PRE-PACKAGED ANTI-MALARIAL TABLETS OR SYRUP:

WHICH IS THE BETTER OPTION FOR THE TREATMENT OF MALARIA IN CHILDREN 0 - 5?

A dissertation submitted to the University of Ghana (School of Public Health) in partial fulfillment for the award of Master in Public Health, September 1998
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DECLARATION

I hereby declare, that except for references to other people’s works which have been duly cited, this work is the result of my own research and that this dissertation has neither in whole nor in part been presented for another degree.

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Ms. Agnes Konadu-Boateng, Ms Victoria Mensah and Ms. Rose Nketia for all their help with the secretarial work.

Finally, but by no means the least, all the research assistants without whom this data would have been very difficult to collect.
DEDICATION

To Kwabena,

Nana Yaw and

Nana Yaa:

“You were always there for me”
EXECUTIVE SUMMARY

This study was carried out in the Cape Coast Municipality of the Central Region of Ghana.

Objectives of the Study were:

1. To describe the problem of compliance with chloroquine syrup in children 0-5 in terms of the kind of measures used, the frequency of administration and the number of days medication is administered.

2. To describe and compare compliance with anti-malarials (chloroquine) among clients receiving pre-packaged tablets to those receiving syrups for their children 0-5 years.

3. To determine the perceptions of mothers concerning the acceptability, convenience and ease of administration of pre-packaged tablets for children.

4. To compare the costs to the mother when pre-packaged chloroquine tablets are prescribed as against syrup.

METHODS USED

Data for this study was collected using both quantitative and qualitative methods. It was predominantly a quantitative study with a small element of qualitative to dilate a bit more on perceptions of mothers.

Information was collected predominantly in the homes of clients who had attended the clinic and been diagnosed as having malaria four days previously.
FINDINGS

Compliance with chloroquine syrup was very poor. Only 42.4% of clients could do as they were told by the Prescriber compared to 91.0% compliance with the pre-packaged tablets.

- A variety of measures with different volumes were being used to represent a 5 ml. Teaspoon. These ranged from 1 ml. To 9 ml. Some clients used two different measures with different volumes to administer the syrup.
- Compliance with pre-packaged chloroquine tablets was more than twice that with the syrup in all cases.
- A majority of mothers found the pre-packaged tablets acceptable, convenient and easy to administer.
- About 63% preferred pre-packaged tablets to syrup.
- Cost of treatment with pre-packaged chloroquine tablets is about one-third that of the syrup.

CONCLUSION

Pre-packaged chloroquine tablets for children 0-5 years are a viable alternative to chloroquine syrup to improve compliance and cut down cost to the patient.

Mothers have shown a willingness to go along with this change and this potential must be explored.
RECOMMENDATIONS

♦ There is an urgent need for the manufacturers of chloroquine tablets to consider manufacturing tablets of lower strength for children. Such tablets must be made, if possible, sweeter and easily dissolvable.

♦ Policy makers must consider the introduction of pre-packaged chloroquine tablets such as described for the treatment of malaria in children instead of the syrup. Since the packaging serves as a reminder of the dosage instruction, it will eliminate the problem of non-compliance with the treatment of malaria in children 0-5 years, improve the quality of care in the home and cut down cost at the same time.

♦ Policy makers must consider ensuring that whenever syrups have to be dispensed, standard 5ml. measures are supplied at little or no extra cost to the patient.

♦ Dispensers must supply clients with just the amount of syrup needed for adequate treatment of each episode of illness to avoid a situation where the mother continues giving the medication “until the child is well”.
<table>
<thead>
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<th>Abbreviation</th>
<th>Description</th>
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</thead>
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<td>Ministry of Health</td>
</tr>
<tr>
<td>TBA</td>
<td>Traditional Birth Attendant</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
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CHAPTER 1

INTRODUCTION

1.1 STATEMENT OF THE PROBLEM

Malaria is the most frequently reported disease in Ghana from all institutions, making up 40–50% of all new cases at the Outpatients department. It is also the leading cause of admissions to the hospital and the second most common cause of death (after Anemia) nationally. Malaria remains the biggest cause of loss of the number of days of healthy life (MOH 1992) and thus is responsible for a high level of morbidity and mortality especially among high-risk groups including children under five years.

Treatment of malaria, however, takes place largely at the household level even when people visit the hospital and treatment is prescribed. The correct treatment is a dose of 10mg of chloroquine phosphate per kilogramme body weight daily for the first two days and half that dose for the third day.

The dose administered at home for syrups prescribed, however, depends on the mother’s perception of instruction she receives at the clinic as well as the kind of measure she has at home for syrups.

Studies carried out in the Wenchi and Dangme West districts of Ghana among others showed that mothers administering syrups tended to either under-dose or over-dose their children (Yeboah Antwi et al, 1997) (Agyepong et al, 1997) (McCombie et al, 1996). Over-dosage, involved the continuation of syrup chloroquine administration long after the prescribed three days whilst under-dosage involved the administration of a lower dose than that prescribed. This was found to be because they quite often forgot the
instruction they were given, “the child is still not better” or because the syrup is not finished yet.”

It was observed in the Dangme West study that a wide variety of "teaspoons" were being used for dispensing the chloroquine. Most of these appeared to measure less than the expected five milliliters. The extent of this problem was however not investigated during the study (Agyepong et al, 1997). This situation as observed has implications for the development of chloroquine toxicity or resistant mutant strains of the malaria parasite; an unfortunate circumstance, since chloroquine is still the cheapest anti-malarial on the market. (Ofori-Adjei et al, 1996) (Hellgren Vet al, 1994)

Non-compliance was found to be more of a problem with syrups than with tablets and did not improve as significantly as it did with tablets when interventions were put in place. Such interventions in the past included improved client – provider communication and pre-packaging plus labeling of the syrup dispensed at the health facility. Pre-packaging of syrups in the Wenchi study was carried out by filling plastic bottles with the required syrup by weight with labels showing dosage in pictorial form.

Even after this, compliance with syrup for children came up to only 54.3% as compared with 82% with pre-packaged tablets for adults (Yeboah-Antwi et al, 1997).

Improved client – provider communication in the Dangme West study only increased strict compliance with syrup from 9% to 21% (Agyepong et al, 1997). Strict compliance in both cases meant doing just as the prescriber said. Finally, syrup chloroquine on the average tends to be more expensive than the tablets making the total cost to the mother higher.
1.2 JUSTIFICATION OF THE STUDY

Pre-packaged tablets which involve putting tablets in polythene packs divided into three sections each containing the daily dose has been found to improve compliance among adults considerably as compared to tablets that are all packed together. This was found in the Wenchi study in Ghana (Yeboah-Antwi et al, 1997).

Other studies elsewhere have come up with similar results. A study carried out in the Hunan Province of the People’s Republic of China showed that packaging anti-malarials in blister packs improved compliance. (Qingjun et al, 1995). Pre-packaging anti-malarials in Burkina Faso where polythene bags were used also resulted in improvement in compliance (Pagnoni et al, 1997).

All these studies however looked at compliance in adults because traditionally adults are given tablets while children receive syrup.

Non-compliance with syrup seems to have persisted to a certain degree in spite of several attempts to improve upon it. This situation brings up the following questions that need to be answered:

“Is the problem of non-compliance with chloroquine syrup treatment related to the formulation of the drug?”

“Will pre-packaged tablets for children as has been found in adults serve as a communicator, reminding mothers of how to administer the drug to their children and thereby improving compliance?”

“If it does, could this then open up possibilities of manufacturers developing much sweeter, “easy-to-dissolve” tablets for children?”

“How acceptable will this change be to mothers with children 0 – 5 years?”

“Will this then also reduce the cost of treatment to the mother as well?”
Overall, improvement in compliance will also delay the time when we have to contend with resistance to cheap and effective drugs like chloroquine.

1.3 OBJECTIVES OF THE STUDY

Against this background, the study aimed to do the following:

General Objective:

To describe and compare the ease of administration, costs and compliance with chloroquine syrup as against pre-packaged tablets for children 0-5 years.

Specific Objectives:

1. To describe the problem of compliance with chloroquine syrup in children 0-5 in terms of the kind of measures used, the frequency of administration and the number of days medication is administered.

2. To describe and compare compliance with anti-malarials (chloroquine) among clients receiving pre-packaged tablets to those receiving syrup for their children 0-5 years.

3. To determine the perceptions of mothers concerning the acceptability, convenience and ease of administration of pre-packaged tablets for children.

4. To compare the costs to the mother when pre-packaged chloroquine tablets are prescribed as against syrup.
1.4 BACKGROUND INFORMATION ON STUDY LOCATION

Cape Coast Municipality

The study was carried out in the Cape Coast Municipality, which is located in the Central Region of Ghana and is the regional capital. The size is about 1007 km² with a population of about 116,408 (projected from the 1984 census).

The topography is mainly a coastal low land with scattered hills in and around the Municipality. The Vegetation is coastal Savannah with wet rainforest inland. There are two rainy seasons: a major one in May/June and a minor one in October/November. The dry season however occurs in the period December to March. The Municipality falls within two of the eco-epidemiological areas i.e. coastal lagoons and mangrove swamps.

Health facilities include a mix of both governmental and private and health delivery is structured along a 3-tier system of Primary Health Care. At the District level, management is by a District Health Management Team headed by the Municipal Director of Health Services. A new Regional hospital has been constructed and was commissioned in August this year. As such, the old Regional hospital has been converted into a district hospital. There is also a quasi-government hospital belonging to the University of Cape Coast.

The four sub-districts at level B, are served by 2 health centres and two Maternal and Child Health Centers. One of the maternal and child health centers is located on the premises of the University of Cape Coast hospital.
At the community level, there are 12 private clinics. Altogether 5 pharmacies and 42 chemical sellers serve as drug outlets. 48 trained Traditional Birth Attendants (TBAs) take care of deliveries in the community with 48 registered traditional healers and other unregistered ones providing alternative health care.
LITERATURE REVIEW

Malaria still remains a formidable foe after defying all efforts aimed at its eradication in the fifties. The control of this disease still poses a problem which health policy-makers and workers are grappling with, fighting on many fronts. Wherever malaria is present, it interferes with human progress and development; and only bringing it under control can its disrupting effect be overcome (Nakajima H., 1991).

The World Health Organization (WHO) estimates that between one and two million persons die from malaria each year and most of those who die are children aged under-five. In 1990 alone, malaria was the cause of 800,000 deaths among children aged under-five (Benzzeroug E. H., 1991).

The Ministry of Health in its situational analysis in 1992 identified malaria as the commonest reason for seeking medical care in Ghana. The ministry also identified the same disease as the major cause of morbidity and mortality in children below five years of age. This vulnerable group includes infants beyond 3 – 6 months who have lost their maternal protective immunity and young children five years and below who have not yet developed sufficiently high local immunity (MOH; 1992).

Currently, case management is the mainstay of malaria control in Ghana with the aim being reduction of morbidity and mortality through prompt diagnosis and effective management of acute clinical episodes of malaria (Agyepong I. et al, 1997).
Chloroquine, in spite of the problem of resistance encountered in some countries, remains the cheapest and most widely used anti-malarial. In Ghana where studies have shown that Chloroquine is still an effective drug for treatment of malaria, it is the first line drug (Afari et al, 1996).

It has been observed however that a high level of misuse occurs with the use of chloroquine and this is not any better when the patient has sought care at the health center (Reubush T. K. et al; 1995) (Ofori Adjei et al; 1996).

The situation is worse when it comes to the chloroquine syrup. Due to uncertainty about how much to give, how frequently and for what duration, a lot of overdosing and under-dosing of the syrup is done. In addition to this, a variety of measures meant to represent teaspoons are in use and it is unlikely that they measure the 5ml they are meant to measure.

Compliance rates for children-prescribed medication have been found to be very similar to those for adults since children are dependent upon parents to give them their medication (Smith Dorothy L.; 1989).

In Malawi, Deborah Helitzer-Allen and others identified the bitter taste of chloroquine and the use of culturally inappropriate health education messages as two of the main reasons for non-compliance of pregnant women with weekly malaria chemoprophylaxis. In that study, improvements in the drug formulation, that is, the use of a sugar-coated chloroquine phosphate product yielded the highest change in compliance among all interventions tried (Helitzer-Allen D; 1993).

To solve the problem of non-compliance among adults, pre-packaging of chloroquine tablets has also been carried out with remarkable success (Yeboah-Antwi et al; 1997) (Qingjun et al, 1995) (Pagnoni et al, 1997).
Compliance packaging (pre-packaging) has been advocated as a patient education tool. The separate dosage units and separate days indicated, help remind the patient when and how much of the medication to take. This is especially important because it is known that up to 10% of hospital admissions are have been reported to be the results of non-compliance with medication (Smith Dorothy L.; 1989)

Though there is a dearth of literature on the subject as relates to children, it is expected that results similar to those of the adults will be obtained if children are given pre-packaged tablets rather than the usual syrup.

Above all greatly increased attention must be given to the improvement of home treatment of malaria if we are to make any strides in malaria control and also postpone the day when there will be a global resistance of the malaria parasite to cheap and effective anti-malarials like chloroquine.
CHAPTER 3

METHODOLOGY

3.1 STUDY DESIGN

The study involved the introduction of pre-packaged (polythene pack divided into three parts each containing the daily dose) chloroquine tablets rather than syrups for children 0-5 years diagnosed with malaria. The impact of this intervention was then compared with what happens normally i.e. the administration of syrup chloroquine for this age group.

All mothers visiting the two Health centers (Ewim and Adisadel) on a particular day and whose children fell into this category received pre-packaged chloroquine tablets whilst those who visited the following day received syrup chloroquine as usual. Tablets and syrup were therefore given on alternate days till the required sample size was obtained. All children who received tablets formed one group while those who received the syrup formed the another.

This was done to avoid a situation where mothers who received tablets would question why others received syrup and as a result become suspicious. Due to the fact that chloroquine tablets are meant for adults who swallow them, most of the current brands of the tablet form a suspension when dissolved instead of a solution. To ensure that children received the complete dose, a particular brand of chloroquine, which had been found to dissolve easily as well as forming a homogenous solution was used for the study.
Fortunately, this particular brand was what was being dispensed in both dispensaries of the two clinics where the studies were carried out. In addition to this, mothers were also counseled at the dispensary to ensure that no particles remain behind by stirring very well before administering the medication. They were advised to add a little honey or sugar to the mixture to mask the bitter taste of chloroquine to some extent.

All mothers had their detailed home addresses taken down by trained research assistants at the dispensary and accompanied home to see where they lived. They were then followed up in their homes on the fourth day after attending the clinic and interviewed with a questionnaire. The purpose of this interview was to find out whether the medication was taken according to the dispenser’s advice; i.e. in terms of the measure used to dispense the medication (in the case of syrups), the frequency per day as well as the duration of administration. The perception of mothers as regards pre-packaged tablets for their children was also sought.

Staff of the health center pre-packaged enough chloroquine tablets for a week on a day in the previous week. Packages were thus available in eight treatment regimes based on weight. In view of the strength of the current formulation of chloroquine tablets, it was recognized that doses supplied might not be very accurate. However, the policy for this study, was to supply a dose as close to what is required by weight as possible, erring on the side of over rather than under dosage. Some tablets had to be broken into halves and quarters to ensure that the patient received a dose as close to what was required as possible. Charts displaying appropriate doses for various weight ranges were supplied to prescribers for use after training. (See Appendix 3)
Studies conducted in Cape Coast had shown that the sensitivity when prescribers diagnosed a case as malaria was very high about 90.3% (Marfo C. et al, in 1997) The assumption for this study therefore was that the right diagnosis would be made to a degree of at least 90.3%

A simple heat cutting and sealing instrument was used for the pre-packing.

3.2 SAMPLING

Mothers who visited the Ewim and Adisadel Health centers and whose children 0-5 years were diagnosed as having malaria were put into the two different groups depending on whether they received tablets or syrups. Those who received tablets formed one group (Tablet group) whilst those who received syrup formed another (Syrup group).

3.2.1 Sample Size Calculation:

A sample size based on the difference between two proportions was calculated with an expected compliance of 40% in the syrup group and 60% in the tablet group. The appropriate sample size for the study therefore based on a power of 80% and a confidence interval of 95% was one hundred and seven (107) children in each group. We decided to use one hundred and fifty in each group however to allow for potential drop-outs.

The formula used was as follows:

\[
m' = \sqrt{c(a/2) * \sqrt{r+1} * PQ - c (1-b) * \sqrt{r * P1Q1+P2Q2}}
\]

\[
m = .25m' * \sqrt{1+\sqrt{1+2* (r+1) / (m' * Abs(P2-P1))}}
\]

(Fleiss J. L & Wiley J. 1981)
3.2.2 Final Sample Size

We had hoped to get a sample of 300 children 0 – 5 years with equal numbers for both groups. It was however difficult to do this even with an extension of the data collection period to five weeks instead of the initial 2 weeks planned. Finally a total of 301 children five years and below were obtained, including 155 children who received pre-packaged chloroquine tablets and 146 children who received syrup chloroquine. Two of the children who received syrup, however, ended up being admitted in hospital that same night and were therefore dropped out of the study. Finally two hundred and ninety-nine (299) children were involved in the study.
<table>
<thead>
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<th>VARIABLE NAME</th>
<th>OPERATIONAL DEFINITION OF VARIABLE</th>
<th>VARIABLE MEASUREMENT</th>
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</thead>
<tbody>
<tr>
<td>NAME</td>
<td>Name of Child</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Name of Caretaker/Mother</td>
<td></td>
</tr>
<tr>
<td>AGE</td>
<td>Age of Child</td>
<td>Years</td>
</tr>
<tr>
<td></td>
<td>Age of Mother</td>
<td></td>
</tr>
<tr>
<td>WEIGHT</td>
<td>Weight of Child</td>
<td>Kilograms</td>
</tr>
<tr>
<td>HIGHEST EDUCATIONAL LEVEL</td>
<td>Highest Educational level achieved by mother</td>
<td>Nil, Primary, JSS, SSS, Vocational, Polytechnic, University</td>
</tr>
<tr>
<td>FORMULATION</td>
<td>Formulation of Chloroquine given</td>
<td>Tablets, Syrup</td>
</tr>
<tr>
<td>RELATIONSHIP</td>
<td>Relationship of Caretaker/ respondent to child</td>
<td>Mother, Aunt, Sister, Grandmother, etc.</td>
</tr>
<tr>
<td>OCCUPATION</td>
<td>Mother's main occupation</td>
<td>Fisherman, Trader, Farmer, Medical Officer, etc.</td>
</tr>
<tr>
<td></td>
<td>Father's main occupation</td>
<td></td>
</tr>
<tr>
<td>PERSON WHO BROUGHT CHILD TO CLINIC</td>
<td>Is Respondent the one who brought child to Clinic?</td>
<td>Yes, No</td>
</tr>
<tr>
<td>PERSON WHO ADMINISTERED MEDICATION</td>
<td>Is Respondent the one who administered the medication?</td>
<td>Yes, No</td>
</tr>
<tr>
<td>DOSE GIVEN</td>
<td>Dose of Chloroquine mother actually gave</td>
<td>X - teaspoonfuls/tablets X - times daily for X - days Where X = 1, 2, 3, 4, 5, etc.</td>
</tr>
<tr>
<td>COMPLIANCE</td>
<td>Is dose given what was prescribed?</td>
<td>Yes, No</td>
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<tr>
<td></td>
<td>Level of Compliance based on</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Volume of measure/ No. of tablets</td>
<td>Correct Dose, Overdosage, Underdosage</td>
</tr>
<tr>
<td></td>
<td>• Frequency of administration</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• No. of days medication administered</td>
<td></td>
</tr>
<tr>
<td>RECOVERY OF CHILD</td>
<td>Has child recovered?</td>
<td>Yes, No</td>
</tr>
<tr>
<td>VARIABLE NAME</td>
<td>OPERATIONAL DEFINITION OF VARIABLE</td>
<td>VARIABLE MEASUREMENT</td>
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<td>---------------------</td>
<td>--------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>TYPE OF MEASURE</td>
<td>Type of Measure used to dispense syrup</td>
<td>Dropper</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Spoon</td>
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<tr>
<td></td>
<td></td>
<td>Cup</td>
</tr>
<tr>
<td>VOLUME</td>
<td>Volume of Measure used to dispense syrup</td>
<td>Milliliters</td>
</tr>
<tr>
<td>CHILD’S BEHAVIOUR</td>
<td>How did child behave when medication (tablets) was administered?</td>
<td>• Vomit or spit some out</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Vomit or spit all of it out</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Refuse to swallow it</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Swallowed it all</td>
</tr>
<tr>
<td>EXTRA DRUG</td>
<td>Did mother have to buy extra drug before child recovered?</td>
<td>• Yes</td>
</tr>
<tr>
<td>EXTRA HEALTH CARE</td>
<td>Did mother have to seek extra health care before child recovered?</td>
<td>• No</td>
</tr>
<tr>
<td>NAME OF DRUG</td>
<td>Name of extra drug mother bought</td>
<td></td>
</tr>
<tr>
<td>COST</td>
<td>Cost of extra treatment/extra health care bought/sought.</td>
<td>Cedis</td>
</tr>
<tr>
<td>ACCEPTABILITY</td>
<td>Mother’s Perception of Pre-packaged Tablets In terms of Acceptability</td>
<td>• Very much acceptable</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Acceptable but with reservation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Not acceptable</td>
</tr>
<tr>
<td>CONVENIENCE</td>
<td>Mother’s Perception of Convenience of administering Pre-packaged tablets</td>
<td>• Very convenient</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Inconvenient</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Very inconvenient</td>
</tr>
<tr>
<td>EASE OF ADMINISTRATION</td>
<td>Mother’s Perception of Ease of administration of medication in the form of tablets</td>
<td>• Very easy</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Fairly easy but a few reservations</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Not easy at all</td>
</tr>
<tr>
<td>PREFERENCE</td>
<td>Mother’s overall Preference for particular formulation</td>
<td>• Tablets</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Syrups</td>
</tr>
</tbody>
</table>
3.4 DATA COLLECTION TECHNIQUES AND TOOLS

3.4.1 Data Collection Techniques

The following data collection techniques were used:

i) Observation/Measurement

Observation of:

♦ The variety of measures used by mothers (followed up from the two health centers) in the home for the measurement of anti-malarial syrups. The volume of each of these measures was ascertained using a calibrated syringe.

♦ All children involved in the study were weighed at the clinic using a weighing scale and weights recorded.

ii) Questionnaire Administration

Questionnaires were administered to mothers involved in the study to:

♦ Find out how the medication was administered and whether they complied with what the prescriber said or not.

♦ Determine their perception and acceptance of pre-packaged anti-malarial tablets for the treatment of malaria in children 0-5 (for mothers whose children received tablets).

iii) Focus Group Discussions were held with two groups of:

♦ Mothers whose children received pre-packaged tablets
To determine their perception and acceptance of pre-packaged anti-malarial tablets for treatment of malaria in children five years and below.

3.4.2 Data collection Tools

These included:

- Graded Measuring syringe
- Weighing scale
- Questionnaire
- FGD Guide

Twelve research assistants assisted the principal investigator to collect the data.

3.5 Exclusion Criteria

The following groups of people were excluded from the study:

- Severely ill patients e.g. patients who were vomiting profusely, weak or needed admission in the opinion of the prescriber.
- Mothers who absolutely refused to accept any formulation on any particular day when it was being given (none of these were encountered).
- Patients that were prescribed other anti-malarials apart from chloroquine.
- Patients who received chloroquine injection.
3.6 Pretesting

Data collection tools were pre-tested at the Ewim Urban Health Center. Interviewers translated the questionnaires into Fanti (the local language) and back into English during their training to ensure that the questions were phrased as they were meant to be. Care was taken to ensure that children involved in Pretest did not form part of the actual sample.

3.7 Data Storage and Analysis

Data collected on the field was checked for completeness and internal consistency, coded, and packaged into well-labeled envelopes and stored. Validation of 4% of the data collected was carried out to ensure accuracy of responses. These were all generally found to be accurate. Data was then entered onto a data entry form designed using EPI INFO version 6.0. The results of the focus group discussions were analyzed manually whilst the quantitative data was analyzed using EPI INFO.

3.8 Ethical Consideration

♦ Permission was sought from the Municipal Health Administration as the local health authority before the study was carried out.

♦ Informed consent was obtained from respondents before administration of questionnaires.

♦ Mothers/Carers preference or choice was taken into consideration; It was planned that mothers who absolutely refused to take tablets for their children would be supplied with syrup. However no such situation arose.
Rather, three mothers accepted the tablets, and had a change of mind when they went home. This resulted in their purchasing syrup for their children instead.

Out of the six children who were said to have vomited all the tablets two were said not to have recovered by the day 4 visit. They were therefore asked to report to the clinic where they would have received free chloroquine syrup if it was confirmed that they were suffering from malaria. However none of them reported.

3.9 Potential Source of Bias/Limitations:

Out of the twelve research assistants, only one worked in one of the clinics in the Public health department. All the rest were non-clinical staff. This was done to reduce bias in clients responses which might occur if they thought there was a likelihood of meeting them again at the clinic after for instance not complying with treatment.
CHAPTER 4

RESULTS

A total of three hundred and one (301) patients 0-5 years with malaria were initially recruited into the study. Out of these 155 received the pre-packaged chloroquine tablets while 146 received the syrup. However two of those who received syrup ended up being admitted in hospital that same night. They did not have the opportunity to take the treatment and were as such excluded from the study.

Finally, two hundred and ninety-nine (299) patients made up of 155 patients who received the pre-packaged tablets and 144 patients who received syrup as is usual were involved in the study.

The modal weight of the children was 8.1 – 12kg.

4.1 THE PROBLEM OF COMPLIANCE WITH SYRUP

Only 42.4% of clients who received syrup complied with the treatment.

Compliance as used here meant doing exactly as the Prescriber said.

Compliance was looked at in relation to the type of measure used, the frequency of administration per day and the duration.

4.1.1 Type of Measure used for Syrups

Seventy nine percent (79.9%) of the respondents who received syrup used a spoon of some sort to measure the dose. Some were teaspoons whilst others were dessertspoons and tablespoons.
The rest, 20.1%, used a cup to measure the daily dose. This included one lady who used the cover of a bottle as a cup. The measures used had a variety of volumes, which ranged from 1ml to about 9mls. The level of variation is seen in table 1.

Four clients used two different measures to administer the chloroquine syrup to the same child. They used one measure on an occasion and another at a different time or on a different day.

Table 1: Variations in the volume of Home measures used by clients for syrups

<table>
<thead>
<tr>
<th>Volume</th>
<th>Frequency</th>
<th>Percentage of Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;2.5mls</td>
<td>9</td>
<td>9.0</td>
</tr>
<tr>
<td>2.5 – 4.99mls</td>
<td>86</td>
<td>59.7</td>
</tr>
<tr>
<td>5mls</td>
<td>28</td>
<td>19.4</td>
</tr>
<tr>
<td>&gt;5mls</td>
<td>17</td>
<td>11.8</td>
</tr>
<tr>
<td>TOTAL</td>
<td>*140</td>
<td>100%</td>
</tr>
</tbody>
</table>

*Four of the clients used two different measures and were not included in this analysis. The volume of their measures also ranged between 1 and 9 ml.

4.1.2 Frequency of administration of the Syrup per day

The frequency of administration varied. Clients were to administer the medication once a day. However, there were variations in the frequency of administration of the syrup.

Some administered it once a day, others twice and three times a day respectively. Some others gave the medication a different number of times per day over the three to four day period. This can be seen in table 2.
It was a completely different story with the tablets. All the non-compliance had to do with either not administering at all or not completing the course. There was no problem with frequency of administration.

Table 2: Frequency of administration of syrup per day

<table>
<thead>
<tr>
<th>Number of times/day</th>
<th>Number of clients</th>
<th>Percentage of total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Once/day</td>
<td>87</td>
<td>60.4</td>
</tr>
<tr>
<td>Twice/day</td>
<td>21</td>
<td>14.6</td>
</tr>
<tr>
<td>Three times/day</td>
<td>20</td>
<td>13.9</td>
</tr>
<tr>
<td>Mixed</td>
<td>16</td>
<td>11.1</td>
</tr>
<tr>
<td>TOTAL</td>
<td>144</td>
<td>100.0%</td>
</tr>
</tbody>
</table>

4.1.3 Duration of Administration of the Syrup

Though the greater majority, 94.3% administered the chloroquine syrup for only 3 days, 5.7% of clients administered the medication for more than the stipulated 3 days and were still administering the syrup at the time of the day 4 visit.

4.1.4 Accuracy of Dosage

The accuracy of the dose administered was analyzed by considering the total dose given up to the time of the Day 4 visit. The accuracy of the daily dose was not considered in this case. It was expected that by the time of the visit the clients should have administered chloroquine syrup amounting to 25mg/kg body weight to the child. The analysis was therefore carried out in two ways:
Assuming the use by client of an accurate 5ml measure to represent a
teaspoon.

Taking into consideration the actual volume of the measure used by the
client to represent a teaspoon.

Most of the clients (47.9%) were found to have overdosed their children when
a 5ml- teaspoon measure was assumed because they either administered
more doses per day than prescribed or gave the chloroquine syrup for a
longer duration than expected. Only 42.9% had given the correct dose.

However, when the actual volume of measure used was taken into
consideration the number giving the correct dose reduced to about one
quarter of the original number i.e. 8.6% while the proportion of clients who
under-dosed their children increased from 9.3% to 47.1%.

Tables 3 and 4 show the changes more clearly.

Table 3: Accuracy of total Amount of Syrup given up to time of
Day 4 visit

<table>
<thead>
<tr>
<th>Accuracy of total dose administered</th>
<th>Assuming a Standard 5ml Teaspoon/Cup Measure</th>
<th>Taking the actual Measure Used into Consideration</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
<td>%</td>
</tr>
<tr>
<td>Under-dosage</td>
<td>13</td>
<td>9.3</td>
</tr>
<tr>
<td>Correct dosage</td>
<td>60</td>
<td>42.9</td>
</tr>
<tr>
<td>Over dosage</td>
<td>67</td>
<td>47.9</td>
</tr>
<tr>
<td>TOTAL</td>
<td>140</td>
<td>100%</td>
</tr>
</tbody>
</table>
Measures vs. Considering actual measure used.

Table 4: Comparison between the expected total dose and the actual administered

<table>
<thead>
<tr>
<th>Assuming Standard 5ml Measure</th>
<th>Considering Actual Measure Used</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Under-dosage</td>
</tr>
<tr>
<td>Under-dosage</td>
<td>12</td>
</tr>
<tr>
<td>Correct-dosage</td>
<td>38</td>
</tr>
<tr>
<td>Over-dosage</td>
<td>16</td>
</tr>
<tr>
<td>TOTAL</td>
<td>66</td>
</tr>
</tbody>
</table>

*Four clients who used two different measures with different volumes were excluded from this analysis

4.2 COMPLIANCE WITH PRE-PACKAGED TABLETS VERSUS SYRUP

There was a significant difference in compliance between clients who received pre-packaged tablets and those who received syrup for treatment of malaria.

Whilst 91% of the tablet group did exactly as the prescriber had said, only 42.4% of the syrup group did as they were told (chi-square=78.27; p-value<0.00001). Table 5 below shows this very clearly.
Table 5: A Comparison of Compliance with treatment between clients Who received Pre-packaged tablets and those who received Syrup

<table>
<thead>
<tr>
<th>Formulation</th>
<th>Number of Clients receiving Formulation</th>
<th>Percentage Compliance</th>
<th>Non Compliance</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Syrup</td>
<td>144</td>
<td>42.4%</td>
<td>57.6%</td>
<td>100%</td>
</tr>
<tr>
<td>Pre-packed Tablet</td>
<td>155</td>
<td>91.0%</td>
<td>9.0%</td>
<td>100%</td>
</tr>
</tbody>
</table>

Three of the respondents who received tablets changed the prescription and purchased syrup for their children instead because according to them, “we know of only syrups for children. Tablets are not for children, they are for adults.”

Other reasons for non-compliance with treatment in both groups are listed in table 6 below:

Table 6: Reasons for Non-compliance with treatment

<table>
<thead>
<tr>
<th>Reasons why clients did not comply with tablets</th>
<th>Reasons why clients did not comply with syrup</th>
</tr>
</thead>
<tbody>
<tr>
<td>Child vomited the medication so I stopped.</td>
<td>I thought that was what I was told to do.</td>
</tr>
<tr>
<td>Forgot to give third day dose because child was well.</td>
<td>The syrup was too bitter.</td>
</tr>
<tr>
<td>The child vomited after the tablets were given so I stopped because I thought may be “ene no ngyi” (an akan phrase meaning she is allergic to it)</td>
<td></td>
</tr>
<tr>
<td>Turned the satchet upside down. Started with day 3 dose first then day 2 and 1 in that order.</td>
<td></td>
</tr>
<tr>
<td>We know of only syrups for children. Tablets are not for children. They are for adults.</td>
<td></td>
</tr>
<tr>
<td>I stopped the treatment because my child was itching.</td>
<td></td>
</tr>
</tbody>
</table>
4.2.1 Relationship between Compliance and whether Counseling was received directly at the clinic or through another person

In general, there was no significant difference between the tablet and syrup group in terms of the proportion of those who brought the child to the clinic and also administered the medication themselves and those who did not, but received the instruction from another person (chi-square=0.10; p-value = 0.7495).

Compliance was generally lower in both groups when the person who received the instruction was not the same as the one who administered the medication. In each case however, compliance among the tablet group was more than twice that of the syrup group as can be seen in table 7 below.

Table 7: Compliance with Pre-packaged Tablets versus Syrup: depending on whether respondent received counseling on how to administer medication directly or through someone

<table>
<thead>
<tr>
<th></th>
<th>PRE-PACKAGEDTABLETS</th>
<th></th>
<th>SYRUP</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>COMPLIANCE (%)</td>
<td>NON-COMPLIANCE (%)</td>
<td>COMPLIANCE (%)</td>
<td>NON-COMPLIANCE (%)</td>
</tr>
<tr>
<td>Instructions</td>
<td>91.5</td>
<td>8.5</td>
<td>42.7</td>
<td>57.3</td>
</tr>
<tr>
<td>Received Directly</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Counseling</td>
<td>85.7</td>
<td>14.3</td>
<td>38.5</td>
<td>61.5</td>
</tr>
<tr>
<td>received through</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>someone</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4.2.2 Relationship between Compliance and Educational level of mother

There were differences in compliance among mothers of different educational level. The lowest compliance was in the primary school level group and this was the same whether the client received tablets or syrup. At all levels of education, however, compliance among the Tablet group was about twice that of the Syrup group. From secondary school level up-wards through post-
secondary up to university there was a steady increase in both groups. The differences between the various levels was however not significant except between the Secondary level and the subsequent higher levels among the syrup group where there is a big increase in compliance (chi-square=9.47; p-value>0.05)
### Table 8: Level of compliance with treatment among mothers of different educational background: Tablets versus Syrup

<table>
<thead>
<tr>
<th>Educational Level of Mother</th>
<th>Total Number</th>
<th>Compliance with Tablets (%)</th>
<th>Compliance with Syrup (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nil</td>
<td>67</td>
<td>94.6</td>
<td>43.3</td>
</tr>
<tr>
<td>Primary</td>
<td>46</td>
<td>85.0</td>
<td>26.9</td>
</tr>
<tr>
<td>Middle School/JSS</td>
<td>151</td>
<td>91.6</td>
<td>42.6</td>
</tr>
<tr>
<td>Secondary/Commercial/Vocational</td>
<td>23</td>
<td>81.8</td>
<td>41.7</td>
</tr>
<tr>
<td>Post Secondary</td>
<td>10</td>
<td>100</td>
<td>83.3</td>
</tr>
<tr>
<td>University/Polytechnic</td>
<td>2</td>
<td>-</td>
<td>100</td>
</tr>
</tbody>
</table>

### 4.2.3 Relationship between Compliance and mother and father's occupation

There were no significant differences in compliance among people of different occupations. For every occupation however, compliance among the Tablet group was about one and a half times to twice that of the Syrup group.

### 4.3 RECOVERY: PRE-PACKAGED TABLETS VERSUS SYRUP

There was no significant difference in recovery between clients who received pre-packaged tablets and those who received syrup (chi-square=0.32; p value=0.5695).

It was difficult to explain why slightly more of the Syrup group, than the Tablet group, were said to have recovered at the time of the visit.
Table 9: Recovery of children according to mother's perception.

<table>
<thead>
<tr>
<th>Formulation</th>
<th>Total number of Clients</th>
<th>% of total Recovered at time of Visit</th>
<th>% of total not Recovered at time of Visit</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Syrup</td>
<td>144</td>
<td>95.1</td>
<td>4.9</td>
<td>100%</td>
</tr>
<tr>
<td>Pre-packaged tablets</td>
<td>155</td>
<td>92.9</td>
<td>7.1</td>
<td>100%</td>
</tr>
</tbody>
</table>

4.4 PERCEPTION OF MOTHERS CONCERNING ACCEPTABILITY, CONVENIENCE AND EASE OF ADMINISTRATION OF PRE-PACKAGED TABLETS

4.4.1 Acceptability to Mother

Ninety percent (90.3%) of mothers said that the pre-packaged tablets were acceptable to them. The main reason given was that the packaging was good, attractive and the numbering helped them to remember each day’s dose.

A little over three percent (3.9%) said the pre-packaged tablets were acceptable but they still had reservations whilst approximately six percent (5.8%) said it was NOT ACCEPTABLE. Three of the latter group showed their stance in no uncertain terms by buying syrup instead of administering the tablets supplied by the dispensary.

The reasons given by the latter two groups were the similar.

See Table 10 and 11.
Table 10: Perception of mothers’ concerning Acceptability, Convenience and Ease of administration of pre-packaged tablets

<table>
<thead>
<tr>
<th>Acceptability</th>
<th>Very much Acceptable</th>
<th>Acceptable with Reservation</th>
<th>Not Acceptable</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>90.3%</td>
<td>3.9%</td>
<td>5.8%</td>
<td>100%</td>
</tr>
<tr>
<td>Convenience</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Very Convenient</td>
<td>79.4%</td>
<td>18.1%</td>
<td>0.6%</td>
<td>1.9%</td>
</tr>
<tr>
<td>Inconvenient</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Very Inconvenient</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not Applicable</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ease of Administration</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Very Easy</td>
<td>65.1%</td>
<td>27.7%</td>
<td>5.2%</td>
<td>1.9%</td>
</tr>
<tr>
<td>Fairly Easy but----</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not easy at all</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not Applicable</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 11: Reasons for Mothers’ Perceptions Concerning Acceptability, Convenience and Ease of Administration

<table>
<thead>
<tr>
<th>Acceptability</th>
<th>Convenience</th>
<th>Ease of Administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not acceptable</td>
<td>Not convenient</td>
<td>2.0% of total</td>
</tr>
<tr>
<td>Almost acceptable</td>
<td>Not convenient</td>
<td>3.9% of total</td>
</tr>
<tr>
<td>Acceptable</td>
<td>Convenient</td>
<td>11.2% of total</td>
</tr>
<tr>
<td>Very acceptable</td>
<td>Very convenient</td>
<td>3.9% of total</td>
</tr>
<tr>
<td>Not easy at all</td>
<td>Not easy</td>
<td>2.0% of total</td>
</tr>
<tr>
<td>Fairly easy</td>
<td>Fairly easy</td>
<td>11.2% of total</td>
</tr>
<tr>
<td>Very easy</td>
<td>Very easy</td>
<td>17.8% of total</td>
</tr>
</tbody>
</table>

Notes:
- Table 11: Ratings for Mothers’ Perceptions Concerning Acceptability, Convenience and Ease of Administration
- It’s effective, it works fast
- Its hygienic
- The packaging is good, attractive, and the numbering is helpful. No need for bottle. It’s easy to remember and administer the dosage.
4.4.2 Acceptability to child

The acceptability of the pre-packaged tablets to the child, was assessed by considering the behaviour of the child when the medication was administered. Information on the child's behaviour was provided by the mother. About eighteen percent (18.1%) of children spat or vomited some of the medication out; six patients who were said to have vomited or spat all the drug out formed 3.9% of the total sample of those who received tablets. Three patients forming 1.9% were not given the tablets at all by their mothers. 76.1% of the patients swallowed all the medication given. Out of the six who vomited out all the drugs, five were said to usually behave the same way with the syrup.

4.4.3 Convenience to mother

About seventy-nine percent (79.4%) said the use of the pre-packaged tablets was convenient whilst 18.1% said it was inconvenient. One person said it was very inconvenient. Reasons given can be seen in Table 11.

4.4.4 Ease of Administration

About sixty-five percent (65.2%) said the administration of the pre-packaged tablets was very easy whilst 27.7% said that even though they found it easy, they still had some reservations. These reservations were similar to reasons given by the 5.2% who said it was not easy at all.
4.4.5 Preference of Mothers

When it came to preference 61.9% of mothers preferred tablets whilst 37.4% preferred the syrup. This included three mothers who showed their preference in the strongest terms by not giving the tablets at all and buying chloroquine syrup for the child. One person could not decide on any one option.

4.5 Cost: Pre-packaged Tablets versus Syrup

One tablet of chloroquine cost $\textcelsius40.00 whilst a bottle of chloroquine syrup (about 60mls) cost $\textcelsius600 at the dispensary.

The Heat Sealing machine used for the packaging cost $\textcelsius130,000.00 and was a one-off expenditure. Polythene in which the tablets were packed cost a total of about $\textcelsius3,000.00 for all the 155 patients who received the tablets.

Whilst the average cost for treatment with chloroquine syrup is about $\textcelsius600 plus the cost of the bottle which is $\textcelsius150 making a total of $\textcelsius750, for the tablets, the maximum a child 0-5 years will pay for a course of treatment is $\textcelsius200.00.

If the cost of the polythene for pre-packaging is added, it adds at most $\textcelsius20.00 to the cost, making a total of $\textcelsius220.00.

*The current exchange rate is US$1.00 to $\textcelsius2,080.00*
CHAPTER 5

DISCUSSION

This study has demonstrated that it is possible to remarkably improve compliance with chloroquine treatment for children whilst cutting down considerably on cost. It has also demonstrated that though traditionally, tablets have not been used for children, there is a great potential for exploring the avenue of pre-packaged chloroquine tablet use since mothers have shown in this study that they are willing to go along with such a change. They have gone further by indicating a definite preference for the pre-packaged tablets for various reasons. 61.9% of respondents whose children had been given the tablets, preferred that to syrup.

This tallied closely with their perception of ease of administration (65.2% said administration was easy) which actually took into consideration the reaction of the child when the drug was administered.

5.1 PROBLEM OF COMPLIANCE WITH CHLOROQUINE SYRUP

There is definitely a problem with the administration of chloroquine syrup at home and this is especially so with people of lower education. A second look must be taken at this problem the use of pre-packaged tablets promoted.
Variability in Volume of Measures Used for Chloroquine Syrup

The wide variation in the measures that were being used was an eye-opener. The issue needs to be given serious consideration. Often when we have in the clinic told clients “give your child one teaspoonful of this syrup once daily”, we have done so under the assumption that they have at home, a teaspoon that measures 5ml.

However it has become obvious from this study that the clients’ teaspoons could measure anything between 1ml and 9mls. The majority of clients in this study had spoons/cups measuring 2.5 – 4.99mls. This situation, obviously, will lead to a high level of under-dosage or over-dosage as indeed was found. It appears however that the greater problem is that of under-dosage from the results of this study and others (McCombie S. C.; 1996). The implications for the development of resistant strains of the malaria are enormous (Ofori Adjei D. et al; 1996) (Hellgren et al; 1994)

This is in sharp contrast to the almost total compliance with the pre-packaged tablets which does not need to be measured and has the daily dose clearly demarcated.

There is therefore a need to consider the manufacture of chloroquine tablets of lower strength for children. These if possible must be sweetened and easy-to-dissolve or effervescent. However it appears from this study that even if it is impossible to sweeten chloroquine, administering the tablets as they are now is a much better option than the syrup.

If the administration of syrup to children is to be continued, however, a standard 5ml measure must be provided with the syrup each time. This will
still however not solve the problem of mothers not being sure of how many times a day they are to administer the medication and for how long.

**Frequency of Administration**

Use of Pre-packaged tablets will solve completely the problem of how many times a day to administer chloroquine as was found in this study.

**Duration of Treatment**

In contrast to what has been found in other places, very few clients, 5.7%, continued the administration beyond day 3 (Agyepong et al.;1997) (Yeboah-Antwi et al,1997). This is however a reflection of the number said to have recovered at the time of visit (about 95.1%).

Mothers during the focus group discussion emphatically said that chloroquine syrup is to be administered “until my child gets well, then I stop” So it pre-supposes that they stopped because their children were well.

During the period of study one lady reported with her child to whom she had been administering chloroquine syrup twice daily for over 2 weeks without improvement until she decided to bring him. That child was not included in our study.

A way out would be to provide the exact amount of chloroquine syrup needed by the child to take care of the duration aspect of it and limit the number of days that the mother would be tempted to continue giving the medication. This again would still not solve the problem of how much to give and how often in the day.
5.2 COMPLIANCE WITH TABLETS VERSUS SYRUP

Compliance with the pre-packaged tablets, which was found to be about double that of syrup in all cases is very significant. Out of the 155 clients who received the pre-packaged tablets, 91.0% complied with the treatment, that is, they did just as the prescriber said. In contrast only 42.4% of the 144 patients who received chloroquine syrup complied.

All patients had been seen by the same prescribers who had a chart for reference to enable them prescribe by weight. They were also seen by the same dispensers who provided both counseling on how to take the formulations and pictorial aids on the label of the syrups. The three sections of the pre-packaged tablets had also been numbered to indicate the daily dose.

It appears it was much easier for patients to comply with the tablets because as one respondent said “what I need to give each day is known and easy to determine. I don’t have to worry about measuring”. One lady said during the focus group discussion that, “the numbering of the package helps me to remember. As for 1,2,3 even if you haven’t been to school you can still recognize and understand it “. The few who did not comply with the tablets did not do so because they had always known that tablets were for adults so they thought there must be something wrong.

In the Malawi study, it was noticed, that one of the reasons why there was such a high level of compliance with the new formulation they introduced was that the community had no prior experience with the new formulation and there was no traditional prohibition limiting its use (Helitzer-Allen D. et al;
The level of compliance obtained in that study when both health education at the ante-natal clinic and the new formulation were combined was 87%. This was less than the 91% obtained in this study with patient counseling at the dispensary and the change in formulation and packaging.

There was generally no contradiction in this study between the advice of the health workers and the belief structure of the community except for the few parents who must have held really strongly to the belief that “tablets are not for children”.

Others did not comply because the child vomited. Some of these respondents, as it turned out during the FGD’s did not add sugar or honey as instructed to sweeten it. In the Malawi study, the new formulation was pink, sugar-coated and therefore non-bitter, which the original chloroquine tablets are (Helitzer-Allen D. et al; 1993). It appears therefore that the very bitter taste of chloroquine tablets and even the syrup does contribute in some way to the low compliance. However this factor does not affect the compliance as much as does the inability to remember the dosage instructions.

This is confirmed by similar results obtained in other places including the Wenchi study in Ghana where the compliance among adults was found to improve considerably when pre-packaged tablets were given (Yeboah-Antwi et al, 1997),(Qingjun et al, 1995),(Pagnoni et al, 1997).

It is worth mentioning however that compliance with the pre-packaged tablets might be as high as it is, because this is something new to the mothers who are likely to take more care. It is possible that compliance might fall over time. This is however a subject for further study where the pre-packaged tablets are administered over a period.
With the syrup, however, during a focus group discussion, it was realized that most mothers had their pre-conceived ideas as to how much and how many times to give the syrup. Some said, “as for chloroquine it is always given, twice a day”. Others insisted that it was given three times a day, whilst others also insisted on once a day. It did not seem as if they listened to the dispensers’ instructions; possibly because they assumed they knew.

It was also possible that they forgot the instruction given. When asked, they insisted that what they did was what they remember being told to do. Other studies found the same problem. (Agyepong et al, 1997) (Yeboah Antwi et al, 1997).

There seems to be a perennial problem therefore with administration of syrup where mothers get confused as to how much they are to give, how often in a day and for how long. Pre-packaged tablets brought up no such problems.

**Compliance versus Educational Level of Mother**

Compliance among mothers with no education was much better than among those with only primary school education. For the same level of education however compliance was about double for the tablets.

The relationship between compliance and education was not found to be significant. This was no different from what was found in Malawi where the relationship between compliance and education was not found to be significant. (Helitzer-Allen D. et al;1993)
Compliance versus Mother and Father’s Occupation

The kind of occupation the parents were engaged in, did not have any effect on how much they complied with treatment.

For the same occupation however, the compliance with tablets was about twice that with the syrup in almost all cases.

5.3 RECOVERY

Recovery in this case relied on the mother’s perception of her child’s health. It was considered that, since it was the mother who decided her child was ill and therefore reported at the clinic, she can be relied on to give a fair judgement of his/her recovery.

With the level of under-dosage seen with the syrups it was expected that more children who were given tablets would recover as compared to syrup but this was not seen.

The best thing would have been to pay a visit on Day 7 to confirm recovery but this was not possible in the context of this study.

5.4 PERCEPTION OF MOTHERS OF PRE-PACKAGED TABLETS

Though 90.3% of mothers said “yes, the pre-packaged tablets are very much acceptable” and 79.4% said tablets were convenient to use for the various reasons already stated, only 65.2% said it was easy to administer. This takes into consideration the reaction of the child to the medication.
It can be seen that mothers stated their preference taking this into consideration because 61.9% preferred the tablets to the syrup.

One recurring reason was that tablets work faster and the dose could be remembered easily, because of the numbering on the package. One lady mentioned in the FGD that she thought the syrup in the dispensary was dilute. During the study it was observed that a substantial number of patients avoided the dispensary and bought their medication from drug stores in town.

The clients who received pre-packaged tablets however were convinced to buy at least the tablets to which they obliged.

Another lady said “I give the syrup to my child for a long period before he recovers unlike the tablets” Looking at this statement in the light of the percentage of clients who under-dose their children, one can understand why this is so.

Pre-packaged tablets for children therefore are a viable alternative to avoid under-dosage and over-dosage as well.

Apart from improving compliance, a situation where truly, syrups contain less of the active ingredient than expected due to over-dilution down the market line to the consumer can be avoided.

5.5 COST

The tablets are cheaper for the mother than the syrup.

The Heat sealing machine is a capital expenditure and is a one-off cost of C130,000.00 which, considering it life-span, is negligible. So is the cost of electricity. Together they will not add any significant amount to the cost.
With the cost of living escalating every day and children bearing the brunt of its effects, any cost reduction to the mother is significant and due consideration must be given to the use of prepackaged tablets which are cheaper.

5.6 SUMMARY OF CONCLUSIONS

Pre-packaged tablets for children must be considered as a viable alternative for the treatment of malaria to improve compliance and cut down drastically on under-dosage and over-dosage which has implications for development of resistant strains on one hand and toxicity on the other.

It must be considered because it removes the problem of a variety of measures with different volumes being used in the home to represent a 5ml teaspoon and the mother’s dilemma of how many times per day as well as how many days to administer the syrup.

Finally, cost to the mother which has become a very important function in these days of high cost of living, has been shown to be cut down to about one-third when pre-packaged tablets are given instead of syrups.
REFERENCES


The Epidemiology of Malaria with special emphasis on Transmission, Morbidity, Mortality and disease control in Ghana. Nougouchi Memorial Institute of Medical Research, University of Ghana, Legon. Unpublished Research Report


Can Improvements in the Quality of Client-Prescriber and Client-Dispenser Communication improve Patient Compliance with Chloroquine? Unpublished Research Report

Malaria and Drug Resistance. World Health, the magazine of the WHO Aug-Sept 1986:7-9

Strategies for Africa. World Health, the magazine of the WHO sept-oct 1991:5


Malaria Parasites and chloroquine concentration in Tanzanian School Children. Tropical Med. Parasitol. 1994; 45(4) 293-7
CHAPTER 6

RECOMMENDATIONS

The home is an important component of management of acute clinical episodes of malaria. This method is currently the mainstay of control in Ghana.

All efforts must therefore be made to improve this very important component by making it easier for patients to comply with treatment prescribed. The following are recommended:

◆ There is an urgent need for manufacturers of chloroquine tablets to manufacture of tablets of lower strength for children. Such tablets, must be made, if possible, sweeter and easily dissolvable.

◆ Policy makers must consider the introduction of pre-packaged chloroquine tablets such as described for the treatment of malaria in children instead of the syrup. Since the packaging serves as a reminder of the dosage instruction, it will eliminate the problem of non-compliance with treatment of malaria in children 0-5 years, improve the quality of care in the home and cut down cost at the same time.

◆ Policy makers must also consider ensuring that whenever syrups have to be dispensed, standard 5milliliter measures are supplied at little or no extra cost to the patient.

◆ Dispensers must supply clients with just the amount of syrup needed for adequate treatment of each episode of illness to avoid a situation where the mother continues giving the medication “until the child is well”.

REFERENCES


The Epidemiology of Malaria with special emphasis on Transmission, Morbidity,Mortality and disease control in Ghana. Nougouchi Memorial Institute of Medical Research, University of Ghana, Legon. Unpublished Research Report


Can Improvements in the Quality of Client-Prescriber and Client-Dispenser Communication improve Patient Compliance with Chloroquine? Unpublished Research Report

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Strategies for Africa. World Health, the magazine of the WHO sept-oct 1991:5


Malaria Parasites and chloroquine concentration in Tanzanian School Children. Tropical Med. Parasitol. 1994; 45(4) 293-7


Malaria Control: history shows its possible. World Health, the magazine of the WHO Sept-Oct 1991:5

Breaking the fatal cycle of transmission. World Health, the magazine of the WHO Sept-Oct 1991:2


A community based program to provide prompt and adequate treatment of presumptive malaria in children. Transactions of the Royal Society of Tropical Medicine and Hygiene, 91:512-517


Compliance Packaging: A Patient Education Tool
American Pharmacy, Vol NS29, No. 2 February 1989/126

The Impact of Pre-packaging of anti-malarial drugs on cost to patients and compliance to treatment. Unpublished Research Report
ADDRESS CARD

DATE OF CLINIC VISIT:........................................................................................................

NAME OF CHILD: ............................................................................................................

NAME USED AT HOME: ....................................................................................................

AGE OF CHILD: .................................................................................................................

WEIGHT OF CHILD: ...........................................................................................................

NAME OF MOTHER/CARETAKER: ......................................................................................

NAME USED AT HOME: ....................................................................................................

DETAILED ADDRESS (Describe fully): ................................................................................

........................................................................................................................................

........................................................................................................................................

........................................................................................................................................

FORMULATION OF CHLOROQUINE GIVEN (TICK):

☐ TABLET

☐ SYRUP

PRESCRIPTION/INSTRUCTIONS GIVEN TO MOTHER BY PRESCRIBER:

DAY 1 .................................................................................................................................

DAY 2 .................................................................................................................................

DAY 3 .................................................................................................................................
Appendix 1

QUESTIONNAIRE FOR MOTHERS/ CHILDCARETAKERS

PART A

Introduction: Good Morning/Afternoon. We are carrying out a study into the treatment of children at home. We notice you visited the clinic 4 days ago and would like to ask you a few questions on this issue.

- Interviewer ID No.: ------------ Community: ------------
- Respondent Name: --------------------------- Sub-district: ---------------------
- Age of Respondent:-----------years
- Age of child: -------------- years Weight of child --------------
  (Fill in from address card)
- Relationship of Respondent to child:-----------------------------
- Age of Mother:---------------------------------years
  (If not the same as respondent)
- Mother’s main Occupation:---------------------------------------------
- Father’s main Occupation:-------------------------------------------
- Highest Educational level of Mother/Principal Child Caretaker:-
  □ Nil □ Primary □ Other, (specify) --------------
  □ Post Secondary □ University □ Middle School/JSS

1. Is Respondent the one who brought the child to the clinic?
   □ Yes □ No

2. Is Respondent the one who administered the chloroquine medication?
   □ Yes □ No

3. What medication were you given at the clinic, when you last visited? Can I see them?
   (list drugs and select chloroquine container/pack. If not included ask
4. How did you actually administer/administering it?

<table>
<thead>
<tr>
<th>UNIT OF DOSE</th>
<th>DAILY DOSE</th>
</tr>
</thead>
<tbody>
<tr>
<td>--------------</td>
<td>------------</td>
</tr>
<tr>
<td>tsp./tabs</td>
<td>Day 1:</td>
</tr>
<tr>
<td>tsp./tabs</td>
<td>Day 2:</td>
</tr>
<tr>
<td>tsp./tabs</td>
<td>Day 3:</td>
</tr>
<tr>
<td>tsp./tabs</td>
<td>Other:</td>
</tr>
</tbody>
</table>

(To be filled in by interviewer after comparison with address card)

☐ Same as prescriber said
☐ Different from what Prescriber said

5. Has your child recovered now? Yes ————
   No ————

PART C

(FOR CHLOROQUINE SYRUP RECIPIENTS ONLY)

6. Can you show me what you used at home to measure the dose? (Interviewer to use syringe to measure volume)

Type:
☐ Cup
☐ Spoon
☐ Dropper

Actual Volume ———— mls.
PART D

(FOR CHLOROQUINE TABLET RECIPIENTS ONLY)

7. When administering the tablets, did the child
   □ Vomit or spit some of it out
   □ Vomit or spit all of it out
   □ Refuse to swallow it
   □ Swallowed it all

8. Does your child behave the same way with Chloroquine syrup also?
   □ Yes    □ Not Applicable
   □ No
   (If yes, skip question (9).

9. If no how does he/she behave when being given Chloroquine syrup?
   ..............................................................................................................
   ..............................................................................................................

10. Did you have to buy any extra drug before the child recovered?
    □ Yes
    □ No
    (If no skip question 11)

11. What drug did you buy?
    ..............................................................................................................

12. Did you have to seek any extra health care before the child recovered?
    □ Yes
    □ No

13. What was the total cost of extra treatment/health care?
    ........................................... cedis
14. How acceptable are the Pre-packaged tablets to you?

- [ ] Very much acceptable
- [ ] Acceptable but with reservation
- [ ] Not acceptable

Reason?

15. How convenient are the Pre-packaged tablets for use? (probe for having to crush and dissolve before administration)

- [ ] Very Convenient
- [ ] Inconvenient
- [ ] Very Inconvenient

Reason?

16. How easy are the pre-packaged tablets to administer?

- [ ] Very Easy.
- [ ] Fairly Easy but with few reservations:

Reason?

17. Overall which formulation do you prefer?

- [ ] Tablets
- [ ] Syrups

18. Why do you prefer syrups/Tablets?
Appendix 2

FGD FOR MOTHERS WHERE CHILDREN RECEIVED TABLETS

Introduction: Good Morning/Afternoon. We are carrying out a study into the treatment of children at home. We notice you visited the clinic four days ago and would like to ask you a few questions on this issue.

There is no wrong or right answers we would like to hear the views of everyone present here.

Before we go on, we would like to introduce ourselves by mentioning our names (how we would like to be called here) and what we do.

This tape recorder here is for recording the conversation so that I don’t forget some of the important things you say.

1. What do you think about administering pre-packaged tablets to children? (Probe)
   ______ In terms of your compliance with the dose prescribed
   ______ In terms of cost
   ______ In terms of convenience of use
   ______ In terms of acceptability to your children
   ______ In terms of ease of administration

2. Do you have any suggestions to improve compliance and ease of administration?

3. Would you like to continue receiving pre-packaged tablets in future or would you prefer the syrup?

4. Is there anything else about this discussion that you would like to tell me that I haven’t brought up yet?
### Appendix 3

**WEIGHT CHART FOR PRESCRIPTION OF CHLOROQUINE TABLETS BY WEIGHT**

<table>
<thead>
<tr>
<th>WEIGHT</th>
<th>NUMBER OF DAYS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>DAY 1</td>
</tr>
<tr>
<td>Up to 3.4 kg</td>
<td>¼ tab</td>
</tr>
<tr>
<td>3.5 kg to 7.4 kg</td>
<td>½ tab</td>
</tr>
<tr>
<td>7.5 kg to 11.0 kg</td>
<td>¾ tab</td>
</tr>
<tr>
<td>11.1 kg to 15.0 kg</td>
<td>1 tab</td>
</tr>
<tr>
<td>15.1 kg to 18.0 kg</td>
<td>1 ¼ tabs</td>
</tr>
<tr>
<td>18.1 kg to 22.0 kg</td>
<td>1 ½ tabs</td>
</tr>
<tr>
<td>22.1 kg to 26.0 kg</td>
<td>1 ¾ tabs</td>
</tr>
<tr>
<td>26.1 kg to 30.0 kg</td>
<td>2 tabs</td>
</tr>
</tbody>
</table>

**WEIGHT CHART FOR PRESCRIPTION OF CHLOROQUINE SYRUP BY WEIGHT**

<table>
<thead>
<tr>
<th>WEIGHT</th>
<th>NUMBER OF DAYS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>DAY 1</td>
</tr>
<tr>
<td>Up to 4 kg</td>
<td>½ tsp.</td>
</tr>
<tr>
<td>4.1 kg to 8.0 kg</td>
<td>1 tsp</td>
</tr>
<tr>
<td>8.1 kg to 12.0 kg</td>
<td>1 ½ tsp.</td>
</tr>
<tr>
<td>12.1 kg to 16.0 kg</td>
<td>2 tsp</td>
</tr>
<tr>
<td>16.1 kg to 20.0 kg</td>
<td>2 ½ tsp.</td>
</tr>
<tr>
<td>20.1 kg to 24.0 kg</td>
<td>3 tsp.</td>
</tr>
<tr>
<td>24.1 kg to 28.0 kg</td>
<td>3 ½ tsp.</td>
</tr>
<tr>
<td>28.1 kg to 32.0 kg</td>
<td>4 tsp.</td>
</tr>
</tbody>
</table>