PRIORITY SETTING IN SELECTION AND DISTRIBUTION OF NEW ANTIMALARIALS IN TANZANIA: ANALYSIS AND EVALUATION AGAINST ACCOUNTABILITY FOR REASONABLENESS

By

Amani Thomas Mori

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CERTIFICATION

The undersigned certify that they have read and hereby recommend this dissertation titled ***Priority setting in selecting and distributing new antimalarials in Tanzania: Analysis and evaluation against Accountability for Reasonableness,*** for acceptance by Muhimbili University of Health and Allied Sciences in fulfillment of the requirements for the degree of Master of Arts in Health Policy and Management.

_____

Prof. Ole Frithjof Norheim

(Supervisor)

Date: _____



Dr. Eliangiringa Kaale

(Supervisor)

Date: 18/10/2010

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I, **Amani Thomas Mori**, declare that this **dissertation** is my own original work and that it has not been presented and will not be presented to any other university for a similar or any other degree award.

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DEDICATION

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DECLARATION OF CONFLICT OF INTERESTS

This thesis was funded by Norad's Programme for Masters Studies (NOMA); and the contents are free of bias and are purely intended for academic or research purposes. I declare there is no conflict of interests which may have resulted from the financial, institutional or personal connections.

ABSTRACT

Background: Tanzania like many other malaria endemic countries changed its National Malaria Treatment Policy in 2006 due to parasite resistance to Sulphadoxine/Pyrimethamine (SP). Selection of Artemether-Lumefantrine (ALu) as the first line antimalarial drug and its selective distribution to Public and Faith based health facilities were two priority-setting decisions underlying the policy change. However, today, there are people who are still using Sulphadoxine/Pyrimethamine because they have no access to Artemether-Lumefantrine.

Objective: To analyze and evaluate whether the priority decisions for selection and distribution of subsidized Artemether-Lumefantrine satisfies the conditions of fair process as suggested in the ethical framework of accountability for reasonableness.

Method: A Qualitative study involving review of the guidelines and in-depth interviews with key informants from the task force was conducted. The analysis followed an editing organizing style. The audio data was transcribed into text and loaded into QDA program whereby coding, connections and analysis was performed. The results are presented under the four thematic areas of the accountability for reasonableness (AfR) framework which are publicity, relevance, appeals & revision and the enforcement conditions.

Results: *Publicity*: The decision and the rationales for selection of Artemether-Lumefantrine were made public, contrary to the selective distribution decision and its rationales. Public and the patients were indirectly but inadequately represented. There was no explicit mechanism to involve the stakeholders and as a result the task force lacked professional, institutional and countrywide representation. *Relevance*: Selection of Artemether-Lumefantrine was based on relevant evidence; however its selective distribution was partly based on donor requirement. *Appeals & Revision*: there was no well defined and reliable appeal mechanism, apart from the use of newspapers. *Enforcement*: There was not any enforcement mechanism to ensure the other three conditions are fulfilled.

Conclusions and Policy implications: The change of National Malaria Treatment Policy was necessary, however the priority decisions of selection and distribution of Artemether-Lumefantrine which underlined this change does not fully satisfy the four conditions of fair process prescribed in the ethical framework of accountability for reasonableness.

Decision making in priority setting is considered to be a technical area for experts and their views are assumed to represent those of other people in the society. This study suggests involvement of 'lay' people and other stakeholders directly through personal representation complemented by inputs obtained from large scale survey studies, focus group discussions and by rapid appraisal method.

Task forces or committees are formed to oversee priority setting decisions; however, the whole process is conducted in *ad hoc* and under limited freedom to discuss issues of significant implications.

Reliable appeal and revision mechanisms need to be put in place to accommodate new findings, arguments and deliberations once priority decisions have been made. This will make the whole process of policy making to be continuous rather than an event.

LIST OF ABBREVIATIONS

ADDO	Accredited Drug Dispensing Outlets
AfR	Accountability for Reasonableness
ALu	Artemether-Lumefantrine
AQ-AS	Amodiaquine-Artesunate
AS-SP	Artesunate-Sulphadoxine/Pryrimethamine
CIH	Center for International Health
GFMAT	Global Fund for Malaria, AIDS and Tuberculosis
MSD	Medical Store Department
MOHSW	Ministry of Health and Social Welfare
MUHAS	Muhimbili University of Health and Allied Sciences
NMCP	National Malaria Control Program
PPP	Public Private Partnership
TFDA	Tanzania Food and Drugs Authority
WHO	World Health Organization

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1. INTRODUCTION

1.1 Background

Inhabited by more than 45 million people and located between latitudes 1°S and 12°S and longitudes 30°E and 40°E, is the United Republic of Tanzania, which covers an area of 945,050 km^2, including 59,050 km^2 of inland waters. Tanzania is among the poorest countries of the world, ranked 151th on Human Development index, with a GDP per capita of 400 US $ and 13.3 percentage of total budget spending on health [1].

With very limited health budget, prioritization of drugs to which the Government will allocate its financial resources is an inescapable task. Tanzania, like many other malaria endemic countries, decided to change its treatment policy to more effective Artemisinin Combined Therapies (ACTs) due to wide spread parasite resistance to Sulphadoxine/Pyrimethamine (SP) which was the first line drug for uncomplicated malaria [2]. There is wide diversity on population's drug choices (i.e. acceptability) which are determined by fundamental factors such as contraindications due to pre-existing disease conditions, individual perceptions on the effectiveness of the drug, duration of treatment, number of pills to take at a time, taste of the drug, perceived side effects, dosage forms and gender issues.

WHO recommends the change of national malaria treatment policy when the total treatment failure proportion exceeds 10 percent [3]. In most cases cheap and widely accessible drugs are replaced by drugs which are more effective but more expensive with limited distribution which means a certain proportion of people may not have access to it. The change of first line antimalarial drug to Artemether-Lumefantrine and the subsequent decision of its selective distribution to the public and Faith Based health facilities are by large priority setting decisions. Daniels and Sabin suggested that these priority decision outcomes have to fulfill the four conditions of accountability for reasonableness (AfR) ethical framework to be considered fair and legitimate [4].

1.1.1 Burden of malaria

Since colonial era, malaria has maintained its position as the most life threatening public health disease in terms of morbidity and mortality exerting a powerful negative influence on the overall development of the country. Malaria accounts for over 30% of the national disease burden, making it a top health priority for allocation of scarce resources for its prevention and control [5]. It is responsible for more than one-third of deaths among children under the age of 5 years and for up to one fifth of deaths among pregnant women [5]. On out patients' visits, it accounts of 38.9 percent for under fives and 48 percent for those aged 5 years and above [6]. In hospital admissions it accounts of 33.4 percent for under fives and 42.1 percent for those aged 5 years and above [6].

More worse, malaria is implicated in decreased learning capacity in children, students, and trainees in the 5–25 age range and in loss of economic productivity in the workforce age range 15–55 years [7]. It is documented that malaria reduces the national economic growth by 1.3 percent [8]. In general, $2.14 is spent on malaria control per person per year, representing 39% of the country's health expenditure and 1.1% of its GDP [9]. It features strongly in the National Package of Essential Health Interventions, and ranks high in the National Health Research Priorities [10]. Globally the costs of malaria are overwhelming, US $12 billion a year in lost productivity in Africa alone and, in countries with a very heavy malaria burden, as much as 40% of public health expenditure goes to malaria [11]. Malaria is a real burden of the already fragile and overstretched health care delivery system.

1.1.2 Ethical priority issues with malaria treatment policy change

Limit setting, priority setting and rationing have been used interchangeably by scholars in the literature, however some scholars define Priority setting in the field of health as the process of resource allocation among competing health intervention programs [12]. Other scholars however have defined Rationing as the process of withholding a potentially beneficial health care through financial or organizational structure of the health care system in place [13]. In this thesis the words are used synonymously but with the adoption of the first definition.

Of recent, there have been fierce discussions at national and international discourse when it comes to National Malaria Treatment Policy change. At the core of these discussions are clashing views about when to change, which evidence counts and which do not count, which drugs to use and which group should get it, when universal access is not possible.

In nearly all societies people believe access to health care should be based on need, not on ability to pay because health is of special moral importance [14]. This moral obligation is in many ways made difficult by scarcity of resources, especially in developing countries. Governments and authorities are therefore forced to set priorities, however priority setting is often greeted with mistrust and with challenges to the moral authority, or legitimacy, of those who set the priorities, and this is especially true in the mixed, public and private, non universal coverage system [4]. In doing so, quite often, the negatively affected consumers and stakeholders always ends up questioning the grounds and kind of reasons the policy makers ware guided with to achieve the consensus. Sadly, it is regrettable but equally inescapable fact that no society has been able to reach anything resembling a consensus on how much should be spent on health care, or how the allocated resources should be distributed [15]. During the development of the current National Malaria Treatment Policy, the Ministry of Health and Social Welfare through the task force team was confronted by priority setting issues in two ways:

The first priority setting challenge was to select the best Artemisinin combination therapy (ACTs) among those which were recommended by WHO. Unlike other infectious diseases, 95 percent of the population gets malaria [5]. It is nearly impossible to meet all the individual drug preferences of this proportion of population by selecting one and obviously we expected a certain proportion of this group not to accept the outcomes of this priority decision. WHO recommends change of policy when resistance is at ten percent [3], this means the 90 percent proportion of people may really not be willing to give up a drug which they still believe cures them.

We must elaborate clearly here before we go further that, the procurement of Artemether-Lumefantrine was to be funded by the Global fund and therefore patients were to get it at highly subsidized prices or free of charge. This financing mechanism lead us to the second priority setting challenge, the issue of selective distribution, that is the facilities from which the subsidized drug will be accessed, which would actually determine who gets it. The policy decision was that the subsidized ALu to be accessed from the public and Faith Based health facilities. The public health care facilities were/are not enough and they were/are still facing multiple problems of scarce human resource of all kinds (physicians, pharmacists, nurses, laboratory personnel's). The existing workers are de-motivated due to low payments, poor working environments and over burdened with jobs. This may be an explanation of why 82 percent of all malaria case management occurs in the private sector each year [9], and that around 60 percent of all malaria episodes are treated by purchase of drugs from the drug shops and peddlers [16].

It must as well be taken into consideration that, branded ALu known as Coartem® from the same manufacturer was already registered in Tanzania and was available in the private for profit health care facilities. These being hospitals, pharmacies and *duka la dawa baridi* (DLDB), raises the concern of conflict of interests, which could have a significant influence on the distribution of the subsidized one. The *duka la dawa baridi,* even with their extensive coverage to rural areas were widely known for malpractice and in fact they were only authorized to sell non prescription medicines of which ALu was not on the list. These circumstances were critical in any decision regarding where to distribute the new packed, subsidized ALu so as to make it available to as many people as possible but in an efficient and effective way to minimize misuse and wastage. This priority setting decision must be guided by distributive principles of justice which those affected view as reasonable in meeting the health care needs fairly [4].

1.1.3 Case management as malaria control strategy in Tanzania

Globally, down to national and house levels, malaria threat has continued to grow despite the existence of effective control technologies such as insecticide-treated bed nets (ITNs), indoor residual spraying (IRS), Artemisinin Combination therapies (ACTs), and rapid diagnostic tests. While there is evidence that each of these approaches is effective in combating malaria, significant implementation challenges have prevented more widespread adoption of these potentially effective solutions. Without more attention to these policy challenges, malaria control efforts will be severely hampered.

Malaria case management, malaria vector control using Insecticide Treated Bed nets, malaria intermittent treatment for pregnant mothers, malaria epidemics prevention and control are operational strategies which are complemented with information, education and communication and operational research as supportive strategies used to combat the public health threat posed by malaria in Tanzania [5]. The objective was and has been to prevent mortality and reduce morbidity due to malaria by 25% by 2007 and by 50% by 2010 [17]. Deaths attributable to malaria are mainly associated with the use of less effective antimalarial drugs, delayed health seeking, and reliance on clinical judgment without laboratory confirmation in most peripheral health facilities.

1.1.4 Antimalarial drugs dispensing channels in Tanzania

Tanzania has a stable government run health service throughout its 26 regions. Each region is divided into districts, with a government-run or mission-government co run district hospital as well as other government and private health facilities. Primary Health Care services form the basis of the pyramidal structure of health care services. Both public and private providers are working in dispensaries, health centers and at least one hospital at the district level. Currently there are 4,679 dispensaries and 481 health centres throughout the country [18]. There are 55 district hospitals owned by Government and 13 Designated District Hospitals, owned by Faith Based Organizations (FBO). Furthermore, there are 86 other hospitals at first referral level (owned by Government, parastatals and private sector) [18]. There are 18 Regional Hospitals,

functioning as referral hospital for district hospitals and 8 consultancy and specialized hospitals in the country. About 90% of population lives within five kilometers of a primary health facility [18].

The drug distribution channel in Tanzania is fragmented and complex in operation. Apart from the hospitals, dispensaries and health centers, the private drug shops form another major channel of antimalarials distribution. They include the Pharmacies, drug shops commonly known in Swahili as *Duka la dawa baridi* (DLDB) and the Accredited Drug Dispensing Outlets (ADDO). Much of the Tanzanian populations purchase pharmaceutical products from the small drug shops, *duka la dawa baridi* (DLDB), which are licensed to sell only over-the-counter drugs but frequently also sell prescription medicines [19]. Tanzania is served by approximately 339 pharmacies registered with the Tanzania Food and Drugs Authority (TFDA) and more than 4,600 DLDB, or non pharmacy drug outlets [19] and by 2007 the number of ADDO shops were expected to reach 1,321 in 21 districts, serving around 14.3 percent of the population [20].

Approximately 80 percent of all pharmacies to which approximately 20 percent of the population has access to, are concentrated in three urban centers—Dar es Salaam, Arusha, and Mwanza, yet the majority of Tanzania's population live in rural areas [21, 22]. That justifies the decision of the Ministry of Health and Social Welfare to adopt the ADDO program to improve access to affordable quality drugs and services in drug retail outlets in rural or peri-urban areas. ADDO's were authorized to stock a limited list of prescription only medicines including ALu. It must be noted that the ADDO project actually aimed to replace the *duka la dawa baridi* shops which are notorious for malpractice. The sustainability and monitoring of the ADDO programme has been subjected to fierce discussions among the stake holders. Major concerns has been their supervision, studies have shown that, the same way as the *duka la dawa baridi*, they break the rules by selling unauthorized medicines [21]. ADDOs stock subsidized ALu to make them accessible in poor rural areas and this by large have increased coverage of these effective drugs to more people [21]. Private pharmacies stock the braded ALu (Coartem®) which costs more than 10 US Dollars per dose as compared to the subsidized

ALu which is sold at approx 1 US Dollar in ADDO shops and free in public and Faith Based facilities. The distribution of subsidized ALu is complex, and this has left a certain proportion of people out of the minimum standard of care the national antimalarial treatment policy calls for. It must be noted that many people opt to seek antimalarial in dispensing outlets rather than visiting health centers, dispensary or even hospitals. Therefore private sector plays a significant part in malaria case managements.

1.1.5 The Importance and problems of the private drug dispensing channels

It is estimated that, each year, around 82 percent of all malaria case treatments takes place in the private sector [23]. Another study reported that around 60 percent of all malaria episodes in Sub Saharan Africa are treated through purchase of drugs from shops and peddlers [16]. Even with this significant contribution, controlling the practice of the private sector has remained the major challenge to the authorities, especially the dispensing outlets. Knowing this, in recent years the Government through the Ministry of Health and Social Welfare has shown considerable commitment and efforts in regulating private health providers, however there are clearly limits to the control of private sector behavior. Tanzania's large and sparsely populated border makes it difficult to stop the illegal importation and distribution of medicines which are counterfeit, expired, unregistered and above all banned for use due to technical reasons like being resistant or monotherapies which are likely to induce resistance to the existing highly effective drugs.

Geographically, Tanzania is very diverse, some areas are difficult to reach by roads and hence the *duka la dawa baridi* and the Accredited Drug Dispensing Shops which serve these areas are even difficult to supervise as compared to pharmacies. They are known for malpractice and irrational dispensing being a major problem. Patients do not tell the truth about their previous use of antimalarials and hence they use multiple drugs consecutively, either as full dose or incomplete dosage. A recent study prove that self reporting of previous antimalarial intake is unreliable, the study reports an incredibly and indeed worrying proportion of patients with detectable sub therapeutic drug levels of antimalarials in plasma, some with more than

one drug [24]. This study shows that influencing individual behaviour with regard to treating malaria is critical in the battle against malaria control and the growing drug resistance. The regulation of self treatment poses a particularly difficult problem for policy-makers, especially when malaria is endemic and resistance to anti-malarial medicines is already high and increasing [23]. Policy makers in countries highly affected by malaria are facing a difficult, yet challenging and tricky problem of guaranteeing easy and early access to effective and high quality antimalarials while at the same time preventing wastage due to uncontrolled and unnecessary use. We argue that policy decisions must come out of proper assessment of multiple factors, not only drug resistance. Proper argumentation and discussions based on knowledge of drug use behaviour in specific areas can help the policy makers to come up with more sustainable achievement on the field.

1.1.6 National guideline for diagnosis and treatment of malaria

National Malarial Treatment Policy is a reference document which aims to attain uniform malaria case management all over the country [2]. The policy document prescribes recommendations that represent the minimum level of care that patients suffering from malaria should expect at different levels of health care in public and private sectors [2]. Ideally, a National Malarial Treatment Policy should consist of evidence-based recommendations on the rational use of available antimalarial drugs in that country, with clear guidelines for health care workers providing early diagnosis and prompt treatment. The guiding principle is to guarantee access to antimalarial drugs that are safe, affordable, effective, acceptable and of good quality for community members infected with malaria [2]. Ideally the practice of malaria management by therapeutic agents must reflect what is stipulated in the national antimalarial treatment policy. The current guideline which came into effect in 2006 specifically recommends that, ALu as first line therapy for uncomplicated malaria while Quinine is recommended as the second line drug in case of treatment failure or the presence of contraindication to the first line drug for treatment of uncomplicated malaria and it remains the drug of choice for treatment of severe malaria [2]. SP is recommended as the drug of choice

for Intermittent Preventive Therapy (IPT) for pregnant women who are not hypersensitive to sulfonamides.

1.1.7 The Problem of malaria resistance as a basis for policy change

Chloroquine (CQ) was the first line drug of choice for malaria for long time because of its efficacy, wide availability and relatively cheap for the majority of the population [25]. However in late 1970's, documented reports of parasite resistance started to emerge in East Africa [25]. The process of changing policy did not progress until a pivotal meeting of Ministry of Health representatives, scientists, stakeholders, clinicians and WHO representatives in May 1999 took place to build consensus [26]. By this time the average countrywide CQ resistance was 60 percent [2].

Despite repeated previous presentations of scientific data arguing for change, the window of opportunity was not there, those studies were claimed to have been conducted in an ad hoc and isolated manner, and results could not be generalized [26]. There was distrust of data, compounded by little communication among the scientific community, control staff and Ministry of Health officials. Allegations were there that the pharmaceutical companies had influenced some scientists, and that the media provoked the debate over the loss of Chloroquine [26]. The process that ultimately resulted in the change of policy was clearly guided by a small number of individuals who were involved in different ways with malaria (research, technical advice, programme responsibilities) [26]. Task Forces were developed after the 1999 meeting to plan implementation. In the 2002-2003 budgetary session, the then Minister for Heath and Social Welfare declared in the Parliament of the United Republic of Tanzania her Ministry's decision to suspend the continuous use of Chloroquine as the first line drug against malaria, based on sound evidence pointing to high cure-rate failure of about 60 percent [27]. Fully implementation of SP occurred in August 2001 despite the fact that reports suggesting the resistance to SP were coming out from researches. By this time, however, there was no alternative drug while waiting for evaluations studies for Artemisinin Combined Therapies which were regarded as long term solutions. Because of the increased resistance of the malaria parasites to antimalarial monotherapies, in order to preserve the efficacy and

effectiveness of the existing drugs and to ensure optimal cure, the Ministry of Health and Social Welfare launched a consultative processes in mid 2003 to select alternative options to the interim antimalarial drug, Sulphadoxine/Pyrimethamine [2].

In January 2004, the Ministry of Health appointed another taskforce to explore suitable alternative for the failing Sulphadoxine/Pyrimethamine after being convinced by research findings that the resistance was at alarming levels [28]. There are no clear indications of how resistance was distributed all over the country, in other words it is what Tarimo argues as "lack of comparable countrywide data for policy decisions"[29]. He argued that policy decisions on antimalarial drugs are often hampered by the lack of adequate clinical and scientific data to enable clinical assessment of the magnitude of the problem of resistance for decision making. The pharmacokinetic properties (late parasites stage specificity action) and pharmacodynamic properties (lack of antipyretic effects) made some prescribers and clients to maintain the notion that Sulphadoxine/Pyrimethamine is slow acting, which might negatively influence acceptability of its wider use for malaria control [29]. WHO recommends looking at other criteria such as therapeutic efficacy, consequent effectiveness of the antimalarials in use, changing patterns of malaria associated morbidity and mortality, consumer and provider dissatisfaction with the current policy, availability of new products, strategies and approaches when we want to change policies [3].

1.2 Literature review

1.2.1 General

It is a common practice for Ministries of health to set priorities on which drug or drugs they will list in their guidelines as the first choice in the management of malaria and sometimes where to distribute them, in response to scarcity of resources. Accountability for Reasonableness is a leading framework in analyzing priority decisions in health care and over the last decade has been gaining increasing acceptance worldwide, arguably to the point of becoming the dominant paradigm in the field of health policy [15, 30, 31]. Its application in Tanzania has been very limited and to date, it has not been used to evaluate priority setting for antimalarial drugs in hospitals and at national levels. Daniels and Sabin, who developed the framework, suggest that 'accountability for reasonableness' is relevant to pharmaceutical priority setting:

''Managing access to pharmaceuticals is a microcosm of the limit-setting problems of health care systems as a whole. . . If we are right that accountability for reasonableness is a solution to the legitimacy problem in health systems as a whole, then it should be possible to illustrate what such accountability would mean in practical terms ....''[4]

I acknowledge that Artemisinin Combination Therapies are the best weapons against malaria but its effective utilization has been slow and limited due to number of reasons which I argue may be grounded on the policy decisions themselves.

1.2.2 Agenda setting and policy process

In an attempt to consider the role of ethical analysis in health policy, a useful starting point is to take into account the political nature of the agenda setting and the actual policy making process. Policy formulation process begins by the agenda setting process, how an issue becomes prominent in the eyes of policy makers. Policy is usually determined through complex interactions among key stakeholders, including public agencies, private market sector, consumers, regulatory agencies, media and the scientific community. Important

influencing factors include perceptions of policy legitimacy, support/opposition from competing interest groups, degree of congruence with existing values, perceived logistical feasibility, and anticipated future benefits/costs if adopted [32].

The Hall model [33], Kingdon model [34] and Weiss model [35] are three theoretical models which elaborates how issues become policy agenda and the policy formulation process. Hall proposes that pressing issues and their likely response with high legitimacy, feasibility and support always get into governments agenda. Weiss proposes the interplay of three sets of forces, the ideologies and interests of participants and the information available to them. By ideology he refers to philosophical issues, principles and political orientation, and central to these are implicit ethical and moral values. Kingdon's three streams approach model is the one I will adopt much in my discussions. He proposes that, policy is made through three streams of processes, the problem stream, the politics stream and policy stream which operates independently of each other [34]. When these three streams coincide together then a window of opportunity opens and the issue gets into the policy agenda. Kingdon argues this process to consist of many ideas floating around, bumping into one another, forming and reforming as they encounter new ideas and forming combinations and recombinations like in primeval soup [34].

1.2.3 Politics in policy formulation process

A distinctive feature of politics is the pursuit of power. Kingdon proposed to be focused on the roles played by visible and hidden participants when we intend to do policy analysis. Visible participants work openly in getting issues into agenda. The hidden participants work behind the closed doors, these are the experts, the community of academics, researchers and consultants who work less on getting issues into the agenda and more on proposing alternative options for solving problems that do get onto governments agenda [36]. Hidden participants may at times, however, play active roles in getting attentions for problems – especially in partnerships with the media or among themselves. The distribution of power determines whose ideology, interests and information will be dominant. And this is the true picture for

Tanzania, very hot debates among the researchers, politicians and in the communities which at last called for more systematic discussions at the ministry level [26]. Researchers with interesting findings, especially if they challenge the current policy may leak information to the press or call press attention to a scientific article in the journal or present their findings to key stakeholders rallying for support to call for policy change. Mugittu *et al* study findings on baseline parasite resistance markers for SP [28] and on its efficacy two years later after its countrywide deployment [37], were strongly used to advocate for policy change. However another study contrasted some earlier reports by showing that SP was still effective in other places [29]. The fact that Mugittu's study took on board very convincing and powerful actors from the National Malaria Control Programme, National Institute of Medical Research, very experienced researchers on malaria, academicians and medical personnel, it was by no means very convincing to the Ministry of Health and Social Welfare that policy change was necessary. Even where research plays a significant role in decision making, Weiss argues that it should not be forgotten that research itself is shaped by values filters and selectivity, from the formulation of the initial question to the development of the conclusions [35]. Donor agencies, international organization and Manufacturing Pharmaceutical companies also have critical roles to play in the process, especially in poor countries and at times they are so powerful to the extent that, unless you bow to their conditions, the desperate need for help may not come.

WHO signed a Memorandum of Understanding with the Norvatis, the manufacturing company ALu (Coartem®) in 2001, to make these drugs available at production cost for malaria endemic countries, specifically for distribution in the public sector [38]. The same drug had been in use in the Private sector in Tanzania, even before the policy change, which I may think was a reason for restriction in the public facilities. Kenya like Tanzania changed its national malaria treatment policy earlier, in April 2004 [39]. The interests of different actors were evident and deserve some close examination in this thesis report. Similarly as in Tanzania, WHO was pushing for switch to Artemisinin Combination Therapies and in particular ALu, however the local authorities were reluctant. The reason being lack of nationally generated, comparable efficacy and sensitivity data, by this time only one study for review pre-

publication report on clinical efficacy of ALu was undertaken in Kenya [40]. The authorities insisted one study for the whole country was insufficient and hence called for multi-site comparison of ALu and Amodiaquine-Artesunate. WHO kept on insisting that some countries like Zambia and Zanzibar had changed their policies based on International and regional data only [41], as an effort to move quickly to other implementation issues were urgent, especially meeting the round four of proposal submission to Global Fund to Fight HIV/AIDS, Malaria and Tuberculosis (GFMAT) [42]. These nationwide comparative studies were not finished and with intense discussions which followed, at last ALu was declared as the choice for Kenyans. Three days after this announcement, a regional meeting of 13 countries which were using Amodiaquine-Artesunate was called, Kenya as a host, to show their disagreement with the decision [40]. This raised confusions and divisions among the people, the media seemed to endorse Amodiaquine-Artesunate as opposed to what the Ministry of Health had announced [40]. The Pharmaceutical Society of Kenya (PSK), publicly accused WHO for monopoly due to single outsourcing of malaria drug (ie ALu from Norvatis Pharmaceutical company). It went on publicly to question the choice of ALu as the first line antimalarial drug by organizing workshops, presentations and letters to the media and the Ministry of Health [40].

A heuristic model which frames the determinants of health policy as a set of competing rationalities, (ie cultural rationality, political rationality and technical rationality), has been proposed in one way to illustrate politics and the reasons why evidence-based health policy is difficult a difficult task [43]. Cultural rationality reflects values, ethics and perceptions which are dominant in the communities. Political rationality encompasses distribution and management of power, willingness of policy makers to have transparent processes and be accountable and the ability of interest groups to influence the policy processes and outcomes. Technical rationality involves the application of research evidences in policy decision, it is however argued to be the weakest link in the chain even though it is useful in handling uncertainties. Those arguments are based on claims that research evidences are dominated by positivist science which aims to represent universality, where decision making is more often and broadly known to be context-specific. To build health policy based on greater technical rationality, diverse forms of evidence which takes into accounts the local factors, sound and

reliable information about the likely impact, evaluation of costs and benefits distributions, sufficient managerial and service delivery capabilities and effective communication among different policy actors are important. Unfortunately, these elements are rarely or not present at adequate quantity and quality in many resource limited countries [43].

1.2.4 Need of procedural ethical framework to guide malaria policy decisions

As we have seen in the proceeding sections, malaria poses a tricky and unique set of challenges that limit decision makers' ability to effectively confront and control the burden of this disease. Combating vector-borne diseases involves multiple actors at multiple scales, including international donor organizations, national governments, universities, nongovernmental organizations, local health providers, and individual communities and households [44]. These actors vary in terms of their perspectives and priorities, creating a difficult scenarios for those tasked with the responsibility of making decisions and they may feel significant pressure from different stakeholders to adopt one approach or another [40, 44]. These actors as we said earlier have their own interests, values and ideologies which they always protect at how they argue and perceive issues at decision making process. International donors may favor an approach that conflicts with the preferences of national agencies or local communities [40, 44]. This is why I argue, in the presence of these complex priorities setting environment, procedural ethical framework is an important tool to ensure decisions are smoothly made in such a way that fairness is maintained throughout the process.

Amartya Sen, argued that "The foundational idea of fairness can be given shapes in many ways, central to it must be a demand to avoid bias in our evaluations, taking note of interests, or by our personal priorities or eccentricities or prejudices". "It can broadly be seen as a demand for impartiality"[45]. It is well recognized that good policy making should be informed by evidence, but good policies however, also require explicit and systematic analysis of the values underpinning decisions, and of ethical consequences of those decisions [46].

Rawls, argues that if decisions were to be made behind a 'veil of ignorance', he refers this as original position, then at large they would be fair and just if they fulfill his three principles of justice [47]. If all the parties which were involved in making decisions for the national malaria treatment policy change were put under this 'veil of ignorance', would they have acted in a similar way? Would they have set the same limits in the distribution of an effective drug using the same arguments? Would they have selected the same drug as the first choice? Would they have used the same research evidence or would they have waited for more evidence? or would they have produced the same guideline document? As much as we want to engage in this discussion, we must note that, this ethical analysis by Accountability for Reasonableness looks at the process which leads to the decision and not merely on the outcome of the process. Accountability for reasonableness is gaining popularity on fair way of setting priorities in health care and is probably the only approach to priority setting that is empirically based, ethically justified, and focused on process and its no wonder that has been used by both decision makers and scholars to identify good practices and opportunities for improvement in relation to priority setting [48, 49].

1.2.5 Priority setting in developing countries

In less wealthy countries the dominant approach to priority setting has been Burden of Disease (BOD) and cost effectiveness analysis (CEA), which is also helpful, but insufficient because it focuses on a narrow range of values – need and efficiency – and not the full range of relevant values, including legitimacy and fairness. Kapiriri et al. evaluated priority setting in Uganda and found that the BOD/CEA approach was: too technical, requiring expertise that was unavailable, did not involve relevant people, did not include other values that were important to Ugandans (e.g. protecting the vulnerable) and was too opaque [50]. Mshana et al introduced the AfR framework in priority setting decisions during planning at district and regional level in Southern highland zone of Tanzania and found that it was viewed by both the district and government planners with enthusiastic favour because it was the first framework that directly addressed their priority setting concerns [51]. They commented that the approach enabled

wider participation, enables scrutinizing and development of relevant criteria and enabled greater transparency.

Johansson et al, conducted a similar study to this one and concluded that the National HIV treatment guidelines in Tanzania and Ethiopia were developed through a method which fails to satisfy conditions of fair process due to the following shortfalls: neither guideline document gives enough information about the rationale behind the recommendations or the development process for them to be considered fair tools for patient selection, the medical criteria in the guidelines are explicit and were made public but their scientific and ethical rationales is not publicly accessible, even though several stakeholders were involved and workshops functioned as open hearings during the development, information about this involvement was scarce in the guidelines, the guidelines were based on expert opinions and consensus rather than evidence based development methods, lack of explicit decisions and rationales and recommendations from the WHO were copied without much discussion, disagreement or adjustment etc [52]

1.2.6 Priority setting in developed countries

Number of examples exists in the literature on how developed countries set priorities on new technologies in health care and their evaluations using the AfR framework. The case of child B in UK in 1995 give an impression of the challenges involving priority setting even in developed countries, that followed the decision of pediatricians to withhold a costly second bone marrow transplant from a child with acute myeloid leukemia due to die 6-8 weeks [53, 54]. This decision was received with intense public discussion and debates. From the beginning when rationing was introduced in UK, it has been a subject of debate in the British National Health Service (NHS) [55, 56]. The National Institute for Clinical Excellence (NICE) was formed in 1999, as special health authority to: appraise new and existing health technologies, to develop and disseminate clinical guidelines and to oversee clinical audit and confidential inquiries [57, 58]. Glen Robert studied priority setting in UK and weighed the

practice of NICE against the Accountability for Reasonableness and found that the four conditions are to large extent fulfilled [59].

At the National level, the agenda papers and minutes of all NICE Board meetings are publicly available and it ensures that its deliberations, conclusions and the reasons for its advices are as transparent as possible. NICE also has a set of mechanisms to get inputs from the public including involving public representatives [60]. On relevance; clinical effectiveness, cost effectiveness and affordability have been outlined as appraisal criteria. NICE also created a room for appeals by manufacturers, sponsors, patients and care's representative groups and appropriate professional group[61]. However the Appeal Panel has a restricted role of hearing appeals which falls in only within the three areas, out of that the appeal will not be considered. This is rather not a real appeal mechanism but in one way or another it may serve the purpose. The regulation of NICE's processes for making decisions is examined and its officers implicitly held to account for reasonableness by the Parliamentary Health Select Committee which comprises of diverse members from political parties. One of the mandates is to ensure that NICE is actively promoting interventions with good evidence of clinical and cost-effectiveness so that patients have faster access to treatments known to work [62]. There are also mechanisms in place to monitor the independence of NICE in making decisions [59]. Therefore broadly, NICE meets the four conditions of accountability for reasonableness.

Marc Berg and Tom van der Grinten researched priority setting in Netherland's health care system and evaluated the practice against the Accountability for Reasonableness framework and in summary he founded that the four conditions are largely not satisfied [63]. Publicity: Netherland resembles many other countries in that information about priority-setting decisions and their rationales are hardly accessible to ordinary and lay people. There are some little attempts to stakeholders in the process but at large public's involvement is unsatisfactory. On relevance; open debates, coordinated discussions and exchange of arguments about issues of priority setting and rationing between the stakeholders are absent. Similarly, there is no explicit appeal mechanism, national committee for priority setting is not there and law courts are being used to appeal against the outcomes of rationing decisions. The enforcement is as

well not proper and is strongly influenced by the propensity to cooperate between the main stakeholders, government, providers of health care and insurers.

1.2.7 Gaps in literature

The high demand of health care services in developing countries is unmatched by extreme shortage of resources, yet many studies on priority setting have been conducted in wealthy countries where diseases like malaria, HIV/AIDS, Tuberculosis etc, which consumes a lot of resources are nearly nonexistent. Where poverty is dominant, priority setting decisions are extremely painful and at times they separate life and death. While there have been studies relevant to decision making in the policy process, none have described priority setting in drug selection and their distribution in Tanzania. The available literature on malaria treatment policy development process mostly reports on agenda setting, use of research evidence in policy change and costs of policy change. To the best of our knowledge there is no study ever analyzed the actual process of how drugs are selected and where they should be distributed during the National Malaria Treatment Policy development and evaluated against a framework of how it should be done. This knowledge gap presented an opportunity for this research.

1.3 Problem statement

Escalating pharmaceutical expenditure has led to an increased need for priority-setting in medicinal care in both developed and developing countries [64]. With malaria, previous cheap but ineffective drugs are being replaced by effective but costly drugs with limited accessibility. Many malaria endemic countries have changed their malaria treatment policy to more effective but costly Artemisinin Combined Therapies because of parasite resistance to the existing first line drugs. With very much constrained budgets, the Ministry of Health and Social Welfare therefore had to select one drug among the available Artemisinin Combined Therapies recommended by WHO. ALu was selected to be the first line drug of choice for therapeutic management of uncomplicated malaria in Tanzania.

The Ministry of Health and Social Welfare also decided that the subsidized ALu could only be accessed through the public and Faith Based health facilities and later through the Accredited Drug Dispensing Outlets. The guiding principles were to promote safe, effective, of good quality, affordable, accessible and acceptable malaria treatment. However, a complete and non-contradictory set of rational decision principles alone does not solve the problems encountered in priority setting [65].

Justice is essential in the provision of health care needs under any kind of resource constraints. Priority setting in health care is partly subjective and value-based in nature and it has been argued that it needs to involve stakeholders other than experts in decision-making [31]. In many developing countries where rationing in health care is inevitable due to extreme scarcity of resources, priority decision making processes are at times not guided by ethical procedures and as a result certain proportion of people may disagree with the priority decision outcomes. In many occasions the issue of antimalarial drugs resistance occupies the central part of the discussions in the policy process sometimes forgetting other contextual factors which can hugely impair the implementation and hence the effectiveness of the new policy. Sometimes, there is no consensus between the researchers themselves, political leaders and the policy makers regarding the evidences which necessitate the policy change [66]. Number of examples of decisions which were initially made simply on technical basis but later revealed a lot of ethical underpinnings is not uncommon in our settings [67]. Decisions were and still being made by malaria endemic countries regarding this more expensive treatment for first-line treatment of uncomplicated malaria, without proper consideration of the context in which it will be deployed, and this has seriously compromised its field effectiveness [68]. It is no wonder that the current malaria treatment policy is yet to attain uniform malaria case management and the targeted minimum level of care that patients suffering from malaria should expect at different levels of health care in public and private sectors [2]. Justice requires fairness in developing the National Malaria Treatment guidelines which set limits of the minimum level of care the patients should expect at health facilities in the public and private sectors. The criteria recommended by WHO to change the policy, alone can not solve the basic problem of how to arrive at decisions which will be considered to be a product of fair

and legitimate process by the affected stakeholders even if they do not agree with the outcomes [3].

Health policy analysts have been criticized in the literature for ignoring the profoundly political nature of policy change and for only providing prescriptive suggestions for changing policy, without including sufficient information on the process of change or reasons for policy reform failures or success [69, 70]. Fair process informs the stakeholders not only about the decisions but also the reasons and grounds on which the decisions were made. It also opens room for revisions to accommodate new evidence based appeals. It therefore leads to acceptance of the priority decision outcomes by the affected stakeholders and the public population. It is therefore necessary to analyze and evaluate the priority decisions of selecting and distributing the new first line antimalarial drug in order to come up with recommendations which if implemented will improve future process of national guideline development for diagnosis and treatment of malaria.

1.4 Research question

Are the priority-setting decisions of selecting and distributing ALu, fully satisfying the conditions of fair process according to the ethical framework of Accountability for Reasonableness?

1.5 Study Objectives

General objective is to analyze and evaluate whether the priority decisions for selection and distribution of subsidized ALu satisfies the conditions of fair process as suggested in the ethical framework of accountability for reasonableness in order to improve the decision making in future National Malaria Policy formulation.

1.5.1 Specific objectives

1. To determine whether the publicity condition was satisfied during the priority setting process of selecting and distributing Artemether-Lumefantrine
2. To determine whether the relevance condition was satisfied during the priority setting process of selecting and distributing Artemether-Lumefantrine
3. To determine if there was a reliable appeal and review mechanism for the affected stakeholders to challenge the outcomes of the priority decisions or accommodates new developments.
4. To determine if there was an independent public or private enforcement entity to ensure the above three conditions are met.

1.6 Study rationale

This study aimed at introducing the AfR framework as a guiding tool to assess malaria policy making process in Tanzania. AfR evaluates decisions according to the process that produces them, rather than their content and conclusions. Conformance with some of these principles is a feature of best practices in a variety of public and private institutions. AfR enables us to follow the sequence of events during policy development from the beginning to the end and hence improve our understanding of policy process. It facilitates the isolation of areas of weakness which needs improvements.

1.7 Analytical framework

The principle of justice is concerned with the questions of fairness and equity, it takes on board a group of norms for fair distribution of benefits, risks and costs [46]. Theories of justice, at least in health care require distribution of health care services according to need (concept of equity). Applications of principles of distributive justice in health have its foundation mostly from Rawl's theory of '*justice as fairness*' [47]. Even though health care was not among Rawl's category of primary goods, he argued that if a social contract was to be signed in a 'veil of ignorance', he proposed that the contract must contain provisions to;

protect equal basic liberties, to guarantee fair equality of opportunity and to allow inequalities only if it aims to favour the worst off. This is because in this veil of ignorance which he refers to original position, we don't have a clue of our identities or even our positions in the societies and hence we all aims to make sure the neediest who might be ourselves or our relatives are given prior consideration. In his book entitled *Just health: meeting health needs fairly*, Daniels extended Rawl's theory of justice to health and health care, arguing that fair equality of opportunity principle can be constrained in a situation of unequal distribution of health and health care [14]. Societies have moral obligation task to make sure whenever possible people remain healthy and hence close to normal body functioning so that they can all retain the capability to utilize and transform the wide range of opportunities open or granted to them to their preferred utilities. At least we have consensus that priority setting is inevitable when resources are not enough, in both developed and developing countries, priorities are set at all levels of the government.

The situation is more stringent in developing countries where resources are extremely scarce and governments are pressed by competing demands in all sectors. In the health sector where this work is focused, the debates on how efficiently to allocate the scarce resources among the competing health needs are always intense and compelled by disagreements. Therefore limit setting/rationing is inevitable, societies simply can not meet all medical needs and certainly not all medical preferences and sometimes authorities are forced to decide where to allocate the resources within the health care system structure. How should decisions about such limits be made? Confronted with the challenge of absence of widely accepted consensus on principles on how to distribute scarce resources fairly, Daniels and Sabin suggest that we give up on our struggles to find principles that will give us perfect solutions and instead put emphasis on procedures or process that will guarantee fairness and legitimacy of whatever outcomes they generate [4]. If we can not agree on views regarding the key issues underlying disputes about health care resource allocation, they argue, we should at least be able to agree on fair ways of making the unavoidable decisions that even those who disagree with the outcome should, and hopefully will, accept as reasonable and legitimate [4].This was the basis for the development of Accountability for reasonableness (AfR) ethical framework. Therefore

Accountability for reasonableness was developed as a framework to provide procedural justice in priority setting decisions in the presence of disagreements or lack of consensus so that even those who would be adversely affected by the decision outcomes will have reason to abide by them because of their acceptance of how it was reached.

1.7.1 Accountability for Reasonableness framework

Accountability for Reasonableness sets out four conditions as the requirements for fair process:

1. *Publicity condition:* Decisions regarding both direct and indirect limits to care and their rationales must be publicly accessible. The process of priority setting must be open, transparent and consultations and public hearings should be held. Publicity and involvement of key stakeholders are particularly important in contexts where policy and programmatic decisions occur in a multi-actor environment and affect large parts of the population.
2. *Relevance condition:* The rationales for priority-setting decisions should aim to provide a reasonable explanation of how organizations and health providers seek to meet the health needs of a population under reasonable resource constraints. Specifically, a rationale will be reasonable if it appeals to evidence, reasons, and principles that are accepted as relevant by fair-minded people who are disposed to finding mutually justifiable terms of cooperation. By 'fair-minded' people we do not simply mean our friends or people who just happen to agree with us.
3. *Appeals and Revision condition:* There must be mechanisms for challenge and dispute resolutions regarding priority-setting decisions, and, more broadly, opportunities for revision and improvement of policies in the light of new evidence or arguments.
4. *Enforcement or regulation:* There must either be a voluntary or public regulation of the process to ensure that conditions 1-3 are met.

1.8 Conceptual framework

The analysis will base on the following conceptual framework (Figure 1)

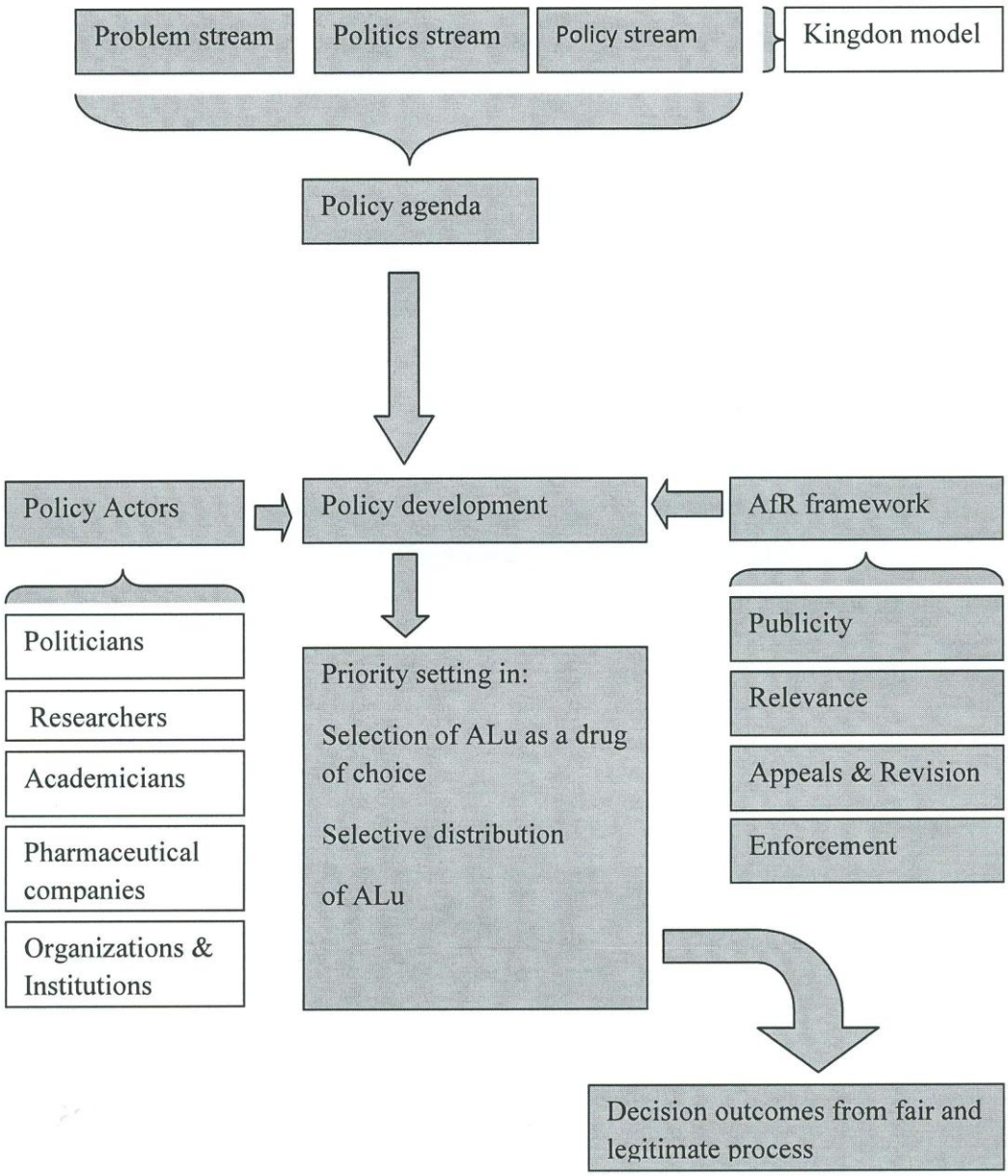


Figure 1: Conceptual framework.

2. METHODOLOGY

2.1. Study type and participants

This is a descriptive, cross-sectional study, where in-depth interviews with key informants who were involved in the process of guideline change were conducted. The guidelines were also reviewed to supplement the interview data.

2.2. Sampling

Sampling of key informants was purposeful in order to explore the perceptions of people with different backgrounds and perspectives from the acknowledgement list of the National Guidelines for malaria diagnosis and treatment, 2006. Their experiences lie in the following areas: treatment of malaria patients, procurement, management and dispensing antimalarials, experts in malaria research and administration of large public health initiatives. The individuals represent National government hospital, the National Malaria Control Programme, WHO country office, Ministry of Health and Social Welfare Headquarters, Tanzania Food & Drug Authority, Medical Stores Department and Muhimbili University of Health and Allied Sciences.

2.3. Sample size estimation

We selected the sample of 15 participants based on Guest *et al* recommendations on sample size estimation [71]. However we managed to interview 12 participants only. Among the three individuals who we didn't manage to interview, two were outside the country for official duties and studies and another did not consent to participate because he was not fully involved in the change of policy.

2.4. Data collection tools

Data collection tools included the digital audio recorder (SANYO®) and the interview guide. The interview guide consisted of questions corresponding to the Accountability for Reasonableness framework [4]. Some of the questions were based on the review of another

predefined normative rationing framework specifically developed to evaluate the development of treatment guidelines [13]. The four conditions of the framework were the main categories. Under the publicity condition we had five sub-categories which were: the accessibility of the decision and the rationales by the public, presence of explicit procedure to select the taskforce team members, public and patient involvement and consultations. These subcategories were important for us to evaluate the publicity and the transparency/openness of the priority-setting decisions.

Under the relevance condition we had four sub-categories which were the medical considerations, affordability of ALu, availability of the affordable ALu and the cost-effectiveness. We thought these were important factors to take into account when the decisions were being made. We did not have sub-categories on appeals & revision and the enforcement mechanisms (Figure 2).

2.5. Data management

Immediately after each interview the audio data were transcribed into text, Microsoft word® - Rich Text Format and saved in a flash disk which was kept by the investigator.

2.6. Data analysis procedures

The textual data were analyzed using Atlas.ti® Qualitative Data Analysis (QDA) computer program, using editing analysis style method [72]. First the template was prepared based on the interview guide which corresponds to AfR framework. Analysis of the textual data in the QDA program and content analysis of the guidelines were done sequentially, starting with the data in the QDA program then documentary review and analysis of the guidelines. Meaningful units or segments of the text in the transcribed interviews and the guideline documents that corresponds to the template or related to this study were identified. These units were coded using the template, according to Kvåle's analysis approach [73]. This approach involves defining of codes before an in-depth analysis of the data. Network of each code with their corresponding quotations under their sub-categories were formulated with the QDA program

and this enabled us to read and compare the responses of each participant for each code for the transcribed interviews and the guideline documents. Then a memo was written summarizing the ideas which emerged from the quotations of each code supplemented by those ideas which emerged from the similar code in the guidelines documents. These memos were linked to their codes. A network of all codes under their sub-categories, this time replacing the quotations with their corresponding memos was made using the QDA program and this enabled us to analyze the texts in the memos and reach the conclusion of each sub-category. These conclusions were again written as memos. Finally the network of the four conditions as main categories of fairness with their memos was made and it could easily be seen whether the four conditions were satisfied or not by reading what message the memo carried (Figure 2.)

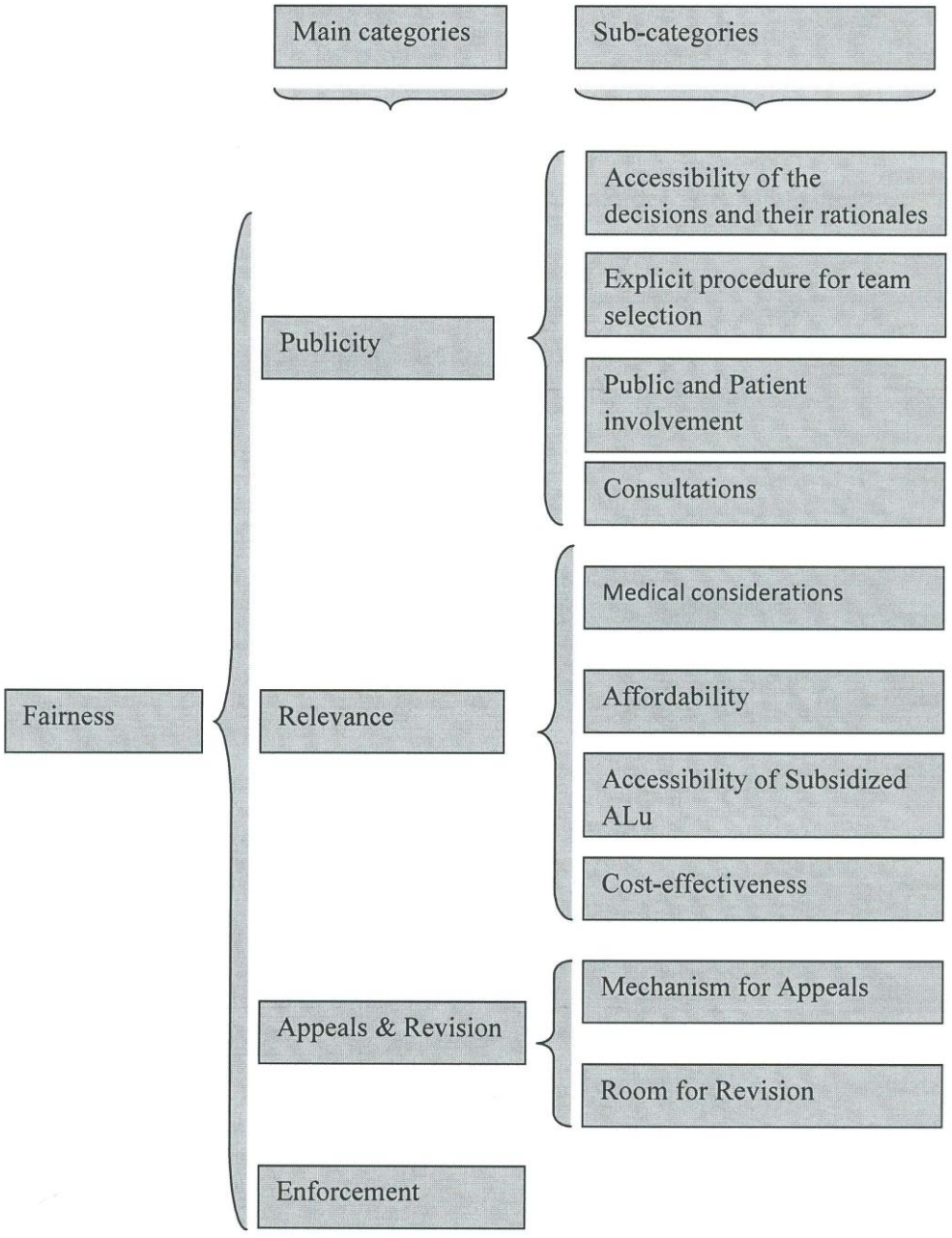


Figure 2: Analytical framework

2.7. Study process and ethical consideration

The participants were contacted physically and explained about the study, then a consent to participate was sought. Appointments were made about the day, time and place to carry the interviews. The time to run the interview was predetermined in the pilot study and in average each interview took 30 minutes. MUHAS Ethical Committee granted me the ethical clearance with Ref. No. MU/PGS/SAEC/Vol. III/185 to conduct the study.

3. RESULTS

For each of the four AfR conditions, we present its description first and then evaluate the extent to which the condition is met.

3.1. Publicity condition

i) Accessibility of the decisions and their rationales

Regarding the decision and rationales to change the national malaria treatment policy, the participants said that various mechanisms including the media channels were used to make sure the decision and the rationales reached as many people as possible.

"(...) so you find that we were just trying to see which medium we are going to use to make people aware of the change and how we are going to communicate effectively so that people understands why we are changing and moving to ACTs" (Participant 1)

Participants from the National Malaria Control Program (NMCP) acknowledged that all the public health facilities from the dispensary level to the region received the guideline document which contains the rationales for selection of ALu. Trainings were as well conducted all over the country.

"Every hospital, public health dispensary in every region in every district received the guideline and they were trained. There is a training manual that goes with this guideline." (Participant 8)

They also said there is a section within the National Malaria Control Program which deals with Information, Education and Communication (IEC) which draws partners from various organizations, and it is this organ which disseminated the information using the radios, Television programs and the News papers to the general population. Also they said Population

Service International (PSI) was hired to do advocacy campaigns about the new drug. Other respondents said meetings with other stakeholders like pharmacists were held as a means of disseminating information about the new drug and the policy.

"Usually we do have a cell at NMCP which deals with IEC (Information, Education and Communication) and this IEC have a technical working group which draws partners from different areas and are the one through our communication strategy which derived several modalities for informing them through the electronic medias like radio, like TV then they had papers like news papers, leaflets etc and that was the first time I remember the communication strategy of NMCP was implemented." (Participant 4)

However other participants acknowledged not to have participated in the dissemination of information task and expressed their worries if the target population really understood the message.

"I have seen several announcement in the mass media, radio, TV, for example use combination therapy for malaria but whether it is really effective, I don't know, remember announcing in the mass media is one thing but are you sure the message is reaching the targets? Listening is one thing and understanding is another thing." (Participant 10)

Regarding the selective distribution decision of subsidized ALu and its rationales; the participants said that it was an operational decision made by the task force team which would change over time and therefore could not appear on the guidelines.

ii) Explicit procedure for selection of stakeholders

The expertise in the task force team was wide as written in the policy document, ranging from; Pediatricians, Obstetrician/ Gynecologists and Physicians all from MNH or MUHAS, National

Officers from WHO-Tanzania, IMCI-MOH, Pharmacists from MSD, TFDA and MOHSW, Officers from National Malaria Control Programme, Clinical Pharmacologists and Parasitologists from MUHAS. Out of the 25 members of the team, only four had Pharmacy education background, the rest were Medical doctors by profession. Some of the participants said they were involved because of their positions in the organizations.

"Ok, by then I was working with WHO as the national program officer for malaria. So it was because of that position I came to be the taskforce member." (Participant 5)

Other participants said that the main reason for their selection was because they have previous links with National Malaria Control Program or the Ministry of Health either through research activities or long years of working together in various aspects of malaria.

"I am a clinician, I have been treating babies I don't remember exactly for how long but since 1995, I have been working with National Malaria Control Programme as a facilitator,(…), when the issues of changing the guideline came (...), then those are the reasons I get involved, because it is quite a long time I have been working with them." (Participant 10)

One participant from the National Malaria Control Program said that they did not have explicit procedures to select the task force members but they know them. Those who are called are the main stakeholders. One participant did not hesitate to express his frustrations on how members are selected.

"Sometimes I feel as if it is not adequate because if I did not contact those people with my research findings, I may not have been invited. So there might be other people who are in the field but because they have not made contact with Ministry of Health officials, they may not have a chance to be a part and parcel of the task force team." (Participant 7)

The issue of professional representation triggered conflicting views from the participants. The team was completely lacking anybody from the nursing profession. I observed during the interview that some participants had the perception that nurses were not required in the team. However other participants viewed the exclusion of nurses in the task force team as discrimination.

"I remember in the training the nurses were there but in the task force I don't remember exactly, the nurses were not there (...), I see it as discrimination." (Participant 9)

One participant went far to suggest that the Ministry of Health and Social Welfare is highly biased because of the domination of Medical Doctors.

"Myself I am a medical doctor, (...). Next time we expect to include the nurses, economists etc. The Ministry of Health is somehow biased, I can say is biased, the doctors are dominating." (Participant 9)

iii) Patient and Public involvement

Some participants said that patients were not involved in the process while some said patients were indirectly represented through research and their views were conveyed by the physicians who were part of the task force team.

"We got information, It was more of a surrogate representation because with clinical officers and medical officers, when they prescribe they get the information from patients and they told us what patients fill about malaria in generally, so it was more of a surrogate and not direct patient committee interaction" (Participant 2).

Regarding the involvement of the general public, some participants saw the inclusion of civil societies in the consultation process was the best way to get the voices of the general public in the process.

"*Members from the civil societies are expected to represent the views of the public, so they have got the voices of those people*" (Participant 9).

One participant however, had a different view and he argued that, since malaria affects almost everybody there was an assumption that all the team members were the patient representatives.

"Our aim at that time was to serve the patient and we are all potential patients, much as I am healthy and I am not on the bed I am also a potential patient, my wife is a potential patient, my child is a potential patient so taking somebody from the sick bed doesn't really add much of value." (Participant 12)

Other participants were very negative and view the idea of patient and public involvement in the policy discussion as inappropriate because it is an expert's field.

"This is a technical issue, and in technical issues you have to follow the expertise. From the technical point of view you don't include patients and general public. There can be a debate within the task force but you don't include the patient or public, they will not understand" (Participant 8)

iv) Consultations

Participants said many consultations were held before and even after the assembly of the task force. They ranged from individual persons, institutions, Non-Governmental Organizations, professional organizations to stakeholders meetings.

"I think, if you look at the task force on its own you will not know what proceeded before that. You might have a biased view and think that this task force was not representative enough. But it was the result of a lot of work before hand. For example professional bodies were contacted before even the task force got together. So information was collated in the task force but it was the culmination of a number of different forums to meet professionals, to meet individuals, to go to the communities. I know the background so I know it indeed take into considerations the other organs." (Participant 5)

Some participants shared with us that at times the draft document was sent to neighboring or partner countries to get technical advice from them. The first guideline draft was reviewed by experts from NIMR, CEEMI, Malaria Consortium-Kampala, WHO Afro, Medicins sans Frontiere, Ifakara Health Institute and Edwardo Mondlane-Maputo (Mozambique). The participants said that the participants from councils were involved, they gave inputs during the zonal training sessions which were conducted countrywide. The new policy was as well shared by all District Medical officers.

"We did a trial, pilot trial in various areas to see whether it was relevant and actually even the clinicians, the prescribers; the District Medical officers were also involved to get their inputs" (Participant 3)

3.2. Publicity condition: Evaluation

This condition falls short in some few critical areas.

1. Regarding the selection of Artemether-Lumefantrine; the decision to switch to Artemisinin Combined Therapies and the problem of parasite resistance to SP as a major reason was communicated through advocacy campaigns and publicity by National Malaria Control Program and the Ministry of Health and Social Welfare using different media. However, the rationales for selection of ALu among other Artemisinin Combined Therapies are not easily accessible by the public, patients and other stakeholders who were not directly

involved with the task force. These rationales are written on the main guideline document which is difficult to assess by health professionals in the private sector [74] as well as in the public health facilities.

2. The decision and the rationales for selective distribution of ALu are not public; patients wonder why they don't get the subsidized ALu when they go to some health care facilities where they are always given SP or Amodiaquine.

3. We found that the procedures by which some of the stakeholders were selected is not explicit. Some stakeholders were involved because of their positions in their organizations; however some were involved because they have links with MoHSW or NMCP, either through research or other activities. The major disadvantage of this approach is that you may end up missing important stakeholders who are in the field but have no contacts with the staffs at the MoHSW or NMCP and also it may constrain freedom of discussion with a fear of disrupting the existing working links.
4. The team lacked professional, institutional and countrywide representation. Professionally the team involved mostly medical doctors while other health care professionals like nurses were not there all and others were minimally represented. Nurses are key people in patient care and their contribution must be acknowledged even in policy change. The old era of Doctors dominance in patient care is over and does not fit in the modern patient care and above all is not focused at improving the health care delivery systems. There is no inclusion of practicing pharmacists who work in hospitals or those involved in dispensing in community pharmacies. We think proper representation of health care professionals including the nurses, medical lab personnel's, health officers and involvement of both patients and people from the general public would facilitate discussions on broad categories of issues with wide perspectives, which ultimately will enhance accountability for reasonableness.

5. We noted that almost all health care and academic members are from MNH or MUHAS

while there are other similar institutions in the country which could have been included. Even if the idea was to minimize costs, we think we must aim towards a wider and broader participation which will ultimately lead to acceptance and legitimacy of the policy. Broad participation is vehicle towards publicity and ensures that issues are optimally discussed in a wider perspective.

With these shortfalls we think the publicity condition was not fully satisfied for both drug selection and its selective distribution.

3.3. Relevance condition

i) Medical considerations

From the participant's responses and guideline review, it emerged that the issue of parasite resistance to SP was the major factor for National Malaria Treatment Policy change.

"The only thing we were guided by was the percentage of resistance, when we were changing from SP to ALu, people said that resistance to SP had exceeded 25% in those sentinel sites of Tanzania. When we reached 25% and above then we were told by WHO and by experts, those people who manage those sentinel sites that we have to change now. So we were guided by the level of resistance." (Participant 2)

The rationales for selection of ALu are explained in the guidelines as quoted below:

"SP resistance by that time was well above the upper limit. The ACTs recommended by WHO for all African region were limited, three choices were available at the time of policy change and these were; SP-Artesunate (SP-AS), Amodiaqine-Artesunate (AQ-AS) and Artemether-Lumefantrine (ALu). ALu was the only fixed combination drug among the three. Since the efficacy of ACTs is related to the efficacy of the individual components, the first

option (SP-AS) was considered as unsuitable because of SP resistance which was the basis for policy change. The two remaining choices had equal therapeutic efficacy hence other factors were brought into the discussion table to solve the puzzle. These other factors were; the potential for creation of parasite resistance, compliance and pharmacological safety profile. Amodiaquine, the component of AQ-AS combination had already shown some degrees of parasite resistance in the country and there were unproved concerns about the possibility of cross resistance with CQ. Amodiaquine safety profile had already created concerns among the health care providers and the general public. The negative perception and the risk of potential side effects were very much considered. Fixed combinations were found to have better compliance. On medical criteria therefore the task force recommended ALu to be the first choice in the management of uncomplicated malaria in Tanzania. ALu however is contraindicated to pregnant women in the first trimester and also to children of less than 5 kg because there was no enough research data to guarantee its safety in these two groups. Another issue was the fact that there was no liquid formulation for ALu during that time. Therefore the choice was very much constrained by these two issues so adjustments were done that in the first trimester Quinine will be used for pregnant women"[2].

ii) Affordability of Artemether-Lumefantrine

The participants acknowledged affordability of ALu was a very important issue. One participant emphasized that procurement of ALu by the Government funds would have slashed the Ministry of Health and Social Welfare's budget by more than half. They said however, that the issue of cost was not discussed because WHO had already agreed with Norvatis Pharma, the manufacturing company, to procure the supply of ALu at production cost and the Global fund had agreed to procure the drug for developing countries. Therefore ALu was going to be given free of charge or at very subsidized price.

"The issue of affordability came like this; there was an opportunity for us to get external funding through Global funds and WHO had already consulted with the pharmaceutical company, which was one pharmaceutical company at that time making ALu to get an

affordable price for the public sector. So this WHO had done, so if you go to private sector you will get the different price from what WHO had arranged with the company. So we said that if we could get funds through external funding then we could get ALu for the public sector, so we wrote the proposal to Global fund and we were successful." (Participant 12)

One participant however, expressed cautions regarding the sustainability and responsibility of recipient countries to deal with the health care problems of their people.

(...)but again there is an issue of being in control of your major health challenges, I mean as a country you can not just sit and wait to see that somebody is taking the burden of maintaining your population(...), imagine if Global fund for that matter does not keep on sustaining this". (Participant 12)

iii) Accessibility of affordable Artemether-Lumefantrine

This part mainly tried to look on the selective distribution of the subsidized ALu. The participants said that the subsidized ALu were to be accessed in public health care facilities and Faith based first, then later to Accredited Drug Dispensing Outlets. There were number of reasons given by the participants on this prioritization. First of all, they claimed that, Global Fund decided to fund the public and faith based organizations and this decision was very much supported by the local authorities because of the following factors:

i) There was a worry that the subsidy mechanism was not fully in place to involve the private sector
ii) The private sector would sell the drug for profit which wasn't the aim of the global fund
iii) The government had allocated a lot of funds to the public facilities hence people were encouraged to go there

iv) Those who go to private sector were viewed as those who can afford expensive medicines

v) The private sector was labeled as where malpractice and irrational dispensing are common and also the idea that the private sector are mostly in urban areas and offer service to 20% of the population only.

"The private sector was left out at that time. We thought because we are getting these funds Global Fund whom has decided to support government facilities and since we were starting we said ok lets start with the public facilities first and once the system is well established then we can go to the private facilities as well, and that's how it worked, because later on, the private sector was also brought on board. At that time the subsidy mechanism of these drugs have not yet been worked out so by involving the private sector it would have been a problem because the drugs would have been very high price and may be patients could not afford",... "So it was really because of the funding mechanism as the funders were ready to fund the public facilities only." (Participant 4)

One participant was uncomfortable with this selective distribution claiming it is unfair, and that the subsidized ALu should be accessible to everybody in all well functioning health care facilities.

"I think that is wrong, personally I think that is wrong. I think we should have ALu everywhere for everybody. The policy is for everybody, If you look in the policy guideline for Tanzania it does not say it is only for public, it caters for everybody in both private and public. I think it is wrong, It needs change, It is wrong." (Participant 2)

Another participant who works at a tertiary hospital expresses his concerns about what is really happening in the field and said the decision about the selective distribution of subsidized ALu was weak.

"That one is an area which really has a problem. Initially it started with the public and Faith based organizations.(...)This is a tertiary hospital and sometimes I receive patients from the dispensary they have been given SP and Amodiaquine and they sometimes ask why are they still prescribing this SP and Amodiaquine while we know the first line is Artemether-Lumefantrine? Unless when we have the mechanism to involve the private (...), may be this was the weakness." (Participant 10)

Another participant expressed his frustrations about the urban poor populations who have to make a choice between long waiting and unreliable public facility services and reliable but unaffordable services in the private sector.

"But on the other hand, of course we are shying away from the reality that even in the urban centers there are very poor populations as well. These have no choice, they either have to go to the crowded public facilities, they have to wait there sometimes up to 8 hours to see the clinicians and it is not even guaranteed that when they go to the dispensing window they will get the prescribed dose of ALu. So these are the challenges we have, may be there would have been other avenues to make sure everybody whether in urban or rural can have full access to subsidized ALu. We have a marginalized population in urban centers who are poor, who are struggling with daily lives, they have more health challenges than other people, I can imagine." (Participant 12)

iv) Cost-effectiveness of Artemether-Lumefantrine

Some participants said that there were no research studies by that time which indicated the cost-effectiveness of ALu compared to other drugs. Some of them mentioned issues of drug

misuse like treating any fever as malaria and compliance to treatment as some of the factors which determine cost-effectiveness. Others assumed that since the drug is most efficacious then automatically was going to be cost-effective because with time cases of malaria were going to decrease.

"It is not easy to say, there are a lot of issues one has to analyze before coming to that one.(...)I don't remember if there was any small scale study to evaluate the cost effectiveness of ALu versus the other. It is very difficult to make comment on that." (Participant 10)

However one participant said, through his clinical practice, the critical cases of malaria has decreased and he ascertains this to effectiveness of the medicine.

"Was not discussed, may be it needs some study. I don't know exactly how much but comparatively am seeing a lot of improvement. Even admissions, those ones with severe malaria, cerebral malaria with coma, now days they are few and this could be explained by the effectiveness of Artemether-Lumefantrine. As a tertiary hospital in the past we used to have a lot of patients coming in coma due to cerebral malaria but now days they are few, it is not a research data but anecdotal data." (Participant 10)

3.4. Relevance condition: Evaluation

i) Selection of Artemether-Lumefantrine

The change of National Malaria Treatment Policy to Artemisinin Combined Therapies was based on relevant evidence of parasite resistance to SP. The selection of ALu as the best choice among the available Artemisinin Combined Therapies was systematically done based on relevant evidences. Unlike other Artemisinin combinations, no resistance has been documented on the individual drugs which are co-formulated to make ALu and this is very strong evidence in antimalarial selections. However with this advantage over other drugs, ALu has its major disadvantage which lies on its large amount of pills the patients has to take, more

frequently, over a relatively long duration of treatment. Four tablets after every twelve hours, with fatty meals, for three days seems too much for patients who were used to single dose of three pills of SP. This has an impact on compliance and hence therapeutic effectiveness of the drug. There was no cost-effectiveness studies which were there to guide the selection process, instead the therapeutic efficacy was the only clinical evidence which was of help to the task force team. Even with these shortcomings, there was no any alternative option which the task force team would have looked upon.

ii) **Selective distribution of Artemether-Lumefantrine**

The reasons which were given for selective distribution of ALu to Public and Faith Based health facilities do not appeal to evidences. The justifications given are largely based on assumptions and negative perceptions about the private sector. We think well functioning and regulated private for profit health facilities and pharmacies were ideal channels to complement the public sectors so as to ensure many people have access to the drug since studies had already proved that. Contextual factors are very important as far as the policy implementation is concerned, failure to take them into consideration can lead to very poor policy outcomes.

Relevance condition on the selection of ALu is satisfied, contrary to the selective distribution decision.

3.5. Appeals and Revision condition

i) Appeals

There were different views from the participants regarding the issue of appeals. Their first impression on appeals was related to the complaints over safety issues of the selected drug. Accessibility in terms of drug availability or its affordability or individual preferences were not considered as relevant concerns that people may appeal for. The participants

acknowledged how difficult it may be for an individual person to challenge the policy decision unless has very concrete scientific findings presented in a scientific forum.

"I think the best way for those people to come up with challenges is to provide scientific data in the scientific forum, it is impossible for an individual to come up and say this is not the right drug just like they did to some other drugs, or some politician to say this drug is affecting people without coming up with proper scientific data. Because there are many issues that have to be taken on board when you want to challenge a particular policy, you really have to come up with concrete information to cement your challenge. To show that what you are saying had a meaning and not just a hear say or a shout over." (Participant 1)

Some participants mentioned the use of media especially the news papers as a mechanism by which the affected stakeholders can use to voice their concerns. However other participants argued that messages in the media are presented as blames rather than real scientific concerns.

"(...) from the community side, I think the only chance they have is to just to express in the news papers and other groups. But otherwise I don't see any other channels at the moment." (Participant 1)

Some participants suggested that their concerns can be channeled to the district all the way to the national level.

"The program works with the implementing organs, the districts. The districts work with the people so they receive the concerns then forwards them to the region then to the ministry of health, so that is the mechanism actually." (Participant 4)

Some participants mentioned Pharmacovigillence forms are the available tools to monitor safety profile of drugs but others questioned their reliability.

"But even the Malaria Control Programme itself apart from implementation of this new policy is also doing pharmacovigillence. That is trying to follow up to the users whether there is any adverse effects, collect this information, of course in collaboration with TFDA and then see if there is anything really coming up which needs to change treatment policy or anything like that. So from the treatment policy, itself, there are mechanisms of trying to tract if there are any adverse effects coming up from this drug. (Participant 3)

The use of pharmacovigillence forms was however challenged by other participants and considered unreliable.

"It is one avenue but it is not satisfactory, because most of our clinics are crowded, before you can take a minute or two to fill that form, twenty people are shouting at you. Attend this child who has high fever or take sometime filling this form and there no person around you who you could delegate such a function. That is a challenge. I think the adverse drug reactions are there and they will continue to be there. We need to set another mechanism to monitor drug effects. Depending on the yellow forms the way they are, it does not work." (Participant 12)

Another participant said that there is no organized mechanism by which the affected stakeholders can challenge the decision in light of new evidence or deliberations.

"I am not sure exactly if there a very organized mechanism but through the scientific forums can be possible." (Participant 4)

ii) Revision

There was much agreement in the discussion from almost all the participants that with established facts and evidence the policy decision can be revised even though it is difficult. However, the focus was mainly on the magnitude of side effects and resistance. Safety of

drugs and their effectiveness are seen as the only concern which can necessitate the revision of the policy decisions.

"I think it might be possible even though it is a little bit tough. It might be possible because the Ministry of Health and National Malaria Control Program are not working in isolation. So what made the policy to be changed is what will also make this policy to be changed if it doesn't work out basing on scientific facts which has been established." (Participant 8)

Another participant was more critical and said that the issue of side effects is rather individual based and can not be generalized to the whole population. Limited accessibility of ALu was not mentioned as a concern which can actually lead to revision of the decision.

3.6. Appeals and Revision condition: Evaluation

There was no uniformity among the various responses we got, and this suggests lack of mechanism for appeals and the unpopularity of the notion that policy decisions can be challenged once they are passed. The participants considered issues of side effects as the only concern which may necessitate decision revision. Limited access due to selective distribution of the drug was not their major concern. Lack of proper appeals mechanism made it difficult to agree with the optimism of the participant that the policy decision can be revised to accommodate new resolutions in the light of new evidence or deliberations.

The appeals and revision condition for drug selection and selective distribution were not fully satisfied.

3.7. Enforcement condition

The participants said that there was no third part organ, public or private which was there to enforce the other three conditions of AfR.

"From the Ministry part that was done but apart from that I don't think if there was any third party, and of course TFDA was on board, but apart from that I don't think there was any third party."(Participant 5)

Other participants suggested the community and WHO were the regulating organs, however others said WHO was involved as a partner to offer technical assistance rather than the enforcing organ.

"I am not sure if there was a watch dog, I think it is really very important, because sometimes people say may be the drug manufacturing companies is pushing for policy change and if we don't have it, then it is a problem." (Participant 10)

Some of the participants showed so much trust and belief on the process itself so that there was no need to have an enforcing organ.

"I don't believe so, because when we were developing the guideline, what we did is that the key stakeholder under the championship of National Malaria Control Programs was doing that. So the country through the Ministry of Health had to come up with some thing that will be implementable. So we believed in the process and as the government you have to believe in your organs to produce something that will be workable. Having a trust in these institutions, these key institutions which contribute to the implementation of policy to sit down together, I believe that was enough to make sure the guideline and the policy developed to be sound and fair to most areas of implementation"

Scientific evidence was also considered as enforcing mechanism by some members.

"The issue here is scientific evidence. Now scientific evidence is very clear, it has to be there, you may have a watchdog but if they don't understand the scientific basis of that evidence then they will be talking non sense. Here the watch dog it self is the science." (Participant 8)

The fact that the task force took on board the representative from various organs and institutions and that the Ministry of Health was keeping a close eye on the whole process and preserved the mandates of the final say, made some participants to conclude that such an organ was not necessary. However other participants disagreed with this suggestion and emphasized the importance of having independent enforcement mechanism during policy change.

"I am not sure if there was a watch dog, I think it is really very important, because sometimes people say may be the drug companies is pushing for policy change and if we don't have it is a problem."

3.8. Enforcement condition: Evaluation

The demand of enforcement was seen as new, awkward and finally unnecessary by some members even though others saw the logic it carries. This condition was not satisfied.

4. DISCUSSION

This study describes the long and complex sequence of events involving the change of Tanzania National Malaria Treatment Policy. This process bears all the characteristic of agenda setting and policy process as proposed in the Kingdon's three streams approach [34]. It carries all the features of other priority setting decisions which at all times involves the balancing of multiple, often competing goals and values in the context of diverse stakeholders relationships, limited resources and the vagaries of political cycles [75]. The influence of power and lobbying in this policy process are evident, some individuals and groups were better positioned than others to influence priority setting outcomes, and the owner of financial resources in this case the Global fun had the final say in determining the policy direction. Power differences extended down to professional status, historical dominance of particular health delivery system, patients versus clinicians, institutional status and reliability of research findings. These played a major role to fine-tune the outcome of the policy process. Power differences as we may have realized had the pre determining effects on issues which were discussed. The power differences affected how individuals and groups could have effectively participated in decision making process and ultimately undermined the overall legitimacy and fairness of priority setting decision outcomes.

When evaluated according to AfR we see that publicity condition is not fully satisfied. Publicity requires that the decision and its rationales be publicly accessible to clinicians, patients and citizens. Rationales such as the ones for coverage for new medicines such as ALu and the contents of drug formulary must be publicly accessible to the stakeholders. This study however found that the decision and rationales for selection and coverage of ALu are not publicly accessible. AfR requires those who we have put our trusts on, to make priority decisions to do so explicitly rather than assuming that keeping the decisions they make 'close to the chest' is the best way to manage painful priority setting decisions which set painful restrictions [76]. Publicity requires openness and transparency, however we found there was no explicit procedure to involve the stakeholders. Daniels and Sabin however argued that because we lack explicit and publicly endorsed mechanisms that can guarantee the selection

process as a form of democratic representation, then stakeholder's participation is neither necessary nor sufficient condition for establishing legitimacy. However, appropriately conducted stakeholders participation allows the discussion and consideration of broader range of issues aired in the decision making process and the participating stakeholders become a potential vehicle for achievement of publicity [4]. However, there are concerns about the perceived lack of knowledge of lay people in the area populated by professionals, the risk of populism and the perceived public resistance to be involved in rationing [77].

This study evaluated the composition of the task force, in terms of different categories of health care professionals, patients, institutions and country wide representation. We found that the team was largely made of medical doctors, four pharmacists and no nurse was included in the team. Patients were as well not directly involved in the team. This lack of enough representatives from other professions and patients was much based on the notion that medical doctors can represent the views of the patients better than other health care personnel's. We argue that, patient care is the responsibility of all the health care professionals even though their roles may differ. In many developing countries medical doctors spend very little with patients because of large numbers of patients they have to attend, and this put them in a difficult position to spend time long enough to get the feelings and views of their patients. Nurses have better interactions with patients, in hospitals for admitted patients because they are the ones who frequently administer medications and spent more time with them, obviously they can represent the views of patients in a much broader way.

Similarly the task force lacked institutional and national representation and we argue this can have negative impact to the acceptability and legitimacy of the priority policy decisions. Even though we argue for more professional and institutional representation, this should not aim to replace the patients and the public since there are evidences that health professional's views can considerably differ from those of their patients [78]. Therefore we should try to obtain the views of the public and patients totally uncontaminated by professional's views or information. There are different methods to engage the public in priority decisions. Some mass

approaches such as public meetings, telephone hotlines, advertisements in news papers, reply from simple questionnaires, large scale surveys using self completion questionnaires or interviews can be very useful [77]. Small scale discussions can as well be used to identify and assess issues of concerns to users or the public. Rapid Appraisal technique which was pioneered in developing countries to determine community views by interviewing key people (e.g teachers, home helps, corner shop owners, students etc) who are in touch with local opinion may as well be a useful technique [77]. Last on this part, we think to enhance AfR, the consumers or patient's need to be told the rationales of the decisions so that they can argue with full information even if they were not involved in the original priority setting decision.

We found that Relevance condition for selection of ALu is probably satisfied, contrary to selective distribution decision. Daniels and Sabin points out that the relevance condition does not mean that all parties will agree with the specific decisions made, rather most important is that those making the decision and those affected by it accept that the grounds upon which it is made are relevant [79]. The guideline document says explicitly that malaria parasites resistance to SP was the main driver of policy change, we must understand that SP was rather an interim choice in the first guideline change in 2001 from Chloroquine. Of all the other antimalarials which were recommended by WHO, ALu was seen as the optimal choice based on scientific evidence and arguments. However this choice was not supported by any economic evaluation studies on cost-effectiveness at the time of policy change, however studies conducted after the policy change indicated that ALu and AQ-AS were the most cost effective choice [80]. Clinical effectiveness which encompasses actual or projected benefits which may include reduction in morbidity or mortality, improved quality of life or other measures of positive outcome was the only available information for ALu [81]. For ALu to be cost-effective, reliable diagnosis and compliance to full course of treatment is crucial [80], however studies are showing that many doses of these effective and yet expensive drugs are lost due to unnecessary treatment of febrile episodes as malaria cases due to inadequate slide reading and symptomatic diagnosis [82, 83]. This misuse of effective and yet expensive drugs is a common practice in many places. On the other hand, the major disadvantage of ALu is its

long dosage regimen of many tablets which are taken more frequently, which determines the patient compliance and hence its field of clinical effectiveness. Regardless of these shortcomings on drug selection, the rationales given are reasonable in the context on which the decision was made.

Fully utilization of affordable Artemisinin Combination therapies due to limited access is still the most challenging task for many malaria endemic countries especially in Sub-Saharan Africa. It is well known that access of health care services in the public sector in many developing countries in the Tropic is inadequate due to multiple challenges which they are facing, including critical shortage of human resource for health, poor infrastructure and difficult working conditions [84]. Studies have shown that the private sector accounts for more than 80 percent of malaria treatment cases and pharmacies, drug shops and peddlers' accounts to 60 percent of all antimalarials used for treatment of malaria [9, 16], therefore I think prioritization of the public facilities on the first place didn't take into account this important factor. Big Hospitals and pharmacies had all the qualities to be used as access point for this medicine. Limited availability and accessibility of affordable Artemisinin Combination therapies have affected negatively the impact of these drugs in reducing mortality and morbidity due to malaria in the shortest possible time as was initially projected. Only few countries which have changed their national malaria policies to Artemisinin based combinations are in frame to achieve the Millennium Development goal of 50 percent reduction in malaria mortality [38].

Whenever possible, national authorities, donors and partners involved in the fight against malaria should design mechanisms to involve the Private for profit facilities as an attempt to increase coverage of effective antimalarials. Public Private Partnership (PPP) approach is an opportunity in Tanzania and other countries which should be utilized to its full potential in the fight against malaria. A combination of delivery, financial, and governance arrangements tailored to national or sub national contexts needs to be considered [85]. Donors should think

of adjusting their policies and fund the procurement of different Artemisinin based Combination drugs to make them affordable and accessible to both private and public facilities. The decision of the head of state to announce universal access to subsidized Artemether-Lumefantrine from both private, public and Faith Based Organizations is a necessary step in ensuring all patients have access to effective antimalarials [86]. The rationales for selective distribution of ALu therefore are not considered relevant because they don't appeal to evidence, reasons and principles which aim to meet health care needs fairly under this scarcity of resources.

The Appeals and revision condition was not satisfied. To my knowledge there are no formal appeals mechanisms in Tanzanian health care system for priority setting decisions related to access to new drugs or health care. This study did not find any explicit appeal mechanisms for the malaria treatment policy and it indicates how difficult it is for the affected stakeholders to interact with the policy process. I found no fully functioning mechanism for those affected by the priority decisions concerning the selection of ALu and the selective distribution to challenge it. The participants were narrowly focused on the side effects resulting from the use of Artemether-Lumefantrine as the only possible complaint which can be raised by the consumers. The lack of consensus among the participants on appeal mechanism suggests that good arguments which plausibly challenge the original decision can have no clear way back into the decision table. This creates a difficult situation to make any improvement on a fault policy decisions. There are complaints in the communities about the new drug and people usually use the newspapers to forward their complaints but the efficiency and usefulness of the use of newspaper is unknown [87].

The Enforcement condition was not satisfied. This condition recognizes that public regulation may be necessary if self regulation proves unsuccessful or inadequate. Some participants were explicit that there was no need of any organization to foresee the enforcement of other three conditions to ensure the policy by large aimed to benefit the public through a fair process. We

strongly differ from this suggestion and agree with other participants who suggested that the third party organ is important. In the presence of enforcement mechanisms we strongly believe that there would have been better involvement of patients, public and representation of diverse forms of health care professionals. This mechanism would have called for proper ways by which the concerns of the consumers could be channeled into the decision tables and cause the revision of the decisions.

4.1 Strengths of the study

The Qualitative research method enabled us to obtain detailed understanding of the policy change. Using other methods it is difficult to study complex phenomena where the researcher wants to capture views of individual persons, their feelings, their understandings, their interpretations, believes and ideologies. Problems related to issues of values and interests can not so easily fit in quantitative and statistical analyses methods of research. We conducted in depth interviews with task force members with wide experiences and perspectives which enabled us to get their deep seated understanding and perceptions. With this method the participants shared their views well beyond what we expected to hear and what is written in the literature. This method enabled to hear conflicting views from the participants. As far as we know, this is among few qualitative studies which map the malaria policy change process against AfR, a globally recognized ethical framework for priority setting decisions in health care.

4.2 Limitations of the study

We used Accountability for Reasonableness as an evaluative framework; although it has objections to its use as an approach to achieve justice and fairness [15, 88] and differences may exists between AfR's definition and participant's views on the concept of fairness and its evaluation. The results from the interviewed participants may not be general views of the whole group as we only interviewed part of the task force team who may not be the true representation of the group. As it emerged from the interviews, other decisions were made

before the task force assembly and other were not made by the task force per se. I therefore believe this study is missing views of other individuals at the Ministry level where most of these decisions were made. Due to resource and time constraints, we did not interview any individual from the consultation group or from the general population or patient representative, or health care professionals outside the taskforce team. We strongly believe, they posses important and reliable information related to this study.

Similarly, I realized when I had already started data collection that WHO had reached an agreement with the Norvatis, the Manufacturing Company and the sole supplier of ALu (Coartem®) to supply the medicines at production cost and the Global fund was the financing institution, we think we missed to interview responsible officials from these institutions, as they would have provided us with the full explanations on some aspects of their agreement including the details about the subsidy mechanisms and the distribution restriction imposed to other facilities. WHO officials were interviewed, but not specifically on the issue of Memorandum of Understanding with Norvatis. We regret not to have realized this earlier on before we were constrained by time.

4.3 Ethical dilemmas

With this study we were able to identify ethical dilemmas in the process of changing the National Malaria Treatment Policy.

First: The generalization problem

'To what extent should we allow parasite resistance among small proportion of people to outweigh more significant benefits to large group of people and vice versa?'

It has been recommended by WHO to change national malaria treatment policies when parasite resistance is 10 percent [3]. Change of malaria treatment policy in most cases is followed by banning the failing drugs from continuous use by the public as it happened to

Chloroquine and now SP. This is ethically controversial because resistance to small proportion of the population is generalized to the whole population which ultimately causes the change of first line drugs, and in effect, large proportion of people is forced to forgo more significant benefits. When resistance is 10 percent, it actually means that it is this proportion which needs the new effective treatment, and not the remaining 90 percent, however, it is the parasite which is resistant to the drug and not human beings. This means anybody can have the resistant strains. We argue that in a situation when there is no cross resistance between the failing drug and the new ones, may be banning the failing drug is not ethically acceptable. For those patients who use SP and get cured probably will not use ALu, only those who are not cured will go for ALu. If this approach is complemented with intensive public education on rational medication use, prevention strategies and proper diagnosis, we may get better results with fewer resources. The current interventions should aim to maximize the impact of the available resources.

Second: Unfair donor's requirements versus best outcome problem

'*How much priority should be given to the public facilities even when they can't meet all the population health needs?*'

Even though studies have shown that the public health facilities were incapable of meeting all the population health needs and that the private sector plays a major role in malaria case management, donor's and the manufacturing company insisted on funding and distributing the subsidized ALu through them. This is an ethical dilemma, where the drug is not accessible to areas where we expect to get the best outcomes simply because the donor and the supplier have the final say in whatever strategies the policy makers in recipient countries wish to implement. Policy makers were left with no choice in this dilemma but to agree with their requirements. It is even more ethically complicated when we consider that the same supplier had the same drug in the private for profit facilities, now how could they have allowed subsidized ALu to compete with another similar product of their own? The manufacturer of

ALu decided to pack the two products in different packages to differentiate the one in the private for profit and the subsidized one in public, Faith Based and Accredited Drug Dispensing health facilities.

Third: The sustainability problem

'For how long will governments in developing countries put the health of their citizens in donor's hands?'

Sustainability is very crucial in any health intervention program. The current approach of donor's financing does not offer long term survival strategy and it is unimaginable if donors were to stop to finance the procurement of the new antimalarials to most developing countries. Study participants said they were in dilemma of surrendering the responsibility of the Government to take care of their people's health problems in donor's hands. They asked what if they immediately stop, what will happen to the people? I think it is naive to think that the new drugs will led to sustainable achievements if other strategies especially improvement in infrastructure are not stepped up. While donors are helping, the recipient countries should invest heavily on prevention strategies so that even if funding is to stop at least they would have dramatically slowed down the vector transmission rates. Recipient countries have an obligation to meet the health needs of their people and they should not rely solely on donors.

4.4 Policy implications

Despite the fact that this study gives a snap-shot analysis and evaluation of one scenario of national level priority setting, it also offers some insight to numerous issues of policy importance.

1. Despite the unquestionable impact of painful limits imposed to those in need of particular services, this study found that the priority setting decisions are often made without

their direct involvement. Instead, decision making in priority setting is considered to be a technical area for experts only and as such, lay people would barely have a significant role to play. Views of experts are assumed to represent those of lay people in the society. However, this study indicated, priority settings being often characterized by politics and influence of those with authorities and power and largely they determine the outcomes of the whole process. At times, decisions are biased to their own interests. The said representations are neither sufficient nor adequate in guaranteeing that the voices of lay people in the societies are properly heard. This study suggests involvement of lay people and other stakeholders directly through personal representation complemented by inputs obtained from large scale survey studies, focus group discussions and by rapid appraisal methods among many other approaches to make sure that almost everybody is involved in the process. The study also suggests direct involvement of wide range of health care professionals, institutions and organizations across the whole country in opposite of the current dominance of one profession and lack of countrywide representation. This will increase the acceptability and legitimacy of the outcomes.

2. While task forces or committees are formed to oversee priority setting decisions, the whole process is conducted in ad hoc and under limited freedom to discuss issues of significant implications on the outcome of the process. As we have realized in this study, some decisions were made outside the task force and the members were literally informed on the details of those decisions. We suggest an explicit approach in priority setting by establishing favorable environment where issues are openly discussed.

3. It is said that beggars have no choice, but we suggest that donors and other partners should at times adjust their policies and interests to fit the local context of their recipient countries which are in desperate need of their help. Multiple types of Artemisinin based drugs from multiple manufacturers can be the best alternative approach rather than the current system of financing one drug from one manufacturing company for the whole country. The diversity of human beings could be taken into account as an important component which can

increase the acceptability and hence the effectiveness of the new policy because practically it is difficult for one drug to fulfill the preferences of all humans at all the time.

4. Reliable appeal and revision mechanisms need to be put in place to accommodate new findings, arguments and deliberations once priority decisions have been made. This will make the whole process of policy making to be continuous rather than an event. It was proved in this study that once the decisions have been made then ordinary citizens can not push their concerns back into the policy process, and as a result they use various channels mostly by writing articles in news papers, which we think is not an effective way.

5. CONCLUSIONS

The Ministry of Health in collaboration with the National Malaria Control Program and the task force committee were the three major organs which oversee the change of the National Malaria Treatment Policy change in Tanzania. We strongly commend their hard work even though the process failed to fully satisfy the requirements of fair process conditions as suggested in the accountability for reasonableness framework. Our findings are based on guideline document review and interviews with some of the task force team members. Although we believe we tried much to interview people with various diversity and perspective, we acknowledge their views might not represent the views of the whole group. One may argue that they worked under very limited resources and what is important is that people have access to effective antimalarial drugs, we think it is true but the end does not justify the means; justice requires fairness in setting limits even under considerable resource constraints. At times, health is determined more by fairness or unfairness of social structures than by medical or health services per se [89].

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