OBSTACLES TO MALARIA CONTROL POLICY IN NIGERIA: AN ASSESSMENT OF THE IMPACT OF COUNTERFEIT DRUGS AND REGULATORY POLICIES.

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Abstract  
The paper examined the obstacles that frustrate malaria control policy in Nigeria. Random sampling was used in choosing 6 states and 66 numbers of respondents by states for the study. Statistical tools such as, frequency tables; correlation coefficient and chi-square were used. The correlation coefficient revealed high correlation between counterfeit drugs and high failure rate of malaria control. The chi-square test revealed that drug regulation policies in Nigeria are effective, that the high rate of the fake drugs in Nigeria is as a result of other factors like insufficient enlightenment campaign and surveillance strategies by the National Agency for Food and Drug Administration and Control (NAFDAC). Some of the recommendations proffered are, that drugs for malaria treatment and control should be tested before use to ensure that they satisfy the anti-malaria treatment needs, there should be strict enforcement of drug registration guidelines. Drugs imported into the Country should be those whose quality certification can be readily obtained from local institutions.

Keywords: Malaria policy, immunization, insolubility of problem, drug

Introduction  
Globally, millions of deaths attributable to malaria are still being recorded. The disease has continued to constitute not only a huge epidemiologic burden in Africa but has also continued to cripple the economic development in the region. According to facts from Federal Ministry of Health (2008), it is estimated that approximately 30% of the Nigerian population live in areas of high to very high malaria transmission intensity while 67% live in the moderate transmission zone. In Nigeria, the disease is responsible for 60% outpatient visits to health facilities, 30% childhood deaths, 25% of death in children under one year and 11% maternal death (FMOH 2008). The estimated number of fever and malaria episodes per person and year is about 3.5 and 1.5 respectively for children under 5 and 1.5 and 0.5 for those 5 years and older and a total of 70-110 million clinical cases per year. The current malaria related annual deaths for children under 5 years of age are estimated at around 300,000 (285,000-331,000), and 11% of maternal deaths (FMOH 2008).

Malaria’s economic impact is enormous with about ₦132 billion lost to Malaria annually in form of treatment costs, prevention, loss of man hours etc. It has been estimated that malaria causes a loss of between 1-5% of total GNP annually in Nigeria (Leighton et al 1993). At the household level, it is estimated that between 3-11% of annual household income could be lost due to malaria from both lost workdays and treatment and control expenditures (Leighton et al., 1993).
Malaria eradication and the drug situation in Nigeria

Since the introduction of Roll Back Malaria (RBM) strategy, several efforts have been on course towards the reduction of the burden of malaria by formulation of strategic plans. The vision of the current five-year strategic plan (2009 – 2013) is to ensure that Malaria no longer becomes a major public health problem in Nigeria as illness and death from malaria gets significantly reduced. This is to be achieved by ensuring that families will have universal access to malaria prevention and treatment. The ultimate long-term vision is having “A malaria free Nigeria”. Consequently, some of the targets is to see that “at least 80% of fever/malaria patients receive appropriate and timely treatment according to national treatment guidelines and all (100%) pregnant women attending ANC receive at least two doses of Intermittent Preventive Therapy (IPT) by 2013” (FMOH 2008).

Drug treatment therefore is still recognized as one of the key control strategies to winning the war against the malaria scourge in Nigeria. This implies that accessibility, affordability and availability of efficacious drugs must receive due attention especially considering the fact that drug resistance has been one of the major obstacles to fighting the malaria war. Recently, the FMOH took another step towards making this vision a reality by launching the Affordable Medicines Facility for malaria (AMFm).

The Affordable Medicines Facility for malaria (AMFm) is an innovative financing mechanism designed to expand access to affordable Artemisinin-Combination Therapies (ACTs). The aim is to save lives and reduce the use of inappropriate treatments. The AMFm is an initiative hosted and managed by the Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund), with key financial support provided by UNITAID, the United Kingdom and the Bill & Melinda Gates Foundation and with technical support provided by the Clinton Health Access Initiative (CHAI). The first phase of the initiative is being implemented in eight countries: Cambodia, Ghana, Kenya, Madagascar, Niger, Nigeria, Tanzania (mainland and Zanzibar) and Uganda, in Nigeria the grant was signed on the 30th of September 2010 (National Mirror).

An assessment carried out by the FMOH that included a household survey found that 56% of respondents who were ill in the previous two weeks purchased drugs from a private seller compared to 35% who obtained drugs from a public health facility (FMOH 2008). There are 2,751 registered pharmacies giving a ratio of 42,421 people per pharmacy. The informal private sector consists of about 36,000 Patent Medicine Vendors (PMVs) (2002 estimates) and an unknown number of drug sellers.

Findings from a survey carried out in three regions of Nigeria indicated that Patent Medicine Vendors (PMVs) were the major source of malaria treatment (39% overall), followed by self-treatment (25%), which in many cases also utilize the PMVs (Oladepo, Salam, Adeoye and Osiname, 2007). Less than one quarter of all PMVs interviewed knew about the change in recommended malaria treatment from chloroquine and to ACTs. PMVs still recommended and provided drugs whose efficacy is highly questionable: 92% of shops had sulfadoxine-
pyrimethamine in stock, 72% had chloroquine (both not recommended), whereas only 9% had ACTs. More shops (32%) had monotherapy artesunates than ACTs, even though monotherapy is not recommended due to the risk of promoting drug resistance to artemisinins (Oladepo, Salami, Adeoye, Osiname, 2007).

By and large, laudable efforts have been made to stamp out or control the malaria scourge in Nigeria, but the impact is yet to be seen and felt. The high rate of counterfeit drugs in Nigeria may not be ruled out as a major cause of the insolubility of the problem. Fake, counterfeit, adulterated, substandard and unwholesome product by any name or definition is just as inferior in quality and efficacy. It is also deadly (Osakwe, 2000). At the first international meeting on counterfeit drugs, a workshop organized jointly by World Health Organization (WHO) and the International Federation of Pharmaceutical Manufacturers Association (IFPMA), a counterfeit medicine was defined as: “one which is deliberately and fraudulently mislabeled with respect to identity and/or source (WHO, 1999)”

Counterfeiting can apply to both branded and generic products. It may also include products with the correct ingredients or with the wrong ingredients; it may also come without active ingredients, with insufficient active ingredient or with fake packaging (Osakwe, 2000). World Health Organization (WHO), in its role as the directing or coordinating authority on international health matters and public health has adopted this definition as the primary definition of counterfeit products which other definitions are modeled after. Nigeria (miscellaneous provision) decree No. 25 of 1999 defines fake, counterfeit, adulterated, substandard and unwholesome drugs as follows:

(i) Any drug or drug product which is so colored, coated, powdered or polished that the danger is concealed or which is made to appear to be better or of greater therapeutic value than it really is.
(ii) Any drug which is not labeled in the prescribed manner or which label or container or anything accompanying the drug bears any statement, design or device which makes a false claim for the drug or which is false or misleading.
(iii) Any drug or drug product whose container is so made formed or filled as to be misleading.
(iv) Any drug or drug product whose label does not bear adequate directions for use and such adequate warning against use. Under following conditions:
   - certain contraindicated pathological condition
   - by children where its use may be dangerous to health
   - unsafe dosage
   - certain methods of duration of use.
(v) Any drug or drug product which is not registered by the National Agency for Food and Drug Administration and control under the food, drug and related product
The above comparative presentation of definitions of fake and counterfeit drugs by WHO and NAFDAC highlights the uniform global identification of the problem with allowances for peculiar situations. Circulation of fake and counterfeit drugs is a serious obstacle to realizing development policy objectives of the new states, especially Nigeria the Country of study. The seriousness of the problem requires critical and well articulated solutions.

**Statement of the problem**
Malaria remains a major public health problem in Nigeria. Despite laudable policies formulated by the successive governments in Nigeria to combat this menace, malaria has remained endemic. The numerous drugs available for malaria case management are substandard, fake or counterfeit. This may not be unconnected to prices and issues of affordability emanating from the high cost of Artemisinin-Combination based therapies. The problem may be responsible for the high rate of resistance of the parasite. The development of resistance has threatened the continuing usefulness of the available anti-malaria drugs.

The result of the drug efficacy carried out in the six geo-political regions of Nigeria in 2006 and 2008 revealed high rate of resistance (see table 1).

**Table 1: Therapeutic efficacy of anti-malaria drugs in Nigeria**

<table>
<thead>
<tr>
<th>SN</th>
<th>Zone</th>
<th>* Chloroquine</th>
<th>* Sulphadoxine</th>
<th>** Lumefantrine</th>
<th>** Amodiaquine</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>South-East</td>
<td>3.7%</td>
<td>14.9%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>2</td>
<td>South-South</td>
<td>9.1%</td>
<td>8.5%</td>
<td>87%</td>
<td>82.8%</td>
</tr>
<tr>
<td>3</td>
<td>North-Central</td>
<td>53.2%</td>
<td>82.7%</td>
<td>100%</td>
<td>96%</td>
</tr>
<tr>
<td>4</td>
<td>North-West</td>
<td>40.9%</td>
<td>75.6%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>5</td>
<td>South-West</td>
<td>40.9%</td>
<td>75.6%</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>6</td>
<td>North-East</td>
<td>50.8%</td>
<td>64.8%</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

* 2006 Drug Efficacy study  
** 2008 Drug efficacy study

From the table above, the problem of positive policy outcome as regards anti-malaria policy may largely be due to faking of malaria drugs. The proliferation of fake, counterfeit and substandard drugs tends to have worsened in the 21st century. The problem could be as a result of inefficient drug regulatory policy, high level of corruption by law enforcement agents. Several products
have fallen victim to faking by unscrupulous businessmen in Nigeria. Virtually all products regulated by NAFDAC are involved. There were however drug laws in Nigeria (with deficiencies no doubt). NAFDAC has made it mandatory that drug registration, whether locally manufactured or imported must be in place. Today there are many cases of adverse drug reaction. The weakest point in Nigeria drug regulation policy is probably in the area of implementation and enforcement.

In the light of the foregoing, the following questions become pertinent to guide this study.

1. To what extent has counterfeit drugs contributed to the high failure rate in the treatment of malaria?

2. To what extent has deficiency in drug regulation affected the implementation of national roll back malaria policy?

Objectives of the study

The broad objective of the study was to identify the obstacles to malaria control policy in Nigeria. The specific objectives of the study are (1) to determine if counterfeit drugs contributed to failure rate in the treatment of malaria, (2) to determine the extent to which deficiency in drug regulation has affected the implementation of National malaria control policy

Hypotheses

(1) Ho: There is no correlation between counterfeit drugs and high failure rate in the treatment of malaria.

\[ H_1: \text{There is correlation between counterfeit drugs and high failure rate in the treatment of malaria.} \]

(2) Ho: Deficiency in drug regulation policy is not a major determinant of the insolubility of National malaria control program

\[ H_1: \text{Deficiency in drug regulation policy is a major determinant of the insolubility of National malaria control program} \]

Theoretical Foundation

Malaria regulatory policy in Nigeria is expected to impact positively if well implemented. In the light of this, we have reviewed some salient theoretical paradigms on development and public policy and thus relate them to the study.

According to Chapel (1982), Okoye (2005), Thompson (2009), the theory of development follows in some respects from the doctrine of development policy. Its ramifications are complex
and diversified and as such a bit difficult to summarize. The theory gives a diagnosis of what is already on the ground, sets objectives and suggests ways of achieving them. The implications of the theory have been and still remain relevant.

The basic idea of the theory is that administration has decisive role to play in the effort to generate development. This, however, cannot be the traditional form of administration geared to the status quo, but must be an administration new in both structure and outlook. It must be dynamic and capable of bringing about and controlling change in the fields. It is the driving force behind development and must be able to cope with change.

In this theory, attention was thus turned to the most appropriate ways of passing from an administration which is essentially traditional in its form and functions to an administration which is able and specially geared to development via positive policy outcome (Uduji, 2008). The theory accordingly concentrated on specifying, in detail, the features, structures, machinery, attitudes and modes of behavior of such administration before considering the ways and means of establishing it in the most effective form.

The theory having gained much from a large quantity of work and many successful experiments carried out in developed nations, as well as multidisciplinary research, with the passage of time, came out with the realization, that effective policy implementation is very essential for development.

In the theory, argues Sharma (2008) two things are to be noted from the point of view of adaptation to the socio-economic developmental circumstances:

(a) As it is an innovation, development administration breaks with the heritage of the past, whatever this may be. Its establishment, at least in theory, affords extensive scope for original creation or hold adaptation. One of its tasks, for example is to stimulate public participation in development, which implies careful attention to socio-cultural circumstances. Development administration must not, in fact, be viewed simply as a set of structures tending towards technocracy and isolated from the social context. There is no doubt, however, that structures of this kind are needed, and this directly raises the problem of the administrative capability of each country to provide itself with such structures and to make them work, often using advanced technique or advanced management methods which may not correspond with the environment.

(b) One of the distinctive features of the theory of development administration is the stress laid on the measures which must be taken to influence socio-economic and socio-cultural conditions, including a sustained effort to initiate and further training for those involved in policy implementation. This provides a new approach, as regards both ideas and methods, to the traditional form of policy education. When given locally, it facilitates the necessary change of attitude and makes the technological transfers required easier to effect.
Development theory and policy implementation

Implementation of public policy appears to be more important than the formulation contends Chukwuemeka (2009). Implementation of public policy therefore refers to those activities directed towards putting a project into effect (Onyishi, 2009). The process involves organizing the bureaucracy, marshalling out resources, assigning duties and responsibilities and also making interim decision. It is usually at the policy implementation stage that interest groups and individuals become aware of the assistance of a new policy and usually try to push for either its modification or total rejection. In a given nation be it new or developed nation, policy is implemented by a complex system of administrative agencies, departments and sub-departments. For instance the health department has strong role to play to ensure that malaria control policy achieve the intended impact.

For policy implementation to be effective and successful, the following strategies have to be taken into consideration (Bryan, 2008):

(a) Communication: For implementation to be effective and successful, those to implement must know what they are expected to do. Communication is very vital to ensure that all the stakeholders are duly informed of the policy. The orders must be clear, accurate and consistent. There must be no ambiguity. The distortion must be minimal unless the communication is clear, it will be subject to bureaucratic predation. Poor communication always leads to crisis whether in the family, government or organization or at community level.

(b) Resources: The resources must be there so as to ensure effective policy implementation. There must be adequate staffing, procurement of genuine drugs (malaria policy) etc. In effect, all the necessary structures must be there. Unless the resources are there, the implementation of the policy will be very poor and impact not felt.

(c) Disposition of policy implementer: The disposition and attitude of the policy implementer distorts or enhances policy implementation. The policy implementer must have the desire to carry out the policy to avoid frustration.

(d) Bureaucratic structure: Organizational fragmentation may hinder the coordination of a complex policy requiring the cooperation of many people, division of function can impede the implementation of policy. Rigid rules and regulations can constitute an obstacle; it minimizes the use of initiative and the use of discretionary powers.
(e) Monitoring and evaluation: Most policies are formulated and thereafter the implementation is neither monitored nor evaluated. To minimize the effect of the aforementioned problem, there must be continuous monitoring and evaluation of the implementation process.

**Methodology**

The study was carried out in six states of the Federal Republic of Nigeria, namely: Anambra, Abia, Delta, Ebonyi, Enugu and Imo. The Ministry of Health was studied in each of the selected states.

The study population consisted of management staff of Ministry of Health in each of the six states. Seventy one people were randomly selected from Enugu, while sixty six (66) people were selected from the rest of the five states. The list of the people sampled was drawn from the staff nominal roll. Most of the staff sampled belonged to the policy formulation and implementation categories.

Data for the study were collected from both primary and secondary sources. The primary data were collected using structured questionnaire administered to staff of the Ministry of Health in the selected areas of study. However, focus group discussion was used to elicit data from key staff of NAFDAC office in Enugu. Information sourced included: origin of NAFDAC, National Health policies, drug resistance, health policy implementation, health development, list of blacklisted drug manufacturers in Nigeria and overseas, sample of fake, counterfeit and substandard drugs, list of sanctioned drug importers and marketers.

The questionnaire was administered by the researchers and research assistants across the states selected for the study. A combination of some form of participant observation especially where the researchers were allowed to attend seminars organized by the sampled organizations was also employed. The secondary data were collected from relevant NAFDAC publications, books, journals, bulletins, periodicals, monographs and reports.

The tools used for data analysis were correlation coefficient and chi-square.

<table>
<thead>
<tr>
<th>State</th>
<th>Questionnaire Distributed</th>
<th>Questionnaire Returned</th>
<th>Questionnaire Not returned</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abia State</td>
<td>66</td>
<td>59</td>
<td>07</td>
</tr>
<tr>
<td>Anambra State</td>
<td>66</td>
<td>63</td>
<td>03</td>
</tr>
<tr>
<td>State</td>
<td>Cases</td>
<td>Success</td>
<td></td>
</tr>
<tr>
<td>--------------</td>
<td>-------</td>
<td>---------</td>
<td></td>
</tr>
<tr>
<td>Delta State</td>
<td>66</td>
<td>60</td>
<td>06</td>
</tr>
<tr>
<td>Enugu State</td>
<td>71</td>
<td>68</td>
<td>03</td>
</tr>
<tr>
<td>Ebonyi State</td>
<td>66</td>
<td>56</td>
<td>10</td>
</tr>
<tr>
<td>Imo State</td>
<td>66</td>
<td>54</td>
<td>12</td>
</tr>
<tr>
<td>Total</td>
<td>401</td>
<td>360</td>
<td>41</td>
</tr>
</tbody>
</table>

*Source: Field Survey, 2009*

Percentage of questionnaire returned: $QR = \frac{TQD - QNR}{TQD} \times 100$

Where $QR = \text{Questionnaire returned}$  
$TQD = \text{Total questionnaire distributed}$  
$QNR = \text{Questionnaire not returned}$

From the above:

$QR = \frac{TQD - QNR \times 100}{TQD}$

$TQD = 401 - 42 \times 100$

$= 360 \times 100$

$\frac{401}{401} = 89.8\%$

**Test of hypotheses 1:**

**Table 3 – Daily record of success rate in malaria treatment**

<table>
<thead>
<tr>
<th>Day</th>
<th>No. of malaria cases treated (X)</th>
<th>Success rate (Y)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>6</td>
<td>2</td>
</tr>
<tr>
<td>2</td>
<td>8</td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>10</td>
<td>1</td>
</tr>
<tr>
<td>4</td>
<td>7</td>
<td>1</td>
</tr>
<tr>
<td>5</td>
<td>10</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>41</td>
<td>07</td>
</tr>
</tbody>
</table>

*Source: Field survey, 2009 (information sourced from records by Dr. E. Eze of Ebonyi State General Hospital between Monday 6th – 10th February, 2009)*
Table 4 – Correlation coefficient table

<table>
<thead>
<tr>
<th>X</th>
<th>Y</th>
<th>X-(\bar{X})</th>
<th>Y-(\bar{Y})</th>
<th>(X-(\bar{X}))^2</th>
<th>((\bar{Y})-Y)^2</th>
<th>(X-(\bar{X})) (Y-(\bar{Y}))</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>2</td>
<td>-2.2</td>
<td>0.6</td>
<td>4.84</td>
<td>0.36</td>
<td>1.32</td>
</tr>
<tr>
<td>8</td>
<td>2</td>
<td>-0.2</td>
<td>0.6</td>
<td>0.44</td>
<td>0.36</td>
<td>0.12</td>
</tr>
<tr>
<td>10</td>
<td>1</td>
<td>1.8</td>
<td>-0.4</td>
<td>3.24</td>
<td>0.16</td>
<td>0.72</td>
</tr>
<tr>
<td>7</td>
<td>1</td>
<td>-1.2</td>
<td>-0.4</td>
<td>1.44</td>
<td>0.16</td>
<td>0.48</td>
</tr>
<tr>
<td>10</td>
<td>1</td>
<td>1.8</td>
<td>-0.4</td>
<td>3.24</td>
<td>0.16</td>
<td>0.72</td>
</tr>
<tr>
<td>41</td>
<td>7</td>
<td>0</td>
<td>0</td>
<td>13.2</td>
<td>1.2</td>
<td>3.36</td>
</tr>
</tbody>
</table>

Source: Compiled from table 3

\[ r = \frac{\sum(X-\bar{X})(Y-\bar{Y})}{\sqrt{\sum(X-\bar{X})^2 \sum(Y-\bar{Y})^2}} \]

\[ r = \frac{3.36}{3.36(1-09)} \]

\[ r = +0.84 \]

From the above analysis, 0.84 indicates that there is a strong positive correlation between counterfeit drugs and high failure rate in malaria treatment and control program in Nigeria.

**Hypothesis two:**

Ho: Deficiency in drug regulation policy is not a major determinant of the insolubility of the national malaria control policy.

H1: Deficiency in drug regulation policy is a major determinant of the insolubility of the national malaria control policy.

Table 5 – Respondents’ view on drug regulation
Question: Do you think that the drug regulatory policies in Nigeria are efficient?

<table>
<thead>
<tr>
<th>State</th>
<th>Yes</th>
<th>No</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abia</td>
<td>30(34.2)</td>
<td>29(24.7)</td>
<td>59</td>
</tr>
<tr>
<td>Anambra</td>
<td>29(36.5)</td>
<td>34(26.4)</td>
<td>63</td>
</tr>
<tr>
<td>Delta</td>
<td>30(34.8)</td>
<td>30(25.1)</td>
<td>60</td>
</tr>
<tr>
<td>Enugu</td>
<td>40(39.4)</td>
<td>28(28.5)</td>
<td>68</td>
</tr>
<tr>
<td>Ebonyi</td>
<td>43(32.5)</td>
<td>13(23.4)</td>
<td>56</td>
</tr>
<tr>
<td>Imo</td>
<td>37(31.3)</td>
<td>17(22.6)</td>
<td>54</td>
</tr>
<tr>
<td>Total</td>
<td>209</td>
<td>151</td>
<td>360</td>
</tr>
</tbody>
</table>

Source: Field Survey (2009)

Table 6 – Chi square test of independence for observed and expected frequencies.

<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0</td>
<td>E</td>
<td>0-E</td>
<td>(O-E)^2</td>
</tr>
<tr>
<td>Yes</td>
<td>30</td>
<td>34.2</td>
<td>-4.2</td>
<td>17.64</td>
</tr>
<tr>
<td></td>
<td>29</td>
<td>36.5</td>
<td>-7.5</td>
<td>56.25</td>
</tr>
<tr>
<td></td>
<td>30</td>
<td>34.8</td>
<td>-4.8</td>
<td>23.04</td>
</tr>
<tr>
<td></td>
<td>40</td>
<td>39.4</td>
<td>0.6</td>
<td>0.36</td>
</tr>
<tr>
<td></td>
<td>43</td>
<td>32.5</td>
<td>10.5</td>
<td>110.25</td>
</tr>
<tr>
<td></td>
<td>37</td>
<td>31.3</td>
<td>5.7</td>
<td>32.49</td>
</tr>
</tbody>
</table>

| No  | 29   | 24.7 | 4.3  | 18.49   | 0.74    |
|     | 34   | 26.4 | 7.6  | 57.76   | 2.18    |
|     | 30   | 25.1 | 4.9  | 24.01   | 0.95    |
|     | 28   | 28.5 | -0.5 | 0.25    | 0.00    |
|     | 13   | 23.4 | -10.4| 10.16   | 4.62    |
|     | 17   | 22.6 | -5.6 | 31.36   | 1.38    |
|     | 160  | 359.1| 0    | 480.06  | 17.00   |

Source: Field Survey, (2009)

Decision Rule

Accept ho if tabulated value (T.V) \( \geq \) Calculated value (CV) \( \ldots \ldots \) (1)

Reject ho if T.V. \( \leq \) C.V \( \ldots \ldots \) (2)

Table 6 analyzed
At 0.05 significance level, degree of freedom (df) = (r-1) (c-1)
Df = (2-1) (6-1) = 5 x 1 x 5
TV = 11.070
CV = 17.00

**Decision**

Since TV is less than CV at 5% significance level, we accept the Ho that deficiency in drug regulation policy is not a major determinant of the insolubility of the National malaria program and reject H₁, the alternative hypothesis that deficiency in drug regulation policy is a major determinant of the insolubility of the National malaria control policy.

**Findings and Discussions**

The study revealed that the health policies in Nigeria, especially that of roll back malaria are managed by high incidence of counterfeit and substandard drugs. Data collected from health publications indicates that only about 10% of Nigerians have access to essential and genuine drugs. Physicians per 100,000 people were fewer than 30. The effectiveness of immunization had dropped from 40% in 1990 to 30% between 1996-2009 (Ugwu, 2009). Other factors that were discovered to impinge on the malaria control policy includes poor environment which encourages mosquito breeding. Access to safe drinking water in 2009 was limited to about 50% of the population and less than 40% of the population had access to safe drinking water, as against about 80% in urban areas (NBS, 2009).

The Federal Government of Nigeria document on anti-malaria treatment policy (2009), revealed that 80% of malaria cases are inadequately managed at community level largely due to facilities and inability to differentiate between counterfeit and genuine drugs. Ninety-six percent of the caregivers initiate actions within 24 hours but only 15% of their actions are appropriate due to inadequate dosage resulting from the substandard nature of the malaria drugs. In spite of the fact that only 50% of anti-malaria drugs are produced in Nigeria those imported are not even safe from being faked because it is the same corrupt businessmen in Nigeria that import them. 51% of mothers obtain drugs from patient medicine vendors. 89% of the drugs were found to be substandard and 45% of syrups unsatisfactory (FMOH, 2009).

The study also revealed that the drug regulatory policies in Nigeria are more than efficient. The implementation is also efficient. Time and time again television telecast and radio broadcast show a number of pharmacy companies that were sealed up or drugs suspected to be unsafe burnt by NAFDAC. In spite of that, more and more unscrupulous Nigerians are still engaging in counterfeit drug manufacturing and importation. From NAFDAC publications (2009), a number of pharmaceutical companies in Nigeria, Asia, and Europe have been blacklisted and published. Also comparative listing of WHO and NAFDAC fake/counterfeit drugs has been done.
NAFDAC has also mapped out some strategies for eradicating fake drugs and strengthening regulatory activities. They are:

(a) Public enlightenment campaign

(b) Stopping the importation of fake drugs to Nigeria at source (countries of production)

(c) Monitoring GMP or local manufacturers

(d) Beefing up of surveillance at all ports of entry

(e) Mopping up what is already in circulation

(f) Streamlining and strict enforcement of registration guidelines, staff re-orientation and modernization of the regulatory processes (Abanum, 2009).

**Recommendations**

In order to stamp out the high incidence of counterfeit drugs and make malaria control policy more purposeful, a number of things have to be done:

(a) Effective public enlightenment campaigns should be mounted and should cut across all the sector of the Nigerian society.

(b) There should be more purposeful efforts to stop the importation of fake drugs into Nigeria at source (countries of production).

(c) Surveillance on fake and counterfeit drugs should be beefed up at all ports of entry and inside the Country. This will mean increasing the number of people working for NAFDAC. The law enforcement agents should get involved.

(d) Counterfeit drugs already in circulation should be mopped up.

(e) There should be monitoring of GMP of local manufacturers

(f) Streamlining and strict enforcement of registration guidelines, staff re-orientation and modernization of the drug regulatory processes should be intensified.

(i) Drugs for treatment and prevention of malaria should be tested to ensure that they satisfy the roll-back malaria needs of the vast majority of the people at all levels of health case.

(s) There should be drugs for which quality certification can be readily obtained from local institutions, from which the country of origin or through the auspices of the World Health Organization.

**Conclusion**

For Nigeria to stamp out malaria scourge through the various malaria control programs, there should a drastic reduction of fake/counterfeit drugs. If this is achieved, Nigeria will be a model that will be comparable to other advanced countries of the World.
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