Drug Labelling information and advertisements: Extent of use as sources of drug information by members of the public in Lagos, Nigeria

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ABSTRACT

Drug information is pertinent to promoting rational drug use, drug labels and advertisements are channels through which healthcare professionals, patients, care givers and members of the public get information necessary to make healthcare decisions. This study assessed the extent of use of drug labels and advertisements as sources of drug information by non-healthcare personnel in Lagos, South West, Nigeria. A structured questionnaire was developed and respondents were to indicate how often they obtain drug information from the items listed as possible, drug information sources based on a scale of 1-5. Descriptive statistics was reported as frequencies, percentages, means and standard deviations. Inferential analysis was done by calculation of student t-test and one-way ANOVA as appropriate. P-values less than 0.05 were interpreted as significant. The sources of information were sorted according to the five extracted components, pharmacists were the most consulted source for medicine information with the highest mean score of (3.29), the next most commonly used sources were television (3.26), radio (3.13) and the internet (3.02). Others are literature inserts (3.13) and labels (3.12). A significant difference was found between the components ($P<0.05$), which indicates that the extent of use is different. Females are more likely to use commercial advertisement sources ($P<0.05$), those with higher income are more likely to use doctors, Pharmacists, and labels on medicines ($P<0.05$), while those with low income and unemployed are more likely to rely on free sources such as family members, drug hawkers, and billboards. Members of the public and other non-healthcare professionals rely on the pharmacist and also rely to a very large extent on television, radio, literature inserts, drug labels, nurses and the internet as sources of drug information.

Key Words: Drug labels, advertisement, drug information, Lagos, Nigeria.

INTRODUCTION

At some point in time, everyone is likely to have taken medicines or encountered medicinal products in some form as they are the most popular and useful products used for medical interventions. Drug information is critical to decision making regarding how to take a medicine, when to take it, how long to take it, expected effects and associated risks. There are a variety of medicine information sources available to non-healthcare members of the society, caregivers, and patients. This often leads to decision-making challenges because they cannot easily ascertain the authenticity and reliability of information from the varied sources. Documented sources of medicine information include labels, television, billboards, family and friends amongst others. A label, according to the National Agency for Food and Drug Administration and Control (NAFDAC), refers to a display of written, printed or graphic matter upon the immediate containers to the drug products and other printed matter such as outer wrapper, carton or leaflet associated with the packaging. Labelling is defined as all labels and other written, printed or graphic materials that is upon any article or any of its containers or wrappers, or accompanying such article. The term 'accompanying' is interpreted to mean more than physical association which extends to posters, tags, pamphlets, circulars, booklets, brochures, instruction, websites, etc. A drug label should include: brand name, generic name, indications, active ingredients, dosage details, contraindications, special warnings, side effects, possible drug interactions, address of manufacturer and distributor, date markings, etc (NAFDAC, 2005).

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Labelling information are usually contained in the outer package, primary pack as well as leaflet insert. The outer package is the material that coveys the finished products usually a hard cardboard pack for most products while the primary pack is the packaging which is directly in contact with the product such as bottle, blisters, ampoules, vial, etc. Drug products also have accompanying leaflets which gives summarized information about the drug, indication, side effects etc. In this study, the outer package, primary pack and leaflets were considered as drug labelling and an essential vehicle through which users get information when they handle the product.

For some patients, the drug label may be the only source of information on how to take their medicines (Wolf and Parker 2007). Labels are very important as they guide the user for self-medication which is rampant in developing nations like Nigeria due to the inability to afford hospital or healthcare costs. The effect of self-medication, using prescription only and over the counter medicines and herbal remedies has been shown to cause adverse drug reactions, increase the potential for harmful drug-drug reactions, or drug-disease interactions (Ositchu, 1989; Fabrican and Hirschhorn 1987; Honig and Gillespie 1995).

Drug labelling information contains the instruction that is left with the patient when he is by himself and this informs decisions on how and when to take the drug and what to do in cases of untoward effect. Drug labelling information are required by regulatory authorities to be balanced, not misleading, providing scientifically accurate, up to date and clear instruction to health care practitioners for prescription drugs and to consumers for over-the-counter medicines and supplements (Jadav, Dumatar and Dikshit, 2014). Labelling plays a major role in the presentation of use, safety and effectiveness information, and poor labelling has been cited as a potential cause of medication error (Vrendenburgh and Zackowitz 2008). It is also expected that advertisement of a drug product will promote and support the designated use of a medicine based on the label claims (Kaptchuk and Miller, 2005; Norris, 2005). Overall, drug labels and advertising significantly affect prescribing habits and consequently health outcomes of patients (Ventola, 2011; Weissman *et al.*, 2003; Spurling *et al.*, 2010) therefore, labels should be adequate in content and adverts appropriate, in order to improve patient care. Studies have shown that drug consumers rely on labelling and advertising as two sources of drug information, and appropriate labelling and ethical advertisement promote rational drug use while inappropriate labelling and unethical advertisement have the potential to promote irrational use, over-prescription, drug abuse and misuse among other consequences (Norris, 2005). The FDA estimates that 300,000 preventable adverse events occur each year in the United States because of confusing medical information (Ahn *et al.*, 2014). Patients frequently have difficulty in reading or understanding drug labelling information and use of certain terminology can adversely affect a patient's understanding of medication instructions and may be due to a number of factors such as literacy level (Aspden *et al.*, 2006; Morony *et al* 2015).

Drug advertising is an aspect of drug promotion and it's communicated through the media about medicine paid for by an identified sponsor. It is used to encourage, persuade or manipulate the audience, viewers, readers or listeners to continue with or take some new action. For medicinal product advertisement, the media may include electronic (television, radio, online), print (newspaper, bulletins), and out-of-homes media (billboards, taxi cabs, vehicle-branding, posters, handbills). The main objective of drug advertisement is to promote the use and prescription of the medicine and also act as a source of information to members of the healthcare system and non-healthcare professionals. The amount spent on drug promotion/advertising has also been found to be more than what is spent on research and development (IFPMA, 2017), which underscores the importance of advertising. Studies have shown that medicine promotion affects prescribing habits (Khakhkhar *et al.*, 2013), and the accuracy and usefulness of drug promotion has been widely debated. One of the most popular drug promotional activities of the pharmaceutical industry is the use of product leaflets and brochures (IFPMA, 2017). However, research evidence has shown that promotional leaflets and brochures supplied by pharmaceutical representatives often contain information that is incomplete, unreliable and effectiveness claims may be exaggerated. It is important to critically evaluate their content and compare the information with what is obtained from unbiased sources (Parli *et al.*, 2017).

A variety of sources of drug information has been reported for members of the public such as the internet, patient information leaflet, doctors, pharmacists, television, newspapers, magazines, drug advertisements, relatives, friends and books (Ulla,

2007; Vinker *et al.,* 2007; Medlock *et al.,* 2015). The need to improve the quality of information available to patient is widely acknowledged and research evidence exists that patient information leaflets with information that avoids technical terms and framed in a conversational context have more acceptability (Mauro, 1990). Patients are seeking information more as they get more involved in decision-making process of their health. It is therefore important for patients to be empowered through access to relevant medicine information in order to gain greater control over decisions and actions affecting their health (WHO, 1998). Patients are hungry for health information and are accessing drug information through labels and adverts. There is a dearth of studies on the extent of use of the different information sources by members of the public in Lagos; an investigation can point us to opportunities for improvement. Therefore, the aim of this study was to investigate the extent of use of drug labels and advertisement as sources of drug information by members of the public in Lagos, South West, Nigeria.

METHODS

Settings:

This study was carried out in Lagos, South west Nigeria. It has twenty (20) local government areas and is often described as one of the fastest growing cities in the world. According to the State Government, the state has an approximate population of 24million people and 65% of this population are between 15-35years.

Questionnaire development

The instrument used for this study consisted of two sections. The first section was to collect demographic data such as sex, age, occupation, income and level of education from respondents. The second section consisted of 22 items that researchers have identified as possible sources of drug information to members of the public. Respondents were to indicate how often they obtained drug information from these sources to measure extent of use of these sources for drug-related information based on a scale of 1-5 as follows: not at all = 1, Sometimes = 2, maybe =3, often = 4 and very often = 5.

Data Collection

The participants in this study were members of the public randomly selected from different parts of Lagos, using names of streets in different local government areas in the Nigerian Postal Services (NIPOST) directory. Alternate buildings in each selected street were visited during weekends to administer the questionnaire to any adult that was willing to participate aged 18years and above. Those who could not write or speak English were assisted by a data collector who could communicate in the local Yoruba language. Where this is not possible because the subject cannot communicate in either English or Yoruba or consent was not granted the next available adult was approached to take part in the study. This process was done for a period of eight months using previously trained pharmacy students as data collectors. Sample size was determined to be 1428 at 95% confidence interval with a margin of error of 2.5%

Data Analysis:

The retrieved questionnaires were coded and entered into Microsoft Excel, cross checked for accuracy and loaded into SPSS 21.0 for calculation of percentages, frequencies mean and Standard deviations. The internal consistency of the 22 items of drug information sources was explored through computation of Cronbach Alpha. Principal component analysis employed Varimax rotation with Kaiser Normalization and list wise deletion of missing data. Following the determination of commonalities, none of the items had a factor loading less than 0.4 hence none was excluded in the final analysis. Possible association factors were investigated with the aid of GraphPad Instat 3.0 by the calculation of P-Values using student t-test and one-way Analysis of variance. P-values less than 0.05 were interpreted as significant.

RESULTS

Of the 2500 questionnaires sent out, 1886 were returned and found usable giving a response rate of 75.4%. Majority of the respondents were females (819, 53.4%) while the rest (46.6%) were males. Most of the respondents were aged 25-44years (53.3%) and 570 (37.2%) of them are employed. About 11% (182) are unemployed. About 52% of the respondents earn less than ₦50, 000 a month while only 6.5% (99) earn greater than ₦150, 000. Most were educated with only about 5% (78) being illiterate. See Table 1.

Table 1: Demographic factors of respondents Non Healthcare professionals (n=1886)

Variable	Number of Respondents	Percentage (%)
Sex		
Male	714	46.6
Female	819	53.4
Age (yrs)		
18-24	374	24.4
25-34	452	29.5
35-44	365	23.8
45-54	189	12.3
>55	153	10.0
Occupation		
Employed	570	37.2
Unemployed	182	11.9
Self- Employed	354	23.1
Student	304	19.8
Retired	123	8.0
Income (NGN)		
< 20,000	369	24.1
20,000 - 49,999	423	27.6
50,000 - 119,000	372	24.3
120,000 - 150,000	270	17.6
>150,000	99	6.5
Highest Level of Education		
Nil	78	5.1
Primary	114	7.4
Secondary	433	28.2
Tertiary	908	59.2

Cronbach Alpha for the 22 items to establish the reliability of the instrument was found to be 0.86. Factor loading range was 0.412-0.855. None loaded less than 0.4. The items were sorted according to the five extracted components. Three of the components have a score greater than 3.0 hence represent a high level of usage. Component 3 and 5 had the highest sub mean total score of 3.17 and 3.10 respectively. The items in the component are television, radio and the internet representing the sources from which members of the public usually get advertisement related drug information. Others are literature inserts and labels (component 5). Pharmacist is the single item with the highest mean score of 3.29 ± 1.25. This is followed by Television (3.26 ± 1.22), family members, literature insert, radio and labels on drugs. A significant difference was found between the components (P<0.0001). (See table 2).

Further inferential analysis (see table 3) showed that males are more likely to use items in component 2 and 4 as sources of drug information than females at p<0.01. The items in this component are billboards, family members, neighbors (component 2) and pharmacists, Doctors (component 4). Females are more likely to use advertisement media such as radio, television and the internet (component 3) and read drug labels, literature inserts including asking a nurse (component 5) as sources of drug information (P<0.01). Those who are aged 45-54years are more likely to use component 5 items (p<0.0001) while those 34years and below are most probably likely to use component 3 items as sources of drug information. Those aged 35-44years use component 2 items such as drug hawkers, bill boards and family members more (p<0.0001). Students appeared to use components 3 and 4 items more than any other occupational group (p<0.0001) while the employed use component 5 items more than others.

Table 2: Factor loading and mean usage score of drug information sources Non-healthcare professional (n=1886)

Item	Factor loading	Mean ± SD
Component 1:		
Medical Journals	0.710	2.36 ±1.20
Daily Newspaper	0.710	2.56 ± 1.18
Product Launch	0.530	2.78 ± 1.23
Pharmaceutical Journals	0.677	2.56 ± 1.24
Information from Science Conference	0.642	2.41 ± 1.29
SMS	0.681	2.31 ± 1.23
Handbills or Leave Behinds	0.527	2.74 ± 1.24
Sales Rep	0.412	2.65 ± 1.23
Co-workers in the Office	0.502	2.65 ± 1.21
Textbooks	0.535	2.41 ± 1.27
Sub-mean total		2.72 ± 1.25
Component 2:		
Neighbour	0.720	3.00 ± 1.16
Drug Hawkers	0.659	2.79 ± 1.34
Family Members	0.715	3.23 ± 1.18
Bill Boards	0.632	3.03 ± 1.20
Sub-mean total		3.06 ± 1.22
Component 3:		
TV	0.855	3.26 ± 1.22
Radio	0.808	3.13 ± 1.23
Internet	0.423	3.03 ± 1.28
Sub-mean total		3.17 ± 1.24
Component 4:		
Pharmacist	0.831	3.29 ± 1.25
Doctors	0.587	2.49 ± 1.27
Sub-mean total		2.86 ± 1.25
Component 5:		
Label on Drugs	0.814	3.12 ± 1.17
Literature Insert	0.812	3.13 ± 1.25
Nurses	0.451	3.01 ± 1.23
Sub-mean total		3.10 ± 1.22
	P<0.0001	

Those with higher income are more likely to use components 4 and 5 as sources of drug information at p<0.0001. Those with low income (<N20, 000) are more likely to rely on items on component 2 such as family members as sources of drug information (p=0.0001).

Those with tertiary level of education appears to use items in component 1, 3 and 5 as sources of drug information more than the less educated (p=0.0001). Those with secondary education are more likely to use items in component 2 as sources of drug information (p=0.0001).

DISCUSSION

All end users of medicine, members of the public, patients and care-givers use health information from a variety of sources.

Table 3: Relationship between demographic factors and sources of drug information by non-Healthcare personnel.

Variable	Frequency	Components' score ± SD				
		1	2	3	4	5
Sex						
Male	714	2.19 ± 0.69	3.03 ± 0.85	3.15 ± 0.85	2.76 ± 0.93	0.70 ± 1.31
Female	819	2.25 ± 0.60	2.91 ± 0.98	3.36 ± 0.69	2.36 ± 1.11	0.89 ± 1.56
p-value		0.0688	0.0111	0.0001	0.0001	0.0105
Age						
18-24	374	2.44 ± 1.02	2.75 ± 1.02	3.73 ± 0.86	3.00 ± 1.06	1.73 ± 1.09
25-34	452	2.32 ± 0.78	2.97 ± 0.87	3.13 ± 0.84	2.72 ± 1.06	2.05 ± 1.43
35-44	365	2.22 ± 0.75	3.73 ± 1.06	2.83 ± 0.89	2.59 ± 0.68	1.51 ± 1.51
45-54	189	2.16 ± 0.76	3.13 ± 1.34	2.77 ± 0.83	2.65 ± 1.03	2.33 ± 1.58
>55	153	2.19 ± 0.93	2.30 ± 0.97	2.67 ± 1.11	2.18 ± 1.05	1.63 ± 1.61
p-value		0.0003	0.0001	0.0001	0.0001	0.0001
Occupation						
Employed	570	2.02 ± 0.71	2.98 ± 0.89	3.19 ± 0.76	2.82 ± 1.07	2.24 ± 1.64
Unemployed	182	2.47 ± 0.73	3.33 ± 0.36	3.14 ± 0.77	2.75 ± 0.33	1.78 ± 1.53
Self -Employed	354	2.16 ± 0.39	2.94 ± 0.71	3.06 ± 1.14	2.46 ± 0.78	0.56 ± 0.99
Student	304	2.91 ± 0.39	3.31 ± 0.68	3.59 ± 0.32	3.00 ± 0.94	1.63 ± 1.79
Retired	123	2.55 ± 1.03	2.65 ± 0.94	2.58 ± 0.94	2.67 ± 0.98	2.00 ± 1.97
p-value		0.0001	0.0001	0.0001	0.0001	0.0001
Income						
<20,000	369	2.27 ± 0.83	3.15 ± 0.95	3.13 ± 1.01	2.74 ± 1.21	1.53 ± 1.33
20,000-49,999	423	2.33 ± 0.79	2.75 ± 0.96	3.21 ± 0.97	2.88 ± 0.99	1.97 ± 1.60
50,000-119,000	373	2.38 ± 0.75	2.69 ± 0.79	3.23 ± 0.88	2.59 ± 1.05	2.22 ± 1.58
120,000-150,000	270	2.64 ± 0.70	2.78 ± 0.93	3.30 ± 0.78	2.54 ± 1.00	2.26 v 1.55
>150,000	99	2.35 ± 1.18	2.73 ± 1.22	3.21 ± 1.23	2.94 ± 1.23	3.12 ± 1.30
p-value		0.0001	0.0001	0.2651	0.0001	0.0001
Highest Level of Education						
Nil	78	1.50 ± 0.63	3.41 ± 1.23	3.08 ± 1.05	2.53 ± 1.07	1.11 ± 1.30
Primary	114	2.44 ± 1.48	3.08 ± 1.78	2.97 ± 1.61	2.75 ± 1.53	2.22 ± 2.72
Secondary	433	2.36 ± 0.77	3.57 ± 1.04	3.04± 0.85	2.64 ± 0.83	1.72 ± 1.51
Tertiary	908	2.46 ± 0.74	2.76 ± 0.88	3.27 ± 0.86	2.55 ± 0.98	2.32 ± 1.19
p-value		0.0001	0.0001	0.0001	0.0001	0.0001

With different quality of information available from a variety of sources and the introduction of different drugs into the market, decision-making has become more complex. Medicines have been viewed as active substance plus information (Anyim, 1992). Information is a powerful tool in decision making for patients and provision of complete and accurate information for patients is an integral part of pharmaceutical care process as end users desire to understand the importance/relevance of their drugs as well as potential adverse effects.

Many sources of information have been reported for members of the public such as internet, patient information leaflet, doctors, pharmacists, television, newspapers, magazines, drug advertisements, relatives, friends and textbooks. The result from this study confirms previous reports on sources of drug information utilized by patients (Ulla, 2007; Vinker *et al.,* 2007; Medlock *et al.,* 2015; Narhi and Helakorpi, 2007). Findings from this study also report the use of drug hawkers as source of drug information in line with a previous study (Yussuf and Sanni, 2011). Drug hawkers serve as an advertisement medium for drugs especially inside buses and information provided by these drug hawkers poses a significant threat to patient safety because of its poor quality and often leads to self-medication and irrational drug use. This can also be attributed to ignorance by both the consumer and the seller on the correct dosage, duration of treatment and other useful information of the product. The authenticity of the information from these vendors has been a cause for concern. When the relationship between socio-demographic factors and sources of drug information was explored, the level of education has a relationship with the source of drug information; those with tertiary education consulted newspapers, handbills, internet, television and drug information leaflet which is consistent with reports from a previous study which reported that university graduates' rely on these sources of drug information more than those with lower levels of education

(Mohammed *et al.,* 2010). Patients' use of patient information leaflet has also been associated with higher educational levels (Vinker *et al.,* 2007). It is postulated that patients' improved knowledge from reading patient information leaflets provide a probable basis for their dependence on it as a source of drug information (Mohammed *et al.,* 2010), though the flipside is it can lead to increase in self-medication. This report shows that females use patient information leaflet as sources of drug information more than men which conforms to a previous study (Narhi and Helakorpi, 2007) and, members of the public seem to rely significantly more on the pharmacists and doctors for drug information than other sources as previously reported by other studies (Effie, 2015; Oh *et al.,* 2012), this is not unexpected as the ability to provide up to date information on drugs is a fundamental skill possessed by pharmacists (Anyim, 1992) and other healthcare personnel to varying degrees based on training. Patients now participate in health decision making and information on safety, appropriateness and efficacy has become necessary (Omole, 1998). Thus patients seek to be equipped with up to date drug information in order take quality decisions about their health (Williamson, 2014). Pharmacists play critical roles in providing drug information to their patients; it provides a logical explanation for the extent of reliance on pharmacists by most patients as their source of drug information. Respondents who were unemployed and earn less than ₦20,000 significantly used a commercial medium which required little or no expenditure to acquire medicine information such as family members, neighbours, bill boards and drug hawkers. This may be a consequence of their low socioeconomic status as they would have no funds to patronize more expensive sources of drug information.

Since drug labelling information and advertisements are used as sources of drug information, any inaccurate, biased, and obsolete information would have serious implications as it could lead to irrational use of medicines. It is therefore necessary that the content of labels and advertisement be adequately regulated in order to forestall the associated untoward effects, such as increased patient suffering, prolongation of illness and increase in healthcare costs. The current NAFDAC drug labelling and advert regulation should therefore be updated to capture elements in line with international best practices such as that of the United States Food and Drugs Administration (USFDA) and European Medicines Agency (EMA) by ensuring adequate font size to improve readability, writing of product names in braille to aid easy reading by visually impaired patients, stating leaflet approval date and version, calendar packs for tablets/capsules taken as single dose or twice daily should be supplied in blister packs of 7 and labelled with days of the week, to improve adherence and declaration of excipients which are not captured in the current regulation (USFDA, 2015; EMA, 2009; WHO, 2002).

CONCLUSION

Members of the public rely significantly on pharmacists as a source of drug information. This is closely followed by television, radio, drug literature inserts, drug labels, nurses and the internet as sources of drug information. All of these sources except nurses and labels represent commercial sources of drug information provided by manufacturers. Information from commercial sources have often been found to be incomplete, biased and profit orientated. It is therefore important that advertisement and labels being a major source of drug information to members of the public should be adequately regulated by the medicine regulatory agency NAFDAC to promote rational drug use, improve patient care and reduce healthcare costs.

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