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**Research Article**

# STOCK-OUT OF ANTIRETROVIRAL DRUGS: A CROSS SECTIONAL STUDY IN SELECTED HEALTH FACILITIES IN FEDERAL CAPITAL TERRITORY, NIGERIA

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**Abstract**

**Background:** Stock-out associated with antiretrovirals in treatment facilities is one of the factors that can impede the achievement of positive clinical outcome in the treatment of HIV/AIDS. This study aimed at exploring the factors necessitating stock-out of antiretroviral drugs and coping strategies used by hospitals in the Federal Capital Territory to prevent changes in treatment regimen. **Methods:** The study was a cross sectional study, data were collected using a well-structured questionnaire, as well as interview. **Results:** Findings indicates that majority of the patients registered in HIV/AIDS care centres visited were females as indicated by 62.1% of the sample. Up to 87.0%of the study participants had in one time or the other experienced stock-out in their facility. A quarter of the sample(25.0%) admitted changing of regimen during ART stock-out, a similar proportion (25.0%) had experienced stock-out in the last 6 months, 50.0% experienced stock – out in the last 3 months and up to 12.5% experienced stock-out in the last month. Findings further indicated that 12.5% have very slow response when stock-out is reported, more than a third of the study participants (37.5%) reported moderate stock-out and half of the participants (50.0%) reported very fast response. Stock-out was attributed to poor logistics and supply chain as well as change in regimen. One of the major coping strategies indicated by the respondents was shortening of refill period during stock-out. **Conclusion:** Antiretroviral stock-out was frequently experienced in secondary and primary healthcare facilities. This frequent stock out could be attributed to increasing patient population and poor documentation by the facilities.

**Keywords:** Stock-out, HIV/AIDS, Antiretrovirals, Patients, Health Facilities, Mortality, Morbidity.

## INTRODUCTION

HIV/AIDS remains a major public health problem across all continents, causing the death of millions in their prime, disrupting and impoverishing families and turning millions of children into orphans (WHO, 2010). There has been a dramatic change in the global HIV/AIDS landscape because of increased attention to care, treatment and support (UNAIDS 2013). The Joint United Nations Programme on HIV/AIDS launched an initiative called the '90-90-90' initiative for 2020 with the prospective to end the disease by 2030 (UNAIDS, 2014). This means that 90% of all people living with HIV will know their status, receive antiretroviral treatment, as well as being able to suppress the viral load of 90% of persons placed on antiretroviral therapy (ART). As of 2013, up to 9% of the global HIV cases were attributed to Nigeria alone (UNAIDS, 2013; Ogbo *et al*., 2017), and in 2014, the country experienced an incidence of 220000 new HIV cases (Awofala and Emmanuel, 2015). The epidemic is unequally distributed across the 36 states of the Federation, with Ekiti having the lowest number of cases whilst Benue state was reported as having highest number of HIV cases (FMH, 2009).In 2014, it was estimated that about 3.4 million people were living with HIV, and in 2015 the number had increased to 3.5 million with 180000 deaths attributed to the disease (UNAIDS, 2015). The prevalence of HIV in Nigeria is estimated to be 3.4% (FMH, 2013). HIV was reported as a leading cause of death a decade ago, as it was reported to have claimed more than 35 million lives (WHO, 2010). ART initiation reduces HIV replication, suppresses plasma HIV viral loads to unquantifiable levels within 4-6 months (Dybul *et al*., 2002), reduces morbidity and mortality, with resultant improvement in chances of survival (Palella *et al*., 1998). If adequate viral suppression is not achieved, it means therapy has failed and this may require switching to a second line ART regimen which is more expensive (DeGruttola *et al*., 2000). ART is recommended to be offered in a comprehensive manner that includes access to on-going adherence counseling, baseline and routine/periodic laboratory investigations, prevention and management of opportunistic infection (OIs), treatment monitoring and follow-up. ART is effective in reducing transmission of HIV from an infected person to an uninfected person. Widespread and sustained use of ART may lead to reduction of transmission of HIV in communities, which is the epidemiologic objective of ART. Nigeria is a long way off meeting the global target of enrolling 90% of people diagnosed with HIV on antiretroviral treatment (ART). Just 30% of all people living with HIV were receiving treatment in 2016. Amongst children this is even lower, with just 21% on ART (UNAIDS, 2017). Of the people on HIV treatment, only 24% had achieved viral suppression in 2016 (UNAIDS, 2017). One major challenge to ART scale up in Africa is development of drug resistance as a result of poor adherence, which is mainly due to failure to maintain uninterrupted supplies of antiretrovirals (ARVs) leading to drug stock-outs (Schouten *et al*., 2011). A WHO survey showed that 38% of reporting countries had documented at least one stock-out of ARV drugs in health facilities (WHO, 2010). Though many of the ART country programs are donor funded, drug stock-out are reported and this has been attributed to poor procurement and supply chain management system in these countries (Schouten *et al*., 2011). Drug stock outs contribute to treatment discontinuity among other factors such as treatment costs, insufficient human resources, poor infrastructure, and adverse events (Weidle *et al*., 2006). Repeated drug interruptions could cause drug resistance which

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in turn leads to switching of drug regimens or substitutions. For instance, first line antiretroviral therapy (ART) drug regimen are cheaper and switching patients to second line or higher regimens which are more expensive could infer that donor sponsor/government budget on these medicines will increase (Fischer *et al*., 2006). Some of these higher line regimens could be more toxic which could lead to increased adverse events, thus encouraging further treatment discontinuity (Garcia, 2002). These drug interruptions hamper adherence which is key for any treatment efficacy (Oyugi *et al*, 2007). Although research has been conducted on patients in ART programs in Nigeria, most studies have focused on facility-based adherence monitoring and factors associated with poor adherence to ART. Antiretroviral drug stock-out, though recognized as a prerequisite for achieving any level of adherence, has received less attention. Availability of drugs is an important aspect in the ART program. Therefore, a better understanding of the factors necessitating antiretroviral drug availability in Nigeria is needed. It is against this backdrop that this study aimed at exploring the factors necessitating stock-out of antiretroviral drugs and coping strategies used by health facilities in Federal Capital Territory to prevent changes in treatment regimen.

## METHODS

**Study Area:** The study area covers selected tertiary and secondary healthcare facilities in the Federal Capital Territory (FCT). The territory is located just off the confluence of the River Niger and Benue River. It is bounded by Niger state to the west and north, Kaduna to the northeast, Nasarawa to the east and south, and Kogi to the southwest. It is lying between latitude 8.25 and 9.20 north of the equator and longitude 6.45 and 7.39 east of Greenwich Meridian. The FCT has a landmass of approximately 7,315 square kilometers of which the actual city, Abuja, occupies 275.3 square kilometers. The FCT is made up of six Local Area Councils: Abuja Municipal, Gwagwalada, Kuje, Bwari, Kwali and Abaji Area Councils. As at 2012, the HIV prevalence in the FCT was 7.5%; this prevalence reduced to 5.8% in 2014 (NACA, 2015).

**Study Design:** This research is based on a cross-sectional design and data were collected using both qualitative quantitative method of data collection. The research focused on the different factors necessitating antiretroviral drug stock-out and ways in which hospitals in this study cope with these cases of ART stock-out. The questionnaire for the study was designed based on previous research (Monjok *et al*., 2010; Mori and Owenya, 2014; Chineke *et al*., 2015)

**Sample:** The facilities visited include 6 ARVs centres with 18 respondents who were randomly selected from these centres within the study area.

**Study Scope:** The study was undertaken in 6 ARVs centres. These centres includes National Hospital ARV centre, National Institute for Pharmaceutical Research and Development (NIPRD) ARV Centre, University of Abuja Teaching Hospital (UATH) Special Care Centre and General Hospitals (Wuse, Kubwa, Asokoro).

**Data Collection Procedure:** Data were collected with the aid of questionnaire and interview. The questionnaire was administered to the heads of antiretroviral drug department in the 6 health facilities visited. The interviews were transcribed shortly after each interview and the transcripts coded in terms of certain area or subjects and then interpreted.

**Ethical Consideration:** Ethical clearance was obtained from the Health Research Ethics Committee of the Federal Capital Territory (FCT). Informed consent was obtained from each participant before administration of questionnaire. The confidentiality of participants was maintained by using codes, instead of names, to identify them. Participation in this research was voluntary and participants had the right to withdraw from the study at any time without any adverse consequences.

**Data Analysis:** Descriptive statistics was undertaken, and the test for association of different variables under consideration were determined using the multivariate linear regression model at $p<0.05$. All data were analyzed using Statistical Package for Social Sciences (IBM; SPSS Version 21).

## RESULTS

**Demography:** The result of the socio-demographic characteristics of healthcare professionals indicated that 25.0% of the participants were in the age group 20 – 30 years, 37.5% were in age group 31 – 40 years, 25.0% were in the age group 41 – 50 years and 12.5% were in the age group ≥ 51 years. Further details about socio-demographic characteristics are presented in table 1 below.

**Table 1. Socio-Demographic Characteristics**

| Variables | Frequency | Percentage (%) |
|---|---|---|
| **Age (years)** | | |
| 20 – 30 | 4.0 | 25.0 |
| 31-40 | 6.0 | 37.5 |
| 41-50 | 4.0 | 25.0 |
| ≥ 51 | 2.0 | 12.5 |
| **Health Facility** | | |
| Tertiary | 3.0 | 50.0 |
| Secondary | 3.0 | 50.0 |
| Primary | 0 | 0 |
| Designation | | |
| Pharmacist | 10.0 | 62.5 |
| Other healthcare professionals | 6.0 | 37.5 |
| **Years of Practice (years)** | | |
| 1-5 | 1.0 | 12.5 |
| 6-10 | 5.0 | 65.5 |
| >10 | 2.0 | 25.0 |
| **Clients enrolled in HIV care (Gender)** | | |
| Male | 12363 | 37.9 |
| Female | 20232 | 62.1 |
| TOTAL | 32595 | 100 |
| **Clients enrolled in HIV care (Age)** | | |
| Adult | 23864 | 73.2 |
| Children | 8731 | 26.8 |
| TOTAL | 32595 | 100 |
| **Clients on ART (Gender)** | | |
| Male | 11259 | 37.5 |
| Female | 18746 | 62.5 |
| TOTAL | 30005 | 100 |
| **Clients on ART (Age)** | | |
| Adult | 21565 | 71.9 |
| Children | 8440 | 28.1 |
| TOTAL | 30005 | 100 |

**ART Stock-out:** Analysis indicated that 87.0% had in one time or the other experienced stock-out in their facility. A quarter of the sample (25.0%) admitted changing of regimen during ART stock-out. 25.0% experienced stock-out in the last 6 months, 50.0% experienced stock – out in the last 3 months and 12.5% experienced stock-out in the last month. Further details are presented in table 2 below.

**Table 2. ART Stock-out**

| Variables | Frequency | Percentage (%) |
|---|---|---|
| **Ever experienced ART stock-out** | | |
| Yes | 7.0 | 87.5 |
| No | 1.0 | 12.5 |
| **Was regimen changed during stock-out** | | |
| Yes | 2.0 | 25.0 |
| No | 6.0 | 75.0 |
| **When last was stock-out experienced** | | |
| Last 12 months | 0.0 | 0.00 |
| Last 6 months | 2.0 | 25.0 |
| Last 3 months | 4.0 | 50.0 |
| Last month | 1.0 | 12.5 |
| **How fast is response to stock-out?** | | |
| Very slow | 1.0 | 12.5 |
| Moderate | 3.0 | 37.5 |
| Very fast | 4.0 | 50.0 |

**Table 3. Association between variables**

| Variables | Number of clients enrolled | | Number of clients initiated | | Facility | |
|---|---|---|---|---|---|---|
| | Correlation | sig. | Correlation | sig. | Correlation | sig. |
| Ever experienced stock-out In your facility? | -0.010 | 0.889 | 0.060 | 0.380 | 0.163* | 0.016 |
| Is industrial action a necessitating factor for ARV stock-out in your facility? | 0.090 | 0.187 | -0.076 | 0.268 | -0.029 | 0.670 |
| Is patient regimen changed during ARV stock-out? | 0.186** | 0.006 | 0.034 | 0.621 | -0.104 | 0.127 |
| During regimen change is ADR encountered? | 0.228** | 0.001 | 0.068 | 0.320 | -0.052 | 0.447 |
| How often is ADR reported? | 0.228** | 0.001 | 0.058 | 0.391 | -0.075 | 0.273 |
| Is regimen change permanent? | 0.073 | 0.286 | -0.073 | 0.283 | 0.077 | 0.255 |

## Association between variables

There exist a significant association between ART stock-out and the facilities indicating that some of the facilities had higher enrollee compared to ART made available. The change in the ART regimen is significantly associated with number of clients enrolled in the ART programme. The occurrence and report of adverse drug reaction is significantly associated with number of clients enrolled into the ART programme.

## Factors Associated with ART Stock-out and Coping Strategy

The participants of this study indicated that when ART stock-out occurs, it could last for 1 week (75.0%) and 2 – 4 weeks (25.0%). The facilities identified untimely order (37.5%) and inaccurate quantification (62.5%) as the major factors associated to ART stock-out. The causes of ART stock-out were identified as change of regimen (25.0%), poor logistics and supply chain (12.5%), and short dated commodities (62.5%). Facilities under study identified shortening refill period (50.0%), rescheduling appointment (37.5%) and referring patients to other centers as the coping strategies during ART stock-out. ART stock-out was also attributed to short-dated medicines. One of the participants said, "*the major reason we experience stock is due to expiring of certain ARVs"*. One of the major coping strategies in the face of stock-out was shortening of refilling periods. Thus, they give patients a smaller number of pills, usually enough to keep them on treatment for two weeks rather than a month. Then, after they have replenished their stock, they give them out on a monthly basis.

According to one of the participants, "*in our facility we shorten the refill period, instead of giving them a monthly dose we give them enough for a shorter time so that other patients can also get the medicines. By shortening the refill period, every patient will get some pills for some time.*

Another participant who heads a primary facility said *"we do not have stock out most times. The policy changes most especially for our facility that is key in Nigeria has facilitated our stocking of ARVs*.

Some other participants refer patients to other facilities. This strategy, although not very common, was also mentioned, especially for primary level facility. According to one of the participants "*During stock out we reach out to partners, but when they fail to restock, we reach out to pharmacies who can refill clients ART on low cost*".

Other participants noted that patient's appointments were rescheduled. A participant said, "*when we ask for refill in cases of stock-out, patients' appointment is rescheduled because if regimen is changed patients' experiences side effects never experienced before and sometimes stock out doesn't last so they come back for refill*". Other relevant details relating ART stock-out are presented in table 4 below.

**Table 4. Factors Associated with ART Stock-out and Coping Strategy**

| Variables | Frequency | Percentage (%) |
|---|---|---|
| **Causes of stock out** | | |
| Change of regimen | 2 | 25.0 |
| Poor logistic and supply chain | 1 | 12.5 |
| Short-dated | 4 | 62.5 |
| **Duration of stock-out?** | | |
| 1 week | 6.0 | 75.0 |
| 2 – 4 weeks | 2.0 | 25.0 |
| **Factors contributing to ART Stock out** | | |
| Untimely order | 3.0 | 37.5 |
| Inaccurate quantification | 5.0 | 62.5 |
| **What are your coping strategies?** | | |
| **During ART stock-out?** | | |
| Shortening refill period | 4.0 | 50.0 |
| Refer patients to other centers | 1.0 | 12.5 |
| Reschedule appointment | 3.0 | 37.5 |

## DISCUSSION

In the past decade, universal access to antiretroviral therapy (ART) has been gathering momentum as a global health priority. The attainment of global health goals for the control of HIV depends substantially on the capacity of health-systems to ensure enough stock of ARVs to meet the escalating demand for treatment especially at the front-line level of service delivery. To achieve viral suppression, patients on ART require an uninterrupted supply of ARVs. Interruptions in supplies of ARVs have been associated with HIV drug resistance and treatment failure as well as mortality in patients enrolled for care (Pasquet *et al.,* 2010). The stock-out of antiretroviral drugs is an increasingly chronic bottleneck in HIV service delivery in the broader Sub-Saharan Africa region (Poku, 2017). Previous research had examined this phenomenon in national-level drivers of stock-outs in countries with weak medicines supply chain systems (Poku, 2017). The healthcare professionals in this study reported that facility-level contributors to stock-outs include untimely orders of drugs from suppliers and inaccurate quantification of ARV medicines need due to a paucity of ART program data. This is in agreement with report of Zakumumpa *et al*. (2019). The result of this study indicates that stock-outs of ART are frequent in the health facilities surveyed, with stock-outs often lasting several days to weeks and affecting facilities serving varying numbers of patients. The paucity of ART program records relating to the number of patients enrolled on ART was cited as one of the challenges for requisitions of ART. Zakumumpa *et al*. (2018), in suggesting a link between health information systems and medicines supply, suggested a 'systems thinking' perspective in understanding bottlenecks in accessing essential medicines. Study of Zakumumpa *et al*. (2019) found that cases of erratic stock involving under-supply and over-supply of specific drugs were common in participating health facilities. It was common to find that a health facility experienced a shortage of a specific ARV when a neighbouring facility had an excess supply of the same regimen. This scenario points to weaknesses in medicines supply chain system. Findings further indicated that when stock-outs occurred, healthcare professionals at the facilities shortened the refill period, or rescheduled their appointment. The shortening of refill period is important to ensure that patients are maintained on their ART regimens. However, this strategy is associated with increased direct and indirect costs borne by patients and their families in accessing treatment (Veenstra *et al*., 2009). Both direct and indirect costs in accessing care are associated with poor adherence to treatments and treatment interruptions (Laurent *et al*., 2005). Rescheduling appointments as a coping strategy is particularly problematic because of treatment interruptions. Treatment interruptions are associated with high rates of drug resistance, rapid disease progression and greater numbers of deaths (Oyugi *et al*., 2007). Coping strategies like those indicated in this study have been described in response to ART stock-outs in Tanzania, leading to increased cost for patients, higher risk of treatment interruption and emergence of resistant strains (Mori and Owenya, 2014). Stock-outs occurring in 2012 in South Africa led to initiation of patients with less optimal regimens, patients having to return more frequently and an increase in missed drug pick-ups (Brennan *et al*., 2017).

### Conclusion

The frequent stock-outs of antiretroviral were attributed to the increasing HIV client loads. It was indicated that the increasing patient population were not being properly documented by healthcare facilities. As a result, proper ART commodity quantification is impeded which in turn impacted on requisitions. The major coping strategy cited by participants was change in ART regimen and rescheduling appointment. Participants admitted being frequently compelled to switch regimens for patients on ART due to shortages. In some facilities, overstocking was mentioned as a strategy for averting ARV medicines stock-outs which providers described as frequent. It is therefore recommended that frequent monitoring of stock status be ensured as well as frequent monitoring of patients on ARV regimen change so as to prevent stock-out.

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