



Stakeholders' Assessment of the Implementation and Adoption of Drug Mobile Authentication Service in Nigeria

**Charles Maduabuchi Ekeh & Helen Odunola
Adekoya**

Department of Mass Communication, Babcock University, Ilishan-Remo, Ogun State, Nigeria

Abstract

A major challenge facing pharmaceutical industries and indeed health sectors of many countries of the world is drug counterfeiting. Following a protracted battle with fake and counterfeit drug manufacturers in Nigeria and the inability of previous efforts to successfully reduce the volume of fake and counterfeit medicines in the country, the National Agency for Food and Drug Administration and Control (NAFDAC) launched a Mobile Authentication Service (MAS) with which consumers can ascertain the originality of medicines at the point of purchase using their cell phones. However, many years after the launch of MAS in Nigeria the problem of fake and counterfeit drugs remains unabated. This study therefore investigated the views of stakeholders regarding the implementation of MAS in Nigeria. The study was carried out using a qualitative phenomenological-descriptive method. Data was gathered through a semi-structured mail interview and face to face interaction with community pharmacists. Findings revealed that MAS was implemented through collaboration between NAFDAC, MAS providers and HCRs. Whereas stakeholders differ in their opinion on the rate of consumer adoption of the technology, it was discovered that no framework for performance evaluation was included in the guideline for implementation provided by NAFDAC. If the project is well implemented and consumers are well motivated to adopt it, MAS can help to significantly tackle fake and counterfeit medicines proliferation in Nigeria.

Keywords: *Assessment, Implementation, Adoption, Drug Mobile, Authentication.*

Introduction

The challenge of fake and counterfeit drugs is one that has bedeviled the pharmaceutical industry worldwide for many decades. Counterfeit drugs are those with incorrect ingredients, less amount of active ingredients, or medicines manufactured under conditions that lack quality control. Fake drugs on the other hand are medicines that contain no form of active ingredients, but are packaged and sold to consumers as original drugs. Both are very dangerous to health as their consumption not only result in failed prognosis, but also prolong ill health conditions, deformity and sometimes death. Counterfeit medicines, according to the World Health Organization (WHO, 2016), are medicines that have been deliberately or fraudulently mislabeled with respect to identity and/or source. Such medicines could include incorrect ingredients, may mistake the amount of the active ingredients, or are manufactured under circumstances that lack quality control (Adegoke, Ashokoya & Adegoke, 2020). The problem of counterfeit medicines is wide spread affecting both developing and developed nations. The actual prevalence of counterfeit medicines is difficult to ascertain partly due to failure of the majority of member nations in the WHO

to report instances of medicine counterfeiting occurring in their countries (Newton, Green, Fernandez, Day & White, 2006b), but also because, just like other crimes, medicine counterfeiting is an underground business, it often comes to limelight only when deaths resulting from its incidence occur. The extent of the severity of the problem varies widely between countries, ranging from less than 1% in more developed nations to about 50% in some poor countries (Isah, 2018). Fake and counterfeit medicines proliferation is therefore a worldwide problem because its effect has been felt in both developed and developing nations, although more prevalent in developing countries in recent years, with Africa, parts of Asia and Latin America being the most affected regions (Adegoke et al., 2020).

The World Health Organisation (WHO, 2016) estimated that up to 15 % of all drugs sold worldwide are fake. In like manner, the US Food and Drug Administration (FDA, 2017) estimates that fake drugs comprise approximately 10% of the global medicine market with annual criminal sales in excess of US\$35,000,000,000. Antibiotics, anti-tuberculosis drugs, antimalarial and antiretroviral drugs are frequently targeted, with reports of 60% of the anti-

infective drugs in many countries containing active pharmaceutical ingredients outside their pharmacopoeial limits. In 2016, most (54%) of the counterfeit drugs detected were manufactured in India, with China manufacturing 21% and Hong Kong manufacturing 10%. The site of manufacture for these drugs is reported to take place more readily in countries which themselves neither have good purchasing practices nor good regulation (FDA, 2017). Furthermore, the United States Food and Drug Administration (FDA, 2017) also reported on the existence of counterfeit and substandard medicines in both developed and developing countries, with 25% (range between 10%–30%) of the counterfeit and substandard medicines being consumed in developing countries, including Latin America, southeast Asia, or sub-Saharan Africa. Dosage forms for oral administration, e.g, tablets, syrup, and capsules are those most commonly counterfeited (77%), as opposed to injectable formulations (17%).

Interpol and WHO (2014) both reported that the state of fake pharmaceuticals in Africa was anywhere between 30-60%, their report revealed that over 45 million antimalarial drugs valued at over \$438 million were shipped from India and China to West Africa alone. A random analysis of select antimalarials in some countries of Africa also reported by WHO (2014) revealed that 35% failed chemical analyses, 35% failed packaging analysis, and overall, 20% were classified as fake. In 2012, Angolan custom agents busted counterfeiters importing a large amount of fake medicines, with hundreds of containers parked with packets of fake antimalarial drug, Coartem (Faucon, Murphy, & Whalen, 2013). Prior to that, 84 Nigerian children were reportedly killed in 2009 as a result of toxic chemicals that were laced with teething medications for babies (Lydia, 2009). The study by Bate, Jensen, Hess, Mooney and Milligan (2013) published in the international journal of tuberculosis and lung disease revealed that 1 in every 6 pills in Africa is fake. Furthermore, a survey conducted by National Institute of Health, which examined over 2600 malaria drug samples across 21 sub-Saharan African countries determined that 20% of such drugs were fake and one-third were of poor quality. Thus, the health and economic wellbeing of countries in Africa have been grossly violated through the production and importation of fake and counterfeit drugs.

Nigeria is reportedly one of the most affected countries in Africa, being that fake and counterfeit drugs are known to be manufactured in the country in addition to importation from other countries (Spink, Moyer & Rip, 2016), leading to several reports of fatalities from the consumption of fake and counterfeit medicines in the country (Akinyandenu, 2013). In recent years, the country's National Agency for Food Drug Administration and Control (NAFDAC), being the agency responsible for regulation of medicines and other packaged food products, have had to contend with fake and counterfeit drug producers and marketers in the country without much success. For decades, Nigeria has faced an overwhelming drug counterfeiting

problems. A study by the National Agency for Food and Drug Administration and Control, Nigeria (NAFDAC) in 2002 found that nearly 41 percent of pharmaceuticals in the country were counterfeit, and 70 percent were unregistered. Though the agency has made a tremendous effort to reduce the presence and impact of counterfeit drugs in the country, the amount of fake drugs in circulation especially in the market remains alarmingly high. Peddlers throughout the country dispense unwholesome inexpensive drugs to people under the guise of original ones. It is therefore not surprising that the most common fake drugs are those that are in high demand, such as antimalarials, blood pressure medication, and antibiotics. The World Health Organisation (WHO, 2018) estimates that there are nearly 100,000 deaths per year linked to the counterfeit drug trade in Africa alone. In Nigeria, informal distributors can be found in kiosks, open markets, and general stores and sell products at a fraction of the price of official pharmacies or sometimes for the price of original product; many of these drugs are counterfeit, completely fake, or are stored and dispensed improperly.

Since 1993 when NAFDAC was established by the Nigerian government, the agency has applied varied measures in an attempt to curb the menace of fake and counterfeit drugs and other unwholesome food products. In recent years, it has adopted several technological approaches such as Truscan (Raman Spectroscopy), GPHF Minilad and most recently Mobile Authentication Service (MAS) – a mobile technological platform through which consumers can verify the originality of drugs before purchase using their mobile phones. Through this technology, consumers can send a direct short message (SMS) - an assigned 12 digit NAFDAC PIN on the pack of medicine they are about to purchase to a designated code, and receive an instant reply from NAFDAC, confirming the originality or otherwise of the drug in question. Olubukola et al., (2019) posits that MAS is a mobile health technology deployed to hinder the retailing of falsified medicines to consumers. The service is provided by NAFDAC-approved, third party private information-communication technology firms (MAS providers) through a technology known as Sproxil Defender to pharmaceutical manufacturers and importers in Nigeria.

Since 2012, when the mandatory first phase of MAS deployment on all antimicrobials and anti-malaria medicines in Nigeria was rolled out by NAFDAC following a 2-year trial period (NAFDAC, 2017), the service has been in use. However, studies have indicated a lack of awareness of the service by the public (Chinwe & Chinonye, 2017), lack of acceptance and low utilization by community pharmacists (Olubukola, 2019), low utilization of MAS by the public (Ubajaka et al., 2016) and high rate of ‘no response’ cases to queries (Iwokwagh, 2018), coupled with reports of high rate of fake and counterfeit drugs proliferation (70%) in Nigeria (Vanguard, 2019) despite the existence of MAS in the country for many years. These have resulted to a diminishing public trust in the technology, including many consumers alleging to faulty

implementation as the chief reason for low adoption and low usage of the technology, thus accentuating the need for stakeholders to reassess the implementation strategies for MAS in order to enhance its adoption. The objective of this study is therefore to explore the view of major stakeholders involved in the deployment of MAS in Nigeria regarding the success or otherwise of its implementation strategy.

Utilizing the Technology Acceptance Model (TAM) by Davies (1993), which investigates why a user chooses to use or not to use technology, the study sought to extend and advance knowledge on factors that influence the implementation and adoption of mobile authentication service (MAS) technology and its acceptance and use by drug consumers in Nigeria. Davis (1993) hypothesized that one's attitude toward using technology is a function of two beliefs: perceived ease of use and perceived usefulness. Perceived ease of use is the degree to which a person believes that using the system would require minimal effort, whereas perceived usefulness is the extent to which the information system enhances job performance (Lederer, Maupin, Sena & Zhuang, 2000).

Methods

Considering the general objective of this study which investigated the views of stakeholders regarding the implementation of Mobile Authentication Service (MAS) in Nigeria, the study was carried out using a qualitative phenomenological-descriptive method. Participants in the study included stakeholders from the National Agency for Food Drug Administration and Control (NAFDAC) and her partner agencies referred to as MAS providers, Holders of Certificate of Registration (HCR), who are manufacturers of genuine drugs seeking deployment of MAS and Community Pharmacists who are directly in contact with consumers on regular basis. Data was collected through a semi-structured mail interview and face to face interaction with community pharmacists. Ethical approval for the study was obtained from Babcock University Health Research Ethics Committee (BUHREC). Data collection period was between July and September, 2020, following which interviews were then written and prepared for analysis. The analysis of data obtained from interviews was performed using the thematic analysis method.

Results

Theme: Implementation Strategy

All respondents agreed that Mobile Authentication Service (MAS) project was implemented in Nigeria through collaboration between NAFDAC/Sproxil, Holders of Certificate of Registration (HCR) and other service providers such as the telecom companies. Although the guideline for implementation was not made public until 2018 by NAFDAC, the agency largely coordinated the implementation and deployment of

MAS in Nigeria. In the implementation guideline later supplied by NAFDAC, it was indicated that Mobile Authentication Service (MAS) was implemented through collaboration between the National Agency for Food and Drug Administration and Control (NAFDAC) on the one hand and two key stakeholders on the other hand. These stakeholders are: (1) Holders of Certificate of Registration (HCR) who are drug manufacturers seeking to deploy MAS on their registered products; and (2) MAS providers, which are the companies deploying MAS technology, including those seeking entry as a NAFDAC approved service provider. Under the implementation guidelines, Holders of Certificate of Registration (HCRs) who are the manufacturers of genuine drugs listed to be covered by MAS are to apply to existing MAS providers requesting deployment of MAS on their product. The MAS provider will then verify the registration status of such product(s) from NAFDAC in writing, by immediately forwarding to the Agency, the standard notification form as completed by the HCRs/ Holders of Notification as signed by both parties. Upon confirmation of product registration by NAFDAC, respective MAS providers are to deploy the service on such product observing all necessary protocols outlined by NAFDAC as the overseeing Agency. There is provision for a HCR to switch between service providers; however, NAFDAC must be notified in writing. The HCR shall in addition to the letter of intent, forward a detailed transition plan to the Agency. A switch from one MAS provider to another will only be approved after due consideration and implementation of the transition plan. Any complaint arising from agreements between MAS providers and HCRs in the implementation of the scheme is to be forwarded to the Agency who acting as umpire will help see to the resolution of such disagreement. NAFDAC approved the following five (5) MAS Providers to offer MAS technology to Holders of Certificate of Registration (HCR). MAS providers and their corresponding codes are listed in table 1.1.

Table 1.1: Approved list of MAS providers

S/N	MAS Provider	Short Code
1	PharmaSecure	38351
2	Sproxil	38353
3	Savanté	38120
4	UBQ-t/Kezzler	20966
5	M-Pedigree	1393

Source: Guidelines for procurement and management of MAS scheme in Nigeria, (2018)

Although both are powered by the same technology known as Sproxil Defender, each MAS provider is to focus on specific brands of medicines in order to ensure reliability

and efficiency. The list of regulated products covered in the implementation of MAS Scheme includes the following:

1. Antiprotozoal Drugs

- a. Antimalaria drugs (All antimalarial drugs including sulphadoxine-pyrimethamine (SP) and injectables
- b. Antiamoebic, antigiardial and antitrichomonal drugs (metronidazole formulations only infusions, tablets and suspensions).

2. Antibacterial Drugs

- a. Beta-lactam drugs
- b. Penicillins
- c. Cephalosporins
- d. Other beta-lactam antibacterials

3. Other antibacterials

- a. Chloramphenicol
- b. Quinolones
- c. Tetracyclines
- d. Macrolides
- e. Aminoglycosides
- f. Metronidazole
- g. Sulfonamides and trimethoprim

SP3: "...NAFDAC plays a major role in ensuring that all stakeholders comply with regulations while mobile network providers are responsible for ensuring that messages are sent and received without any network glitch or errors, however that has not always been the case...."

NAFDAC plays the coordinating role in the implementation of MAS, active players are the service providers (MAS providers), HCRs, pharmacists and the consumers.

Theme: Rate of Adoption

Whereas stakeholders who are service providers said the rate of adoption of MAS is high based on increased sales of MAS-enabled drugs and the adoption of MAS by some drug manufacturing companies whose products are not required by regulations to use the technology, community pharmacists have a divergent view

SP1: "...Sproxil has already sold millions of anti-counterfeit labels in Nigeria and has set up the first national mobile based anti-counterfeit service...customers include both local companies as well as global pharmaceutical companies such as GSK and Johnson & Johnson, in addition, millions of queries have been received...."

However, the rate of response to received queries was not indicated.

SP2: "...more and more pharmaceutical companies, including those that were not initially required by regulation to deploy MAS on their products are applying to NAFDAC to be included in MAS scheme...that is an indication of a high rate of adoption..."

There was no evidence of widespread adoption by consumers.

SP3: "...the ratio of adoption is like 10 in every 500 people. That is poor, it means many people do not know about MAS or perhaps they have not realized its usefulness..."

Community pharmacists who deal directly with consumers rate the level of adoption of MAS poorly, unlike other stakeholders.

Theme: Challenges of MAS

A major challenge identified by stakeholders affecting MAS negatively is lack of user awareness. Although strategy for awareness creation was stipulated in the guideline for MAS implementation, it appeared to have been poorly executed.

SP2: "...NAFDAC and other government agencies like the National Orientation Agency should take the lead in nationwide awareness creation and public education about MAS..."

MAS providers and HCRs, though getting involved in awareness creation believes it not to be their outright responsibility to do so since NAFDAC agreed in the implementation guideline to coordinate awareness creation for the technology.

SP3: "...it is quite clear that the major drawback for MAS is lack of user awareness and knowledge about the service. How can people use what they do not know exist?..."

Stakeholders expressed the view that the success of MAS in curbing the excesses of fake and counterfeit drugs in Nigeria lies on successful implementation, awareness creation and the adoption of the technology by consumers. In all, responses from all stakeholders in the design and implementation of MAS in Nigeria tend to agree that the technology can be more efficient compared to previous ones deployed by NAFDAC such as TruScan® and RFID if it is properly implemented and monitored

and more awareness created to promote its use. They further highlighted the need for more research to be conducted on the adoption of MAS and that other uses of MAS such as its application in tracking and tracing medicines while they are within the distribution chain can be designed. All stakeholders expressed positive views about MAS and its advantage of targeting the end users and at no cost to them. Stakeholders were of the opinion that MAS system is highly secured and were optimistic that it would be difficult to counterfeit MAS enabled medicines since MAS works in the same manner with mobile phone scratch card production, which till date has not been counterfeited.

Discussion

The study assessed stakeholders' views of the implementation and adoption of Mobile Authentication Service (MAS). Key findings from queries relating to implementation and deployment of MAS in Nigeria revealed that NAFDAC at inception had no detailed framework for the implementation of MAS because the technology was not the agency's own idea but a brainchild of Sproxil, who later sought the partnership of NAFDAC as a regulatory agency to facilitate the adoption of the technology as a device for combating fake and counterfeit drugs at a national level. Being that Sproxil created the technology, the company was saddled with the responsibility of seeking the collaboration of genuine drug manufacturers and network service providers while NAFDAC provided the enabling framework for the collaboration. It was not until 2018, about eight years after MAS was launched in Nigeria that NAFDAC unveiled a written guideline for its implementation as well as details of collaboration between the agency, Sproxil, and other key stakeholders. Details of the implementation guidelines revealed that NAFDAC absolved itself of key responsibilities, taking the position of a coordinating agency, leaving the bulk for Sproxil, network service providers and drug manufacturers.

It was also observed that the nature of MAS design and implementation requires only consumers to authenticate medicines before purchase; pharmacists are only to assist consumers where such consumer is not with a cell phone or perhaps cannot operate the phone for any reason. This implementation strategy absolves the pharmacist of any consequence and may even encourage shady deals in the aftermath. The implementation of SecurPharm in Germany makes it obligatory for pharmacists to authenticate every medicine before dispensing, this way, the pharmacist can further serve as a gateway to checkmate fake and counterfeit medicines before they get to the final consumer, and can even be held liable for dispensing a fake or counterfeit medicine to a consumer should that happen. Oyetunde, Ogidan, Akinyemi, Ogunbameru and Asaolu (2019) noted that getting pharmacists' to authenticate medicines may actually improve use of MAS by consumers. Therefore NAFDAC may need to review its implementation guidelines and seek ways to actively incorporate

pharmacists in promoting the use of MAS by getting them to authenticate drugs before dispensing, and also encourage consumers to do so on their own. The national medicine regulatory authority and MAS providers together with their partners may also need to work on the reliability of MAS by further simplifying processes involved and ensuring prompt response to MAS queries. Agarwal and Prasad (2019) observed that perceived ease of use is one of the strongest influencers of perceived usefulness. This is consistent with past studies involving technology acceptance (TAM) constructs such as Jaruwachirathanakul and Fink (2015) and Huber, Michael, and McCathie (2017) i.e. an individual, who perceives a system to be easy to use, is more likely to perceive the system to be useful. Incorporating pharmacists, who are often present at the point of purchase, can actively promote MAS and help consumers navigate the different platforms of MAS queries. This will not only enhance awareness of consumers about fake and counterfeit medicines, but also improve the use of MAS as corroborated by Hope (2012).

Findings from the views of MAS providers also revealed that MAS, being a complex intervention, appears to have been impacted by the local context, where it was implemented to produce challenges that may have limited its effectiveness. The context where a complex intervention such as MAS is deployed is crucial and may play a role in the success of the intervention. MAS technology is dependent on sending and receiving short message service (SMS) through GSM phones. Therefore, quality of service of network companies has direct effect on quality of MAS provided. In Nigeria, though subscription to GSM services is relatively high, GSM service efficiency is middling. Oyetunde et al., (2019) noted that the service efficiency of GSM in Nigeria is plagued by contextual challenges, like instability in power supply, lack of secured infrastructure and other technical problems. These challenges might have impacted MAS deployment in Nigeria and as a result, its success, or failure, in reducing the circulation of fake and counterfeit medicines is currently difficult to quantify despite that providers indicate that millions of queries have been received and dealt with in recent years. MAS deployment would have benefited from implementation theories, design of measurable outcomes and process evaluation framework from the initiation, as recommended by the Medical Research Council (MRC, 2008) guidance. The guideline highlighted four crucial steps in designing and implementing complex interventions like MAS to include: development, feasibility/piloting, implementation and evaluation. Findings in this study based on responses from MAS providers revealed that NAFDAC was not directly involved in the development, feasibility/piloting and to a large extent, the implementation of MAS. Also, it was discovered that a critical aspect of the MRC's guideline appeared to have been neglected, and that is evaluation, which in real sense should provide an assessment for MAS effectiveness in the long run. The process evaluation framework would identify measurable objective outcomes, which would highlight the mechanisms by which MAS reduces counterfeiting. The responsibility to evaluate the efficiency of MAS so far falls directly on NAFDAC as the agency providing the framework for its deployment in Nigeria especially in regard to future improvement. Although the agency accepted the task of developing a framework for evaluating the

progress of MAS in its implementation guidelines, nothing in this regard was seen by the researcher. As NAFDAC considers aspects for future improvement of MAS, it is important for appropriate framework to be in place to evaluate its current impact on counterfeiting, and the case of a framework for evaluation being in place already, then the agency should do well to implement its provisions. Successful implementation of technological innovations is closely linked with mechanisms that may actively promote, educate, advocate and make necessary connection between people for the innovations (Oyetunde et al., 2019).

This finding implies that despite the implementation and launch of MAS project, evaluation being a critical area has been neglected in its nine years of full deployment, this can negatively impact its continued function. It also negates the stipulation of Medical Research Council (MRC, 2008), and can hamper the progress of Mobile Authentication Service in Nigeria. It is important to explore mechanisms of how interventions, like MAS, bring change or not. This is crucial in order to understand both how the effects of the specific intervention occurred and how these effects might be replicated by similar future interventions. To do this, evaluation is an important step.

Conclusion

The study is an assessment of stakeholders' views on the implementation and adoption of Mobile Authentication Service (MAS) in Nigeria. Based on findings, the study concluded that the implementation of MAS followed a framework that left performance evaluation of the technology at the hands of no one in particular. Stakeholders concentrated on their stipulated roles as provided for on the implementation guideline which failed to spell out in clear terms how performance evaluation will be carried out so as to determine what needs to be done intermittently to ensure that MAS performs optimally bearing in mind that efficient performance of the technology could facilitate its adoption.

Recommendation

Based on findings, it is recommended that since the success of MAS deployment in reducing the circulation of fake and counterfeit medicines in Nigeria is currently difficult to quantify despite that providers indicate that millions of queries have been received and dealt with over the years. NAFDAC should carry out a study to determine the success or otherwise of MAS deployment in this regard. This will enable the agency establish the level of progress made so far in its fight against fake and counterfeit drugs through MAS and to know whether other approaches may need to be incorporated.

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