitaemia Number (%)	Any infection Number (%)	High parasitaemia Number (%)	Any infection Number (%)	High parasitaemia Number (%)
<i>Pf</i>	37 (22.4%)	2 (1.2%)	14 (14.3%)	2 (2.0%)	15 (17.2%)	1 (1.1%)
<i>Non Pf</i>	7 (4.2%)	1 (0.6%)	1 (1.0%)	0 (0%)	7 (8.0%)	0 (0%)
<i>Any species</i>	44 (26.7%)	3 (1.8%)	16 <sup>‡</sup> (16.3%)	2 (2.0%)	22 (25.3%)	1 (1.1%)

\*Denominator is those that were tested for malaria in each intervention survey

<sup>‡</sup>1 malaria result included in total lacked sufficient detail to describe species

As in the cross-sectional surveys, plasmodium falciparum is the most prevalent and small numbers (1 to 2%) of pregnant women suffered with high parasitaemia. The overall prevalence of malaria is lower in these intervention surveys than the CSS1 in which 41.5% of pregnant women tested had malaria parasites, as did 36.6% of non-pregnant women. While there is a drop in prevalence from INT1 to INT2, there is then a rise in prevalence in INT3. It should be noted that the intervention surveys covered a different season of the year.

### Malaria and parity

Assessing the relationship between malaria and parity necessarily limited the analysis to those in whom parity could be determined – this was based on linking identification numbers to information provided in the census and CSS1.

The tables below compare the prevalence of any malaria infection between primipara and multipara. In these tables the data from INT 2 and INT 3 are combined, because it is assumed that pregnant women in INT1 had not been treated with antimalarials prior to the malaria test, but many (but not all) women in INT2 and INT3 would have had at least some treatment with antimalarials prior to the test. In this analysis, within INT1, we are testing whether malaria is associated with parity among women who have not yet started intermittent treatment. Within INT 2 and 3, we are testing whether malaria is associated with parity among women who are already on intermittent treatment.

**Table 23: Parity and any malaria infection in the intervention surveys**

Parity	Any malaria infection			
	INT1		INT 2 and 3	
	Positive	Negative	Positive	Negative
Primiparous	13 (52.0%)	12 (48.0%)	8 (29.6%)	19 (70.4%)
Multiparous	22 (20.0%)	88 (80.0%)	21 (18.3%)	94 (81.7%)
<i>RR of primipara having any malaria infection</i>	RR 2.60 (95%CI 1.53 – 4.42) p=0.001		RR 1.62 (95%CI 0.81 – 3.26) p=0.187	

\*39 (22.4%) results in INT1 lacked information on parity or malaria infection and excluded from analysis; 144 (50.3%) results in INT2 and INT3 lacked information on parity or malaria infection and excluded from analysis.

These results suggest that, in the group prior to the start of intermittent treatment, primiparous women were more likely to have malaria infection than multiparous women. However after intermittent treatment has commenced (in INT 2 and 3), the association between primiparity and malaria infection is not as strong and is not statistically significant. The antimalarial treatment provided as part of the intervention may help to explain this, although seasonality of malarial infection and the small numbers available for analysis will also play a part.

Of the six pregnant women in the interventions surveys who had high parasitaemia, two had sequential malaria results available. One of these cases, a primiparous woman, had a low Pf parasitaemia in INT1, had no infection in INT2 and then had a high Pf parasitaemia in INT3. The other case, a multiparous woman, had a high Pf parasitaemia in INT2 and a low Pf parasitaemia in INT3. Both women were reported to have received antimalarial treatment during the surveys. These cases have several potential explanations: re-infection with *plasmodium falciparum*, (and a lack of prolonged protection from subsequent infection by preventive antimalarial medication); or inadequate clearance of malaria parasites from the medication; or data error; or lack of compliance with treatment.

#### **4.4 *Changes from baseline (Oct-Dec 06) to post-intervention (Nov- Dec 07) cross-sectional surveys***

As discussed above, the second cross-sectional survey, CSS2, was able to access fewer villages than CSS1 for a variety of external factors. In CSS2 there were 527 WRA recruited in Maprik from 33 villages and 394 WRA recruited in Esa'ala from 30 villages. This provides a satisfactory sample size for comparison. There was a smaller proportion of pregnant women in CSS2 than in CSS1, although still more than in the census. While these facts raise the potential for bias, such as a bias to inclusion of healthier villages, a review of those villages that were included suggests that there is not sufficient bias to invalidate the analysis. Comparison of the two cross-sectional surveys allows analysis of changes in anaemia outcomes for non-pregnant as well as pregnant women, following 10 months of intervention. It also allows tracking of malaria trends in Maprik across a 14 month period, and comparison of bed-net use prior to and after the intervention.

#### 4.4.1 Changes in haemoglobin and anaemia between cross-sectional surveys

The table below summarises the changes in mean haemoglobin for different groups of WRA between the two cross-sectional surveys. The changes, in terms of anaemia rates, are displayed in a chart at the end of this section.

**Table 24: Unpaired analysis of change in haemoglobin between CSS1 and CSS2 for different groups of WRA**

		CSS1 Mean* (95% CI)	CSS2 Mean (95% CI)	Difference in means CSS2 – CSS1 (95% CI)	P-value
Maprik	All pregnant	8.74 (8.52 – 8.96) n=154	9.28 (8.98 – 9.57) n=99	0.54 (0.18-0.90)	0.004
	Primiparous	7.69 (7.16 – 8.22) n=25	10.22 (9.44 – 10.99) n=13	2.52 (1.62 – 3.43)	<0.001
	All non-pregnant	10.36 (10.25 – 10.47) n=495	10.62 (10.49 – 10.75) n=424	0.26 (0.09 – 0.43)	0.003
	Young nulliparous (15-21 years)	10.44 (10.16 – 10.72) n=82	11.01 (10.66 – 11.35) n=46	0.57 (0.12 – 1.02)	0.013
Esa'ala	All pregnant	9.59 (9.37 – 9.81) n=162	9.73 (9.29 – 10.17) n=60	0.14 (-0.30 – 0.59)	0.533
	Primiparous	9.84 (9.16 – 10.52) n=31	9.24 (8.30 – 10.19) n=9	-0.60 (-1.95 – 0.75)	0.376
	All non-pregnant	11.15 (11.02 – 11.27) n=473	11.10 (10.92 – 11.29) n=288	-0.04 (-0.26 – 0.17)	0.686
	Young nulliparous (15-21 years)	11.48 (11.15 – 11.81) n=56	11.40 (11.19 – 11.72) n=23	-0.07 (-0.65 – 0.50)	0.792

\*2 and 1 missing or invalid answers from CSS1 and CSS2 respectively in Maprik, and two missing or invalid answers excluded from analysis + 45 (11.4%) missing answers in Esa'ala, were excluded from analysis.

There is a significant rise in haemoglobin for all groups in Maprik, all of which are statistically significant. The greatest rise, by a mean haemoglobin of 2.52 g/dL, is among primipara. There are no significant changes in haemoglobin for these populations in Esa'ala. It should be noted that more than 10% of women in Esa'ala in CSS2 had missing answers for haemoglobin, and this may have affected the validity of the analysis.

## Changes in anaemia in non-pregnant women

Comparisons for anaemia between CSS1 and CSS2, using local definitions, for non-pregnant women were also made, as tabled below:

**Table 25: Changes in anaemia in non-pregnant women, CSS1 to CSS2**

	<i>Haemoglobin (g/dL)</i>			
	<i>Maprik</i>		<i>Esa'ala</i>	
	$\geq 12$	$<12$	$\geq 12$	$<12$
<i>CSS1</i>	43 (8.7%)	452 (91.3%)	128 (27.1%)	345 (72.9%)
<i>CSS2</i>	69 (16.3%)	355 (83.7%)	77 (26.7%)	211 (73.3%)
<i>RR of women in CSS2 not being anaemic</i>	RR 1.87; 95%CI 1.31 – 2.68; p<0.001		RR 0.99; 95%CI 0.78 – 1.26; p=0.922	

\* Anaemia in non-pregnant women is defined as haemoglobin concentration <12g/dL

The proportion of non-pregnant women without anaemia (Hb >12) increased significantly between CSS1 and 2 in Maprik but not in Esa'ala. Young nulliparous women were a particular target group for improved nutrition and changes in anaemia for this group are tabled:

**Table 26: Changes in anaemia, CSS1 to CSS2, for young nulliparous women (15 – 21 years)**

	<i>Haemoglobin (g/dL)</i>			
	<i>Maprik</i>		<i>Esa'ala</i>	
	$\geq 12$	$<12$	$\geq 12$	$<12$
<i>CSS1</i>	6 (7.3%)	76 (92.7%)	18 (32.1%)	38 (67.9%)
<i>CSS2</i>	9 (19.6%)	37 (80.4%)	4 (17.4%)	19 (82.6%)
<i>RR of women in CSS2 not being anaemic</i>	RR 2.67; 95%CI 1.02 – 7.04; p=0.039		RR 0.54; 95%CI 0.21 – 1.43; p=0.270 [2-sided fisher exact]	

\* Anaemia in non-pregnant women is defined as haemoglobin concentration <12g/dL

This shows that the proportion of young nulliparous women who do not have anaemia increased significantly between CSS1 and 2 in Maprik, but not in Esa'ala.

## Changes in anaemia in pregnant women

Changes in anaemia rates, using local definitions, for pregnant women, from CSS1 to CSS2 are tabled below.

**Table 27: Changes in anaemia in pregnant women, CSS1 to CSS2**

	<i>Haemoglobin (g/dL)</i>			
	<i>Maprik</i>		<i>Esa'ala</i>	
	$\geq 10$	$<10$	$\geq 10$	$<10$
<i>CSS1</i>	26 (16.9%)	128 (83.1%)	72 (44.4%)	90 (55.6%)
<i>CSS2</i>	34 (34.3%)	65 (65.7%)	28 (46.7%)	32 (53.3%)
<i>RR of women in CSS2 not being anaemic</i>	RR 2.03; 95%CI 1.31 – 3.17; p=0.001		RR 1.05; 95%CI 0.76 – 1.45; p=0.768	

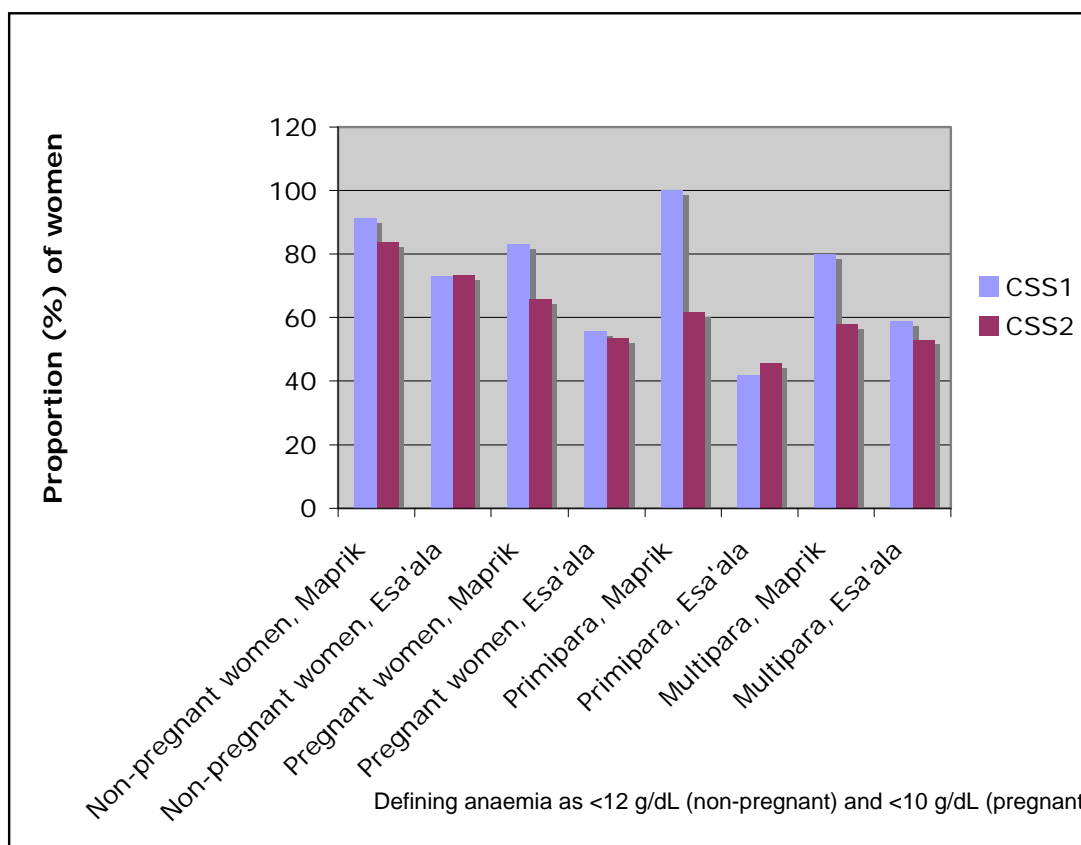
There was a significant increase in the proportion of pregnant women who were not anaemic in CSS2 in Maprik, but not in Esa'ala. This increase was particularly marked in primipara, and particularly due to a marked drop in the number of primipara with severe or very severe anaemia, as shown below.

**Table 28: Changes from CSS1 to CSS2 in the number and percentage of primiparous women in each category of anaemia**

Haemoglobin (g/dL)	Maprik		Esa'ala	
	CSS1 Number (%)	CSS2 Number (%)	CSS1 Number (%)	CSS2 Number (%)
<7	7 (28.0%)	0 (0%)	3 (9.7%)	1 (11.1%)
7 to <10	18 (72.0%)	8 (61.5%)	10 (32.3%)	4 (44.4%)
≥10	0 (0%)	5 (38.5%)	18 (58.1%)	4 (44.4%)

When using a cut-off of 10 g/dL, the proportion of primiparous women in Maprik with haemoglobin >10 increased significantly between CSS1 and 2 (RR Undefined; 95% CI undefined; p=0.003 [2-sided fisher exact]).

**Chart 9: Changes in proportion of women with anaemia among various categories of women from baseline to follow-up (CSS1 to CSS2)**



**4.4.2 Changes in malaria in Maprik between CSS1 and CSS2**

Malaria results have been stratified for pregnant and non-pregnant women, to allow comparison with malaria rates during the intervention surveys. The tables below show rates of infection with any parasite in Maprik, comparing the two surveys.

**Table 29: Changes recorded between CSS1 and CSS2 in the number and percentage of malaria infection (any species) in pregnant and non-pregnant women in Maprik**

	<i>Pregnant</i>	<i>Non-pregnant</i>
<i>CSS 1 Nov – Dec 2007</i>	56 (41.5%)	159 (36.6%)
<i>CSS 2 Oct – Dec 2006</i>	18 (20.0%)	102 (26.1%)
<i>RR of infection in CSS2 compared to CSS1</i>	RR 0.48; 95%CI 0.30 – 0.76; p<0.001	RR 0.71; 95%CI 0.58 – 0.88; p=0.001

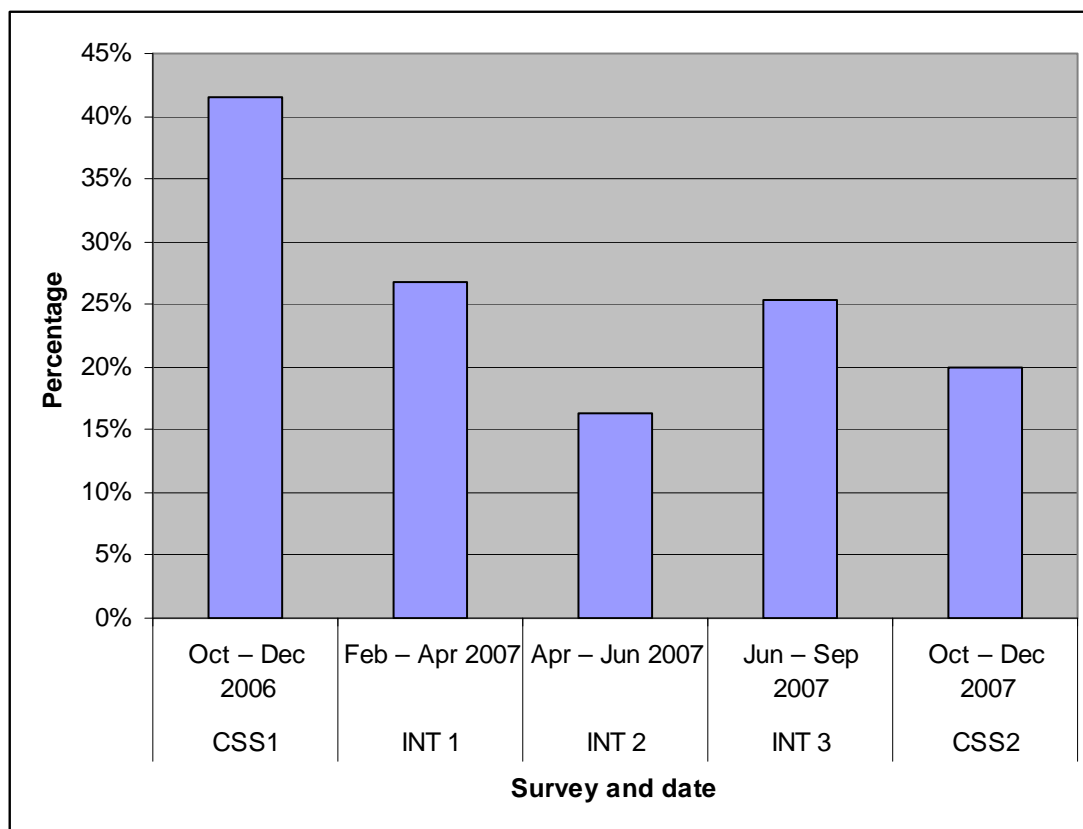
There was a significant reduction (approximately a halving) of malaria infections among pregnant women between CSS1 and CSS2. There was also a significant drop in infections among non-pregnant women. Both CSSs were carried out at a similar time of year, so it is felt that these rates are comparable.

An assessment of trend in malaria infection was carried out for pregnant women, to include the results from the intervention surveys. This covered a period from October 2006 through to December 2007. These results are tabled and charted below.

**Table 30: Trends in any malaria infection among pregnant women in Maprik**

<i>Survey</i>	<i>Date</i>	<i>Malaria infection (%)</i>
<i>CSS1</i>	<i>Oct – Dec 2006</i>	<i>41.5%</i>
<i>INT 1</i>	<i>Feb – Apr 2007</i>	<i>26.7%</i>
<i>INT 2</i>	<i>Apr – Jun 2007</i>	<i>16.3%</i>
<i>INT 3</i>	<i>Jun – Sep 2007</i>	<i>25.3%</i>
<i>CSS2</i>	<i>Oct – Dec 2007</i>	<i>20%</i>

**Chart 10: Trends in any malaria infection among pregnant women in Maprik**



Malaria results from CSS2 also give a second snapshot of the balance of species and parasitaemia among pregnant and non-pregnant women. These are tabled below. Not all records could be included in this analysis. 570 malaria slides were taken during CSS2 in Maprik from which 527 results are available. Of these 486 had valid identification numbers that allowed them to be merged with the main datafiles, and a further two results were dropped because the malaria results shared the same identification number but had discordant results. This left 484 results from CSS2 available for analysis.

**Table 31: Malaria infection in all WRA CSS2. (n=484)**

<i>Plasmodium</i> species	CSS2 sample infected <sup>†</sup> (n=484) Number (%)	High level of parasitaemia* Number (%)	Geometric mean parasite density (95% CI)
<i>P. falciparum</i> <sup>^</sup>	76 (15.7%)	3 (0.6% overall [or 3.9% of those infected with Pf ])	241 (173 – 335)
<i>P. vivax</i> <sup>^</sup>	34 (7.0%)	0 (0%)	61 (49 – 75)
<i>P. malariae</i> <sup>^</sup>	13 (2.7%)	0 (0%)	85 (62 – 116)
<i>P. ovale</i>	1 (0.2%)	0 (0%)	40
Pf and Pv	7 (1.4%)	0 (0%)	-
Pm and Pv	1 (0.2%)	0 (0%)	-
Any malaria species	121 <sup>†</sup> (25.0%)	3 (0.6% overall [or 2.5% of those with malarial infection])	-

\* High level of parasitaemia defined as >5,000/μL for *P. falciparum*. High level of parasitaemia defined as >1,000/μL for other *Plasmodium* species

<sup>†</sup>5 additional results lacked details of malaria species

<sup>^</sup> Includes combined infections

Baseline rates for falciparum and other species are recorded in section 4.3. As with CSS1, pregnant and non-pregnant women were compared. In contrast to CSS1, rates among non-pregnant women were slightly higher in CSS2.

#### 4.4.3 Changes in bed-net usage from pre-program to CSS2

Bed-net usage was assessed in the Census (mid 2006) and then in CSS2 (late 2007). In the census, it was reported that, in Maprik 82.7% of women had a bed-net in their household (mean per household of 2.04) and in Esa'ala 93.9% of women had a bed-net in their household (mean per household of 2.22). So bed-nets were widely distributed, if not used, prior to the start of the EPO program. There had been significant further distribution of bed-nets, through the EPO program and through other means during this period of time. The table below compares the answers to the question "Did you sleep under a bed-net last night" from the census to CSS2.

**Table 32: Bed-net use from Census to CSS2**

"Did you sleep under a bed-net last night"	Maprik		Esa'ala	
	Census	CSS2	Census	CSS2
Yes	2,838 (77.3%)	303 (78.1%)	2,130 (57.6%)	290 (88.2%)
No	834 (22.7%)	85 (21.9%)	1,565 (42.4%)	39 (11.9%)

\*excluding missing answers, noting that missing answers in the census were <1% but missing answers in CSS2 were 26.4% and 16.5% of missing answers from Maprik and Esa'ala respectively

There was a significant rise in reported bed-net use in Esa'ala, however not for Maprik. Comparisons of usage between pregnant and non-pregnant women showed no significant difference between these groups in either district. Because the baseline data was collected in the census (as opposed to CSS1), with minimal demographic data only, it is difficult analyse these populations further. Also, given the fact that the

“before” and “after” surveys in this comparison are very different in sample size and method, it is difficult to draw detailed conclusions from this comparison. As discussed in section three, bed-net distribution took place prior to the intervention in many sites, which also confounds this comparison.

## **4.5 Birth outcomes, delivery complications and birth-weights**

### **4.5.1 Data in the birth register**

The birth register attempted to capture birth outcomes from the period before and during the intervention. Particularly for the period before the intervention, this included birth records from health facilities. For the period of the intervention, this included records kept, as part of the EPO program, by VHVs, as well as records from health facilities. There were 558 records available, across both districts, but there were omissions in a number of fields, understandable when dealing with data collected at community level in PNG. In addition, there were fewer than expected (approximately half expected) births recorded in the register overall, especially in Esa’ala during the intervention period. Of the 558 records:

- Five records lacked sufficient information to make any judgement as to outcomes for the baby or the mother.
- 151 lacked a date of birth. Of those with valid dates, there were 292 birth outcomes recorded for the January 2006 to January 2007 period preceding the study and 114 birth outcomes recorded during the intervention period
- 343 lacked either a birth weight or birth date.

This means that the analyses below are operating from a limited dataset as tabled below, the bias of which is unknown. The reasons for this relate to the real-world situation of operating at community level in PNG, as discussed in section 3, above.

**Table 33: Number and percentage of live births, before and during the intervention period, in Maprik and Esa’ala districts**

<i>District</i>	<i>Pre-intervention</i>		<i>During intervention</i>	
	<i>Live births</i>	<i>Total births</i>	<i>Live births</i>	<i>Total births</i>
Maprik	92 (98%)	94	70 (96%)	73
Esa’ala	196 (98%)	199	39 (98%)	40

### **4.5.2 Maternal deaths**

Out of nine maternal deaths recorded, the dates were known for five. These five known dates were all in the pre-intervention or early intervention period, ranging from 6<sup>th</sup> March 2006 to 16<sup>th</sup> March 2007. The nature of the complication was recorded in three deaths and listed as post-partum haemorrhage for two women, and twin pregnancy with transverse lie for one woman. Six of the deaths were in Maprik and three were in Esa’ala.

### **4.5.3 Complications for mother and baby noted during delivery**

Percentages for maternal complication rates in the results below are based upon the total number of births recorded, and assumes that all complications were recorded. This is likely to seriously under-estimate the true complication rate, especially in Esa’ala. The types of complications noted varied significantly between Maprik and Esa’ala and direct statistical comparisons are not possible.

**Table 34: Number (and proportion) of delivery complications noted in the birth register before and during the intervention, by type of complication and district**

	<i>Maprik</i>		<i>Esa'ala</i>	
	<i>Pre-intervention</i>	<i>During intervention</i>	<i>Pre-intervention</i>	<i>During intervention</i>
Post-partum haemorrhage (includes "lost a lot of blood")	10 (11%)	3 (4%)	2 (1%)	2 (5%)
Prolonged labour	-	-	2 (1%)	-
Twins	-	-	4 (2%)	-
Breech	-	-	2 (1%)	-
Other complication	7 (7%)	2 (3%)	1 (<1%)	-
Total number of deliveries	94	73	196	40

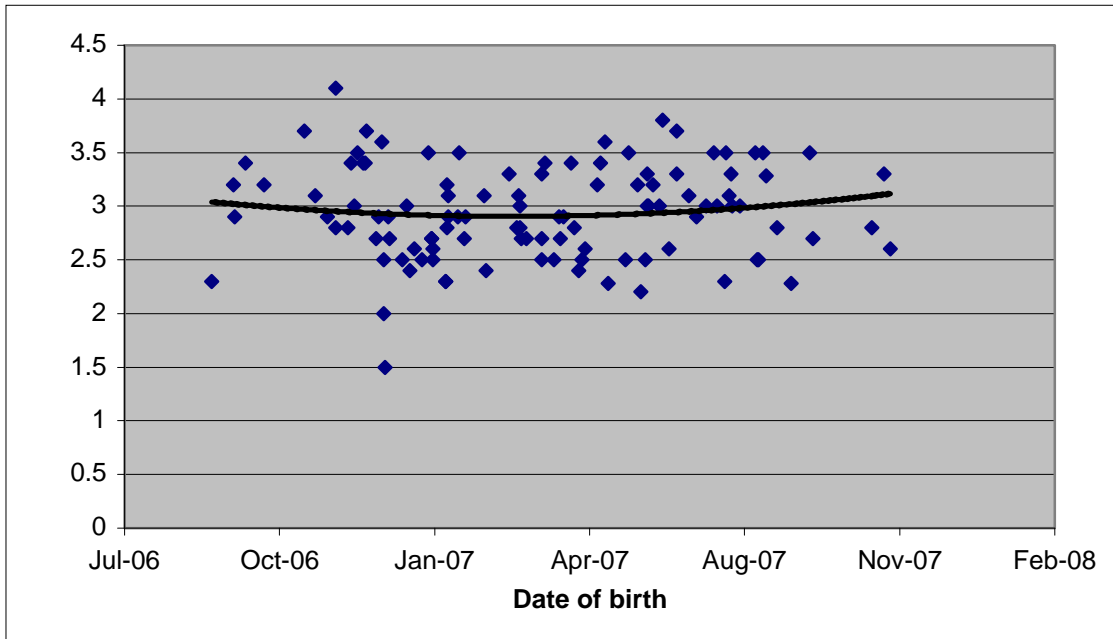
*Note: Percentages show complications as a proportion of all births in the birth record for that period*

There were a small number of birth outcomes other than a live birth noted in the birth register. In Maprik, there was one neonatal death and one unspecified death noted in the pre-intervention period (of 94 deliveries) and one stillbirth and one unspecified death noted in the intervention period (of 73 deliveries). In Esa'ala there was one neonatal death and two stillbirths in the pre-intervention period (of 196 deliveries) and one still-birth noted in the intervention period (of 40 deliveries). The numbers are too small to allow comparisons between districts or over time.

#### **4.5.4 Changes in birth weights**

Change in birth-weight was intended to be a main outcome measure of the EPO program. However, for the reasons noted above, it was difficult to obtain a full number of birth-weight measurements. This means that the data below should be interpreted with caution. It does however show some interesting trends. A number of birth-weights were collected from health centre records prior to intervention, with February 2007 taken as the commencement of the intervention. Intervention period birth-weights were measured by VHV's using a hanging scale, within 24 hours of birth. For purposes of analysis birth-weights were plotted on the charts below, and means were taken of the period prior to and after June 2007. This was taken as a mid-point of the intervention period, hypothesising that four months of micro-nutrient administration across the population of pregnant women would be sufficient to begin to see outcomes in increased birth-weight.

**Chart 11: Birth weights in Maprik before and during the study period**

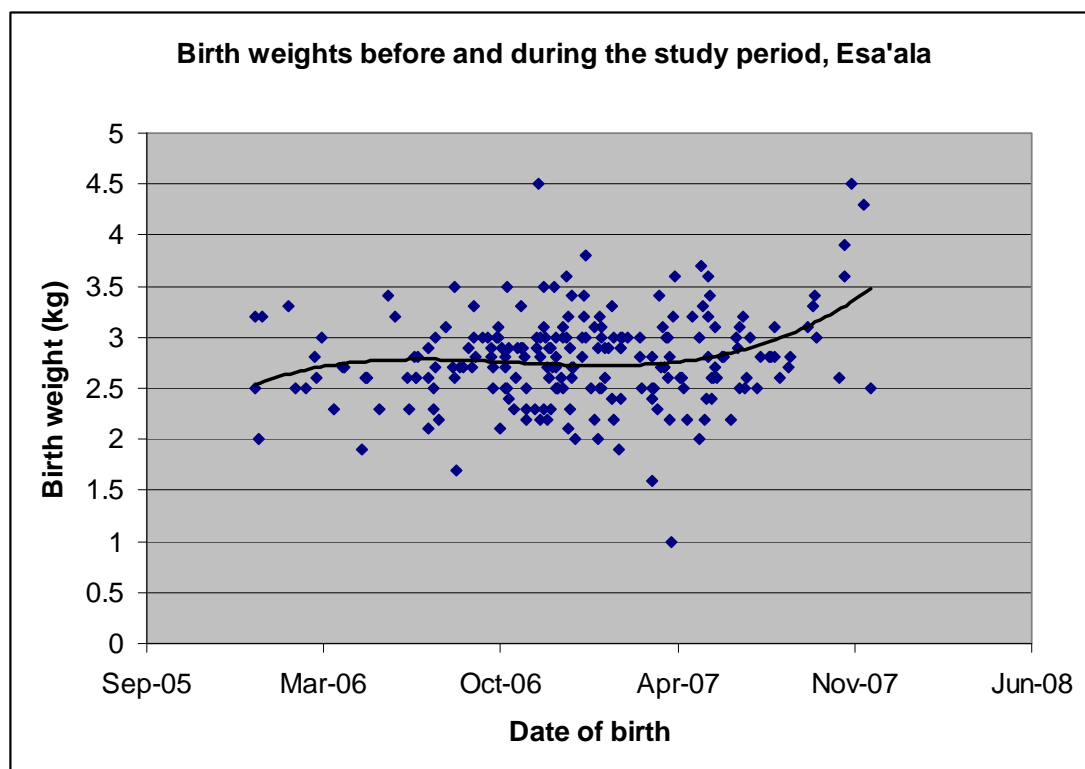


When averaging birth weights in Maprik before and from the intervention mid-point, there is a non-significant increase in the average birth weight, as tabled:

**Table 35: Comparison of mean birth-weights before and from June 2007, Maprik**

Mean birth weight Aug 06 – May 07	Mean birth weight Jun 07 – Nov 07	Difference in means	P-value
2.90 (2.80 – 3.01) n=75	3.04 (2.90 - 3.18) n=33	0.14 (-0.04 – 0.32)	0.129

**Chart 12: Birth-weights in Esa'ala before and during the study period**



When averaging birth-weights in Esa'ala before and from the mid-point of the intervention there is a significant increase in mean birth-weight, as tabled:

**Table 36: Comparison of mean birth-weights before and from June 2007, Esa'ala**

Mean birth weight Jan 06 – May 07	Mean birth weight Jun 07 – Dec 07	Difference in means	P-value
2.74 (2.68 – 2.81) n=176	2.97 (2.81 – 3.12) n=40	0.22 (0.07 – 0.38)	0.005

Different time sequences were compared for Maprik and Esa'ala because different amounts of data were available, by month, in each district.

### 4.6 Delivery of the intervention

The intervention survey records suggest high rates of delivery of interventions in each survey round. In both districts, supply of micronutrients was recorded as 100%, however this referred only to the single dose given to pregnant women on the day of the survey. Daily doses in between surveys were supplied and supported by the VHVs, as discussed below. The delivery of albendazole depended largely on women’s stage of pregnancy and whether they had received a prior dose within four months. In keeping with the records for antimalarials, it seems likely that well over 90% of women who were due for the anti-helminthic in a survey received it.

Recorded delivery of other aspects of the intervention are recorded below. Medications were provided as directly observed treatments, by the health team conducting the survey.

**Table 37: Rates of supply of antimalarial and counselling on HIV**

	INT 1		INT 2		INT 3	
	Maprik	Esa’ala	Maprik	Esa’ala	Maprik	Esa’ala
Antimalarial	100%	100%	95.3%	99.4%	96.6%	100%
Awareness re HIV testing and PMTCT	100%	89.8%	99.4%	96.1%	100%	98.6%

Note: includes missing answers

A critical question relates to the capacity and performance of VHVs in delivering the EPO program in each district. This is discussed more fully in the Annex on Program Implementation, which also includes some qualitative data from program implementers and group interviews with women in the two districts. Data from CSS2 also helps assess the coverage and quality of the program implementation. In this survey, women were asked about their use of micro-nutrients. The overall results were very consistent in both districts. In Maprik 61.0% said they had taken micro-nutrients as planned and 39.0% said they had not (excluding 0.8% missing answers). In Esa’ala 60.2% said they had taken micro-nutrients and 39.9% said they had not.

Women who said they did not take micro-nutrients were asked to nominate the most important reason why they had not. Options on this list were derived, in part, from qualitative data collected during the intervention that raised some questions about the acceptability of the micro-nutrient preparation. The reasons women chose for not taking the micro-nutrients varied between districts, as tabled:

**Table 38: Reasons for not drinking the course of micronutrients\***

	Maprik	Esa'ala
<b>General compliance problems</b>		
Forgot to drink	36 (18.8%)	19 (12.8%)
Forgot to collect next supply	61 (31.8%)	37 (24.8%)
Husband stops you from taking them	1 (0.5%)	0 (0%)
<b>Compliance problems specific to micronutrients</b>		
Smell of the micronutrients	23 (12.0%)	9 (6.0%)
Felt sick drinking micronutrients	18 (9.4%)	4 (2.7%)
Scared you might get sick	10 (5.2%)	0 (0%)
Hungriness	7 (3.6%)	0 (0%)
<b>Issues relating to the program and VHVs</b>		
You were not reminded to take your dose	2 (1.0%)	33 (22.1%)
VHV refused to give micronutrients	1 (0.5%)	24 (16.1%)
Stocks ran out	2 (1.0%)	12 (8.1%)
Distance to collect micronutrients was too far	15 (7.8%)	9 (6.0%)
<b>Other</b>		
Other	16 (8.3%)	2 (1.3%)
Total women who reported not completing micronutrients	192 (100%)	149 (100%)

\*12 (5.9%) and 8 (5.1%) of missing answers from Maprik and Esa'ala respectively, were excluded from analysis

General compliance problems (such as forgetting to take or collect micronutrients) were in the majority in Maprik, accounting for 51% of the reasons women chose as the most important explanation of why they did not take the micro-nutrients. In Esa'ala, a significant proportion of the reasons nominated, 52%, related to problems in the program itself, perhaps relating to the VHVs ability to access stores, or access women. In both districts there was a small but important proportion of women who nominated a reason relating to the smell of the micro-nutrients, or nausea that did or might result from taking them. This group ranged from 8.7% in Esa'ala to 26.6% in Maprik. However it is important to note that the qualitative research suggested that women also disliked the smell of iron and folate tablets – suggesting (not unreasonably) that they smelt like blood.

To attempt to further investigate program delivery through the data, the research team coded each village for “easy access” or “difficult access”. These were codes relative to other villages inside each district and did not compare access between districts. When improvements in haemoglobin levels were stratified by easy or difficult access there was some indication that improvements in both districts in haemoglobin in the intervention surveys occurred more in ‘easy access’ villages. However this was not confirmed by the cross-sectional surveys in any way, so there did not seem to be a directly relationship between a village’s access code and increases in haemoglobin.

The access codes were also used to stratify compliance with taking micro-nutrients, as recorded in CSS2, as tabled:

**Table 39: Number and percentage of women reporting compliance with micronutrient intake (as measured in CSS2) by village access**

<i>Village access</i>	<i>Completed taking micronutrients as planned?</i>	
	<i>Maprik</i>	<i>Esa'ala</i>
<i>Easy access</i> <i>Number (%)</i>	260 (66.0%)	231 (60.0%)
<i>Difficult access</i> <i>Number (%)</i>	57 (47.9%)	6 (66.7%)
<i>RR of women in villages coded 'easy access' being more likely to take micronutrients</i>	RR 1.38; 95% CI 1.23 – 1.68; p<0.001	RR 0.9; 95%CI 0.56 – 1.44; p=0.686

Women in villages in Maprik coded as easier access were significantly more likely to report that they completed micronutrient courses than those in less accessible villages. Access was not significantly associated with micronutrient compliance in Esa'ala. However, fewer people from difficult to access areas were included in CSS2 in Esa'ala (8 of 39 were difficult access villages) and in CSS2 (two of eight difficult to access villages were not included in CSS2).

## 5. Discussion

The reporting of results in this document has attempted to apply some rigour to their presentation and statistical analysis. This has also meant discussion of the constraints operating on both the collection of research data and the delivery of the intervention. So it is important to acknowledge at the outset of this discussion that it is often extremely difficult to undertake either operational research or health development in rural areas of PNG. The fact that some aspects of the EPO program did not go to plan is not unexpected. In fact, it suggests that any results obtained, will have been obtained under something close to ‘normal’ operating conditions for rural health services. Given this, it is impressive that the EPO program has shown demonstrable gains in:

- Reduction of anaemia;
- Reduction of malaria infection; and
- Possibly increased birth-weights.

### 5.1 *Reductions in anaemia and malaria*

Anaemia is clearly a major problem in both districts, with particular impact on pregnant women. The rates of anaemia reported here are much higher than the regional averages reported in the national nutrition survey (NDOH 2007) which records rates of anaemia in non-pregnant women as 46.3% in Islands and 59.8% in Momase. These rates also put these districts at the bottom end of the global spectrum for anaemia in pregnancy. Black et al (2008) report global averages of 42% of pregnant women with anaemia (and assumed that 50% would be iron deficiency in malarious areas), noting that “women of childbearing age are at high risk for negative iron balance because of blood loss during menstruation and the substantial iron demands of pregnancy.”

There were increases seen in both Maprik and Esa’ala in haemoglobin levels in pregnant women and it is plausible to attribute these increases to the EPO intervention, at least in part. The size of the increase was of mean increases of up to approximately 0.7 g/dL, with the range much broader than this, when individual women’s records are examined. This is likely to be life-saving for many women: global analyses have estimated an odds ratio of 0.8 (95% CI 0.70–0.91) for maternal mortality (that is: decreased chance of death) for a 1.0 g/dL increase in mean haemoglobin in late pregnancy (Black et al 2008).

Malaria is clearly a factor in anaemia in pregnancy, but the analysis of the Maprik data showed that there were very strong drivers of anaemia operating independently of malaria, which are likely to relate to other causes noted above. Further, previous studies<sup>2</sup> have demonstrated diverse ranges in haemoglobin values, and the factors that influence anaemia in the different regions of PNG such as diet, amount and sources of income, environment etc. One systematic review (Brabin et al 2001), while only partially relevant to Maprik, is worth noting in that it gives a balance of the contribution of malaria and nutritional anaemia to maternal deaths. This suggested that in holoendemic malarious areas with severe anaemia prevalence, it was estimated

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<sup>2</sup> Personal communications, W. Saweri

that in primigravidae, there would be 9 severe-malaria anaemia-related deaths and 41 non-malarial anaemia-related deaths per 100,000 live births.

The findings from Maprik in this study suggest that primipara are at increased risk of both anaemia and serious malaria infection. It may be that malaria plays a greater role in the anaemia of primipara than in the anaemia that affects other pregnant women. Research in Africa confirms this, and also quantifies the impact of malaria on infant deaths (Menendez et al 2007, Steketee et al 2001).

The EPO program does demonstrate success at reducing rates of malaria infection in Maprik among pregnant women. This is on a background of high baseline rates of malaria infection of between 30 and 40% in this study, which were similar to those measured in nearby Wosera, (Kasehagen et al 2006) with rates of 42.7% (95% CI: 41.1 – 44.2) among 10 – 19 year olds and 22.6% (95% CI: 21.4-23.8) among 20 to 39 year olds.

## 5.2 Birth-weights

Birth-weights are a critical diagnostic measure in promoting newborn survival and it is impressive that the EPO program was able to enable some VHV's to use this measurement well. The difficulties in broadening this to all births, and sustaining it, have also been made clear in this study. It is important not to over-interpret the small sample size. However the increase in mean birth-weights in the second half of the intervention period could be attributed to both micro-nutrient supplements and malaria treatment.

This study found an increase in mean birth-weight of 140g (95%CI: -40 to 320g) in Maprik (although not statistically significant) and 220g (95%CI: 70 to 380g) in Esa'ala. Similar orders of increase have been found in studies elsewhere. Research into micronutrients in Nepal found a significant benefit in birthweight (Osrin et al, 2005), which was sustained in later childhood (Vaidya et al, 2008). It is well understood that many factors affect birthweight outcomes, including nutritional status of the mother and household socioeconomic status, and that it is a health indicator more appropriate for assessing interventions of longer duration than the current study. Thus the small observed changes should be met with cautious optimism. Further longer-term assessment is very important.

Steketee et al (2001) quantified the benefit in improved birth-weight derived from improved control of malaria in pregnancy, and it is possible that reduction in malaria was a contribution to the increase in birth-weights seen in Esa'ala. Unfortunately, the accidental damage to malaria slides in that district meant that this study could not assess this.

It is also worth noting that the baseline BMI measures of mothers in Esa'ala, and pre-intervention birth-weights were concerningly low, and lower than those in Maprik. This may make it easier to detect small improvements in foetal nutrition. The reasons behind these are not testable with this data, it may be hypothesised that some, none, or all of general reductions in infection, general improvements in nutrition, or increased birth spacing helped to contribute.

### 5.3 Delivering micronutrients, antimalarials and bed-nets, and demonstrating program effectiveness

One of the significant achievements of the EPO program is that it demonstrated that a VHV program can reach women with micro-nutrients, with a level of support and training that is feasible within rural health services in PNG. At least 60% of women stated that they had taken micro-nutrients in this effectiveness study and many of those who answered “no” to that question are likely to have taken a partial course. An earlier authoritative review (referred to in SUMMIT, 2008) on the potential for micro-nutrients to improve pregnancy outcomes called for “community evaluations of effect and an expanded evidence base that includes affordability, acceptability and scalability” and the EPO program research has made a start on this for PNG.

A recent study of intermittent preventive treatment for malaria in pregnancy demonstrated the feasibility of community level volunteers and other ‘lay’ health workers in this program. However they found that some malaria-specific aspects were better handled by local health facilities (Mbonye et al 2008). In the EPO program a mixed approach has been modelled, with micro-nutrients and education at community level supported by antimalarials and other aspects delivered through the equivalent of outreach visits by rural health staff. It will be important to carefully consider in future scale-up in PNG two program aspects:

- the importance of continuing outreach and mobile clinics to support VHVs and deliver some services at community level; and
- linkage with delivery care services, noting that the impressive gains in reduced mortality seen in a large-scale Indonesian trial of maternal micro-nutrients (SUMMIT 2008) seem to be due, in part, to the scaffolding of the program onto well established systems for supervised delivery.

Maprik had better outcomes than Esa’ala in improving anaemia among non-pregnant women, which leads to women entering pregnancy in better health, with benefits for the mother and baby. A particular target group of the nutritional intervention is young women before they become pregnant. In Maprik, the improvement in rates of anaemia in the non-pregnant population included a significant improvement in the young nulliparous group. Less anaemia in non-pregnant women relates to an aspect of the intervention that was in main the responsibility of VHVs: weekly micro-nutrients for WRA. It is interesting to note that Maprik had very few women who attributed their failure to take micro-nutrients to aspects relating to VHV program performance – so it may be that this VHV services in this district were better able to reach WRA, as well as pregnant women.

Qualitative data suggests that Esa’ala posed particular logistic difficulties for VHVs as well as the health team. Even villages designated as “accessible” may not be the case in practice. Information from the team suggests that villages in Maprik tended to be larger with more concentrated populations, making service delivery easier. The study area in Esa’ala consisted of more small hamlets, which may be separated by mountains, rivers or dense bushland. This makes it much more difficult for the VHVs working in Esa’ala to meet all the required tasks to be performed by them. However Esa’ala did have an improving trend in many of the areas measured, suggesting that micronutrient and antimalarial uptake was possibly having some impact.

It may have been that it was easier to demonstrate statistical significance in Maprik because the baseline haemoglobin levels were substantially lower than those in Esa'ala. The reasons for this lower starting point cannot be addressed in this study, but they may relate to differences in background nutrition, or rates of infection, including malaria. Another specific confounder could be the prevalence of alpha thalassaemia, which is reported in north coastal PNG. One analysis from there (O'Donnell et al 2006) states that homozygous affected women would have a mean haemoglobin 1.0 g/dL lower than the normal population, but they did not find any association between this and either adverse birth outcomes or malaria infection. Even considering these confounders, it is reasonable to conclude that the intervention in Maprik demonstrated some benefit for the non-pregnant population, particularly in their pre-pregnancy nutrition.

Other nutritional outcomes the study attempted to measure included BMI. There seems to be clear measurement errors which rendered this impossible in Maprik, especially when low rates found at baseline are much less than the 8% for Momase Region found in the national nutrition survey (NDOH 2007). The baseline rates of low BMI in Esa'ala are similar to those registered in the national nutrition survey and represent a serious concern. The failure to show any significant change in BMI in this study may simply be that a longer time frame or larger sample is needed to show effect. This is especially true when the likely contribution of the intervention is indirect, such as reduction in all forms of infection leading to improved body mass.

Although there were suggestions in the study that micro-nutrients may have acceptability problems in terms of smell or nausea, it is important to persist in exploring their use in PNG. There are clear additional benefits to micronutrients over iron-folate preparations, such as the additional increase in birthweight noted in a study in Nepal, and maternal and newborn benefits consolidated in a recent global review (Osrin et al, 2005, Bhutta et al 2008). It is important to note that the National Micronutrient Survey conducted in 2005 found that 70% of eligible women claimed they had received iron-folic acids during their antenatal visit. Thus, the current study cannot conclude that women did not receive iron-folic acid tablets prior to the current intervention. However, if women were already receiving and taking micronutrients, this would raise the baseline level and reduce the likelihood of observed changes as a result of the intervention. The fact that changes have been observed demonstrates the value of the intervention method and use of the micronutrient formulation.

Bed-net distribution was an important contribution to the EPO program, not least because it acted as an incentive to women to take part in the intervention. The loss of recruitment when bed-nets were not available is slightly surprising, but reinforces the need to carefully consider motivation and incentives from community perspectives in future scale-up. The EPO program showed an increase in reported bed-net usage, but was unable to link this to a decline in malaria rates. This was not, however, a primary outcome measure in the design, and it may relate to the fact that bed-nets were widely available across households prior to the study commencement (in some cases these were bed-nets stockpiled for use in the study but which were distributed prematurely).

#### **5.4 Mortality decline and other expected benefits that were unable to be measured or unplanned**

There was a surprisingly high number of maternal deaths recorded in the birth register. The birth register records 535 known live births, and using this as the denominator, this could equate to a maternal mortality ratio of well over 1,000 per 100,000 live births for that 22 month period. Given the low numbers (with unacceptably broad confidence limits) and data omissions, it is not appropriate to formally report a maternal mortality ratio, much less do a time or district comparison. However even if one assumes that all maternal deaths were reported and only half (which is likely) of births were recorded this is still a ratio well above the reported average for PNG. This gives some inkling of the stark reality facing women giving birth in rural and remote PNG where referral for high-level emergency care is not available. There was an option to record referrals in the birth register but very few were noted.

There were a small number of still-births and neonatal deaths recorded in the birth register. Rates cannot be calculated due to the small numbers, however this is less than expected, based on national averages, both in the pre-intervention and intervention periods. It is likely that rates of both are significantly under-reported and reflect the difficulties already discussed in accurate recording of birth outcomes at community level. There is a considerable body of evidence that links the administration of micro-nutrients to reductions in foetal loss and early infant mortality, including the recent publication from Indonesia mentioned above (SUMMIT 2008).

Syphilis seemed to be less prevalent among new pregnancies later in the study period, with later surveys effectively testing new populations. It is not possible to attribute this as a direct program effect but it is possible that an increased focus on testing and referral for pregnant women may result in a general improvement in sexual health. However it must be noted that women in the second cross-sectional survey represent testing of new pregnancies, most of which were not part of the intervention group. So this change cannot be tracked directly to the intervention. However it could be proposed that indirect improvements in attitudes and practices around improved detection and treatment of syphilis contributed to the decline. Numbers are too small for this to be more than a hypothesis. Congenital syphilis was not able to be measured in this study and tracking this would require high-level skills in the assessment of newborns that are perhaps not the highest training priority for village-level newborn care. Stillbirth and miscarriage rates could be proxies for congenital syphilis, and rates in the intervention period are certainly lower than national averages, however, as discussed above, it is likely that a proportion of stillbirths and miscarriages were not recorded.

Other indirect program benefits were observed, including a significant jump in the uptake of family planning in Maprik. This however, like gains in haemoglobin, came from a relatively low base. A notable exception is the comparatively high rates of vasectomy in Maprik, likely to be the result of a UNFPA family planning programme implemented in four provinces (East Sepik Province, Manus, Morobe and Central) in 1996 in which vasectomies were performed. This has clearly contributed to the acceptability of vasectomy in that district, which may have contributed to the increase in vasectomy uptake noted during the study period.

It was also hypothesised that increased emphasis on antenatal care may have an indirect effect in increasing supervised delivery rates. This trend runs counter to current NHIS findings and reasons for the discrepancy between this survey and the NHIS will need to be investigated further. Examination of the latest National Health Information System data does not show any suggestion of improvement in supervised delivery rates, although there is an intriguing increase in village level attended deliveries in Maprik (but without an increase in the overall rate). These figures should be revisited, however, because 2007 reporting is incomplete, with only 87% for Maprik and 83% for Esa'ala submitted.

## **5.5 Future operational research**

There are many unknowns relating to the EPO work at every level of research. However some immediate priorities for operational research into health service delivery for pregnancy outcomes emerge. They include:

- Monitoring future implementation to capture the effect on other birth outcomes;
- Investigating tools and support that would allow more accurate birth records and other aspects of community-level vital events recording, including birth-weight measurement, which has been one of the most difficult aspects of implementation at village level;
- The interaction between malaria, nutrition and pregnancy in PNG;
- Whether differences in malaria could account for differences between Maprik and Esa'ala;
- Role of other contents of the micronutrients, eg Zinc and Vitamin A, in reducing other infections;
- The role of calcium in maternal micro-nutrients (it was not included in this study, nor in the recent Indonesia trial) given that it does have a range of proven benefits in antenatal care, such as modification of pre-eclampsia;
- Investigation of the suggestion of very high maternal mortality in these districts, linkages to supervised delivery in future programs, and the general issue of delivery care in PNG; and
- The current project purposively selected villages based on their access to a health facility and road or sea transport points. The challenge remains to develop novel ways to provide health services to those villagers who remain the most isolated and vulnerable in the population.

## 6. Conclusions and Recommendations

This effectiveness study represents a major achievement by the study directors, health teams and village health volunteers in Maprik and Esa'ala, as well as by IMR, UNICEF and NDOH. The study experienced the full range of constraints that operate in PNG, particularly those relating to adverse weather, political and social tension, and geographic remoteness. Despite this, it was able to demonstrate impact in reductions in anaemia and malaria infection and increased birth-weights. This required the mobilisation of community health staff and volunteers; successful supply logistics and training of volunteers; delivery of pregnancy interventions to at least 60% of the target population; and collection of sufficient quality research data.

This intervention is worth replicating elsewhere in PNG, through both VHVs and rural health staff. Replication and refinement is crucial in order to provide an evidence base for future potential scale-up. Community partners are essential and health facility staff will need to supplement facility-based services with mobile clinics and outreach. The intervention is evaluated as a whole: comprising daily micronutrients for pregnant women, weekly micronutrients for WRA, intermittent preventive treatment for malaria and worms, distribution of insecticide treated bed nets and basic education on pregnancy and childbirth. Future interventions should provide for longer periods of implementation and evaluation to better distinguish between effective elements.

Programs to scale-up this intervention will need particular attention and support to:

- Involvement of all relevant stakeholders from the initial development phases;
- Recording birth outcomes, including weight, at village level;
- Ensuring stable supply of micronutrients to VHVs, either through government pharmaceutical systems (which were not used in this study) or through direct supply to health facilities;
- Good quality training and support materials for VHVs, and support from supervising health staff in areas such as data collection, reporting and monitoring, and regular checks on quality of care;
- Delivery of intermittent preventive treatment for malaria and worms by health staff through both outreach and mobile clinics, with consideration of the possible role of village health volunteers in both areas;
- Use of the experience documented in annexes to help assess likely obstacles to distribution and difficulties in logistics in risk assessment and operational planning;
- Careful provision of sufficient incentives to both volunteers (such as small payments in kind) and pregnant mothers (such as free bednets);
- Consideration of incentives and other means to maximise participation of families in such interventions;
- Attention to attitudinal and social barriers to the involvement of unmarried pregnant women – perhaps through youth-friendly services; and
- Consideration of local surveys to estimate demand and evaluate progress.

Further research needs in PNG are significant, however this study illustrates the need for interventions, and associated operational research to provide evidence, and effectiveness studies on issues including:

- Correction of anaemia in adult and child populations;
- Nature and case management of malaria in pregnancy, especially in first pregnancies;
- Nutrition interventions targeting young women before they get pregnant;
- Novel delivery methods, particularly to reach populations in less accessible areas; and
- Health service delivery research, including the trial of interventions for improved post-natal and delivery care, and their integration with this intervention.

This project demonstrates that operational and effectiveness research in rural PNG is no easy task. It is important to take special care with the design of questions and methodology, especially when large populations are involved. Ethics committees and research planners should consider the appropriateness of studies with control groups, where the need for evidence warrants it. This project also demonstrates the high value of operational research in demonstrating new ways to reach the neediest populations in PNG.

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## **Annex 1: Lessons learned in implementing the EPO intervention**

This annex discusses successes and challenges in the implementation of the program, with suggestions for improvement in other sites. A list of the detailed steps involved in the EPO research process is also provided. Overall, there are several critical elements to the implementation:

- strong role and service by VHVs
- support and training for VHVs, in partnership with health teams
- good community partnerships
- outreach visits by health teams, with good logistic support
- good understanding of WRA and pregnant women
- good collection of records of birth outcomes and other vital events.

### ***A1.1 Successful aspects of implementation suggested to other sites***

#### **Roles of VHVs in delivering the intervention**

The VHVs had several essential roles in the EPO program:

- 1) Delivery of micro-nutrients to WRA and pregnant women, along with other information;
- 2) Collection of data on birth outcomes, including birth-weights; and
- 3) Support to the outreach services and surveys provided by the EPO health and research team.

Some of the aspects that helped make this work well are discussed below, and these are recommended for consideration in other sites.

#### **Partnership with community leaders**

The initial stakeholder meetings that preceded the first survey (census) were essential to gauge interest and inform and involve community leaders. Meetings were held with local stakeholders, including district health officers, district administrators, participating health centre administrators and staff and local mission administrators.

From the EPO program experience, there is no fixed template on how VHVs and the Local Level Government (LLG) members or other community leaders (church or womens' groups particularly) should work. These groups work differently in different places, so it is very important that the initial stakeholder meetings try to understand how each group sees their role and discusses what part they might play in improved pregnancy care. What was important in each village was to introduce the LLG member to both health teams and the VHVs, and encourage the LLG member to take the lead in calling the community together and officially handing over responsibility for the work to the health team and VHVs.

The EPO experience showed that people responded well to their LLG members, and also to other community leaders including church leaders, school leaders and local regular health staff. The EPO program can act as a mechanism to get VHVs seen

alongside prominent figures in communities, which provides political support to their work and encourages greater community response.

### **Partnership between VHVs and health team**

Health teams who visit the villages have a critical role in validating and supporting the work of the VHVs. This also goes for routine health in regular clinics. If they are seen working in active partnership with VHVs this provides a good model and encourages community members to trust VHV services.

Conversely, the role of VHVs in supporting the work of outreach health teams was very important. The health team estimated that 90-100% of VHVs were available at the project sites whenever the EPO teams visited a village, and they were only absent due to sickness or important duties taking them outside the village. As well as encouraging women to attend outreach clinics, VHVs also submitted treatment records and birth register data at this time.

There was an agreed system for interaction between the VHVs and routine health services: if there is an aid post within their area, the VHVs reported to the community health workers (CHW). If there is no aid post around in their area, the VHVs reported to and worked alongside the health centres that operated in their area.

Mr Ali Kevin, IMR, has prepared a step-by-step guide to working in partnership with community leaders and health authorities, as implemented in the EPO program.

### **Access to and use of micro-nutrient supplies by VHVs**

As noted in the main body of the report, the VHVs were successful in ensuring at least 60% of women received micro-nutrients. Their performance in this area was monitored through the 10 weekly health clinics, where they worked with the health team, and the treatment forms allowed analysis of how much micro-nutrient they were using, as well as a tally of the number of women that came to them to collect their daily or weekly doses. VHV supervision of women taking micro-nutrients was very important, as the qualitative data showed that without supervision, some women discarded medications when at home.

Consistent supply of micro-nutrients was important to the EPO program success and this was required several steps:

#### **Step 1: assess numbers of WRA and pregnant women:**

The census of WRA in the villages in the study area was essential to understand the numbers of women likely to be pregnant in the near future. This could be reliably assessed by the number of women reporting menstrual periods, if the numbers with ages between 15-49 years is difficult to measure. For a research study, assigning consistent identification numbers was important. It was then important to identify who among this group is pregnant (possibly 10 to 20% of the WRA) and make a tally of numbers of pregnant and non-pregnant WRA.

#### **Step 2: calculate micro-nutrient supply needs**

This is based on the assumption that pregnant women will take micro-nutrient daily, and non-pregnant WRA weekly. To calculate an eight week supply the following formula was used. For instance, we have 252 pregnant women and 3,427 non-

pregnant women in census data from 39 villages in Maprik. The average number of women needing micronutrients per village was estimated as:

1. Average Pregnant Women:  $\frac{252}{39} = 6$  per village
2. Average Non-pregnant women:  $\frac{3,427}{39} = 88$  per village

Calculation:

Pregnant women: 6 x 7days X eight weeks = 336 micronutrients per village

Non-pregnant WRA: 88 x 1day X eight weeks = 704 micronutrients per village

Since there are 1,000 tablets (micronutrients) in a container, the VHVs are given three containers – two for the eight weeks period and one extra to help them last until the next visit made by the EPO team after eight weeks time.

### **Step 3: supply to VHVs**

In the EPO program supplies were arranged by UNICEF direct to provincial and then district health authorities. VHVs were provided with supplies during outreach visits by the health teams. Extra containers are carried by the EPO team on each patrol after eight weeks time and given to the VHVs to continue treatment. In the first visit to a particular village in the start of the interventions, each VHV was given at least three containers (based on calculations above) to last for two months before the next visit by the EPO team. The micro-nutrients supplied through UNICEF had a satisfactory shelf-life to allow for resupply on this basis.

### **Good understanding of WRA and pregnant women**

Both the VHVs and health teams needed a good understanding of the numbers of WRA and pregnant women in order to carry out their tasks, estimate resources needed for micro-nutrients, other medications, weighing scales etc. For the EPO research this required a rigorous census obtained through a comprehensive house-to-house survey. Even where the EPO intervention is not being implemented as a research study, accurate knowledge of numbers of women is essential both to estimate resources and to undertake good monitoring of the program. In sites where existing records mean this information is not well known, then a very simple baseline survey of WRA, both pregnant and non-pregnant may be an important starting point. In many sites it may be possible for this survey to be carried out by VHVs and CHWs and other health staff working together.

It is also important to have some discussions that are well-facilitated to be open and honest, regarding attitudes to pregnancy and health services. Those used in the EPO program are summarised in the annex below. Particular areas to address are

- attitudes to pregnancy for married and unmarried women,
- any barriers unmarried women might experience,
- attitudes to health care and the various medications used in pregnancy, and
- planning for a safe place for delivery care, including contingency planning for emergencies.

Keeping good records of birth outcomes is also essential to maintain the program's momentum as well as to monitor performance. Some aspects of this were difficult in the EPO program and are discussed in the section below.

## **Logistics and support to enable outreach by health teams**

Careful logistics were essential to the EPO program success. Even when things went wrong, such as the spoiling of malaria slides or errors in bed-net delivery, these were often not in the control of the planning process. Similar logistics are required to enable health teams to do outreach visits in a way that:

- ensures they have adequate equipment and supplies for their visit
- have supplies and resources to support VHVs
- have tools to collect good quality data for either research or monitoring.

It is essential to plan the logistics well in advance of implementation, say at the commencement of the year or during annual plan preparation. Mr Ali Kevin, IMR, has prepared a step-by-step guide to the planning of logistics for supplies, fuel and data, based on the EPO experience. This covers the areas of:

- identifying the various stages in the program implementation
- detailing the activities of each stage
- listing the supplies needed for each activity
- identifying suppliers and order procedures
- establishing a 'middle-man' who can direct supplies to the program site (in some areas this may require partnership with businesses or private enterprise)
- checking and confirmation.

For accurate data records, some form of local identification number, in addition to names and addresses, will help to allow cross-checking of data provided. These may also include batch numbers which can provide an extra check on aspects such as time of year. Double-checking that dates, places and identifying information are correctly entered is essential during data collection.

## ***A1.2 Challenges in program implementation and suggestions for other sites***

### **Monitoring community interest and boosting participation**

The interest of communities needed to be continually checked, as some villages seemed to lose interest for a variety of external reasons, even though they had initially wanted to be included in the survey. Two particular reasons were proximity to urban areas, which took women away from their home-base, and a general low level of understanding of the health issues that the EPO program was trying to address.

In the first instance, other sites may wish to consider a second strategy based on the particular village's circumstances. For example women at peri-urban villages may be included through allowing access to micro-nutrients and IPTp at market places. Or high attendance community events, such as Sunday church services, might be distribution points. Flexibility in providing the service will be needed, for example it may be easier for VHVs to attend weekend events such as church, and there may need to be a linkage with a second health service to enable recording and distribution of services for rural women visiting town.

### **Social and cultural attitudes**

There was some variation in the EPO program in the numbers of unmarried pregnant women taking part in various surveys. The interviews data found that embarrassment

and reticence on the part of unmarried pregnant women was a major barrier to pregnancy care in some cases. It is important to include qualitative data in continuing assessments so issues like this can be recognised. Many such issues are complex and will need support from community leaders and women's networks to try to ensure that social attitudes do not prevent women from accessing essential health care.

Other issues encountered during the EPO program, such as the "666" rumours, were able to be countered through leadership support and good quality information. However it required a mechanism to quickly recognise what was going on and report it to research directors to enable the response. This required good partnership between VHVs, health team and community.

### **Good quality records of birth outcomes, including mortality and birth-weight**

It is important for any program to determine at the beginning what type of information is important to collect. Some information, such as mortality data, nutritional anthropometry and birth weights requires special training and equipment to collect accurately. The EPO program was successful in helping some VHVs collect good birth weight and anthropometry but many VHVs were not able to do this.

It is difficult for retrospective mortality data to be collected through surveys unless a full, careful obstetric history is taken from each woman. This takes additional survey time and so the cost needs to be carefully weighed. For prospective mortality rates, whether maternal, foetal, and infant, it is very easy to get inaccurate data if care is not taken to:

- ensure all possible live births are counted to include in the denominator
- all stillbirths and miscarriages are counted and accurately classified,
- all newborn deaths, including their age, are counted and recorded.

Although difficult, this is an important aspect of the program, especially when community level staff are involved. Not only does it allow monitoring of progress but it involves the community in understanding the reality of their situation and the need for health sector and non-health sector action.

Birth-weights were difficult to record in the EPO program. There were several reasons, including difficulties in ensuring sufficient weighing scales were supplied to all villages, the research restriction that only weights within 24 hours of birth could be counted, and failure of women or families to notify VHVs of a birth, especially in scattered communities with difficult access such as in Esa'ala. However birth-weights are important: firstly to enable recognition of low birth-weight babies who need special care, and secondly to understand whether birth outcomes are improving with new interventions.

Future interventions will need special support to VHVs to ensure they have adequate equipment and training. In sites where this is difficult, families should be educated on the importance of birth-weights and encouraged to visit a facility to record this. The acceptable period for recording a birth-weight could be extended to three days, especially in difficult areas.

There are many other benefits of good quality vital events recording, especially where records are kept and used locally. Linking birth outcomes to other village vital events can provide mutually supportive systems.

### **Motivation and other support for VHVs and community members**

Both VHVs and mothers need motivation to participate in pregnancy programs. Many VHVs do work as volunteers and are dedicated to the welfare of women in their villages. However many VHVs state that they have been working in this way for years and would not want to continue like that. If they are to be used as an integrated part of the health system, incentives of some sort should be considered. In this EPO program, especially in Maprik, small incentives were introduced. When bed-nets or mothers clinic books were distributed, families were asked to at least contribute 50 toea to 2 kina. The money collected from each village was given to the VHVs to buy themselves soap, kerosene and other supplies that would help them perform their jobs.

It is also important to note the motivating effect of free bed-nets on the participation of mothers in this EPO program. While bed-nets might not always be the best incentive in the future, it is important for other programs to consider how to encourage participation. There are examples from other countries, where cash transfers or other incentives are provided to boost the coverage of essential preventive interventions that benefit the community as a whole.

### **Training of VHVs**

As noted in the main body of the report, there seem to be differences between Maprik and Esa'ala in the delivery of the program by the VHVs. It is likely that most of this difference lies in the more difficult environment in Esa'ala. However there may also be some difference in the base level of training in VHV groups, considering the prior training and support that each group had.

In this EPO program there was special attention to the training of VHVs, with consideration of literacy levels. This included sample completion of case report forms for pregnant women, training in tallying of participants, distribution of medicine, and managing and ordering field supplies.

Future sites for EPO programs should collaborate in the production of standard training materials for VHVs in this area. The national VHV Training Resources (available through NDOH) are carefully adapted for low-literacy situations and already contain material addressing pregnancy care. These could be updated to reflect the experience of this EPO program to provide a resource for future sites.

## ***A1.3 Steps in the EPO research process and data collected***

A summary of the EPO research process is provided in the main body of the EPO report. A detailed listing of the steps involved in provided here:

### **1. RECRUITMENT OF STAFF**

#### **1.1. Recruitment of two District Project Officers**

- 1.2. Recruitment of two CHW
- 1.3. Tok saves in each village
- 1.4. Village Level Pregnancy Assistants (VLPA) recruited and trained
- 1.5. Village census and a master list of WRA created

## **2. BASELINE DATA COLLECTION**

- 2.1. Cross sectional survey
  - 2.1.1. 500 WRA in each site
  - 2.1.2. Basic demographic data
  - 2.1.3. Haemoglobin
  - 2.1.4. Body Mass Index (nutrition)
  - 2.1.5. Malaria slide
  - 2.1.6. Bed net use
- 2.2. Survey of all pregnant women
  - 2.2.1. Basic demographic data
  - 2.2.2. Haemoglobin check
  - 2.2.3. Body Mass Index (nutrition)
  - 2.2.4. Malaria slide
  - 2.2.5. Syphilis testing
  - 2.2.6. HIV (Awareness & Voluntary)
  - 2.2.7. Antenatal attendance
  - 2.2.8. Bed net use
- 2.3. Admissions to health centre(s)
  - 2.3.1. H/C records for all women
- 2.4. Formative research
  - 2.4.1. Basic demographic data
  - 2.4.2. Pre-pregnancy factors (nutrition, family planning, timing of first & subsequent pregnancies)
  - 2.4.3. Perceptions of sot blut & sik malaria (including bed net use)
  - 2.4.4. Uptake of medication
  - 2.4.5. Antenatal attendance
- 2.5. Birth weight (120 births)
  - 2.5.1. All babies in village & H/C
  - 2.5.2. H/C records over last year

## **3. DELIVERY OF INTERVENTION**

- 3.1. Weekly clinics conducted by VLPA in each village
  - 3.1.1. Weekly micronutrients to WRA
  - 3.1.2. Daily micronutrients to pregnant women
  - 3.1.3. Tally WRA and treatment
  - 3.1.4. Recruit and record new attendees (pregnant women)
- 3.2. Bi-monthly clinics conducted by DPO with recruited pregnant women in each village
  - 3.2.1. Stage of pregnancy
  - 3.2.2. Haemoglobin check
  - 3.2.3. Malaria slide
  - 3.2.4. Intermittent Preventive Treatment (IPTp)
  - 3.2.5. Treatment with Anti-Helminths (3<sup>rd</sup> trimester)
  - 3.2.6. Syphilis testing

3.2.7. HIV (Awareness of availability of MTCT testing)

3.2.8. Case Report Form completed on assessment

3.3. Birth weight of babies within 24 hours & Weight of mother

**4. POST INTERVENTION ASSESSMENT**

4.1. Cross sectional survey of 500 WRA in each site

4.1.1. Basic demographic data

4.1.2. Haemoglobin check Hb

4.1.3. Body Mass Index

4.1.4. Malaria slide

4.1.5. Bed net use

4.1.6. Attendance at weekly clinic

4.2. Survey with target group

4.2.1. Uptake of intervention during pregnancy

4.2.2. Effect as an intervention

## Annex 2: Summary of qualitative interviews

### A2.1 Methodology

The aim of the qualitative interviews, undertaken at a mid-point in the program, was to assess:

- women's perception of pregnancy
- attitudes and beliefs likely to affect uptake of antenatal care
- current practices and perceived barriers to antenatal care and delivery
- perceptions and beliefs in relation to malaria and anaemia, including any link
- experience of participation in the research project

Women were chosen, from the master list from the census, as a convenience sample of a mix of pregnant and non-pregnant women attending for micronutrient treatment administered by VHVs, interviewed in groups of five to six:

- in five different villages in Maprik
- 15 from about 10 villages in Esa'ala.

A semi-structured questionnaire used to guide discussions. The interviewer used good practice for qualitative data collection:

- open and friendly approach, assurance of anonymity
- encouragement to use whatever language was comfortable
- re-phrasing questions where needed
- avoiding leading questions and prompting specific answers

Five of the Esa'ala interviews were not analysed because there was evidence of bias and interference by interpreters, who were health staff, placing words into the women's mouths. This was compounded by other poor communication in that site. All interviews were taped and transcribed in original speakers' Tok Pisin or English, except for the local language sites in Esa'ala where the translation into English was transcribed. An initial review of interviews was used to generate a list of themes. These themes were then used to code and analyse the transcripts, using Atlas TI software.

### Analysis themes in the interviews:

- |  |                                       |
|--|---------------------------------------|
| · Acceptance of pregnancy                | · Perception of drug during pregnancy |
| · Advise and counseling during pregnancy | · Perceptions of cause of illnesses   |
| · Antenatal visits                       | · Perception of pregnancy             |
| · Assistance during delivery             | · Place of safe delivery              |
| · Barriers to antenatal clinic           | · Problems during delivery            |
| · Barriers to health centre delivery     | · Project benefits                    |
| · Community support                      | · Recommendations                     |
| · Comparison of illness                  | · Treatment of illnesses              |
| · Family planning                        | · Understanding of anemia             |
| · Illnesses associated with pregnancy    | · Understanding of malaria            |
| · MCH Services                           | · Use of bed nets                     |
| · Non compliance to micronutrients       |                                       |

## **Summary of findings from qualitative interviews**

The findings reported here comes from focus group discussions conducted with WRA in East Sepik and Milne Bay provinces. These findings may not be same for other women living in .other settings.

### **Women's perceptions of and acceptance of pregnancy**

Women in both sites recognised common signs and symptoms of pregnancy well. Pregnancy was not a universally positive experience, for many women it brought feelings of depression, and anxiety with impact on behaviour and thinking, especially if there is no support to raise the child. If women are not married and have an unintended pregnancy, this causes anxiety and depression which can lead to no antenatal visits and eventually abortion. The groups reported that some women who are not married and have an unintended pregnancy, may result in negative feelings which can lead to no antenatal visits and, for some, seeking abortion.

Marital status had some impact on this, as does the level of support from husband and family members. For many married women, pregnancy was often a moment of joy because they had planned for it and see it as a gift from God. They are often more content because there is a husband who will support them to raise the child. But even among married women, pregnancy was also sometimes viewed as a burden especially for women with many children already. Some saw pregnancy as something that limited their ability to fulfil other aspects of their required role as women.

### **Complications during pregnancy**

Women regard pregnancy as a normal physical event, however most do see it as raising health concerns. The main concerns raised were the fear of labour pains and the fear of complications that might affect the baby and/or themselves. This was especially the case for women in their first pregnancy.

When asked about complications during pregnancy women were able to identify some of these common complications like odema, leakage of amniotic fluid, premature deliveries, and vaginal bleeding. There were limited understanding of the causes but women said when faced with these situations, they would seek medical help at the health centre.

### **Perceptions of the use of medication during pregnancy**

Women perceived medicines taken at the health centres to be safe for pregnant women. They associated chloroquine with malaria and iron tablets with blood shortage however, more detailed understanding of the role of these medicines was lacking. There was a clear association with higher educational levels and better understanding of the role of medications in pregnancy.

Women complied with these medications because they were being told to by the health worker – especially if given the medication to be taken immediately by the health worker, as in this EPO program. However, if they were given medicines to be administered at home, some women reported that they would tend to discard them rather than taking them.

Some women noted that they thought some medications were harmful in pregnancy. Amoxicillin and analgesics were thought to be dangerous because women reported that these were withheld from pregnant women by health centre staff. Traditional herbs were also discussed. Women from Maprik said they were available but were perceived as harmful therefore not taken. Women from Esa'ala said that their traditional herbs were harmless and that they used them in hot seasons to cool themselves.

Some women reported that they disliked the smell of both micro-nutrients and iron tablets, in some cases stating that they smelt like blood.

### **Advice and counselling during pregnancy**

Access to a health facility enhanced women's capacity to understand pregnancy and was also noted to help them pass on information during informal discussion with other women in the same village. Sharing experiences of pregnancy among women was seen as very informative for primipara and young women. This was primarily seen as a means to provide calm, and to organise the variety of thoughts and emotions they were feeling. It was especially valuable to counter the fear of undergoing complicated deliveries.

Young unmarried women were constrained by social attitudes and low self-esteem. This was reported to restrict their access to advice from other women, and delay visits to antenatal care. However it was noted that many young primipara did attend for antenatal advice.

Health services in antenatal, delivery and postnatal care were seen as important, but generally accepted knowledge and the experience of others was also often taken into consideration. For example, to have a healthy pregnancy women know that they have to have a balanced diet, rest and exercise.

### **Access to antenatal care**

Antenatal care in most places was reported to depend on outreach mother and child health patrols. If health staff did not come on outreach visits, pregnant women walked or travelled to the nearest health centre to seek treatment or have antenatal check ups. Some women reported that outreach patrols emphasised care for babies over care for pregnant women.

Many women understood the importance of antenatal care however physical factors, such as seasonal tasks, weather or geographical barriers delayed or prevented attendance. In most cases, women attended for antenatal care in the second and third semester. They delayed antenatal visits until the pregnancy was definitely confirmed, something that was difficult if women had irregular menstrual periods (which may result from other health problems). Socioeconomic status and educational background, particularly the mother's education level, played an important role.

### **Barriers to antenatal care**

The possibility that fear of being tested for HIV was specifically investigated with the groups. However other barriers were seen as more important, including the role and status of women in the society. For example, unintended pregnancies in teenage and

older women (with the implication of poor family planning) and the subsequent sense of shame, were more important barriers. Other barriers raised were the common ones of physical accessibility like distance, cost, financial constraints, geographical settings, health information and family support. Most women were not sure about the details of testing for HIV and didn't see it as a barrier to antenatal visits. Investigators felt this may reflect low levels of understanding of HIV among these communities, which meant fear of stigma was not yet an issue.

### **Illnesses and treatment during pregnancy**

Women associated both malaria and anaemia as illnesses that occurred during pregnancy. Many women also recognised the link between anaemia and malaria, with anaemia following on from malaria. However most women lacked a clear understanding of why this was the case.

### **Attitudes to family planning**

Family planning was not as high a concern as pregnancy. Women did not discuss it often and it was only raised in situations when a woman is identified as having "too many" children. There were reports of suspicion of adverse side effects of some contraceptive methods. Women in Esa'ala reported traditional methods of contraception or possibly abortion can be used for spacing their children.

### Annex 3: Micronutrient formulation

The micronutrients were supplied as coated tablets in bottles of 1000.

Each tablet contains:

Retinol (Vitamin A)	800 RE
Vitamin E	10 mg
Vitamin D	200 IU
Vitamin B1	1.4 mg
Vitamin B2	1.4 mg
Niacin	18 mg
Vitamin B6	1.9 mg
Vitamin B12	2.6 micro g
Folic Acid	400 micro g
Vitamin C	70 mg
Iron	30 mg (as ferrous sulphate)
Zinc	15 mg (as zinc sulphate)
Copper	2 mg
Selenium	65 micro g (as natrium selenit)
Iodine	150 micro g

## **Annex 4: Consultant's activities, including people consulted**

The steps in this consultancy were:

### **Early February:**

- review of data and preliminary analyses with IMR;
- consultation with UNICEF and other stakeholders

### **Late February:**

- comprehensive review of data set and second cleaning of data

### **March:**

- analysis of data, in consultation with IMR and other researchers (see below)
- preparation of draft report
- presentation of draft report by IMR to UNICEF and NDOH, 19<sup>th</sup> March

### **Late March/early April:**

- finalisation of report to incorporate feedback from stakeholders

### **People consulted:**

- Professor Peter Siba, EPO Program Director, PNG IMR
- Mr Ali Kevin, PNG IMR
- Mr Namarola Lote, PNG IMR
- Ms Grace Pongua, PNG IMR
- Dr Grace Kariwiga, UNICEF PNG
- Dr Anatoly Abramov, UNICEF PNG
- Dr Hilda Polume, NDOH
- Ms Wila Saweri, NDOH
- Professor John Reeder, Burnet Institute (on original design elements and malaria in pregnancy)
- Ms Rachael Hinton (on original design elements)

Ms Sarah Sheridan, MAE, Burnet Institute, provided expert support in data organisation and analysis.