Letter to the Editor

Cabenuva®: Differentiated service delivery and the community Pharmacists’ roles in achieving UNAIDS 2030 target in Nigeria

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The approval of the novel long-acting HIV injection; Cabenuva®- Cabotegravir and Rilpivirine injectable formulation) and the recent call by the World Health Organization for promoting community-based ART management, underscore the remarkable progress towards meeting the Joint United Nations Programme on HIV/AIDS (UNAIDS) 95–95–95 targets by 2030.

As the availability of antiretroviral therapy (ART) for the treatment of HIV/AIDS has increased in resource-limited settings, there has been a move to develop and implement alternative treatment delivery models such as Differentiated Service Delivery (DSD) in high prevalence countries to meet the global targets for HIV treatment while maintaining the quality of care. However, there is limited data on the involvement of community pharmacies in the delivery of ART within the community. Although, in western countries, several studies have documented the different roles community pharmacists can play in the management of HIV/AIDS. Community pharmacists are the most accessible and first points of health care for most clients. They are trusted, highly trained health care professionals. They should be incorporated and allowed to administer the Cabenuva® injection if the battle against the HIV pandemic is to be totally won. In this paper, we, therefore, aim to explore how the community pharmacist can be positioned in HIV service delivery regarding the administration of the Novel long-acting Cabenuva® injection formulation. It is therefore recommended that the Nigerian government embrace community pharmacy-led drug administration initiatives and embark on accredited training programmes for the profession in line with drug administration services. The government should also put in place necessary funding mechanisms for community pharmacists for the extra workload placed on them in administering injection drug formulation in their respective pharmacies.

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1. Body

There continues to be a substantial number of new human immunodeficiency virus (HIV) infections worldwide, with an estimated 1.7 million people newly infected in 2019 (UNAIDS, 2020).

The majority of these are in sub-Saharan Africa (58%), with more than half of these occurring in just 4 countries: South Africa, Mozambique, Nigeria, and Tanzania (Reed et al, 2018). Nigeria has the second-largest HIV burden in the world (UNAIDS, 2020). Although HIV prevalence among adults is much less (1.3%) than other sub-Saharan African countries such as South Africa (19%) and Zambia (11.5%), the size of Nigeria’s population means 1.8 million people were living with HIV in 2019 (UNAIDS, 2017). The Joint United Nations Programme on HIV/AIDS (UNAIDS) estimates that around two-thirds of new HIV infections in West and Central Africa in 2019 occurred in Nigeria, together with South Africa and Uganda, the country accounts for around half of all new HIV infections in sub-Saharan Africa every year. According to the National Agency for the control of AIDS, unprotected heterosexual sex
accounts for 80% of new HIV infections. Approximately 45,000 people died from AIDS-related illnesses in Nigeria in 2019. The Centre for Disease Control reports in 2016 show that 41% of people living with HIV are spread across six states in Nigeria; Kaduna, Akwa Ibom, Benue, Lagos, Oyo, and Kano. The Southern states account for 5.5% of HIV prevalence in Nigeria. While the rates of HIV is higher in rural areas (4%) than in urban ones (3%).

The management of HIV infection has drastically changed over the last 10 years with the development and enhancement of more than 14 antiretroviral medications, including better formulations and various combination pills approved, as well as better adverse drug reaction profile (Mwagomba et al, 2010). Recently, the U.S. Food and Drug Administration (FDA) approved Cabenuva® (cabotegravir and rilpivirine, injectable formulation) as a complete regimen for the management of human immunodeficiency virus type 1 (HIV-1) infection in adults. This is to replace the current antiretroviral regimen in those who are virologically suppressed on a stable antiretroviral regimen; with no history of treatment failure; and with no known or suspected resistance to either cabotegravir or rilpivirine. This is the first FDA-approved injectable, complete regimen for HIV-infected adults administered once a month. Research has shown that the once-monthly ART creates efficiencies for the health system and improves retention in care (Waldrop et al, 2016). The provision of such a service for the people living with the infection will reduce the waiting time in health facilities while increasing access to treatment and reduction in apathy to seeking care thereby leading to stigma reduction in the health care setting (Merico et al, 2013).

Effective HIV prevention measures should ideally emphasize human dignity, responsibility, voluntary participation, and empowerment through access to information, services, and support systems (UNAIDS, 2015). A thorough understanding of common values and belief systems also helps to identify positive values and practices that can facilitate and more effectively promote HIV interventions. Hence, broadening options for service delivery to reduce the burden on strained health systems and extend the reach of services, including greater use of community-based and new partnerships (Fatti et al, 2010), community-based approaches are increasingly being advocated for HIV prevention. Community-based interventions (CBIs) are built on shared values and norms, and belief systems, and social practices, and permit culturally sensitive discussions of HIV, and sexual and reproductive health.

In sub-Saharan Africa, community-based ART is being promoted as the key for managing the over 20 million people living with HIV/AIDS (PLWHA) (Kredo et al, 2010). In the effort to ensure that PLWHA access HIV services, the World Health Organization (WHO) is promoting the use of a community-based ART approach in a global strategy to end HIV/AIDS by 2030. The community-based ART approach is overwhelmingly supported because it seems to be the only viable strategy for delivering HIV treatment services closer to the people and improving ART uptake, retention in care, and decongesting overwhelmed health facilities. The last decade particularly witnessed a progressive shift from hospital-based ART to primary health centers and more recently to the community (Kredo et al, 2010; El-Sadr et al, 2010). In effect, the community-based approach to treating HIV/AIDS has always been in the background but was not well-publicized.

As the availability of antiretroviral therapy (ART) for the treatment of HIV/AIDS has increased in resource-limited settings, there has been a move to develop and implement alternative treatment delivery models (also referred to as “differentiated models of service delivery” or DSD) in high prevalence countries to meet the global targets for HIV treatment while maintaining the quality of care (Roura et al, 2009). Different models of community ART are being implemented in sub-Saharan Africa but there is limited data on the involvement of community pharmacy in the delivery of ART within the community (Rosenquist et al, 2010 and Wools-Kaloustian et al, 2009). In the western countries, however, several studies have documented the different roles community pharmacists can play in the management of HIV/AIDS (Cocohoba et al, 2012, Murphy et al, 2012, and Myers et al, 2019).

2. Community pharmacists as a key driver in reducing HIV burden

Community Pharmacists are accessible health care providers who practice in settings that are conducive to delivering HIV treatment and prevention services (Kazi, et al, 2019). Community Pharmacies (CPs) provide a non-stigmatizing and acceptable venue to receive health services (Qato et al, 2017) which would favor the marginalized community considering the stigma they suffer from the society. More so, CPs offer more flexible business hours than health clinics (McCree et al, 2020). It has been shown that the proximity of pharmacies makes pharmacists and pharmacies optimal partners in the program “Ending the HIV Epidemic” (EHE) efforts. Define EHE (Panel on Antiretroviral Guidelines for Adults and Adolescents, 2012): They also promote long-term adherence, help clients avoid drug interactions, minimizing toxic effects, simplifying treatment regimens, decreasing drug costs, managing co-morbid conditions, and preventing transmission of HIV by achieving undetectable viral load (Grimsrud et al, 2016). Additionally, community pharmacists are already heavily involved in the overall management of PLWHA to meet UNAIDS 95–95–95 targets by 2030 through the differentiated service delivery model of care (DSD) (World Health Organization, 2016). The (DSD) is a client-centered approach that simplifies and adapts HIV services across the cascade, in a way that both serve the needs of various groups of (PLHIV) while reducing unnecessary burdens on the health system (Prust et al, 2017). This model ensures the inclusion and active participation of community pharmacists across various thematic areas from adherence clubs, community adherence groups, to fast-track appointments, and multi-month dispensing. The longer antiretroviral therapy (ART) refills (multi-month prescribing) and differentiating services for sub-populations such as the key populations help improve access to HIV care (Ryder et al, 2003).

Community pharmacies also constitute a unique channel for reaching marginalized populations with disease control interventions. A recent study also shows that community Pharmacists and pharmacies can serve as partners in increasing the number of people aware of their HIV status and linked to care by using pharmacists as HIV testers and counselors and/or pharmacies as HIV testing venues. Let’s bring in HVIST (Collins et al, 2018, and Qato et al, 2017). Because of their accessibility and non-stigmatizing environment, pharmacies may serve as important testing venues for people who have never been tested for HIV and/or for those who live in areas where testing through other organizations (eg, community-based settings) is not available (Fauci et al, 2019, Collins et al, 2017, and Crawford et al, 2016, and). It has also been shown that to improve uptake on Pre-exposure Prophylaxis (PrEP) and Post Exposure Prophylaxis (PEP), a variety of health care settings is a high public health priority (Meyerson et al, 2019).

A quarter to a half of patients in Low and Middle-Income countries seek care at community pharmacies (Bigogo et al, 2010; Onwujekwe et al, 2011).

According to a 2020 report by the President’s Emergency Plan for AIDS Relief (PEPFAR), in Nigeria, community pharmacies already help to expand ART distribution, ease access to care, promote adherence, mobilize resources and alleviate congestion in public hospitals. Recently, the Pharmaceutical Society of Nigeria...
to participate in the provision of care to PLHIV (Gupta et al., 2010). A study in Pune, India between 2004 and 2005 showed a high willingness among community pharmacists to achieve these goals. A cross-sectional survey of 207 randomly selected community pharmacists in Pune, India between 2004 and 2005 showed a high willingness to participate in the provision of care to PLHIV (Gupta et al., 2010).

With task shifting of HIV care for stabilized patients to Community pharmacies and increased uptake of ART services, the spread of HIV can be minimized with sustained viral suppression and contributing to fast-tracking the UNAIDS 95:95:95 strategy, that is, 95% of all people living with HIV will know their status, 95% of people diagnosed will receive sustained antiretroviral therapy (ART), and 95% of people receiving ART will have viral suppression all by the end of 2030. Consequently, the community pharmacist’s role has evolved and expanded to help patients and other health care providers to achieve these goals.

3. Fate of community pharmacists in the era of a one-monthly Cabenuva® injection in Nigeria

The approval of new HIV injection tends to put the question forward if the community Pharmacist will be further utilized in delivering this service. Although the administration of injections has become an increasingly common addition to pharmacists’ scope of practice, there still some countries that do not legally permit community pharmacists to administer injections, which may affect the already established systems of incorporating Community pharmacists into the HIV continuum of care. Nevertheless, four Canadian provinces, all US states, and several other countries have regulations allowing pharmacists to administer injections (Houle et al., 2013). The American Pharmacists Association (APhA) in 2010 provided practice guidance for pharmacy-based medication administration, such as practice development, program structure, education and training, and legal authority. The APhA recently released a report supporting pharmacist involvement in the administration of long-acting injectable medications including long-acting injectable antipsychotics (LAIs) in the Community Pharmacy (Skelton et al., 2017). Also, Community Pharmacists already find their way into the immunization program. They are immunization advocates and act as educators, facilitators, and vaccinators (Weidman-Evans et al., 2016).

In 2015, the United States Ministry of Health made an amendment to the Pharmacists Regulation which allows for qualified community pharmacists to administer vaccinations by the intranasal route, or by intradermal, intramuscular, or subcutaneous injection for the prevention of disease, disorders or conditions, and for the treatment of anaphylaxis. Also, In the US, administering vaccines in a community pharmacy has become accepted by the public, especially for influenza vaccine. Commercial and governmental health plans are beginning to provide coverage for those patients receiving vaccinations at pharmacy locations (Wang et al., 2013, and Bach et al., 2015).

According to the Misuse of Drugs (Amendment No.2) in the UK, independent pharmacist prescribers can prescribe- administer any medicine (except some specific controlled drugs for treating addiction) within their area of competence. Also, in Australia, pharmacists have long played a key role in vaccine advocacy, education, and distribution. In 2014, Australian pharmacists have been administering vaccinations to adults (Bach et al., 2015).

During the COVID-19 pandemic, despite emerging challenges, internationally community pharmacists have been playing key roles in community engagement and public health (Strand et al., 2020). Also, community pharmacists are involved in the mitigation of COVID-19, through screening, disease prevention education, supply of personal protective equipment, and point of care COVID-19 testing in some jurisdictions (Strand et al., 2020). In February 2021 according to the New York Times, in a bid to launch a massive Covid-19 vaccination campaign, the US government sent one million vaccine doses to about 6,500 retail pharmacies. While the Guardian in 2021 also reported that in the UK, the community pharmacies offered shots of the AstraZeneca/Oxford vaccine either on their premises or at designated sites following an NHS approval process that began in November 2020.

In Nigeria, community pharmacies have been recognized as the primary point of access for the provision of basic health care, particularly in urban settings where they are often more accessible than health centers or hospitals (Auta et al., 2014). The Pharmacy practice in Nigeria is regulated by the Pharmacists Council of Nigeria, however, does not license Pharmacists to administer an injection (Pharmacist’s Council of Nigeria, Act 1992). Nevertheless, according to the 2018 National Demographic Health Survey (NDHS), which ranked the country very low on Contraceptive Prevalence Rate (CPR) of 12 percent, Lagos State Government trained Community pharmacists on Family Planning information provision, counseling, and administering short-acting contraceptive.

The Community Pharmacists are accessible health care providers who practice in settings that are conducive to delivering non-stigmatizing HIV treatment and prevention services, (Myers et al., 2019) thus, making their role vital in the effort to ending the HIV pandemic. Moreover, the increasing engagement of pharmacists in drug administration in the developed countries, necessitate the reviewing of existing laws to accommodate a certain degree of participation of community pharmacists in the administration of medicines in general and the new HIV drug in particular in Nigeria. The extended role of community pharmacists in the different community-based HIV intervention models necessitates the need to fully integrate community Pharmacists into administering an injection, particularly, the new HIV injection to meet the Joint United Nations Programme on HIV/AIDS (UNAIDS) 95–95–95 targets by 2030.

4. Recommendations

4.1. Training

It is important to develop the necessary competence within the profession to ensure that if the lobbying is successful, then the community pharmacists will be sufficient in number, and adequately trained to implement this service. This calls for professional bodies like the Pharmacists Council of Nigeria (PCN) to define suitable learning objectives in line with the services planned to be implemented. Such curricula have been developed in multiple countries (Bach and Goad, 2015). Then, an accredited training program for the profession must be developed in line with drug administration services so that a pharmacist who has completed the training can be considered to have the skills and competencies required to implement the planned service. This may require endorsement from one or several universities, or faculties, to deliver an academic diploma commensurate with the level of training.
thus giving credence to the level of qualification. Nationwide rolling out of the training should be implemented to ensure that all community pharmacies have at least one qualified Pharmacist available to perform administering injections when the service becomes available to the public. Training and qualifications already exist in several countries; in the United States of America, for example, the American Pharmacists Association provides certified training that is now used in other regions as well, and the International Pharmaceutical Federation (FIP) offers this training to its members. This will allow community pharmacists to utilize their knowledge and skills as medication therapy experts. It also has the potential of increasing the number of health professionals who can administer Cabenuva® injection thus, benefitting the patients, through increased access and convenience, thereby leading to better HIV treatment coverage and outcomes. Community Pharmacists will now find they have greater opportunities to become a more essential and visible component of public health programmes. It is therefore imperative that policies and practices be entrenched to enable them to provide a wider range of HIV services even as the country moves towards achieving universal health coverage.

5. Conclusion

There is a need and opportunity for community pharmacists to be utilized across key global health areas over and above what is currently being done. From workforce development to drug administration, pharmacists can apply their medication expertise to contribute to gaps in care that align with major global health efforts and programs. The shift pharmacists have made in high-income countries from product-centered to patient-centered services with public health implications took decades to achieve. The shift for pharmacists in low to middle-income countries will also take time. These positive findings underscore the strategic importance of utilizing community pharmacists in the Cabenuva® administration. This would be particularly beneficial in many Nigerian societies where access to HIV services to the highly vulnerable populations – Key population (Gay, Lesbians, and Transgender) is being threatened due to the anti-gay law. In such situations, the administration of Cabenuva® in community pharmacies offers viable, discrete, and cost-effective alternatives for patients and donor agencies that support ART programs. Finally, policymakers should make sure pharmacists in their communities are enabled to effectively support the administration of Cabenuva® as well as other future drugs for public health issues. The above strategies would complement the various efforts being made to actualize the UNAIDS aim of ending the AIDS epidemic by 2030 by achieving 95% diagnosed among all people living with HIV (PLHIV), 95% on antiretroviral therapy (ART) among diagnosed, and 95% virally suppressed (VS) among treated.

Funding

As with all public health policies, the question of funding is vital to ensuring the sustainability of pharmacy-based drug administration interventions. The administration of cabenuva undeniably represents an extra workload for pharmacists, and adequate compensation should be provided to all Community Pharmacists. Pharmacy reimbursement should be integrated into the national health system in the same way as for drugs that are dispensed there. This is a point that needs to be negotiated in every country, or region between relevant stakeholders, according to national structures for public and private healthcare coverage.

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