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Abstract

If access to medicines is obtained by a population largely through market exchange, then consumer rights become a key aspect of the right to health. Medicines markets are dangerously subject to perverse incentives and asymmetric information, and in low income countries are largely unregulated. Research in rural Tanzania explored the information received by those buying medicines at the time of purchase, and the extent to which buyers knew the information they *should* receive. It also examined the extent to which dispensers were aware of good dispensing practice, and compared non-governmental non-profit dispensing with private sector practice in this regard. This paper argues for a shift in the framework of analysis of medicines markets from sources of trust to methods of strengthening implementation of rights; for a clearer incorporation of consumer rights into efforts progressively to implement the right to health; and for a strengthening of NGOs' activity in this regard.

Keywords: consumer rights, medicines, Tanzania, dispensing, regulation

Introduction

> 'All human rights are interrelated, so that the right to health is related to the exercise of other relevant human rights, such as the right to education, information, privacy, association, equality and participation. All human rights are underpinned by freedom from discrimination, which puts a particular emphasis on vulnerable groups…….' (WHO/Monitor, 2003 p 25).

Access to essential medicines forms a central element of the human right to health (Hogerzeil, 2003; Hunt, 2006), and as such, it is increasingly established as enforceable through the courts, especially where there are constitutional provisions on the right to health (Hogerzeil et al, 2006). Yet, the 'fundamental human right to access to essential medicine remains a challenge and requires further action at national and international levels' (Laing et al, 2003:1725), 'Accessibility' of essential medicines is generally understood in several dimensions: geographical availability within and across countries; affordability by the population as a whole; accessible without discrimination; and associating access with reliable information that allows both health practitioners and patients to make appropriate, safe decisions (Hunt, 2006: 13).

In many low income countries including Tanzania, most people who obtain medicines, for themselves and others, do so through market exchange within poorly regulated markets (Mujinja et al, 2003; Kumanarayake et al, 2000). This paper argues that in this context, consumer rights are a key aspect of the right to health. This aspect is however inadequately appreciated in the current research literature, which focuses rather on issues of trust and risk within market transactions, and on information, guidelines and regulation directed to practitioners. Yet effective use of medicine information by *both* providers and clients has been shown to reduce mortality and morbidity of some fatal conditions in some developing countries (WHO, 2003). Consumer medicine information is therefore a basic right within the process of receiving care.

This paper reports results from a survey of medicines dispensing and purchase in rural Tanzania, exploring the information that purchasers at private drug shops and private and non-governmental not-for-profit health facilities received at the time of purchase. The research also investigated, for the first time**,** the extent to which buyers were able to state the information that they *should* receive, and their awareness of consumer rights. The paper contrasts these findings with the claims of dispensers concerning their own

practices; and the extent to which dispensers were aware of good dispensing practice, and experienced regulatory oversight.

Finally, the paper compares non-governmental non-profit dispensing with private sector practice in this regard. There is a presumption in much of the research literature on NGOs in the health sector that, being value-driven and less influenced by the profit motive, they may be more efficient and more ethical: more able to resist perverse market incentives (Leonard 2000). This paper tests this hypothesis for the case of medicines' dispensing.

In summary, the paper argues for a shift in the framework of analysis of markets for essential medicines away from a limited focus on sources of trust, to include more investigation of methods of strengthening implementation of consumer rights, and for a clearer incorporation of consumer rights into efforts to progressively implement the right to health.

Information, trust and consumer rights: purchasing essential medicines in Tanzania

In most rural areas of Tanzania patients (or customers buying medicines) obtain their medicines from the dispensing outlets of both private and public hospitals, health centres and dispensaries, or from private medicine shops, not from pharmacies employing qualified pharmacists (Mujinja et al, 2003; Kumarayake et al, 2003; Chambuso et al, 2004). The private medical shops known as *Duka la Dawa Baridi*[1] constitute the largest network of licensed retail outlets for basic essential drugs in Tanzania. It is estimated that there are more than 4,000 private medical shops across all districts in the country; over 50 percent more than all public health facilities and 11 percent more than all public, voluntary, and religious facilities combined (Kimatta et al, 2007).

The medicine outlets in Tanzania are owned and operated by the government, by non-governmental organizations (NGOs) including faith based organizations (FBOs) and secular NGOs, and by private individuals and companies. Consumers have to pay for their medicine in all privately owned medicine outlets. In most rural public health centres and dispensaries medicines are still given free, if available, but availability is limited. However, with the exception of patients eligible for and actually obtaining exemptions,

consumers are required to pay for medicines in public hospitals**.** Most medicines consumers pay out-of-pocket since less than three percent of the population is covered by the National Health Insurance Fund (NHIF); and the Community Health Funds' (CHF) coverage is very low even in districts where they exist (Kamuzora and Gilson, 2007)..

In this context, the extent to which these market transactions deliver safe and effective use of essential medicines is a key variable influencing public health. 'Essential medicines' here refers to a country's essential medicines list, generally based on WHO advice and adapted to country needs (Laing et al, 2003). The dynamics of pharmaceutical markets tend to result in inappropriate prescribing, sales and consumption, and this has created a need to most developing countries, including Tanzania, to develop essential medicine lists and to require prescribers to prescribe essential medicines (Maiga et la, 2003). In the high income countries, research has addressed patients' rights as consumers of health services; and professional standards and ethical codes of how to handle patients have been developed. Doctor-patient interaction codes and prescribing guidelines have been developed and repeatedly assessed (Veldhuijzen et al, 2007; Horgerzeil et al, 2006; Stevenson et al, 2000; Bensing, 1991). Pharmaceutical and dispensing guidelines have also been developed centring on effective control of non-prescription dispensing (WHO, 2003; Viberg et al, 2005). These professional guidelines emphasize Good Dispensing Practice (GDP), and therefore, among other things, the provision of information and counselling for the effective use of the medicine.

In developing countries the same guidelines, sometimes modified by the WHO (WHO, 2003) and sometimes without adaptation, are also adopted. The Good Dispensing Practice (GDP) guidelines aim to smooth communication between the patient and the dispenser, to enable the patient to reap the benefits of appropriate medication and to minimise adverse reactions, if any (MoH, 1997; Viberg et al, 2005). In Tanzania such dispensing guidelines are used to train dispensers, implying that dispensers, whether trained or not trained, are supposed to abide by them. Some evaluations undertaken to assess the quality of dispensing ask whether these guidelines are followed (Chambuso et al, 2007). However this is addressing only one potential gap in the determinants of effective use of medicines, between policy and practice at the practitioner level (Datye et

al, 2006). It does not necessarily promote effective information use at the consumer level.

There is therefore a second gap, between policy and outcome of dispensing practice, or between dispensers and the consumers of the dispensing information. The assumptions underlying the dispensing guidelines are that the dispenser has clearly defined roles in providing medicine information to consumers; that s/he would communicate all the required information equally to all consumers; and that consumers would follow the advice. However, since these assumptions are all violated in the poorly regulated medicines markets of Tanzania (Mujinja et al, 2003; Kumanarayake et al, 2003; Kumanarayake et al, 2000; and this paper) the role of the patient/consumer necessarily becomes a more active one, rather than the rather passive role the guidelines assume.

As in many Sub-Saharan countries, the private drug shops are the first points of contact for many people when confronted with an illness episode (Shankar et al, 2002; Geissler et al, 2000). Since they lack the necessary consumer information, many people purchase medicines without a prescription. They may also take to the shops prescriptions issued elsewhere, or buy medicines from a prescriber. The risks involved in these transactions are high. Medicines purchased may be appropriate or inappropriate, safe or substandard, and the highest risks attach to buying a prescription medicine without a prescription.

The risks are plainly greater if the consumer is not well informed about the medicine and its effects. Yet many people in Tanzanian rural areas inevitably face such risky decisions with little information regarding medicine consumption, in contexts where there are scant and, in most cases, unaffordable private health facilities and where the nearest government health facilities have no medicine for a good part of the year and are at a very substantial distance (Save the Children, 2005**).** The Tanzanian Ministry of Health, through the Tanzania Food and Drug Authority (TFDA) has recognized the scarcity of the essential medicines in the public health facilities, and the continuing demand therefore for the services of the private medical shops. Yet these shops are known to operate in a manner far below the standards of the TFDA, including the use of staff who lack basic dispensing and business skills.

In this poor and scanty medicine information context, consumers/buyers of medicine are forced to make these risky decisions on the basis of trust of a medicine seller as they do with any other health provider, without complete information about the medicine bought or provided. In the Tanzanian health care market, we know that most people can express knowledge on the charges, prices of medicine, and the behaviour of the health providers (Tibandebage and Mackintosh, 2005). They may not be able equally to express knowledge related to medicines that would be prescribed and dispensed, since this is information has to be given by the dispensers and sellers, and hence difficult to the lay consumer to obtain.

In these socio-economic circumstances, information on essential medicine provided to both providers and consumers has been shown to have more effect in addressing the central public health concern of reducing the burden of disease than if given only to providers (WHO, 2003). However, the research literature has yet to explore in detail the problems of consumer information and consumer rights in largely unregulated rural medicines markets.

Objectives of the paper

This paper addresses three major gaps in the literature. First, it seeks to broaden research and debate from its existing focus on patient's health rights in terms of the rights of the patient to receive information related to care from the prescriber (Hogerzeil, 2006), by addressing the needs and rights of patients to receive information *independent* of the transactional relationship. At present this perspective is largely missing from research on essential medicine in developing countries, where few have argued for the importance of essential information as a route to reduction of mortality and morbidity in low income communities (WHO, 2003). As a matter of public health policy, which focuses on the common interest rather than the individual, finding ways to improve medicine information to *both* providers and consumers is important for ensuring effective use of essential medicine (WHO. 2003).

Second, the paper seeks to broaden empirical research on health market transactions by shifting from a strong focus on trust to include work on consumer rights. This shift in focus throws up new research questions. Whereas the consumer of medicine has to

have money, travel a distance, sometimes explain the health problem to the provider/dispenser when she does not have a prescription, to buy medicine, she may not consider herself as having the right to have information about the medicine she is buying. The research literature tends to accept this perspective, considering medicines information as professional, that is, as an aspect of trust of professionals within the market. Hence improved information is to be provided to the professional. In this conventional view the consumer requires information only about how to take the medicine for the illness, and the rest is a 'property' of the dispenser.

In largely unregulated markets this is a dangerous approach. It is an unwise consumer who trusts a provider in markets that provide strong incentives to cheat. Such trust 'may allow exploitation' (Gilson 2003: 1458). Heath care users are aware of this, and because of lack of information on the side of consumers, *calculative* distrust has been widespread in Tanzania. Users report some providers prescribing expired and inappropriate medicines for the sake of profit (Tibandebage and Mackintosh, 2005).

The research literature has recently focused on the sources of trust in providers, implying that consumer rights arise from such sources of trust (Mechanic, 1996; Mechanic and Meyer, 2000; Gilson, 2003). Consumer rights are rarely argued for as a basis for resource allocation (Newdick and Derrett, 2006), and still rarely considered as part and parcel of health care as a human right that is to be protected (Bhat, 1996). This is striking in an international policy context where rights are progressively becoming dominant individual patient values (Newdick and Derrett, 2006). In a context such as Tanzania, the establishment of the rights of health services and medicines users cannot rely on the relationships of market transactions, since the market would establish consumer rights in a context that favours those who are able to pay within market relationships (Tibandebage and Mackintosh, 2005). In the continuum of care, in research on medicine consumption, pricing, affordability and equity are in the forefront of concerns, but medicine information and consumer medicine information rights are rarely addressed (WHO, 2003).

These reflections raise, third, the question of the role of non-governmental action and of NGO/FBO provision in strengthening consumer rights in the medicines market. The literature on trust and health markets tends to see NGOs in positive terms: Gilson (2003:

1460) refers to ‘organisations with shared values such as public and not-for-profit health providers’ as having scope to reinforce trust between ‘patient and provider’; Leonard (2000) uses evidence of FBO probity and quality to argue for wider use of FBO provision. Yet NGO performance is variable (Tibandebage and Mackintosh 2005). FBOs have been more active in providing health care among the rural poor in Tanzania than private-for-profit health facilities[2]. Provision of health care includes dispensing of medicines for consumers’ use to improve the quality of life. Although dispensing process, which includes provision of medicine information to the consumer, is an equally important aspect of the continuum of care, there is little research on the extent to which FBO dispensing practices reinforce consumer rights.

This paper therefore addresses the gaps in the research literature on the extent of consumer information about medicines in rural low income Africa; the extent to which consumers have any concept of their right to information; and their sources of information. It also compares the information-providing practices of non-governmental non-profit and private commercial medicines outlets, both dispensing facilities and drug shops. Reliable and effective medicine information should enable the patient/client to maximize the benefits of the medication and minimize the adverse reactions, where possible.

The central argument of this paper, based on findings from a medicine dispensing survey conducted in four rural districts of Tanzania, is that the right to medicine information should not be conceived of as necessarily a market relationship. Rather it is a consumer’s right *as a citizen* to know what medicine they require and how they would take it, as well as its effects and side-effects. Such information should *not* necessarily be obtained in the transaction process, but rather outside and before it, as a consumer right. This reconceptualisation implies a role for both governmental and non-governmental public action to support consumer rights.

Since the ultimate aim of dispensing, as per guidelines, is to end up with effective use of medicine, which depends largely on the availability and effective communication of reliable information, this is of public policy importance. The findings are of relevance to policy towards the heterogeneity of medicine outlets, to policy-relevant understanding of differences in the objectives of private and NGO facilities, and to regulatory efforts to

influence the extent to which consumers of medicines receive sufficient information from the dispenser/providers regarding the effective use of the medicines dispensed to them.

Survey questions and methodology

The results reported here are drawn from a larger survey of medicines dispensing and purchase, that also included pricing and prescribing practice, and that in turn formed part of a project tracing the supply chain of essential medicines from India to Tanzania and the role of non-governmental organisations within it[3]. The survey findings discussed in this paper addressed the following research questions:

1. To what extent do consumers of medicines receive reliable and sufficient information from the dispensers/providers regarding the effective use of the essential medicine that are prescribed and or dispensed to them, and their prices?
2. Given the heterogeneity of the medicine outlets and differences in their objectives in Tanzania, does the nature of the information provided differ significantly between the faith-based and other non-governmental non-profit facilities on the one hand, and the commercial facilities and drug shops on the other hand?
3. What do consumers know about their rights regarding medicine information and does that differ significantly by gender and education, by health facility?

On the basis of the findings, this paper discusses the implications for regulation of the medicine sellers/dispensers in different sectors, in the light of the known effects of dispensing medicine improperly. The paper also discusses the need for an active consumer organization focusing on medicines, that can address issues such as ignorance of adverse effects/side effects, and the need for evidence on these effects; also the scope for raising sharply the level of public knowledge and education on rights in relation to medicines purchase and awareness of laws and regulations for medicine consumers. It argues that national regulation by the TFDA alone is insufficient, and that there is a need to develop further decentralised and community perspectives

Study location and scope

This study involved all types of non-governmental medicine outlets; interviewees in the study as a whole included providers (prescribers and dispensers) and owners of FBO/NGOs and private health facilities; importers, distributors, wholesalers and manufacturers were interviewed. The results reported here are mainly from a rural survey

in four districts, and some stakeholder and policy interviews. Stakeholder interviewees from public and private sectors included officials of the Ministry of Health, Tanzania Food and Medicine Administration (TFDA), national faith-based organizations such as the Christian Social Services Commission (CSSC), and the Tanzania Episcopal Conference, as well as private businessmen and pharmacists. Consumers of medicines were also interviewed on exit from the rural facilities and shops.

The rural survey was undertaken in four districts: Manyoni and Singida Rural districts in Singida region; Moshi Rural and Rombo districts in Kilimanjaro region. The regions of Singida and Kilimanjaro were chosen for two reasons. First, they reflect economic variability among Tanzania's regions: Singida is an example of low income and Kilimanjaro of high income regions (URT/REPOA, 2005). Second each had a sufficient number of FBO/NGO medicine outlets to fulfil the study objective of assessing the impact of these on medicines access. The choice among the rural districts in each region was purposive depending on the availability of sufficient number of FBO/NGO and private (shops) medicine outlets.

In each district, two NGO hospitals, eight NGO dispensaries, and eight medicine shops were randomly selected for the study. The medicine shops were all privately owned, and none were officially permitted to sell prescription medicines. Some districts contained fewer than the number of outlets sought, and all existing facilities and shops were included. In total we interviewed 69 medicine outlets: 9 hospitals, 2 health centres, 27 dispensaries and 31 medicine shops. An average of about 5 customers were interviewed on exit from each outlet: a total of 352 consumers at 69 medicine outlets.

Data collection procedures

Data collection instruments were prepared in English. Except for those used for interviewing manufacturers, wholesalers, importers and distributors, they were all translated into Kiswahili, then back into English as a check, then into Kiswahili again before they were piloted. Pre-testing of the research instruments was done in medicine outlets in and outside Dar es Salam region, by research assistants who were all graduates of first degrees in medicine or environmental studies who were all trained and recruited from Dar es Salaam. The questionnaires were then revised before use in the study.

For the rural study, five questionnaires were administered in each medicine outlet: for owners, prescribers, dispensers, and medical sellers if different from dispenser, plus the questionnaire for exit interviews. In addition, all the selected medicine outlets' authorities were asked to fill in information for a selected list of 32 essential medicines, a list which was used as tracer medicines for the whole broader study. These 32 medicines were selected from the National Essential Drug List medicines that are used frequently in primary and secondary care facilities. We adopted the WHO Medicine research guideline (WHO, 2005): for each medicine, information was collected regarding type of medicine, generic or branded, type in stock, the unit of dispensing, the unit buying price, and the unit selling price, plus details of manufacturer and country of origin.

In the questionnaires for owners or managers or their representatives, prescribers, medicine sellers, dispensers, and customers, extensive information on the medicine prescribing, dispensing, customer's rights, affordability, accessibility, regulations, and prices and sources of medicines were solicited.

Characteristics of the Samples

The outlets interviewed are diverse by ownership and level. All nine hospitals were owned by faith-based organisations. One health centre was faith-based, and one privately owned. The 27 dispensaries included 5 in individual private ownership, 4 secular NGO-owned, and 18 faith-based facilities. All 31 medical shops were privately owned. In each, a manager or owner was interviewed when available; 32 prescribers, 31 dispensers, and 27 medical shop sellers (not owners) were also interviewed.

The poorest district with the longest distances for the population to travel yielded the lowest numbers of exit interviewees. The numbers were 98 in Manyoni but only 68 in Singida Rural (both Singida region); 94 in Moshi Rural and 92 in Rombo (Kilimanjaro). As expected, women were in the majority (58%). The age range was wide, 12 to 85 years with a mean of 34 and median 30 years. The vast majority has low educational levels: 9.1% with less than primary education and 71% with primary education only; 16.2% had secondary education and only 3.7% post-secondary. Strikingly, Manyoni had about 14% of the respondents with lower than primary school education or no formal education, well above average for the sample.

Of the exit interviewees, 60.3% were buying medicine for themselves; 20.9% were buying for a child and 10.8% for someone else. In confirmation of the expected loose regulation of sale of prescription medicines, about 34% were buying medicine without a prescription

The characteristics of the facility dispensers are also relevant to interpretation of the findings: 86% were female, aged from 21 to 62 years with a mean of 36, median 32 years. Three were trained as pharmaceutical technicians, 1 as a pharmaceutical assistant and the rest had been trained in other health fields after their basic education. Regarding basic education, of all dispensers, 20 had completed primary school education, 11 had secondary school education and 4 had completed more than ordinary level education

Among the medical shop sellers, 84% were female. Strikingly, therefore, the medicines purchases studied were strongly gendered, weighted to transactions between women. The sellers' age ranged from 23 to 54 years with a mean and median of 35 and 32 years respectively. They were as expected largely untrained. Two were trained in other health fields after their basic education, and two were just business people with no formal health related training. Of the sellers, 19 had completed primary school education, 8 had secondary school education and 4 had completed more than ordinary level education.

Findings

Consumers and Prescriptions

Dispensing prescription drugs in medical shops without a prescription has been reported in Tanzania in a number of studies (Chambuso et al, 2003; Mujinja et al, 2003). In this study we included consumers from health facilities. In an exit interview, consumers who had bought medicine were asked if they had a prescription. Only about 66% of the respondents showed a prescription. Respondents who had lower than primary school education, were more likely to have purchased medicine without a prescription compared to those who had primary education and above, and the higher the level of education the more the likelihood of having a prescription. Comparing prescription by medicine outlets status, respondents who had bought medicine from drug shops were less likely (35.3%) to have a prescription compared to those at health facilities (Table 1).

Table 1: Exit Respondents Buying Medicine with or without a Prescription, by type of Medicine Outlet

Bought with a Prescription	*Type of Outlet*				*Total*
	Drug Shop	*Private Dispensary and Health Centre*	*FBO/NGO Dispensary and Health Centre*	*FBO/NGO Hospitals*	
Yes (%)	*35.29*	*93.75*	*85.59*	*98.18*	*66.38*
NO (%)	*64.71*	*6.25*	*14.41*	*1.82*	*33.62*
Total (number)	*153*	*32*	*111*	*55*	*351*

Pearson chi2(3) = 120.2650 Pr = 0.000

Furthermore, respondents buying medicine for children (77%) were more likely to have a prescription compared who were buying for themselves (63%) or for someone else (55%).The explanation may be that children are more likely to suffer from acute illness and therefore be taken to a health facility and obtain a prescription compared to adults who are likely to contact a medical shop as their first contact when they have a less life-threatening illness. It is also possible that adults prioritise the needs of children.

Information within the medicines transaction

Inquisitive or passive consumers?

Consumers may obtain information about medicines within a transaction, from a dispenser or medicines seller, either by actively demanding information, or by passively receiving it with the medicines. To achieve this, the dispenser or seller themselves needs to be informed; however that information will not necessarily pass to the consumer. The paper first summarises findings about the exchange of information within the transaction from the consumers' point of view: the extent to which information was actively sought, and the actual information provided. It then turns to consumer rights, examining the views of dispensers and consumers as to the information consumers *should* receive. In each case the differences or similarities between the FBO/NGO and private facilities are assessed.

To what extent do consumers actively request information about medicine they buy? Of exit interviewees about 49% of males and 42% of the females said that they had at some time asked for medicine information when buying medicine or being given medicine at a facility. The differences by sex were not statistically significant. Unsurprisingly however, reported ability to ask for information among exit interview

respondents was positively and significantly related to the respondent's level of education (p=0.001**)**. Respondents who had higher level of education were more likely to have asked for medicine information when they bought medicine from an outlet.

The ability to ask for medicine information was also analysed by district. Districts where respondents had a relatively low level education, the respondents were less likely to have had asked for the medicine information (Table 2). Singida Rural's significantly lower score suggests the need for a more intensive medicine information in low income areas. There was no significant difference in the propensity of respondents to ask providers/dispensers for information regarding the medicine that they had bought according to type of drug outlet (p=0.634). Asking for medicine information thus did not depend strongly on where the respondent sought care.

While internationally, with development in and spread of knowledge, patients are becoming more inquisitive about their health and medicines, to the extent of questioning the health services and treatments they receive (Mechanic, 1998; Mechanic and Meyer, 2000), there appears a problem of lack of curiosity about the medicine information in Tanzania linked to low levels of education and deprivation of the people in our study.

Table 2: Percentage of respondents who had ever asked for medicine information from a dispenser/drug seller, by district

Ever asked for medicine information	*District*				
	Manyoni	*Singida Rural*	*Rombo*	*Moshi Rural*	*Total*
Yes (%)	*48.51*	*33.33*	*42.86*	*51.06*	*44.99*
No (%)	*46.53*	*52.38*	*54.95*	*44.68*	*49.28*
I don't remember (%)	*4.95*	*14.29*	*2.20*	*4.26*	*5.73*
Total (number)	*101*	*63*	*91*	*94*	*349*

Pearson chi2(6) = 16.6166 Pr = 0.011

Information provided by dispensers/sellers

From the perspective of the dispenser, as a communicator, passing medicine information to users is part and parcel of good dispensing practise, which aims at achieving a definite outcome that improves the patient's quality of life (Viberg et al, 2005). At a health facility, a dispenser will be the last person a patient would contact on exit, before the patient independently administers the medication. The dispenser is therefore

supposed, by the guidelines and as a communicator, to inform and counsel the patient about the medication in such a manner that the patient takes the medication properly and stores it effectively.

Respondents at the exit interviews were asked to report the information that they were given by the dispensers/sellers when they bought the medicine, and responses (unprompted) were checked off on a pre-designed list drawn from good dispensing practice (using Viberg et al, 2005). Table 3 shows that only two items, *duration of treatment* and *dosage,* out of eleven items expected from the drawn list of items of good dispensing practice, were mentioned by more than 50% of the respondents. About 95% of the respondents mentioned the *dosage (*how many times per day) and 75% mentioned *duration of the treatment* (for how long to take the medicine).

Other important items (Table 3) were not frequently mentioned by respondents; most strikingly, the *name of the medicine* which was mentioned by only 33% of the respondents. This implies that if two thirds of the respondents had to go later to another or the same prescriber or dispenser, and were asked what medicine they took last for that kind of ('same') illness, they would be unable to mention it. Even in the event that they had contracted an adverse reaction from it, there would be no way they could mention the medicine since they had not been told what they had bought for the illness. One might think that those who bought medicine without the prescription would be more likely to know its name, but there was no significant difference between the proportion without this information who had a prescription (65%) and those who did not (71%) (p=0.255). Respondents with lower than primary school education were more likely to have reported lower levels of information on the medicine they bought compared to those with primary school education and above (Tables 2 and 3).

Table 3: Information reported by the exit interview respondents as having been provided by the dispenser at the medicine outlet, by education level of respondent (% of respondents in category)

Information provided by the medicine seller/dispenser to the buyer	*Education level*		
	Lower than Primary N=32	*Primary School n=233*	*Secondary and Post Secondary n=62*
The name of the medicine	*18.75*	*34.33*	*37.09*
The strength of the medicine	*6.25*	*18.45*	*12.90*
The dosage (how many times a day)	*96.88*	*93.56*	*96.88*
The duration of the treatment – in terms of the days	*43.75*	*73.39*	*67.74*
How to take the medication - with or without meals	*25.00*	*35.62*	*45.16*
.Expected Side effects of medicines	*3.13*	*7.30*	*6.45*
Interactions with other medicines	*0.00*	*1.72*	*6.45*
Storage conditions of the medicines	*3.13*	*9.44*	*17.74*
Not to give out the medicines to anyone else without professional advice	*0.00*	*2.58*	*1.61*
Precautions to take when taking the medicine	*3.13*	*2.15*	*3.32*
Other (do not take alcohol, take medicines with water, take full dose)	*0.00*	*3.00*	*6.45*

There was no significant difference between men and women regarding the information they received from the dispensers (Table 4). More than 30% of both sexes were told the dosage, the duration of treatment with the medicine, name of the medicine, and whether to take the medicine with or without food.

Surprisingly, among both males and females, less than 8% were told about the side effects of the medicines they were buying. Medicines have benefits and adverse effects. Even medicines which are over the counter today were once prescription medicine so are likely to create reactions. These results indicate that such important information is not regularly given in Tanzania, implying that people who react to certain medicines cannot identify the problem and report it, nor avoid that medicine in the future. In situations of improper dispensing of medicine and where dispensers do not have enough information regarding the medicine they dispense, there are likely to be substantial numbers of adverse reactions that are not reported: because the consumers are not told and therefore do not know if the medicine reaction has to be reported.

Table 4: Medicine Information provided by the dispenser as reported by the Exit Interview Respondents by gender of the respondent (% of respondents in category)

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Information provided by the medicine seller/dispenser to the buyer	*Gender*		*P value*
	Male n=149	*Female n=203*	
The name of the medicine	*35.07*	*32.12*	*0.578*
The strength of the medicine	*17.16*	*15.54*	*0.696*
The dosage (how many times a day)	*93.28*	*95.34*	*0.423*
The duration of the treatment – in terms of the days	*71.64*	*69.43*	*0.667*
How to take the medication - with or without meals	*33.58*	*38.34*	*0.379*
.Expected Side effects of medicines	*5.22*	*7.77*	*0.366*
Interactions with other medicines	*2.24*	*2.59*	*0.839*
Storage conditions of the medicines	*8.21*	*11.92*	*0.280*
Not to give out the medicines to anyone else without professional advice	*2.99*	*1.55*	*0.379*
Precautions to take when taking the medicine	*1.49*	*3.11*	*0.352*
Other (do oit take alcohol, take medicines with water, take full dose	*2.99*	*5.00*	*0.396*

Are NGOs better?

Do NGO/FBO dispensers do better than private dispensers on information provision? The answer is that marginally, NGOs, and particularly NGO hospitals provided more information than drug shops. For all Good Dispensing Practice items, however, the NGO health centres and dispensaries were recorded by respondents as providing rather less information than the (relatively few) private facilities (Table 5). Specifically, consumers attending NGO/FBO medicine outlets or private facilities were a bit more likely to be clearly told some information on the use of the medicine than were those buying from drug shops. But on many key items, such as name of the drug, strength, duration of use and storage conditions, the lower level NGO facilities had provided rather less information compared to those who attended the private outlets. Furthermore, medical shops sellers had provided almost as much information on some items as the dispensers at prescribing facilities. The information provision at private dispensaries and health centres may reflect the somewhat higher education level of people using those outlets. The differences on this item are not very substantial and do not provide any strong evidence on the issue of quality differences between private-for-profit health sector and NGOs in Tanzania (Munishi et al, 1996; Tibandebage et al, 1998; Mujinja et al, 2003; Kumanrayake et al, 2000; MoH, 2005).

Table 5: Consumers' reported information provided by the dispenser/seller by medicine outlet ownership (%)

Information provided by the medicine seller/dispenser to the buyer	*Type of medicine outlet*				*P value*
	Medical Shops N=153	*Private dispensaries and health centres N=32*	*FBO/NGO Dispensary and Health Centres N=112*	*FBO/NGO Hospitals N=55*	
Told you clearly the use of the medicine	*87.25*	*100*	*94.59*	*98.18*	*0.008*
The name of the medicine	*36.84*	*37.5*	*25.93*	*37.04*	*0.263*
The dosage (how many times a day)	*92.48*	*93.75*	*97.22*	*94.44*	*0.455*
The strength of the medicine	*17.29*	*3.13*	*19.44*	*14.81*	*0.168*
The duration of use – in terms of the days	*65.41*	*81.25*	*64.81*	*87.04*	*0.007*
How to take the medication - with or without meals	*27.82*	*50.00*	*33.33*	*55.56*	*0.001*
Expected Side effects of medicines	*3.76*	*15.63*	*7.41*	*7.41*	*0.11*
Interactions with other medicines	*1.50*	*3.13*	*3.70*	*1.85*	*0.717*
Storage conditions of the medicines	*7.52*	*25.00*	*4.63*	*20.37*	*0.000*
Not to give out the medicines to anyone else without professional advice	*1.50*	*6.25*	*2.78*	*0.0*	*0.238*
Precautions to take when taking the medicine	*1.50*	*6.25*	*0.93*	*5.56*	*0.129*

Exit respondents were also asked how the medicine information they received from the dispensers was given, verbally or in writing or both. For those who responded to this question (93.5%), irrespective of levels of education of the respondent, about 17% of them reported that the information was given just verbally, 2.4% were given the information in writing only, and 81% had the information both in writing and verbally. A large majority (83.4%) get it written down.

Comparing the private and FBO/NGO medicine outlets' dispensers, the privately owned dispensers were more likely to have been reported to have dispensed medicine verbally Furthermore, the dispensers in the private medicine outlets were less likely to give instructions both in writing and verbally (78% compared to 81%), however, these differences were not statistically different (p=0.1469).These results imply that a significant proportion of dispensers in both private and NGO medicine outlets need more training of how to communicate to their clients, and be informed of the benefits and problems of poor communication of medicine information.

Consumers' rights to medicines information

Dispensers' views

We now move from information provided, to evidence about the views of dispensers and consumers on the *rights* of consumers to information. Dispensers in medical shops (private) and health facilities (private and NGO/FBOs) were asked what information they provide to a customer. Only 3 items were mentioned by more than 60% of the medical shops, compared to 8 items mentioned by at least 60% of the health facilities. Worryingly, only 39% and 34% of the medical shops and health facilities mentioned *expiry date* as information frequently provided to their customers (Table 6).

Table 6: Medicine Information Provided to Consumers as Reported by Drug Sellers in Medical Shops and Dispensers in Health Facilities

Information provided	***Type of Health Facility***			
	Medical shops n=31		***Health Facilities n=38***	
	Often	***Rare/Never***	***Often***	***Rare/Never***
The name of the product	24	7	23	15
Country of Origin	5	26	4	34
The strength of the product	13	18	20	18
The reason of using the product for the particular customer	18	13	21	17
The dosage	31	0	38	0
The duration of treatment	28	3	38	0
How to take it (with food, fasting etc)	26	5	35	3
Side effects	13	18	28	10
Interactions with other medicines	13	18	23	15
Cautions (alcohol etc)	21	10	33	5
How to store the product (away from sunlight etc)	19	12	26	12
Expiry date of the medicine	12	19	13	25

If we compare by type of outlet, dispensers from the FBO hospitals (data not shown) mentioned higher levels of information than those from health centre, dispensary and medical shops. The exit interviews also revealed that most of the dispensers only mentioned two items: dosage and duration of treatment. Issues of vital importance like side effects, strength of the medicine, and expiry date were rarely mentioned by the dispensers, according to the exit interviewees. In providing information to consumers, the medical shops thus scored lower than other FBO/NGO and private medical outlets. Other studies in Tanzania (Mujinja et al, 2003; Kumanarayake et al, 2003) not only found low dispensing knowledge among medical shop dispensers, but also indicate that dispensers in medical shops knew little about regulations around medicine dispensing in Tanzania.

Furthermore, dispensers and medical shop sellers were asked if they had ever used the Tanzania Pharmaceutical guidelines handbook, which explains, amongst other things, the information that a consumer is supposed to know when given and or buying medicine. Analysing this helps to understand the gap between policy and practice which is observed in many treatment interventions (Datye et al, 2007). About 82% of the health facility dispensers and 97% of medical shop sellers had never used the guidelines. The difference could be due to the fact that most of the drug shop sellers are not medically trained and would mostly not confident and sure of the names and types of medicine they sometimes required by the customers.

Presumably, in a situation of information asymmetry, the professional is supposed to be more informed about the ethics and responsibilities of the profession than the lay person. The dispenser is supposed to know the rights of the persons who are buying medicine, at least from her training. Sellers in medical shops (private) and dispensers in FBO/NGO and private medicine outlets were asked to mention, apart from the medicine use information like dose, treatment length, and side effects, other important information about which the consumer should be and has the right to be informed. Only two items were mentioned by more than 10% of the dispensers from both medical shops and FBO/NGO and private facilities, these items are (Table 7):

- *to know the price of the medicine before buying:* mentioned by 50% and 44% of the medical shop and FBO/NGO dispensers respectively
- *to get medicines of good quality:* mentioned by 20% of the medical shop dispensers and 17% of the FBO/NGO dispensers
- *other information (including when to come back for the treatment, drinking more water)*: mentioned by 16 out of 30 medical shop dispensers and 24 of the 36 (68%) dispensers from FBO/NGO and private health facilities medicine outlets**.**

Table 7 : Rights of the patient to information as reported by Sellers in Medical Shops and Dispensers in Health Facilities (number of facilities by category)

Kind of Information as right of the consumer buying medicine	Medical Shops n=31	Health Facilities n=38
Know the price of the medicine before buying	15	16
Know the price of other alternative products with the same active ingredients (generics)	2	2
Get other information	16	24
Take legal measures against the pharmacy in case anything bad happens in relation to taking the medicine.	0	2
Be sure of confidentiality.	2	2
Get medicines of good quality.	6	6
Get the cost of the medicines subsidized by the state or insurance company.	0	2
No information is mandatory	1	2

In this study there is evidence that most of the dispensers were not aware of good dispensing practice, hence creating inefficiency in dispensing. One obvious reason, shown above, is that most of them were not trained in a pharmaceuticals-related field to work as effective dispensers. Hence it is hard for them to know procedures, even the basic skills of providing information to the client regarding the medicine she is buying.. A medical store dispenser reported this:

> *……I have heard people complaining that some dispensers do guesswork….they dispense drugs without being sure of the problem….they don't even ask who is the drug for…..if an adult comes without a prescription they would prescribe and dispense an adult dose without asking if the medication if for an adult or someone else……*(A female medical shop dispenser).

Furthermore, although most NGO/FBO and private health facility dispensers and medical shop sellers were not able to clearly specify what is to be considered as the information rights to the consumer, but some were able to elaborate more on what is not right for the consumer. A dispenser in a FBO dispensary elaborated the following:

> *….it's wrong to sell inappropriate drug to the customer - like to give the customer aspirin instead of PenV just because he knows that the customer cannot differentiate the drug because they look alike……..not giving proper information /instructions on how the customer should use the drugs….not giving the customers precaution toward the use of a certain drug….. not giving the patient information on what he should do before taking the medications like eating before taking the drugs or not taking alcohol when on medication……..''* (A man 35 years of age, dispenser)

Customers are on the receiving end: they buy a product that they have little information about, probably hoping that it has some benefits in relieving their health problems, so they are not to be blamed for not knowing what they are buying. However, a dispenser in a dispensary wanted them to know *a priori* what they were buying and blamed them for their low pharmaceutical knowledge:

> *…..the problem is that you are not sure if the customer really knows what he or she wants, …….some of them don't know the medicine and can't even pronounce the names properly…* (A dispenser in a private dispensary).

Although most of the dispensers had low dispensing and consumer rights knowledge, a few were relatively conversant and reported that they advised not only the customers but also the prescribers accordingly. They would respond with advice when the prescribed medicine was not in stock or where the prescribers has inappropriately prescribed the medicine:

> *…….I know if the doctor accidentally prescribe the wrong drug the dispenser is supposed to alert the doctor so that together they can change that prescription for the betterment of the patient but it is wrong for the dispenser to attempt to do the doctors' work. …….* (Dispenser from an FBO Dispensary).

Medicines, apart from treating ill-health, also have some negative effects to the human body, giving some people side effects. But only 19% of all exit interviewees said that they considered information on side effects as their rights and that they needed it. About 11% of all exit interviewees remembered that they had previously experienced side effects from medicines bought or received in a medicine outlet. The exit interview respondents were also asked where they would report a side effect if they experienced one. Many consumers did not know where to go if they ever experienced side effects, while most of them said they would go to see a different provider (65%); only 29% would go back to the medicine outlet where the medicine was obtained. Some of them even said they would do nothing (2%).

Health facility dispensers and medical shop sellers were also asked if they had ever filled an Adverse Drug Reaction (ADR) report. Only one dispenser from NGO/FBO health facility and one seller from a medical shop reported to have ever had ever filled in an ADR. This implies that side effects are rarely reported by medicine consumers, and explains why the exit interview respondents who had at some time experienced side effects did not generally know where to report them.

In general, most of the owners, prescribers and dispensers in medical shops and health facilities reported that consumers need more information about the medicines that they are prescribe, dispensed or buying, implying that the consumer has the right to know the benefits and adverse effects of the medication, before taking it. But, most of them lacked knowledge of what type of information should be made accessible to the consumers by the dispensers, mentioning expiry date, how to take the drug, and with what to take the drug. Of all dispensers, only one mentioned counselling of patients as one of the rights of medicine consumers.

Consumers' views on their rights

The exit interviewees were asked what information they would consider as their right. Generally, consumers had very poor knowledge of their rights regarding medicine information, and there was little difference by gender (Table 8). Of all exit interviewees, about 49% reported that they had the right to know how to take the drug (how many times per day}, 32% mentioned the dose (how many tablets or so), 19.5% side effects of the medicine and 11% the right to know the price of the medicine before buying. Given these results, unsurprisingly, consumers were not able to ask about the medicine information because they knew little about it. Such a situation calls for more consumer medicine information if interventions that depend on taking medicine, like malaria have to succeed.

Table 8: Medicine Information Consumers in the Exit Interviews Reported as their Right to Know by gender (%)

What information is a right	**Gender**		Total
	Male n=149	Female n =253	
To know the dose of the medicine	33.56	30.05	31.53
To know how to take the medicine	53.69	45.81	49.15
To know the side effects of the medicine	20.13	17.24	18.47
To know the price of drugs before buying	8.05	12.32	10.51
To see the drug seller at any time	3.36	2.46	2.84
To return bought medicine	0.00	0.00	0.00
To return bought medicine and get refunded	0.00	0.00	0.00
Others	4.70	2.96	3.69

Consumers' right to a full dose

A final aspect of rights not mentioned in the information lists above is the importance of taking a full dose of a medicine, and hence the right to access to a full dose. Under-dosing has serious implications for microbial resistance, and hence for the health of populations. However this study demonstrates not merely the prevalence of under-dosing, but also the extent to which this has become a prescribing norm. Of exit patients

interviewed, over 15% said they received only a part dose, and this went up to over a quarter in drug shops (Table 9). In addition, some had found drugs unavailable. Only in the hospitals had this been avoided: though this may be explained if those unable to pay may avoid hospital visits.

Table 9: Experience of exit interviewees by type of outlet.

Characteristic	Private drug shop	Private disp. /h.c.	FBO/NGO disp. / h.c.	FBO hospital	Total
Found some or all drugs unavailable (%)	13.73	12.50	5.36	0	**8.81**
Unable to afford some or all of available drugs (%)	8.45	12.50	9.09	0	**7.67**
Received part not full dose (%)	25.71	15.63	10.00	0	**15.48**

Worse, the interviews with dispensers show that the provision of part doses to those who cannot pay has become a dispensing norm in these areas of rural Tanzania. Of the 31 drug sellers interviewed, all but two said that if a customer was unable to pay for a whole dose, a part dose would be sold. Many clearly felt this to be the correct approach. The following responses were typical.

> *some even cannot buy half of the dose… very few patients can afford to buy the whole dose. ….It is usual for us to sell part of the dose.* [drug shop seller, Manyoni]
>
> *we sell them part of the dose and advice them to come back and complete the dose but very few come back. This could mean they have gone to other shop for the rest of the dose or even they have stopped the medication* [drug seller, Singida Rural]

One seller said that rather, people without money were sent away; one said:

> *I normally give them the drug and they will bring the money later when they get them. I don't give half the dose because it wont help him.*

This seller was working in the better off area of Rombo.

In general, the dispensers reported lower levels of request for half doses in the better off areas, but it was still prevalent, and the drug shop dispensing norm the same. Even in the facilities, the practice of giving half doses was widespread. All private dispensary or health centre dispensers except one stated that this was their practice, and in the NGO facilities, two thirds of the dispensers also said they routinely gave part doses when patients could not pay. More awareness was displayed about the possible effects, but this was nevertheless a normal, established practice. In some facilities in each sector the response depended on knowledge and trust, through knowing the client:

> *For those whom we know we give them for credit and they will give us the money when they get. For those whom we don't know we give them the portion of the dose depending on the money they have and advice them to come for the other portion of the dose as soon as they get the money*.[dispenser private dispensary Manyoni]
> *We give our customers half of the doses or we sometimes give them the whole dose and write on their hospital cards so that they pay during next visit. However this is done for few patients whom we know and those who live near by the hospital. Sometimes we just give them for free.* [dispenserNGO dispensary Manyoni]

The exceptions were found in both poorer and better off districts, and hospitals were more likely to take a principled line:

> *We give them drugs free of charge or we give them drugs which have been offered by the charity organisation. For those who are very very poor and the elderly we register them in our books so that they can keep on getting free services. We don't give half doses.*[dispenser NGO hospital Moshi Rural]

However another NGO hospital in a better off area simply sent such patients away:

> *We give them information about that drug and we tell them top go and buy at the drug shop when they get money. For the elderly and orphans we just give them the drugs.*[dispenser NGO hospital Rombo]

In each of these cases, as with others, the only exceptions to the norm are patients who are known. The examples illustrate the limits to trust as a basis for effective medicines access: access to a full dose of needed drugs should be based on the need, not on personal relationships of trust.

How should medicine outlets in the rural areas be regulated?

Who should regulate and when?

In Tanzania, the medicine outlets are regulated by the TFDA, which has regulators in the districts, and by recently formed Ward regulatory committees. About 85% and 90% of the health facility dispensers and medical shop sellers respectively reported that their outlets had been inspected at some time in the past. However the visits were irregular: only about 66% of the dispensers and 47% of medical shop sellers had had their outlets inspected at least once within six months prior the interview. Most of the respondents from the NGOs/FBOs stated that the frequency of inspection should be increased; and to strengthen the regulation, the regulatory committees should include medical shop owners, consumers and other private medicine outlet owners. Some held the opinion that TDFA should make sure that whoever wants to open a medicine outlet must have a trained dispenser, who also understands the regulations surrounding dispensing practice.

What should be regulated?

A majority of the owners, dispensers, prescribers and sellers stated that information given to the consumers should be monitored, and consumers should be given proper information about the medicines received or bought. However, most of them also reported that there are medicine outlets that do not give consumers sufficient correct information regarding medicines.

In this study consumers were also asked of what should be done medicine information and how the information given should be regulated. An exit respondent in Manyoni district said:

> *……The government should take measures against drug shops that do not use use trained drug sellers… and those who cannot give health education to consumers …* (a 45 years man, Manyoni)..

Furthermore, the dispensers in health facilities and sellers in medical shops were asked whether they were aware of dispensing malpractice and if so what therefore should be regulated and how. One medical shop seller had this to say:

> *"….we know our shops are prohibited from selling antibiotics … but these sell faster and have more profit margin than the non-prescription medicine….. and also because our salaries are very low …some sellers put them in the shop without knowledge of the owner so that they can make money…"* (A 30 year old lady in a Medical Shop, Moshi Rural).

Another dispenser in a private dispensary in another district confirmed that:

> *Dispensing without a prescription is not allowed for some medicine, …….also not to give out an overdose or under dose and giving drugs without proper information….. it is not up to the required dispensing regulations …. but we do….sometimes for human grounds."* … *However, the drug sellers and all dispensers in health facilities should give the right information to their clients.* . (A Dispenser in a private dispensary).

An exit interviewee from Singida emphasised that information about medicine bought is important and "t*he government [TDFA] should make it mandatory ……." (A 36 years old exit interviewee).*

How should it be regulated?

Most of the owners, dispensers, prescribers and medical shop owners reported that the District Health Team (DHMTs) and TFDA should increase the frequency of visiting

medicine outlets, and retrain medicine dispensers. Some also said that TFDA should train dispensers in both medical shops and health facilities, before and even after the outlet is opened. A dispenser in a dispensary in Moshi Rural district said "*Education for dispensers once every year once new drugs comes out then the dispensers should educate the consumers about their rights".* Frequent training for dispensers and medical shop sellers is important to improving the quality and quantity of information provided to consumers. Better information provision may also reduce the cost of regulation.

As the study results show medicine information is an important aspect of GDP, and therefore for the users of the medicine. The users are the ultimate focus of dispensing practice, and it is the appropriate use of the medicine that would significantly contribute to its effectiveness in reducing the burden of diseases. Since medicines are also poison, proper medicine information for both dispensers and consumers is of vital importance, hence regulation of the information is also an important public health policy.

Discussion

The results of this study show that most health facility dispensers and medical shops, like the consumers, are ignorant of the information that the consumer of medicine requires in order to maximize the benefits of using the medication and minimize the adverse effects. It also implies that the sources for such information are not clear. While the dispensers and sellers have not read the guidelines, the consumers expect to get information from the dispensers who themselves have scanty knowledge. Consumers not knowing where to report the side effects, avoid returning to the first outlet by going on to a different provider. So the dispensers miss the opportunity of identifying who gets the side effects from the medicine they dispense.

An intermediary, outside the immediate transaction process, is clearly needed to break this deadlock. The best option seems to be the creation of civil society organizations that could work with the government (TFDA) to provide reliable and effective communication regarding effective use of medicine, and management of side effects. A civil society organization which is non-governmental, community based and independent of religious denomination is more likely to reach substantial numbers of people than a statutory body. The government cannot reach all potential medicine consumers, due to

scarcity of the resources and the size of the country, civil society organizations would assist in passing this information to the potential medicine consumers in communities

In a situation where there is severe shortage of public knowledge on medicine information, such organizations would play an agency role, in which, among other things, consumers of medicine would report their adverse effects to the societies. Civil societies are known for mobilising and educating people, especially where people cannot easily access information. A good example is that of civil societies working in the HIV and AIDS area in Tanzania that have supplemented the government efforts in providing HIV and AIDS information. Such civil societies may also help consumers in preparation of charter, for discussion with the government machinery that would spell out consumer rights. In Tanzania FBO/NGO facilities play a great role in providing health service especially in curative care- mostly their role is noticeable in serving the poor areas by reducing the people's health care seeking transaction costs. This is a narrow role that does not necessarily include fighting for consumer rights. For implementing the public-private partnership policy (MoH, 2005) they would probably contribute to training of dispensers but rarely in spreading health information to different populations.

Providing information has costs. Reliable and effective information for consumers regarding the medicine they are buying and taking is an important public health agenda, because of its importance in reducing the burden of disease, especially in poor communities which cannot *afford* information (WHO, 2003). The results of this study therefore imply that for the medication that is dispensed effectively to reduce the burden of disease, as an objective of public health policy, dispensers and medicine sellers as well as consumers have to be enlightened about the importance of medicine information. The findings also imply a need for the TFDA to extend its training to the health facilities and medical shops as well as to consumers of medicines, - that is, to communities. Furthermore, the information has to be de-professionalised, since most of the dispensers, in our study, are not professional pharmacists and most consumers are also ignorant about medicines.

It may also be that medicine information is regarded by consumers as professional information. So they believe that the lay person is not supposed to ask about it, but just to accept what the dispenser/provider says about the medicine being dispensed. In such

communities, interventions that focus on knowledge on medicines are essential. This is also necessary given the extent of self medication among people in rural communities in developing countries (Geissler et al, 2000; Shankar et al, 2002). In countries in Sub-Saharan Africa, like Zimbabwe for instance, there are patient charters that officially detail what their people are entitled for in the health care provision[4], and in case of an adverse effect, patients therefore are more likely to know where to report it; and also to be informed of other regulations surrounding medicine consumption. This will not necessarily guarantee knowledge but would play an important role in contributing to changing the existing narrow culture in medicine information provision and use.

As noted above, about two thirds of the exit respondents had a prescription, and there was no statistically significant difference in the proportion having a prescription among those who had ever asked for some information and those who had never asked for any. A prescription is a note that is written by someone presumed to have more knowledge than the client, and therefore likely to be *trusted* by the client. The information written on the prescription is interpreted also by someone seen as medical personnel, the dispenser or seller, who similarly is assumed to have a professional knowledge than the client. The consumer is therefore likely to place calculative trust in the dispenser and medicine seller (Mechanic, 1996; Gilson, 2003; Tibandebage and Mackintosh, 2005), a trust that may be misplaced: since most exit patients at health facilities had prescriptions and only minority at the medical shops, the prescriber is more likely to be trusted compared to the dispenser. But, in a knowledge-inquisitive-stricken environment a consumer is likely to take on trust what is said by the provider and or dispenser with no more questions

The dispensers and medicine sellers are also supposed to be informed of the human right perspective of the medicine information. Dispensers and medical shop sellers who do not communicate in the right way about medicine use may not be aware of the fact that medicine information is a basic human right of the person receiving the medicine (Hogerzeil, 2006). Recognising the importance of clear, readable and understandable labelling, as part of GDP, to medicine users, steps have been taken in other countries to simplify and improve the communication on over the counter (OTC) medicines. This is done to make sure that clients of OTC, of all kinds, can clearly understand the written and verbal information about the medicines so that they effectively treat their illnesses

and facilitate consumers to reap the benefits of medicine[5]. This move recognises that medicine information is a human right, and the users have to benefit and not be harm by them. Such actions are of vital importance even in areas where most of the dispensers are not professionals, and consumers are less inquisitive and sometimes ignorant of their rights.

Surprisingly, more than 17% and 6% of the exit respondents who were buying medicine for a child and someone else respectively, were given verbal explanation only. Studies have shown that medicine left over are used. In the event that the dose has been forgotten, and a child has an illness episode, the child is likely to be given a wrong medicine, overdosed or under dosed. In GDP, clear labelling of medicines is emphasized to minimize such consequences. The dispensers have to be informed of the consequences of dispensing children's or someone's medicine without a written communication such as labelling of the medicine. Such actions may act against the aim of essential medicine in public health policy. Dispensers need to be exposed to training in GDP and be informed that giving medicine properly is part and parcel of implementing the requirements of effective use of essential medicine (WHO, 2003).

Dispensers as well as prescribers are trusted as providers of health services, by their customers, as patients (Mechanic, 1996; Gilson. 2003; Tibandebage and Mackintosh, 2005), and their trust is probably based on the perception that they are professionals and they have the knowledge that their customers do not have, in most cases (Dibben et al, 2000). The advice and information they provide to the customers is therefore trusted and expected to bring about maximum benefits of the medicine and eventually a better outcome. In the rural areas of Tanzania, where most of the facilities are medical shops and dispensaries, with such levels of dispensing knowledge, this situation calls for a public health policy attention.

Medicine information provision has to be regulated by the government agencies or in partnership with private providers and civil society organizations. Effective and efficient regulations requires an efficient regulatory framework (Kumanarayake et al, 2000; Kumaranayake et al, 2003), and effective regulatory mechanisms (Mujinja et al, 2003) coupled with adequate financing, regulating equipment, sufficient and qualified regulators in collaboration with responsive regulatees (Tibandebage et al, 2000;

Kumaranayake et al, 2003; Mujinja et al, 2003). The regulatees should be aware of what the regulator is regulating (Kumanarayake et al, 2000), and the regulator should know what s/he is regulating and for whose benefit. In this study, respondents called for regular inspection of medicine outlets. However, TDFA as the regulator may not have the capacity to effectively regulate these outlets in the whole country, due to lack of human and financial resources, as it has been identified in some studies (Kumanarayake et al, 2003). Delegation of regulation becomes a necessity in a resource constraint situation.

One attempt to address this problem at drug shop level is the collaboration the TFDA has established with Management Sciences for Health (MSH) to create a process of accreditation of the private medical shops to become *Duka la Dawa Muhimu*[6] This project sets up Accredited Drug Dispensing Outlets (ADDO), which are permitted to sell some prescription medicines[7]. The project is implemented in phases. Furthermore, the sustainability of ADDO is questionable since those who are trained to manage the shops, in most cases, are not the capital owners. The absence of ownership may stimulate the trained shop attendants to quit the place to search for more lucrative employment in pharmacies in urban areas. This would result into reversing of the intended outcome of providing medicine information to the rural poor, and consequently that of reducing morbidity and mortality in these areas. Therefore, this policy initiative is mainly provider-oriented, and from being potential points for implementing many other preventive interventions, does not include direct advocacy for effective medicine information to consumers to be provided by current rural medicine outlets as a catalyst for effective medicine use. Potentially however such information can have a positive public health impact on morbidity and mortality among rural populations, if sustained.

The on-going ADDO programme implemented by the Ministry of Heath (TFDA) which is planned for a scale-up to all districts aims at improving access and quality of medicines to people living in rural and peri-urban areas by training dispensers, allowing ADDOs to dispense more drugs and use them as points for implementing some public health interventions in the district. But, there will still be a gap between GDP policy and or guidelines with practise which is aimed at improving accessibility and eventually reduction of the burden of diseases if the training that is and will be undertaken would remain in the circles of medical shops dispensers and few health facilities, as it is now.

To bridge this gap dispensers from both public, private and FBO/NGO and consumers in the respective districts would have to be involved in the training and regulating the ADDO programme to effectively improve the understanding and use of the information provided by the trained dispensing practitioners. The involvement of the dispensers and consumers on understanding the importance of medicine information are of great public health concern would also reduce the problem of lack of people who have to be trained as dispensers (as shown in TFDA Workshop Report, 2008) and therefore the ADDO operationalisation would be used as a cost-effective entry point which need a well coordinated grassroots information provision and regulating organizations linked to the functions of TFDA.

References

Bensing, J. (1991). Doctor-patient communication and the quality of care *Social Science and Medicine*. 32(11):1301-10

Bhat R. 1996. Regulating the private health care sector: the case the Indian Consumer Protection Act. *Health Policy and Planning* 11(3) 265–79.

Chambuso, MHS., Leshabari, MT, Mujinja, PGM and Kabati, CIA. (2004). F*actors contributing towards the price of drugs in Tanzania*. A Research Report Funded by TFDA, Dar es Salaam

Chambuso M, Mugoyela V, Kalala W.(2007). Consumer survey of malaria fact card: an educational and communication tool in Tanzania. *East Afr J Public Health.* Oct;4(2):59-63.

Datye V, Kielmann K, Sheikh K, Deshmukh D, Deshpande S, Porter J, Rangan S. (2006). Private practitioners' communications with patients around HIV testing in Pune, India. *Health Policy Plan.* Sep;21(5):343-52.

Dibben, M.R., Morris, S.E. and Lean, M.E.J., (2000), Situational trust and co-operative partnerships between physicians and their patients, *Qualitative Journal of Medicine* 93: 55–61.

Geissler PW, Nokes K, Prince RJ, Odhiambo RA, Aagaard-Hansen J, Ouma JH (2000). Children and medicines: self-treatment of common illnesses among Luo schoolchildren in western Kenya. *Soc Sci Med.* Jun;50(12):1771-83.

Gilson, L. (2003) 'Trust and the development of health care as a social institution' *Social Science and Medicine* 56 :1453-1468

Hogerzeil, H (2003).Access to essential medicines as a human right. *WHO Essential Drugs Monitor*. no. 32. Switzerland, Geneve

Hogerzeil, H.V., Samson, M., Casanovas, J.V., Ocora, L.R. (2006) 'Is essential medicines as part of the fulfilment of the right to health enforceable through the courts?' *The Lancet* Vol. 368 July 22nd.

Hunt, P. (2006) '*The right of everyone to the enjoyment of the highest attainable standard of physical and mental health'* United Nations General Assembly Sixty First Session Report by the Special Rapporteur 13th September.

Kamuzora, P., and Gilson, L. (2007) Factors influencing implementation of the Community Health Fund in Tanzania .*Health Policy Plan*. Mar;22(2):95-102. .

Kimatta, S., R. Valimba, E. Shekalaghe, and W. Nkondokaya. 2007. *Supervisory Visit Report: in Accredited Drug Dispensing Outlets , Ruvuma Region Tanzania, February to March 2007.* Submitted to the U.S. Agency for International Development by the Rational Pharmaceutical Management Plus Program. Arlington, VA: Management Sciences for Health.

Kumaranayake, L., Hongoro, C., Lake, S., Mujinja, P., Mpembeni, R. (2003) 'Coping with private health markets: regulatory (in) effectiveness in Sub-Saharan Africa' in *The New Public Private Mix in Health: Exploring Changing Landscapes*. Söderlund, N., and Mendoza-Arana, P (Eds) Alliance Publication.

Kumaranayake, L., Mujinja, P.G.M., Lake, S., Hongoro, C. and Mpembeni R. (2000)

‘How Do Countries Regulate the Health Sector? Evidence from Sub-Saharan Africa’ *Health Policy and Planning*, 15(4):357-367, December.

Laing R, Waning B, Gray A, Ford N, 't Hoen E (2003) 25 years of the WHO essential medicines lists: progress and challenges. *Lancet.* May 17;361(9370):1723-9.

Leonard D.K. (ed.) (2000) *Africa’s Changing Markets for Health and Veterinary Sciences: the New Institutional Issues* St Martin’s Press

Maiga, FI., Haddad, S., Fournier, P., and Gauvin, L. (2003). Public and Private Sector Responses to essential drugs policies: a multilevel analysis of drug prescription and selling practices in Mali. *Social Science and Medicine* 57:937-948

Mechanic (1996).Changing Medical Organizations and Erosion of Trust. *Milbank Quarterly*. 74(2):171-89.

Mechanic, D.The functions and limitations of trust in the provision of medical care. *Journal of Health Politics, Policy, and Law* 23, 4(1998), 661-686

Mechanic, D., & Meyer, S. (2000). Concepts of trust among patients with serious illness. *Social Science and Medicine*, 51, 657-668.

Ministry of Health (2005*): Public Private Partnership for Equitable Provision of Quality Health Services: A Technical Review*. Ministry of Health, Dar es Salaam,Tanzania. March

Ministry of Health (1997). *Guidelines on Good Dispensing Practice* Dar es Salaam.

Mujinja, PG.M. Mpembeni, R. and Lake, S. (2003) ‘Regulating private drug outlets in Dar es Salaam: Perception of key stakeholders’ In *The New Public Private Mix in Health: Exploring Changing Landscapes.* Soderlund, N. and Mendoza-Arana (Eds). Alliance Publication.

Newdick and Derrett (2006) Access, equity and the role of rights in health care *Health Care Anal.* Sep;14(3):157-68.

Save the Children UK (2005) *An Unnecessary evil? User fees for healthcare in low-income countries*. A research report. Dar es Salaam, Tanzania

Shankar PR**,** Partha, P., and **S**henoy, N (2002). **‘**Self-medication and non-doctor prescription practices in Pokhara valley, Western Nepal: a questionnaire-based study’ *BMC Family Practice* 2002, **3:**17

Stevenson F, Barry CA, Britten N et al. 2000. Doctor-patient communication about drugs: the evidence for shared decision-making. *Social Science and Medicine* 50: 829–40.

Tanzania Food and Drug Authority (2008). *Stakeholders meeting report on accredited drug dispensing outlet (ADDO) program scalability and sustainability,* Workshop held at St. Gaspars Conference Centre, Dodoma 5th july 2008

Tibandebage, P., Semboja, H., Mujinja, P. and Ngonyani, H. Private Sector Development: The case of Private Health Facilities. *ESRF Discussion Paper* no. 26.

Tibandebage, P. Mackintosh M (2005) ’The market shaping of charges, trust and abuse: health care transactions in Tanzania’ *Social Science and Medicine* 61: 1385-1395

United Republic of Tanzania (URT) (2005) Poverty and Human Development Report: The Research and Analysis Working Group. *M*kuki Nyota Publishers Dar es Salaam, Tanzania.

Veldhuijzen, W., Ram, P., van der Weijden, P., Niemantsverdriet, S., van der Vleuten, C. (2007). Characteristics of communication guidelines that facilitate or impede guideline use: a focus group study. *BMC family practice,* vol 8 (issue) : pp 31.

Viberg, N.T., Phare Mujinja, Göran Tomson, Cecilia Stålsby Lundborg (2005)**:** The Role of the Pharmacist in nine African countries- A Qualitative Interview Study *Pharm World 0:1–10.*

World Health Organization (WHO) (2003). 25 years of Essential Drugs Progress. *Essential Drugs Monitor* no. 32 pg 24

World Health Organization (WHO) (/Monitor). *WHO Policy Perspectives on Medicines—Equitable access to essential medicines: a framework for collective action*, March. Geneva, Switzerland.

World Health Organization (WHO) (2004). *Measuring Medicine Prices, Availability , Affordability and Price Components.* First Edition. Geneva, Switzerland

[1] Literally, 'cold' medicine shop: a shop not permitted to sell prescription medicines with the exception of some malaria medicines

[2] Interview at Christian Social Services Council Dar es Salaam 14/09/06

[3] 'Non-governmental action to improve access by the poor to good quality low cost drugs', a project forming part of the ESRC research programme on Non-Governmental Public Action; see acknowledgements and disclaimer.

[4] Personal communication with Prof. Nyazema, Zimbabwe October, 2004

[5] http://www.peublo.gsa.gov/cic_text/health/new/medicine-label/499_otc.html accessed on 19/10/2007

[6] This is a Kiswahili translation of an ADDO, which means a medical shop that dispenses 'essential' medicine including some of the prescription drugs attended by a person trained by the ADDO programme, but not equivalent to a pharmacy operated by a oproffesional pharmacist

[7] Interview in Dar es Salaam 30/09/06; see also Kimatta, et al, 2007