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FACTORS CONTRIBUTING TO ANTIMALARIAL DRUG RESISTANCE IN RACHUONYO DISTRICT, KENYA.

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Abstract.

Drug resistance has been identified as one of the factors that lead to severe malaria and high mortality as observed in malaria endemic areas. The main objective of this study was to establish the factors that contribute to essential drug resistance in the treatment of malaria in Rachuonyo District, Kenya. Qualitative and quantitative data were collected among 380 respondents including health care providers, people seeking malaria treatment and Community Own Resource (CORPs), from 47 registered health facilities. The study revealed that all health facilities were using general-purpose trucks to transport antimalarial drugs and did not have functional wall thermometers and that eighty seven per cent (87%) of health care providers did not check storage conditions of drugs upon reception. Ninety seven per cent (97%) of the health care providers used physical examination for clinical diagnoses that is subject to errors that may lead to irrational drug use. Thirteen per cent (13%) of health care providers had no idea that antimalarials suspensions can undergo fermentation when not properly stored. Forty percent (40%) of the selected health facilities had current recommended antimalarial treatment drugs in stock. The use of such vehicles can affect the potency of the drugs, as they do not have the necessary equipments to control adverse temperatures and this may contribute to loss of potency. Some health facilities did not have the current recommended antimalarial drugs in stock implying that patients attending treatment in these facilities could have been treated with less effective drugs or they could have been sent to purchase them yet they are expensive and not easily available. In conclusion the results of this study indicate that management, administrative factors and policy issues could be a leading cause of antimalarial drug resistance and a case control study to explore the exact extent of drug resistance in this population in relation to the identified factors is urgently recommended.

Key words. Management, Administration, Policy issues and Antimalarials drug resistance.

Introduction

Drug resistance is the ability of a parasite to multiply in the presence of concentrations of a drug that normally destroys parasites of the same species or prevents their multiplication. Malaria is a parasitic disease caused by protozoan parasites of the genus Plasmodium. Only four Plasmodia species develop in humans; which *are Plasmodium falciparum, plasmodium vivax, plasmodium ovale,* and *plasmodium malariae*. Among the four named species, *Plasmodium falciparum* causes a life-threatening form of malaria. *Plasmodium Ovale* and *plasmodium vivax* have liver forms *(hypnozoites)* that may lead to relapses after the initial blood infection has been cured. *Plasmodium malariae* is a very rare species in Kenya and not easy to come by while *Plasmodium falciparum* and *plasmodium vivax* are the main species of public health importance. *Plasmodium Falciparum* is the commonest species throughout tropics and sub- tropics. Transmitted from person to person through the bite of infected female anopheles mosquito, parasite must live part of its life in the mosquito before it can infect another person. In the blood, the parasite develops asexually and this is responsible for clinical attacks while the sexual development is responsible for disease transmission. Parasites can be transmitted by transfusion of blood from an infected to another person and occasionally vertically from mother to fetus. The incubation period in humans varies according to Plasmodium species. *Plasmodium falciparum* takes shortest duration of (9-13 days) while *Plasmodium malariae* takes longest duration (years) [1].

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Minimum time between the initial infection of mosquito and development of clinical symptoms in human is 3-4 weeks [1]. *Plasmodium falciparum* is the commonest species in Kenya and is associated with significant morbidity and mortality. Resistance of *Plasmodium falciparum* infections to chloroquine developed and spread rapidly over the past 10-20 years. In 1998, Kenya changed her treatment policy from chloroquine to sulfadoxine- pyrimethermine (SP), but resistance to SP has increased rapidly as shown in a study on factors that contribute to drug resistance [2].

The main aim of this study was to look into major issues that could lead to antimalarial drug resistance. These issues include drug management, administrative factors and policy issues. Drug management has been found to be one of the major issues that contribute to antimalarial drug resistance in Kenya [2]. Quality of manufactured or imported drugs could be good but they lose their potency due to management issues like transportation, storage and records keeping. Drugs could lose their potency at the point of consumption as a result of administration issues such as patient assessment, drug prescription and drug dispensing. Drug policy was another area looked at as drugs could be of good and recommended quality but lose their quality if issues such as; supervision, surveillance and change of drug regimen were not attended to [2].

Methodology

This was a descriptive study conducted in all the 47 health facilities of Rachuonyo District. Quantitative and qualitative research methods of data collection were used. Study populations comprised of the health facility heads, healthcare providers in charge of drug administration, drug store, people seeking malaria treatment upon exit and community own resource persons. Health facility heads, healthcare providers administering drugs, those heading drug stores and the

people attending malaria treatment during period of data collection were included in the study. Health care providers who had been interviewed were excluded in the Key informant interviews (KII) and people who attended malaria treatment on same day and were interviewed using exit interview questionnaires were also excluded in the Focus Group Discussions (FGD) which comprised of at least six groups of fifteen participants.

The interviewees were randomly selected then divided proportionately per health facility malaria prevalence. Health facility head, one health provider administering drugs and one provider taking care of drug store per facility were purposively selected and interviewed. The sample size of 380 was estimated using Fischer's formula and this was divided proportionately among the forty seven health facilities [3].

Structured and semi-structured questionnaires were used to collect quantitative data while interview guides and key informant interviews were used to collect qualitative data. All data collected were counter checked to ensure reliability and validity. Quantitative data were cleaned and analyzed using SPSS version 10.0 computer programme. Qualitative data were analyzed manually according to thematic areas. Findings were presented on tables, graphs, cross-tabulations, narrative summary and frequencies.

Prior consent to undertake the study was obtained from District medical services officer of Health Rachuonyo, Health facility's heads and respondents individually after assuring them of anonymity/ confidentiality in the information they would provide.

Results

During survey between months of November and December 2008, 380 people seeking medical attention due to malarial infection and 47 healthcare providers were interviewed. Eight focus group discussions and twenty key informant interviews were conducted. This chapter presents the results of this study.

Management factors

Sixty six percent of level 2-4 health facilities (66.0%) received their drug supplies from the Central medical stores in the ministry of health as shown in *Table1*. Eighty nine point four percent, (42/47) of the health facilities used general-purpose enclosed lorries as precautionary measure to transport their drugs as *Table 2* shows. The results from the qualitative findings confirmed this and one key informant had this to say "y*edhe itingo mana gi lorry mag tin'go kuoyo, gitin'go gi bende ewi bodi mag matatu moko bende e tok pick- up ma kata koth goyo kendo chien'g chamogie mani ok ber nikech katarech mose thoo irito maber maloyo yedhe mathiedho dhano e Kenya ka".* Meaning, "drugs were carried using lorries that are supposed to carry sand, on top of luggage carriers of passenger vehicles and on pick-ups where they sometimes exposed to adverse weather conditions. This practice is not good because even dead fish are given better care than drugs that are used for treating people here in Kenya".

Figure 1 shows that 79%, (37/47) of the health facilities were not equipped with cold storage facilities and all of them did have functional wall thermometers for monitoring temperatures in the stores.

Figure 2 shows that 94%, (44/47) of health facilities health care providers ensured that drugs delivered corresponded to ones listed on the delivery notes and only 13%, (6/47) of the health care providers did actually check on the labels and the expiry dates for each drug. In the key informant interviews many of the said that their facilities not ordering drugs from KEMSA because the agency supplied drugs using the push system meaning that they supplied drugs without consideration of the requirements and needs of the health facilities leading to wastage.

Administrative factors

Thirty percent, (14/47) of the health care providers evaluated patient's knowledge on a particular drug before administering it as shown in *figure 3*. Ninety one point five percent, (43/47) of the health care providers, relied on patients' history for making a diagnosis while 93.6%, (44/47) used the signs and symptoms to identify a particular diagnosis as 23%, (11/47) of them were using probable cause to identify a particular diagnosis.

The findings from the focused group discussions (FGDs) showed that many patients were only questioned on the clinical symptoms and were never subjected to laboratory diagnosis even where the facilities were available. Seventy four percent, (35/47) of the health care workers had met some patients who demanded certain drugs to be prescribed to them because of their experiences with such drugs and the majority of the workers did not prescribe to them as per their patients demand.

Twenty three point seven percent, (90/380) of the patients were asked about their general background during assessment and 17.1%, (64/380) were asked for specific malaria information, as 92.1% were asked about the general information. Only 10.8%, (41/380) of patients were educated about the efficacy of the drugs, 16.8%, (64/380) about the side effects and 43.9%, (140/380) about the importance of antimalarial drugs dispensed to them.

The focused group discussions revealed that, many of the patients were not educated on how to take the drugs apart from being informed of the frequency of taking the drugs and were sometimes told to take the drugs as written on the envelopes which sometimes confused them.

Policy issues

From key informant interviews the main factors that came out that could contribute to drug resistance in selected facilities were; unavailability of drugs recommended by Division of Malaria Control, cost of the drugs if patients are given prescriptions to buy from local drug stores and sometimes these drugs are not even available in these local stores. All health facilities were stocking generic drugs whose efficacy are not assured and were sourcing them as shown in *figure 4* with the

majority of the facilities receiving them from government stores. According to the key informants most of the drugs supplied to the health facilities are generics and they therefore have no confidence that they can treat malaria.

Discussion

This study has revealed that a large percentage of health facilities from levels two to four received their drug supply from central medical stores headquarter. These drugs were not transported in the correct vehicles and were exposed to adverse management conditions that could reduce their potency and efficacy. All the health facilities visited, general-purpose vehicles were used to transport drugs to them without taking precautions to monitor and control environmental conditions during transportation. It is therefore possible that these drugs could reach their destinations when their condition has deteriorated due to incorrect means transport, which may reduce their quality and hence contribute to drug resistance. According to the clinical guidelines drugs should usually be maintained always at recommended temperatures and failure to do so may lead to deterioration in quality [4].

The lack of cold storage facilities meant that most of the drugs were stored at room temperature which varies from time to time depending on the season of the year. This means that it is possible that sometimes the store temperature may exceed the temperatures recommended for most of antimalarial drug storage (25-30^{o}C) and this may affect the quality of these drugs. The lack of wall thermometers in all of the health facilities indicated that all facilities were unable to monitor the temperatures of the stores and therefore precautions could not be taken to guard against extreme temperature variations which would interfere with quality of the drugs. This goes against the recommendations of the world health Organization that recommends that each drug store should have a wall thermometer for monitoring temperatures in drug stores [5].

According to Medicines Sans Frontieres in their Essentials Drugs Practical Guidelines it is recommended that drugs be arranged and labeled in common language for ease of identification and record keeping [6]. Many health facilities in this study did not arrange and label antimalarial drugs in any common language within store and this may lead to misplacement and difficulty in identifying antimalarial drugs within store and this may lead to the dispensing of incorrect drugs and then leads to irrational drug use that may contribute antimalarial drug resistance. This finding goes against the recommendations of Medical San Frontiers on labeling of drugs in the pharmacy even by local language so as to ease identification and avoid mislabeling that may lead to dispensing of wrong medications [6].

According to the World Health Organization Record keeping is another important area that should be considered when looking at issues to do with drug resistance. It is recommended that records be available to demonstrate that all the relevant procedures were followed during manufacture and all records are safely stored for an adequate period and held under conditions that guarantee their security and confidentiality unless otherwise required by the national legislation [7]. In this study it came out that many facilities ordered antimalarial drugs in boxes of which different boxes contain different amount of doses with no clear records making it difficult to evaluate consumption.

Many of the facilities did not order according to consumption data and ran the risk of under-stocking and operating without the recommended drug and then using alternative or substandard drugs and this can easily lead to drug resistance sub-therapeutic effects of these alternatives. According to the WHO records of antimalarial drugs ordered in and out of the stores are important, as that would give clear information to plan for estimated consumption within a given period of time and if this is not done facilities risk having stock-outs and its consequences [7].

From the results of this study it has been shown that in many facilities important details were not checked on receipt of the drugs from the supplier. In addition many of the facilities failed to check the storage and these could impact negatively on the quality of these drugs. According to World Health Organization the stability of antimalarial drugs depends on environmental factors such as temperature, air, light, and humidity and studies have shown that these drugs deteriorate if stored under sub-optimal conditions making them loose their potency and this promotes drug resistance if used in this state for the treatment of malaria [8].

This study has shown that in some facilities proper patient evaluation was not done before the administration of antimalarial drugs to the patients. Failure to do proper patient evaluation commonly leads to misdiagnosis which may lead to improper treatment and thus contribute to antimalarial drug resistance [9].

The practice of depending on clinical diagnosis without laboratory testing that was rampant in most of the health facilities could lead to misdiagnosis and this could in turn lead to inaccurate diagnosis and the use of wrong drugs for treatment. According to studies by USAID such practices may lead prescribing or dispensing an antimalarial drug when the person does not have malaria. Such behaviors can lead to parasite adaptation to medicines and therefore resistance to drugs [10].

According to this study many health care providers did not spare time to educate their patients on the use of the dispensed antimalarial drugs to establish whether a patient understood why the drug was prescribed for them. According to Baer and Bradley, patients need to be educated on several issues when receiving drugs including the reason why they have to use the drug, time to take the drug, efficacy and the route of administration, adverse effects of the drug and when to contact a physician while using that drug. The way the patient self-administers the drug provides insight into why a particular drug regimen succeeds or fails [10].

Lack of diagnostic facilities and laboratories in most poor nations mean that health workers are forced to engage in the kind of symptom-based guesswork that often lead to misdiagnosis and increases the likelihood of prescribing the wrong medication. Misdiagnosis may also lead to prescriptions of drugs in inadequate quantities for example according to a study undertaken in Vietnam in 1997. In this study rapid diagnostic kits were

lacking in many health facilities and were also not undertaking microscopy and this could lead to misdiagnosis and treatment [11].Detailed history taking was not practiced in many health facilities and this could lead to inaccurate diagnosis, prescription, and then dispensing. According to the World Health Organization asking only a few questions to get information would lead to getting insufficient information that may lead to incorrect treatment which is more dangerous than no treatment at all as it may also contribute to drug resistance [10].

Drug side effects are another area that may lead to drug resistance. According to the findings of this study drug education was not provided to many of the patients. Many patients were are not educated about the side effects of drugs and when they encounter side effects they may stop using them and take alternative drugs and this may encourage development of drug resistance. This has been proven by a study by Musa in 2008 whose findings indicate that patients who have not been educated in the effects of drugs may stop using them when they encounter side effects [11].

Resistance to antimalarial drug could also result if the drug administration interval is not followed. Lack of patient education often results in poor adherence. In this study many of the health workers did not educate their patients on the importance of sticking to the correct intervals. They were advised in a way they could not comprehend or sometimes the interval was written on the drug envelops which may be misinterpreted and this may lead to drug resistance. Musa in his study on drug resistance in 2008 reported similar findings [12].

This study revealed that the frequency of doing supervision was so high in most health facilities. The frequent supervision is difficult to sustain and therefore most people have recommended periodic inspection. According to some studies, frequent inspection normally provides and keeps on repeating same information while periodic inspection may give varied information as it is done after some period of time when changes may have occurred [13]. Frequent inspection may provide a lot of information that is difficult to analyze and interpret hence can not be accurately used to procure antimalarial drugs leading to stock-outs. When facilities are stocked out the chances of prescribing poor quality drugs is high and this may lead to drug resistance [14].

The widespread use of generic drugs in most health facilities as shown in this study may also contribute to drug resistance especially when bought from unknown suppliers. According to Nugent most generics are usually of low quality due to reduced content of active ingredients. Their use may lead to inability to completely clear parasites from the circulation encouraging the emergence of resistant strains and this may contribute to antimalarial drug resistance [15].

It was established that a few health facilities did not have current antimalarial drugs in stock at the time of this study. Patients who attended these health facilities seeking for treatment would not therefore access these drugs and may end up receiving other antimalarial drugs which may not be very effective against malaria. These findings are similar to those by Shunmay in 2004 who, got similar results [16]. According to WHO such patients when given prescriptions may not have enough money to buy the drugs and may end up with cheap substitutes and sometimes when they do have the money may not get the right drug in the local chemists and these may contribute to drug resistance [17].

Recommendations

1. From the results of this study it is recommended that trucks that supply drugs be fitted with proper functional air conditioned equipments so that drugs are transported and maintained under correct temperatures as recommended by manufactures, so that the quality of the drug is not interfered with.
2. Government ministries in partnership with other training institutions should organize for the training of frontline health care providers on how to handle and rationally use antimalarial drugs.
3. Rapid diagnostic kits for malarial testing should be procured, supplied and used in health facilities lacking microspic capacities so that confirmation of malaria may be done before instituing treatment.
4. The government and its partners should conduct studies to test the efficacy of antimalarial drugs at different levels of procurement and to the point of consumption to determine their quality so that appropriate interventions may be instituted.
5. Health facilities should be supplied with adequate stocks to reduce the frequency of stock-outs and this will encourage the health personnel to stick to the treatment guidelines.

Acknowledgement

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Table 1. Facility level compared with sources of drugs supply.

	Sources of drugs			
Facility level.	**District Medical Store**	**Regional or Provincial Medical Store**	**Headquarters Medical Store**	**Buy from wholesalers/Distributors**
2	2.1%(1)	4.3%(2)	36.9%(22)	27.7%(13)
3			22.6%(7)	
4			6.5%(2)	
	2.1%	**4.3%**	**66.0%**	**27.7%**

Table 2. Precautions taken during transportation of drugs.

Precautions taken during transport	**Number (Proportion)**
General purpose vehicle	89.4%, (42)
Canvas and/or enclosed lorry	8.5%, (4)
No special mode of transport	2.1%, (1)
Total	**100%, (47)**

Table 3. Patients knowledge determination on a drug regimen.

Knowledge area	**Yes**	**No**
Taking time	78.7%, (37/47)	21.3%, (10/47)
Dosage	76.6%, (36/47)	23.4%, (11/47)
Efficacy	23.4%, (11/47)	76.6%, (36/47)

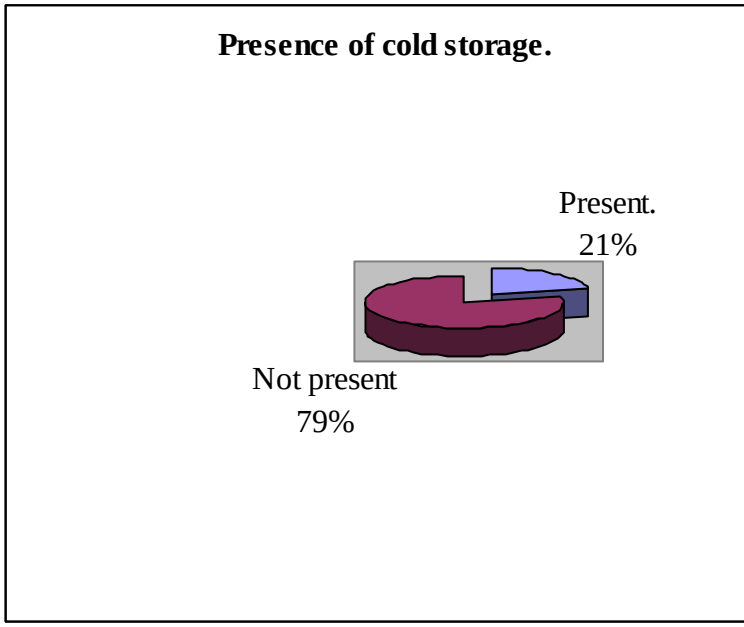


***Figure 1*. Presence of cold storage facilities**

Figure 2. **Comparison of drugs received against packing list.**

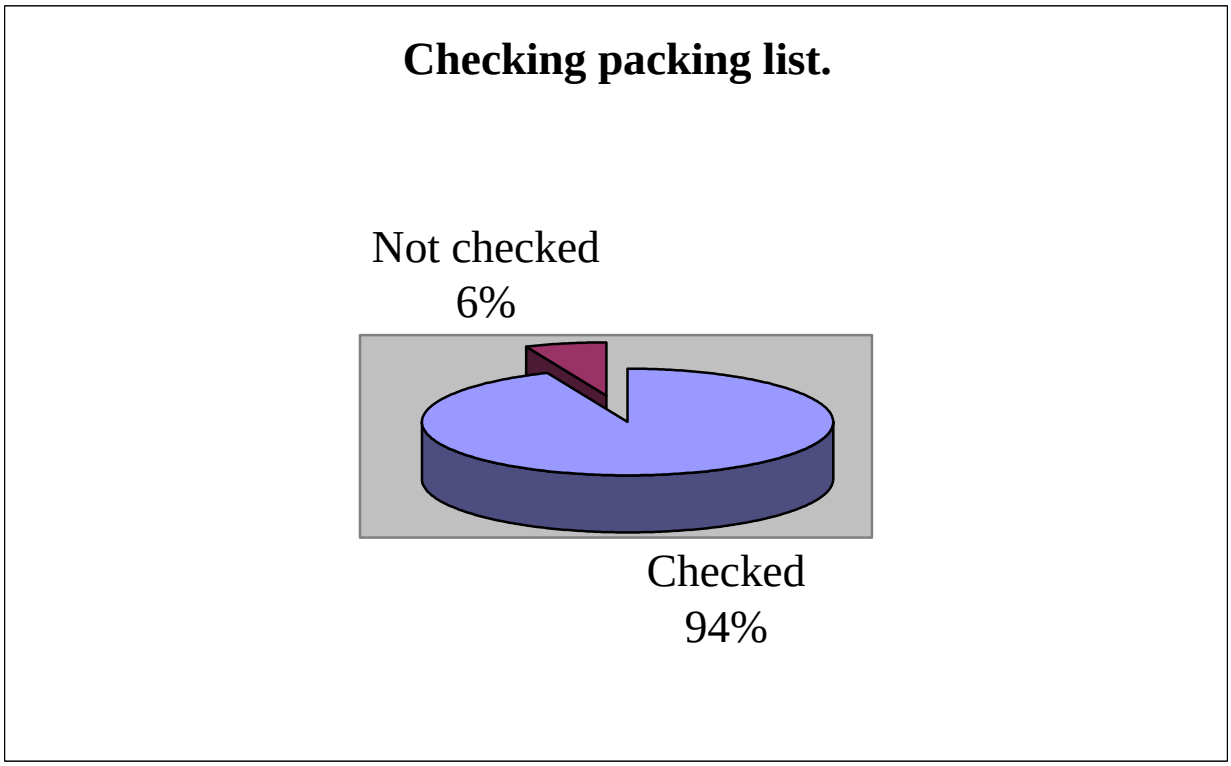


Figure 3. **Evaluation of patients health need before administering drugs.**

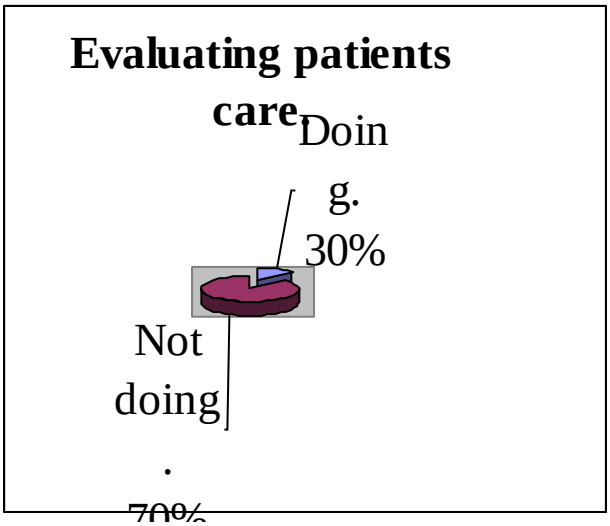
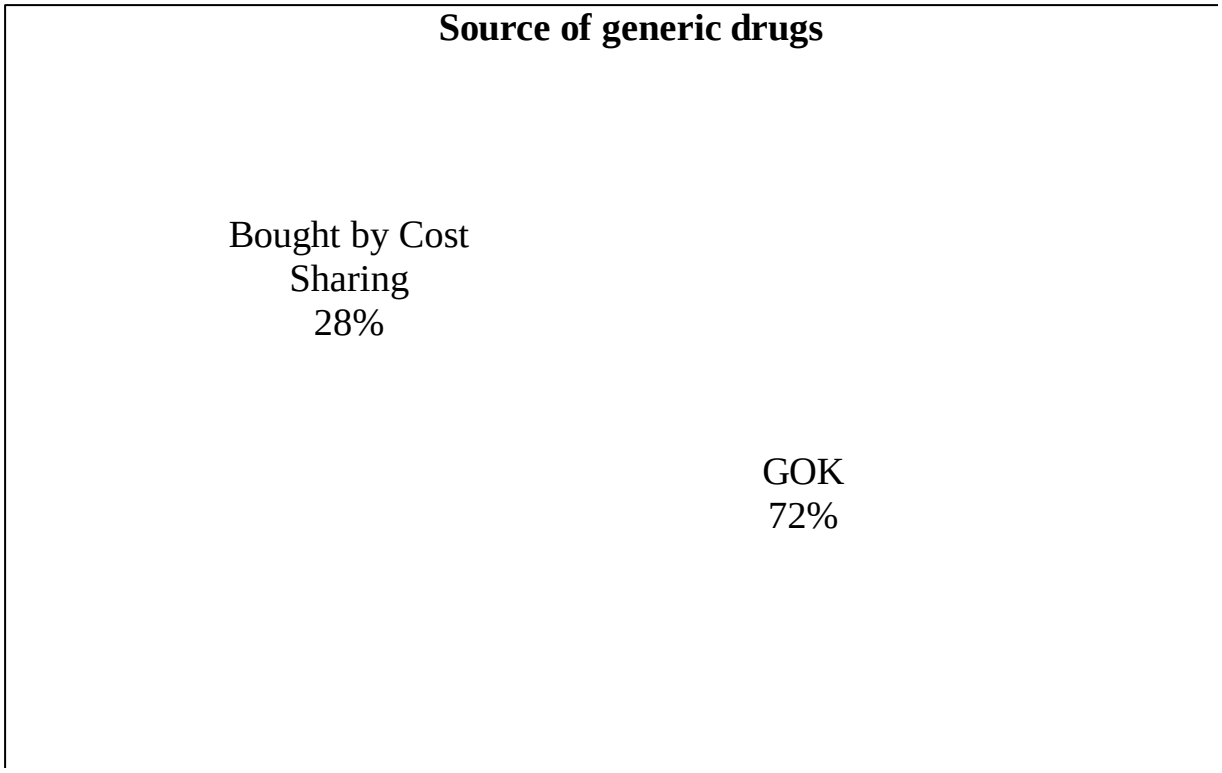


Figure 4. **Sources of generic drugs.**



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