Quality analysis of some first-line HIV/AIDS medicines dispensed in Lusaka District Health Facilities of Zambia

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A dissertation submitted in partial fulfillment of requirements of the University of Zambia for Masters in Public Health (MPH)

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DECLARATION

I hereby declare that the work presented in this study for the Master of Public Health has not been presented whether wholly or in part for any other study programme and is not being submitted for any other Masters programme. This work is entirely the result of my own independent investigation. The various persons and sources to which I am indebted are acknowledged.

Signed…… Date……

Munkombwe Derick (Candidate)

Supervisor:

I, the undersigned have read this dissertation and have approved it for examination.

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APPROVAL

Examiners:

This dissertation for Munkombwe Derick is approved in partial fulfillment of the requirements for the award of the Master degree in Public Health (MPH) by the University of Zambia.

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CERTIFICATE OF COMPLETION OF DISSERTATION

I……hereby certify that this dissertation for the Master of Public Health degree program is the product of my own work and attest that it has not been submitted whether wholly or in part to another university.

I/We……..having supervised and read this dissertation am/are satisfied that this is the original work of the author under whose name it is being presented. I/We confirm that this work is completely satisfactory and is ready for presentation to the examiners.

Signature of supervisor…….Date…….

Signature of co-supervisor……..Date……

Signature of Head of Public Health Department…….....Date……..

ABSTRACT

In the last few years governments around the world have pledged to massively scale up the delivery of antiretroviral drugs (ARVs) to achieve universal access for all. However, recent reports of generic medicines including ARVs containing little or no active pharmaceutical ingredients are disturbing.

In Zambia anecdotal data show that there is an increase in morbidity and mortality in people living with HIV/AIDS due to ARV drug resistance, treatment failure and adverse drug reactions. For instance, a physician at the University Teaching Hospital (UTH) reported that his eight patients did not respond to any combination after developing resistance to first-line ARVs (Geloo 2005). It is a well known fact that poor drug quality can contribute to poor treatment outcomes of the patient. In Zambia there is currently insufficient publicly available data describing the ARV drug quality in terms of active pharmaceutical ingredients (API), and labeling standards according to official monographs. The purpose of this study was to determine the quality of some first-line HIV/AIDS medicines dispensed in health facilities and to assess the proportion of substandard ARVs in Lusaka District.

A Cross Section Survey was conducted in nine health facilities of Lusaka District, using convenience sampling technique. A few ARV drug samples were selected randomly from the nine facilities. Eleven sample units were analyzed. Each sample unit was sealed in a tin of either 30 or 60 tablets. The tablets were removed from their original containers and number coded before taken for analysis after recording the names, strengths, batch numbers and expiry dates.

The quality analysis of (1) Stavudine (d4T)/Lamivudine (3TC)/Nevirapine (NVP), (2) Lamivudine (3TC)/Zidovudine (AZT), (3) Nevirapine (NVP), (4) Efavirenz (EFV) and (5) Stavudine (d4T)/Lamivudine (3TC) was carried out using the protocol adapted from German Pharm Health Fund (GPHF-minilab) that employs Thin Layer Chromatography (TLC) techniques at Tejay Pharmaceutical Laboratories in Lusaka, Zambia. A total of eleven drug samples were assayed and analyzed.

The analytical tests that were performed included: the identification of the API, measurement of the percentage content of API in the samples and assessment of packaging material according to prescribed monographs.

The findings of the study indicated that:

- In all the samples assayed, API was identified as per label claim on the container.
- One (3A) of the eleven samples was found to contain less than 80% API content. Sample 3A had Nevirapine percentage content less than the recommended 80-100%.
- Samples 1B and 1C did not comply with the labeling requirements on the package according to the Statutory Instrument No. 47 of 1993. They did not reflect medicine category on the package.
- All the eleven samples complied with labeling information on the inserts as per standard.

The meaning of the results is that over 94% of the first-line HIV/AIDS medicines sampled contained the API in the right amounts as per label claim on the packages and that on average over 90% of these drugs were correctly labeled in accordance with the Statutory Instrument No. 47 of 1993 of PRA, Ministry of Health in Zambia.

Finally, from the study it can be concluded that first-line HIV/AIDS medicines dispensed in Lusaka District of Zambia are of good quality and meet the requirements as stipulated in the official monographs.

DEDICATION

To **my wife** Eustekia Mutinta Hadunka, **our sons** Munkombwe Derick Jr. and Munkombwe Habwami.

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ABBREVIATIONS

3TC	Lamivudine
AFSSAPS	Agence Francaise de Securite Sanitaire des Produits de Sante
AIDES	Association of AIDS Patients
AIDS	Acquired Immune Deficiency syndrome
API	Active Pharmaceutical Ingredient
ARVS	Antiretroviral drugs
AZT	Zidovudine
BP	British Pharmacopoeia
CSO	Central Statistics Office
D4T	Stavudine
EFV	Efavirenz
GPHF	German Pharma Health Fund
GS	General Sale
HAART	Highly Active Anti-Retroviral Therapy
HIV	Human Immunodeficiency Virus
MDG	Millennium Development Goals
MOH	Ministry of Health
MSF	Medecins Sans Frontieres
NAC	National HIV/AIDS/STI/TB Council
NVP	Nevirapine
POM	Prescription Only Medicine
PRA	Pharmaceutical Regulatory Authority
TLC	Thin Layer Chromatography
UNAIDS	United Nations Joint programme on HIV/AIDS
USP	United States Pharmacopoeia
WHO	World Health Organization

OPERATIONAL DEFINITIONS

Active Pharmaceutical Ingredient- refers to drug substance of pharmaceutical product with therapeutic activity.

Analysis – refers to detailed examination of anything complex in order to understand its nature or to determine its essential features.

Antiretroviral drug - will referrer to Stavudine (d4T), Lamivudine (3TC), Nevirapine (NVP), Efavirenz (EFV) and Zidovudine AZT).

Batch number- the serial number on the container or package from which a drug is taken to constitute a sample.

HIV/AIDS – refers to a serious condition that weakens the body's immune system, leaving it unable to fight off illness, resulting from a viral infection known as Human Immunodeficiency Virus.

HIV/AIDS medicines – refer to antiretroviral drugs used in treatment of HIV/AIDS patients.

Medicine/Drug – will mean a medicinal substance used to treat an illness, relieve a symptom, or modify a chemical process in the body for a specific purpose.

Official monographs – all Pharmaceutical Standard Reference Books such as the British Pharmacopoeia and the United States Pharmacopoeia.

Public Institutions – all health institutions owned and run by the government in Lusaka District.

Quality – refers to combination of attributes or characteristics of a product that determine the degree of acceptability and efficacy of the product.

Quantity- will refer to how much of active ingredient there is in a medicine.

Substandard drug – will mean a drug product with incorrect quantity of active pharmaceutical ingredient(s) or different or absence of active ingredient as stated on the label and/or with poor packaging material and will includes counterfeit drugs.

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