Perception of Nigerians on the Use of Information Technology in Managing Counterfeit Drugs II: Detection of Counterfeiting

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ABSTRACT

In Nigeria, ill-implementation of the National Drug Policy, in addition to other factors, contributed to the widespread of counterfeit drugs, though many international organizations are concentrating their activities on how to fight these drugs. Almost all these efforts are focused on various stages of pharmaceutical manufacture and distribution chain, while less or rare efforts are invested at terminal intervention by the end users. This study focuses on end users. The paper is concerned with the detection of counterfeit and sub-standard drugs by end users in the six geopolitical zones of the Federal Republic of Nigeria, namely South-West, South-South, South-East, North-East, North-West and North-Central. That is, a pilot study was conducted to identify capability of Information Technology to detect counterfeit drugs in Nigeria. A total of 1800 questionnaires were distributed at random, using simple sampling technique, across the six geopolitical zones. Out of this, 1501 responses (83.4%) were received and 1391 were valid. The 1391 valid participants were selected for the study. Both descriptive and inferential analytical methods were used via the Statistical Package for the Social Sciences (SPSS) version 20. PHP (Hypertext Preprocessor) is the scripting language used at the server-side of this paper. The authors examined the role of information technology as a tool for reducing counterfeit drugs in Nigeria. Majority of respondents indicated that they were not aware of the use of information technology to detect fake drugs. It was observed that the level of awareness about Information Technology on fake drug management is low compared to awareness on technology devices. This study concluded on the need for medication user to have a tailored information system to address the issue of counterfeit drugs in Nigeria.

Keywords: *Counterfeit (Fake) drugs, Health Information System, SPSS, ANOVA, PHP, The six geopolitical zones of Nigeria*

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1. INTRODUCTION

Counterfeit drugs are giving sleepless nights to international bodies, governments, pharmaceutical companies, healthcare providers, counsumers and others. Many laws and decrees were issued on the sales of counterfeit drugs but without technological intervention, it cannot see the light (Isah, 2012).

Technology acceptance research is not a new field anymore, has been active for more than 20 years and can be found in every field of life. Many researchers design several theoretical models that explain the acceptance behaviour of end users of latest information technologies (Alomary and Woollard, 2015).

One of the well-known models related to technology acceptance and use is the technology acceptance model (TAM) (Bosede, 2015). This model was originally proposed by Fred Davis (Davis, 1989). TAM has proven to be a theoretical model in helping to explain and predict user behaviour of information technology. TAM is considered as an influential extension of theory of reasoned action (TRA); Researchers proposed TAM to explain why a user accepts or rejects information technology by adapting TRA. TAM also proposes that external factors affect intention and actual use through mediated effects on perceived usefulness and perceived ease of use. The perception of respondents in this study may be influenced by several variables.

According to the TAM, if a user perceives a specific technology as useful, he will believe in a positive use-performance relationship. Since effort is a finite resource, a user is likely to accept an application when he perceives it as easier to use than another. Gaining an understanding of user beliefs regarding a system is important since they may influence acceptance and usage.

Counterfeit means the act of making a product to look like the original of its nature, usually for making money by dishonest or illegal purposes. World Health Organization Scientific Group has defined a drug as "any substance or product that is used or intended to be used to modify or explore physiological system or pathological states for the benefit of the recipient" (WHO, 2007).

To overcome and minimize the risk of counterfeit drug at User side, there is the need for development of an Information System which will enable End-User to check for authenticity of the medication in addition to be able to confirm the product at hand, therapeutic use, dosage form, manufacturer and additionally expiry date.

World Health Organization (WHO) defined Counterfeit Medicine as "one which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredient or with fake packaging" (WHO, Counterfeit Drug, 1999).

Nigeria, like many other nations, recognizes the importance of protecting its citizen from the danger of fake and substandard products. To keep human life safe is considered as a top priority of any administration in the government bodies. The need for regulating and controlling of product activities, importation to the country, exporting of products out of the country, advertisement of consumable products, the distribution, sale and use of food, drugs or medicines and others related consumable products is what gave birth to the establishment of Nigeria's National Agency for Food and Drug Administration and Control (NAFDAC) by the Federal Government of Nigeria. With inspiration from a 1988 World Health Assembly resolution which requested countries' to assist in fighting the global danger posed by counterfeit drugs, Nigeria's NAFDAC was established to ensure the eradication of counterfeit pharmaceuticals products and other consumables that are imported to Nigeria.

NAFDAC has since raised awareness about counterfeit drugs and its complications in Nigeria and also in other countries. NAFDAC has effectively created 6 zonal offices and 36 state offices and all offices are equipped properly to perform the agency's function. Creation of the zonal offices and state offices was aimed at making the services accessible to stakeholders. (NBS, 2015). Figure 1 shows officers of NAFDAC and Nigeria's National Drug Law Enforcement Agency (NDLEA) in action, destroying counterfeit drugs seized from fake drugs dealers during their patrol.

The problem of Counterfeit Drugs, according to World Health Assembly, is that Information on the scale of the problem is inadequate and there are little global studies conducted (WHO, Counterfeit Drug, 1999).

In an earlier paper (Amusa & Oluwade, 2019A), the focus was on the perception of Nigerians with respect to information technology use in preventing counterfeit drugs. The present paper is concerned with the detection of counterfeit drugs. Besides trying to detect counterfeit drug, the present paper deals with the detection of sub-standard products. It will also contribute to the principle of pharmaco-vigilance which is aimed at improving patient care and safety in relations to the use of medicine and to help in mitigating medication errors (Amusa & Oluwade, 2019B).

2. LITERATURE REVIEW

Some of the techniques and strategies employed in combating counterfeit drugs include Radio Frequency Identification and Detection (RFID), Near Infrared Spectroscopy, Raman Spectroscopy, Fluorescence and Phosphorescence measurements, Nuclear Magnetic Resonance imaging, X-ray and radio frequency analysis, tamper resistant tape, fingerprints, holograms and colour-shifting inks and dyes (Nuhu, 2011) (Ortiz et. al., 2012).

In the light of her contribution to the combat against counterfeit drug, the Nigerian authority issued a directive under the 'Nigerian Counterfeit and Fake Drugs and Unwholesome Processed Foods - Miscellaneous Provisions – Decree' and defines counterfeit medicine as " any drug product which is not what it purports to be; or any drug or drug product whose container is so made, formed or filled as to be misleading; or any drug product whose label does not bear adequate directions for use and such adequate warning against use in those pathological conditions or by children where its use may be dangerous to health or against unsafe dosage or methods or duration of use; or any drug product which is not registered by the Agency in accordance with the provisions of the Food, Drugs and Related Products" (Clift, 2010). This definition is more holistic and it covers both counterfeit and sub-standard drugs that may find their way in circulation.

Evolution of smartphone and its application can also be employed in the fight against falsified drugs. That is, the examination and analysis which are normally done in the laboratory can be easily done with smartphone. According to (Yu et. al., 2016), image processing approaches were developed to enable image processing to be performed locally with the smartphone processor, and it can even be examined remotely by connecting to a server at the laboratory. Researchers demonstrated identification and characterization of pharmaceutical products via Thin Layer Chromatography (TLC). Using a custom cradle which interfaces with a smartphone, this process serves to detect counterfeit drugs in circulation.

The World Health Organization (WHO) created IMPACT (International Medical Products Anti-Counterfeiting Taskforce) (IMPACT, 2006). The taskforce has been active in building international collaboration that (1) seeks solutions to the worldwide counterfeit drug challenge and that (2) raises awareness of the dangers of counterfeit medical products. IMPACT also emphasizes the priority action which countries should take to combat the counterfeiting, such as strengthening legislation. IMPACT further revealed that counterfeit drugs is a lucrative industry because of high demand. Also, counterfeiters do not need large facilities or infrastructure; small backyards or ordinary house space is sufficient to carry out their activities. Figure 2 shows the flyer designed and distributed by International Medical Products Anti-Counterfeiting Taskforce to serve as means of awareness for the public and other stakeholders in combating counterfeit pharmaceutical products. The image was released during the campaign of IMPACT on counterfeit drug.

(Sakamoto et. al., 2017) contributed to on-going fight against counterfeit drugs by presenting a study using the characteristic terahertz spectrum based on the manufacturing process which can be utilized as fingerprint information to detect fake counterfeit drugs (Sakamoto et. al., 2018). Some manufacturers go beyond the normal process and use the technology of softgel (a pharmaceutical dosage form just like usual capsule, but used to encapsulate liquid drug) to protect the authenticity of their products. In 2015, at anti-counterfeiting conference in Xiamen-China, (Zheng et. al., 2015) proposed a machine vision system for special shaped softgel inspection which can be used to detect counterfeited or sub-standard softgel dosage form pills.

Godlee (2012) reported that the world currently has tighter laws to tackle fake tobacco products than it does to tackle fake drugs. The result is that fake and substandard drugs continue to harm and kill people around the world, affecting both proprietary and generic drugs, and haunting rich countries as well as poor (Godlee, 2012). Figure 2-1 shows the counterfeit incident regions of the world.
In addition, a survey conducted by a team of researchers at Department of Pharmaceutical Technology and Industrial Pharmacy, College of Pharmaceutical Sciences, University of Nigeria, Nsukka, Enugu State, Nigeria and Department of Pharmaceutical Microbiology, Faculty of Pharmaceutical Sciences, University of Port Harcourt,

Rivers State, Nigeria shows that storage practices by patent medicine stores and homes are poor when compared to hospitals (Obitte et. al., 2009). The study also revealed that NAFDAC in recent times achieved a great feat by at least closing down Onitsha drug centre in Eastern Nigeria. Onitsha market is considered as a major illegal regional drug market and other counterfeited goods in Africa. The market has been levelled with charges of stocking fake and adulterated drugs.

Radio Frequency Identification technology (RFID) was and is still employed in the pharmaceutical distribution and supply chain. Its short-coming however is that it is not applicable to the pill level; it can be used only for packages and containers. Counterfeiters can easily use this flaw in RFID to carry out their malicious action via cloning attack on the entire RFID systems. To address this problem (Yang, Botero, Shen, Forte, & Tehranipoor, 2017) proposed pill-level Unclonable Chipless RFID (UCR) which can be employed to detect fake drugs at pill level.

3. METHODOLOGY

The methods used in this paper are similar to those in the authors' earlier paper (Amusa and Oluwade, 2019A). The investigation conducted could be considered as exploratory and descriptive. It sought to determine the present awareness and satisfaction of the population with current technology services used in combating counterfeit drugs in Nigeria. The target population is the set of all Nigerians who use mobile telephone.

3.1 Data Collection

The survey method was used wherein data were collected from participants at selected areas in each of the 6 geopolitical zones of the Federal Republic of Nigeria namely, South-West, South-South, South-East, North-East, North-West and North-Central as shown in Figure 3. The target samples to represent the population were those who can easily identify English letter alphabets. 300 questionnaires were distributed equally at each zone making a total of 1800. For the Secondary sources, some data were collected from the Nigerian National Bureau of Statistics (NBS) Nigeria (NBS, 2017) and the National Information Technology Development Agency (NITDA) Nigeria (NITDA, 2017).

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Explanations on the components of the figure are provided below:

1 - Mobile User: Anybody using or operating mobile phones (in this study, user who sends text message enquiring for appropriate response from the content provider)
2- Cell Tower or Base Station: A base station is a transmitting tower mounted at suitable places to be able to transmit and receive enough signal for proper communication with mobile phones up to few kilometres. Cell Towers transmit radiation continuously, so people living within 10's of meters from the tower will receive 10,000 to 10,000,000 times stronger signal than required for mobile communication (Kumar, 2010).
3- SMSC Service Provider: When a user sends a text message to another user (in this study to Drug Regulatory Agency), the phone actually sends the message to the SMSC, which stores the message and then delivers it when the recipient is on the network, the SMSC access protocol which is Short Message Peer-to-Peer (SMPP) protocol enable interactions between external SMEs and service centers (Brown, Shipman, & Vetter, 2007).
4- SMS Broker or Aggregator: An aggregator acts as a business entity that negotiates agreements with network providers to act as a middleman providing access to a cellular network for messaging services to third parties who have no direct relationship with the cellular network; for the purpose of this study, a life license was procured from Smsenabler to be able to implement the systems. The message aggregator uses the SMPP to maintain connections with carrier networks. Typically, aggregators provide access to their servers either through SMPP or

using custom APIs written in Java, PHP, Perl, and so on. We used PHP in this study for its simplicity.
5- Content Provider: A mobile content provider is an entity that provides value-added content and applications for mobile devices.

In this study, content provider is Drug Regulatory Agency. A mobile phone user sends an interactive text message to retrieve information while the content provider returns the information in the form of text message back to the user through the aggregator. Figure 5 shows the Out-Put (Response from system to user's mobile phone). The file generated at the administrative side is shown in Figure 6.

4. RESULTS AND DISCUSSION

In this section, the interpretation of data, results and discussion are presented based on the data collected from the six geo-political zones of the Federal Republic of Nigeria. Just as discussed in (Amusa & Oluwade, 2019A), 300 questionnaires were distributed to 300 persons in each geopolitical zone, making it a total of 1800 distributed questionnaires. Out of this, 1501 responses (83.4% of distributed questionnaires) were received. 1391 of the received questionnaires were valid, which represents 92.7% of the total response and 72.3% of distributed questionnaires.

4.1 Biodata of Respondents

The biodata of respondents have been extensively discussed in (Amusa & Oluwade, 2019A). Table 1, Table 2, Table 3, Table 4 and Table 5 show the information of respondents with respect to age, gender, educational background, location and working sector respectively. In Table 5, 38 respondents did not provide information on their sector, which makes the total number of valid respondents to be 1353 instead of 1391.

4.2. Basic Information on Drugs

This section gathers data on the respondents' sources of medication information, medication procurement and their capability to identify fake drug. These data have been presented in (Amusa & Oluwade, 2019A). Among others, majority of respondents (50.4%) get their source of medication through physicians, majority of respondents (54.1%) prefer to get their medication in Government hospital pharmacist centre (54.1%) while majority (32.9%) could not identify fake drugs

4.3 Analysis on Level of Awareness

This section focuses on respondents' knowledge of fake drug, use of fake drug and means of detecting fake drug. In line with the presentation in (Amusa & Oluwade, 2019A), majority of respondents (80.6%) know very much about a fake drug and majority of respondents (44.3%) have never used fake drug that was eventually discovered to be fake. In addition, as shown in Table 6, majority of respondents were aware about means of detecting fake drugs in Nigeria.

The relationship between socio-demographic factors of respondents awareness about fake drugs in Nigeria was studied using statistical multivariate model (multiple regression). This has been described in (Amusa & Oluwade, 2019A). It was discovered that education, sector and source of information contribute significantly to respondents' level of awareness on existence of fake drug in Nigeria. Respondents age, gender, profession and location do not contribute significantly to their level of awareness.

4.4 Applicability of Information Technology

In this section, the authors analyze the adequacy of available information technology in detecting fake drug.

Table 7 shows that majority of respondents (55.6%) a indicate that there is no adequate technology to detect fake drug. 37.3% of respondents indicate that technology is very adequate and 7.1% cannot say about adequacy of technology for detecting fake drugs in Nigeria. Generally, respondents have shown that there is no significant available technology that is adequate for drug counterfeits in Nigeria. In Table 8, 15 respondents left the question unanswered, which makes the total number of valid respondents to be 1376 instead of 1391. The table depicts the response on accessibility of technology for fake drug detection in Nigeria. Majority of respondents (53.5%) do not have access to the technology for detection. 38.2% of respondents have access and 8% of respondents cannot say about accessibility of technology for detecting fake drugs in Nigeria.

Table 9 indicates that there is a significant relationship between the location and the accessibility of technology to detect fake drugs. Since the P value (0.000) obtained is less than 0.05, this means that locations of respondents have significant contribution to their accessibility of the technology to detect fake drugs in Nigeria. The level of accessibility of technology to detect differs across locations in Nigeria.

4.5 Respondents' Satisfaction on Existing Technology

Figure 7 shows respondents' level of satisfaction about existing technology. The respondents' satisfaction about existing technology to manage fake drugs in Nigeria is classified into satisfied and not satisfied. Majority of respondents (65%) were not satisfied on existing technology for detecting counterfeits drugs.

5. CONCLUSION

This paper has presented a report on studies conducted in the six geopolitical zones of Nigeria on the perception of citizens on the role of information technology in managing counterfeit drugs. A previous paper (Amusa & Oluwade, 2019A) focuses on prevention of counterfeit drugs while the present paper is concerned with detection. 30 questionnaires were distributed per geopolitical zone giving a total of 1800. However, only 1391 questionnaires were validly returned.

In general, it can be said that Nigeria is relatively at par with other international bodies in combating counterfeit drug, even though a lot has to be done to achieve the aim of making sure that consumables in circulation are free of fake and substandard products.

This study confirmed the need to have a tailored information system to detect counterfeit drug. It was observed, among others, that facets of the pharmaceutical systems in Nigeria remain fairly vulnerable to corruption. This supports the findings of other researchers on this issue e.g. (Garuba, Kohler, & Huisman, 2009) . The findings also indicate that educational status of respondents is a factor that determines their level of knowledge about counterfeit drugs in Nigeria. The study also finds that fake drugs cannot be identified conveniently in Nigeria. Furthermore, it was discovered that a significant proportion of respondents have used drugs which were eventually discovered to be fake. This is an alert that active and positive action needs to be taken by relevant authorities to address this. Furthermore, level of awareness of respondents shows that majority of respondents were aware about means of detecting fake drugs in Nigeria.
Generally, respondents have shown that there is no significant available technology that is adequate for drug counterfeits in Nigeria. This study confirms the conjecture that the lack of political will from the government to provide necessary infrastructure is a source of annoyance to some local pharmaceutical manufacturers, and this prevents them from operating optimally. However, further analysis revealed that a significant number of respondents/citizens do not have access to the technology for detecting fake drug. Militating factors and bottlenecks in the operations of pharmaceutical manufacturing businesses in Nigeria include high cost of energy and fueling, tariffs and stringent tax regimes imposed by various government agencies.

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Figure 1: Officers of NAFDAC and NDLEA on action (NAFDAC, 2016)

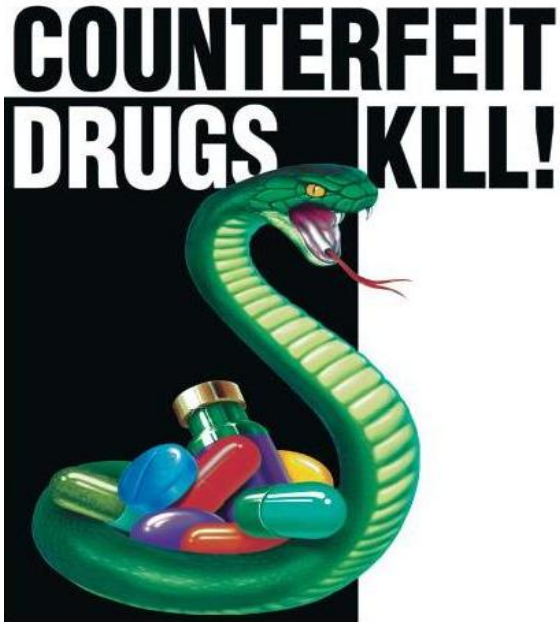
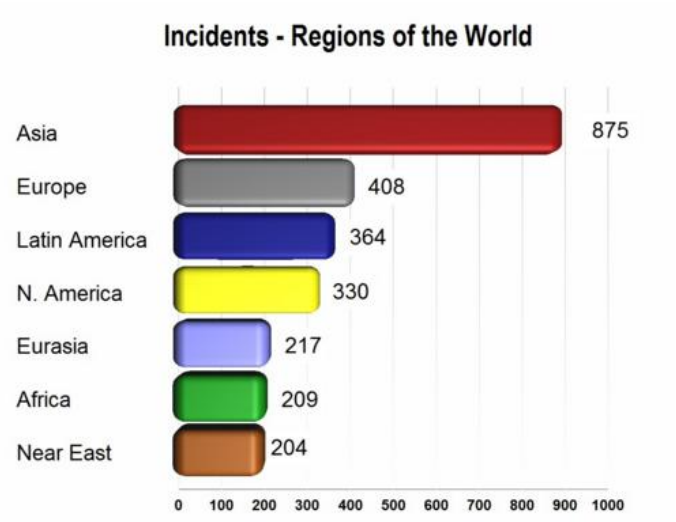


Figure 2: WHO Flyer on Counterfeit Drug

Source : (IMPACT, 2006)



0-1: Counterfeit Incident-Regions of the World
Source: Pharmaceutical Security Institute

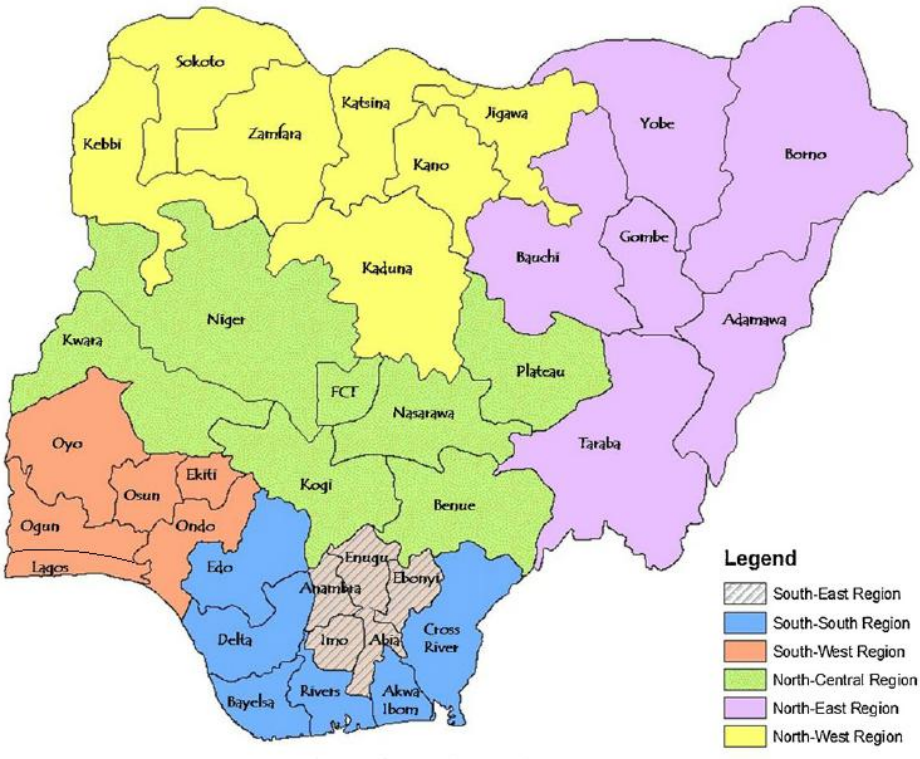


Figure 3: Map of Nigeria showing the 6 Geopolitical Zones Source: (Nimc, 2018)

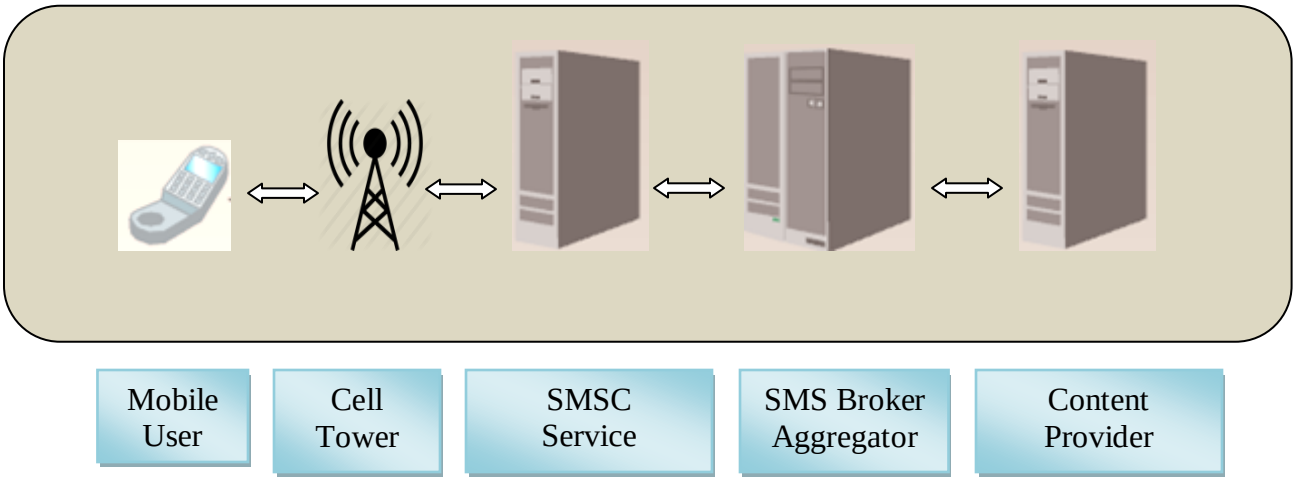


Figure 4: Process of Communication between a Mobile User and a Content Provider (Amusa & Oluwade, 2019A)

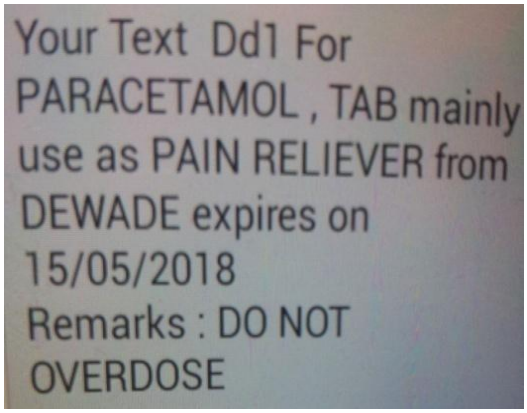


Figure 5: Response from System to User's Mobile Phone
Source: Field demonstration, 2015

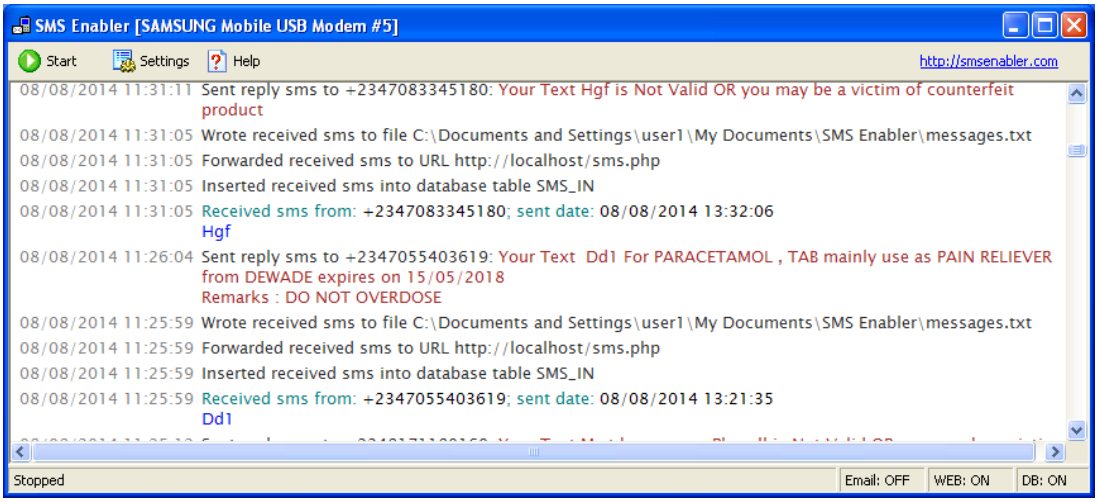


Figure 6: Generation of file at the Administrative side (Amusa & Oluwade, 2019A)

Table 1 – Respondents according to their age group

VARIABLE	FREQUENCY	PERCENTAGE %
AGE		
Below 20 years	193	13.9
20 - 40 years	784	56.4
40 - 60 years	395	28.4
60 years above	19	1.4
Total	1391	100

Table 2 – Respondents according to their gender

VARIABLE	FREQUENCY	PERCENTAGE %
GENDER		
MALE	721	51.8
FEMALE	670	48.2
Total	1391	100

Table 3 – Respondents according to their Education background

VARIABLE	FREQUENCY	PERCENTAGE %
EDUCATION		
Primary	37	2.7
Secondary	147	10.6
OND / HND	320	23.0
BSc / BA / MBBS	631	45.4
MA/MSc	228	16.4
PhD	22	1.6
Total	1391	100

Table 4 – Respondents according to their Location

VARIABLE	FREQUENCY	PERCENTAGE %
LOCATION		
North West	238	17.1
North East	186	13.5
North Central	242	17.4
South West	266	19.1
South East	224	16.1
South South	233	16.8
Total	1391	100

Table 5 – Respondents according to their working sector

VARIABLE	FREQUENCY	PERCENTAGE %
SECTOR		
Private	669	49.4
Government	684	50.6
Total	1353	17.4

Table 6 - Respondents' awareness about means of detecting fake drugs

Statement/ Question: Are you aware about means of detecting fake drugs		
	FREQUENCY	**PERCENTAGE**
Not at all	257	18.5
A little	410	29.5
Somewhat	230	16.5
Very much	457	32.9
I cannot say	37	2.6
TOTAL	1391	100

Table 7: Adequacy of available Information Technology for Fake drug detection

Statement/ Question: Do you think available technology is adequate for Detecting Fake Drug?		
PERCENTAGE %	**FREQUENCY**	
Not at all	773	55.6
Very much	519	37.3
I cannot say	99	7.1
TOTAL	1391	100

Source; Field Survey, 2015

Table 8 – Accessibility of Technology for Fake Drug Detection

Statement/ Question; What do you have to say about accessibility of

technology for detecting Fake Drug?		
	FREQUENCY	**PERCENTAGE**
Not at all	736	53.5
WVery much	526	38.2
I cannot say	114	8.3
TOTAL	1376	100

Table 9 - Cross Tabulation (Chi-Square) Of Respondents Location And Accessibility of Technology for Detecting Fake Drugs

Accessibility of Technology to detect * LOCATION Cross Tabulation

Accessibility of Technology to detect fake drugs		LOCATION						Total
		North West	North East	North Central	South West	South East	South South	
Not Accessible	Count	40	31	33	32	34	27	197
	%	2.9%	2.3%	2.4%	2.3%	2.5%	2.0%	14.3%
Little Accessible	Count	82	73	87	128	76	94	540
	%	6.0%	5.3%	6.3%	9.3%	5.5%	6.8%	39.2%
Somewhat Accessible	Count	54	37	54	49	58	52	304
	%	3.9%	2.7%	3.9%	3.6%	4.2%	3.8%	22.1%
Very much Accessible	Count	33	35	38	42	35	38	221
	%	2.4%	2.5%	2.8%	3.1%	2.5%	2.8%	16.1%
I cannot say	Count	27	10	27	14	17	19	114
	%	2.0%	.7%	2.0%	1.0%	1.2%	1.4%	8.3%
Total	Count	236	186	239	265	220	230	1376
	%	17.2%	13.5%	17.4%	19.3%	16.0%	16.7%	100.0%

$X^2 = 32.711$, **DF = 20, P - Value = 0.046**

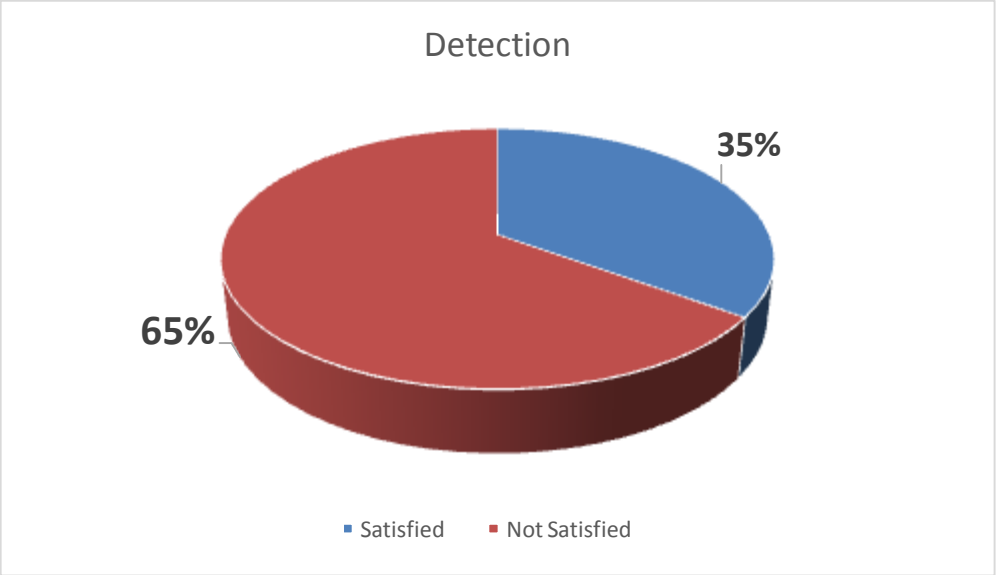


Figure 7: Mean score Percentage of Respondents Level of Satisfaction on effect of Information technology on Fake Drug