An Evaluation of Public opinion on quality of Pharmaceutical products marketed in Anambra state, Nigeria.

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ABSTRACT

INTRODUCTION

Pharmaceutical products are subject to rigorous quality assurance checks in order to ensure that drug products are of required quality, are safe and have good efficacy. However, the emergence of substandard drug products have largely impacted both the health and perception of the public towards drug use. This work aims to identify those trends in public opinion among both prescribers and end-users within Anambra State, Nigeria.

METHOD

This was a descriptive cross-sectional study carried out in 2019. Data collection was quantitative using a pre-tested self-administered questionnaire to four hundred participants, comprising of medical doctors, nurses, pharmacists and end-users. Data analysis was done using SPSS version 16. Statistical significance was set at 5 percent (p<0.05). Ethical approval was obtained from Nnamdi Azikiwe University Teaching Hospital Ethics and Advisory Committee

RESULTS:

Majority (57.9 %) of the respondents think that the drugs marketed in Anambra state are somewhat effective. About a quarter (23.5 %) of the respondents had no idea of what to look out for when checking substandard drugs. About two-third (65.4 %) of our participants had used substandard drugs at least once in the past two years, out of which 51.1 % of them chose to discard the drugs whenever in their possession, 32.3 % of them returns the drugs to the outlets from where they were purchased, while only 16.5 % reports the drugs to the regulatory authority. 42.1 % of the medical doctors and nurses had no knowledge about the storage conditions of magnesium sulphate
injection and 57.1% of them affirmed that there was no available means of documenting ineffective or substandard drugs in their facilities.

CONCLUSION

This study brings to light the possible contributions of poor-quality medicines. A high percentage of the respondents had no idea of what to look out for while checking for substandard medicinal product. More campaigns against fake/substandard drugs should be carried out at intervals.

KEYWORDS: Substandard products, Quality Assurance, Drug quality, Counterfeit drugs
INTRODUCTION

Poor-quality medicines present a serious public health problem, particularly in emerging economies and developing countries like Nigeria [1, 2]. It poses a significant impact on the national, clinical and economic burden [3]. Major interest has largely been on the increasing availability of deliberately falsified drugs, despite the fact that substandard drugs are reaching patients due to poor manufacturing and quality-control practices in the production of genuine drugs both as branded or generics [3]. Over the years, authorities have focused on the control of deliberately falsified drugs, but poor-quality original drugs, i.e. those that have gone through some sort of regulatory procedure, are more commonly seen and pose a greater threat to patient health [4]. Addressing the issue of poor-quality medicines is complex and requires coordinated collaboration of industry and government across the supply chain. [5, 6].

“Quality assurance” is a wide-ranging concept covering all matters that individually or collectively influence the quality of a product. Assurance of pharmaceuticals is an important requirement governing the testing of chemicals to obtain appropriate information on their properties and to ensure their safety with respect to human health and the environment [7]. Quality assurance of medicine plays a major role in ensuring that medicines intended for human use meet the minimum requirements or specifications [8, 9]. Quality assurance of pharmaceuticals is a major public health challenge, because of the growing inflow of drugs across-borders [8].

The quality of a medicinal product coming off the production line is determined by the start-up materials, plant environment manufacturing equipment, and technical know-how invested in developing and manufacturing the pharmaceutical. The medicine that ultimately reaches the patient, however, is further affected by packaging and by transportation and storage conditions. Studies have shown that about 20 % of sampled drugs fail quality assessment tests [10]. Drug
quality is a source of great concern worldwide, especially in developing countries and the failure of an effective control mechanism is a leading cause of the present proliferation of fake and substandard drugs in many countries [11]. It therefore is imperative that Quality assessment of pharmaceuticals be routinely carried out in order to stop the kind of product which is not suitable for the aims of which it has been prescribed from being in circulation [11]. These quality assessment protocols could either be microbiologically to detect the presence of living cells (Pyrogens, microorganisms) in the products or chemically and critical elements such as Active Pharmaceutical Ingredient (API).

Although accurate global estimates of the prevalence of Substandard and counterfeit drugs are not available, a reasonable prevalence estimate for falsified medicines in developing countries ranges from 10% to 30% [1, 12]. The incidence of adulterated and fraudulent manufactured drugs is not a new problem in Nigeria, with the recent expansions in industrialization and trade aggravating the scale of the problem [13-15]. According to the WHO, up to 10% of the drugs worldwide may be counterfeits, 50% of them involved antimicrobial drugs, and 78% were from developing countries [1, 10]. Moreover, 59% of cases with available information on the quality of drugs were fraudulent, and only 7% had the standard concentration of the active drug [1, 16, 17]. A WHO study of drug product quality in developing countries in Africa found that 7.6% of major antibiotic formulations contained no active ingredient, whereas 17.8% of antibiotics and 13% of anti-parasitic products were substandard by WHO criteria but not necessarily counterfeit [1]. The actual prevalence of counterfeit drugs is not known presently because drug counterfeiting is an underground business that is only known or identified with its adverse effects [18].

The regulatory bodies responsible for drug regulation in Nigeria includes; The National Agency for Food and Drug Administration and Control (NAFDAC), the Pharmacists Council of Nigeria
(PCN) and The Federal Task Force on Counterfeit and Fake drugs [19-22, 15]. NAFDAC was established by decree No.15 of 1993 as amended by Decree No. 19 of 1999 and is therefore in-charge of regulation and control of production, importation, exportation, advertisement, use and sale of all drugs, processed food, cosmetics, medical services, including all drinks, and chemicals. It was established to: conduct appropriate tests and ensure compliance with standard specifications designated and approved by the council for the effective control of quality of food, drugs, cosmetics, medical devices, and their raw material as well as their production processes in factories and other establishments; undertake appropriate investigation into the production premises and raw materials for food, drugs, cosmetics, medical devices, and establish relevant quality assurance systems, including certification of the production sites and of the regulated products; inspect imported food, drugs, cosmetics, medical devices, and establish relevant quality assurance systems and of the regulated products; grant authorization for the import and export of narcotic drugs and psychotropic substances as well as other controlled substances [20]; collaborate with the National Law Enforcement Agency in measures to eradicate drug abuse in Nigeria. The Pharmacist Council of Nigeria (PCN) determines the standard of knowledge and skill to be attained by person seeking to become registered member of pharmacy profession, has established mandatory registration which would be required prior to practicing as a pharmacist or pharmaceutical agents; this would ensure that quacks are not allowed to practice.

Despite the unending efforts, to ensure and maintain quality, defective products occasionally slip through, posing a threat to the general health and wellbeing of the population. The presence of these defective pharmaceutical products has influenced the general opinion of patients and healthcare personnel towards drug use. This has led to erroneous perceptions that only branded products from innovator Pharmaceutical companies are of good product quality, leading to a bias
towards its use and reduced acceptance of other generics within the general population. Therefore, our work aims to identify the trends of public perception to drugs sold within Anambra State, Nigeria.

MATERIALS AND METHOD

Ethical Approval

Ethical approval was obtained from the Ethics and Advisory Committee of Nnamdi Azikiwe University Teaching Hospital Nnewi, Anambra State, Nigeria with approval number, NAUTH/CS/66/VOL.12/111/2019/054. The study secured written informed consent from the respondents.

Study population

A descriptive cross-sectional study was conducted to assess the opinion of the people on the quality of drugs marketed and sold in Anambra state. The major language of the people in the state is Igbo while their major occupation is trading. The state shares boundary with Enugu state in North, Delta state in the South, Imo state in the East. The study population consisted of doctors and nurses working in the Obstetrics and Gynecology unit in hospitals or in maternity hospitals where magnesium sulphate is in use; pharmacists involved in the production of drugs as well as hospital pharmacist and those in community pharmacies and then other individuals that are not health professionals but have used pharmaceutical products before.
Inclusion Criteria

Criteria for recruitment for this study includes an age minimum of 18 years for the different subgroups of respondents. Additionally, only doctors and nurses in the obstetrics and gynecology unit of the hospitals were recruited.

Exclusion Criteria

A refusal to participate in the study or age lower than 18 years were excluded from the study. Also, doctors and nurses not in the obstetrics and gynecology unit of the hospitals were excluded.

Sample size determination

The sample size was determined using the formula for determining the sample size of finite population [23].

\[
\text{Minimum Sample Size (n)} = \frac{N}{1+Ne^2} \quad \text{Equ 1}
\]

Where,

\( n \) = Minimum sample size,

\( e \) = maximum acceptable margin of error (95 % confidence level = 0.05)

\( N \) = population of people living in Anambra state above 19years=2,190,481(Census, 2006)

\( l \) = a theoretical constant

\[
2^{190,481} = \frac{2^{190,481}}{1+2^{190,481} \times 0.05^2} = 399.92697002.
\]

A total of 400 consenting individuals were recruited into the study.
Sampling technique and selection of respondents

Multistage sampling was used to select public and private healthcare facilities from the three senatorial zones in Anambra State. It was further used to guide the selection of respondents and ensure representativeness.

Stage 1: Selection of towns in the senatorial zones in the state

Three towns, one in each of the three senatorial zones of the state were selected. These towns are the most popular and most populated as well as the ones with most health facilities in the state. For the Anambra central, Awka was selected, Anambra North had Onitsha as the town used while Anambra South had Nnewi as town used.

Stage 2: selection of Health facilities

The facilities that were used were selected based on the fact that they all offer obstetrics and gynecology services in the state and also because they are the most frequented by individuals. They include:

1 public (federal) and 4 private health facilities were selected in Nnewi,

1 public (state) and 3 private health facilities were selected in Awka,

1 public (mission) and 1 private health facility was selected in Onitsha.

Stage 3: Selection of End-users

To ensure even representativeness of these groups of respondents, people from all works of life were recruited. They include students in tertiary institutions, traders in the markets, bankers, patients’ relatives in the hospitals, civil servants (lecturers, accountants, Lab technicians), among others.
Stage 4: selection of Healthcare providers

The pharmacists that met the inclusion criteria and signed the informed consent form confirming willingness to participate from both the public and private health facilities were included in the research.

The doctors and nurses who work especially in the obstetrics and gynecology unit of the hospitals were selected. The choice of obstetrics and gynecology unit was based on our selection of Magnesium sulphate (which is only used in this unit in the hospital) for knowledge assessment of this sub-group of respondents.

Data collection technique and management

Quantitative data were collected using a pre-tested self-administered questionnaire. [24, 25]. The questionnaire was pre-tested among 15 individuals consisting of 3 doctors, 2 nurses, 5 pharmacists and 5 end-users who met the inclusion criteria. The components of the research questionnaire were: socio-demographics, the extent our population is concerned about quality standards of medicinal products, opinion towards the quality standards of drugs, the opinion of the health practitioners on the quality of magnesium sulphate injection they use. Many options were offered on each question for respondents to choose from, and the questionnaire was self-administered without respondent’s personal details (anonymity), to reduce chances of social desirability bias. In addition, respondents were required to complete the questionnaires and return them immediately, as they took about 10 minutes to complete. Some participants were helped to complete their questionnaire. The questionnaire clearly stated there were no right and wrong answers and that the study only sought to assess current practice.
Data Analysis

Data entry, clean-up, and analysis were performed using IBM SPSS v.16. Analysis conducted included frequency distribution and likert mean calculations. The likert mean values were interpreted as follows:

1 – 2.4: Disagreed; 2.5-3.4: Neutral; 3.5-5: Agreed.

Results

Four hundred (400) respondents participated in this study. Table 1 shows the socio-demographic characteristics of the respondents. Sixteen percent (16 %) of the respondents were doctors, 3.8 % nurses, 23.5 % were pharmacists while 56.8 % were end-users. The respondents were mostly within the age of 20-29 years (196 {49%} respondents). The category grouped as “others” include traders, civil servants, hospital patients and students.
Table 1: Socio demographics of respondents

| Characteristics       | Pharmacist | Doctors | Nurse | End-Users | Total   |
|-----------------------|------------|---------|-------|-----------|---------|
| **Sex**               |            |         |       |           |         |
| Male                  | 40 (42.6)  | 50 (78.1)| 0 (0) | 67 (29.5) | 157 (39.2) |
| Female                | 52 (55.3)  | 11 (17.2)| 15 (100)| 156 (68.7)| 234 (58.5) |
| No Response           | 2 (2.1)    | 3 (4.7)  | 0 (0) | 4 (1.8)   | 9 (2.2)  |
| **Age category**      |            |         |       |           |         |
| <20 years             | 7 (7.4)    | 2 (3.1)  | 2 (13.3)| 22 (9.7)  | 33 (8.2)  |
| 20-29 years           | 59 (62.8)  | 36 (56.2)| 5 (33.3)| 96 (42.3) | 196 (49.0) |
| 30-39 years           | 21 (22.3)  | 22 (34.4)| 6 (40.0)| 55 (24.2) | 104 (26.0) |
| 40-49 years           | 5 (5.3)    | 2 (3.1)  | 2 (13.3)| 26 (11.5) | 35 (8.8)  |
| ≥ 50 years            | 0 (0)      | 2 (3.1)  | 0 (0) | 22 (9.7)  | 24 (6.0)  |
| No Response           | 2 (2.1)    | 0 (0)    | 0 (0) | 6 (2.6)   | 8 (2.0)   |
| **Educational Status**|            |         |       |           |         |
| None                  | 0 (0)      | 0 (0)    | 0 (0) | 1 (0.4)   | 1 (0.2)   |
| Primary               | 0 (0)      | 0 (0)    | 0 (0) | 6 (2.6)   | 6 (1.5)   |
| Secondary             | 0 (0)      | 0 (0)    | 9 (60.0)| 35 (15.4) | 45 (11.2) |
| Tertiary              | 58 (61.7)  | 27 (42.2)| 5 (33.3)| 127 (55.9)| 216 (54.0) |
| Postgraduate          | 33 (35.1)  | 35 (54.7)| 1 (6.7)| 48 (21.1) | 117 (29.2) |
| No Response           | 3 (3.2)    | 2 (3.1)  | 0 (0) | 10 (4.4)  | 15 (3.8)  |
| **Marital status**    |            |         |       |           |         |
| Single                | 59 (62.8)  | 37 (57.8)| 5 (33.3)| 120 (52.9)| 221 (55.2) |
| Married               | 34 (36.2)  | 25 (39.1)| 9 (60.0)| 93 (41.0) | 161 (40.2) |
| Widowed               | 0 (0)      | 0 (0)    | 0 (0) | 6 (2.6)   | 6 (1.5)   |
| No response           | 1 (1.1)    | 2 (3.1)  | 1 (6.7)| 8 (3.5)   | 12 (3.0)  |
| **Total**             | 94 (23.5)  | 64 (16.0)| 15 (3.8)| 227 (56.8)| 400 (100.0)|
The perceptions on the effectiveness of marketed pharmaceutical products of the respondents are as shown in Figure 1. More than half (87.1%) of the respondents think the pharmaceuticals were somewhat effective even though a small fraction (12.8%) think the drugs are “ineffective”.

Figure 1: The perception of drug quality by different occupation
The opinion decision of population on quality standard of drugs was assessed (Table 2). Their responses were analyzed on a five-point Likert scale.

**Table 2: Opinion decision of population on quality standards of drugs on a Likert scale**

| S/N | Questions                                                                 | Pharmacist Responses (Mean) | Medical Doctors Responses (Mean) | Nurses Responses (Mean) | Clients Responses (Mean) | Five (5) point Likert scale |
|-----|---------------------------------------------------------------------------|-----------------------------|---------------------------------|-------------------------|--------------------------|-----------------------------|
| 1   | The quality standard of medicinal products should be considered before usage | 94 (4.70)                   | 64 (4.92)                       | 15 (4.93)               | 216 (4.53)               | All Agreed                 |
| 2   | The quality standard of medicinal products must be very high for Optimal activity | 93 (4.51)                   | 64 (4.55)                       | 15 (4.67)               | 212 (4.18)               | All Agreed                 |
| 3   | The label of medicinal products often indicates their quality             | 94 (3.44)                   | 64 (3.39)                       | 15 (3.67)               | 216 (3.37)               | All were neutral           |
| 4   | Maintaining proper records of Drug Distribution helps track Drug standard | 94 (4.59)                   | 64 (4.61)                       | 15 (4.73)               | 215 (4.24)               | All agreed                 |
| 5   | The quality standard of drug can be destroyed by poor handling           | 94 (4.40)                   | 64 (4.42)                       | 15 (3.93)               | 216 (3.88)               | All Agreed                 |
| 6   | Most medicinal products are effective at poor standards                  | 92 (2.15)                   | 63 (1.87)                       | 14 (1.50)               | 211 (2.29)               | All Disagreed              |
| 7   | The quality of products made outside Nigeria are better than those produced in Nigeria | 94 (3.04)                   | 63 (3.10)                       | 15 (4.27)               | 213 (3.44)               | Only nurses agreed others were neutral |
On the section that assessed the extent our population is concerned with the quality of marketed medicinal products, the respondents were asked 4 questions of which they gave their own personal responses. These questions with the frequency of their responses are recorded in Table 3.

**For Question 1:** On how to recognize substandard drugs, 189 (47.2%) of the respondents chose “false package and content” while 18 (4.5%) of the respondents chose “Others” and specified that it depends on how the drug worked on them.

**For Question 2:** shows the response of the participants on how many times they have encountered substandard products in the past two years. A total of 136 (34.0%) respondents have encountered substandard drugs 1-2 times.

**For Question 3:** shows the summary of actions taken by the respondents when they encounter a substandard drug. A total of 207 respondents choose to “discard the drugs” when encountered while only 67 respondents chose to “reports to drug authorities”.

**For Question 4:** shows the summary of indicators of drug quality with “NAFDAC number” having the highest number of respondents and “Price” having the least number of respondents.

Table 4 show pharmacists’ opinion on the quality of pharmaceutical manufactured in Anambra state with 52 (64.2%) pharmacists stating that the drug quality is not low (that high to very high). The level of implementations of the requirements for quality system in drug manufacture were indicated to be acceptable (that those that selected between good to excellent) by 78 (83%) respondents. Finally, 33 (47.8%) respondents ranked “Efficacy” as the most important factor for assessing pharmaceutical quality, followed by “NAFDAC number” and then “Price”.
Table 3: The extent our respondents are concerned with quality standards of marketed medicinal products

| S/ N | Questionnaires | Responses (%) |
|------|----------------|---------------|
| 1    | How do you recognize substandard Drugs? | I don't Know Package and Content False | Typo errors in leaflet and packaging Others No response |
|      |                | 94 (23.5) 189 (47.2) 86 (21.5) | 18 (4.5) 13 (3.2) |
| 2    | How many times have you encountered substandard drugs in the past two years? | Not at all 1-2 times 3-4 times | > 5 times No response |
|      |                | 129 (32.2) 136 (34.0) 57 (14.2) | 69 (17.2) |
| 3    | What actions do you take when you encounter substandard drug? (Required multiple answers) | Discard Return drug to outlet Report to drug authorities | 207 131 67 |
| 4    | What do you consider as Drug Quality Indicators (Required multiple answers) | Efficacy Price Country of Origin Packaging/Labelling NAFDAC Seal or certification ISO | 218 69 88 157 248 161 |
Table 4: Pharmacists’ opinion on the quality of pharmaceutical manufactured in Anambra state

| S/N | Questionnaires                                                                 | Responses (%)       | 1 | 2 | 3 |
|-----|--------------------------------------------------------------------------------|---------------------|---|---|---|
|     | Perception on the quality of pharmaceutical manufactured in Anambra            |                     |   |   |   |
| 1   |                                                                                   | Very low            | 5 (6.2) | 24 (29.6) | 45 (55.6) | 7 (8.6) |
|     | Level of implementations of the requirements for quality system in drug manufacture |                     |   |   |   |
| 2   |                                                                                   | Very poor           | 1 (1.2) | 4 (4.8)   | 35 (42.2) | 33 (39.8) | 10 (12.0) |
|     | Ranking of factors for pharmaceuticals to be of good quality                   |                     |   |   |   |
| 3   |                                                                                   | 1Price              | 5 (7.2) | 20 (29.0) | 5 (7.2)   | 33 (47.8) | 3 (4.3)   | 394.3 |
|     |                                                                                   | 2Efficacy           | 1Price  | 2NAFDAC  | 2Efficacy | 1Efficacy | 2Price    | 3Efficacy |
|     |                                                                                   | 3NAFDAC             | 3Efficacy| 3NAFDAC  | 3Price   | 3NAFDAC   | 2Price    | 3Efficacy |
Table 5 shows the responses of the Doctors and Nurses on the knowledge on the storage condition of magnesium sulphate. A total of 57.9% of doctors and nurses knew accurately the right storage of magnesium sulphate which is “shelves in room temperature”. Quite an alarming proportion (42.1%) of them didn’t know the right storage of magnesium sulphate. Majority (57.1%) of the respondents do not have any available means of documenting the ineffectiveness of MgSO₄ in their facility. While 39.0% of the respondents had no idea about any documentation of drug ineffectiveness, 3.9% said there was availability of documenting the drug ineffectiveness but didn’t specify where it is being documented.

On effectiveness or ineffectiveness of the brands of MgSO₄ marketed in Nigeria, majority (67.5%) of the respondents thinks the MgSO₄ marketed are effective. 28.6% had no idea about its effectiveness or ineffectiveness while 3.9% thinks they are ineffective.
Table 5: The Doctors and Nurses on the knowledge on the storage condition of MgSO₄

| S/N | Questionnaires Accessed                              | Responses (%)          |
|-----|------------------------------------------------------|------------------------|
| 1   | The storage of MgSO₄                                 | Fridge                 |
|     |                                                      | Shelves at room        |
|     |                                                      | temperature            |
|     |                                                      | Dark room              |
|     |                                                      | Others                 |
|     |                                                      | 22 (28.9)              |
|     |                                                      | 44 (57.9)              |
|     |                                                      | 8 (10.5)               |
|     |                                                      | 2 (2.6)                |
| 2   | How knowledgeable the respondents were on the storage of MgSO₄ | Not knowledgeable      |
|     |                                                      | Knowledgeable          |
|     |                                                      | 32 (42.1)              |
|     |                                                      | 44 (57.9)              |
| 3   | Availability of means of documentation              | Unavailable            |
|     |                                                      | I don’t know           |
|     |                                                      | Available              |
|     |                                                      | 44 (57.1)              |
|     |                                                      | 30 (39.0)              |
|     |                                                      | 3 (3.9)                |
| 4   | Experiences of quality of MgSO₄ marketed in Anambra State | Ineffective            |
|     |                                                      | I don’t know           |
|     |                                                      | Effective              |
|     |                                                      | 3 (3.9)                |
|     |                                                      | 22 (28.6)              |
|     |                                                      | 52 (67.5)              |
| 5   | Who procures the MgSO₄ when needed                   | The Client             |
|     |                                                      | The health facility    |
|     |                                                      | 35 (45.50)             |
|     |                                                      | 42 (54.5)              |
Discussion

The healthcare system in most developing countries is weak. The situation is even exacerbated when the individuals who consume these pharmaceuticals do not know what to look out for when they come across a substandard product making them trust more of imported goods than indigenous products. Survey findings showed that more than half (56.8 %) of the respondents were drawn from the end-users while the other respondents (43.2 %) were health professionals. About half (49 %) of the respondents were within the age of 20-29 years with over-half (54.0 %) having at least a tertiary education as their highest educational qualification.

On the perception of drug quality by different occupation (figure 1), majority (87.1%) of the respondents think the drugs marketed in Anambra state are effective but were all, with exception of the nurses, neutral as to whether the foreign/imported brands were better than locally produced brands (Table 2). In a similar study, Builders et al (2019) surmised that nurses and pharmacists believed that locally manufactured drugs were of lower quality than their foreign counterparts [27]. These locally manufactured drugs were also characteristically more affordable and accounted for a higher portion of generic substitutions made by pharmacists [27, 28]. These negative perception on generic locally manufactured drugs were based on efficacy and safety concerns, as well as a result of presence of atypical side effects [29]. In contrast, another study conducted in Mauritius showed that most of the respondents saw the quality of medicines produced locally as being “quite good” with part of the reasons given by the public being that the raw materials used for the production comes from abroad [24]. This particular reason gives importance to the role of regulatory agencies like NAFDAC.
Our work also shows the level of trust placed on this agency (NAFDAC) with 248 respondents (Table 3) choosing it as the primary means of identifying substandard drugs in Nigeria. Other top indicators were “Efficacy” with 128 respondents and “seal of ISO” with 161 respondents (Table 3). However, it’s not uncommon to encounter drugs bearing fake NAFDAC numbers further showing the necessity for a more efficient verification system for the NAFDAC numbers. These newer verification approaches introduced by NAFDAC for alternative drug verification include: Truscan, Black Eye, Global Pharma Health Fund Minilab Test Kit, Radio Frequency Identification (RFID) and Mobile Authentication Service (MAS) [20, 30]. The MAS has been widely adopted by manufacturers through the use of “Scratch panel stickers” and text based technology that would inform the consumers if the intended drug to be purchased is fake. However the author noted that the use of the MAS awareness was poor, with those in urban areas more likely to make use of it [20].

It is also important to note that only 67 of the 227 respondents from the End-users indicated that they would report to the authorities if they encountered a sub-standard drug. As a result, incidence of these sub-standard drugs are under-reported leading to misleading statistics on counterfeit drugs in the country [20]. “Price” as an indicator of drug quality had the lowest frequency (7.3%) in this study which is in keeping with findings made by Ndichu et al., (2019) in their study on “the evaluation of the quality of anti-hypertensive drugs in Lagos state”. It was discovered that the price of a product is not related to the quality of that product [26].

On how to recognize substandard drugs, it was discovered that 23.5% of the respondents’ majority being from the public had no idea what to look out for when checking for substandard drug. This population is somewhat alarming as many of them might have consumed substandard/ fake drugs in the past without knowing minding the high prevalence of fake medicinal product in our locality.
A greater percentage (65.4%) of the respondents had encountered substandard drug at least once in the past two years with 17.2% haven encountered it above 5 times, further buttressing the claim above. An even more disturbing trend as shown by this study reveals that over half of the respondents chose to “discard” the substandard drugs when encountered. About 32.3% “returns the drug back to outlet purchased from”, most probably to get a refund of their money while only 16.5% of the respondents “report to drug authorities”. Factors that have encouraged the proliferation of these sub-standard drugs in Nigeria includes its affordability, corruption and mild sanctions to those that manufacture these drugs, which currently stands at five hundred thousand Naira (N500,000) [31]. It is a well-known fact that an effective drug surveillance system requires a robust feedback. Therefore, the reluctance to make use of services such as the MAS, coupled with reluctance to report to the authorities and the financial constraints that would see individuals asking for their money back (from sellers of these sub-standard drugs) is responsible for the continued persistence of these genre of drugs within our healthcare sector [20, 31].

Worthy of note also in this study is that amongst the doctors and nurses who mainly prescribe and administer this drug (Magnesium Sulphate), 42.1% of them were not knowledgeable on the storage condition of Magnesium Sulphate. A similar trend was observed in the study by Ejekam et al., (2019) which showed that as much as 41% of the Doctors and 52% of the nurses had no knowledge on the storage of oxytocin [25]. The Doctors and Nurses in our study further admitted to the unavailability (57.1%) of a documentation system for reporting/recording ineffective Magnesium Sulphate encountered; this can be extended to other ineffective drugs encountered. While 39.0% admitted to not being aware of any such documentation system, only 3.9% admitted to the availability of a documentation system but did not state where such documents could be found which makes their response questionable. Ejekam et al., (2019), in line with our work
showed that 64.3% of Doctors and Nurses had no available means of documentation for
substandard drugs encountered in their facility while the rest rather documents in the patient case
note or clinical forms [25].

CONCLUSION

Our study shows that sub-standard drugs that the population is aware of the circulation of sub-
standard but are not informed of the channels of reporting, leading them to choose to live with the
current status-quo. The population agreed that quality is integral to the activity of a drug and
perceived drugs sold in Anambra to be effective. They, with exception of the nurses, however did
not know whether the locally manufactured drugs were as effective as the imported brands.

Nigeria was unable to attain the United Nations SDG 3 set in 2015, which is Good Health for all.
If we must attain this goal by the year 2030, then we need to pay a special attention to the quality
of drugs used in general health care as well as regulate the influx of pharmaceutical products in the
country.

Abbreviations

ISO: International Standard Organization

NAFDAC: National Agency for Food and Drug Administration Control

SDG: Sustainable Development Goal

PCN: Pharmacist Council of Nigeria

USP: United States Pharmacopeia

WHO: World Health Organization
Declarations

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Authors’ contributions

EJN carried out the study and drafted the original manuscript; CEU participated in the design of the study and manuscript revision; USU revised the manuscript; UCO did statistical analysis and manuscript revision; ANO conceptualized the study, participated in study design and manuscript revision.

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Availability of data and materials

The datasets used and/analyzed during the current study are available from the corresponding author on reasonable request.

Consent for publication

Not applicable

Competing interests

The authors declare that they have no competing interests.
Ethical approval and consent to participate

Ethical approval was obtained from the Ethics and Advisory Committee of Nnamdi Azikiwe University Teaching Hospital Nnewi, Anambra State, Nigeria with approval number, NAUTH/CS/66/VOL.12/111/2019/054. The study secured written informed consent from the respondents. Anonymity of participants’ data was maintained by not including names of participants.

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