OFFICE OF THE AUDITOR GENERAL

PERFORMANCE AUDIT REPORT

ASSESSING THE EFFICIENCY OF THE MANAGEMENT OF TREATMENT FOR PEOPLE LIVING WITH HIV AND AIDS

NOVEMBER 2013

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The Honourable Speaker of the National Assembly

In accordance with Section 13 of the Auditor-General Act, 2010, I have the honour to submit the performance audit report on the Management of Treatment for people living with HIV and AIDS for presentation to the National Assembly in accordance with Section 22 (2) of the Act.

Marc Benstrong

AUDITOR GENERAL

Office of the Auditor General

Victoria, Seychelles

November 2013

Acknowledgements

I wish to express my personal gratitude to members of my staff who carried out their duties willingly and satisfactorily despite certain constraints. I also acknowledge the assistance and co-operation given by the staff of the Ministry of Health, the Communicable Disease Control Unit and other stakeholders who appreciate the role of my office and recognize the valuable contribution it makes in ensuring and enhancing the accountability of public funds and promoting good practice across the Government.

Finally, I would like to thank the Finance and Public Accounts Committee (FPAC) of the National Assembly who reviews my report and makes appropriate recommendations to the Government for improvements.

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List of Acronyms and Abbreviations

AIDS	**Acquired Immunodeficiency Syndrome**
ARV	**Antiretroviral**
CDCU	**Communicable Disease Control Unit**
DSRU	**Disease Surveillance and Response Unit**
FAHA	**Faith and Hope Association**
FBOs	**Faith-Based Organisations**
HAART	**Highly Active Antiretroviral Therapy**
HASO	**HIV and AIDS Support Organisation**
HIV	**Human Immunodeficiency Virus**
NGOs	**Non-Governmental Organisations**
PLWHAs	**People Living With HIV and AIDS**
STI	**Sexually Transmitted Infection**
WHO	**World Health Organization**

Executive Summary

1. Since the introduction of HIV testing in 1987, a cumulative of 542 (311 Males and 231 Females) HIV and AIDS cases have been detected as at March 2013. The most affected age group is 30-34 years.

2. In 2001 antiretroviral therapy was firstly introduced in the Seychelles and many HIV-infected individuals have accessed free treatment and as at March 2013, the number of individuals on HAART stood at 190 (103 Males and 87 Females). Cumulative loss to follow up for this same period was 97 cases and cumulative defaulters on HAART were 37.

3. The CDCU, which falls under the portfolio of the Ministry of Health, is the sole specialist referral centre in the Seychelles for the management of all sexually transmitted infections (STIs) which includes HIV and AIDS, management of Tuberculosis, Leprosy, Hepatitis B and C, and traveller's health. The duties of the CDCU are not confined only to the management of people living with HIV and AIDS but also to other programmes as mentioned above.

4. This report evaluates the extent to which the CDCU is managing the treatment of people living with HIV and AIDS in order to ensure adherence to treatment for the period of January 2008 to March 2013.

Key Findings

5. A cumulative of 24 drop-out cases on HAART was reported by the end of 2012. For the first quarter of 2013 there was an additional 13 drop-out cases on HAART reported, totalling to 37 drop-out cases on HAART by the end of March 2013. Similarly, the number of new AIDS cases and the number of AIDS-related deaths have also increased of which 60 per cent of the new AIDS cases reported

for the first quarter of 2013 were known HIV individuals who had defaulted on treatment over the years.

6. Although the CDCU runs various sensitisation programmes, they do not run specific programmes to promote treatment compliance in people living with HIV and AIDS. We observed through the Health Education activity calendar of the CDCU that most of the activities were related to the sensitisation of the general public on the dangers and prevention of HIV, AIDS, STIs and Hepatitis C and not on the importance of adhering to treatment and follow-ups in respect of HIV and AIDS. Nevertheless, we do acknowledge the fact that one-to-one education and sensitisation is being done by the CDCU but this is not sufficient as only those who visit the CDCU will benefit.

7. Non-adherence to treatment is on the increase which in turn brings about mutations resulting in resistance to various antiretroviral, therefore, the necessity to introduce new and more costly antiretroviral. As a result, new drugs would have to be procured which will be more costly to the government.

8. Viral load test is very important in the treatment for HIV and AIDS as it monitors the level of virus in a HIV-infected individual over time and also monitors the effectiveness of the drugs prescribed to an individual as well as adherence to treatment. The viral load Cobas Amplicor machine was not operational due to non-availability of the reagents from September 2012 to May 2013.

Recommendations

9. It is crucial that the CDCU establishes why there has been an increase in the number of HIV-infected individuals defaulting on treatment. This will allow them to design their work plan in the most effective way and build on any weaknesses that may be present.

10. We recommend that the CDCU integrates in its calendar of activities additional programmes specific to adherence to treatment in respect to HIV and AIDS. This would ensure that the objective of treatment compliance can be targeted amongst HIV and AIDS individuals who are already on treatment and those who will eventually start treatment, as well as the general public which can also benefit through such programmes.

11. It is vital that the CDCU finds the most effective means of ensuring that HIV-infected individuals adhere to treatment to ensure that the most efficient use is made of drugs prescribed. Additionally, this would reduce the chances of additional costs having to be incurred by the Government to procure new and more expensive drugs.

12. The Ministry of Health should ensure that the procurement process to purchase the equipment and supplies necessary for the treatment of people living with HIV and AIDS is responsive to changing circumstances. It is also vital to ensure that procurement is properly planned.

1. Introduction

1.1. Background to the audit

The Ministry of Health has been in the forefront in the national response to HIV and AIDS fight ever since the first HIV case was detected in 1987. This role is assigned to a specialist referral centre, the CDCU which administers treatment, care and support to PLWHA.

Since the introduction of HIV testing in 1987, a cumulative of 542 (311 Males and 231 Females) HIV and AIDS cases has been detected as at March 2013. The most affected age group is 30-34 years and the least affected age group is <15 years[1].

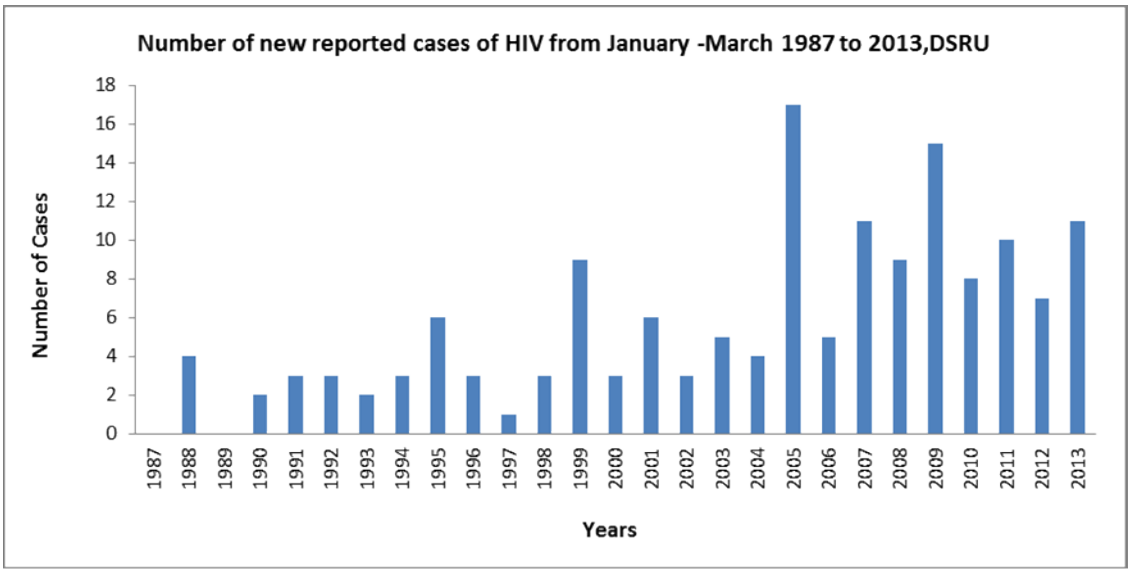
In 2001, HAART was firstly introduced for free in the Seychelles and many HIV-infected individuals have accessed treatment and as at March 2013, the number of individuals on HAART stood at 190 (103 Males and 87 Females).

1.2. Motivation

The year 2012 marked 25 years after the first HIV case was detected in the Seychelles. In his message to mark World AIDS Day 2012, the President said that the battle against HIV and AIDS has to be won and that this can only be done if we remain united in our effort. "We need more hands on board. We need more people to get engaged in treatment, care and support and prevention if we are to achieve the three zeros being promulgated by the UNAIDS.... After 25 years of lessons, we cannot overemphasise the devastation and catastrophe that the HIV and AIDS may cause in our small community"[2].

[1] Disease Surveillance and Response Unit Report, 1st Quarter of 2013
[2] Newspaper: Seychelles Weekend Nation, 1st December 2012

Figure 1: Number of new reported HIV cases from January-March 1987 to March 2013



Source: Disease Surveillance and Response Unit Report 1st Quarter of 2013

During the period of January 2008 to March 2013, the highest recorded number of new HIV cases was in 2009, 15 new cases. In 2010, there was significant reduction in the number of new cases but there was a rise again in 2011. For the first quarter of 2013 the Ministry of Health recorded 11 new HIV cases, an increase of 57 per cent in new HIV cases in comparison to the first quarter of 2012, age ranging from 9 months old (a female) to 54 years old (a male).

The situation with HIV and AIDS regarding the number of individuals either dropping out of treatment, referred to as defaulters and not turning up for follow up appointments are referred to as loss to follow-up was described as alarming by the Director of Epidemiology and Statistics late in 2012 following the publication of the DSRU quarterly report. As of March 2013,

the number of cumulative loss to follow up was 97 cases and the cumulative defaulters on HAART was 37, which represents 16 per cent of the HIV and AIDS individuals eligible for treatment.

Given the increase in the number of HIV and AIDS cases and the alarming situation in individuals defaulting on treatment, we seek to assess the efficiency of the CDCU in managing treatment for people living with HIV and AIDS.

1.3. Design of the Audit

1.3.1. Audit Objective

The objective of the audit was to assess the effectiveness of the CDCU in managing treatment for people living with HIV and AIDS to ensure adherence to treatment.

The audit was designed based on the use of two main questions which are as follows:

Audit Question 1: To what extent is educational/ sensitisation programmes conducted to ensure that PLHWA adhere to treatment?

Audit Question 2: To what extent is the CDCU managing and monitoring the adherence to treatment?

1.3.2. Audit scope

The audit was conducted on the activities performed by the CDCU in providing treatment, care and support to PLWHA. The focus of the audit was based around the effectiveness with which the services are provided in ensuring adherence to treatment.

1.3.3. Time limitations

The audit covered the period from January 2008 to March 2013.

1.3.4. Geographical limitations

The audit covered the three main islands of Seychelles, being Mahé, Praslin and La Digue. Most visits and interviews were conducted at the CDCU which is the sole specialist referral centre in the country.

1.3.5. Audit methods

The following audit methods were applied to obtain data:

1.3.5.1. Data collection

The main methods of data collection employed during the conduct of the audit were interviews with numerous health officials, NGOs, FBOs and individuals living with HIV and AIDS and review of documents.

- **Interviews**

  Numerous interviews were conducted during the main study which was mainly with the staff working at the CDCU which included doctors, nurses, health information officer and the dispenser with the aim of understanding their roles and responsibilities in the Unit. Other interviews were conducted with members of some NGOs, FBOs and people living with HIV and AIDS.

- **Documents review**

  Various documents provided by the CDCU were reviewed with the aim of understanding the process of treatment and the different activities undertaken by the CDCU in ensuring adherence to treatment.

1.3.5.2. Data analysis

Data collected throughout the audit was reviewed and compared against the set assessment criterions.

1.4. Description of the audit area

The Communicable Disease Control Unit (CDCU) is a specialist referral Unit which operates under the Disease Prevention Section of the Public Health Department, headed by a Health Commissioner. The Public Health Department falls under the Ministry of Health.

There are currently 8 staff working at the CDCU on a full time basis and 4 part time staff on a weekly basis. Their duties are not confined to the HIV and AIDS programme only but also to the management of all sexually transmitted infections (STIs), management of Tuberculosis, Leprosy, Hepatitis B and C, and traveller's health which includes Malaria and Yellow Fever prophylaxis and other programmes such as the National Program for Reproductive Health, National Program for Children and School Health, National Program for Diabetes amongst others.

The Unit is headed by a Programme Manager and other staffs attached to the Unit include a full-time doctor and two part-time doctors, nursing officers, communicable disease control officer, health information officer amongst other support staffs.

The CDCU was set up in 1987 when the first HIV case was detected and is responsible for running the National Program for Prevention and Control of HIV and AIDS and STIs in the Seychelles.

1.4.1. Goals and Objectives

The objectives of the CDCU in relation to HIV and AIDS management and control include:

- Reduce the number of HIV and AIDS cases
- Reduce the number of complications related to HIV and AIDS
- Increase the number of HIV tests per annum
- Increase the number of HIV tests in regard to pregnant women
- Increase adherence to treatment
- Reduce mortality in HIV and AIDS

1.4.2. Activities of the CDCU

In order to attain the above objectives, the CDCU carries out the following activities in relation to HIV and AIDS:

- Voluntary counselling and testing
- Rapid testing
- Individual/Couple counselling and guidance
- Contact tracing
- Antiretroviral treatment
- Prevention of Mother to Child Transmission
- Treatment of opportunistic infections
- Awareness programmes on HIV and AIDS
- Outreach activities
- Condom promotion and distribution

1.4.3. Funding

The main source of funding for the HIV and AIDS treatment, care and support is the Government of Seychelles through the Ministry of Finance.

2. Systems and Process Description

2.1. Roles and responsibilities of key players

The roles and responsibilities of key players identified for the audit are set out below.

2.1.1. Ministry of Health

The Ministry of Health receives annual government funding from the Ministry of Finance in order to operate. The Ministry of Health then allocates funds to the different Units, such as the CDCU, within the Ministry, based on a budget prepared by the Units. Additionally, the Ministry of Health also procures drugs on behalf of the CDCU through its Pharmaceutical Department as the procurement process is centralised.

2.1.2. Ministry of Community Development, Social Affairs and Sports

There are functional structures under this Ministry which assist both people who have been infected and affected by HIV and AIDS. The Agency for Social Protection offers financial support whilst the Social Services and Probation Services offer counselling and support.

2.1.3. Non-Governmental Organisations (NGOs)

Apart from the CDCU, NGOs also offer care and support as well as financial assistance to both people infected and affected by HIV and AIDS. Additionally, they run different activities including sensitisation programmes to the general public at large.

2.1.4. Faith-Based Organisations (FBOs)

FBOs have informal structures for support which is used by both people infected and affected by HIV and AIDS.

2.2. Process Description

2.2.1. Testing

All government health centres conduct voluntary counselling and testing. In addition, rapid tests are also carried out on ad hoc basis, for instance during outreach activities conducted by the Ministry of Health. The blood samples taken from health centres and rapid tests are forwarded to the central laboratory of the Ministry of Health whereby the necessary tests are performed. A second or confirmation test is performed on blood samples with 'reactive' test results in order to confirm whether an individual is HIV positive or not.

Blood samples taken from individuals are assigned with a code when sent to the laboratory to ensure that the results remain confidential. Subsequently, the individual is referred to the CDCU whereby a personal file is created and all the necessary documents pertaining to the individual are kept in the file. The CDCU administers the treatment regime for all HIV individuals.

Apart from the Ministry of Health, most private clinics in the Seychelles perform HIV tests. However, it is only the Ministry of Health that performs the confirmation tests and thus 'reactive' test results from both government and private clinics are referred to the CDCU.

2.2.2. Treatment

Antiretroviral Therapy is highly recommended for all HIV-infected individuals eligible for treatment as per WHO criteria in order to reduce disease progression amongst the population, and in working towards 'zero AIDS-related deaths' which is one of the three goals set by UNAIDS and adopted by the Ministry of Health.

Before any HIV-infected person is placed on HAART, this person is expected to undergo a counselling session known as 'Education Thérapeutique'. This counselling session aims to provide the person with necessary information on HIV and AIDS relating to sexual behaviours that increases the risk of infection, different methods of prevention, the risks and benefits of therapy adherence amongst other information.

Treatment is initiated only when both patient and treating doctor feels that the patient has all the information and is ready. After the HIV-infected person has been issued with their prescription, they are referred to the pharmacy for drug collection. Drugs are normally dispensed at the CDCU itself where the Unit is equipped with its own pharmacy. The person will be issued with one month to six month stock of drugs depending on their adherence to treatment. The maximum stock of six months is normally issued to people who are travelling.

Apart from visits to collect their treatment, a person is required to visit the doctor for follow-ups every three months whereby numerous tests are performed.

2.2.3. Care and Support

There are various bodies involved in providing care and support to PLWHA. The main organisations include the CDCU, the different health centres in the country, three main NGOs being HASO, SOLIDAIRE and FAHA and various FBOs such as the Catholic and Anglican churches and the Agency for Social Protection.

Care and support is provided to both those who are infected and affected by HIV and AIDS and is in both financial and non-financial terms.

2.2.4. Monitoring

The main body responsible for monitoring and evaluating the HIV and AIDS situation and other communicable and non-communicable diseases in the Seychelles is the DSRU, whilst the monitoring of adherence to treatment is done by the CDCU.

The DSRU compiles and produces quarterly reports of the HIV and AIDS situation in the Seychelles. Where they find the situation alarming, the DSRU notifies the public through the media.

When monitoring individuals, CDCU classifies them into two categories being 'loss to follow up' and 'drop outs'. An HIV-infected person who has started therapy is considered as a 'loss to follow up' when the person does not turn up for follow-up sessions for a period of six months. On the other hand, a person is considered as a 'drop-out' if they fail to collect their drugs for three consecutive months.

3. Findings, conclusions and recommendations

The findings, conclusions and recommendations are set out below:

3.1. Increase in non-adherence to treatment

As mentioned in Part Two of the report, CDCU categorises PLWHA as either 'loss to follow-up' or 'drop-outs' for monitoring purposes. A person is considered as a 'loss to follow-up' if they have not accessed the service for more than six months, whilst a 'drop-out' relates to an individual who has defaulted on treatment for more than three months.

As of March 2013, 97 (60 Males /37 Females) cases did not access the service for over six months representing 28 per cent of loss to follow-up amongst the people living with HIV and AIDS and a cumulative of 37 (19 Males/ 18 Females) cases defaulted treatment representing 16 per cent of the HIV and AIDS clients eligible for treatment. Similarly, six new AIDS cases and three AIDS related deaths were reported for the first quarter of 2013.It has been noted in the DSRU report[3] that 60 per cent of the new AIDS cases reported for the first quarter of 2013 were known HIV individuals who had defaulted treatment and follow-ups over the years.

Conclusion

A cumulative of 24 drop-out cases on HAART was reported by the end of 2012. For the first quarter of 2013 there was an additional 13 drop-out cases on HAART reported, totalling to 37 drop-out cases on HAART by the end of March 2013.

Similarly, the number of new AIDS cases and the number of AIDS-related deaths have also increased, of which 60 per cent of the new AIDS cases

[3] DSRU Report 1st Quarter 2013

reported for the first quarter of 2013 were known HIV individuals who had defaulted on treatment over the years. A 500 per cent increase in new AIDS cases and a 50 per cent increase in AIDS related deaths were recorded from January to March 2013, as compared to January to March 2012.

Despite the efforts being put forth by the Ministry of Health and other stakeholders, the situation whereby HIV and AIDS individuals are not adhering to treatment is worsening and is likely to keep the same pace if the root causes to why individuals are not adhering to treatment are not established.

Recommendation

It is crucial that the CDCU establishes why there has been an increase in the number of HIV-infected individuals defaulting on treatment. This will allow them to design their work plan in the most effective way and build on any weaknesses that may possibly be present.

3.2. Programmes conducted by the CDCU

The programmes undertaken by the CDCU are as per a Health Education activity calendar which is drawn up each year through its yearly work plan.

We observed that the activities were mostly based on sensitisation on the dangers and prevention of HIV, AIDS, STIs and Hepatitis C to different groups of the population. However, we did not find activities relating specifically to the adherence of treatment in respect of HIV and AIDS.

We were informed by health officials that PLWHAs are sensitised on a one-to-one basis whenever they visit the CDCU. However, we did not find any activities or programmes which were specific in promoting treatment compliance in the same way as other activities are conducted by the CDCU.

Conclusion

Although the CDCU runs various sensitisation programmes, they do not run specific programmes to promote treatment compliance in people living with HIV and AIDS. We observed through the Health Education activity calendar of the CDCU that most of the activities were related to the sensitisation of the general public on the dangers and prevention of HIV, AIDS, STIs and Hepatitis C and not on the importance of adhering to treatment and follow-ups in respect of HIV and AIDS. Nevertheless, we do acknowledge the fact that one-to-one education and sensitisation is being done by the CDCU but this is not sufficient as only those who visit the CDCU will benefit.

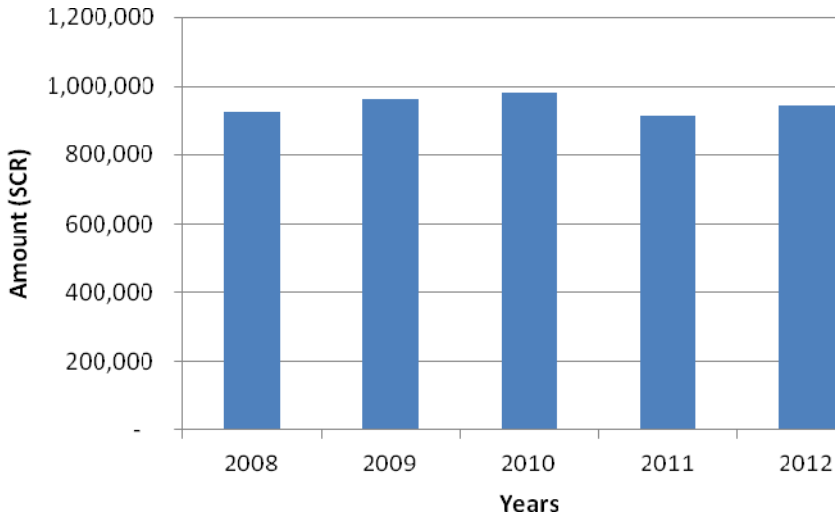
Recommendation

We recommend that the CDCU integrates in its calendar of activities additional programmes specific to adherence to treatment in respect to HIV and AIDS. This would ensure that the objective of treatment compliance can be targeted amongst HIV and AIDS individuals who are already on treatment and those who will eventually start treatment, as well as the general public which can also benefit through such programmes.

3.3. Prescribing antiretroviral

The average expenditure for ARVs has been generally consistent between 2008 and 2012 where there was a slight increase between 2008 and 2010 and an insignificant decrease in 2011 as shown in the graph below. There was a slight increase in 2012 as compared to 2011.

Figure 2: Yearly average expenditure on ARVs January 2008 to December 2012



Source: Office of the Auditor General analysis of Ministry of Health's yearly average expenditure statistics on ARVs

Drugs prescribed are normally referred to as HAART, whereby it is a combination of different drugs. The CDCU has the responsibility of finding the most suitable HAART combination for each individual living with HIV from the ARVs available at their pharmacy. Currently, the CDCU can offer different combinations whereby the drugs needed are procured by the Ministry of Health.

Following interviews with health officials at the CDCU and review of statistics published by the DSRU, we found that many individuals were not adhering to treatment and thus new combinations of HAART had to be prescribed for them. The interviews also revealed that if an individual is constantly being prescribed with new combinations of HAART, eventually the CDCU would run out of options and without treatment the HIV-infected

individual would move to the AIDS stage which would ultimately lead to death.

A cumulative of 107 (64 Males/ 43 Females) HIV and AIDS deaths have been reported since 1993 to March 2013 whereby 60 per cent of deaths occurred in males and 40 per cent in females.

AIDS mortality has been on the increase from 1993 to 2001 but since the introduction of HAART in 2001, there has been a gradual decline in the mortality compared to previous years. AIDS-related mortality was at a maximum of 16.33 per cent in 1998 and after the introduction of HAART in 2001 it fell to 1.96 per cent in 2003 and 0.83 per cent for the first quarter of 2013.

Nevertheless, there are many other drug combinations available worldwide at higher costs. In the event that the available combination of HAART is no longer effective as a result of non-adherence, additional costs would have to be incurred by the Government of Seychelles, due to its free health care policy.

Conclusion

Non-adherence to treatment brings the necessity to change combinations of HAART and the risk of the available options being ineffective. As a result, new drugs would have to be procured which will be more costly to the government.

Recommendation

It is vital that the CDCU finds the most effective means of ensuring that HIV-infected individuals adhere to treatment to ensure that the most efficient use is made of drugs prescribed. Additionally, this would reduce

the chances of additional costs having to be incurred by the Government to procure new and more expensive drugs.

3.4. Equipment necessary for treatment not operational

As part of the treatment for a person living with HIV and AIDS, follow ups should be conducted by the CDCU every three to six months depending on each individual's case whereby numerous tests are performed including viral load tests which generally aims to monitor the level of virus in a HIV-infected individual on treatment over time. The HIV viral load test is a quantitative measurement of HIV nucleic acid (RNA) that reports how many copies of the virus are present in the blood.

According to the health officials at the CDCU, the viral load test is very essential for people living with HIV and AIDS for numerous reasons. A viral load test is usually conducted before a HIV-infected individual is placed on antiretroviral therapy. After this individual has started treatment, viral load tests will be conducted at least twice a year to monitor the effectiveness of the drugs prescribed for the individual and act as a means of determining whether drugs are being taken as prescribed. Additionally, the viral load machine is a very important tool in allowing medical officers to determine the most effective mode of delivery for pregnant women who have been infected with HIV. Further, the viral load machine is also used for early infant diagnosis whereby it helps in detecting whether an infant has been infected with HIV prior to delivery. It has been proven that if the viral load level is kept low for as long as possible, it decreases the complications of HIV disease, slows the progression from HIV infection to AIDS and prolongs life.

However, despite the significance of the viral load machine and following interviews conducted with health officials at the CDCU, we found that the viral load Cobas Amplicor machine was not operational from September

2012 until May 2013, at the time of writing the report. Additionally, the interviews revealed that failure of the machine to be operational was due to non-availability of the reagent for the machine as this was no longer being produced by the supplier.

Conclusion

The viral load Cobas Amplicor machine used to test the viral load level was not operational for almost a year due to non-availability of the reagent for the equipment. However, if the Ministry of Health had maintained stocks of the reagent then the risk of the machine not being operational for such a long time would have been minimised. This indicates that there was no proper planning by the Ministry of Health to determine that the reagent for the old machine was no longer being manufactured and that a new machine would have to be procured, in spite of the Ministry of Health having been informed by the supplier that the reagent would no longer be produced by them.

Recommendation

The Ministry of Health should ensure that the procurement process to purchase the equipment and supplies necessary for the treatment of people living with HIV and AIDS is responsive to changing circumstances. It is also vital to ensure that procurement is properly planned.