

**School of Pharmacy**

**THE IMPACT OF AN INTERVENTION PROGRAM FOR THE  
TREATMENT OF MALARIA IN CHILDREN IN PAPUA NEW  
GUINEA**

**Isaac B Joshua**

**This thesis is presented for the Degree of  
Master of Pharmacy  
of  
Curtin University of Technology**

**March 2003**

## **Declaration**

‘This thesis contains no material which has been accepted for the award of any other degree or diploma in any university. To the best of my knowledge and belief this thesis contains no material previously published by any other person except where due acknowledgement has been made’.

---

Isaac B Joshua

26<sup>th</sup> March 2003

## ACKNOWLEDGEMENTS

I would like to sincerely thank my Supervisor, Professor Bruce Sunderland for his endless contributions, advice, support, patience and encouragement throughout my study and especially in the writing up of this thesis.

I would also like to thank Mr Sam Kove and his staff of NCD Health Services especially staff of Gerehu and St Therese clinics for their friendliness and support during the implementation of the research project.

I thank Dr Jackson Lauwo for facilitating the research protocol which was approved by the PNG Medical Research & Ethics Committee.

My thanks also go to AusAid for the scholarship, and Curtin University of Technology School of Pharmacy and its staff for the facilities and friendliness especially Dr Kevin Batty for reading the document with constructive comments, Mr John Hess for the IT requirements and Ms Jenny Lalor for data analysis by SPSS.

Above all I thank God, who is the Creator and Source of all things for giving me the knowledge, wisdom, and understanding.

Finally, I thank my wife Judith and son Clement who kept me company and supported me throughout my study.

## TABLE OF CONTENTS

Acknowledgement.....	i
List of Tables.....	v
List of Figures and Appendices.....	viii
Abbreviations.....	ix
Abstract.....	x
1. Introduction.....	1
1.1 Malaria as a disease.....	3
1.2 Malaria in children.....	4
1.3 Drug treatment of malaria in children.....	4
1.4 Rational Use of Drugs (RUD).....	7
1.4.1 World Health Organisation.....	8
1.4.2 PNG Government support for RUD.....	8
1.4.3 Characteristics of Rational Drug Use.....	9
1.4.4 Drug compliance.....	11
1.5 Influencing prescribing.....	14
1.5.1 Drug use process.....	14
1.5.2 Factors affecting prescribing.....	17
1.5.2.1 Prescribing factors.....	19
1.5.2.2 Consumer factors.....	19
1.5.2.3 System factors.....	20
1.6 Drug Utilization Review (DUR).....	20
1.6.1 History.....	21
1.6.2 Definition.....	21
1.6.3 DUR process.....	22
1.6.4 DUR key elements.....	24
1.6.5 Intervention methods used in DUR in influencing prescribing.....	26
1.7 Evidence based medicine.....	28
1.7.1 The Cochrane collaboration.....	29

1.7.2	Meta-analysis	32
1.8	Role of guidelines/programmes	33
1.8.1	Standard treatment guidelines (STG)	34
1.8.2	PNG standard treatment guidelines for children	34
1.9	Project objectives	35
1.10	Research justification/significance	35
2.	Methodology	37
2.1	Background to study area	37
2.2	Development of questionnaires	38
2.3	Standard treatment guidelines	39
2.3.1	Uncomplicated malaria	40
2.3.2	Severe malaria	40
2.3.3	Treatment failure malaria (resistant-malaria)	42
2.3.4	Prophylaxis malaria	42
2.4	Administration of the protocols	43
2.5	The conceptual framework of the study	44
2.6	Sample selection	45
2.6.1	Pre-intervention study	46
2.6.2	Intervention protocol	48
2.6.3	Post-intervention study	50
2.6.4	Follow-up study	50
2.6.5	Control study	51
2.7	Statistical analysis	51
2.8	Ethical issues	52
3.	Results	53
4.	Discussion	75
4.1	Status of anti-malarial drug usage under drug policies	75
4.1.1	African countries	75
4.1.2	Industrialized countries	77
4.1.3	Western Pacific region	78
4.1.4	Drug policy and usage in PNG	79

4.2 Processes in health clinics in PNG	82
4.2.1 Prescribing	82
4.2.2 Issuing drugs	82
4.2.3 Administration of drugs	83
4.3 Methodology for DUR	83
4.3.1 Steps in the DUR cycle	83
4.3.2 Identification and determining targets for DUR	84
4.3.3 DUR endpoints	85
4.3.4 DUR intervention phase	86
4.3.5 Evidence of benefits of DUR programs	87
4.4 Outcomes of this study in PNG health clinics	88
4.4.1 The intervention program	94
5. Conclusion	97
6. Limitations of the study	100
7. Recommendations	101
8. References	103

## LIST OF TABLES

Table 1.1 Are the results of this single study valid?.....	32
Table 2.1 Treatment A.....	40
Table 2.2 New treatment B.....	41
Table 2.3 Old treatment B.....	41
Table 2.4 Treatment C.....	42
Table 2.5 Prophylaxis treatment.....	43
Table 2.6 A sample label for amodiaquine 100mg tablets.....	49
Table 3.1 Patient demographics at the clinic pre-post and control pre-post groups..	54
Table 3.2 Patient symptoms in control pre-post and clinic pre-post groups.....	55
Table 3.3 Number of episodes of illness requiring a previous consultation.....	56
Table 3.4 Prescribers compared at the clinic pre-post and control pre-post groups..	56
Table 3.5 Prescribers compared at the clinic and control groups.....	56
Table 3.6 Appropriate drug specifications for fever/malaria in control pre-post and clinic pre-post groups.....	57
Table 3.7 Appropriate drug specifications for fever/malaria comparing control-pre with control-post group.....	57
Table 3.8 Appropriate drug specifications for fever/malaria comparing clinic-pre with clinic-post group.....	58
Table 3.9 Appropriate drug specifications for fever/malaria (only amodiaquine, Fansider <sup>®</sup> , and chloroquine) for all groups.....	58
Table 3.10 Appropriate drug specifications for fever/malaria (only amodiaquine, Fansider <sup>®</sup> , and chloroquine) for the control pre-post groups.....	59
Table 3.11 Appropriate drug specifications for fever/malaria (only amodiaquine, Fansider <sup>®</sup> , and chloroquine) for the clinic pre-post groups.....	59
Table 3.12 Number of doses, frequency, and duration with a classified appropriateness for all drugs prescribed during the period of study comparing control pre-post and clinic pre-post groups.....	60
Table 3.13 Doses, frequency, and duration appropriateness of amodiaquine and Fansider <sup>®</sup> tablets comparing control pre-post groups.....	62

Table 3.14 Doses, frequency, and duration appropriateness of amodiaquine and Fansider <sup>®</sup> tablets comparing clinic pre-post groups.....	63
Table 3.15 Interviewed group (carers) in control pre-post and clinic pre-post groups.....	63
Table 3.16 Medicines given on previous consultations since birth in control pre-post and clinic pre-post groups.....	63
Table 3.17 Number of drugs taken by patient since birth compared separately in all groups pre-post, control pre-post and clinic pre-post.....	64
Table 3.18 Patient carers responses to duration of drug administration (How many days did you give it?) in control pre-post and clinic pre-post groups.....	65
Table 3.19 Patient carers responses to frequency of drug administration (How many times per day did you give it?) in control pre-post and clinic pre-post groups.....	66
Table 3.20 Patient carers responses to dosage of drug administration (How much medicine did you give each time?) in control pre-post and clinic pre-post groups.....	67
Table 3.21 Patient carers responses to uses of drug (What is the medicine for?) in control pre-post and clinic pre-post groups.....	68
Table 3.22 Do the medicines bother the child compared in control pre-post and clinic pre-post groups.....	69
Table 3. 23 Do the medicines bother the child compared in control pre-post groups.....	69
Table 3.24 Do the medicines bother the child compared in clinic pre-post groups...	69
Table 3.25 Patient carers responses to storing, reading labels and understand instructions, remember to give the medicines and to give medicines on time compared in all groups pre-post, control pre-post and clinic pre-post groups.....	70
Table 3.26 Give herbal or local remedies compared in control pre-post and clinic pre-post groups.....	71
Table 3.27 Give herbal or local remedies compared in control pre-post groups.....	71



Table 3.28 Give herbal or local remedies compared in clinic pre-post groups.....	72
Table 3.29 Follow up data comparing all groups.....	72
Table 3.30 Follow up data comparing control pre-post and clinic pre-post.....	73
Table 3.31 COMBO fever or malaria or enlarged spleen comparing control and clinic groups.....	73
Table 3.32 Frequencies for fever and drug combination compared in control and clinic groups.....	74
Table 4.1 Steps in the DUR cycle.....	84
Table 4.2 Endpoints targeted by DUR activities.....	86

## LIST OF FIGURES AND APPENDICES

Figure 1.1 The current drug process.....	15
Figure 1.2 Monitoring outcomes modifying the drug use process into a pharmaceutical care system.....	16
Figure 1.3 Quality cycle for DUR/DUE.....	23
Figure 2.1 A view of Gerehu Clinic.....	38
Figure 2.2 The typical process for receiving treatment at the UHC.....	43
Figure 2.3 Patients (children & adults) waiting in the reception at Gerehu Clinic.....	44
Figure 2.4 Conceptual framework.....	45
Figure 2.5 A child being weighed at Gerehu Clinic.....	47
Figure 2.6 Researcher interviewing a carer at St Therese Hohola Clinic.....	50
Appendix 1 Patients' information sheet and consent form.....	a
Appendix 2 Participant's details form.....	c
Appendix 3 Survey on the use of anti-malarial drug treatment form.....	d
Appendix 4 Follow-up details form.....	e
Appendix 5 Sample of drug labels.....	f

## ABBREVIATIONS

PNG	Papua New Guinea
DUR	Drug Utilisation Review
DUE	Drug Utilisation Evaluation
MSC	Medical Store Catalogue
NDP	National Drug Policy
RUD	Rational Use of Drugs
WHO	World Health Organisation
EBM	Evidence-Based Medicine
HEO	Health Extension Officer
NO	Nursing Officer
MO	Medical Officer
STG	Standard Treatment Guidelines
UHC	Urban Health Clinic
DATIS	Drug and Therapeutic Information Services
SD	Standard Deviation
SHPA	Society of Hospital Pharmacists of Australia
DDT	Dichlorodiphenyl trichloroethylene
OTC	Over The Counter
USA	United States of America
ASCEPT	Australasian Society of Clinical and Experimental Pharmacology and Toxicology
PDSA	Plan-Do-Study-Act
IMI	Intra-Muscular Injection
NCD	National Capital District
UK	United Kingdom
OBRA'90	Omnibus Budget Reconciliation Act of 1990
NSAID	Non-steroidal anti-inflammatory drugs
SPSS	Statistical Package for Social Science
P	Probability

## ABSTRACT

Malaria is more prevalent today and the death toll is on the increase annually. It is one of the leading causes of morbidity and mortality worldwide and most of these deaths are in the poorest regions of the world. About 500 million cases are reported annually with more than 2 million deaths, and most are children. It is the major killer in the tropics and a major public health problem in developing countries and Papua New Guinea (PNG) is no exception. Resistant strains have been reported. This may be enhanced by inappropriate human behaviour in the use of anti-malarial drugs. Human factors include inappropriate prescribing and patient behaviour in using anti-malarial drugs. Despite the establishment of the standard treatment guidelines for malaria in PNG, three out of every four patients have chloroquine-resistant falciparum malaria and malaria remains a major health problem.

The aim of this study was to evaluate the influence of an education program on patients carers' understanding and effective use of anti-malarial drugs for the treatment of uncomplicated malaria in children in general health clinics in PNG.

The trial design involved a pre-post intervention study with a control group. The study was undertaken in the National Capital District, Papua New Guinea using one Clinic as the intervention site and another as the control site. The two clinics were similar in characteristics as confirmed in the study by demographic data where there were no significant differences observed. The data collection took place over the period February to April 2002. It included observation of drug provision at study sites and interviews of patient carers on the first day at the clinic and a follow up seven days later.

Three questionnaires were developed to evaluate the process and outcomes of malaria drug treatment in the above health facilities. Prescribing data were collected from prescriptions and patient carers' interviewed prior to the intervention program. Following the provision of drug information to patient carers, similar drug information and compliance questioning was undertaken. Differences in the pre-post elements of the

study and in the control group over the study period were evaluated using Chi-Squared, Kruskal-Wallis, Fisher's Exact or Student's t-tests as appropriate.

In excess of 100 patients in the pre- and in the post intervention phases were evaluated for their understanding and effective use of the anti-malarial drugs. In addition, 100 clients were in the control group at another clinic. Patients had attended the clinic up to 8 times in the previous year with a median of 2 visits. Amodiaquine, Fansidar<sup>®</sup>, albendazole and paracetamol made up a total of 60% of the drugs prescribed. The use of medicines was strongly supported with 94.4% indicating no problems with the medication. Only 3% of patients received herbal or local remedies for malaria treatment. In patients 10 years or less or their carers, it was found, there was a significant improvement in the carers understanding of the medications. There was a statistically significant improvement in patient outcomes from 57.9% to 92.3% reported as cured following the intervention program. The study has also identified low levels of appropriate administration of antibiotic suspensions in children by patient carers. For example, incorrect responses recorded for amoxicillin suspension were 80.8% (143), Septrim<sup>®</sup> tablets 92% (23), Septrim<sup>®</sup> suspension 86% (123), erythromycin suspension 100% (26), and chloramphenicol suspension 84.4% (38).

In this study the face to face (one-to-one) education program was used to influence patient carers understanding and effective use of drugs. The intervention program involved advising, informing, encouraging, and counselling the patient carers verbally on the appropriate and effective use of medicines. The verbal message was reinforced by a suitable label typed in English and Pidgin-English where instructions were clear, simple and unambiguous. The label was then attached to the envelopes or containers containing the drugs. On feedback, the information on the understanding and effective use of drugs was re-emphasized to the carers to reinforce their understanding for future references. Results showed that the intervention program made an impact in improved patient carers understanding and effective use of drugs and children's health outcomes.

In conclusion, it is evident that a patient intervention program designed to improve the dosages and frequency of administration of anti-malarial drugs in PNG had no statistically significant outcome. This may be because the current level of understanding was quite high (>70%) and the study experienced a ceiling effect. However, as shown in the results, the patient carers understanding on the appropriate and effective use of drugs was lower during the pre-intervention and control group. When compared clinic-pre with clinic-post, there was a significant difference ( $P < 0.05$ ) in the cured group and the improved cure rate increases from 57.9% to 92.3%. When compared control pre with control post groups, there was no significant difference ( $P > 0.05$ ) in the cured group. Therefore, the study identified an improvement in patient outcomes with respect to malaria. Hence, the simple intervention program in influencing patient carers understanding of the appropriate and effective use of medications led to a marked improvement in patient outcomes.

## 1.0 INTRODUCTION

The malaria parasite has been our companion and an adversary especially in the tropics for decades and despite efforts to reduce or eradicate the disease, we are still in danger (1). Indeed, malaria is more prevalent today and the death toll is on the increase in spite of the fact that certain areas of the world are less exposed. It is one of the leading causes of morbidity and mortality worldwide and most of these deaths are in the poorest regions of the world (2).

Nearly 500 million cases are reported each year with more than 2 million deaths and the number of children dying of malaria is estimated to be four every minute (1). Although frightening, these figures are only part of the story, as they do not account for the severe social and economic consequences of the disease both for the affected individuals and for the mostly Third World countries where they live (3). Attempts have been made worldwide to eliminate malaria by means of insecticides and anti-parasitic drugs which, in many areas showed initial success. Yet malaria has become a more serious disease because of the growing resistance of the *Anopheles* mosquito to DDT and of the human malaria parasite, *Plasmodium falciparum*, to almost all available anti-malarial drugs (1).

In the tropics malaria is a major killer, especially of young children, and it remains a major public health problem. In Papua New Guinea (PNG) one of the leading causes of morbidity and mortality is malaria and it constitutes most outpatient treatment at 27% of cases, hospital admissions at 15% of cases, and deaths at 12% of cases (4).

Currently in PNG, case management is one of the cornerstones of malaria control with the aim of reducing morbidity and mortality through prompt diagnosis and effective management of acute clinical episodes with anti-malarial drugs. Poorly managed episodes take longer to clear and are more likely to lead to acute life threatening complications such as cerebral malaria and severe anemia. Poorly managed disease episodes can occur not only due to a lack of prompt treatment with appropriate drugs, but also as a result of the use of anti-malarial drugs in sub-therapeutic doses (5).

The use of anti-malarial drugs particularly in sub-therapeutic doses contributes to the development of parasitic resistance (5). Since resistance to chloroquine was first reported by Young & Moore in 1961, resistant strains have been reported from most parts of the world (6-10). Parasite resistance is emerging for most available anti-malarial drugs. This is particularly a cause for concern in PNG where chloroquine and amodiaquine, both low cost, safe anti-malarials, are still clinically effective. Despite the establishment of malaria standard treatment guidelines for children (11), malaria still remains a major health problem in PNG.

Human behaviour is one major contributor to the development of parasite resistance (5). Widespread and frequent use of sub-curative doses exposes the parasite to sub-optimal drug levels of the anti-malarial in the blood and accelerates the development of resistance (5). Such behaviour includes incorrect prescribing practices, uninformed use within the household as part of self-medication, as well as non-compliance of patients to the full therapeutic dose regimen (5, 12). A study using qualitative research was undertaken in parallel with routine service delivery in Ghana and suggested that formal sector prescribers and dispensers do not always provide readily, adequate comprehensive information on the types of drugs prescribed, the duration of treatment or the appropriate daily dose (5). This may be a quality of care problem that they postulate could lead to poor patient compliance with recommended doses. In a review of the literature on patient compliance in the developing world, Homedes & Ugalde (13) found that generally, patients knew very little about the nature of their own illness, why they were taking a particular medicine or its potential side effects. Edwards & Pathy (14) found that counselling patients on the appropriate use of drugs upon hospital discharge by a physician, pharmacist, or a nurse caused an improvement in drug compliance by the patient.



### 1.1. Malaria as a disease

The early discoveries of malaria are well known and have been recounted in popular format (15, 16). The first sighting of the parasite by Alphonse Laveran in Bone in 1880, the discovery of the complete mosquito cycle in avian malaria by Ronald Ross in Calcutta on July 4, 1897, and the recognition of the anopheline transmission of human malaria by Giovanni Batista in Rome in November 1898 are the foundation from which all malaria research has emanated (17).

A recent report by the WHO (18) has identified malaria as a major cause of morbidity and mortality in tropical and sub-tropical regions of the world. The disease has been classified as an “emerging infection” by many national and international health authorities (19), due to the increased global incidence of the disease.

Malaria in humans is caused by the infection with protozoan parasites of the Genus *Plasmodium*. Four species of Plasmodia infect humans and these are *Plasmodium falciparum*, *P. vivax*, *P. malariae*, and *P. ovale* (20). The former species is considered to be the most virulent as it causes the condition known as cerebral malaria, which is often fatal. The *anopheline* mosquitoes transmit all four species.

The life cycle of the malaria parasite is complex. The sporozoites are transmitted to humans by the bite of the infected mosquitoes of the genus *Anopheles*. The sporozoites circulate for a short time in the blood, then invade liver cells, where they develop into exoerythrocytic schizonts during the next 5 to 15 days (21). *Plasmodium vivax*, and *P. ovale* have a dormant stage, the hypnozoite (22, 23), that may remain in the liver for weeks or years before the development of exoerythrocytic schizogony. This occurrence results in relapses of infection. *Plasmodium falciparum* and *P. malariae* have no persistent phase. An exoerythrocytic schizont contains 10,000 to 30,000 merozoites, which are released and invade the red blood cells. The entire invasion process takes about 30 seconds (21).

## **1.2. Malaria in children**

Each year, there are an estimated 300-500 million clinical cases of malaria and it is estimated to kill more than 2 million people annually, the majority of whom are children under 5 years of age in developing countries and PNG is no exception (24).

Children infected with malaria commonly suffer from high fever and severe aches but symptoms may also include cough and diarrhoea (24). Any child who presents with fever in a malaria endemic region or who recently visited such a region, must be suspected to have malaria until proven otherwise, and requires urgent treatment. Early diagnosis and treatment will save lives and prevent the development of complications.

Untreated malaria in a young child or in a non-immune individual may become complicated; the patient presents with a very high body temperature, drowsiness, convulsions and coma indicating heavy parasitaemia and cerebral malaria. Other complications may include bleeding, jaundice, diminished urine output, all signifying liver and/ or kidney failure (24).

Generally in PNG, malaria is a major health problem and is the leading causes of morbidity and mortality. It constitutes in total most outpatients which ranked 1<sup>st</sup> at 27% of cases, admissions which ranked 2<sup>nd</sup> at 15% of cases, and deaths which ranked 2<sup>nd</sup> at 12% of cases and children are the most affected (4). Furthermore, three out of every four patients have chloroquine-resistant *Falciparum* malaria. Therefore, it causes much ill health, suffering and death and continues to increase in numbers and severity nationwide.

## **1.3. Drug treatment of malaria in children**

National anti-malarial drug policies by WHO normally recommend at least two standard treatment regimens for uncomplicated *falciparum* malaria (25, 26). There is a first-line treatment recommended for routine use, and second-line alternatives for treating

infections that are not cured by the first-line treatment, or for which the first-line treatment is contraindicated (27). Standard treatment drugs vary according to local policy and local patterns of malaria parasite resistance to the drugs available. The main options recommended by the WHO for first- or second-line oral treatment of uncomplicated malaria are regimens using the drugs chloroquine, sulfadoxine-pyrimethamine, mefloquine and quinine (27).

However, the decision of which drugs to use is becoming more of a problem in areas where malaria parasites are becoming more resistant to these and other established drugs (28). For example, in Thailand, there is a high level of resistance to chloroquine, sulfadoxine-pyrimethamine and quinine, and increasing resistance to mefloquine. A similar pattern is emerging in countries neighbouring Thailand, including Myanmar and Cambodia (29). In Vietnam, where mefloquine is expensive and not readily available and quinine is still largely effective, the WHO recommended quinine plus tetracycline over 7 days for treatment of uncomplicated malaria in adults (30). A similar pattern of decreasing effectiveness of antimalarial drugs (multi-resistance) is emerging in other malaria endemic areas and one alternative is a relatively new group of antimalarial drugs derived from artemisinin (28).

PNG has the following treatment regimens for malaria (11). Treatment A (Table 2.1) is for the treatment of uncomplicated malaria and has amodiaquine, chloroquine, and Fansidar<sup>®</sup> tablets. Treatment B (Table 2.2-3) is for treatment of severe malaria and has Artemether Inj, artesunate tablets & Fansidar<sup>®</sup> tablets (use quinine 300mg tablets if artemether & artesunate are not available). Treatment C (Table 2.4) is for the treatment of resistant malaria or treatment failure malaria and has artesunate tablets and Fansidar<sup>®</sup> tablets (use quinine 300mg tablets if artesunate is not available). For prophylaxis treatment (Table 2.5), amodiaquine and chloroquine tablets are used.

In accordance with the PNG recommended standard treatment for malaria for children (11), the following are recommended for implementation nation-wide.

The first-line drug regimens for uncomplicated malaria state: (a) amodiaquine 100mg tablets or chloroquine 150mg tablets are to be given once a day for 3 days, and (b) Fansidar<sup>®</sup> tablets are to be given on day 1 as an initial dose together with either amodiaquine or chloroquine.

The second-line drug regimens for severe malaria in new treatment B state the following:

- A single dose of Fansidar<sup>®</sup> is to be given on day 3 of treatment or on the first day of oral treatment if this is after day 3.
- Artemether IMI is to be given once daily until child improves.
- When the child has improved and can take oral treatment, give oral artesunate tabs once daily to complete a total of 7 days.
- The dose of artemether IMI on day 1 is higher than the dose for the following days.
- Only use quinine if artemether injection and artesunate tablets are not available.

The second-line drug regimens for severe malaria in old treatment B state the following:

- Quinine is to be given twice daily by injection until child improves then followed by oral quinine 3 times daily for 3 days.

- The total course of quinine (IMI then oral) may be 4-7 days.
- Fansidar<sup>®</sup> is to be given on the first day of oral quinine.

The third-line drug regimens for treatment failure malaria or resistant malaria state the following:

- Artesunate 50mg tablet is to be given once a day for 7 days and Fansidar<sup>®</sup> tablets to be given on day 3 of treatment.
- If artesunate is not available, then give quinine tablets 3 times a day for 3 days and give a single dose of Fansidar<sup>®</sup> tablets on the first day of treatment.

For the prophylaxis treatment of malaria, amodiaquine and chloroquine tablets are to be used. Children with an episode of malnutrition, anaemia or a very large spleen (at or below the level of the umbilicus), give once a week on the same day each week for 3 months or until the problem is resolved.

#### **1.4. Rational Use of Drugs (RUD)**

Rational use of drugs is well recognized as an important part of health policy (12). Are drugs being used rationally? This is a question and most people and agencies would desire to see that drugs are prescribed and used appropriately. To the patients, rational use of drugs requires that they receive medications appropriate to their clinical needs, in doses that meet their own requirements, for an adequate period of time, and at the lowest cost to them and their community (31). The need for medical audit to assess and improve the quality of medical care is now widely recognized (32-35). Hence, mounting evidence supports the World Health Organization (WHO) contention that drugs are frequently not used to their full potential, nor according to generally accepted criteria (36).

Plumridge (32) has indicated that differences in drug consumption patterns between comparable populations in developed countries and the mortality or morbidity following adverse reactions, the abuse of drugs and antibiotic resistance have been attributed to

prescribers. Since, most drug consumption is regulated to prescribing physicians, their prescribing habits are important when considering the irrational or excessive use of drugs. The WHO recommended that factors such as confirmed efficacy, abuse potential and cost be considered in any selection or control procedures concerning drugs (32).

#### **1.4.1. World Health Organisation (WHO)**

WHO plays a key supporting role by helping countries to assess their needs, identify problems and find solutions. The WHO Conference of Experts on the Rational Use of Drugs, held in Nairobi on 25-29 November 1985 was an important turning point which made way for its member countries to develop a National Drug Policy or its equivalent to ensure that drugs were being used appropriately. Today, nearly 90 countries have national drug policies in place or in preparation; and the WHO Model List of Essential Drugs has been widely adapted by national authorities and three out of every four countries in the world now have an essential drugs list (37).

#### **1.4.2. PNG Government Support for RUD**

Increasing concerns regarding access to and appropriateness of drug treatments led many governments in developing countries to develop national policies and regulations intended to increase the affordability, supply, safety, and rational use of pharmaceuticals. The report of the Nairobi Conference on Rational Use of Drugs in 1985 stated that there was a general agreement on the importance of government involvement in the formulation, implementation, and strengthening of national drug policies and regulatory mechanisms (38). The government interventions in drug systems take many forms such as national policies, programs and regulations, and these are the basic devices employed by most governments (39).

PNG since 1950 has succeeded in developing, maintaining and financing a pharmaceutical supply system, which provides continuous access to a limited range of essential drugs, of acceptable quality and at reasonable cost, tailored to each level of

health care (40). At independence in 1975, the PNG population was about 1.5 million and available resources at that time were adequate to fund a free drug supply system in the public sector. Nearly thirty years later the population has increased to more than five million and its health institutions have expanded in size, numbers and complexity. Appreciation of the effectiveness of modern medicine has grown and with it, the demand for public health services indeed, also for pharmaceuticals. New diseases for example heart disease, cancer, HIV & AIDS, have appeared, creating demand for additional and more specialized medicines.

Within this background, it was fitting that PNG consolidate its experiences in the field of essential drugs through a National Drug Policy (NDP), which would serve as the guiding document for legislative reforms, staff development and management improvements. With these reforms PNG would have a framework potentially able to control and regulate the availability, quality, safety, and rational use of drugs.

PNG until recently has not had a policy of such nature on medicinal drugs. The absence of a clear policy has resulted in the uncontrolled and unregulated importation of medicinal drugs and medical supplies. In June 1998, the PNG government approved its first ever NDP with the main objective to “improve the health of the people by preventing and treating diseases through the availability and rational use of safe, effective, good quality and affordable drugs” (40). This policy provides for a regulated importation and control over all drugs and medical supplies through registration and monitoring. In line with the NDP, the government also in September 1999, went further by approving its new Medicines and Cosmetic Act (41), which among its’ responsibilities, will control the registration of all drugs used in PNG.

### **1.4.3 Characteristics of Rational Drug Use**

Regarding Rational Use of Drugs; one of the aims of the NDP is to promote the rational prescribing and dispensing of drugs by all health personnel and the appropriate use of drugs by patients. This will be achieved through appropriate training, relevant

legislation, independent drug information, standard treatment manuals and public education (12, 40, 42) and these are:

- **Education and Training**

All health workers in the public and private sector involved in diagnosis, prescribing and dispensing will be fully trained in the essential drug concept, stock management and rational use of drugs. Sufficient emphasis will be placed on the essential drug concept, rational drug use and patient counseling. Prescribing and dispensing will continue to be by generic name in accordance with the Standard Treatment Guidelines (11) and the Medical Store Catalogue (MSC) (40). The use of generic products and compliance to standard treatment guidelines will also be promoted in the private sector. The study by Hassan et al concluded that proper training, i.e. ‘immunising future doctors using problem-based pharmacotherapy teaching, is an efficient way of teaching rational prescribing (43).

- **Drug Information**

Information on drugs is to be accurate, unbiased, relevant, and openly distributed to all health workers in the public and private sectors (40). Official publications such as Medical Store Catalogue, Standard Treatment Guidelines, will be distributed by the Health Department in PNG. A drug information unit will be established which will include this among its responsibilities to monitor adverse drug reactions (40).

- **Drug and Therapeutic Committees**

Health workers will be encouraged to participate in collaborative management of drugs in their institutions to ensure rational and cost-effective use of drugs. The Pharmaceutical Advisory Committee will be recognized as having the primary



responsibility in institutionalizing rational and cost-effective use of drugs and will issue guidelines for the formation and functioning of these committees (40). The local committees will be responsible for among other duties, to determine the quantity of drugs needed and enforce the rational use of drugs by all health workers.

- **Advertising and Promotion**

The policy will ensure that advertising and marketing of drugs will not induce irrational use (40). Ethical criteria for promotion of drugs will be developed based on the “WHO ethical criteria for medicinal drug promotion” and these will be included in the legislation and regulations to ascertain their enforcement. The Department of Health will ensure that promotion of drugs will be based on scientifically established evidence and that advertisements to the public are educational and restricted to over the counter drugs (OTC).

With these strategies, PNG hopes to ensure that drugs are being used appropriately by both prescribers and patients.

#### **1.4.4. Drug Compliance**

Apart from prescribers non-compliance with standard treatment guidelines, patients' non-compliance to drug therapy has also contributed to the problems of irrational use of drugs. Medication noncompliance is a serious, costly and a longstanding problem faced by healthcare practitioners in the United States of America (USA) and worldwide and continues to cost billions of dollars annually with respect to poor health outcomes (44). Patient non-compliance with drug regimens continues to be a major problem in virtually all medical specialties, patient populations, and health settings (45). Studies have shown that approximately 25% of all prescribed doses are omitted by patients (46).

Compliance is defined as a behaviour in which a patient adheres to a treatment regimen prescribed by a physician. Providing patients with information to enhance their understanding of both their medications and disease states promote better health outcomes through compliance to prescribed treatment regimens (44, 47).

The different types of non-compliance have been identified (12, 44, 48):

- Patient “unwillingness” to initiate therapy

In this situation, the patient fails to have the prescription dispensed owing to embarrassment, stubbornness, and denial of the disease.

- Missing doses

Skipped doses are usually inadvertent and a result of forgetfulness, but may also be attributed to complex drug regimens. These can also occur in multiple doses taken per day at regular intervals (e.g. every 6 hours) or additional requirements (e.g. must be taken after food or without food, etc).

- Discontinuation of a drug due to intolerable adverse effects

In this situation, the patient may stop taking a drug due to adverse effects. Sometimes patients who fail to see immediate improvement of their symptoms may also stop taking the drug.

- Self-adjusting the dose

The patient may choose to alter the dose either feeling better and reducing the dose or increasing the dose if no improvement, without consulting the physician.

- Lack of patient education on appropriate uses of drugs

A typical example would be an asthma patient who is not given proper instruction on the use of an inhaler or not advised properly on the use of their medicines.

- Lack of money

Patient inability to meet the cost of the medication.

- Lack of labeling

Where drugs are issued to patients with no proper labels.

- Cultural perceptions of drugs

In developing countries there are many strong domestic traditions such as the belief that a simple purge is better than medicines or believers in bush teas and grandmother's remedies who tend to pick up their medication but are reluctant to use it (48). What is perceived as rational drug prescribing in a developed country may be irrational for a developing country (49).

- Concordance

Concordance is an agreement or partnership between patient and prescriber about obtaining the best use of treatment, compatible with what the patient desires and is capable of achieving (50). Thus, achieving concordance between doctor and patient by identifying beliefs about illness, treatment and medicine-taking is a worthy concept. It should impact positively on compliance with treatment and thus health outcomes may be improved. Lack of concordance may lead to drug non-compliance.

The following activities have been shown to improve medication compliance (12, 44).

- Patient education
- Patient motivation
- Patient counseling
- Follow-up
- Continuous reinforcement of the importance of medication compliance
- Pamphlets, workbooks and other forms of written patient information
- Rewards and incentives
- Tailoring drug therapy to patients' needs
- Reminders (phone call or mail) of missed repeat prescriptions
- Self-monitoring of medication dosage (calendars, checklists, self-counts)

### **1.5. Influencing prescribing**

Prescribing is an activity central to general practice. Medication prescribing is an essential aspect of medical practice, but prescribing medications appropriately is an intricate task (51). Hence, the modification of prescribing behaviour is a difficult and complex task. According to Plumridge (32), as prescribing is conducted in an intricate environment involving medical, social and marketing forces, it is not a static, standardized process but a dynamic and highly individualized one. The factors which influence prescribing are complex and have been studied by many researchers in trying to identify the best methodologies for promoting quality prescribing practices within the bounds of limited health resources.

#### **1.5.1. Drug use process**

According to Segal & Wang (51), finding opportunities to influence prescribing can be discovered by an examination of the drug use process. Figure 1.1 outlines the current drug use process which shows a linear process starting with a patient becoming aware of a medical problem and seeking a physician assistance (52). As usual, the physician

initiates a diagnostic strategy that typically includes the collection of subjective and objective information from the patient, the assessment of that information, and the construction of a therapeutic plan which often includes the writing of a prescription (51). The patient then takes the prescription to a pharmacy in order to obtain the medicine and for most, this episode of care ends upon leaving the pharmacy with the intent to consume the medication.

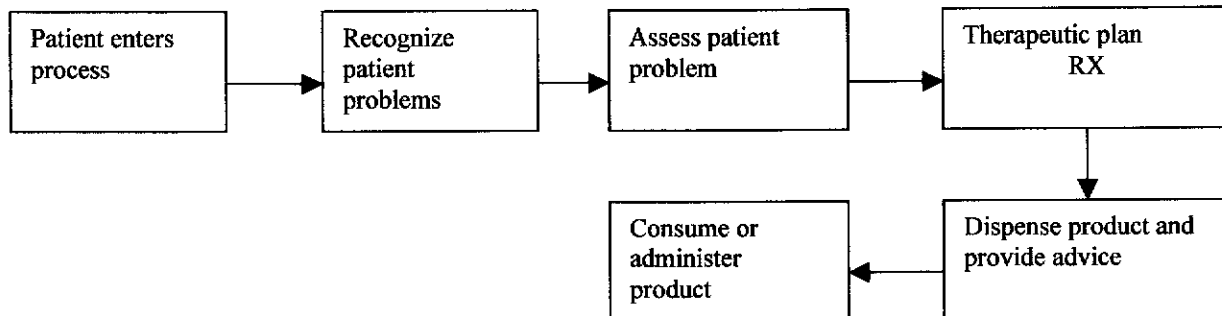


Figure 1.1: The current drug use process (51)

Hepler & Grainger-Rousseau (52) argue that prescribing should be directed at explicit, realistic objectives that the prescriber should communicate to whoever will monitor the outcomes of therapy. These authors suggest that prescribing the drug of choice is not the end of the drug use process. Instead the act of prescribing a drug is probably closer to the beginning of the drug use process. The medical literature supports the assertions, that prescribing the drug of choice does not guarantee a good patient outcome and that poor outcomes probably have more to do with what happens after a drug is prescribed (51). Examples include the morbidity that results from improper inhaler technique for asthma medications, and poor monitoring of drug effects by health care providers and patients (53, 54).

The concept of pharmaceutical care brings into focus where in the drug use process improvements may be made. Figure 1.2 changes the linear drug use process into a pharmaceutical care use system.

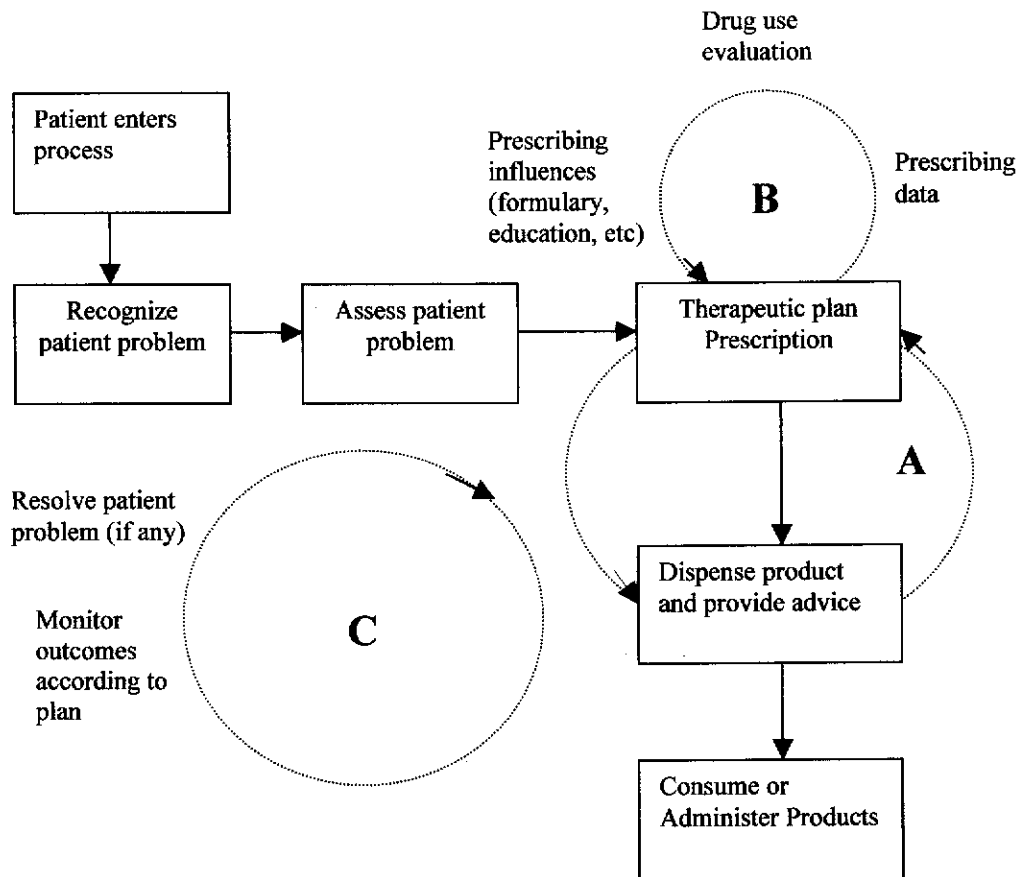


Figure 1.2: Monitoring outcomes modifying the drug use process into a pharmaceutical care system (51).

According to Hepler & Grainger-Rousseau (52), pharmaceutical care requires that at least three activities be performed.

(i). *Initiating therapy by designing and implementing a therapeutic plan intended to produce a set of therapeutic objectives*: This activity is usually done by a physician in today's drug use process without conveying the entire plan to a pharmacist. However, in a pharmaceutical care system, the therapeutic plan along with its objectives would be shared with the pharmacist, and possibly influenced by the pharmacist as well. This represents the first opportunity for influencing prescribing (52).

(ii). *The monitoring of therapy*: This includes deciding what essential information is needed to evaluate progress toward therapeutic objectives, and when and how to obtain it, and then collecting and documenting it.

(iii). *Managing therapy*: This includes revising the therapeutic objectives, the therapeutic plan, or the therapy itself after evaluating patient progress and pertinent, biological, psychological, social, and economic issues (52).

### **1.5.2. Factors Affecting Drug Prescribing**

Numerous studies have examined this area attempting to identify the best methodologies for promoting the quality of drug prescribing within the limited health budgets (55-57). DUR is designed to reinforce those positive influences and reduce the negative factors. Segal & Wang (51) and Lipton & Bird (55) outlined these influencing factors as prescribing factors, consumer factors and system factors, and these may also interact with each other. However, to manage those factors effectively, there are several intervention strategies, which may be required to influence prescribing behaviour.

According to Plumridge (32), these are:

- **Re-educative strategies**

A re-educative strategy is one whereby the relatively unbiased presentation of fact is intended to provide a rational justification for action. It assumes that humans are rational beings capable of discerning fact and adjusting their behaviour accordingly when facts are presented to them.

- **Persuasive strategies**

These strategies attempt to bring about change partially through bias in the manner in which a message is structure and presented. They attempt to create change by reasoning.

- **Facilitative strategies**

These involve the use of another person to assist an individual change his or her behaviour. The use of these strategies assume that the target group recognizes a problem, is in general agreement that remedial action is necessary, and is open to external assistance and willing to engage in self-help.

- **Power strategies**

These involve the use of coercion to obtain the target's compliance. The exertion of power is based on the dependency of the target group on the change agent for satisfaction of goals. The ability to use power strategies is increased when goals controlled by the change agent are important motivational objectives of the target group, when alternatives to these goals are limited or non-existent, and if the cost of alternatives is prohibitive. Rewards for compliance and punishment for non-compliance are necessary. Also the target group may be capable of varying degrees of retaliation.

- **Combined strategies**

Combined strategies use two or more of the preceding strategies simultaneously or sequentially and most interventions are of the combined type.



### **1.5.2.1. Prescriber Factors**

The following may affect the behaviour of prescribers and includes (55);

- Cultural influences of prescriber
- Age and gender of prescriber
- Geographical and socio-economic location
- Fiscal and time restraints
- Inadequate knowledge of pharmacotherapy
- Inadequate knowledge of drug costs
- Rapidly changing drug therapy
- Habits and beliefs of prescriber
- Influence of industry representatives
- Specialist's involvement
- Involvement in medical education

While DUR cannot correct factors such as prescribers' predispositions or prior training, it can remind physicians of basic principles and provide the up-to-date information needed for optimal prescribing. Appropriate education and provision of feedback information can overcome many of these influences on drug prescribing (51).

### **1.5.2.2. Consumer Factors**

Drug-therapy problems related to patient and family influences include patients' unwillingness to take appropriate drugs and demands for inappropriate drugs (55). Patient demographic characteristics and cultural beliefs also may influence prescribing. For example, there is evidence that females, regardless of age or symptoms, receive more prescriptions than males (58). In general each of these problems are amenable to detection and correction by DUR programs.

### 1.5.2.3. System Factors

Exogenous or system factors that influence prescribing decisions are (55);

- Drug policies
- Formularies
- Practice organization
- Reimbursement
- Drug company promotion
- Fragmentation of care
- Medical/prescription records
- Drug information quality

DUR can be useful in detecting prescribing patterns resulting from system-related factors. Such reviews can highlight these problems, and can provide the level of detail needed by health care agencies to address policy and organizational issues related to the prescribing and use of drugs.

### 1.6. Drug Utilization Review (DUR)

The technique of drug utilization review (DUR) can provide a useful means of determining whether drug use is appropriate in the treatment of patients (59). For DUR to be of benefit, actual practice must be compared to previously determined and understood standards of best practice. In PNG, the anti-malarial drugs used within the clinic settings will be evaluated for conformation with the national guidelines/essential drug list and standard treatments. Several DUR studies have been performed in various countries to investigate drug consumption, prescribing habits, and prescribed daily doses. For example, a knowledge-attitudes-practice study was done on anti-malarial drugs utilization by females in Ethiopia (60) and indicated literacy and village were the most important variables associated with knowledge about preventing malaria. Using DUR, this study was designed to determine whether the national guidelines and standard

treatments were being followed when anti-malarial drugs were prescribed and whether patients have been taking their medicaments at regular intervals.

### **1.6.1. History**

The terms Drug Utilization Review (DUR) and Drug Use Evaluation (DUE) are frequently interchangeable but currently DUR appears to be the favoured term and is used in this document. After decades of research on quality of drug therapy, preventable adverse drug reactions, inadequate patient compliance, and cost containment pressures, considerable interest arose in the late 1980s in USA in promoting large-scale DUR and DUE initiatives (61, 62). Subsequently, Federal legislation, the Omnibus Budget Reconciliation Act of 1990 (OBRA'90), was passed that required online prospective DUR and retrospective DUR for ambulatory Medicaid patients (63).

### **1.6.2. Definition**

DUR is an authorized, structured, and continuing program that reviews, analyses, and corrects inappropriate patterns of drug use, measures the effectiveness of corrective actions taken to normalize undesirable patterns of drug use, interprets patterns of drug use against predetermined standards, remedy strategies for improving physician prescribing practices and evaluates and assesses the impact of remediation efforts (55). DUR is a form of epidemiological study, developed to determine 'what happens to drugs when they enter the community, which factors influence their usage, and what is their effect in the community' (64). Furthermore, DUR is defined as an authorized, structured, and continuing program that reviews, analyses, and interprets aggregate patterns of medication use measured against predetermined standards and criteria established for specific health care delivery systems (65).

Patterns of drug utilization can be determined in reviews (66) and these are:

- (i). Retrospective DUR detects patterns in prescribing, dispensing, or administering drugs to prevent recurrence of abuse or inappropriate use and serves as the framework for developing prospective standards and target interventions. Most of the current DUR programs use this approach, which is least disruptive to health care providers and patients.
- (ii). Concurrent DUR is performed during the course of drug therapy. Interventions to correct problems may have a greater benefit to the patient when they are initiated early in the sequence of dispensing and medication administration.
- (iii). Prospective DUR is performed in daily practice by assessing a prescription for appropriateness, medication's dosage, directions, and concomitant therapy for drug interactions or duplicate therapy.

### **1.6.3. DUR Process**

The process of formal DUR is cyclic and dynamic; and the methodology has evolved basically from traditional medical research methods and Total Quality Management principles (56). Hence, the process can be described simply in terms of the quality improvement cycle as in Figure 1.3

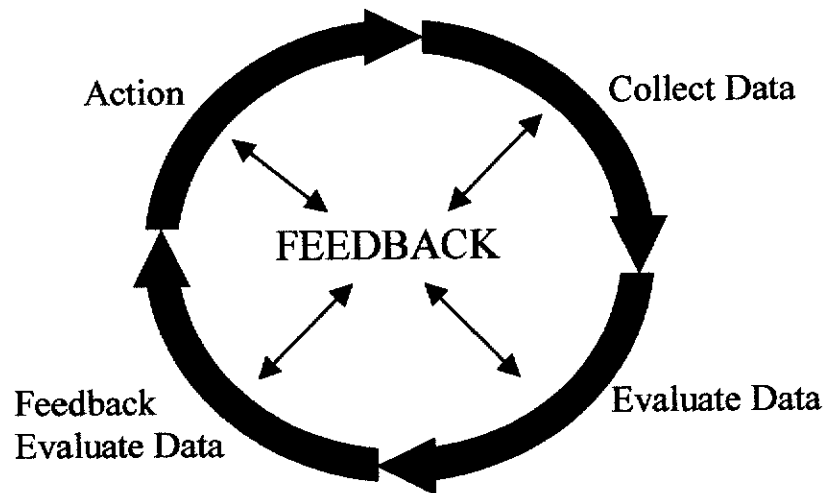


Figure 1.3: Quality cycle for DUR/DUE (56)

The Society of Hospital Pharmacists of Australia (SHPA) DUR/DUE Starter Kit is a good guide to the process (67). The steps are basically (56):

- Background literature search
- Design the structure of DUR strategy
- Obtain the appropriate approval and support
- Construct criteria
- Apply criteria to database
- Evaluate and analyze
- Establish prescribing patterns
- Establish intervention strategies

- Reapply criteria to database after application of interventions
- Revise criteria as needed and repeat process

#### 1.6.4. DUR Key Elements

A number of researchers support the Australasian Society of Clinical and Experimental Pharmacology and Toxicology (ASCEPT) in identifying key elements required for successful DUR programs (67-69). ASCEPT described them in five areas (70) and outlined by Fellows (56):

- **Clearly defined organisational and reporting structure, and relationships within the institution**

The body responsible for conducting DUR and enhancing prescribing in the institution must have a clearly defined organisational position and a reporting structure directly to senior executive level. It is also critical that this body has credibility with the prescribers and other clinicians. The institution needs to give the DUR body authority and support to implement decisions and strategies.

- **Cooperative stakeholding by important interested parties, particularly medical, pharmacy and nursing staff, but with operative autonomy.**

DUR programs may involve many disciplines and it is important to ensure that interactions between these disciplines are clear with regard to DUR programs. The optimum membership of a DUR team has not been clearly determined and will probably need to vary depending on the task. However, the literature supports the need for multi-disciplinary input including representatives from medical, pharmacy, clinical pharmacology, nursing and quality improvement. Ideally the team should have one full time representative.

- **Capacity to carry out independent reviews**

It is important to maintain open and transparent DUR activities that are non-threatening to clinical staff. The literature has clearly supported the need to create "ownership" of policies and guidelines among staff who will be affected by them. DUR has been most successful when the clinical staff acknowledge it as a valuable contributor to quality prescribing/evaluation of drugs use rather than a policing mechanism to cut costs.

- **Personnel skills at an appropriate level**

Membership of the supervising body, which initiates DUR must be at a senior level. Members of the body need to have access to knowledge and skills in a number of areas including research, drug purchasing, pharmacology, information technology and behavioural and influencing skills.

- **Hardware, software and library support**

DUR/DUE can be a labour intensive and onerous task if collecting data manually. DUR will be most prevalent and most successful where there is easy access to required data and modern technology. It is especially valuable where drug usage data is linked to the main hospital computer systems. Library support is invaluable for extensive literature reviews. The critical issue with DUR or any tool designed to enhance quality prescribing is that having established that a problem exists then a suitable and effective intervention needs to be devised in order to address the identified problem. A number of interventions have been trialed both in community and in hospital environments and frequently the use of more than one intervention is necessary. Before interventions can be developed for enhancing the appropriate use of medicines, there is a need to review what factors influence prescribing practice and patients' use of medicines.

### 1.6.5. Intervention methods used in DUR in influencing prescribing

Kubacka (66) outlined two intervention methods used in DUR programs that can influence practitioner prescribing and these are the administrative procedures and educational approaches. In addition, Segal & Wang (51) added another two methods such as feedback and incentives.

- **Administrative structure/process**

Prescribing restrictions and protocols, financial incentives, and consultation requirements, alone or in combination, are initiated as administrative procedures. Although these options are common in DUR, they represent restrictive and punitive measures and are usually met with considerable resistance from prescribers, pharmacists, pharmaceutical manufacturers, and patients. Additional difficulties can also occur. For example, when prescribing restrictions are initiated, a less desirable therapy may be substituted and also, when restrictions are withdrawn, appropriate prescribing trends may not continue (66).

- **Educational Approaches**

Seminars, journal articles, interventions through letters or telephone calls, and visits are some of the various approaches used to educate prescribers, pharmacists, and patients. Also referred to as academic detailing or educational outreach, this one-to-one dialogue conducted by peer reviewers ensures that the information presented is relevant to the practitioner's practice (71, 72).

The most successful Australian academic detailing program has been the Drug and Therapeutics Information Service (DATIS) which was established to provide advice and information on drugs and therapeutics (56). It focuses on academic detailing which consists of a pharmacist visiting doctors and providing up to date unbiased drug information. One positive outcome that has been assessed from



DATIS is that hospital admissions caused by gastrointestinal pathologies commonly associated with NSAID use declined in the geographical areas where the program was operating (73). Therefore this successful method although, costly, is currently used in several DUR programs.

- **Feedback**

The provision of regular feedback to physicians has been shown to be effective in reinforcing messages related to improving prescribing quality. Given the complexity of a physician's practices, reinforcement often is required to remind the decision maker of the desirability, opportunity, or need for change. Continuous computerized reminder systems have been shown to prevent omission of essential care, although such systems are effective only as long as reminders continue (51). Feedback seems to be most effective in changing behaviour when it is provided in a timely fashion, when provided relative to peers, and when compared with education and either incentives or administrative strategies (74).

- **Incentives**

Incentives have been shown to be powerful motivators of behaviour change (51). Incentives may be financial or social/behavioural and either positive or negative. In general positive incentives are thought to be more effective than negative incentives (75). Incentives need to be administered so that physicians are not forced to choose between personal and or organizational financial viability and patients' care (76).

- **Combined strategies**

This uses two or more of the above strategies simultaneously or sequentially.

### 1.7. Evidence based medicine

Evidence-based medicine (EBM) has philosophical origins which extend back to the mid-19<sup>th</sup> century and earlier. It can be expressed as the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients (77). The practice of EBM means integrating individual clinical expertise with the best available external clinical evidence from systematic research.

According to Sackett et al (77), EBM is simply:

(i). By individual clinical expertise, it means the proficiency and judgement that individual clinicians acquire through clinical experience and clinical practice. Hence, increased expertise is reflected in many ways, but especially in more effective and efficient diagnosis and in the more thoughtful identification and compassionate use of individual patient's predicaments, rights and preferences in making clinical decisions about their care; and

(ii). By best available external clinical evidence, it means clinically relevant research, often from the basic sciences of medicine, but especially from patient-centered clinical research into the accuracy and precision of diagnostic tests (including the clinical examination), the power of prognostic markers and the efficacy and safety of therapeutic, rehabilitative and preventive regimens. External clinical evidence both invalidates previously accepted diagnostic tests and treatments and replaces them with new ones that are more powerful, more accurate, more efficacious and safer.

Medical practitioners use both individual clinical expertise and the best available external evidence and neither alone is enough. Without clinical expertise, practice risks becoming tyrannized by external evidence, for even excellent external evidence may be inapplicable to or inappropriate for an individual patient. Without current best external evidence, practice risks becoming rapidly out of date, to the detriment of patients.

Sackett et al (77) went further to say that the practice of EBM is a process of life-long, self-directed learning in which caring for patients creates the need for clinically important information about diagnosis, prognosis, therapy and other clinical and health care issues.

### **1.7.1 The Cochrane Collaboration**

According to Sackett et al (77), the information source for clinicians seeking EBM goes a big step further by synthesizing evidence systematically across all trials of a given intervention. It is an outgrowth of the scientific methods developed to combine (into overviews or meta-analyses) the growing numbers of randomized trials of the same or similar treatments for the same health condition. When properly carried out on as high a proportion as possible of all relevant trials (since MED-LINE misses about half the published trials' detailed journal searching, often by hand, is required to avoid bias), these systematic reviews provide the most accurate and authoritative guides to therapy. The performance of systematic reviews of therapy is so logical a step in progress toward evidence-based health care that it has become the focus of a rapidly growing international group of clinicians, methodologists and consumers who have formed the "Cochrane Collaboration". The systematic reviews that are beginning to flow from this collaboration, updated each time an important new trial is reported, are providing the highest levels of evidence ever achieved on the efficacy of preventive, therapeutic and rehabilitative regimens. They are published on computer disk and CD, on the Internet and in a variety of other forms (including the EBM journals of secondary publication). The most recent version, the Cochrane Library, also includes a related database of published systematic reviews abstracted by the York Centre for Reviews and Dissemination at the University of York in the UK. Thus, busy clinicians seeking clinical 'bottom lines' will increasingly be able to eschew non-expert 'expert' reviews and self-serving commercial sources and find brief but valid summaries of best evidence on a growing array of clinical topics, appraised according to uniform scientific principles.

In 1972, epidemiologist Archie Cochrane called for the establishment of a central

international register of clinical trials. (It was Cochrane who, as a rebellious young medical student, marched through the streets of London in 1938 bearing a placard that stated, "All effective treatments should be free". His book *Effectiveness and efficiency* caused little reaction at the time but captures the essence of today's evidence based medicine movement. Though he never lived to see the eponym, Archie Cochrane's vision of a reliable, comprehensive and accurate medical database, the Cochrane Controlled Trials Register, is approaching reality (79).

Published articles are entered on to the Cochrane databases by members of the Cochrane Collaboration, an international network of (mostly) medically qualified volunteers who search a particular clinical journal back to the very first issue. Using strict methodological criteria, the searchers classify each article according to publication type (randomised trial, other controlled clinical trial, epidemiological survey, and so on) and prepare structured abstracts in the required style. The collaboration has already identified over 30,000 trials that had not been appropriately tagged in Medline (79).

- **The Ten Principles of the Cochrane Collaboration**

The Cochrane Collaboration has evolved rapidly since it was inaugurated, but its basic objectives and principles have remained the same as they were at its inception. It is an international organization that aims to help people make well informed decisions about health care by preparing, maintaining and ensuring the accessibility of systematic reviews of the effects of health care interventions. The Collaboration is built on ten principles (80):

- collaboration
- building on the enthusiasm of individuals, avoiding duplication
- minimizing bias
- keeping up to date
- striving for relevance

- promoting access
- ensuring quality
- continuity
- enabling wide participation

Good decisions about health care rely on more than good reviews of the results of research. The Cochrane Collaboration will make the results of research assessing the effects of health care more easily available.

However, as Cochrane made clear in 'Effectiveness and Efficiency', reliable evidence about the effects of specific elements of health care, although essential for improving decisions about health care and research, is only part of what is needed for better decision-making. If better decisions are to lead to improved health, then, effective mechanisms are needed for implementing them efficiently. Forms of care that have been shown to do more good than harm should be encouraged, while those that do more harm than good need to be discarded. The many forms of care which have unknown effects should, as far as possible, be used in the context of a research program to find out whether they help or do harm. In addition, if people are to receive care which is appropriate, then policy makers and decision makers - ranging from ministers of health to individual clinicians and patients - must consider people's needs, the availability of resources, and priorities (79).

In making decisions about the care of individual patients, for example, the results of the reviews must be integrated with the clinician's expertise, which has been acquired through experience and practice. The results of the reviews must also be integrated with the patient's expertise, which derives from their knowledge of their condition (particularly if it is a chronic or recurrent health problem), the treatments on offer, and the responsiveness or otherwise of the former to the latter. If operating in synchrony, these complementary forms of expertise are reflected in more efficient diagnosis and in more thoughtful identification and compassionate use of the predicaments, rights, and preferences of individual patients in making decisions about their care (79).

### 1.7.2 Meta-analysis

A meta-analysis is defined as a statistical synthesis of the numerical results of several trials that all examined the same question (78). Meta-analysis is a statistical procedure that integrates the results of several independent studies considered to be "combinable" (80, 81). A well conducted meta-analysis will allow a more objective appraisal of the evidence than traditional narrative reviews, provide a more precise estimate of a treatment effect, and may explain heterogeneity between the results of individual studies.

Having found some possibly useful evidence about therapy, you have to decide where to start in its critical appraisal. The question is 'Is this evidence about a treatment valid?' Meta analysis will help and critically appraise evidence about therapy for its closeness to the truth (77). This can be undertaken by asking some simple questions and often you will find their answers in an abstract that accompanied the evidence. For example, Table 1.1 summarized guides for assessing evidence that have combined the results of several trials into an overview or systematic review.

**Table 1.1 Are the results of this single study valid? (77)**

The main questions to answer:

1. Was the assignment of patients to treatments randomized and was the randomization list concealed?
2. Were all patients who entered the trial accounted for at its conclusion and were they analyzed in the groups to which they were randomized?
3. Were patients and clinicians kept 'blind' to which treatments were being received?
4. Aside from the experimental treatment, were the groups treated equally?
5. Were the groups similar at the start of the trial?

When several randomized trials of the same treatment for the same condition have been carried out, an overview which systematically reviews and combines all of them would

provide a better answer than a critical appraisal of just one of them. These significantly contribute to the development of guidelines and formularies.

### **1.8. Role of guidelines/programmes**

Of the 5000 million people in the world, 1300-2500 million have little or no regular access to essential drugs (82). The WHO Action Program on Essential Drugs and Vaccines is supporting developing countries in the implementation of national essential drugs programmes (83). Basically, the two main objectives of such national guidelines are to improve the availability and rational use of essential drugs (84).

Essential drugs are those that satisfy the health care needs of the majority of the population and they should be available at all times in adequate quantity and in suitable dosage forms and at a price that is affordable by an individual or the community (85). The study by Hogerzeil et al (84), conducted in Yemen, assessed the availability and rational use of drugs in a random sample of 19 peripheral health units in which an essential drugs programme had been in operation for 2 years. It was found that the model list or programme significantly improved the quality of health care, availability and rational use of essential drugs in those peripheral health units. Better quality of care was achieved when the list of essential drugs was linked to evidence-based treatment guidelines (86), especially when the supply system guarantees the availability of the selected drugs. Model lists have proved to be invaluable in improving the quality of health care and reducing costs (84, 87).

Furthermore, according to WHO (85), treatment guidelines can:

- Focus training and serve as a standard for supervision and medical audit; prescribers become more familiar with the drugs and can better recognize adverse drug reactions.
- Lower costs are achieved through selecting cost-effective treatment

- A limited range of drugs in the supply may lead to economies of scale and competition between manufacturers, further reducing the costs.

### **1.8.1. Standard Treatment guidelines (STG)**

Local manuals are needed in every health system because of differing decisions about drug choices and the patterns of illness within a country. Disease orientated manuals are called standard treatment guidelines, treatment protocols, or prescribing policies. The selection of drugs to be included on the essential drug list is based on the prevalence patterns of illnesses and the standard treatment guidelines decided upon to treat these conditions. STGs list the preferred drug and non-drug treatments for common health problems experienced by people in a specific health system. Each drug treatment should include each health problem the name, dosage form, strength, average dose (pediatric & adult), number of doses per day, and number of days of treatment. Other information on diagnosis and advice to the patient may also be included.

Standard treatments have been used for many years in some countries and now exist for common illnesses of children, adult and obstetrics and gynecology in PNG. The existence of STGs is necessary for consistency, therapeutically effective, and economically efficient use of drugs.

### **1.8.2. PNG Standard Treatment Guidelines for Children**

PNG has been a forerunner in the development and maintenance of standard treatment guidelines for almost four decades now since 1960 (11). They have formed an important and integral part of clinical care of patients and a teaching and reference document for health workers. The standard treatment books provide treatment regimens for all common and serious diseases and conditions of children in PNG. The treatment regimens are linked to the medical supply system and the training of health workers. Given the state of its economy, health status indicators, disease trends and the structure



of the National Health System, there are limited options other than to pursue cost-effective treatment regimens as prescribed in the pediatric standard treatment book (11).

### **1.9. Project Objectives**

The main objectives of the study are:

- To evaluate the effect of an intervention program on patient carers in the understanding of the use of anti-malarial drugs in children for uncomplicated malaria.
- To evaluate the level of appropriate and effective use of the anti-malarial drugs for uncomplicated malaria.
- To provide the patient carers with appropriate drug information on the management of uncomplicated malaria.

### **1.10. Research Justification/significance**

One of the objectives of the PNG National Drug Policy is to promote the rational prescribing and dispensing of drugs by health personnel and appropriate use of drugs by patients (40). This study will assess the impact of an intervention program on the use of anti-malarial drugs in children for uncomplicated malaria in PNG. This is important to ensure the rational and cost-effective use of anti-malarials. Malaria is still the leading cause of death and morbidity in PNG (89). The utilization of anti-malarial drugs through the health services in developing countries is often poor; drugs shortages are common and over-prescription and overuse of injections are significant problems (90). In addition, increasingly, people are resorting to self-medication for malaria, which may cause delays in seeking proper treatment in cases of failure, especially in areas where chloroquine resistance has increased rapidly (90). Although chloroquine is still widely used to treat falciparum malaria, resistance has spread to most of the endemic zone and quinine is emerging as the only effective treatment for malaria, though resistance to this

drug threatens to become a problem (89). Treatment guidelines are developed not only for optimum disease treatment but also to minimize the development of resistance.

This study will investigate the impact of an intervention program on malaria drug treatment for uncomplicated malaria in children in the age group of 0 to 10 years in PNG. It is hoped that this research and its evaluation would provide a model which would lead to improved appropriate and effective use of the anti-malarial drugs.

## **2.0 METHODOLOGY**

This study was designed using a pre-post evaluation with an intervention and control.

### **2.1 Background to study area**

There are a total of twenty provinces in PNG and the National Capital District (NCD) is one of them. The health care delivery system in PNG has three levels: health centres/clinics/aidposts at the primary level, supported by provincial hospitals and finally the central referral hospitals, which are located in the two major cities (Port Moresby and Lae). The health services in the provinces are coordinated by the Provincial Health Advisors, Nursing Officers, and Health Extension Officers, mainly undertake activities at the health centres, including prescribing and drug management.

The study was conducted using two Urban Health Centres (UHC) (Gerehu and Hohola St Therese Clinics) in the NCD. There are 15 urban health centres in the NCD which serve about 300,000 people. The selected centres are headed by a senior nurse and staffed by several nurses and community health workers. There are several medical practitioners who serve these centres on a daily rotating basis, but, most of the patients are seen by the nurses, who are also responsible for the prescribing and drug management. Drugs are given to these patients free of charge if available.

Statistics on the leading causes of morbidity and mortality rates in NCD have indicated malaria constituted most of the outpatient visits and ranked 1<sup>st</sup> at 28.3% of cases, hospital admissions ranked 5<sup>th</sup> at 4.6% of cases, and deaths ranked 9<sup>th</sup> at 6.9% of cases (4).



Figure 2.1: A view of Gerehu clinic

The data collection took place over a two-month period in February and March 2002. It included observation of drug provision at study sites and interviews of patient carers on the first day at the clinic and a follow up seven days later.

Three questionnaires were developed to evaluate the process and outcomes of malaria drug treatment in the above health facilities. The questionnaires focused on the following areas:

## 2.2 Development of Questionnaires

Questionnaire A collected the participant's details and included:

- Patient's name, date of birth, weight, and gender
- Name of clinic
- Frequency of malaria episodes
- Current diagnosis
- Drugs given (name, dose, frequencies, duration)
- Who was interviewed?
- Prescriber
- Date of attending the clinic

Questionnaire B surveyed the use of drug treatment and required:

- Listing of all medicines taken after consultations with prescribers at the clinic since birth
- Identifying whether any medicines taken in the past have given rise to problems for the child and by how much
- Identifying the problems that caregivers sometimes have with children's medicines such as storing the medicines, reading and understanding the label, remembering to give the medicines, and to give the medicines at the correct time.
- Whether herbal or local remedies were given to the child to assist in treating malaria.

Questionnaire C recorded (i) the date when the child was cured, for how long and whether the child completed the treatment, and (ii) If not cured, what did the carer do? Reviewed again at the clinic, go to hospital, or remain at home.

Owing to literacy reasons, the questionnaires were often completed by the researcher on questioning the carer. Pidgin-English language, the common language widely spoken in PNG was used throughout the study. Informed consent was provided before the process was convened. A sample of the patients' information sheet and consent form is included in Appendix 1.

### **2.3 Standard Treatment Guidelines**

Standard treatment guidelines developed by the National Health Department of PNG (11) were used as the basis for the assessment of appropriate prescribing and effective use of drugs for children for malaria.

According to the guidelines (11), Table 2.1-5 described the various drug dosages for treating malaria in PNG.

### 2.3.1 Uncomplicated malaria

The first-line drug for treating uncomplicated malaria in PNG is either amodiaquine with Fansidar<sup>®</sup> or chloroquine with Fansidar<sup>®</sup> according to details in Table 2.1.

**Table 2.1: Treatment A (11)**

Weight Kg	Amodiaquine 100mg tablets	Chloroquine 150mg tablets	Fansidar <sup>®</sup> tablets Single dose
3-5.9	50mg	¼ tab	¼ tab
6-9.9	100mg	½ tab	½ tab
10-14.9	150mg	1 tab	1 tab
15-18.9	200mg	1 tab	1 tab
19-27.9		1½ tabs	1½ tabs
28-36.9		2 tabs	2 tabs
37-49.9		3 tabs	2½ tabs

However where chloroquine and amodiaquine resistance is high, then the second-line recommended anti-malarial drugs are used. These are quinine, artemisinin derivatives and Fansidar<sup>®</sup>.

### 2.3.2 Severe malaria

The second-line drug for treatment of severe malaria is outlined in Table 2.2 and 2.3.

**Table 2.2: New treatment B (11).**

Weight Kg	Artemether (80mg/mL) IMI Day 1 (mL)	Artemether (80mg/mL) IMI Day 2-7 (mL)	Artesunate 50mg tab tablets Day 2-7	Fansidar <sup>®</sup> tablets Day 3 Treatment
3-5.9	0.25 mL	0.25 mL	12.5mg	¼ tab
6-12.9	0.5 mL	0.25 mL	25mg	½ tab
13-18.9	0.75 mL	0.5 mL	37.5mg	1 tab
19-24.9	1 mL	0.5 mL	50mg	1½ tabs
25-30.9	1.25 mL	0.75 mL	75mg	2 tabs
31-36.9	1.5 mL	0.75 mL	75mg	2 tabs
37-43.9	1.75 mL	1 mL	100mg	2½ tabs
>44	2 mL	1 mL	100mg	2½ tabs

## Notes:

- A single dose of Fansidar<sup>®</sup> is to be given on day 3 of treatment or on the first day of oral treatment if this is after day 3.
- Artemether IMI is to be given once daily until child improves.
- When the child has improved and can take oral treatment, give oral artesunate tabs once daily to complete a total of 7 days.
- The dose of artemether IMI on day 1 is higher than the dose for the following days.
- Only use quinine if artemether injection and artesunate tablets are not available.

**Table 2.3: Old treatment B (11)**

Weight Kg	Quinine IMI (120mg/2mL or 600mg/10mL)	Quinine 300mg Tablets	Fansidar <sup>®</sup> Tablets
3-3.9	0.5 mL	¼ tab	¼ tab
4-5.9	1 mL	¼ tab	¼ tab
6-9.9	1.5 mL	¼ tab	½ tab
10-14.9	2 mL	½ tab	1 tab
15-19.9	3 mL	½ tab	1 tab
20-24.9	4 mL	1 tab	1½ tabs
25-29.9	5 mL	1 tab	1½ tabs
30-39.9	6 mL	1½ tabs	2 tabs

## Notes

- Quinine is to be given twice daily by injection until child improves then followed by oral quinine 3 times daily for 3 days.
- The total course of quinine (IMI then oral) may be 4-7 days.
- Fansidar<sup>®</sup> is to be given on the first day of oral quinine.

### 2.3.3 Treatment failure malaria (resistant-malaria)

Treatment C is for treatment failure malaria (resistant-malaria). Artesunate 50mg tablet is to be given once a day for 7 days and Fansider<sup>®</sup> tablets to be given on day 3 of treatment.

**Table 2.4 Treatment C**

Weight Kg	Artesunate Oral Tab Day 1 single dose	Artesunate Oral Tab Day 2-7 once daily	Fansidar <sup>®</sup> Tablets Single dose
4-5.9	½ tab	¼ tab	¼ tab
6-8.9	¾ tab	½ tab	½ tab
9-12.5	1 tab	½ tab	1 tab
12.6-18.5	1½ tabs	¾ tab	1 tab
18.6-24.9	2 tabs	1 tab	1½ tab
25-31.9	2½ tabs	1½ tab	2 tabs
32-37.5	3 tabs	1½ tab	2 tabs
37.6-50	4 tabs	2 tabs	2½ tabs

Notes:

The dose of artesunate on day 1 is higher than the dose on the following days.

If artesunate is not available, then give quinine tablets 3 times a day for 3 days (Table 2.3) and give a single dose of Fansider<sup>®</sup> tablets on the first day of treatment.

### 3.3.4 Prophylaxis treatment

Table 2.5 outlined the prophylaxis treatment of malaria and has amodiaquine and chloroquine tablets. For children with an episode of malnutrition, anaemia or a very large spleen (at or below the level of the umbilicus), these either amodiaquine or



chloroquine tablets are given once a week on the same day each week for 3 months or until the problem is resolved.

**Table 2.5 Prophylaxis treatment**

Weight (kg)	Amodiaquine	Chloroquine
3 – 5.9	¼ tab	
6 – 9.9	½ tab	
10 – 19.9	1 tab	
20 – 29.9		1 tab
30 – 49.9		1½ tabs
Adult		2 tabs

#### 2.4 Administration of the protocols

Participants usually their carers, agreed to voluntary inclusion into the study. The expected patient flow pattern was as follows:



Figure 2.2: The typical process for receiving treatment at the UHC.

Figure 2.2 shows the typical process a patient has to follow to get treatment at the UHC. The patient would normally go to the cashier, paid the consultation fee of 50 toea and proceeded to the reception room to wait in a queue. Once their turn comes, they are referred to see either a Nursing Officer (NO) or a Health Extension Officer (HEO). The complicated cases would be referred to see the Medical Officer (MO). After diagnosis, the patient then proceeded to the Dispensary or Treatment Room for the tablets/injections. After getting the medicaments, the patients were then directed to see the researcher where informed consent was obtained prior to the interview. The study

was approved by the NCD Health Division allowing it to be conducted in their clinics. The Nurses, Health Extension Officers and Medical Officers were aware of the study being carried out at the clinics evaluating patients understanding and effective use of medicines.



Figure 2.3: Patients (adults & children) waiting in the reception at Gerehu Clinic.

## 2.5 The conceptual framework of the study

The conceptual framework of the study is illustrated in Figure 2.3. This is derived from the work of Segal & Wang (51), Riewpaiboon (90), Fellows (56) and Lipton & Bird (55).

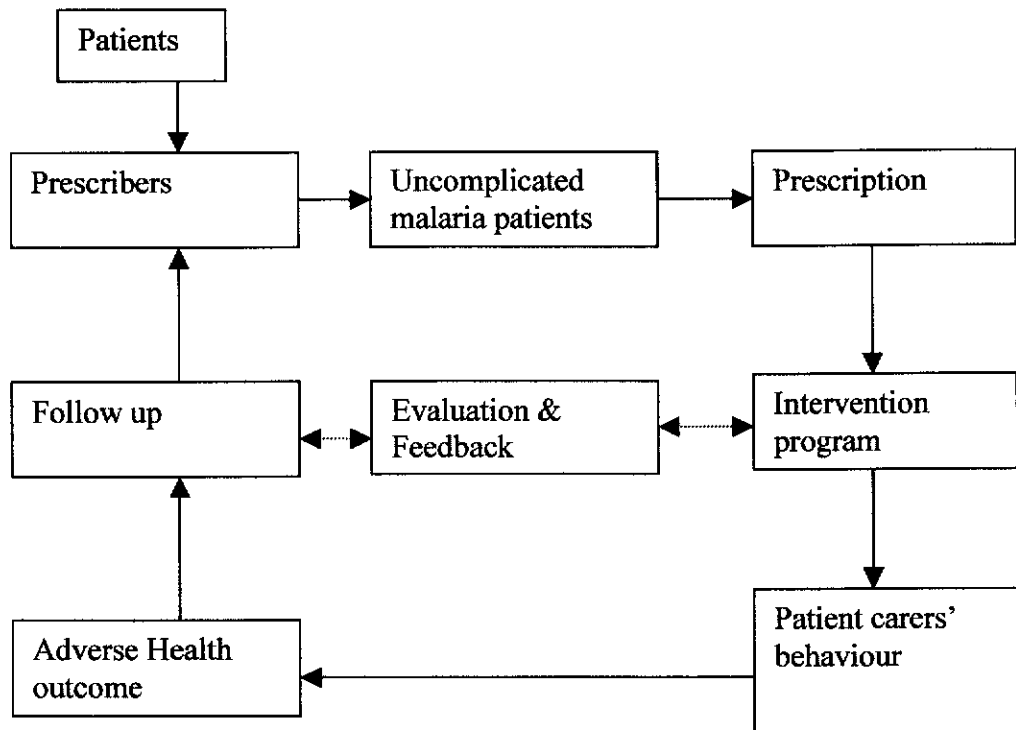


Figure 2.4: Conceptual framework

## 2.6 Sample selection.

The study was carried out at Gerehu and Hohola St Therese Clinics in the NCD. The pre- and post intervention was carried out at Gerehu Clinic and the control at Hohola St Therese Clinic. The sites were chosen by convenience and the safety of the researcher was also considered. Gerehu served a large population that could over a period of time provide a sufficient number available to the study. The control group site was chosen based on it being a different population, but was assumed to have similar characteristics and therefore avoiding the carry over effects of the intervention program. It was confirmed in the study that there were no significant differences ( $P > 0.05$ ) in the demographic variables (gender, age, and weight) between the groups (Table 3.1). Most of the prescribing at both clinics were done by Nurses (94.4%) as shown in Table 3.4-5. There was no difference ( $P > 0.05$ ) within the groups in regard to patient carers (those interviewed) where most were mothers (82.5%) as shown in Table 3.15. Therefore, the two clinics (groups) appeared to be comparable and similar in characteristics.

A space with a table and chairs next to the treatment room was provided to the researcher in undertaking the interviewing of patient carers. The interviewing of carers took approximately 10 minutes.

The inclusion criteria to the study were:

- Children within the age group of 0 – 10 years were included in the study
- having diagnosed with uncomplicated malaria and prescribed with the first-line drugs of antimalarials.
- Those who (carers) consented to participate.

The exclusions criteria to the sample were:

- Those who do not give consent to participate
- Children with severe/complicated malaria or other concomitant diseases
- Those who were more than 10 years of age
- Children in the intervention study who had participated in the pre-intervention study

The subjects were selected using convenience sampling. A sample size of 103 subjects participated during the pre-intervention, and 100 for the post-intervention with formal medical diagnosis of uncomplicated malaria. Another 100 subjects participated for the control, which was studied over the period of both phases of the pre-post intervention protocols.

### **2.6.1 Pre-intervention study**

A total of 103 patients were recruited during this stage. The researcher noted and recorded the following criteria on a standard form in the presence of the patient and carer. There was no intervention occurred in this element of the study. To follow up on the progress of the child and in the interest of the study, the carers were advised to come

back to the clinic after 7 days and report to the researcher whether the child got well or not. The following data were recorded.

- (i). Name of child
- (ii). Date of attending the UHC
- (iii). Child's date of birth
- (iv). Name of clinic
- (v). Diagnosis (a) Current (b) previous (frequency)
- (vi). Weight of child
- (vii). Prescriber (a) Nurse (b) HEO (c) MO (d) Other
- (viii). Drugs (a) Name (b) dose (c) frequency (d) duration

The above information was available from a health book/card held by the patient or carer and completed at each consultation by the prescriber.



Figure 2.5: A Child being weighed at Gerehu Clinic

### 2.6.2 Intervention protocol

One of the important considerations in the design of the intervention was that it needed to be one that could be promoted subsequently by primary health care services within the study context of PNG, if it proved effective. Though the ultimate goal was to effectively improve the understanding and effective use of the anti-malarial drugs treatment for uncomplicated malaria on an outpatient basis, the hypothesis was that one way to accomplish this was to improve provider-patient communication. This required an intermediate intervention program to change the behaviour of patient carers from a situation of inadequate communication from health workers on drug use and supplying poorly labeled drugs to one where they are provided significantly more verbal information and labeled drugs in a way patient carers could easily interpret and understand.

Not all clients in the study area are literate and labeling drugs with labels written in English was not felt to be an adequate communication strategy. The intervention therefore involved providing more verbal information to patient carers as well as providing drug labels which provide information on the recommended daily dose with other relevant information, pasted on the envelopes/containers of anti-malarial tablets and given to patient carers.

The intervention program undertaken was in the following manner:

- (i). A dispensing label written in English and Pidgin-English outlining the drug name, strength, dose, dose frequencies, duration, and any other relevant information in taking the drugs and importance of completing the course of treatment was attached to the drugs (Appendix 5).

AMODIAQUINE 100mg TABLETS (Infant Camoquine)
<p>Chew ..... tablet daily after food for 3 days and drink plenty of water or fluids. Keep the medicine in a safe cool place. Bring the child back to the clinic if there is no improvement after treatment, or if the child is getting worse. If the child vomits the tablet, give another dose.</p> <p>Kaikai ..... kiau long wanwan dei behind long kaikai inap long tripela dei na dringim planti wara. Putim marasin long gutpela ples. Bringim pikinini kam bek long haus sik suppose em i no orait or em bagarap. Suppose pikinini i traoutim marasin, givim em narapela kiau.</p>

Table 2.6 A sample label for amodiaquine 100mg Tablets

(ii). The carer was verbally advised and counseled in simple terms using mainly the Pidgin-English language emphasizing the following:

- (1). Why the drugs were given
- (2). Dosages, dose frequencies, duration and directions in taking the drugs. If necessary, the preferred relationship to meals and to other medication, and the need to take repeated dosages within the same day at regular intervals, was also stated.
- (3). The importance of completing the treatment.
- (4). That drugs should be taken at a regular interval at the exact time to maintain its effectiveness considering its half-life factor.
- (5). Tablets should be crushed evenly and mixed with something sweet to improve taste so that the child can take them easily.
- (6). Tablets should be stored in a cool safe dry place preferably in a closed container/cupboard away from the reach of children. Liquid suspensions should be stored in a refrigerator. If no refrigerator, the suspensions should be stored in a cool dry place away from direct sun light. Any liquid suspensions leftovers after completion of treatment should be discarded.
- (7). Bring the child back to the clinic if there is no improvement after treatment, or if the child is getting worse.
- (8). If the child vomits the medicines on administration, give another dose.



(9). To follow up on the progress of the child and in the interest of the study, the carers were advised to come back to the clinic after 7 days and report to the researcher whether the child got well or not.

### **2.6.3 Post-intervention study**

A total of 100 patients were similarly recruited during this stage. The researcher continued recording the information as during the pre-intervention stage. A dispensing label outlining the directions of taking the drugs and the importance of completing the course of treatment was attached to the drugs' packet/bottle. In addition, the carer was verbally advised and counselled, emphasizing the directions and the importance of completing the treatments.



Figure 2.6: Researcher interviewing a carer at St Therese Hohola Clinic

### **2.6.4 Follow-up study**

To follow up on the progress of the child and in the interest of the study, the carers were advised during the pre-post intervention and control stage to come back to the clinic after 7 days and report to the researcher whether the child was well or not.



Home tracing was a fairly difficult process in the study setting due to the following reasons:

- Not safe for the researcher to undertake home visits
- it would be expensive in terms of researcher time and transport
- Most patients lived in settlements or surrounding urban communities and street names, house numbers or addresses are either non-existent or hardly used.

Therefore, the patient carers were encouraged to return to the clinic after 7 days for the interest of improving the child's drug treatment. Those that returned voluntarily from each of the pre-intervention, post-intervention and control groups had the recorded followed-up data recorded on their attendance (Appendix 4.). The data collected included the period of illness, number of health centre visits, hospitalisation or other outcome from the diagnosis and treatment.

#### **2.6.5 Control study**

A total of 100 subjects were recruited to participate as controls at St Therese Hohola clinic. The process was repeated having the patients interviewed by the researcher noting the set criteria as before in pre- and post-intervention. No intervention occurred in this element of the study. To follow up on the progress of the child and in the interest of the study, the carers were advised to come back to the clinic after 7 days and report to the researcher whether the child got well or not.

#### **2.7 Statistical analysis.**

The SPSS package version 11 for windows was used to analyze the data for differences in pre- and post-intervention levels of (i) appropriate drugs (ii) appropriate doses (iii) appropriate intervals and (iv) appropriate duration. Tests used for continuous data were students t-test or one-way analysis of variance and for categorical data, analysis was by Chi-squared, Kruskal-Wallis and Fisher's Exact tests as appropriate.

The initial sample size was calculated with a two-tailed significance level at 5% probability and statistical power of 80%, assuming a 50% appropriate and effective use of medicines in the pre-intervention stage and an improvement to 75% from the intervention. Thus if 100 subjects were included in each group, significant statistical results in each area of the study would be achieved.

## **2.8 Ethical Issues**

The research protocol was approved by the PNG Medical Research Advisory Committee including giving ethical clearance for it to be carried out in PNG. In addition, it was approved by the Human Research Ethics Committee of Curtin University of Technology. All participants were informed on the nature of the study, its length and their right to withdraw. Informed consent was sought for participation. (see Appendix 1). Personal details were removed from the data collection forms upon the completion of the data collection and were replaced with an appropriate numeric code. In accordance with NH & MRC (National Health & Medical Research Committee) requirements on “data storage and retention”, only the de-identified data would be stored in a locked cupboard in the School of Pharmacy and no individual patient data will be published. At the completion of the study all data will be archived for a minimum of 5 years.

### 3.0 RESULTS

The questionnaires developed for this study were in the first case for recording demographic and patient history data related to previous visits and follow-up. A sample is included in Appendix 2 and 4.

To evaluate the level of understanding and effective use of medicines, and drug compliance, a validated questionnaire was employed (91). This questionnaire requested responses by patient carers to question in the following:

- Listing all the medicines child needs to take after consultation with the prescriber since birth and answer questions relating to drug administration
- Do medicines bother the child and by how much?
- List any problems encountered with medicines such as store the medicine, read the label and understand instructions, remember to give the medicines, and to give the medicines at the correct time
- Give herbal or local remedies to assist in treating malaria in child?

A copy of the questionnaire is included in Appendix 3. The intervention materials such as drug labels were pre-prepared for the study and samples are provided in Appendix 5.

A total of 303 children participated in the survey in both the control and clinic groups as shown in Table 3.1. Out of this, 25 (8.3%) participated in control-pre, 75 (24.8%) in control-post, 103 (34.0%) in clinic-pre, and 100 (33.0%) in the clinic-post intervention periods.

**Table 3.1: Patient demographics at the clinic pre-post and control pre-post groups**

		Subgroup				Total
		Con-pre	Con-post	Clin-pre	Clin-post	
Sample size	<b>N</b>	25 (8.3%)	75 (24.8%)	103 (34.0%)	100 (33.0%)	303 (100.0%)
Age (years)	<b>Mean</b>	1.90	1.99	2.78	2.32	2.36
	<b>SD</b>	2.14	1.93	2.60	1.98	2.23
	<b>P-value<sup>1</sup></b>	0.079				
Weight (kg)	<b>Mean</b>	10.04	10.16	11.87	11.01	11.01
	<b>SD</b>	3.97	3.60	5.51	5.25	4.92
	<b>P-value<sup>1</sup></b>	0.094				
Gender	<b>Male</b>	15 (60.0%)	35 (46.7%)	59 (57.3%)	51 (51.0%)	160 (52.8%)
	<b>Female</b>	10 (40.0%)	40 (53.3%)	44 (42.7%)	49 (49.0%)	143 (47.2%)
	<b>P-value<sup>2</sup></b>	0.455				

P-value<sup>1</sup> from oneway-anova TestP-value<sup>2</sup> from Pearson Chi-Square Test

Although the criteria admitted subjects up to 10 years, the mean age for the study was about 2 years old. There was no significant difference in age in any of the subgroups. The young age would reflect the high susceptibility of this age group to malaria. On a weight basis, the overall mean for all groups was 11.01 kg. There was no significant difference in weights for all groups. A total of 160 (52.8%) males and 143 (47.2%) females participated in the study and there was no significant difference in gender in all groups.

**Table 3.2 Patient symptoms in control pre-post and clinic pre-post groups**

Symptoms	Subgroup				Total	P-value
	Con-pre	Con-post	Clin-pre	Clin-post		
<b>Fever</b>	24 (8.2%)	71 (24.4%)	99 (34.0%)	97 (33.3%)	291 (100.0%)	0.893
<b>Cough</b>	18 (7.8%)	57 (24.8%)	66 (28.7%)	89 (38.7%)	230 (100.0%)	0.001
<b>Running nose</b>	3 (7.5%)	6 (15.0%)	17 (42.5%)	14 (35.0%)	40 (100.0%)	0.417
<b>Diarrhoea</b>	7 (11.7%)	15 (25.0%)	18 (30.0%)	20 (33.3%)	60 (100.0%)	0.702
<b>Short of breath</b>		1 (14.3%)	1 (14.3%)	5 (71.4%)	7 (100.0%)	0.177
<b>Cold</b>		1 (33.3%)		2 (66.7%)	3 (100.0%)	0.492
<b>Vomitted</b>		1 (6.3%)	5 (31.3%)	10 (62.5%)	16 (100.0%)	0.042
<b>Headache/dizzy</b>		4 (26.7%)	8 (53.3%)	3 (20.0%)	15 (100.0%)	0.276
<b>Abdominal pain</b>		1 (25.0%)	3 (75.0%)		4 (100.0%)	0.298
<b>Neck/groin rashes</b>		1 (50.0%)	1 (50.0%)		2 (100.0%)	0.682
<b>Malaria</b>			4 (100.0%)		4 (100.0%)	0.049
<b>Enlarge spleen</b>			2 (66.7%)	1 (33.3%)	3 (100.0%)	0.583
<b>Pain</b>			2 (66.7%)	1 (33.3%)	3 (100.0%)	0.583
<b>Blood in stool</b>			1 (100.0%)		1 (100.0%)	0.583
<b>Sores on body/eyes</b>			2 (66.7%)	1 (33.3%)	3 (100.0%)	0.583
<b>Pussy ear</b>				1 (100.0%)	1 (100.0%)	0.565
<b>Flu</b>				4 (100.0%)	4 (100.0%)	0.042

P-value from Pearson Chi-Square Test

All diagnoses for the recorded visits were documented and are summarized in Table 3.2. It is noted that it was common for more than one symptom to be recorded. Rarely was a specific diagnoses recorded. For example, malaria was only recorded as a diagnosis in 4 out of 303 patients. Fever was the most common reported symptom which was correlated with malaria. Cough is also commonly found and this symptom showed a significant difference amongst the groups largely from the control-pre subgroup. This is a symptom that may have resulted in prescribing outcomes. A range of symptoms were recorded which only amounted to a small proportion of the total and any significant differences found in the sub-groups had little impact on the focus of the study. The Standard Treatment for Common Illnesses of Children in Papua New Guinea (11) required where fever was a symptom to include treatment for malaria.

**Table 3.3 Number of episodes of illness requiring a previous consultation**

Subgroup	Number of episodes in last 12 months			Total number of previous episodes	
	N	Mean	SD	Mean	SD
Con-pre	25	2.44	1.45	2.80	1.76
Con-post	75	1.44	1.73	2.87	2.04
Clin-pre	101	2.23	1.31	2.79	1.59
Clin-post	95	2.83	1.69	3.20	1.67
Total	296	2.49	1.57	2.94	1.76

Overall patients attending both clinics had encountered an overall average of approximately 3 previous episodes resulting in a clinic or hospital consultation since birth. The small difference in these values simply related to the young age of the population evaluated. As the population was young, it is not surprising the previous 12 months reflected most of the previous treatment episodes with a total average mean of about 2½.

**Table 3.4 Prescribers compared at the clinic pre-post and control pre-post subgroups**

Prescriber	Subgroup				Total
	Con-pre	Con-post	Clin-pre	Clin-post	
HEO	2 (8.0%)	1 (1.3%)		9 (9.0%)	12 (4.0%)
Nurse	23 (92.0%)	70 (93.3%)	103 (100.0%)	90 (90.0%)	286 (94.4%)
Doctor		4 (5.3%)		1 (1.0%)	5 (1.7%)
P-value	0.001				

P-value from Pearson Chi-Square Test

Though statistically, there was a significant difference in the group, the vast majority of prescribing (94.4%) was performed by nurses at the clinics. The result shown in Table 3.4 resulted from the small differences for HEO and Doctor where there were low numbers or zero in some cells.

**Table 3.5 Prescribers compared at the clinic and control groups**

Prescriber	Group		Total	P-value
	Control	Clinic		
Nurse	93 (93.0%)	193 (95.1%)	286 (94.4%)	0.311
Other	7 (7.0%)	10 (4.9%)	17 (5.6%)	

P-value from Fisher's Exact Test

There was no difference as shown in Table 3.5 for prescribers between the control and clinic group when comparing Nurses with others.

**Table 3.6 Appropriate drug specifications for fever/malaria in control pre-post and clinic pre-post subgroups**

Count	Subgroup				Total
	Con-pre	Con-post	Clin-pre	Clin-post	
Not appropriate	14 (58.3%)	37 (52.1%)	36 (36%)	27 (27.8%)	114 (39%)
All aspects appropriate	10 (41.7%)	34 (47.9%)	64 (64%)	70 (72.2%)	178 (61%)
P-value	0.002				

P-value from Pearson Chi-Square Test

There was a significant difference (Table 3.6) evident in the drugs prescribed in the groups in terms of their appropriate specifications for fever/malaria during the period of the study. These were some drugs that were prescribed together with the anti-malarials recorded during the study and were outside the Standard Treatment for Common Illnesses of Children in Papua New Guinea (11). Such drugs were primaquine tablets, Septrim® suspension, chloramphenicol suspension, and erythromycin suspension. Overall over 60% of drugs prescribed for fever/malaria were appropriate.

**Table 3.7 Appropriate drug specifications for fever/malaria comparing the control pre with control post group**

Count	Subgroup		Total
	Con-pre	Con-post	
Not appropriate	14 (58.3%)	37 (52.1%)	51 (53.7%)
All aspects appropriate	10 (41.7%)	34 (47.9%)	44 (46.3%)
P-value	0.387		

P-value from Fisher's Exact Test

There was no significant difference (Table 3.7) between the control-pre and control-post group. No intervention occurred in relation to prescribing and it is notable the presence of the researcher had no influence.

**Table 3.8 Appropriate drug specifications for fever/malaria comparing the clinic pre with clinic post group**

Count	Subgroup		Total
	Clin-pre	Clin-post	
Not appropriate	36 (36.0%)	27 (27.8%)	63 (32.0%)
All aspects appropriate	64 (64.0%)	70 (72.2%)	134 (68.0%)
P-value	0.141		

P-value from Fisher's Exact Test

There was no difference in the clinic-pre and clinic-post group (Table 3.8) where again the researcher had no impact on prescribing and the study was not carried out with that objective.

**Table 3.9 Appropriate drug specifications for fever/malaria (only amodiaquine, Fansidar®, and chloroquine) for all groups**

Drug	Count	Subgroup				Total	P-value
		Con-pre	Con-post	Clin-pre	Clin-post		
Amodiaquine 100mg tablet	Dose not approp	5 (29.4%)	6 (14.0%)	4 (5.9%)	3 (4.0%)	18 (8.9%)	0.004
	Dose appropriate	12 (70.6%)	37 (86.0%)	64 (94.1%)	72 (96.0%)	185 (91.1%)	
	Freq appropriate	17 (100.0%)	43 (100.0%)	68 (100.0%)	75 (100.0%)	203 (100.0%)	
	Duration approp	17 (100.0%)	43 (100.0%)	68 (100.0%)	75 (100.0%)	203 (100.0%)	
Fansidar® tablet	Dose not approp	6 (33.3%)	5 (11.4%)	9 (12.0%)	8 (9.9%)	28 (12.8%)	0.057
	Dose appropriate	12 (66.7%)	39 (88.6%)	66 (88.0%)	73 (90.1%)	190 (87.2%)	
	Freq appropriate	18 (100.0%)	44 (100.0%)	75 (100.0%)	81 (100.0%)	218 (100.0%)	
Chloroquine 150mg tablet	Dose not approp			1 (14.3%)	1 (16.7%)	2 (13.3%)	0.946
	Dose appropriate	1 (100.0%)	1 (100.0%)	6 (85.7%)	5 (83.3%)	13 (86.7%)	
	Freq appropriate	1 (100.0%)	1 (100.0%)	7 (100.0%)	6 (100.0%)	15 (100.0%)	
	Duration approp	1 (100.0%)	1 (100.0%)	7 (100.0%)	6 (100.0%)	15 (100.0%)	

P-value from Pearson Chi-Square Test

There was a difference (Table 3.9) in the dose prescribed being not appropriate compared with dose appropriate for amodiaquine 100mg tablet. This may be due to the low representation of cases (8.9%) which indicated the dose as not appropriate.



**Table 3.10 Appropriate drug specifications for fever/malaria (only amodiaquine, Fansidar®, and chloroquine) for the control pre-post group**

Drug	Count	Subgroup		Total	P-value
		Con-pre	Con-post		
Amodiaquine 100mg tablet	Dose not approp	5 (29.4%)	6 (14.0%)	11 (18.3%)	0.153
	Dose appropriate	12 (70.6%)	37 (86.0%)	49 (81.7%)	
	Freq appropriate	17 (100.0%)	43 (100.0%)	60 (100.0%)	
	Duration approp	17 (100.0%)	43 (100.0%)	60 (100.0%)	
Fansidar® tablet	Dose not approp	6 (33.3%)	5 (11.4%)	11 (17.7%)	0.049
	Dose appropriate	12 (66.7%)	39 (88.6%)	51 (82.3%)	
	Freq appropriate	18 (100.0%)	44 (100.0%)	62 (100.0%)	
Chloroquine 150mg tablet	Dose appropriate	1 (50.0%)	1 (50.0%)	2 (100.0%)	
	Freq appropriate	1 (100.0%)	1 (100.0%)	2 (100.0%)	
	Duration approp	1 (100.0%)	1 (100.0%)	2 (100.0%)	

P-value from Fisher's Exact Test

There was a difference ( $P < 0.05$ ) for prescribed Fansidar® tablets when the dose not appropriate group was compared with dose appropriate. This again may be due to the small number of doses prescribed as not appropriate (17.7%).

**Table 3.11 Appropriate drug specifications for fever/malaria (only amodiaquine, Fansidar®, and chloroquine) for the clinic pre-post group**

Drug	Count	Subgroup		Total	P-value
		Clin-pre	Clin-post		
Amodiaquine 100mg tablet	Dose not approp	4 (5.9%)	3 (4%)	7 (4.9%)	0.445
	Dose appropriate	64 (94.1%)	72 (96.0%)	136 (95.1%)	
	Freq appropriate	68 (100.0%)	75 (100.0%)	143 (100.0%)	
	Duration approp	68 (100.0%)	75 (100.0%)	143 (100.0%)	
Fansidar® tablet	Dose not approp	9 (12.0%)	8 (9.9%)	17 (10.9%)	0.433
	Dose appropriate	66 (88.0%)	73 (90.1%)	139 (89.1%)	
	Freq appropriate	75 (100.0%)	81 (100.0%)	156 (100.0%)	
Chloroquine 150mg tablet	Dose not approp	1 (50.0%)	1 (50.0%)	2 (15.4%)	0.731
	Dose appropriate	6 (85.7%)	5 (83.3%)	11 (84.6%)	
	Freq appropriate	7 (100.0%)	6 (100.0%)	13 (100.0%)	
	Duration approp	7 (100.0%)	6 (100.0%)	13 (100.0%)	

P-value from Fisher's Exact Test

It is noted in the clinic groups, no differences were found in any of the dosage parameters. In addition, these showed high levels of appropriate prescribing.

**Table 3.12 Number of doses, frequency, and duration with a classified appropriateness for all drugs prescribed during the period of study comparing control pre-post and clinic pre-post groups**

Drug	Count	Subgroup				Total (%)	P-value
		Con-pre	Con-post	Clin-pre	Clin-post		
Amodiaquine 100mg tablet	Dose not approp	6 (26.1%)	6 (9.0%)	5 (5.7%)	5 (5.5%)	22 (8.2%)	0.009
	Dose appropriate	17 (73.9%)	61 (91.0%)	83 (94.3%)	86 (94.5%)	247 (91.8%)	
	Freq appropriate	23 (100.0%)	67 (100.0%)	88 (100.0%)	91 (100.0%)	269 (100.0%)	
	Duration approp	23 (100.0%)	67 (100.0%)	88 (100.0%)	91 (100.0%)	269 (100.0%)	
Fansidar® tablet	Dose not approp	6 (30.0%)	6 (12.2%)	10 (12.3%)	8 (9.6%)	30 (12.9%)	0.110
	Dose appropriate	14 (70.0%)	43 (87.8%)	71 (87.7%)	75 (90.4%)	203 (87.1%)	
	Freq appropriate	20 (100.0%)	49 (100.0%)	81 (100.0%)	83 (100.0%)	233 (100.0%)	
Chloroquine 150mg tablet	Dose not approp			1 (10.0%)	1 (14.3%)	2 (9.5%)	0.895
	Dose appropriate	1 (100.0%)	3 (100.0%)	9 (90.0%)	6 (85.7%)	19 (90.5%)	
	Freq appropriate	1 (100.0%)	3 (100.0%)	10 (100.0%)	7 (100.0%)	21 (100.0%)	
	Duration approp	1 (100.0%)	3 (100.0%)	10 (100.0%)	7 (100.0%)	21 (100.0%)	
Quinine 300mg tablet	Dose not approp		1 (33.3%)			1 (14.3%)	0.212
	Dose appropriate		2 (66.7%)	4 (100.0%)		6 (85.7%)	
	Freq not approp		2 (66.7%)			2 (28.6%)	0.053
	Freq appropriate		1 (33.3%)	4 (100.0%)		5 (71.4%)	
	Duration not app			1 (25.0%)		1 (16.7%)	0.439
	Duration approp		2 (100.0%)	3 (75.0%)		5 (83.3%)	
Amoxicillin 250mg tablet	Dose not approp		3 (60.0%)	9 (47.4%)	8 (80.0%)	20 (58.8%)	0.237
	Dose appropriate		2 (40.0%)	10 (52.6%)	2 (20.0%)	14 (41.2%)	
	Freq appropriate		5 (100.0%)	19 (100.0%)	10 (100.0%)	34 (100.0%)	
	Duration approp		5 (100.0%)	19 (100.0%)	10 (100.0%)	34 (100.0%)	
Amoxicillin 125mg/5mL suspension	Dose not approp	2 (25.0%)	2 (16.7%)	2 (13.3%)	1 (5.3%)	7 (13.0%)	0.537
	Dose appropriate	6 (75.0%)	10 (83.3%)	13 (86.7%)	18 (94.7%)	47 (87.0%)	
	Freq appropriate	8 (100.0%)	12 (100.0%)	15 (100.0%)	19 (100.0%)	54 (100.0%)	
	Duration approp	8 (100.0%)	12 (100.0%)	15 (100.0%)	19 (100.0%)	54 (100.0%)	
Septrim® tablet	Dose not approp	1 (25.0%)	2 (100.0%)	1 (5.0%)	1 (9.1%)	5 (13.5%)	0.002
	Dose appropriate	3 (75.0%)		19 (95.0%)	10 (90.9%)	32 (86.5%)	
	Freq appropriate	4 (100.0%)	2 (100.0%)	20 (100.0%)	11 (100.0%)	37 (100.0%)	
	Duration approp	4 (100.0%)	2 (100.0%)	20 (100.0%)	11 (100.0%)	37 (100.0%)	
Septrim® suspension	Dose not approp	2 (22.2%)	2 (12.5%)		3 (60.0%)	7 (21.9%)	0.131
	Dose appropriate	7 (77.8%)	14 (87.5%)	2 (100.0%)	2 (40.0%)	25 (78.1%)	
	Freq not approp	1 (11.1%)				1 (3.1)	0.451
	Freq appropriate	8 (88.9%)	16 (100.0%)	2 (100.0%)	5 (100.0%)	31 (96.9%)	
	Duration not app		1 (6.3%)			1 (3.2%)	0.809
	Duration approp	8 (100.0%)	15 (93.8%)	2 (100.0%)	5 (100.0%)	30 (96.8%)	
Erythromycin 125mg/5mL suspension	Dose not approp		1 (11.1%)			1 (7.7%)	0.786
	Dose appropriate		8 (88.9%)	2 (100.0%)	2 (100.0%)	12 (92.3%)	
	Freq not approp		5 (55.6%)			5 (38.5%)	0.164
	Freq appropriate		4 (44.4%)	2 (100.0%)	2 (100.0%)	8 (61.5%)	
	Duration approp		8 (100.0%)	2 (100.0%)	2 (100.0%)	8 (100.0%)	
Chloramphenicol 125mg/5mL suspension	Dose not approp		4 (36.4%)	4 (57.1%)	7 (53.8%)	15 (48.4%)	0.604
	Dose appropriate		7 (63.6%)	3 (42.9%)	6 (46.2%)	16 (51.6%)	
	Freq not approp		1 (9.1%)			1 (3.2)	0.391
	Freq appropriate		10 (90.9%)	7 (100.0%)	13 (100.0%)	30 (96.8%)	
	Duration approp		11 (100.0%)	7 (100.0%)	13 (100.0%)	31 (100.0%)	
Albendazole 200mg tablet	Dose not approp	3 (23.1%)	3 (11.1%)	1 (1.9%)	4 (8.3%)	11 (7.7%)	0.061
	Dose appropriate	10 (76.9%)	24 (88.9%)	53 (98.1%)	44 (91.7%)	131 (92.3%)	

	Freq appropriate	13 (100.0%)	27 (100.0%)	54 (100.0%)	48 (100.0%)	142 (100.0%)	
Tinidazole 500mg tablet	Dose not approp	1 (50.0%)	3 (30.0%)	1 (50.0%)		5 (29.4%)	0.558
	Dose appropriate	1 (50.0%)	7 (70.0%)	1 (50.0%)	3 (100.0%)	12 (70.6%)	
	Freq not approp		1 (10.0%)			1 (5.9%)	0.863
	Freq appropriate	2 (100.0%)	9 (90.0%)	2 (100.0%)	3 (100.0%)	16 (94.1%)	
Benzyl-penicillin 600mg/2mL inj	Dose appropriate	5 (100.0%)	3 (100.0%)	4 (100.0%)	5 (100.0%)	17 (100.0%)	
	Freq appropriate	5 (100.0%)	3 (100.0%)	4 (100.0%)	5 (100.0%)	17 (100.0%)	
Aspirin 300mg tablet	Dose not approp				1 (100.0%)	1 (16.7%)	0.112
	Dose appropriate	1 (100.0%)	2 (100.0%)	2 (100.0%)		5 (83.3%)	
	Freq not approp	1 (100.0%)	2 (100.0%)	2 (100.0%)	1 (100.0%)	6 (100.0%)	
Paracetamol 120mg/5mL elixir	Dose not approp	5 (33.3%)	22 (53.7%)	22 (31.9%)	19 (29.2%)	68 (35.8%)	0.060
	Dose appropriate	10 (66.7%)	19 (46.3%)	47 (68.1%)	46 (70.8%)	122 (64.2%)	
	Freq not approp	15 (100.0%)	41 (100.0%)	69 (100.0%)	65 (100.0%)	190 (100.0%)	
Primaquine 7.5mg tablet	Dose appropriate		3 (100.0%)	2 (100.0%)		5 (100.0%)	
	Freq appropriate		3 (100.0%)	2 (100.0%)		5 (100.0%)	
Aminophylline 100mg tablet	Dose appropriate			3 (100.0%)		3 (100.0%)	
	Freq not approp			3 (100.0%)		3 (100.0%)	
	Duration not app			1 (100.0%)		1 (100.0%)	
Erythromycin 250mg tablet	Dose appropriate				2 (100.0%)	2 (100.0%)	
	Freq not approp				2 (100.0%)	2 (100.0%)	
	Duration approp				2 (100.0%)	2 (100.0%)	
Paracetamol 500mg tablet	Dose not approp		1 (100.0%)	4 (100.0%)	3 (75.0%)	8 (88.9%)	0.495
	Dose appropriate				1 (25.0%)	1 (11.1%)	
	Freq not approp			1 (25.0%)		1 (11.1%)	0.495
	Freq appropriate		1 (100.0%)	3 (75.0%)	4 (100.0%)	8 (88.0%)	
Salbutamol 4mg tablet	Dose appropriate		1 (100.0%)			1 (100.0%)	
	Freq appropriate		1 (100.0%)			1 (100.0%)	
	Duration approp		1 (100.0%)			1 (100.0%)	

P-value from Pearson Chi-Square Test

There was a significant difference ( $P < 0.05$ ) shown for amodiaquine 100mg tablets when the dose not appropriate category was compared with dose appropriate category. This difference may be due to the small number of cases in the dose not appropriate (8.2%) data. There was also a significant difference ( $P < 0.05$ ) shown for Seprim<sup>®</sup> tablets and this may be due to the small number of cases (13.5%) of dose not appropriate versus dose appropriate (86.5%). The dose not appropriate category for amoxicillin tablets was 58.8% (20). The frequency category prescribed for paracetamol elixir was 100% (190) of cases. The dose not appropriate category prescribed for chloramphenicol suspension was 48.4% (15) of cases. No intervention occurred with prescribing regimens so any differences arising usually relate to small numbers or other events.

Table 3.12 shows the prescribing of drugs for a broader range of diagnoses. Although the treatment of fever/malaria showed high levels of appropriateness, this finding does

not translate into some other treatments. For example, amoxicillin 250mg tablets showed inappropriate dosage at a 60% level, but could have been influenced by the fixed dose product. Although the suspension was available, its poor shelf-life might be a factor in the prescribing of the tablets. The higher level of inappropriate dosages for chloramphenicol suspension and paracetamol elixir are noteworthy. The high level of inappropriate dosage for paracetamol tablets is of significant concern. Although this may partly relate to a fixed dose tablet, an elixir is available with a reasonable stability profile. Inappropriate dosages commenced in a clinic can have long-term adverse carry-on effects for drugs readily available without a prescription. This effect is also noted where the frequency for paracetamol elixir is inappropriate on all occasions. The usual prescribed frequency was to be taken as a single dose whereas the Standard Treatment for Common Illnesses of Children in Papua New Guinea (11) indicated to be taken 4 times a day/every 6 hours. Therefore, prescriber education is appropriate in these circumstances in relation to the possible need for on-going treatment at home.

**Table 3.13 Doses, frequency, and duration appropriateness of amodiaquine and Fansidar® tablets comparing control pre-post groups**

Drug	Count	Subgroup		Total	P-value
		Con-pre	Con-post		
Amodiaquine 100mg tablet	Dose not approp	6 (26.1%)	6 (9.0%)	12 (13.3%)	0.047
	Dose appropriate	17 (73.9%)	61 (91.0%)	78 (86.7%)	
	Freq appropriate	23 (100.0%)	67 (100.0%)	90 (100.0%)	
	Duration approp	23 (100.0%)	67 (100.0%)	90 (100.0%)	
Fansidar® tablet	Dose not approp	6 (30.0%)	6 (12.2%)	12 (17.4%)	0.082
	Dose appropriate	14 (70.0%)	43 (87.8%)	57 (82.6%)	
	Freq appropriate	20 (100.0%)	49 (100.0%)	69 (100.0%)	

P-value from Fisher's Exact Test

For further statistical analysis, data in Table 3.12 have been sub-grouped into control-pre and control-post as shown in Table 3.13. However, the difference ( $P < 0.05$ ) shown for amodiaquine 100mg tablets is only due to the small number of subjects in the dose not appropriate (13.3%) category compared with the dose appropriate (86.7%) category in the control-pre and control-post subgroups. Data for the clinic-pre and post data are shown in Table 3.14 where no differences are evident for the two groups.

**Table 3.14 Doses, frequency, and duration appropriateness of amodiaquine and Fansidar® tablets comparing clinic pre-post groups**

Drug	Count	Subgroup		Total N = 303	P-value
		Clin-pre	Clin-post		
Amodiaquine 100mg tablet	Dose not approp	5 (5.7%)	5 (5.5%)	10 (5.6%)	0.605
	Dose appropriate	83 (94.3%)	86 (94.5%)	169 (94.4%)	
	Freq appropriate	88 (100.0%)	91 (100.0%)	179 (100.0%)	
	Duration approp	88 (100.0%)	91 (100.0%)	179 (100.0%)	
Fansidar® tablet	Dose not approp	10 (12.3%)	8 (9.6%)	18 (11.0%)	0.380
	Dose appropriate	71 (87.7%)	75 (90.4%)	146 (89.0%)	
	Freq appropriate	81 (100.0%)	83 (100.0%)	164 (100.0%)	

P-value from Fisher's Exact Test

**Table 3.15 Interviewed group (carers) in control pre-post and clinic pre-post groups**

Interviewed group	Subgroup				Total	P-value
	Con-pre	Con-post	Clin-pre	Clin-post		
Mother	19 (76.0%)	64 (85.3%)	84 (81.6%)	83 (83.0%)	250 (82.5%)	0.966
Father	3 (12.0%)	5 (6.7%)	9 (8.7%)	9 (9.0%)	26 (8.6%)	
Other	3 (12.0%)	6 (8.0%)	10 (9.7%)	8 (8.0%)	27 (8.9%)	

P-value from Pearson Chi-Square Test

There was no significant difference in the groups shown in Table 3.15 between the carers who participated in the study in any of the subgroups evaluated. Most of the carers interviewed were mothers (82.5%).

**Table 3.16 Medicines given on previous consultations since birth in control pre-post and clinic pre-post groups**

Activity	Count (No. of drugs)	Subgroup				Total
		Con-pre	Con-post	Clin-pre	Clin-post	
Drug/s given on previous consultation	0			3 (2.9%)	5 (5.0%)	8 (2.6%)
	1		10 (13.3%)	4 (3.9%)	8 (8.0%)	22 (7.3%)
	2	5 (20.0%)	25 (33.3%)	18 (17.5%)	23 (23.0%)	71 (23.4%)
	3	11 (44.0%)	33 (44.0%)	50 (48.5%)	48 (48.0%)	142 (46.9%)
	4	9 (36.0%)	7 (9.3%)	27 (26.2%)	14 (14.0%)	57 (18.8%)
	5			1 (1.0%)	2 (2.0%)	3 (1.0%)
Mean		3.16	2.49	2.94	2.64	
SD		0.75	0.84	0.95	1.05	
P-value		0.009				

P-value from Pearson Chi-Square Test

Data compiled in Table 3.16 show that 46.9% (142) patients were found to have taken a total of three different drugs in their life time. This shows a relatively small number of drugs previously prescribed to this patient group.

**Table 3.17 Number of drugs taken by patient since birth compared separately in all groups pre-post, control pre-post and clinic pre-post**

Group	Activity	Subgroup	N	Mean Rank	P-value
All groups	No. of drugs taken	Con-pre	25	187.02	0.000
		Con-post	75	125.89	
		Clin-pre	103	170.39	
		Clin-post	100	143.88	
		Total	303		
Control	No. of drugs taken	Con-pre	25	65.90	0.001
		Con-post	75	45.37	
		Total	100		
Clinic	No. of drugs taken	Clin-pre	103	110.65	0.023
		Clin-post	100	93.10	
		Total	203		

P-value from Kruskal-Wallis Test

Analysis of these data (Table 3.17) using the Kruskal-Wallis Test also identified significant differences between control-pre and control-post subgroups ( $P < 0.05$ ) including for clinic-pre and clinic-post groups ( $P < 0.05$ ). There is also a significant difference ( $P < 0.05$ ) between all the groups. These data show that the patient groups in both “post” subgroups had been given lower numbers of medications on previous consultations with the health services. Standard deviation data although of limited validity for these data however indicates a wide range is evident in the population. The impact of this difference is difficult to isolate but could imply that carers in the “post” subgroups may have slightly less experience with medications from previous consultations.

**Table 3.18 Patient carers responses to duration of drug administration (How many days did you give it?) in control pre-post and clinic pre-post groups**

Drug	Days count	Subgroups				Total	P-value
		Con-pre	Con-post	Clin-pre	Clin-post		
Amodiaquine 100mg tablet	Incorrect	4 (18.2%)	13 (20.6%)	24 (27.9%)	24 (29.3%)	65 (25.7%)	0.519
	Correct	18 (81.8%)	50 (79.4%)	62 (72.1%)	58 (70.7%)	188 (74.3%)	
Chloroquine 150mg tablet	Incorrect			2 (28.6%)	2 (100.0%)	4 (30.8%)	0.098
	Correct	1 (100.0%)	3 (100.0%)	5 (71.4%)		9 (69.2%)	
Quinine 300mg tablet	Incorrect	1 (100.0%)		1 (100.0%)		2 (100.0%)	
	Correct						
Amoxicillin 250mg tablet	Incorrect		5 (100.0%)	10 (100.0%)	9 (100.0%)	24 (100.0%)	
	Correct						
Amoxicillin 125mg/5mL susp	Incorrect	8 (57.1%)	25 (54.3%)	37 (67.3%)	39 (62.9%)	109 (61.6%)	0.586
	Correct	6 (42.9%)	21 (45.7%)	18 (32.7%)	23 (37.1%)	68 (38.4%)	
Septrim® tablet	Incorrect		1 (50.0%)	10 (90.9%)	8 (66.7%)	19 (76.0%)	0.265
	Correct		1 (50.0%)	1 (9.1%)	4 (33.3%)	6 (24.0%)	
Septrim® suspension	Incorrect	12 (63.2%)	16 (48.5%)	30 (76.9%)	33 (63.5%)	91 (63.6%)	0.100
	Correct	7 (36.8%)	17 (51.5%)	9 (23.1%)	19 (36.5%)	52 (36.4%)	
Erythromycin 125mg/5mL susp	Incorrect	3 (100.0%)	13 (100.0%)	5 (100.0%)	4 (80.0%)	25 (96.2%)	0.224
	Correct				1 (20.0%)	1 (3.8%)	
Chloramphenicol 125mg/5mL susp	Incorrect	1 (100.0%)	7 (87.5%)	14 (77.8%)	12 (66.7%)	34 (75.6%)	0.624
	Correct		1 (12.5%)	4 (22.2%)	6 (33.3%)	11 (24.4%)	
Aspirin 300mg tablet	Incorrect	1 (100.0%)		1 (100.0%)		2 (100.0%)	
	Correct						
Paracetamol 120mg/5mL mixt	Incorrect	13 (100.0%)	13 (100.0%)	64 (100.0%)	19 (100.0%)	109 (100.0%)	
	Correct						
Primaquine 7.5mg tablet	Incorrect	2 (100.0%)	1 (100.0%)	3 (100.0%)	1 (100.0%)	7 (100.0%)	
	Correct						
Aminophylline 100mg tablet	Incorrect			2 (100.0%)	1 (100.0%)	3 (100.0%)	
	Correct						
Salbutamol 4mg tablet	Incorrect	2 (100.0%)		1 (100.0%)	1 (100.0%)	4 (100.0%)	
	correct						

P-value from Pearson Chi-Square Test

The data in Table 3.18 indicated a high level of consistency which in total showed 74.3% (188) correct for amodiaquine duration of administration in all groups. The data also indicated some incorrect responses in all the subgroups from the patients' carers on the duration of drug administration. It is notable that 100% (24) of cases were incorrect for amoxicillin 250mg tablets and 76% (19) incorrect for Septrim® tablets. For other liquid medications, 61.6% (109) were incorrect for amoxicillin 125mg/5mL suspension; 63.6% (91) incorrect for Septrim® suspension; 96.2% (25) incorrect for erythromycin 125mg/5mL suspension; 75.6% (34) incorrect for chloramphenicol 125mg/5mL suspension; and 100% (109) incorrect for paracetamol 120mg/5mL elixir. There was no

carer interventions carried out during the study other than for the anti-malarial medications.

**Table 3.19 Patient carers responses to frequency of drug administration (How many times per day did you give it?) in control pre-post and clinic pre-post groups**

Drug	Frequency count	Subgroups				Total	P-value
		Con-pre	Con-post	Clin-pre	Clin-post		
Amodiaquine 100mg tablet	incorrect	4 (18.2%)	15 (23.8%)	24 (27.9%)	24 (29.3%)	67 (26.5%)	0.699
	correct	18 (81.8%)	48 (76.2%)	62 (72.1%)	58 (70.7%)	186 (73.5%)	
Chloroquine 150mg tablet	incorrect			2 (28.6%)	2 (100.0%)	4 (30.8%)	0.098
	correct	1 (100.0%)	3 (100.0%)	5 (71.4%)		9 (69.2%)	
Quinine 300mg tablet	incorrect	1 (100.0%)		1 (100.0%)		2 (100.0%)	
	correct						
Amoxycillin 250mg tablet	incorrect		5 (100.0%)	10 (100.0%)	9 (100.0%)	24 (100.0%)	
	correct						
Amoxycillin 125mg/5mL susp	incorrect	11 (78.6%)	32 (69.6%)	51 (92.7%)	49 (79.0%)	143 (80.8%)	0.030
	correct	3 (21.4%)	14 (30.4%)	4 (7.3%)	13 (21.0%)	34 (19.2%)	
Septrim <sup>®</sup> tablet	incorrect		1 (50.0%)	11 (100.0%)	11 (91.7%)	23 (92.0%)	0.056
	correct		1 (50.0%)		1 (8.3%)	2 (8.0%)	
Septrim <sup>®</sup> suspension	incorrect	13 (68.4%)	26 (78.8%)	38 (97.4%)	46 (88.5%)	123 (86.0%)	0.013
	correct	6 (31.6%)	7 (21.2%)	1 (2.6%)	6 (11.5%)	20 (14.0%)	
Erythromycin 125mg/5mL susp	incorrect	3 (100.0%)	13 (100.0%)	5 (100.0%)	5 (100.0%)	26 (100.0%)	
	correct						
Chloramphenicol 125mg/5mL susp	incorrect	1 (100.0%)	7 (87.5%)	15 (83.3%)	15 (83.3%)	38 (84.4%)	0.965
	correct		1 (12.5%)	3 (16.7%)	3 (16.7%)	7 (15.6%)	
Aspirin 300mg tablet	incorrect	1 (100.0%)		1 (100.0%)		2 (100.0%)	
	correct						
Paracetamol 120mg/5mL mix	incorrect	13 (100.0%)	13 (100.0%)	64 (100.0%)	19 (100.0%)	109 (100.0%)	
	correct						
Primaquine 7.5mg tablet	incorrect	2 (100.0%)	1 (100.0%)	3 (100.0%)	1 (100.0%)	7 (100.0%)	
	correct						
Aminophylline 100mg tablet	incorrect			2 (100.0%)	1 (100.0%)	3 (100.0%)	
	correct						
Salbutamol 4mg tablet	incorrect	2 (100.0%)		1 (100.0%)	1 (100.0%)	4 (100.0%)	
	correct						

P-value from Pearson Chi-Square Test

As shown in Table 3.19 there are high levels of appropriate responses overall amounting to 73.5% (186) from patients' carers for amodiaquine 100mg tablets and 69.2% (9) for chloroquine 150mg tablets for frequency of administration. However, some high levels of incorrect responses were also recorded for the following drugs; amoxycillin 250mg tablets 100% (24), amoxycillin suspension 80.8% (143), septrim tablets 92% (23), Septrim<sup>®</sup> suspension 86% (123), erythromycin suspension 100% (26), chloramphenicol suspension 84.4% (38), and paracetamol elixir 100% (109).



**Table 3.20 Patient carers responses to dosage of drug administration (How much medicine did you give each time?) in control pre-post and clinic pre-post groups**

Drug	Dose count	Subgroups				Total	P-value
		Con-pre	Con-post	Clin-pre	Clin-post		
Amodiaquine 100mg tablet	incorrect	4 (18.2%)	14 (22.2%)	25 (29.1%)	30 (36.6%)	73 (28.9%)	0.175
	correct	18 (81.8%)	49 (77.8%)	61 (70.9%)	52 (63.4%)	180 (71.1%)	
Chloroquine 150mg tablet	incorrect			2 (28.6%)	1 (50.0%)	3 (23.1%)	0.545
	correct	1 (100.0%)	3 (100.0%)	5 (71.4%)	1 (50.0%)	10 (76.9%)	
Quinine 300mg tablet	incorrect	1 (100.0%)		1 (100.0%)		2 (100.0%)	
	correct						
Amoxycillin 250mg tablet	incorrect		5 (100.0%)	10 (100.0%)	9 (100.0%)	24 (100.0%)	
	correct						
Amoxycillin 125mg/5mL susp	incorrect	8 (57.1%)	23 (50.0%)	39 (70.9%)	40 (64.5%)	110 (62.1%)	0.173
	correct	6 (42.9%)	23 (50.0%)	16 (29.1%)	22 (35.5%)	67 (37.9%)	
Septrim <sup>®</sup> tablet	incorrect		1 (50.0%)	11 (100.0%)	10 (83.3%)	22 (88.0%)	0.106
	correct		1 (50.0%)		2 (16.7%)	3 (12.0%)	
Septrim <sup>®</sup> suspension	incorrect	12 (63.2%)	18 (54.5%)	33 (84.6%)	37 (71.2%)	100 (69.9%)	0.043
	correct	7 (36.8%)	15 (45.5%)	6 (15.4%)	15 (28.8%)	43 (30.1%)	
Erythromycin 125mg/5mL susp	incorrect	3 (100.0%)	13 (100.0%)	5 (100.0%)	4 (80.0%)	25 (96.2%)	0.224
	correct				1 (20.0%)	1 (3.8%)	
Chloramphenicol 125mg/5mL susp	incorrect	1 (100.0%)	7 (87.5%)	14 (77.8%)	11 (61.1%)	33 (73.3%)	0.433
	correct		1 (12.5%)	4 (22.2%)	7 (38.9%)	12 (26.7%)	
Aspirin 300mg tablet	incorrect	1 (100.0%)		1 (100.0%)		2 (100.0%)	
	correct						
Paracetamol 120mg/5mL mix	incorrect	2 (15.4%)	4 (30.8%)	24 (37.5%)	8 (42.1%)	38 (34.9%)	0.407
	correct	11 (84.6%)	9 (69.2%)	40 (62.5%)	11 (57.9%)	71 (65.1%)	
Primaquine 7.5mg tablet	incorrect	2 (100.0%)	1 (100.0%)	3 (100.0%)	1 (100.0%)	7 (100.0%)	
	correct						
Aminophylline 100mg tablet	incorrect			2 (100.0%)	1 (100.0%)	3 (100.0%)	
	correct						
Salbutamol 4mg tablet	incorrect	2 (100.0%)		1 (100.0%)	1 (100.0%)	4 (100.0%)	
	correct						

P-value from Pearson Chi-Square Test

Table 3.20 data also indicated high levels of understanding of 71.1% (180) for the dosage of amodiaquine tablets, 76.9% (10) for chloroquine tablets, and 65.1% (71) for paracetamol elixir as correct responses from carers. However, incorrect responses were recorded for the following drugs; amoxycillin 250mg tablets 100% (24), amoxycillin suspension 62.1% (110), Septrim<sup>®</sup> tablets 88% (22), Septrim<sup>®</sup> suspension 69.9% (100), erythromycin suspension 96.2% (25) and chloramphenicol suspension 73.3% (33). The overall finding of poor understanding of carers for dosages of antibiotics is of concern as low doses potentially give rise to resistant strains. In the case of Septrim<sup>®</sup> products, higher dosages have potentially toxic effects.

**Table 3.21 Patient carers responses to uses of drug (What is the medicine for?) in control pre-post and clinic pre-post groups**

Drug	uses count	Subgroups				Total	P-value
		Con-pre	Con-post	Clin-pre	Clin-post		
Amodiaquine 100mg tablet	incorrect	10 (45.5%)	25 (39.7%)	25 (29.1%)	22 (26.8%)	82 (32.4%)	0.184
	Correct	12 (54.5%)	38 (60.3%)	61 (70.9%)	60 (73.2%)	171 (67.6%)	
Chloroquine 150mg tablet	incorrect			2 (28.6%)	2 (100.0%)	4 (30.8%)	0.098
	Correct	1 (100.0%)	3 (100.0%)	5 (71.4%)		9 (69.2%)	
Quinine 300mg tablet	incorrect	1 (100.0%)				1 (50.0%)	0.157
	Correct			1 (100.0%)		1 (50.0%)	
Amoxicillin 250mg tablet	incorrect		5 (100.0%)	10 (100.0%)	9 (100.0%)	24 (100.0%)	
	Correct						
Amoxicillin 125mg/5mL susp	incorrect	14 (100.0%)	46 (100.0%)	55 (100.0%)	62 (100.0%)	177 (100.0%)	
	Correct						
Septrim <sup>®</sup> tablet	incorrect		2 (100.0%)	11 (100.0%)	12 (100.0%)	25 (100.0%)	
	Correct						
Septrim <sup>®</sup> suspension	incorrect	19 (100.0%)	33 (100.0%)	39 (100.0%)	51 (98.1%)	142 (99.3%)	0.623
	Correct				1 (1.9%)	1 (0.7%)	
Erythromycin 125mg/5mL susp	incorrect	3 (100.0%)	13 (100.0%)	5 (100.0%)	5 (100.0%)	26 (100.0%)	
	Correct						
Chloramphenicol 125mg/5mL susp	incorrect	1 (100.0%)	8 (100.0%)	18 (100.0%)	18 (100.0%)	45 (100.0%)	
	Correct						
Aspirin 300mg tablet	incorrect	1 (100.0%)		1 (100.0%)		2 (100.0%)	
	Correct						
Paracetamol 120mg/5mL mix	incorrect	4 (30.8%)	1 (7.7%)	16 (25.0%)	3 (15.8%)	24 (22.0%)	0.408
	Correct	9 (69.2%)	12 (92.3%)	48 (75.0%)	16 (84.2%)	85 (78.0%)	
Primaquine 7.5mg tablet	incorrect	2 (100.0%)	1 (100.0%)	3 (100.0%)	1 (100.0%)	7 (100.0%)	
	Correct						
Aminophylline 100mg tablet	incorrect			2 (100.0%)		2 (66.7%)	0.083
	Correct				1 (100.0%)	1 (33.3%)	
Salbutamol 4mg tablet	incorrect	2 (100.0%)			1 (100.0%)	3 (75.0%)	0.135
	Correct			1 (100.0%)		1 (25.0%)	

P-value from Pearson Chi-Square Test

Table 3.21 data indicated that 67.6% (171) for amodiaquine tablets, 69.2% (9) for chloroquine tablets, and 78% (85) for paracetamol elixir gave correct responses from carers. However, high levels of incorrect responses were recorded for the following drugs; amoxicillin 250mg tablets 100% (24), amoxicillin suspension 100% (177), Septrim<sup>®</sup> tablets 100% (25), Septrim<sup>®</sup> suspension 99.3% (142), erythromycin suspension 100% (26) and chloramphenicol suspension 100% (45). It is notable again that there was a lack of understanding of the role of antibiotics in treatment of infections.

**Table 3.22 Do the medicines bother the child compared in control pre-post and clinic pre-post groups**

Activity	Count	Subgroup				Total N = 303
		Con-pre N = 25	Con-post N = 75	Clin-pre N = 103	Clin-post N = 100	
Do medicines bother the child	No	20 (80.0%)	75 (100.0%)	92 (91.1%)	99 (99.0%)	286 (95.0%)
	Yes	5 (20.0%)		9 (8.9%)	1 (1.0%)	15 (5.0%)
<b>P-value</b>	0.000					

P-value from Pearson Chi-Square Test

A total of 95% (286) of cases indicated (Table 3.22) that the medicines do not bother the child. The significant difference may be due to the very small number 5% (15) indicating the medicines do bother the child. Overall these data indicate little problems arising from previous medications. This may be partly because of the small number of previously administered medications.

**Table 3.23 Do the medicines bother the child compared in control pre-post groups**

Activity	Count	Subgroup		Total
		Con-pre	Con-post	
Do medicines bother the child	No	20 (80.0%)	75 (100.0%)	95 (95.0%)
	Yes	5 (20.0%)		5 (5.0%)
<b>P-value</b>	0.001			

P-value from Fisher's Exact Test

Using Fisher's Exact Test, there was a significant difference shown for control-pre and control-post as shown in Table 3.23.

**Table 3.24 Do the medicines bother the child compared in clinic pre-post groups**

Activity	Count	Subgroup		Total
		Clin-pre	Clin-post	
Do medicines bother the child	No	92 (91.1%)	99 (99%)	191 (95%)
	Yes	9 (8.9%)	1 (1%)	10 (5%)
<b>P-value</b>	0.010			

P-value from Fisher's Exact Test

Using Fisher's Exact Test, there was a significant difference shown for clinic-pre and clinic-post as indicated in Table 3.24. It is notable that the clinic post-groups included children who had been administered less previous medications.

**Table 3.25 Patient carers responses to storing, reading labels and understand instructions, remember to give the medicines and to give medicines on time compared in all groups pre-post, control pre-post and clinic pre-post groups**

Group	Activity	Subgroup	N	Mean Rank	P-value
All groups	Store the medicines	Con-pre	25	164.92	0.000
		Con-post	75	177.00	
		Clin-pre	102	104.46	
		Clin-post	100	177.00	
	Read label /understand instructions	Con-pre	25	168.46	0.000
		Con-post	75	144.13	
		Clin-pre	102	105.21	
		Clin-post	100	200.00	
	Remember to give the medicines	Con-pre	25	118.20	0.000
		Con-post	75	116.19	
		Clin-pre	102	107.25	
		Clin-post	100	231.45	
	To give the medicines on time	Con-pre	25	115.10	0.000
		Con-post	75	116.59	
		Clin-pre	102	107.68	
		Clin-post	100	231.48	
Control groups	Store the medicines	Con-pre	25	47.50	0.014
		Con-post	75	51.50	
	Read label /understand instructions	Con-pre	25	56.36	0.153
		Con-post	75	48.55	
	Remember to give the medicines	Con-pre	25	51.00	0.884
		Con-post	75	50.33	
	To give the medicines on time	Con-pre	25	49.78	0.836
		Con-post	75	50.74	
Clinic groups	Store the medicines	Clin-pre	102	77.48	0.000
		Clin-post	100	126.00	
	Read label /understand instructions	Clin-pre	102	69.64	0.000
		Clin-post	100	134.00	
	Remember to give the medicines	Clin-pre	102	60.37	0.000
		Clin-post	100	143.45	
	To give the medicines on time	Clin-pre	102	60.37	0.000
		Clin-post	100	143.45	

P-value from Kruskal-Wallis Test

Data in Table 3.25 specifically focus on the educational aspects of the intervention program. Using Kruskal-Wallis Test (Table 3.25), there was a significant difference between all the groups for each of the questions asked, i.e. store the medicines, read & understand instructions, remember to give the medicines, and to give the medicines on time. In the control group, there was a difference ( $P < 0.05$ ) between the control-pre and control-post on storing the medicines.

In the clinic group, the data shows a significant difference in all the subgroups with regard to store the medicines, read & understand instructions, remember to give the medicines, and to give the medicines on time. The higher values in the mean rank indicate improved patient carers' understanding and effective use of that activity in drug use. The lower values indicate no improvement. These data reflect the influence of the intervention program at the clinical intervention site and has achieved statistically significant improved outcomes in all four criteria in relation to patient carers understanding on the effective use of the administered medications.

**Table 3.26 Give herbal or local remedies compared in control pre-post and clinic pre-post groups**

Activity	Count	Subgroup				Total
		Con-pre	Con-post	Clin-pre	Clin-post	
Give herbal/local remedies	No	23 (92.0%)	74 (100.0%)	95 (94.1%)	99 (99.0%)	291 (97.0%)
	Yes	2 (8.0%)		6 (5.9%)	1 (1.0%)	9 (3.0%)
P-value	0.032					

P-value from Pearson Chi-Square Test

The difference in the overall data (Table 3.26) may be due to the small number of patients (3%) indicating the use of herbal/local remedies. 97% (291) of the cases indicated that they don't use local remedies to treat malaria in children. In a country with a perceived high level of herbal remedy use, it is notable that for their young children there was a strong preference for allopathic medicines.

**Table 3.27 Give herbal or local remedies compared in control pre-post groups**

Activity	Count	Subgroup		Total	P-value
		Con-pre	Con-post		
Give herbal/local remedies	No	23 (92.0%)	74 (100.0%)	97 (98.0%)	0.062
	Yes	2 (8.0%)		2 (2.0%)	

P-value from Fisher's Exact Test

There was no difference in control-pre and post groups.

**Table 3.28 Give herbal or local remedies compared in clinic pre-post groups**

Activity	Count	Subgroup		Total
		Clin-pre	Clin-post	
Give herbal/local remedies	No	95 (94.1%)	99 (99.0%)	194 (96.5%)
	Yes	6 (5.9%)	1 (1.0%)	7 (3.5%)
<b>P-value</b>	0.061			

P-value from Fisher's Exact Test

There was no difference in the clinic-pre and post groups. The difference in Table 3.26 has not translated into the subgroups at the two locations because of the very small numbers in the "yes" groups.

**Table 3.29 Follow up data comparing all groups**

Activity	Count	Subgroup				Total N = 303	P-value
		Con-pre N = 25	Con-post N = 75	Clin-pre N = 103	Clin-post N = 100		
Are they cured	No	3 (27.3)	9 (31.0%)	16 (42.1%)	3 (7.7%)	31 (26.5%)	0.007
	Yes	8 (72.7%)	20 (69.0%)	22 (57.9%)	36 (92.3%)	86 (73.5%)	
Finish taking the medicines	No	1 (9.1%)		2 (5.3%)		3 (2.6%)	0.189
	Yes	10 (90.9%)	29 (100.0%)	36 (94.7%)	39 (100.0%)	114 (97.4%)	
If not cured, what did you do	Review at clinic	3 (100.0%)	9 (100.0%)	16 (100.0%)	3 (100.0%)	31 (100.0%)	

P-value from Pearson Chi-Square Test

Comparing Clinic-pre with clinic-post (Table 3.29), there was an improved cure rate from 57.9% (22) to 92.3% (36) and 42.1% (16) reduced to 7.7% (3) were not cured. A total of 97.4% of cases indicated finished taking the medicines and 31 (26.5%) cases indicated that they were not cured and return to the clinic for further investigation/review.

With regard to carers that returned to the clinic to provide the outcome of their treatment as part of the research protocol: It was too dangerous for the researcher to visit patient carers in their houses to follow up the outcome of the intervention program. The outcome is therefore more likely to favour those not cured as they could return to the clinic for further treatment. All patients were treated the same but there is a possibility of a Hawthorn Effect from those receiving the intervention on returning. It is noted however that 39% (77) returned to respond at the clinic, 40% (40) at the control group.

Although these numbers are a little low, their comparability in both areas of the study and at approximately 40% provides a reasonable basis the intervention influenced overall outcomes. It is of interest however the cure rates for the control groups were uniformly high.

**Table 3.30 Follow up data comparing control pre-post and clinic pre-post**

Activity	Count	Subgroup		Total	P-value
		Con-pre	Con-post		
Are they cured	No	3 (27.3%)	9 (31.0%)	12 (30.0%)	0.570
	Yes	8 (72.7%)	20 (69.0%)	28 (70.0%)	
Finish taking medicines	No	1 (9.1%)		1 (2.5%)	0.275
	Yes	10 (90.9%)	29 (100.0%)	39 (97.5%)	
If not cured, what did you do		3 (100.0%)	9 (100.0%)	12 (100.0%)	
		Clin-pre	Clin-post		
Are they cured	No	16 (42.1%)	3 (7.7%)	19 (24.7%)	0.000
	Yes	22 (57.9%)	36 (92.3%)	58 (75.3%)	
Finish taking medicines	No	2 (5.3%)		2 (2.6%)	0.240
	Yes	36 (94.7%)	39 (100.0%)	75 (97.4%)	
If not cured, what did you do		16 (100.0%)	3 (100.0%)	19 (100.0%)	

P-value from Fisher's Exact Test

Data in Table 3.30 show no difference in the control-pre and post group for cured as an outcome. There was a significant difference in clinic pre and post group ( $P < 0.05$ ) in those reporting as cured in the clinic-post groups versus the clinic-pre group. In terms of follow up there was no significant difference in those reported as cured in the control-pre and control-post subgroups. On finish taking the medicines, there was no difference in the control-pre and post groups and clinic-pre and post groups. The marked improved outcome for cured for the study is heartening. It was only possible through the follow-up by patients returning to the clinic as most carers cannot be telephoned.

**Table 3.31 COMBO fever or malaria or enlarged spleen comparing control and clinic groups**

Count	Subgroup		Total
	Control	Clinic	
No drug combination	33 (34.7%)	41 (20.8%)	74 (25.3%)
Amodiaquine & Fansidar®	60 (63.2%)	143 (72.6%)	203 (69.5%)
Chloroquine & Fansidar®	2 (2.1%)	13 (6.6%)	15 (5.1%)
P-value	0.016		

P-value from Pearson Chi-Square

Table 3.31 shows those patients diagnosed with fever and/or malaria and/or enlarged spleen. These were diagnoses that required treatment with anti-malarial drugs. Of the 292 patients presenting with any of these symptoms 218 (74.6%) received at least one anti-malarial drug treatment according to the Standard Treatment for Common Illnesses of Children in Papua New Guinea (11). There was a significant difference between the control and clinic groups in the provision of anti-malarial drug treatment. It is also noteworthy that of the 292 patients with the above symptoms, 193 (63.7%) as shown in Table 3.32 received antibiotic treatment. The Standard Treatment for Common Illnesses of Children in Papua New Guinea (11) do not allow for treatment of fever with antibiotics indicating a high level of inappropriate prescribing. Antibiotics are limited to the treatment of mild pneumonia, otitis media, infected skin sores, swelling of lymph glands and tonsillitis. There was a significantly higher level of antibiotics prescribing in the control group.

**Table 3.32 Frequencies for fever and drug combination compared in control and clinic groups**

Activity	Count	Subgroup		Total
		Control	Clinic	
<b>FEVCOMB fever and drug combination</b>	Fever amox sept eryth chlor BP	72 (72.0%)	121 (59.6%)	193 (63.7%)
	Not have combination	28 (28.0%)	82 (40.4%)	110 (36.3%)
<b>P-value</b>	0.023			

P-value from Fisher's Exact Test

There was a significant difference ( $P < 0.05$ ) in the fever and drug combination interaction for these groups.



## **4.0 DISCUSSION**

### **4.1 Status of anti-malarial drug usage under drug policies**

The WHO recommends that activities to strengthen the pharmaceutical sector be organized under the umbrella of a national drug policy (92). In many countries, a national essential drugs programme is the mechanism for implementing such a policy, usually with emphasis on drug selection, procurement, distribution and use in the public sector (42). The objectives of any national anti-malarial drug policy are firstly to make effective, safe, low-cost essential drugs available and affordable for the entire population, and secondly to ensure that drugs are of appropriate quality and are used rationally (93, 94).

#### **4.1.1.African countries.**

In Africa and elsewhere, chloroquine has been the traditional first-line anti-malarial drug because it satisfies the above objectives well. However, resistance to this drug is rapidly developing in Africa and other developing countries and these countries will sooner or later be forced to make a decision to change their recommendation once there is evidence of high drug resistance rendering chloroquine as the first line drug ineffective (93). The level of treatment failure currently recommended for a change is 25%, based on a 14-day follow-up of treated mild malaria cases (95).

Kitua (93), considered that such a change will be extremely difficult for policy and decision-makers in many malaria-endemic areas of Africa because there are not many other anti-malarial drugs with similar qualities to chloroquine on the market. Except for sulphadoxine-pyrimethamine, most other drugs would be unaffordable by the governments and intended users. Other problems include safety, treatment regimen and dose, availability and distribution channels, acceptability, and adequate and correct information about the drug. Difficult as it may be, the decision will have to be made when the time comes because otherwise thousands of lives of affected people will be at stake, most of whom will be young children and pregnant women. This amongst other

issues has led to the development and establishment of drug policies in a number of African countries.

Chidomere (96) outlined the following pertinent observations on the nature or characteristics of the drug legislation and registration procedures in some African countries:

- **Drug Control and Pharmaceutical Practice**

The control of drugs and the professional practice of pharmacy in some countries has been separated into different legislation or acts such as in Gambia, Nigeria, and Zimbabwe. In others, they are embodied in the same legislation or act, for example, in Cameroon, Ghana, Sierra Leone, Egypt, Kenya, Malawi, Tanzania, and Uganda. A separation emphasizes the control of the products as being different from the control of the professional practice by pharmacists, and may be necessary especially in countries where the controls are carried out by different bodies or levels of government.

The possession of adequate drug control legislation by some African countries is one thing, while the implementation or enforcement is another. The constraints militating against effective implementation may be due to either:

- (a) the laws have not been backed up with the necessary regulations or
- (b) where the laws and regulations exist, the absence of the necessary enforcement machineries which may be due to economic, technical and sometimes political constraints.

African countries can be broadly classified into two groups: (a) those with adequate or strong legislation and (b) those with inadequate or weak legislation, based upon the present development of their drug legislation. The legislation is described as adequate if it meets the immediate needs of the country. This does not necessarily imply effective implementation or enforcement. Economic,

technical and manpower constraints hinder the establishment of enforcement machineries necessary for the effective and total implementation of the provisions in the legislation and regulations of many African countries. For example, the machinery for drug registration, inspection, laboratory quality control and post-marketing surveillance cannot, at present, be effectively implemented by many African countries, because of the lack of the necessary technical and manpower resources. The lack of national drug policies also adversely affects effective implementation in many African countries.

Generally, many of the smaller and poorer countries of the East, Central and Southern Africa possess inadequate and weak drug legislation. Some of these countries receive technical assistance from international agencies and from regional cooperation organizations such as the Southern African Development Coordination Conference, which was established through international aid a quality control laboratory to serve the countries of the region.

- **Drug Registration Procedures in African Countries**

Many African countries have enacted legislation and regulations for the registration of drug products. However, the drug registration procedures in many of these countries are generally not as stringent as in the developed countries of Europe and America, where scientific drug registration data is subject to extensive expert examination, backed up by laboratory and clinical control tests lasting from one to three years or more before a new drug product is registered. In some African countries, drug registration is no more than a listing exercise allowing any product to be manufactured or imported from anywhere in the world.

#### **4.1.2 Industrialized countries**

During the last decade many industrialized countries have developed policies similar to those underlying essential drugs programmes in developing countries (42). For example,

in Australia, the Pharmaceutical Benefit Scheme (which covers 85% of all drug use in the country) applies very strict criteria, including comparative cost-effectiveness, for the drug to receive reimbursement (97, 98). In the US, many managed care organizations operate on the basis of clinical guidelines, recommended formularies, and generic substitution (99, 100). In the UK, practice formularies and budget-withholding are increasingly common (101-103). The US also mandates drug utilization review programmes and pharmacist counseling to improve drug use in the publicly-funded Medicaid programme (104, 105). In Scotland, a collaborative network of the Ministry of Health and professional bodies develops national evidence-based clinical guidelines, with the primary objective of improving the quality of care, not necessarily reducing cost (106).

#### **4.1.3 Western Pacific Region**

The WHO has continued to provide technical support to countries in the Western Pacific region to strengthen drug policy and legislation, which is the foundation of quality assurance systems. Eighteen countries and areas of the region have national drug policies approved or endorsed by their government with the aim of ensuring the availability of safe, effective drugs of an acceptable quality and price to those in need. Twenty-seven countries have developed drug legislation while in other countries and areas of the region, activities will continue to develop such legislation (107).

A national drug policy was established in PNG in 1998 and initiated in the Commonwealth of the Northern Mariana Islands. A masterplan has been developed for the implementation of Vietnam's national drug policy. Preparations for a national drug policy in Samoa are underway. With technical support from WHO, drug regulation has been improved through the drafting of new drug legislation in PNG and development of drug registration systems and procedures in Cambodia, Fiji, and the Lao Peoples Democratic Republic. Besides, in the Lao Peoples Democratic Republic and PNG, computerized systems are also being developed for drug registration (108). Drug legislation in Brunei Darussalam has been revised and improved. Drug legislation in Vietnam is also being revised and strengthened (107).

#### **4.1.4 Drug policy and usage studies in PNG**

PNG like the African countries and those other countries in the Western Pacific region is no different as it faces the similar problem of malaria. With limited resources and increasing anti-malarial drug resistance, it has to develop and implement alternative strategies to contained the disease. Therefore, to eradicate or reduce the increasing prevalence of malaria in PNG, and given the seriousness of the situation, the Department of Health devised the following strategies/interventions.

- **National Health Plan 2001-2010**

The National Health Plan 2001-2010 has become the policy framework within which all health services must be planned and implemented. The goal of the Plan is to improve the health of all Papua New Guineans through the development of a health system that is responsive, effective, affordable and accessible to the majority of our people (4). This goal is in line with the National Goals and Directive Principles as enshrined in the Constitution. The priority of the Plan is to ensure that the people of PNG, in particular women and children, attain good health. This will be achieved through access to health education, elimination of immunisable diseases, safe motherhood, control of priority diseases, good nutrition, safe water supply, quality patient care and effective collaboration with all partners. Among its objectives, the government would ensure to improve diagnostic and treatment services for malaria; increase community awareness, education and partnership; improve surveillance and reporting (4).

- **National Drug Policy**

The PNG Government in 1998 established its first National Drug Policy. The policy main objective was to “Improve the health of the people of PNG by preventing and treating diseases through the availability and rational use of safe, effective, good quality and affordable drugs”. One of its supporting objectives

was to “Promote the rational prescribing and dispensing of drugs by the health personnel and the appropriate use of drugs by the patients” (40). This is designed to be achieved through the following interventions:

### **Education and Training**

All health workers in the public and private sector involved in diagnosis, prescribing and dispensing will be fully trained in the essential drug concept, stock management and rational use of drugs. Sufficient emphasis will be placed on the essential drug concept, rational drug use and patient counseling.

### **Drug Information**

Information on drugs is to be accurate, unbiased, relevant, and openly distributed to all health workers in the public and private sectors. A drug information unit will be established which will include this among its responsibilities; it will also monitor adverse drug reactions.

### **Drug and Therapeutic Committees**

Health workers will be encouraged to participate in collaborative management of drugs in their institutions to ensure rational and cost-effective use of drugs. The Pharmaceutical Advisory Committee will be recognized as having the primary responsibility in institutionalizing rational and cost-effective use of drugs and will issue guidelines for the formation and functioning of these committees. The local committees will be responsible for among other duties, to determine the quantity of drugs needed and enforce the rational use of drugs by all health workers.

### **Advertising and Promotion**

The policy will ensure that advertising and marketing of drugs will not induce irrational use. The Department of Health will ensure that promotion of drugs will

be based on scientifically established evidence and that advertisements to the public is educational and restricted to over the counter drugs (OTC).

Theoretically, these interventions are recommended but the implementation and achievement of outcomes is yet to be realized in PNG.

- **Medical Store's Catalogue (MSC)**

The MSC is the essential drug list and contained all the essential drugs mostly generics and vaccines used in PNG. It also contained hospital sundries items, laboratory reagents and equipment, X-ray equipment, and surgical instruments and hospital equipment. Items have been divided into five categories according to the qualifications of the health workers allowed to order them (109). PNG since 1950 has succeeded in developing, maintaining and financing a pharmaceutical supply system, which provides continuous access to a limited range of essential drugs, of acceptable quality and at reasonable cost, tailored to each level of health care (40). The MSC has worked well for PNG over the years and other countries in the pacific region have envied. However, as has been observed within the last few years, PNG currently is faced with a problem of drug shortages which is experienced nation-wide. The problem of drug shortages is beyond the scope of this study and needs further investigation.

- **Medicines and Cosmetic Act**

PNG over the years has a Drug Act which was inherited from the colonial era but was never used or effective. Fortunately in accordance with the NDP, the Health Department developed the Medicines and Cosmetic Act. It was finally approved by the Government in September 1999 by an Act of parliament which among its' responsibilities; will control the registration of all drugs used in PNG. Its achievement is yet to be seen (41).

- **Standard Treatment for Common Illnesses of Children in PNG**

This document has formed an important and integral part of the clinical care of patients and is a teaching and constant reference document for health workers. The standard treatment books provide treatment regimens for all common and serious diseases and conditions of children in PNG (11). The treatment regimens are linked to the medical supply system and the training of health workers. This document has functioned successfully for PNG over the years. However, recently the prevalence of malaria has gradually increased annually and drug resistance is a concern as reported in the National Health Plan 2001-2010 (4). The underlying issue needs to be investigated further.

## **4.2 Processes in health clinics in PNG**

### **4.2.1 Prescribing**

Most urban health clinics are managed by a Nursing Officer and staffed by Nurses and Community Health Workers. As shown in our studies 94.4% of prescribing at the clinics was performed by Nurses. Theoretically, this may be unacceptable, but it has become common practice in PNG where at the urban clinics, most prescribing is undertaken by Nurses. Most rural health centres are managed by HEOs and they would undertake most of the prescribing.

### **4.2.2 Issuing drugs**

Dispensing of drugs at the clinics was undertaken by nurses and community health workers. As observed during the study, tablets were placed in sealed paper envelopes with only the name of the drug written on it. Usually most drugs have no suitable labels with only the time indicated as to when to give it to the child. For example, if a drug is to be taken 3 times a day, then a time slot of 6 am, 2 pm and 10 pm was written as to



when the drug is to be given. Most times the strength of the drug was not written on the label including other relevant information.

As observed, advice given to patient carers on appropriate and effective use of medicines was always given in haste and this may have an effect on drug compliance. This is an example of poor communication between the prescriber and patient/carer as highlighted by Sachs & Tomson (49) in their study. Lack of communication between prescriber and patient was the main obstacle (48).

#### **4.2.3 Administration of drugs**

Administration of drugs at the clinics was mostly undertaken by nurses and community health workers. Initial doses were given at the clinics. Liquid doses were given directly to the child while tablets were crushed in a medicine measure mixed with water and then given to the child. Possibly due to the slight bitter taste of the drug, it was observed that quite a significant number of children vomited the medicine at the clinic. The Standard treatment for Common Illnesses of children in PNG (11) states, “if a child vomits, give another dose of drug”. Unfortunately, this did not always happen. This was an anecdotal report as the study design was not recording the frequency of this occurrence.

### **4.3 Methodology for DUR**

Dartnell (110) outlined the following aspects of DUR methodology which can be used as a tool to evaluate patient/carers understanding and effective use of drugs.

#### **4.3.1 Steps in the DUR cycle**

DUR is cyclic and dynamic process involving several steps; some of which contribute to the investigative phase, and some to the interventional phase (110). A number of steps or components have been described for the DUR cycle (111, 112). These are summarized in Table 4.1. The model for achieving drug use improvement is similar to other quality

improvement models such as described in the Breakthrough Series Guides (113). The first part of this model identifies clear aims, quantitative measures of improvement, the changes that are most likely to result in improvement (114). The second part of the model uses the Plan-Do-Study-Act (PDSA) cycle to test and implement changes in real work settings (114).

It was this process (Table 4.1) that was followed in the development and implementation of the study.

**TABLE 4.1: Steps in the DUR cycle (110)**

- |  |
|--|
| <ol style="list-style-type: none"> <li>1. Identification of target.</li> <li>2. Assembly of DUR team.</li> <li>3. Design of study.</li> <li>4. Approval of study.</li> <li>5. Development of measurement instruments and criteria.</li> <li>6. Data collection and criteria application.</li> <li>7. Evaluation and analysis of results.</li> <li>8. Reporting and feedback.</li> <li>9. Design and implementation of intervention strategies.</li> <li>10. Re-assessment and revision of problem</li> </ol> |
|--|

#### **4.3.2 Identification and determining targets for DUR**

There are many practical points which can influence the choice of targets for DUR and these are; evidence of a problem, consensus that there is a problem (among the key stakeholders), resources to tackle the problem, support to tackle the problem, and confidence that it will not be a futile exercise. If there is a positive finding on each of these points, priority for various projects could then be assigned according to local needs. Ideally maximum achievable benefit would be sought in choosing targets where deficiencies are frequent, serious and correctable (115).

DURs have largely focused on drugs with a high volume of use, high frequency of adverse drug events, or high cost. The volume of use of a drug is dependent on the setting and patient case mix. Whether or not a drug is high cost is dependent on volume of use, unit cost, drug administration costs, and the cost of other similar drugs (110).

For example, antibiotics are generally used in high volume in hospitals and have been a frequent target for DUR. Excessive and inappropriate antibiotic use selects for resistance and exposes their recipients to the needless risk of adverse reactions, their use has been a global concern (116-118). In PNG, the incidence of malaria has been increasing annually despite the establishment of standard treatment guideline for children for treatment of uncomplicated malaria.

For example, in this study the primary target was children under 10 years of age treated for uncomplicated malaria. This is an important group of patients with a common disease. Although the cost of treatment is relatively low, the outcome from inappropriately treated malaria is very significant, usually requiring hospitalization and can result in death. It is evident from this study that of 292 children presenting with symptoms of fever, malaria or enlarged spleen that only 218 (74.6%) were treated with anti-malarial drugs. This finding is of concern in relation to the PNG treatment guidelines.

#### **4.3.3 DUR endpoints**

There are a range of endpoints that DUR activities may aim to achieve or demonstrate. These need to be defined before the investigative phase is undertaken, along with the method of measurement. The effect of interventions can be gauged by assessing changes in resource utilisation (ie drug use), patient care, or attitudes or knowledge of practitioners or patients (119, 120). Other measurements may focus on the processes of drug use (eg concordance with criteria, guidelines, protocols or restrictions) or structures associated with drug use (eg. access to services) (110) (Table 4.2).

**TABLE 4.2: Endpoints targeted by DUR activities (110)**

- Improved access to drug or therapeutic information.
- Improved patient understanding about illness or drugs.
- Improved clinician knowledge about therapy.
- Improved concordance with guidelines.
- Reductions in requirement for drug administration.
- Reduction in drug expenditure.
- Reduction in the use of laboratory tests, monitoring or investigational procedures.
- Reductions in hospital length of stay.
- Reduction in hospital (re-) admission rates.
- Reduction in adverse drug reactions.
- Improved rates or cure, or reduction in illness severity or death.

Generally, DUR activities aim to achieve "stand out" improvements in practice and use. A new role for DUR may be to evaluate (categorize) practice according to the level of evidence that underpins it. In addition, by connecting practice measurements to outcomes contributes to the evidence for best practice. The building of evidence and opinion then can be used to modify the inputs (information, education and training) and factors influencing practice (110). In this study both process evaluations and patient outcomes on understanding and effective use of drugs were studied.

#### **4.3.4 DUR intervention phase**

No particular type of intervention is inherently effective; its success is dependent on the circumstances in which it is used (110). However, above all else, it would appear that multi-faceted interventions targeting different barriers to change have the greatest chance of improving drug use (121-123). More complex strategies, which are generally more effective at changing practices are generally more expensive (124). There may also

be local experience addressing the drug use problems to be targeted providing guidance on the choice of strategy. To achieve sustained change, strategies will need to be recycled (110). In this study the intervention was delivered to patient carers in the form of additional information regarding the medication how it should be taken and the how to store the medication. The nature of the intervention used in this study has not been reported previously. However, other studies involving interventions in developing countries have (5, 12, 42, 125).

#### **4.3.5 Evidence of benefits of DUR programs**

The results of DUR may be expressed in both economic terms (eg, dollars saved, bed-days saved, or measures of cost-effectiveness) and clinical terms (eg, relief from suffering, quality of life, length of illness episode, length of hospital stay, diminished prevalence of side-effects) (70). In addition to this, DUR may play a substantial role in improving education on drugs and therapeutics.

Although there are good examples of individual DUR projects having success in economic, clinical or educational terms, there is little evidence available regarding the benefit of an entire DUR program. Unambiguous demonstration of the effectiveness of DUR programs would require formal prospective controlled trials which is seldom possible (70).

Some programs have estimated very large economic gains from the implementation of DUR programs. For example, US practitioners from the New York Hospital claimed annual savings of more than US\$1.7 million from revision of antibacterial, H<sub>2</sub>-antagonist, 5-HT<sub>3</sub> growth factor and ICU protocols (126). However, presumably in this case the baseline was very poor. The Drug Audit Programme at the Royal Perth Hospital also estimated that it has achieved considerable expenditure savings over many years. In this case, practice change implemented in one year is correlated with drug expenditure reductions several years later and savings after the first year are accrued (34). The Programme is estimated to save about \$1 per head of population served by the hospital.

Extrapolation of the results provided an estimate of potential national annual savings in the range \$15-18m (70). In addition, the ASCEPT DUR Network believes that if hospital DUR programs become routine and comprehensive drug policies are put in place country-wide, there should be flow-on effects for government subsidised prescribing generally (70).

Despite the absence of strong evidence, DUR practitioners are confident that DUR programs are 'value for money' and a well-designed DUR program reduces expenditure on drugs to an extent that is greater than the costs of the program (70).

#### **4.4 Outcomes of this study in PNG health clinics**

This study was designed to test the hypothesis that by introducing an intervention program to improve patient information including proper labeling of drugs on the use and administration of anti-malarial drugs, would improve drug compliance and patient outcomes. The study design involved a pre-post intervention at a test clinic site with a second clinic acting as an overall control particularly for external occurrences that could have influenced outcomes other than the intervention. The following studies are related to this hypothesis:

Firstly, Agyepong et al (5), evaluated strategies to improve adherence to recommended chloroquine treatment regimes. Their study presented the results of an intervention carried out as part of the activities of a District Health Management Team responsible for integrated primary health care delivery in a rural district in Ghana. Their aim was to test the impact of a combination of improved information provision to patients and drug labeling on adherence to recommended anti-malarial treatment regimens focusing on oral chloroquine for the outpatient management of acute uncomplicated malaria. The study had a quasi-experimental pre-test post-test control group design with partly random allocation by clinic. The results showed that the intervention improved the flow of information to clients prescribed chloroquine, and better labeling of drugs for the home treatment of acute clinical episodes of malaria in the intervention area. There

definitely was an increase in client adherence with prescribed doses in all clinics in the intervention area.

Secondly, Nshakira et al (125), have assessed the appropriate treatment of malaria and use of antimalarial drugs for children's fevers in district medical units, drug shops and homes in eastern Uganda. The objective was to evaluate the quality of pharmaceutical care for malaria in children in eastern Uganda prescribed treatments at government health units and drug shops, and administered by caretakers at home; and to assess its appropriateness in relation to national treatment guidelines, which recommended chloroquine over 3 days. A total of 463 children under 5 years whose caretakers attended two drug shops and two government health units to seek treatment for fever were evaluated. The children were examined and the caretakers interviewed on the day of enrolment in the study (day 0), and in their homes on days 3 and 7. Data were collected on drug use prior to attending the shop or health unit, the treatment provided at these study sites, and the administration of drugs at home over the following 3 days. Before attending the study sites, 72% of children had already been given treatments, and 40% had received the recommended drug, chloroquine. Health workers prescribed chloroquine for 94% of the children, but only 34% of the recommended doses followed treatment guidelines. Two-thirds of the children were prescribed an injection of chloroquine. By day 3, according to caretaker reports, about 38% of the children had received chloroquine in compliance with the instructions given by the health workers and drug shop attendants, Only 28% of the children had received chloroquine at the optimal dose of 20-30 mg/kg recommended by the national policy. It was found, the methods used were useful for examining adherence of both caretakers and health care providers to national guidelines and the extent to which caretakers were compliant with providers' prescriptions.

In order to assess the quality of drug treatment, it is useful to evaluate the impact of human behaviour on the understanding and use of anti-malarial drugs. Human factors involve drug prescribing by prescribers and patient behaviour in understanding and use of the antimalarial drugs as stipulated in the standard treatment guidelines. However,

prescribers and patients' compliance may be complicated and difficult. In this study the carers' understanding and use of the medicines was evaluated by a questionnaire interview. The prescribers' decisions were not influenced throughout the study. Also, the patient carers understanding in the use of medicines was not changed during the pre-intervention period and for the control group. Any Hawthorn effect of the researcher should be evident in the control group. There was no evidence of such an effect.

The strength of the study design for the PNG clinic evaluation was that carers understanding in the use of the anti-malarial drugs was evaluated by an interview using a standardized questionnaire during the patient visits to the clinics and to evaluate their level of understanding of the medicines prescribed for them. The questionnaire had been validated in other settings and it had an advantage of simplicity and of short duration (93). The methodology relied on the carers' reports and to measure outcomes, the carers were asked to report back to the researcher to evaluate outcomes from the medicines prescribed for them. Although it may be disputed that carers' reports may not be completely accurate, a study by Marsh and colleagues (129) compared mothers' reports about doses of chloroquine with plasma chloroquine concentrations in children in Kenya and found a high degree of agreement.

In this study the choice of drug prescribed for the treatment of uncomplicated malaria in PNG as being deemed appropriate was based upon standard guidelines for common illnesses of children in PNG(11). The high conformity in the case of amodiaquine tablets (88.8%) and Fansidar<sup>®</sup> (76.9%) would indicate the treatment guidelines do impact on prescribing practice. In the case of malaria treatment in children the desired outcome is 100% conformity.

Compliance with the standard treatment for common illnesses of children in PNG of using amodiaquine tablets, Fansidar<sup>®</sup> tablets and chloroquine tablets as the first-line drugs was in agreement with a population-based study of drug use in 1994, where chloroquine as an approved drug to be used as the first-line drug in line with the national standard treatment guidelines accounted for 90% of the anti-malarial drugs used in Uganda. (130).



Practical difficulties in administering oral tablets to children and frequency of vomiting the administered dose were noted during the study. There is a policy especially to manage the vomiting which according to the Standard Treatment for Common Illnesses of Children in PNG (11), “if the child vomits the tablet, give another dose”.

Unfortunately as observed, this was not always undertaken. Although not recorded in this study where this occurred the policy was not always followed and therefore inadequate dosing occurred.

The prescribed dose for amodiaquine tablets to treat uncomplicated malaria was appropriate in 91.8% (247) of cases, for Fansidar<sup>®</sup> tablets was appropriate in 87.1% (203) cases and for chloroquine tablets was appropriate in 90.5% (19) cases. Overall, the dosage patterns did not vary systematically between the clinics and was satisfactorily adherent to Standard Treatment for Common Illnesses of Children in PNG (11).

Amodiaquine, Fansidar<sup>®</sup> and chloroquine tablets dosages can be calculated according to age or weight. Age by date and weight (kg) was taken in all health clinics consultations. The lack of availability of oral liquid formulations of these products for infants and children is an issue that warrants investigation.

About 47% (142) of sick children had received an average of three prior drugs, 23.4% (71) received two drugs and 19% (57) had received four drugs during their life-time since birth. This is in accordance with the expectations of a young population.

Only 3% of patients indicated the use of herbal/local remedies while 97% of the cases indicated, they don't use local remedies to treat malaria in children. In a country with a perceived high level of herbal remedy use, it was notable that for children, there was a strong preference for allopathic medicines. As observed, drug shortage has become prevalent and may have led to the high volume of use of herbal/local remedies and complementary medicines among the adults in PNG.

The use of both anti-malarial drugs and antibiotics was especially pronounced at the clinics, where about 18% of children were given amoxicillin suspension, 11% were

given Septrim<sup>®</sup> suspension, 4% were given erythromycin suspension and 10% were given chloramphenicol suspension. According to the Standard Treatment for Common Illnesses of Children in PNG (11) regarding the treatment of uncomplicated malaria and fever, the prescribing and use of these antibiotics is inappropriate without other defined symptoms.

In other cases as was observed during the study, drug shortages were a problem. This may have led to the interchangeable use of the different antibiotics at the clinics. For example, if amoxicillin suspension was out of stock, then Septrim<sup>®</sup> or chloramphenicol suspension was given instead. The inappropriate use of antibiotics is a cause for concern in that resistance towards antibiotics may develop in the community possibly because of the intense pressure to prescribe them. Chloramphenicol should be limited to use in specific infections.

Antipyretics especially paracetamol elixir were given in about 63% (190) cases, in line with standard treatment guidelines for children. Aspirin was given in about 2% (6) of cases. This may be a small number but in light of concern about the risk of Reyes syndrome, there is a need for information for prescribers on the avoidance of aspirin for young febrile children (129, 131).

The issue of compliance by patient carers may be problematic in the situation that characterizes the study area and probably much of PNG today. Is it meaningful to measure patients/carers' compliance with prescribers' instructions? Krause et al (132) underlined the importance of studying compliance with guidelines and prescriptions at all steps of the health care process in order to identify the step with the greatest need for improvement. For this study a validated questionnaire was used for compliance monitoring (93). Other methodologies have been applied (5, 127) but in this case this was the most appropriate for the methodology.

This study (Table 3.25) found no differences on the patient carers' responses in the storing of drugs, reading labels and understanding instructions, remembering to give the medicines and to give the medicines at the correct time for the control and pre-

intervention periods of the study. However, there was a significantly improved difference observed during the post-intervention period in that the patient carers understanding and use of the drugs prescribed improved in the sense that they better understood how to administer the medicines effectively which evidently resulted in a significant improvement in patient outcomes in the post-intervention clinic group. The results indicated that the education element of the intervention program achieved improved outcomes in relation to patient carers understanding on compliance and effective use of the administered drugs. That they were able to store the medicines properly, understand label and read instructions, remember to give the medicines, and to give the medicines on time. Reports of other studies conducted in an outpatient settings have generally shown improvement in compliance, patient knowledge, patient satisfaction and relatively short-term indicators of improved pharmacotherapy (14, 133-136).

According to this study, given the overall importance of the care provided at home and the clinics, it seems preferable to address both users and providers of medicine in efforts to make malaria drug treatments more appropriate and therefore effective. Hence in the long term, this could help reduce the malaria resistance strains evident in PNG where currently three out of four patients have chloroquine-resistant falciparum malaria (89).

This study included as part of the intervention improved labeled information to carers on when the medication should be administered. This is a normal expectation for the provision of medicines and should be incorporated into standard practice. The development of standard labels in a format similar to those in Appendix 5 was effective and should be adopted as a first step.

Shown in Table 3.18-21, it was found that the administration and use of the antibiotics by the patient carers was very poor. For example, Table 3.19 showed some high levels of incorrect responses recorded for amoxicillin 250mg tablets 100% (24), amoxicillin suspension 80.8% (143), Septrim<sup>®</sup> tablets 92% (23), Septrim<sup>®</sup> suspension 86% (123), erythromycin suspension 100% (26), and chloramphenicol suspension 84.4% (38).

Hence, this is a very serious issue as this may lead to drug resistance.

Another observation of interest that is incidental to the study is the fact that patient carers interpreted the interview and follow-up visits with the researcher as a sign of improved quality of care. In fact the researcher was very well received. Almost all carers were very pleased with the visits and appeared to interpret them as a sign that the health system was showing more concern and interest in their children's welfare. There is considerable evidence that patients want to know more about the drugs they take and 92% of the respondents indicated that having a pharmacist available for personal consultation was important to them (137). The possibility of integrating an interview for patient education on effective use of drugs and follow up visits as routine for clinical cases of malaria may be worth exploring. It is unlikely a pharmacist could be made available routinely although the workforce availability is improving. However having a person (nurse, pharmacist, pharmacy technician) who counsels patients on their medicines and ensures they are appropriately packaged and labelled would in accordance with this study provide improved outcomes.

#### **4.41 The Intervention program**

Numerous studies have outlined the various intervention programs or strategies that can be used to influence prescribers and patients in the appropriate use of medicines (12, 33, 42, 45, 52, 57, 112, 138-140). In this study the face-to-face (one-to-one) education program is used to influence patient carers on understanding and effective use of drugs.

The intervention program involved advising, informing, encouraging, and counselling the patient carers verbally on the appropriate and effective use of medicines. Refer section 2.6.2 for more details on the implementation of the intervention program. It was found that formal counselling brought about an increase understanding on the use of drugs and an appreciable improvement in drug compliance observed in the counselled groups (14). The counseling activities of pharmacists have a vital bearing on patient drug compliance (48, 138). Furthermore, the 2-way communication process was used

and the patient carers were encouraged to ask questions or discuss any issues regarding the child's drug treatment. This is a very important process, because it encouraged patients to get involved in their treatment. The study by Lee and Garvin (141) concluded that researchers and practitioners must move beyond traditional practices of information *transfer* (based on a monologue) toward a more useful and appropriate concept of information *exchange* (based on a dialogue) as a first step in reorienting health communication practices currently in place. The verbal message was reinforced by a suitable label typed in English and Pidgin-English and the instructions were clear, simple and unambiguous. The label was then attached on the envelopes or containers containing the drugs.

A substantial number of patient carers reported during the follow-up stage to indicate the child's health outcome whether the child gets cured or not, or was there any adverse drug reaction experienced. The health outcome indirectly indicated the outcome of the intervention scheme, whether the program has succeeded or not. Those not cured were referred back to prescribers for further medical examination. Table 3.29 showed 38.6% (117) of patients returned in all groups (control pre-post and clinic pre-post) during follow-up. 26.5% of cases indicated not cured and 73.5% indicated cured.

The success or failure of the intervention program was then evaluated and noted during the evaluation stage. On feedback, the information on the understanding and effective use of drugs was re-emphasized to the carers to reinforce their understanding for future references. This is a cyclic and dynamic process as in DUR (Figure 1.3) where failures are corrected or improved and the process continues for maintaining the rational use of drugs by patient carers.

Above all, our intervention program made an impact in improved understanding and effective use of drugs, drug compliance and patient health outcomes. As shown in Table 3.25, the data reflect the influence of the intervention program at the clinical intervention site and has achieved statistically significant improved outcomes in all four criteria in relation to patient carers understanding on the effective use of the administered

medications. When comparing clinic-pre with clinic-post in Table 3.30, there was a significant difference ( $P < 0.05$ ) in the cured group and the improved cure rate increases from 57.9% to 92.3%. When compared control pre with control post groups (Table 3.30), there was no significant difference ( $P > 0.05$ ). This indicated that our intervention program has made an impact in improving patients' health outcome in the study setting.

## 5.0 CONCLUSION

It is evident that a patient intervention program designed to improve the administration of anti-malarial drugs in PNG had no statistically significant improvement. This may be because the current level of understanding was quite high (>70%) and the study experienced a ceiling effect. However, as shown in Table 3.25 the patient carers understanding on the appropriate and effective use of drugs was lower during the pre-intervention and control group. When comparing clinic-pre with clinic-post in Table 3.30, there was a significant difference ( $P < 0.05$ ) in the cured group and the improved cure rate increases from 57.9% to 92.3%. When compared control pre with control post groups (Table 3.30), there was no significant difference ( $P > 0.05$ ) in the cured group. Therefore, the study identified an improvement in patient outcomes with respect to malaria. Hence, the simple intervention program in influencing patient carers understanding of the appropriate and effective use of medications led to a marked improvement in patient outcomes.

The study has also identified low levels of appropriate administration of antibiotic suspensions in children (Table 3.18-21) by patient carers. Therefore, a patient education program on the understanding and use of antibiotics should be encouraged and implemented to address the issue. The strategies employed by the PNG government to reduce or eradicate the prevalence of malaria in PNG have shown the guidelines are followed in a high percentage of cases. The disease has however slightly increased within the last decade. Some of this may arise from the finding that 25.3% of patients presenting with symptoms requiring malaria treatment did not receive anti-malarial therapy. Others may arise from the noncompliance and lack of understanding in the use of anti-malarial drugs shown in this study where there was a significant difference (Table 3.25) in the clinic-pre and control groups compared with clinic-post group. Further research needs to be carried out to find out why malaria has increased and why the current treatment guidelines are not having a greater overall impact.

The development and implementation of DUR programs is non-existent in PNG. Evidence has shown the technique is very useful and therefore should be established in PNG to evaluate and where necessary ensure appropriate use of drugs by prescribers and patients/carers.

During the intervention period, it was observed that patient carers were very interested to see the researcher. For the first time there was someone available at the clinic to talk to them about their children's medicines. They viewed this as a sign that the health care provider was interested in their health. This indicated that the activity should be encouraged and if others (doctors, nurses, HEOs, Community health workers) are not able to undertake this responsibility, then may be the pharmacists and pharmacy technicians should take up the challenge. As pharmacy education is now evolving more towards patient care, this may be a good opportunity for pharmacists and pharmacy technicians to take up this responsibility in PNG.

Inappropriate prescribing particularly of antibiotics was observed during the study but an intervention to correct this was beyond the scope of this study. Table 3.12 shows the prescribing of drugs for a broader range of diagnoses. For example, amoxycillin 250mg tablets showed inappropriate dosage at a 58.8% level and the higher level of inappropriate dosages for chloramphenicol suspension and paracetamol elixir are noteworthy. The findings indicate that further work is required to improve prescribing practices. May be prescriber education is appropriate in these circumstances in relation to the possible need for on-going treatment at home.

This study used the face to face (one-to-one) education program to influence patient carers understanding and effective use of drugs. The intervention program involved advising, informing, encouraging, and counselling the patient carers verbally on the appropriate and effective use of medicines. The verbal message was reinforced by a suitable label typed in English and Pidgin-English and the instructions were clear, simple and unambiguous. The label was then attached on the envelopes or containers containing the drugs. On feedback, the information on the understanding and effective



use of drugs was re-emphasized to the carers to reinforce their understanding for future references. Above all, results showed (Table 3.25, Table 3.29, and Table 3.30) that the intervention program made an impact in improved patient carers understanding and effective use of drugs and children's health outcomes.

## 6.0 LIMITATIONS OF THE STUDY

- Only the short-term impact of the training program was evaluated. There is literature, including work done in Ghana, documenting the fact that a one off training program does not usually cause a sustained change in provider behaviour (142). Reinforcing mechanisms are needed. The follow on to this study is to design a checklist for supervisors to use in primary care clinics that incorporates evaluation of the adequacy of the information provided to patient carers on understanding and effective use of drugs. This study has shown that it is possible to increase information provision to patient carers by providers in health care clinics, at least in the short run. Increase in information provision to clients is associated with improved compliance to therapy. There definitely was an increase in patient carers' understanding of medications in the intervention period and improved patient outcomes. The long-term effect of this study may be well worth studying on any future research in the study setting.
- This study was conducted in an urban health clinic. There are also rural health centres in PNG. There may be few differences in between the urban and rural settings. There may be other assumptions but the most obvious one would be, health personnel and patient carers are more exposed to the latest information on drugs in the urban than the rural sector.
- Development of systems that enable improvement in the provision of medicines including labeling, packaging, and a greater use of liquid preparations for children are essential. The study was performed in an environment of poor labelling and packaging and a lack of liquid formulations for children. Some of those fundamental issues may have contributed to the value of the intervention which may have a modified outcome if some of these fundamental issues were addressed.

## 7.0 RECOMMENDATIONS

Based on the information gathered in the study the following recommendations are made:

- Pharmacists and Pharmacy Technicians should undertake more patient counseling and education on appropriate and effective use of drugs and if possible do a follow-up. The education program to increase the patient carers understanding and effective use of drugs would improve patient outcomes and drug compliance as shown in the study.
- Pharmacy Technicians should be employed at the clinics where a significant amount of drugs are being dispensed.
- Proper labeling and packaging of drugs should be encouraged and incorporated into standard practice.
- Various quality assurance mechanisms such as DUR, DTC, in the drug process should be encouraged and established in PNG.
- Prescriber education on rational use of drugs is to be encouraged and implemented.
- Further study is needed to expand and assess the long-term effect of this study to include both rural and urban health clinics.
- Liquid suspensions of the anti-malarial drugs should be considered to address the practical difficulties in administering oral tablets to children.

- As observed during the study, drug shortage was more common in the clinics. Although this wasn't part of this study, further assessment should be encourage to evaluate the continuous drug shortages experienced in PNG.
- Education programs on the use of antibiotics should be undertaken. As observed in this study, antibiotics were being used interchangeably (e.g. 1<sup>st</sup> line and 2<sup>nd</sup> line drugs, were being used regularly).
- The Standard Treatment for Common Illnesses of Children in PNG should be evaluated to assess its effectiveness. Despite its establishment since 1960s, malaria in PNG has increased within the last decade.
- Despite the small percentage of children using herbal/local remedies, from observation, it is widely used among the adults in PNG. Therefore, further study is required to evaluate its use.

## 8.0 REFERENCES

1. Wahlgren M, Perlmann P, editors. *Malaria : Molecular and Clinical Aspects*. Australia: Harwood academic publishers; 1999.
2. Whitty CJM, Rowland M, Sanderson F, Mutabingwa TK. *Malaria*. *British Medical Journal* 2002;325:1221-24.
3. WHO. Roll Back Malaria: 2001-2010 United Nations Decade to Roll Back Malaria. Economic costs of malaria. WHO <http://www.rbm.who.int> 2002:1-11.
4. Papua New Guinea National Health Plan 2001-2010: Health Vision 2010. Port Moresby: Department of Health; 2000.
5. Agyepong IA, Ansah E, Ggyapong M, Adjei S, Barnish G, Evans D. Strategies to improve adherence to recommended chloroquine treatment regimens: a quasi-experiment in the context of integrated primary health care delivery in Ghana. *Social Science & Medicine* 2002;55:2215-26.
6. Black RH, Canfield CJ, Clyde DF, Peters W, Wernsdorf WH. In: Bruce-Chwatt, editor. *Chemotherapy of malaria*. 2nd ed. Geneva: World Health Organization; 1981.
7. Editorial. Chloroquine resistant malaria in Africa. *Lancet* 1985;i:1487-88.
8. Menon A, Snow RW, Otoo L, Greenwood BM. Decline in sensitivity of *Plasmodium falciparum* to chloroquine in the Gambia. *Lancet* 1987;i:1029-39.
9. Neequaye JE, Ofori-Adjei S, Odame I, Coker L, Mensa-Annan B. *Falciparum Malaria not sensitive to chloroquine emerges in Africa in 1987*. *Ghana Medical Journal* 22 1988.
10. Salako LA, Aderounmu FF. In Vivo Chloroquine and Mefloquine resistant *Plasmodium falciparum* in Nigeria. *Lancet* 1987:572-3.
11. *Standard treatment for common illnesses of Children in Papua New Guinea : A manual for Nurses, Health Extension Officers and Doctors*. 7 ed. Port Moresby: PNG Printing; 2000.
12. Le-Grand A, Hogerzeil HV, Haaijer-Ruskamp FM. Intervention research in rational use of drugs: a review. *Health Policy and Planning* 1999;14:89-102.

13. Homedes N, Ugalde A. Patients' compliance with medical treatments in the third world: what do we know? *Health Policy and Planning* 1993;8:291-314.
14. Edwards M, Pathy MSJ. Drug counseling in the elderly and predicting compliance. *Practitioner* 1984;228:291-300.
15. Desowitz RS. *The Malaria Capers*. New York: W. W. Norton; 1991.
16. Harrison G. *Mosquitoes, Malaria and Man : A history of the hostilities since 1880*. New York: E. P. Dutton; 1978.
17. Desowitz RS. Milestones and Millstones in the History of Malaria. In: Wahlgren M, Perlmann P, editors. *Malaria : Molecular and Clinical Aspects*. Australia: Harwood Academic Publishers; 1999. 1-16.
18. W.H.O. WHO report 1996 : *Fighting disease : Fostering development*. Geneva: World Health Organisation; 1996.
19. Lederberg J, Shope RE, Oaks SC, editors. *Emerging Infections : Microbial Threats to Health in the United States*. Washington DC: National Academic Press; 1992.
20. Karen PD. The epidemiology of malaria. In: Wahlgren M, Perlmann P, editors. *Malaria : Molecular and Clinical Aspects*. Australia: Harwood Academic Publishers; 1999. 57-86.
21. Fujioka H, Aikawa M. The malaria parasite and its life-cycle. In: Wahlgren M, Perlmann P, editors. *Malaria : Molecular and Clinical Aspects*. Australia: Harwood Academic Publishers; 1999. 19-55.
22. Krostoski WA, Collins WE, Bray RS, Garnham PCC, Cogswell FB, Gwadz R. Demonstration of hypnozoites in sporozoite - transmitted plasmodium vivax infection. *American Journal of Tropical Medicine and Hygiene* 1982;31:1291-93.
23. Krostoski WA, Garnham PCC, Bray RS, Garnham PCC, Killick-Kendrick R, Draper CC. Observation on early and late post-sporozoite tissue stages in primate malaria : Discovery of a new latent form of plasmodium cynomolgi (the hynozoite) and failure to detect hepatic forms within the first 24 hours after incubation. *American Journal of Tropical Medicine and Hygiene* 1982;31:24-35.

24. UNICEF. Malaria prevention and treatment : The global malaria burden. *Prescriber* 2000;1-16.
25. W.H.O. Guidelines for developing national drug policies. Geneva. WHO 1988.
26. W.H.O. Management of uncomplicated malaria and the use of antimalarial drugs for the protection of travellers. Report of an informal consultation, Geneva. WHO 1996.
27. W.H.O. Antimalarial drug policies. Report of an informal consultation, Geneva. WHO 1994.
28. McIntosh HM, Olliaro P. Artemisinin derivatives for treating uncomplicated malaria (Cochrane Review). *The Cochrane Library* 2000.
29. Wernsdorf WH. Epidemiology of drug resistance in malaria. *Acta Tropica* 1994;56:143-56.
30. W.H.O. Practical chemotherapy of malaria. Geneva. Technical Report Series (1990)805. WHO 1990.
31. Management Sciences for Health. *Managing Drug Supply*. West Hartford, USA: Kumarian Press; 1997.
32. Plumridge RJ. Intervention strategies aimed at modifying prescribing behaviour. *Australian Journal of Hospital Pharmacy* 1984;14:93-100.
33. Fellows L, Hughes JD. A survey of drug audit practices and promotion of quality prescribing in Australian hospitals with a focus on psychotropic drugs. *The Australian Journal of Hospital Pharmacy* 2000;30:196-201.
34. Gent M, Millar JA, Garas B. Royal Perth Hospital Drug Audit Programme. Annual Report to the Divisional Directors Forum, 1996-97. Perth: Royal Perth Hospital; 1997.
35. Herk RV, Klazinga NS, Schepers RMJ, Casparie AF. Medical audit: threat or opportunity for the medical profession. A comparative study of medical audit among medical specialists in general hospitals in the Netherlands and England, 1970-1999. *Social Science & Medicine* 2001;53:1721-32.
36. W.H.O. The selection of essential drugs. Geneva. World Health Organisation 1977;17(Technical report series No. 615).
37. W.H.O. General policy issues. *WHO Drug information* 1999;13:1-3.

38. W.H.O. The rational use of drugs. Report of the conference of experts, Nairobi, November 1985. Geneva. World Health Organisation. 1987.
39. Ratanawijitrasin S, Soumerai SB, Weerasuriya K. Do national medicinal drug policies and essential drug programs improve drug use?: a review of experiences in developing countries. *Social Science & Medicine* 2001;53:831-844.
40. The National Drug Policy for Papua New Guinea. 1 ed; 1998.
41. Papua New Guinea Medicines and Cosmetic Act, 1999. Port Moresby; 1999.
42. Laing RO, Hogerzeil HV, Ross-Degnan D. Ten recommendations to improve use of medicines in developing countries. *Health Policy and Planning* 2001;16:13-20.
43. Hassan NAGM, Abdulla AA, Bakathir HA, Al-Amoodi AA, Aklan AM, de-Vries TPGM. The impact of problem-based pharmacotherapy training on the competence of rational prescribing of Yemen undergraduate students. *European Journal of Clinical Pharmacology* 2000;55:873-6.
44. Mistry SK, Sorrentino AP. Patient nonadherence: the \$100 billion problem. *American Druggist* 1999;216:56-62.
45. Cramer JA, Spilker B, editors. Patient compliance in medical practice and clinical trials. New York: Raven Press; 1991.
46. Cramer JA. Compliance with contraceptives and other treatments. *Obstetric and Gynecology* 1996;88:S4-S12.
47. Compliance: Is there a role for the pharmacist? *Chemist & Druggist* 1995:I-IV.
48. Pereira LMP, Granger-Pierre J. Rational drug use in Tobago. *World Health forum* 1995;16:29-32.
49. Sachs L, Tomson G. Medicines and culture-A double perspective on drug utilization in a developing country. *Social Science & Medicine* 1992;34:307-315.
50. Rossi S. Compliance or concordance. *Australian Prescriber* 2000;23:105.
51. Segal R, Wang F. Influencing Physician Prescribing. *Pharmacy Practice Management Quarterly* 1999;19:30-50.
52. Hepler C, Grainger-Rousseau T. Pharmaceutical care versus Traditional drug treatment: Is there a difference? *Drugs* 1995;49:1-10.



53. Manasse H. Medication Use in an Imperfect world: Drug misadventuring as an issue of public policy, part 1. *American Journal of Hospital Pharmacy* 1989;46:929-944.
54. Spitzer W. The use of beta-agonists and the risk of death and near death from asthma. *New England Journal of Medicine* 1992;326:501-506.
55. Lipton HL, Bird JA. Drug utilization review in Ambulatory settings: State of the science and directions for outcomes research. *Medical Care* 1993;31:1069-82.
56. Fellows L. A survey of drug audit practices and promotion of quality prescribing in Australian hospitals with a focus on psychotropic drugs [Master of Pharmacy (Clinical Pharmacy)]. Perth: Curtin University of Technology; 1999.
57. Eckert GM, Ioannides-Demos LL, McLean AJ. Measuring and modifying hospital drug use. *Medical Journal of Australia* 1991;154:587-92.
58. Sayer GS, Britt H. Sex differences in prescribed medications: Another case of discrimination in general practice. *Social Science & Medicine* 1997;45:1581-87.
59. Carruthers AA, Krska J. Thrombolytics-a drug utilization review in a district general hospital. *Clinical Pharmacy and Therapeutics* 1997;22:335-38.
60. Yeneneh H, Gyorkos TW, Joseph L, Pickering J, Tedla S. Antimalarial drug utilization by women in Ethiopia : a knowledge-attitudes-practice study. *WHO Bulletin* 1993;71:763-72.
61. Schulke DG. A congressional perspective on inappropriate drug therapy and drug utilization review. *Clinical Pharmacology and Therapeutics* 1991;50:606-11.
62. Schulke DG. Inappropriate drug therapy and drug use review: An Annotated Bibliography for State Policymakers. United States Senate Special Committee on Aging 1991:1-6.
63. Drug utilization review: Mechanisms to improve its effectiveness and broaden its scope. *Journal of the American Pharmaceutical Association* 2000;40:538-545.
64. Tognoni G, Laporte JR. From clinical trials to drug utilization studies. In: Dukes MNG, editor. *Drug utilization studies : methods and uses: WHO regional publications*; 1994. 23-41.

65. Edgren B. DUR and DUE in management competition. In: Wertheimer A, Navarro R, editors. *Managed care pharmacy : principles and practice*. New York: Pharmaceutical Products Press; 1999. 119-29.
66. Kubacka RT. A primer on drug utilization review: Using information obtained from drug utilization reviews, pharmacists can make drug therapy more appropriate, effective, and cost-efficient. *Journal of the American Pharmaceutical Association* 1996;NS36:257-79.
67. Australian Drug Usage Evaluation Starter Kit: SHPA Committee of Specialty Practice in Drug Usage Evaluation; 1998.
68. Committee of Specialty Practice Report. SHPA standards of practice for drug usage evaluation. *Australian Journal of Hospital Pharmacy* 1996;26:240-6.
69. McGuire TM, Petrie GM. A hitchhiker's guide to establishing a drug utilisation evaluation program. *Australian Journal of Hospital Pharmacy* 1995;25:315-23.
70. ASCEPT DUE Network. Development of drug usage evaluation in hospital practice in Australia and New Zealand. Melbourne: Australasian Society of Clinical and Experimental Pharmacology and Toxicology; 1998.
71. Soumerai SB, Avorn J. Principles of educational outreach ('academic detailing') to improve clinical decision making. *JAMA* 1990;263:549-556.
72. Avorn JL, Soumerai SB. Improving drug therapy decisions through educational outreach: A randomised controlled trial for academically based "detailing". *New England Journal of Medicine* 1983;308:1457.
73. May FW, Rowett DS, Gilbert AL, McNeece I, Hurley E. Outcomes of an educational-outreach service for community medical practitioners: non-steroidal anti-inflammatory drugs. *Medical Journal of Australia* 1999;170:471-4.
74. Schwartz J, Cohen S. Changing physician behaviour. In: Mayfield J, Grady M, editors. *In primary care research. An agenda for the 90s*. Washington DC: US Dept of Health and Human Services Public Health Service; 1990. 45-54.
75. Evidence-Based Care Resource Group. Evidence-based care: 1. Setting priorities. How important is this problem? *Canadian Medical Association Journal* 1994;150:1249-54.

76. Hillman A. The impact of physician financial incentives on high-risk populations in managed care. *Journal of Acquired Immune Deficiency Syndromes Human Retrovirology* 1995;8:S23-30.
77. Sackett DL, Richardson WS, Rosenberg W, Haynes RB. Evidence-based Medicine: How to practice and teach EBM. Melbourne: Churchill Livingstone; 1997.
78. Greenhalgh T. How to read a paper: The basics of evidence based medicine. London: BMJ Publishing Group; 1997.
79. The Cochrane Collaboration. <http://www.cochrane.org/cochrane/cc-broch.htm> 2002.
80. Egger M, Smith GD, Phillips AN. Meta-analysis: Principles and procedures. *British Medical Journal* <http://bmj.com/archive/7121/7121ed.htm> 1997;315.
81. Stangl DK, Berry DA. Meta-analysis: Past and Present Challenges. In: Stangl DK, Berry DA, editors. *Meta-Analysis in Medicine and Health Policy*. New York: Marcel Dekker Inc; 2000.
82. W.H.O. The world drug situation. Geneva. World Health Organisation 1988;53.
83. W.H.O. Summary of progress in the WHO Action Programme on Essential Drugs and Vaccines. Geneva. World Health Organisation 1987;Doc WHO:DAP 87.
84. Hogerzeil HV, Walker GJA, Sallami AO, Fernando G. Impact of an essential drugs programme on availability and rational use of drugs. *Lancet* 1989;141-2.
85. W.H.O. The Use of Essential Drugs: Ninth report of the WHO Expert Committee (including the revised Model List of Essential Drugs). Geneva: World Health Organization; 2000.
86. Grimshaw J, Russell IT. Effect of clinical guidelines on medical practice: a systematic review of rigorous evaluations. *Lancet* 1993;342:1317-22.
87. Quick JD, editor. *Managing drug supply*. West Hartford, CT: Kumarian Press; 1997:122-123.
88. Foster S. Pricing, Distribution and use of antimalarial drugs. *WHO Bulletin* 1991;69:349-63.

89. Phillips RE, Solomon T. Cerebral Malaria in Children. *Lancet* 1990;336:1355-60.
90. Riewpaiboon A. Design and Evaluation of an Incentive scheme for Promoting Rational Antibiotic Prescribing in a Provincial Hospital in Thailand. Perth: Curtin University of Technology; 1998.
91. Svarstad BL, Chewning BA, Sleath BL, Claesson C. The brief medication questionnaire: A tool for screening patient adherence and barriers to adherence. *Patient Education and Counseling* 1999;37:113-24.
92. WHO. Guidelines for National Drug Policies. Geneva. World Health Organisation 1988.
93. Kitua AY. Antimalarial drug policy : making systematic change. *Lancet* 2000;354:32.
94. Brudon P, Rainhorn JD, Reich MR. Indicators for Monitoring National Drug Policies: A practical manual: WHO; 1999.
95. WHO. WHO antimalarial-drug policy guidelines. Geneva. World Health Organisation 1998.
96. Chidomere EC. Drug Regulation in African Countries. 2nd ed: Interpharm Press, Inc.; 1991.
97. Drummond MF. Basing prescription drug payment on economic analysis: the case of Australia. *Health Affairs* 1992;11:191-6.
98. Freund DA, Evans D, Henry D, Dittus R. Implications of the Australian guidelines for the United States. *Health Affairs* 1992;11:202-6.
99. Lipton HL, Gross DJ, Stebbins MR, Syed LH. Managing the pharmacy benefit in medicare HMOs: what do we really know? *health Affairs* 2000;19:42-58.
100. Gold MR, Hurley R, Lake T, Ensor T, Berenson R. A national survey of the arrangements managed-care plans make with physicians. *New England Journal of Medicine* 1995;333:1678-83.
101. Baines DL, Whynes DK, Tolley KH. General practitioner fund-holding and prescribing expenditure control: Evidence from a rural English health authority. *PharmacoEconomics* 1997;11:350-8.

102. Petchey R. General practitioner fundholding: weighing the evidence. *Lancet* 1995;346:1139-42.
103. Bloor K, Freemantle N. Lessons from international experience in controlling pharmaceutical expenditure. II: Influencing doctors. *British Medical Journal* 1996;312:1525-7.
104. Brushwood DB. The pharmacist's duty under OBRA-90 standards. *Journal of Legal Medicine* 1997;18:475-509.
105. Soumerai SB, Lipton HL. Computer-based drug-utilization review-risk, benefit, or boondoggle? *New England Journal of Medicine* 1995;332:1641-5.
106. Petrie JC. Clinical guidelines in Scotland: a SIGN of the times. *Essential Drugs Monitor* 1996;22:13-14.
107. WHO. Proposed Programme Budget 2000-2001. In: World Health Organisation; 2002.
108. WHO. The Work of WHO in the Western Pacific Region: Report of the Regional Director - 1 July 1998 - 30 June 1999. WHO 1999.
109. Papua New Guinea Department of Health Medical Store Catalogue. 8th ed. Port Moresby: Government Printer; 1996.
110. Dartnell JGA. Understanding, influencing and evaluating drug use. Melbourne: Therapeutic Guidelines Limited; 2001.
111. Society of Hospital Pharmacists of Australia. Committee of Soecialty Practice in Drug Usage Evaluation. SHPA standards of practice for drug usage evaluation in Australian hospitals. *Australian Journal of Hospital Pharmacy* 1996;26:240-6.
112. Erwin WG. The definition of drug utilisation review: statement of issues. *Clinical Pharmacology and Therapeutics* 1991;50:596-9.
113. Carver P, editor. Breakthrough series guides. Boston: Institute for Healthcare Improvement; 1998.
114. Leape LL, Kabcenell A, Berwick DM, Roessner J. Reducing adverse drug events. 1st ed. Boston: Institute for Healthcare Improvement; 1998.
115. Williamson JW. Formulating priorities for quality assurance activity: description of a method and its application. *JAMA* 1978;1978:631-7.

116. Wise R, Hart T, Cars O, Streulens M, Helmuth R, Huovinen P, et al. Antimicrobial resistance is a major threat to public health (editorial). *British Medical Journal* 1998;317:609-10.
117. Standing Medical Advisory Committee, Sub-Group on Antimicrobial Resistance. The path of least resistance. London: Department of Health, UK; 1998.
118. Centre for Disease Control and Prevention. The C.A.U.S.E.: Careful Antibiotic Use to Prevent Resistance: <http://www.cdc.gov/ncidod/dbmd/cause/april97.html>; 1997.
119. Ioannides-Demos L, Eckert GM, Mclean AJ. Pharmacoeconomic consequences of measurement and modification of hospital drug use. *PharmacoEconomics* 1992;2:15-33.
120. Blackburn JL. Impact of drug usage review on drug utilization. *PharmacoEconomics* 1993;3:14-21.
121. NHS Centre for Reviews and Dissemination. Getting evidence into practice. *Effective Health Care* 1999;5:1-16.
122. Greco PJ, Eisenberg JM. Changing physicians' practices. *New England Journal of Medicine* 1993;329:1271-3.
123. Davis DA, Thomson MA, Oxman AD, Haynes RB. Changing physician performance. A systematic review of the effect of continuing medical education strategies. *JAMA* 1995;274:700-5.
124. Oxman AD, Thomson MA, Davis DA, Haynes RB. No magic bullets: a systematic review of 102 trials of interventions to improve professional practice. *CMAJ* 1995;153:1423-31.
125. Nshakira N, Kristensen M, Ssali F, Whyte SR. Appropriate treatment of malaria? Use of antimalarial drugs for children's fevers in district medical units, drug shops and homes in eastern Uganda. *Tropical Medicine and International Health* 2002;7:309-316.
126. McConnell K. Evidence that appropriate-use programmes cut costs. *Inpharma* 1996:7-8.

127. Marsh VM, Mutemi WM, Muturi J. Changing home treatment of childhood fevers by training shop keepers in rural Kenya. *Tropical Medicine and International Health* 1999;4:383-389.
128. Adome RO, Whyte SR. Popular pills, community drug use in Ugandi. *Het Spinhuis*, Amsterdam. 1996.
129. Nyamongo IK. Home case management of malaria: an ethnographic study of lay people's classification of drugs in Suneka Division, Kenya. *Tropical Medicine and International Health* 1999;4:736-743.
130. Kruase G, Borchert M, Benzler J, Diesfeld HJ. From diagnosis to drug taking: staff compliance with guidelines and patient compliance to prescriptions in Burkina Faso. *International Journal of Quality of Health Care* 2000;12:25-30.
131. Clifford MR, Batty KT, Davis TME, Davis W, Stein G, Stewart G, et al. A randomised controlled trial of a pharmaceutical care programme in high-risk diabetic patients in an outpatient clinic. *The International Journal of Pharmacy Practice* 2002;10:85-9.
132. Hatoum H, Akhras K. A 32 year literature review on the value and acceptance of ambulatory care provided by pharmacists. *Annals of Pharmacotherapy* 1993;27:1106-19.
133. Knowlton C, Thomas O, Williamson A, Gammaitoni A, Kirchain W, Buttarro M. Establishing community pharmacy-based anticoagulation education and monitoring programs. *Journal of American Pharmaceutical Association* 1999;39:368-74.
134. Foss M, Schoch P, Sintek C. Efficient operation of a high-volume anticoagulation clinic. *American Journal of Health-System Pharmacy* 1999;56:443-9.
135. Communicating with patients about their medications. *The New England Journal of Medicine* 1991;325:1650-2.
136. Hazra A, Tripathi SK, Alam MS. Prescribing and dispensing activities at the health facilities of a non-government organisation. *The National Medical Journal of India* 2000;13:177-82.

137. Gonzalez-Martin G, Joo I, Sanchez I. Evaluation of the impact of a pharmaceutical care program in children with asthma. *Patient Education and Counseling* 2002;49:13-18.
138. Homedes N, Ugalde A. Improving the use of pharmaceuticals through patient and community level interventions. *Social Science & Medicine* 2000;52:99-134.
139. Lee RG, Garvin T. Moving from information transfer to information exchange in exchange in health and health care. *Social Science & Medicine* 2002;56:449-64.
140. Ofori-Adjei D, Arhinful DK. Effect of training on the clinical management of malaria by medical assistants in Ghana. *Social Science & Medicine* 1996;42:1169-76.



**Appendix 1****The Impact of an Intervention Program for the Treatment of Malaria in Children in PNG.****Patients' information Sheet**

This information sheet is for you to keep.

School of Pharmacy, Curtin University of Technology is undertaking the research that is designed to assess the impact of an intervention program for the treatment of malaria in children in PNG.

There has been limited research carried out on malaria drug treatments in children in PNG. In the tropics malaria is a major killer, especially of young children, and it remains a major public health problem. In PNG one of the leading causes of morbidity and mortality is malaria and constitutes most outpatients / admissions and deaths. Despite the establishment of malaria standard treatment guidelines, malaria still remains a major health problem nation-wide. This study will investigate the impact of an intervention program on the prescribing of malaria drug treatment for uncomplicated malaria in children in the age group of 0 to 10 years. It is hoped that this research and its evaluation would provide a model that may lead to appropriate and effective use of the anti-malarial drugs in PNG.

This study will take place over a two-month period starting in February 2002 and has been approved by the Curtin University Human Research Ethics Committee. Confidentiality and security of your child's personal information will be guaranteed according to the guidelines of NHMRC/AVCC Statement.

Data will be collected via an interview and a short questionnaire. The history involved and outcomes of participating into the malaria drug treatment will be collected. It will take approximately up to 10 minutes of your time. All interview and questionnaire information will remain confidential and each form given a unique code. The names of the patients will be blackened out on application of the code. The personalized information will only be known to the researcher. The results of the study will only be presented as compiled data and will not identify individual patients.

Participation in the project will not interfere or influence the treatments your child received which will be the standard care normally provided by the Clinic. There is no requirement for your child to participate and non-participation will not influence his/her treatment. We would also seek permission to access your child's past treatment records.

However, as the project is designed to improve the malaria treatment outcomes, we would request your child's participation.

### PARTICIPANT CONSENT FORM

I/We have been well informed of the aims and significance of this research, and I/We know all the information I/We provide on behalf of our child will be confidential. Our child will participate in the research voluntarily without any coercion or inducement. We guarantee all the information provided is correct and true. We understand we have the right to withdraw consent to further involvement in the research at any time without any negative consequences to our child or his/her treatment.

Therefore, I/We give our support to the above criteria for our son/daughter to participate in the assessment of an intervention program in the prescribing of malaria drug treatment in children. This includes access to past treatment records.

Child's Name:.....

Parent/Carer Name:.....

Address:.....

.....

Phone No:.....

Suburb:.....

Parent/Carer Signature.....

Date:.....

.....

Researcher: Isaac Bokuluwih Joshua

Address: P.O.Box 844,  
Boroko.  
NCD.

Phone: 3243846

E-mail: [joshuaib@hotmail.com](mailto:joshuaib@hotmail.com)

Signature: ..... Date .....

**Appendix 2****PARTICIPANT'S DETAILS**

Child's Name:

Code:

Child's dob:

Child's weight:

Name of Clinic:

Gender:

Current diagnosis:

Date:

Previous diagnosis &amp; frequency:

Prescriber: (a) HEO: (b) Nurse: (c) Doctor: (d) Other:

Drug (1) (a) Name: (b) dose: (c) freq: (d) duration:

Drug (2) (a) Name: (b) dose: (c) freq: (d) duration:

Drug (3) (a) Name: (b) dose: (c) freq: (d) duration:

Interviewed (Carers)

### Appendix 3

#### SURVEY ON THE USE OF ANTIMALARIAL DRUG TREATMENT IN CHILDREN IN PNG

**Q1. Please list below all the medicines your child needs to take after consultation with the Medical Doctor. For each medicine you list, please answer each of the questions in the box below.**

IN THE PAST CONSULTATIONS WITH THE DOCTOR					
a. Medicine name & strength	b. How many days did you give it?	c. How many times per day did you give it?	d. How much medicine did you give each time?	e. For what reason were you giving it?	f. What is the medicine for?

**Q2. Do any of the medicines bother your child in any way? YES .....NO .....**

**(a). IF YES, please name the medicine and check below how much it bothers your child.**

Medicine name	How much did it bother your child?				In what way did it bother your child
	A lot	Some	A little	Never	

**Q3. Below is a list of problems that people sometimes have with their medicines. Please check how hard it is for you to do each of the following for your child:**

	Very hard	Somewhat hard	Not hard at all	COMMENT (Which medicine)
a. Store the medicine				
b. Read the label or understand instructions				
c. Remember to give the medicines				
d. To give the medicines at the correct time				

**Q4. Do you give herbal or local remedies to assist in treating malaria in your child?**

YES..... NO.....

If yes, please state what you use:.....

**Appendix 4****FOLLOW UP DETAILS**

Child's Name:

Code:

Child's age/DOB:

Child's weight:

Name of Clinic:

Date:

Gender:

Stage: PI / I / C

**CURED**

When?

How long?

Did you finish the medicine?

**NOT CURED (What did you do?)****(a) Review at clinic.**

Did you finish the medicine?

**(b) Hospital.**

When?

How long stayed in the hospital?

**(c) Home. (re-contact to see when cured)**

When cured?

How long?

## **Appendix 5**

### **AMODIAQUINE 100mg TABLETS**

(Infant Camoquine)

Chew ..... tablet daily after food for 3 days and drink plenty of water or fluids.

Keep the medicine in a safe cool place. Bring the child back to the clinic if there is no improvement after treatment, or if the child is getting worse. If the child vomits the tablet, give another dose.

Kaikai ..... kiau long wanwan dei behind long kaikai na dringim planti wara.

Putim marasin long gutpela ples. Bringim pikinini kam bek long haus sik suppose em i no orait or em bagarap. Suppose pikinini i traoutim marasin, givim em narapela kiau.

### **CHLOROQUINE 150mg TABLETS**

Take ..... tablet daily after food for 3 days and drink plenty of water or fluids.

Keep the medicine in a safe cool place. Bring the child back to the clinic if there is no improvement after treatment, or if the child is getting worse.

Kisim ..... kiau long wanwan dei behind long kaikai na dringim planti wara.

Putim marasin long gutpela ples. Bringim pikinini kam bek long haus sik suppose em i no orait or em bagarap.

### **QUININE 300mg TABLETS**

Take ..... tablet 3 times daily after food for 3 days.

Keep the medicine in a safe cool place. Bring the child back to the clinic if there is no improvement after treatment, or if the child is getting worse.

Kisim ..... kiau tripela taim long wanwan dei bihind long kaikai na drigim planti wara.

Putim marasin long gutpela ples. Bringim pikinini kam bek long haus sik suppose em i no orait or em bagarap.