BMJ Open

Stakeholder perspectives on the demand and supply factors driving substandard and falsified blood pressure lowering medications in Nigeria: a qualitative study

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To cite: Shedul G, Sanuade OA, Ugwuneji EN, *et al*. Stakeholder perspectives on the demand and supply factors driving substandard and falsified blood pressure lowering medications in Nigeria: a qualitative study. *BMJ Open* 2022;**12**:e063433. doi:10.1136/bmjopen-2022-063433

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2022-063433).

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Received 31 March 2022
Accepted 13 December 2022

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ABSTRACT

Objectives Although substandard and falsified (SF) blood pressure (BP) lowering medications are a global problem, qualitative research exploring factors driving this in Nigeria has not been reported. This study provides information on factors driving demand for and supply of low-quality BP lowering medications in Nigeria and potential strategies to address these factors.

Methods This was a cross-sectional qualitative study. Between August 2020 and September 2020, we conducted 11 in-depth interviews and 7 focus group discussions with administrators of health facilities, major manufacturers and distributors of BP lowering medications, pharmacists, drug regulators, patients and primary care physicians purposively sampled from the Federal Capital Territory, Nigeria. Data were analysed using directed content analysis, with the aid of Dedoose.

Results We found that demand for SF BP lowering medications in Nigeria was driven by high out-of-pocket expenditure and stockouts of quality-assured BP lowering medications. Supply of low-quality BP lowering medications was driven by limited in-country manufacturing capacity, non-adherence to good manufacturing and distribution practices, under-resourced drug regulatory systems, ineffective healthcare facility operations, poor distribution practices, limited number of trained pharmacists and the COVID-19 pandemic which led to stockouts. Central medicine store procurement procedures, active pharmaceutical ingredient quality check and availability of trained pharmacists were existing strategies perceived to lower the risk of supply and demand of SF BP lowering medications.

Conclusion Our findings suggest that demand for and supply of SF BP lowering medications in Nigeria are driven by multi-level, interrelated factors. Multi-pronged strategies need to target stakeholders and systems involved in drug production, distribution, prescription, consumption, regulation and pricing.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The qualitative approach contributes to an in-depth understanding of the factors driving the risk of substandard and falsified (SF) blood pressure (BP) lowering medications in Nigeria and potential areas for strengthening new strategies to reduce this risk.
⇒ Unique insights from this paper are information from Nigeria and a focus on BP lowering medications which have not been the focus of previous qualitative research on SF medications.
⇒ The current study identified potential effects of the COVID-19 pandemic on the supply of SF BP lowering medications.
⇒ The purposive sampling frame means that the results cannot be generalised to the whole of Nigeria.
⇒ Experiences of all stakeholders involved in the supply and use of BP lowering medicines in all 37 states in Nigeria were not captured because the sample was limited to stakeholders in the Federal Capital Territory (1 out of 37 states in Nigeria).

INTRODUCTION

Elevated blood pressure (BP) is a leading modifiable risk factor for global cardiovascular disease (CVD) morbidity and mortality,[1–3] including in Nigeria which is the most populous country in Africa.[4 5] Hypertension control programmes need reliable and affordable supplies of quality, generic BP lowering medicines to achieve widespread hypertension control.[6] However, there is suboptimal availability of affordable and quality BP lowering medicines in most low/middle-income countries (LMICs), including Nigeria, a challenge which may increase as rates of hypertension continue to grow.[7–10] As a result, there is a risk for falsified or substandard medications entering the supply chain, posing a threat to patients and health systems.[11]

The WHO defined falsified medicines as products that are fraudulently manufactured with their identity misrepresented and

distributed with bad intent, while substandard medications are products that are registered by the regulatory authorities but fail to meet quality standards.[12] Although substandard and falsified (SF) medications are a global problem, they are pervasive in LMICs with the burden estimated to be as high as 10% of all medicines.[12–15] Some LMICs are targets for manufacturers of SF medicines because of gaps in under-resourced regulatory systems, poor governance and shortage of health products.[14 16–19] These risks are largely attributed to misalignment between supply chain market drivers of pharmaceutical manufacturing and distribution, and out-of-pocket (OOP) expenditure, especially in the context of expanding universal health coverage.[20] Stockouts can further incentivise the use of SF medicines to fill the void.[20] Pisani *et al* showed that other factors driving SF medicines in LMICs include: (1) limited technical capacity among producers, (2) buying from informal markets for convenience and affordability due to OOP payment for medicines, (3) donors' activities which undermine national efforts to build sustainable markets and (4) weak systems to mitigate demand for and supply of SF medicines.[18]

When present, most pharmaco-surveillance and supply chain strengthening programmes in LMICs like Nigeria focus on communicable diseases rather than non-communicable diseases including CVD.[13] In Nigeria for example, the last mapping activity of the Federal Ministry of Health (FMoH) on multilateral, bilateral and non-governmental organisations' support in medicine procurement and distribution was in 2010 and focused on communicable disease.[17] Also, recent investments made by the Nigerian government on supply chain through organisations such as the National Supply Chain Integration Project have focused on medicines for communicable diseases and vaccines. Nevertheless, available evidence has shown that 24.6% of amlodipine and 31.9% of lisinopril in Nigeria[9] and 24.3% of generic BP lowering medications in 10 other African countries[21] are of substandard quality. The last mapping activity conducted by FMoH showed that the procurement and supply of medicines in Nigeria was uncoordinated, fragmented and unplanned.[17] However, one of the strategic focuses of the National Agency for Food and Drug Administration and Control (NAFDAC) between 2020 and 2023 is to strengthen Good Distribution Practice of regulated products from pre-shipment and local manufacturers to the end user.[22]

National drug distribution guidelines were embarked on by the government to revamp the drug distribution method in Nigeria. Suggestions were made to dismantle the open drug market to achieve a sustainable decrease in the circulation of counterfeit drugs across the country and sub-Saharan Africa (SSA).[23] Nigeria is also about to implement a track-and-trace surveillance system under the leadership of NAFDAC. As the most populous country in Africa and with a high burden of SF medicines, understanding upstream drivers of SF medicines will be useful for maximising the success of strategies like track-and-trace. We present the results of a qualitative study of market risk to understand the demand and supply factors driving SF BP lowering medications in the Nigeria public sector and the role of strategies to address factors that directly or indirectly increase the risk for SF medications. To our knowledge, this is the first qualitative exploration of the risks and potential interventions for ensuring availability of quality BP lowering medications in Nigeria. BP lowering medications have not been a focus in previous qualitative research related to SF medications. Addressing SF BP lowering medications is important to minimise the burden of hypertension and hypertension complications like hypertensive heart failure, stroke and chronic kidney disease.

METHODS

Study design and setting

We conducted a cross-sectional qualitative study in the Federal Capital Territory, Nigeria to understand factors driving the risk of falsified and substandard BP lowering medications. The interview guides were adapted from the framework developed by Pisani *et al*, which was developed to understand the risks of and interventions to prevent SF medications in China, Indonesia, Turkey and Romania.[18] Details of the interview guides are provided in online supplemental table 1.

Study population

Data collection took place between August 2020 and September 2020. We purposefully sampled stakeholders involved in the supply and use of BP lowering medicines and in the management of patients with elevated BP. Participants were purposively sampled from three of the six area councils of the Federal Capital Territory (Abuja Municipal Area Council, Bwari and Gwagwalada) because they have the largest number of qualified stakeholders among the six area councils. Eleven in-depth interviews (IDIs) were conducted and these included administrators of health facilities (n=4), major manufacturers and distributors of BP lowering medications (n=3), primary and secondary healthcare facilities and community pharmacists (n=2), and regulators of medicines supply from Pharmacists' Council of Nigeria (PCN) and from the NAFDAC (n=2). While community pharmacists are responsible for dispensing and supplying prescription medicines to community residents, PCN is a federal government parastatal responsible for regulating and controlling pharmacy education, training and practice in Nigeria. NAFDAC regulates and controls the manufacture, importation, exportation, distribution, advertisement, sale and use of food, drugs, cosmetics, medical devices, packaged water, chemicals and detergents in Nigeria. We also conducted seven focus group discussions (FGDs) with a total of 18 participants (FGDs 1–4, three stakeholders per group; FGDs 5–7, two stakeholders per group) including primary care physicians, pharmacists and patients. The number of interviews conducted in this

study was determined by stakeholder mapping and the feasibility of the number of stakeholders we were able to interview within the study timeframe. We conducted a mapping of stakeholders who can influence the demand and supply of quality and SF BP lowering medications in Nigeria. We identified 29 participants who were in 7 FGDs and 11 IDIs. All identified stakeholders who were approached consented to participate in this study, and they were consequently interviewed.

Interview procedures

Written informed consent for interview and recording was obtained from each participant. The IDIs and FGDs were performed face-to-face with participants on different days in settings (eg, participants' clinic and workplace) to ensure confidentiality. Interviews were conducted by study members (two females and two males) trained in qualitative methods, namely four Nigerian coauthors (GS, ENU, PP and IO), including two interviewers with pharmacy management expertise (GS, ENU). We established rapport with some of the participants prior to the commencement of the study building on pre-existing relationships. The duration of interviews ranged from 32 min to 57 min. Most interviews were conducted in English language, one was conducted in Hausa (one of Nigeria's three major languages) and one was conducted in colloquial English (Pidgin). The interviews in Hausa and Pidgin were conducted by interviewers who were fluent in these languages. Interviews were audio-recorded, and notes were also taken during the interview sessions with the permission of participants. Participants were informed about the aim of the study and the goal being to understand their perspective on BP lowering hypertensive medications. None of the participants refused to participate or dropped out and we did not return transcripts to participants for comments. We have provided further details about participant recruitment, interviews and data handling following the Consolidated criteria for Reporting Qualitative research guidelines. A reflexivity statement which outlined authors' roles in the research is provided in online supplemental table 2.

Analysis

All recorded IDIs and FGDs were transcribed verbatim. The FGDs in Hausa and colloquial English (Pidgin) were translated and transcribed into English by a professional translator who was fluent in English, Hausa and Pidgin. To minimise bias, fluent speakers (GS and ENU) reviewed the transcripts of the interviews conducted in Hausa and Pidgin for both linguistic and content translation. All data and transcripts were anonymised and stored in a secured database at Northwestern University. We analysed the data using directed content analysis,[24] with the aid of Dedoose (Los Angeles, California: SocioCultural Research Consultants, www.dedoose.com).[25] The coding process started with the codes that were derived from Pisani *et al*'s market risk framework.[18] The Pisani codebook was adapted as a starting point for our deductive analysis because the study focused on factors driving SF medicines in four LMICs (China, Indonesia, Turkey and Romania) just like Nigeria. We also saw Pisani *et al*'s framework as a comprehensive framework to guide country-specific, system-wide analysis. The deductive coding stage was followed by identification of inductive codes, which focused on new concepts which emerged outside the framework developed by Pisani *et al* (online supplemental table 3).

Coding of initial transcripts was done as a team led by qualitative researchers (TMO, LRH) with disagreements resolved by consensus. Final coding was done by GS, ENU and TMO and disagreements were resolved by LRH using directed content analysis, we identified factors driving SF BP lowering medications into demand and supply sides. Demand side factors focused on drivers of population access and uptake or SF BP lowering medicines. Supply side factors focused on the production, distribution and availability of SF BP lowering medications across Nigeria. We also extracted identified strategies that were thought to reduce demand and supply of low-quality BP lowering medications and suggestions for strengthening or new strategies from participants.

Patient and public involvement

Patients or participants were not involved in the design, intervention, research question or outcome measures of the current study but were contributors to data.

RESULTS

Participants' characteristics are provided in table 1. A total of 29 people participated in the study with two-thirds (62.1%) males and 58.6% younger than 50 years of age. The largest representation was at the federal level, and the single largest participant group were pharmacists (34.5%) followed by administrators and regulators (20.7%), patients (17.2%), physicians (17.2%) and manufacturers and distributors (10.3%).

The results are divided into three broad sections with each focusing on demand and supply sides: (1) factors driving risk of SF BP lowering medications; (2) current actions to minimise demand and supply of SF BP lowering medications and (3) additional potential strategies which can contribute to future work to reduce SF BP lowering medications in Nigeria (online supplemental table 4). A framework for how these demand and supply factors were found to potentially increase and decrease the risk of SF BP lowering medications in FCT, Nigeria was then developed (figure 1).

Factors driving risk of SF BP lowering medications

Demand side

We identified two interrelated factors which were associated with increased demand for SF BP lowering medications, including: (1) poverty/poor economic condition in Nigeria and high OOP BP medication expenditure and (2) stockouts.

Table 1 Participant characteristics

Characteristics	IDIs (n=11) n (%)	FGDs (n=18) n (%)	Total (n=29) n (%)
Sex			
Male	7 (63.6)	11 (61.1)	18 (62.1)
Female	4 (36.4)	7 (38.9)	11 (37.9)
Age, years			
<40	4 (36.4)	4 (22.2)	8 (27.6)
40–49	2 (18.2)	7 (38.9)	9 (31.0)
50–59	5 (45.5)	5 (27.8)	10 (34.5)
>60	0 (0.0)	2 (11.1)	2 (11.1)
Participant type			
Administrators	4 (36.4)	0 (0.0)	4 (13.8)
Regulators	2 (18.2)	0 (0.0)	2 (6.9)
Pharmacists (hospital or community level)	2 (18.2)	8 (44.4)	10 (34.5)
Patients	0 (0.0)	5 (27.8)	5 (17.2)
Physicians	0 (0.0)	5 (27.8)	5 (17.2)
Manufacturers and distributors	3 (27.3)	0 (0.0)	3 (10.3)
Level*			
Local	2 (18.2)	2 (11.1)	4 (13.8)
State	3 (27.3)	7 (38.9)	10 (34.5)
Federal	3 (27.3)	9 (50.0)	12 (41.4)

*Level does not include participants who were manufacturers and distributors.
FGDs, focus group discussions; IDIs, in-depth interviews.

Poverty/poor economic condition in Nigeria and high OOP BP medication expenditure

Participants reported that poor economic conditions in Nigeria, including high rates of poverty, and relatively high OOP expenditure of quality BP medicine make it difficult for people living with hypertension to afford quality BP lowering medicines. Participants reported that some people living with hypertension are unable to afford quality BP lowering medications, especially more expensive drugs classes like angiotensin receptor blockers, with the resultant effect being increased demand for cheaper but potentially lower quality medicines. Limited affordability of some BP lowering medications may also drive manufacturers and suppliers to produce or import cheaper SF medicines . Additional contributors related to limited financial resources among patients included the lack of health insurance coverage for medications and the chronic nature of hypertension which demands long-term use of BP lowering medications, increasing the impact of OOP expenditure.

> You know, no matter how cost-effective a drug can be, there are people that cannot afford it. And sometimes, they use more than two BP lowering medications. Then for some class of patients, where they have angiotensin receptor blockers (ARBs), that one is always an issue. They are unable to afford it, and most of the time, they really need it, and that's it. (FGD 4, pharmacist from secondary healthcare facility)

Stockouts

Participants noted that stockouts force patients to look outside regular and trusted sources of BP lowering medications. As a result, patients may purchase these medications at sources with higher risks of being substandard or falsified, including informal pharmacy markets. Stockouts also erode trust in facilities especially public sector ones and further push patients to patronise other sources of medications where access to quality of medicines is not assured. Further, we found that stockout can be driven by patients' preference for a particular brand of medicines, which results in a situation where demand for that brand exceeds its supply. This lack of supply chain monitoring contributes to stockouts.

> So, if you talk about fake, we come to the hospital because in the hospital you cannot have fake. And that is why I get annoyed when they say it's out of stock. (FGD 3, patient from tertiary healthcare facility)

Supply side

The supply side factors identified which contribute to the supply of SF BP lowering medications across Nigeria include limited in-country manufacturing capacity, nonadherence to good manufacturing and distribution practices, weak systems of drug regulation, inconsistent quality assurance and postmarket surveillance process due to limited resources, ineffective healthcare facility operations, poor distribution practices, limited number of trained pharmacists and the COVID-19 pandemic. Participants mentioned that these factors also combined to create an even greater challenge of supply of SF BP lowering medications than individual factors.

Limited in-country production

Participants mentioned that there is low in-country production of quality BP lowering medications in Nigeria, which provides an opportunity for SF BP lowering medications either produced or imported into the country to fill potential gaps from demand or actual stockouts. Participants reported concerns about this reliance on BP lowering drug importation making it difficult to assure quality and increasing the risk of substandard medications, including the risk from longer distribution and storage periods compared with locally manufactured medications. Respondents also reported that poor economic policies leading to increased importation and Naira devaluation, as well as unfavourable government policies (eg, lack of government subsidies for costs of production and high import taxes), may lead some manufacturers and distributors to compromise on good manufacturing, procurement

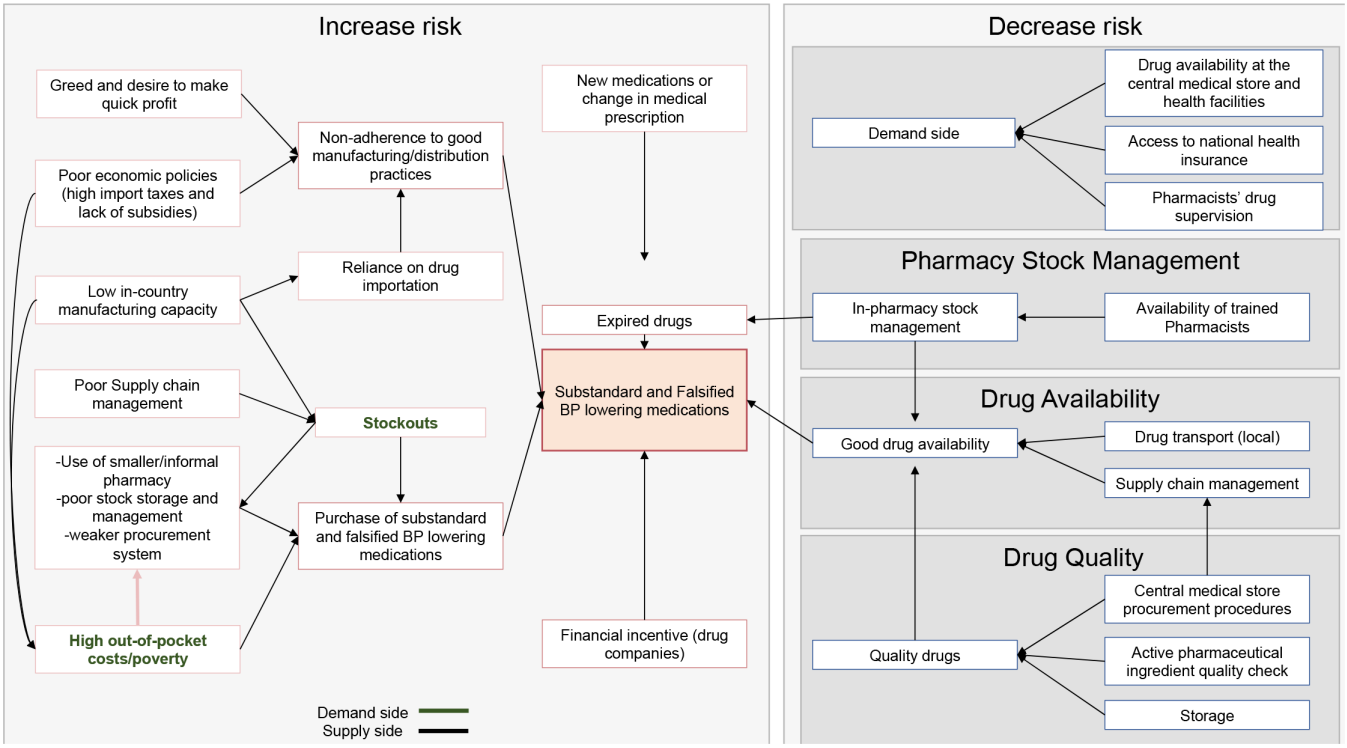

Figure 1 Factors identified as driving risk of substandard and falsified blood pressure lowering medications in Nigeria. BP, blood pressure.

practices, storage and distribution practices to reduce costs which can increase the risk of falsified medications as well as for substandard products at the point of consumption.

> Actually, the factor is just policy. One, in the country where, will I say, up to eighty to eighty-five percent of our drug consumption is still dependent on importation. You can't guarantee a mere quality. (IDI 9, State level supply chain manager)

Non-adherence to good production and procurement practices

In addition, some pharmaceutical manufacturing and distribution companies were felt to not always adhere to good practices and may prioritise profits over quality practices. Concern about these behaviours was mentioned by patients, pharmacists, supply chain managers and drug regulators. For example, participants mentioned that some of the pharmaceutical and manufacturing distribution companies capitalise on the high level of poverty in Nigeria by bringing into the country medications that even though may not have the right active pharmaceutical ingredients (APIs) but are affordable by an average Nigerian.

> So, each time there is fall in the price in dollars, it affects the cost of all these goods that come in, because the marketers will never want to lose their money. So, the only option left will be probably to compromise on quality. (IDI 9, State level supply chain manager)

Drug regulation

The system of drug regulation in Nigeria was also identified as contributing to the supply of SF BP lowering medications. Some federal drug regulator respondents noted that since most medications are imported, high taxes on imported medicines increased costs and risk of weakened supply chain of quality BP lowering medicines. While regulations exist, the limited resources of the food and drug regulatory agency facilitate the existence of parallel markets which offer SF medications.

Participants also noted that the challenges of routine quality assurance process of NAFDAC due to low laboratory testing capacity. This capacity gap makes it difficult for this regulatory body to maintain the desired level of testing needed to ensure quality medicines which are imported or produced and distributed across Nigeria. Further compromising the existing system, NAFDAC was noted to have inadequate staff strength needed to perform adequate postmarket surveillance.

> But we also have to look at the various brands in the market, most of these BP lowering medications are numerous. So, for me, I feel it will be very tasking for NAFDAC to really inspect them. I don't think they have enough staff and facilities to do that, so, that might be a loophole where fake drugs can thrive. (FGD 4, pharmacist from secondary healthcare facility)

Participants noted that the weakness in regulation of the Nigerian healthcare system has led to the proliferation

of unlicensed pharmacies. As a result, some people own and operate pharmacies and prescribe medicines without licenses, which increases the demand and supply of SF BP lowering medications.

> Somebody who is having a pharmacy is treating patients, recommending, and giving medicines, whether it's good or bad. Well, it's not something I can make a lot of comment about because it's part of the society (Nigeria). But if you want to wipe it away, let the hospital, government hospital, be functioning properly, so that people will be ready to come here. (FGD 3)

Ineffective healthcare facility operation

Some pharmacists mentioned that poor inventory and delays in suppliers' payments due to bureaucracy within the healthcare facility also contribute to stockouts and risk of substandard medications. They noted that poor communication flow between the central medical store and healthcare facilities sometimes leads to drug expiration because healthcare facilities may not be aware that certain medicines are available at the central medical store, at the same time, the central medical store may also not be aware of the need for medicines at the facilities.

> Prior to now, the communication flow between health facilities and Central Medical Stores was not adequate. And it led to even the Central Medical Stores having drugs that were expiring because the health facilities are not aware that they have such drugs. (FGD 4, pharmacist from secondary healthcare facility)

This poor communication could result in a situation where certain medicines remain at the central medical store longer than necessary and may even be near expiration before they are supplied, while stockouts occur locally. On other factors which increased the risk of expired medications, a supply chain manager mentioned that change in prescription patterns at the healthcare facility level could lead to reduced demand for in-stock medications and so expiration. This poor function was also identified as a reason why people went to unlicensed pharmacies. e.

Poor storage

The lack of infrastructure to store large quantities of BP lowering medicines resulted in poor storage and was also identified as a risk to medicine quality. For example, some pharmacists noted challenges with getting enough space to store procured BP lowering medications under the required temperature range, threatening medication potency. Finally, since some SF BP lowering medications are smuggled into the country to avoid the high taxes, improper storage conditions during this process was identified as also reducing quality of available medications.

> We all know what drug moieties are all about. For instance, a drug can still be potent at the point of importation, but because of ordinary storage condition, it can lose its potency, long before the expiration date. And as long as we import, you cannot guarantee storage condition during the course of importation. So, some potency could have long been lost. (IDI 9, state level supply chain manager)

Other factors

Respondents noted several other factors including human resources and COVD-19 pandemic. The limited number of trained pharmacists in the country, especially in health facilities, contributes to the supply of SF BP lowering medications. For instance, some private hospitals do not have trained pharmacists to determine the quality of drugs procured and dispensed within the hospitals. Without sufficient pharmacy oversight, such hospitals may risk dispensing SF BP lowering medications. Participants also noted that lockdown of health services during the COVID-19 pandemic affected supplies of medicines because some of the BP lowering medications in Nigeria are imported, resulting in stockouts, which further exacerbated the supply-demand mismatch and consequently increase in SF BP lowering medications. Participants also stated that cost of imported BP lowering medications increased during the pandemic and such products were more frequently out of stock than prior to the pandemic, thus increasing market for SF BP lowering medications.

Factors and strategies to minimise the risk of demand for and supply of SF BP lowering medications

Respondents identified a number of existing factors and strategies in place which reduced the risk of SF BP lowering medications, although some needed strengthening.

Demand side

Participants identified that four factors that lowered the risk of demand for SF BP lowering medications, including: (1) availability and affordability of medicines from the central medical store; (2) access to functional national health insurance scheme, which enhances affordability of quality BP lowering medicines for covered individuals; (3) supervision by pharmacists to ascertain appropriateness and quality of medicines and to prevent stockouts and (4) purchase of medicines at the healthcare facility instead of outside pharmacies.

Supply side

Participants also identified a number of supply side strategies which reduce the risk of SF BP lowering medications in circulation. One strategy was the procurement quality checks and good supply chain management practices by central medical stores. Participants also remarked that the medicines supplied at central medical stores are NAFDAC-certified and undergo quality control checks, even if capacity for checking all medications was limited. The strategy of serialisation (ie, tracing a medicine by using a unique serial number from the manufacturer right to the patient) and authentication by NAFDAC

allows them to be able to confirm the quality of medicines at the endpoint. NAFDAC's capacity with an analytical laboratory available to conduct quality tests on APIs was identified as a factor that reduces supply of low-quality BP lowering medications. These actions may help to enhance adherence to good manufacturing and distribution practices.

Further, participants noted that procurement guidelines in healthcare facilities also reduces risk of poor-quality BP medicines facilitated by trainings that pharmacists undergo to identify and prevent procurement of low-quality BP lowering medications. These trainings include effective supply chain management, detection and monitoring of SF medicines, drug procurement. As a result, pharmacists are better able to select medicines based on quality and affordability and purchase from reputable companies. This training also supports the central medical store procurement of quality BP lowering medications.

Suggested additional strategies for reducing SF medicines

Demand side

Participants also identified additional actions which could increase the market demand for less expensive medications, which may have a higher risk of being SF. They identified a need for strong communication to increase public awareness to purchase medicines from licensed and registered pharmacies and to know the locations of such pharmacies.

Supply side

Manufacturing, distribution and importation

Participants suggested that manufacturers should ensure that APIs used for drug production are safe for patients' consumption by adhering to good manufacturing practices. Good manufacturing practice that involves quality assurance of materials and processes as well as good packaging will also ensure safe effective medicines. Participants also identified the need for manufacturers to ensure that distributors follow necessary storage procedures, although they identified the challenge of a resulting increase in manufacturers' costs and subsequently, medication prices. An additional strategy identified was establishing an active and passive capture of adverse events by manufacturers and distributors with reliable reporting system. In addition, proper supply chain monitoring of BP lowering medicines should be established across the local, state and federal government levels.

Regulatory bodies

Much of the input was on strengthening strategies already in existence. For example, they suggested that regulatory bodies should strengthen the system of registering and monitoring pharmaceutical companies to enhance accountability in manufacturing and distribution of BP lowering medications. Reflecting the external sources, they also suggested that regulatory measures are strengthened to check the quality of BP lowering medications at the borders when they are coming in and before they are being distributed across the country which is critical to maintain quality supply chain management and quality of BP lowering medicines. Reflecting the limited resources, they also noted that more officers may be needed to allow NAFDAC to carry out on-site assessments overseas to ensure fidelity to quality control measures.

Local, state and federal government

Some participants noted that lower import taxes should be considered to increase importation of quality medicines, ensure availability of medicines across Nigeria and reduce cost of medicines. This approach may reduce both the supply of low-quality BP lowering medications and demand for cheaper and often lower quality drugs. Participants also recognised the need for strengthening transportation across the country in order to improve the efficiency and speed of the supply chain including reducing risk of substandard medications and prevent stockouts. Finally, they noted the importance of developing a functional health insurance programme to cover treatment of non-communicable diseases, to reduce costs and increase uptake of quality BP lowering medications.

Procurement, dispensing and storage

Respondents suggested that pharmacists should purchase BP lowering medications from central medical stores at all times because these medicines are cheaper, more affordable, and of reliable quality, reducing availability of SF medications. Some participants suggested that selection of companies to supply BP lowering medications by pharmacists should be based on merit of quality and affordability. It was suggested that such companies should be screened first before drugs are supplied and must have license to procure medicines. After this, prices should be compared across different companies and clinical presentations should be done for any new drug moiety. This process would directly reduce the supply of SF BP lowering medicines and reduce cost. Participants stated that drug regulators in Nigeria should ensure that good storage condition are maintained from the manufacturer to the distributor, through the pharmacy and then to the end users. This can be partly achieved by ensuring that appropriate infrastructure such as functional air conditioners and inverters (which give constant alternating current voltage at its output socket when there is no electricity) (due to poor power supply) are in place.

In addition, expansion and strengthening of existing strategies to improve availability of BP lowering medications is needed. For example, functional drug revolving funds, which are based on a system already existing in the public sector where other drugs are sold with a limited (eg, 5%) markup above procurement price to cover supply side costs. The subsequent revenue is used to replenish the drug stocks would be a potential way to ensure availability and affordability for BP lowering medications. However, work needed to strengthen the process was also noted.

DISCUSSION

By interviewing key stakeholders in the Nigeria public sector, our study provides information on factors driving the demand for and supply of SF BP lowering medications in Nigeria and outlines the strategies for overcoming these risks. Even though the factors driving SF BP lowering medicines were classified under broad factors, the narratives in the results captured the dynamics of how the factors driving substandard medicines were different from falsified medicines. For instance, participants noted that limited in-country production increased reliance on drug importation thus increasing the risk of substandard medications through longer distribution and storage periods. On the other hand, participants mentioned that poor economic and unfavourable government policies encouraged cost cutting by pharmaceutical companies to protect profit margins and meet local demands, and which consequently increase the risk of drug falsification. While Nigerian health experts and the community are worried over the existence of low-quality BP lowering medications in the country,[26] these results provide important evidence on the factors driving availability of poor quality of BP lowering medications which can be used to inform strategies to strengthen existing systems or new ones needed to address this growing crisis. Similarities and differences between our study findings and that of Pisani *et al* are presented in box 1. Our findings were compared with that of Pisani *et al* to show what was found in the countries studied by Pisani *et al* and what emerged from this study of SF BP lowering medications in Nigeria.

We found that BP lowering medicines are at elevated risk of falsification when there is a high market demand for these medications, further amplified by cost and scarcity of quality medications. The nature of health system financing mechanisms in Nigeria provides a basis for increased demand for low-quality BP lowering medications because healthcare is mostly funded through OOP payment.[27 28] As a result, it is often difficult for people to sustain access to quality medicines due to poverty, cost, stockouts, low health insurance coverage and the chronic nature of hypertension management. We found that High OOP expenditure pushes people to demand cheaper medicines from 'high risk outlets', which are more likely to sell low-quality BP lowering medications. This finding is similar to another study in Nigeria, which showed that relatively high cost of drugs has made access to quality medicines difficult for many Nigerians because a large proportion of the population lives below the poverty line.[29] Widening the national health insurance scheme coverage geographically and in terms of the scope of medicines covered may help to reduce OOP expenditure. Also, creating a system where Drug Revolving Fund can thrive will help to improve the availability and affordability of quality-assured BP lowering medications.[30] Also, evidence shows that the prices of generic and brand BP lowering medications in SSA[31] and other LMICs[32] are many times higher than international reference prices. An application of international reference prices on BP lowering medications in Nigeria may therefore help to improve adherence and reduce OOP expenditure.

Box 1 Similarities and differences between our study findings and that of Pisani *et al*

Similarities

1. Our study and that of Pisani *et al* showed that multi-level and interrelated factors drive the risk of demand and supply of SF medicines.
2. Pharmaceutical companies' desire to maximise profits emerged as a key factor which increases the risk of supply of SF medicines in Nigeria as well as in China, Indonesia, Turkey and Romania.
3. Our study and that of Pisani *et al* showed that patients acquire medications from unregulated supply chain in response to shortages thereby creating market opportunity for falsifiers.

Differences

1. While our study focused on factors driving the risk of demand and supply of SF BP lowering medications, Pisani *et al* study focused on different kinds of medicines.
2. Pisani *et al* showed that political promises made by the government in China, Indonesia, Turkey and Romania to provide universal health coverage led to public procurement policies targeted at lowering prices of medical products; this political promise led to cost-cutting by pharmaceutical companies, and distributors thus increasing the risk of substandard medicines. This theme did not feature in our study.
3. Our study showed that some of the factors driving the risk of supply of SF BP lowering medicines across Nigeria included limited in-country manufacturing capacity, weak regulatory systems due to limited resources, poor healthcare facility operations and distribution practices, and limited number of pharmacists. These factors were not mentioned in Pisani *et al* study.
4. Our study participants cited COVID-19 pandemic as a factor which affected supplies of medicines, thus resulting in stockouts, and an increased demand for SF BP lowering medications. However, COVID-19 was not mentioned by Pisani *et al* because their research was done before the COVID-19 pandemic.

BP, blood pressure; SF, substandard and falsified.

Further, our findings showed that stockouts was a major driver of SF BP lowering medications in Nigeria and occurred due to low in-country production, poor supply chain management, poor stock storage and management, and weak procurement systems. Implementing policies that increase in-country production and monitor the supply chain for BP lowering medications will go a long way in reducing the risk of demand and supply of SF BP lowering medications in Nigeria. In addition, we found that reliance on BP lowering drug importation makes it difficult to assure quality and it increases the risk of longer distribution and storage periods compared with locally manufactured medications. Addressing this challenge may involve repeat testing following storage or longer distribution periods; this approach prioritises quality over cost.[33]

Our findings showed that supply of SF BP lowering medications in Nigeria is driven by unfavourable government policies that limit in-country manufacturing capacity and create over-reliance on drug importation. Coupled with this, there is no clear monitoring of the APIs which came in through the borders indicating that the quality

of such BP lowering medications may be unknown. The porous nature of Nigeria's borders creates a potential avenue where SF BP lowering medications may gain an entry into the Nigeria market. Other studies have similarly linked the supply of low-quality medicines to drug smuggling cartels who may be motivated to diversify their portfolios.[12 34 35] To improve detection of and prosecution for low-quality BP lowering medications, the Nigerian government may need to have mutual legal assistance or extradition treaties with countries that are major sources of falsified drugs.[12 36]

Further, we found that an under-resourced regulatory system contributes to the supply of low-quality BP lowering medications in Nigeria. Within Nigeria, poor regulation due to low testing capacity and limited postmarketing surveillance create an enabling environment for non-adherence to good manufacturing practices and supply of low-quality BP lowering medications within the country. These findings are consistent with another study in Nigeria, which showed that factors contributing to the supply of low-quality medications including weak law enforcement, proliferation of unlicensed drug dealers, lack of system control, greed, illiteracy, illicit medicine importation and erratic distribution system.[29] Strengthening the national regulatory systems for BP lowering medicines in Nigeria and protecting patients from low-quality medicines will require a strong political will and putting appropriate legislative frameworks, actionable and enforced policies, human resources, technologies, and quality control networks in place.[12] There is a need to enforce national directives to further address SF medicines, including BP lowering medications. An important first step may be passing the bill on counterfeit medication which was presented to the National Assembly in August 2021.[37] This bill can be modelled after the Model Law on Medicine Crime which provides clear guidance on criminalisation against supply of low-quality medicines, as well as incentives for governments to strengthen drug regulatory capacity.[38]

Our study identified factors and interventions that may reduce demand for and supply of SF BP lowering medications in Nigeria, including central medical store procurement procedures, APIs quality check and availability of trained pharmacists to improve supply chain management. Interventions which encourage the continuance and expansion of these activities will be crucial to minimising the risk of demand for and supply of low-quality BP lowering medications in Nigeria. Even though participants mentioned that pharmacists are able to select and purchase quality medicines from reputable companies to reduce the risk of SF medications, there is evidence that even reputable pharmaceuticals are not immune to SF medicines due to difficulty in maintaining a high-quality and reliable manufacturing and distribution system.[36] To minimise supply of SF medicines, reputable pharmaceuticals may need to maintain a supply chain of their own to eliminate supply by unauthorised distributors.

An important intervention to minimise the availability of low-quality medications will be to incentivise and regulate with accountability quality markets and discourage open markets. Open markets are common sources of medicine in Nigeria and provide key opportunities for counterfeiting. Since 70% of drugs are imported from the two world's major sources of counterfeit medicines (China and India), dismantling the open drug market is necessary to achieve sustained decrease in counterfeit drug circulation in Nigeria.[23]

In addition, participants suggested that risk of low-quality BP lowering medications can be reduced through public awareness on how to identify SF BP lowering medications, active postmarketing surveillance to ensure adherence to good manufacturing practices, equipping all borders with necessary equipment to test the APIs of imported medicines, and tax reductions on imported BP lowering medications to reduce cost and ensure broader availability of quality BP lowering medications across Nigeria. These strategies are similar to what previous studies have suggested.[39 40]

LIMITATIONS

Our study includes limitations common to qualitative research. First, our study was based on a purposive sample of stakeholders from the Federal Capital Territory (1 out of 37 states in Nigeria) indicating that the results cannot be generalised to the whole of Nigeria. Also, our stopping criterion was not based on data saturation. Nevertheless, we were able to provide a wide range of opinions and experience from major stakeholders involved in the demand for and supply of BP lowering medications, including at the federal level. Second, three of our audio recordings were not audible and could not be transcribed. Even though we used the field notes taken during these interviews in our analysis, participants may have mentioned other factors driving low-quality BP lowering medication, which were not captured in our analysis. In addition, transcripts were not returned to participants for comments and/or corrections. Despite these limitations, our study is the first study to map out the factors driving the risk of SF BP lowering medications in Nigeria and potential areas for strengthening new strategies to reduce this risk.

CONCLUSION

Our findings suggest that multi-level and interrelated factors drive the demand for and supply of SF BP lowering medications in Nigeria. Multi-faceted strategies to address these factors need to target all stakeholders involved in drug production, distribution, prescription, consumption, regulation and pricing. Also, suggested strategies to lower the risks of SF medicines in Nigeria, as highlighted by the stakeholders, show the potential for combating the proliferation of low-quality medicines in the country. Progress on safeguarding the quality of medicines and combating low-quality medicines is crucial to achieving

the Sustainable Development Goal (SDG) on 'improving access to safe, effective, quality, and affordable medicines and vaccines' (SDG 3). Thus, the Nigerian government can strengthen the political will to implement national directives that address low-quality BP lowering medications to reduce the burden of hypertension-related disease in Nigeria.

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Acknowledgements The authors are grateful to all the participants who took part in this study.

Contributors MDH, DO, AV, GLS and LRH conceptualised and designed the study. ENU, GS, PP and IO collected the data. OAS, GS, TMO, GLS, ENU and LRH conducted the analysis. OAS, GS and ENU drafted the manuscript. All authors reviewed the manuscript and provided important intellectual content. All authors read and approved the final manuscript. LRH is responsible for the overall content as guarantor.

Funding This study was sponsored by the National Heart, Lung, and Blood Institute (R01HL144708). The funders had no role in the design, conduct of the study; collection, management, analysis and interpretation of the data; preparation, review or approval of the manuscript; or decision to submit the manuscript for publication.

Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Ethics approval The study was reviewed and approved by the Ethics Committee at the University of Abuja Teaching Hospital with approval number UATH/HREC/PR/2020/001/008. The aim of the study was explained to the stakeholders prior to the start of data collection, and written consent was obtained. During the informed consent process, we assured participants of maintaining their confidentiality.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request. Data are available upon reasonable request from the corresponding author.

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