REPUBLIC OF KENYA

IN THE HIGH COURT OF KENYA AT KISUMU

CONSTITUTIONAL AND HUMAN RIGHTS DIVISION

PETITION NO OF 2023

IN THE MATTER OF ARTICLES 1, 2, 3, 10, 19, 20(1) & (4), 21, 22, 23, 24, 25, 26(1), 27, 28, 29, 35, 43(1)(a), 47, 53 (1)(c), 165, 232(1), 258 AND 259 OF THE CONSTITUTION OF KENYA, 2010

AND

IN THE MATTER OF SECTIONS 4 (b), (c), (d), (e), (f), (h), (i), (l) (n) AND (m), 14 (f), 20, 24,32, AND 33 (2) AND (5) OF THE EAST AFRICAN COMMUNITY HIV AND AIDS PREVENTION AND MANAGEMENT ACT, 2012

AND

IN THE MATTER OF SECTIONS 4, (c) (d) 5, 8(c) (d) 15 OF THE HEALTH ACT, 2017

AND

IN THE MATTER OF SECTION 19 OF THE HIV PREVENTION AND CONTROL ACT

AND

IN THE MATTER OF SECTIONS 8, 9, 10 AND 16, OF THE CHILDREN ACT, 2022

BETWEEN

FA.....1ST PETITIONER

(Suing on her own behalf and as mother and next friend of DM (A minor)

BK..... ...2ND PETITIONER

CN…… ……3RD PETITIONER

PATRICIA ASERO OCHIENG……4TH PETITIONER

AMBASSADOR FOR YOUTH AND ADOLESCENTS

REPRODUCTIVE HEALTH PROGRAM (AYARHEP)…..5TH PETITIONER

KENYA LEGAL AND ETHICAL

ISSUES NETWORK ON HIV/AIDS (KELIN)……..6TH PETITIONER

KATIBA INSTITUTE……7TH PETITIONER

VERSUS

THE HON. ATTORNEY GENERAL……..1ST RESPONDENT

CABINET SECRETARY FOR HEALTH……2ND RESPONDENT

KENYA MEDICAL SUPPLIES AUTHORITY……..3RD RESPONDENT

CERTIFICATE OF URGENCY

We, **NYOKABI NJOGU** and **KENNETH OTIENO** Advocates, who have the conduct of this matter on behalf of the 1st - 6th Petitioners, and **EMILY KINAMA**, who has conduct of this petition on behalf of the 7th Petitioner, do hereby certify that the Application and Petition filed herein are extremely urgent and should be heard at the earliest opportunity **ON THE GROUNDS THAT**:

a) The 1st petitioner is the mother of DM (a minor) a child living with HIV who between 2021 and 2023 has been unable to consistently access lifesaving antiretroviral medication. The health of DM (a minor) has significantly deteriorated, his quality of life has been negatively affected and he is at risk of death.

b) There is a continuing violation of the constitutional rights of DM, 1st petitioner, as well as other persons living with HIV who since 2021, have had difficulties accessing antiretroviral medication or other commodities required in the prevention and management of HIV.

c) CN and BK are mothers who are living with HIV. In 2021, they were unable to access early infant testing for HIV for their children, and viral load testing for themselves, living unaware of their children's health status and whether their continuing of breastfeeding posed a risk of HIV transmission to their infants.

d) To date, many pregnant women living with HIV have difficulties in accessing viral load testing. There is a continuing violation of the rights of CN and BK, and other breastfeeding mothers who are living with HIV.

e) Sometime in December 2022, the 2nd Respondent instructed persons living with HIV using Tenofovir/Lamivudine/Dolutegravir 300/500/50 mg anti-retroviral medication to return these to the health care facilities where they had been collected. No replacements were issued to those who returned them. There continues to be uncertainty about the availability of HIV-related commodities and antiretroviral medications in Kenya.

f) Unless the application and the petition are urgently heard and determined, people living with HIV, and particularly children living with HIV will continue to have their rights to health and life violated as they continue to lack access to life and health saving medication and commodities.

DATED at NAIROBI this 21st **day of** September **2023**

NYOKABI NJOGU and KENNETH OTIENO

ADVOCATES FOR THE 1st – 6th PETITIONERS

EMILY KINAMA

ADVOCATE FOR THE 7TH PETITIONER

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Ministry of Health.

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(Suing on her own behalf and as mother and next friend of Baby DM (A minor)

BK.....2.ND PETITIONER

CN.....3RD PETITIONER

PATRICIA ASERO OCHIENG.....4TH PETITIONER

AMBASSADOR FOR YOUTH AND ADOLESCENTS

REPRODUCTIVE HEALTH PROGRAM (AYARHEP)....5TH PETITIONER

KENYA LEGAL AND ETHICAL

ISSUES NETWORK ON HIV/AIDS (KELIN).....6TH PETITIONER

KATIBA INSTITUTE.....7TH PETITIONER

VERSUS

THE HON. ATTORNEY GENERAL.....1ST RESPONDENT

CABINET SECRETARY FOR HEALTH.....2ND RESPONDENT

KENYA MEDICAL SUPPLIES AUTHORITY.....3RD RESPONDENT

NOTICE OF MOTION

(Under Articles 27, 28, 29 and 31 of the Constitution of Kenya, 2010, and Rules 3, 4(1), 10(2)(a), 13 and 19 of the Constitution of Kenya (Protection of Rights and Fundamental Freedoms) Practice and Procedure Rules, 2013, and all other enabling provisions of the law)

TAKE NOTICE that this Honourable Court shall be moved on the day of 2023 at 9.00 A.M., or soon thereafter as Counsel for the Petitioners can be heard on an Application

FOR ORDERS THAT:

1. This Application be certified urgent, and service be dispensed within the first instance because the object of this Application will be defeated unless the Application is heard expeditiously.

2. Pending hearing and determination of this application, this Court order that the 1st Applicant/Petitioner and her son DM (a minor), the 2nd Petitioner and the 3rd Petitioner be granted leave to prosecute the application and the Petition using their initials instead of their full names as prescribed in Rule10(2)(a) of the Constitution of Kenya (Protection of Rights and Fundamental Freedoms) Practice and Procedure Rules, 2013.
3. During these proceedings, the identities of these petitioners and DM be concealed in all pleadings, rulings, judgments, court processes, notices as well as in open Court.
4. The identities be revealed to the Respondents only upon them entering a signed undertaking to protect the identity of the 1st, 2nd and 3rd Petitioners and not release those identities, which undertaking be adopted as an order of this Court.
5. Pending hearing and determination of this application and the Petition, the Court do order that the 2nd Respondent:
    a. Within two days of this Court's order facilitate the examination and treatment of DM and ensure that he is provided with a suitable paediatric ARV as well as any other medical treatment that he may require;
    b. Within two days of this Court's order, facilitate viral load testing for the 1st, 2nd and 3rd Petitioners and infant diagnostic testing for their children.
6. Pending the hearing and determination of this suit, the 2nd and 3rd Respondents do publish in at least two newspapers of national circulation as well as on all their social media platforms, a list of all health facilities where antiretroviral

medication, testing for breastfeeding mothers and early infant diagnosis testing can be accessed by persons living with HIV.

7. Further to the prayers above, the Court issue such further directions and orders as may be necessary to give effect to its orders.
8. The costs of the application be in the cause.

WHICH APPLICATION IS BASED ON THE GROUNDS THAT:

1. The petitioners file this petition to challenge the 2nd Respondent's failure to ensure that access to essential medical services and medication for the treatment and management of HIV is available and accessible.
2. The 2nd Respondent's failure and/or refusal to provide essential medical services to DM, as well as to other people living with HIV, risks their lives, health and wellbeing, and continues to infringe on their right to the highest attainable standard of health.
3. The 2nd Respondent's has failed to ensure the availability of early infant diagnosis as well as viral load testing for persons living with HIV, even breastfeeding mothers such as the 2nd and 3rd Petitioners, in violation of their and their infants' rights to life and the highest attainable standard of health.
4. The 1st Petitioner and her son, BK and CN (the applicants) continue to face victimization and social stigma because of their health status. If their identity is disclosed, it will lead to further stigma and will result in an undue limitation on their constitutional right to privacy.

5. The applicants are willing to disclose their identities to this Court under confidential cover. They are also willing to disclose their identities to the respondents upon them filing with this Court a written undertaking that they

will keep those names and identifying information confidential and not release them to members of the public.

6. It is in the interests of justice that the orders sought are granted as no parties will be prejudiced.

WHICH APPLICATION is further supported by the affidavits sworn by FA, BK, CN and Allan Maleche as well as by the Petition and supporting affidavits, and on such other or further grounds as may be adduced at the hearing.

DATED at KISUMU this 21st **day of** September **2023**

NYOKABI NJOGU and KENNETH OTIENO

ADVOCATES FOR THE 1-6TH PETITIONERS

Kinama

EMILY KINAMA

ADVOCATE FOR THE 7TH PETITIONER

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ISSUES NETWORK ON HIV/AIDS (KELIN)……6TH PETITIONER

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VERSUS

THE HON. ATTORNEY GENERAL……1ST RESPONDENT

CABINET SECRETARY FOR HEALTH……2NDRESPONDENT

KENYA MEDICAL SUPPLIES AUTHORITY……3RD RESPONDENT

AFFIDAVIT OF FA IN SUPPORT OF THE NOTICE OF MOTION

I, **FA,** a resident of Nyalenda within Kisumu County, and a citizen of the Republic of Kenya, do solemnly make oath and state as follows:

1. I am the 1st Applicant/Petitioner in this case and competent to swear this Affidavit.

2. I swear this Affidavit in support of the Notice of Motion and the Petition, including the prayers that the Petition be certified urgent and that I be granted leave to prosecute the application and the petition using my initials and using the initials of my son, DM.

3. I also rely on the petition and the supporting affidavit accompanying the petition.

4. I am a casual labourer working within Kisumu County and earning approximately Kshs 200-300 a day.

5. I am the mother of DM, a baby boy who was born on 18th December 2016.

6. In 2018, DM fell very ill and was diagnosed with HIV.

7. DM was then put on anti-retroviral treatment (ARVs). He was first prescribed Septrin until July 2018, when a drug called Kaletra Syrup was added to his regimen.

8. DM continued to take Kaletra Syrup until February 2021, when the medical personnel at Tivoli Centre gave me Kaletra tablets for DM. They did not explain why they changed this regimen.

9. Kaletra tablets are big, and DM is unable to swallow them. I was told by medical personnel to put the medicine in pellet form in DM's food and feed him this food. This had the effect of making the food very bitter and DM was unable to eat.

10. This forced me to have to crush and dissolve the tablets and pellets in water and force him to drink the water. Even after crushing the drugs and dissolving them in water, DM was still unable to keep the drugs down as they are very bitter, and he would therefore vomit anytime he takes his medicine.

11. As a result of the difficulties of DM keeping down the dissolved Kaletra tablets, and his inability to eat food that has been mixed up with Kaletra pellets, DM was unable to keep any food or water down and was, as a consequence , also not able to ingest the ARVs. He, therefore, was not on consistent medication during this time until the end of 2022.

12. Because of the lack of antiretroviral treatment, DM continued to get very unwell. He had rashes on his body, swellings on his neck, infections in his ears and was very weak.

13. I took DM to Jaramogi Oginga Odinga Teaching and Referral Hospital where I was informed that his condition was as a result of lack of ARVs.

14. To date, DM continues to suffer from infections and still gets sick. I eventually sought medical treatment with the help of the 6th Petitioner. The doctors there informed me that his illness was because he has not consistently been on medication in a form that he is able to digest.

15. I have brought this Petition because my son has not been getting his essential medication and is now suffering from complications.

16. In the interim, I ask this Honourable Court to intervene urgently and direct the Respondents to ensure the availability of a suitable drug that I can give my son so that he can regain and maintain his health.

17. I am concerned that DM's growth and development in these essential early stages of his life have been permanently damaged, and he continues to be at risk of him dying if he is not able to access effective, paediatric-appropriate ARVs immediately.

18. I am afraid that if this Court does not direct the 2nd respondent to ensure the availability of suitable drugs for children living with HIV, such as my son, that there will be needless death of other children too.

19. I also ask this court to allow me to prosecute this application as well as the petition using my initials as I risk facing further stigmatisation due to my economic and health status.

20. I am fearful that if I disclose my identity to the general public, I will be subject to further shame, and stigmatization based on my health information.

21. As this application and the Petition further concern the health status of a minor, DM, it is important that his rights to dignity and privacy similarly be protected by securing his anonymity in these proceedings.

22. I am willing to confidentially disclose my identity and that of DM to the Court and to the Respondents by providing our names and any other relevant information as may be directed by the Court. I am willing to do so if the Respondents assure me and this Court that my identity and that of DM will remain confidential and be used only in relation to these proceedings.

23. It will be in the interests of justice for the Court to grant the orders in this motion as no parties will be prejudiced. The grant of the urgent relief will further protect the rights to dignity, life and the highest attainable standard of health from being irreparably harmed.

24. What I have deponed to is true to the best of my knowledge, information and belief, save for information whereof sources of information have been disclosed.

SWORN in KISUMU this 21st **day of** September **2023**

By the said FA) FA
) DEPONENT
)
BEFORE ME)
)
)
COMMISSIONER FOR OATHS)

DRAWN & FILED BY:-

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KENYA MEDICAL SUPPLIES AUTHORITY.....3RD RESPONDENT

AFFIDAVIT OF ALLAN ACHESA MALECHE IN SUPPORT OF THE NOTICE OF MOTION

I, **ALLAN ACHESA MALECHE**, a citizen of Kenya and resident of Nairobi, within the Republic of Kenya do solemnly make oath and state as follows:

1. I am the Executive Director of the Kenya Legal & Ethical Issues Network on HIV & AIDS (KELIN), the 6thPetitioner herein, and have the authority to swear this Affidavit.

2. I swear this Affidavit in support of the Notice of Motion and the prayers particularized therein. I also rely on the Petition and my Affidavit supporting the Petition.

3. The Petition accompanying this motion concerns that unavailability of paediatric anti-retroviral medication (ARVs) as well as a lack of essential commodities that are in use for testing and detection of HIV, which commodities are an essential component of the treatment and management of HIV.

4. I am aware that the wholesome comprehensive and effective diagnosis and management of HIV requires that there be proper testing and diagnosing of the virus, that the person living with HIV be linked to medical care that is appropriate, and actually receives it, and that he or she be retained in continuous management so that viral suppression be achieved and maintained.

5. Since February 2021, KELIN has received complaints from various individuals such as the 1st Petitioner who had been unable to access ARV medication from public healthcare facilities and who have reported that they are unable to access testing for HIV at public health facilities.

6. While the initial stockouts and later complete stockout of anti-retroviral were in some instances resolved, the 6th Petitioner still receives reports from persons living with HIV about lack of suitable paediatric ARVs, early infant diagnostic testing and viral load testing.

7. The 1st, 2nd and 3rd Petitioners approached the 6th Petitioner for assistance because they have been unable to procure suitable ARVs and prophylaxis, or early infant diagnostic testing for their children.

8. Through its internal advocacy processes, the 6th Petitioner also became aware that since January 2021, for a period of one year and five months thereafter, there was a stark stock out in public healthcare facilities of ARVs and other essential commodities used in the detection, treatment and management of HIV.

9. We later came to learn through the media that the reason for the stock out of ARVs was seemingly as a result of a stalemate between the Kenya Medical Supply Authority (the 3rd Respondent herein) and the United States Agency for International Development (USAID) that has affected the distribution of essential medicines and commodities used in the management of HIV and prevention of AIDS. These commodities include condoms and kits required to perform early infant testing and viral load testing. (**Annexed hereto and marked AM1 is a copy of the media excerpt)**

10. Due to that dispute, children living with HIV were unable to access ARV medication, which is necessary for their health and to preserve their lives.

11. Additionally, infants born to mothers living with HIV face a high risk of infection due to unavailability of the ARVs which are used as prophylaxis to prevent mother to child transmission of HIV. This is particularly important to enable mothers living with HIV to breastfeed their children safely.

12. Moreover, that dispute has meant that since February 2021, there was wide scale non availability of testing kits to ensure that early infant diagnosis of babies, which is done as a component of prevention of mother to child transmission of HIV, is conducted. As a result, women who are breastfeeding such as the 2nd and 3rd Petitioners found themselves in situations where they are unable to ascertain their

health status or the status of their children, and accordingly to access appropriate healthcare if indeed their children have contracted HIV.

13. In addition to this, in October and November 2022, the 2nd Respondent has indicated that the antiretroviral medication Tenofovir Disoproxil, Lamivudine and Dolutegravir (TLD) that is being distributed through the 3rd respondent must be recalled and returned to medical facilities. **(Annexed hereto and marked AM2 is a copy of the circular from the 2nd Respondent.)**

14. This has resulted in interruptions in care for people living with HIV (PLHIV) and has meant that their health and lives have been threatened.

15. The above situation is a crisis for PLHIV and infants at risk of HIV that requires appropriate and urgent intervention commensurate with the grave risk to these peoples' and children's lives and wellbeing.

16. In relation to the order for anonymity, the 1st, 2nd and 3rd petitioners are currently experiencing grave difficulties and victimisation, discrimination, social stigma due their HIV status. If their identities are disclosed to the public, it will lead to further stigma and will result in an undue infringement on their constitutional right to privacy and the privacy of their health information.

17. As both the Petition and motion involve the health status of minor children (both directly for DM and indirectly for the breastfeeding mothers) it is necessary that the applicants/Petitioners' identifying information be anonymised. This will protect these minors from discrimination and ensure they are able to approach this Court for relief without the risk of their dignity and privacy being infringed.

18. In the period of the stockouts, KELIN, networks of persons living with HIV as well as other stakeholders engaged the 2nd and 3rd Respondents to address the cause of the stockouts, but these efforts bore no fruit. **(Annexed hereto and marked AM3 is a bundle of letters demonstrating the efforts taken by the 6th Petition and other stakeholders)**

19. As at filing of this motion, while supply of ARVs appears to have has restarted to a certain extent, there continue to be reports of lack of diagnostic testing and condoms around the country. **(Annexed hereto and marked AM4 is a bundle of news reports demonstrating lack of commodities used in the management of HIV)**

20. I ask this Court to grant the orders sought in the motion so that persons living with HIV can get information on where they can access immediate health and life saving care and that the 1st to 3rd applicants can access immediate life-sustaining healthcare treatment.

21. This petition is urgent because persons living with HIV continue to be denied access to health care services, particularly to access to medicines which is a violation of their rights to health, dignity and life.

22. I emphasise that the healthcare interventions, which the applicants seek to be provided urgently in this motion, are indeed integral components of the minimum package of care stipulated in the State's Minimum Package of Care in HIV Services Provision. This package encompasses a range of basic services, including but not limited to diagnosis, Screening for exposure, Early infant diagnosis, ARV

prophylaxis for exposed children, the provision of cotrimoxazole preventive therapy starting at 6 weeks of age, mandatory TB screening for all HIV-exposed and infected children during each visit, and ongoing clinical and laboratory monitoring, among others. The applicants are therefore not requesting extraordinary or exceptional care in terms of the urgent relief, only those which are deemed by the Kenyan state itself to be essential to their health and survival. **(Annexed hereto and marked AM5 is a copy of Kenya's Minimum Package of Care in HIV services provision)**

23. It will be in the interests of justice for the Court to grant these orders as no parties will be prejudiced.

24. What is deponed to in this affidavit is within my knowledge save for information the sources whereof are otherwise disclosed.

SWORN at **NAIROBI**
this 21st day of September 2023)
By the said
ALLAN MALECHE)
) **DEPONENT**
BEFORE ME)
)
COMMISSIONER FOR OATHS)

LYDIA W. MWANGI COMMISSIONER FOR OATHS P.O. Box NAIROBI

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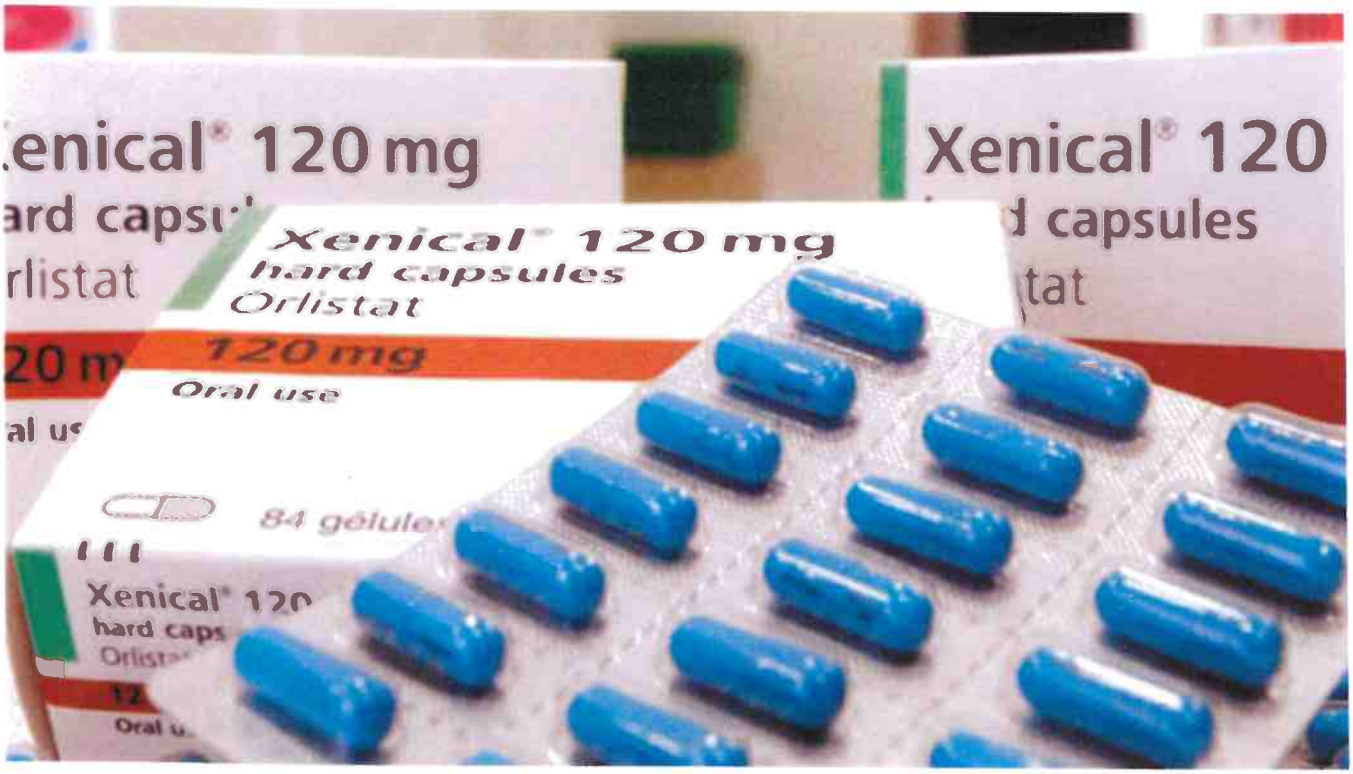
ECONOMY (/BD/ECONOMY)

America, Kenya tax row freeze Sh1 billion HIV drugs

THURSDAY MARCH 18 2021



HIV drugs. FILE PHOTO | NMG

Life-saving HIV and tuberculosis drugs worth Sh1.1billion are stuck at the port of Mombasa following a tax tussle between the Kenyan government and the US Agency for International Development (USAid).

The consignment of medication has been lying at the port since January 18 after the State handed a Sh90 million tax bill to a privately owned American firm, Chemonics which had imported it on behalf of USAid.

Kenya argued that the import arrangement flouted the tax waiver policies on government-to-government donations and that Chemonics had to pay duty as a private entity before the cargo could be released.

"USAid kindly requests your urgent intervention and assistance in clearing these obstacles with Pharmacy and Poisons Board (PPB) Import declaration Form(IDF)/import permit applications and tax and duty waivers," says a letter to the Ministry of Health (MoH) signed by USAid mission director Mark Meassick dated January 29.

The Sh1.1 billion consignment is part of a Sh7.6 billion worth of antiretrovirus donation by the USAid to the Health ministry.

Drug donations are normally expected to list government agencies and ministries as consignees in order to qualify for duty and tax waivers. This means that the consignment would have been consigned to the Kenyan government.

Any importations through private firms do not qualify for special exemptions and are subject to the normal clearance procedure, which involves inspection at the port by the Kenya Bureau of Standards (Kebs) and imposition of taxes, including the railway development levy (RDL).

USAid in its letter to the Health ministry notes it had encountered challenges in obtaining import permits from the PPB that are preventing "us from proceeding with importation and customs clearance for a number of urgently required commodities".

Items withheld at the port include HIV testing, treatment and prevention commodities such as ARVs, laboratory reagents as well as TB diagnostic and prevention medications.

The commodities include those for early infant diagnoisis (EID), viral load (VL) monitoring and key antiretroviral medicine Tenofovir/Lamivudine/and Dolutegravir (TLD).

Sources told the Business Daily that USAid was meant to import the medical commodities in October 2020 but went mum despite requests from the Ministry of Health asking on the status of the consignment.

In January, USAidwrote to the ministry announcing that the commodities were within Kenya, introducing a third party as consignee and requesting for tax waiver.

It is now emerging that the Health ministry had advised USAid to change the listed consignee from the private company to Kenyan government.

But as the standoff persisted, stocks of the life-saving medication continued to run low at government facilities amid calls for a speedy resolution of the row.

A lobby, the National Empowerment Network of People Living with HIV and Aids in Kenya (NEPHAK), urged the Health ministry to facilitate the entry of the consignment into the market to avert suffering for thousands of patients.

"We understand a shipment of ART (antiretroviral therapy) from the US government is sitting at the port under unclear circumstances, "NEPHAK director Nelson Otwoma said in a letter to Health ministry.

About 1.3 million adults in Kenya are living with HIV/Aids, an estimated 4.9 percent of those aged between 15 to 64, according to the Kenya Population-based HIV Impact Assessment 2018.

The HIV prevalence was found to be highest among women, at 6.6 percent, compared to men at 3.1 percent. The Covid-19 pandemic has meant that HIV positive patients who have a compromised immune system should be extra cautious to prevent infection.

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INSIDE DEVELOPMENT | HIV/AIDS

Supplies run low as Kenya and US standoff over HIV drugs

By ***Sara Jerving*** *// 21 April 2021*

Protestors gathered in downtown Nairobi to demand ARV drug release from the Port of Mombasa in Kenya. Photo by: Sara Jerving / Devex

Levi Knowles has lived with HIV for 13 years but manages it through medication. He typically receives a three-to-six-month supply of antiretroviral therapy. But in recent months, the clinic has only given him enough drugs to last about a week.

This is because the Kenyan government has been in a stand-off with the U.S. Agency for International Development over a large batch of ARV doses and other donated health supplies that have been stuck at the port of Mombasa since mid-January.

Because of this, antiretroviral treatment in the country, which is needed for the 1.2 million HIV-positive people, is running "dangerously low," according to civil society organizations. Treatment for children and lab reagents for testing HIV in babies are already completely out of stock. Most counties also don't have tuberculosis tests.

As a result of the shortages and rationing Knowles has resorted to skipping doses as he can't afford to go to the clinic every week.

"I'm playing with my immunity," he said. "I don't want to gamble with my life — but the government is gambling with my life."

'Holding us hostage'

Jane Gotiangco, a spokesperson for the U.S.-based private firm Chemonics explained that at the end of a five-year contract between USAID and the Kenya Medical Supplies Authority, USAID instead asked the Global Health Supply Chain-Procurement and Supply Management — implemented by Chemonics and a consortium of partners — to procure HIV, malaria, and family planning commodities for Kenya.

Civil society organizations in Kenya speculate that USAID decided to not use the Kenya Medical Supplies Authority for this shipment because of allegations of corruption and mismanagement of COVID-19 funds.

> *"[The standoff] risks rolling back decades of long gains made in the fight and management of HIV/AIDS."*
>
> *— Diana Gichengo, campaigns manager, Amnesty International Kenya*

In response, the Kenyan government initially demanded 90 million Kenyan shillings ($832,000) in importation taxes on the drugs, saying it wasn't a tax-exempt government to government donation, but has since waived these taxes. But according to a statement from local civil society organizations, the government is still insisting the drugs be delivered through its own system and not USAID's private partner.

A U.S.-based health expert from a civil society organization operating in Kenya, who wished to remain anonymous, said the matter is at a standstill as the new U.S. administration sees this as a diplomatic issue, adding that the U.S. President's Emergency Plan For AIDS Relief refused to address the issue at the country's operational planning meeting for Kenya on Tuesday citing the same reason.

"For civil society that's a slap in the face, because it's literally people's lives. Access to your drugs right now — and we aren't going to talk about it because it's a diplomatic issue? No, it's a life and death issue," the source said.

A USAID spokesperson said the agency has "been working on this jointly with the Government of Kenya and other international donors ... In order to achieve this, we are having urgent and ongoing diplomatic conversations with [Government of Kenya] representatives. We do not discuss diplomatic conversations publicly."

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As a stop-gap measure, the Kenyan government made an arrangement with the Global Fund to Fight AIDS, Tuberculosis and Malaria to support the country with drugs for the next three months, these shipments started this week.

Levi Knowles holds up his empty bottle of ARV pills at a protest in Nairobi, Kenya. Photo by: Sara Jerving / Devex

At a press conference in Nairobi on Tuesday, representatives from over a dozen civil society groups and people living with HIV said this recent shipment of drugs is only a bandaid to a larger problem, as it's unlikely to lead to multi-month supplies and will continue to result in people skipping doses.

"They take today, they skip tomorrow, so that they can extend the days before they go back to the clinic," said Bernard Baridi, chief executive officer at Blast, an organization for young people living with HIV.

They emphasized that many people will likely skip doses because it's impractical for them to go to the clinic every week amid COVID-19 movement restrictions, taking time off of work, paying for transport each way, and risking COVID-19 exposure. People often travel long distances for their ARVs to avoid bumping into people they know at a clinic, because of the stigma surrounding HIV.

The CSOs warned that missed doses could increase mother-to-child transmission of HIV and sexual transmission of the disease. Interrupted treatment can also lead to opportunistic infections, such as tuberculosis, and HIV drug resistance.

They called upon the Kenyan Ministry of Health to inform the public about any reforms on government "leakages" and "wastages" to "restore donor confidence." They also pleaded with USAID to immediately release the drugs to credible organizations operating in Kenya like NGOs or faith-based organizations.

"They are holding us hostage," said Patricia Asero, treatment advocate and chairperson of the International Community of Women Living with HIV in Kenya.

Kenya's faith leaders preach knowledge about HIV

The Kenya National AIDS Control Council has drawn on religious texts to help faith leaders deliver science-based messages about HIV prevention, treatment, and stigma to their congregations.

In a press release issued Tuesday, Amnesty International's Kenya office said it was "deeply concerned" about the drug shortages and the "lack of accountability" at Kenya Medical Supplies Authority.

The situation "risks rolling back decades of long gains made in the fight and management of HIV/AIDS," said Diana Gichengo, campaigns manager for the organization.

Difficult memories

Shortages of HIV drugs in Kenya remind 24-year-old Queenter Mugweru of a darker time in the country's history. Both her parents are HIV positive and the disease was passed along to her at birth.

When she was young, her parents didn't have access to HIV drugs. At one point, her mother got very sick. Her parents would attend support groups preparing them to die. They wrote her a book of memories to remember them by, expecting they wouldn't be around to raise her.

Thankfully, her parents survived, but her 1-year-old sibling died from the disease, making her an only child.

"I don't want us to go back to where we once were. When I look at my parents, they look much better in comparison to those days," Mugweru said. "HIV should not be

something that keeps you in bed ... not with all of the technology and where we are today."

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Global Health | Funding | Trade & Policy | Humanitarian Aid | United States | Kenya

ABOUT THE AUTHOR

Sara Jerving sarajerving

Sara Jerving is a Senior Reporter at Devex, where she covers global health. Her work has appeared in The New York Times, the Los Angeles Times, The Wall Street Journal, VICE News, and Bloomberg News among others. Sara holds a master's degree from Columbia University Graduate School of Journalism where she was a Lorana Sullivan fellow. She was a finalist for One World Media's Digital Media Award in 2021; a finalist for the Livingston Award for Young Journalists in 2018; and she was part of a VICE News Tonight on HBO team that received an Emmy nomination in 2018. She received the Philip Greer Memorial Award from Columbia University Graduate School of Journalism in 2014.

Why Kenya's HIV patients feel noose tightening

Wednesday, August 11, 2021

Ms Patricia Asero, chairperson of the National Empowerment Network for People Living with HIV. Photo credit: Steve Otieno | Nation Media Group

By Steve Otieno
Reporter
Nation Media Group

Patricia Asero is living with HIV. She says she is yet to receive her six-month supply of life-saving antiretroviral drugs (ARVs), as was the case with HIV patients before.

Ms Asero, who is also chairperson of the National Empowerment Network for People Living with HIV, is now living in fear, as are other Kenyans who are HIV-positive.

children in boarding schools whose parents keep calling me asking that I do something so that their children get at least three months' supply of ARVs and finish their school terms without worries," she said.

"This is a very dangerous thing to do. HIV is not a light disease where one can determine when to or not to take their drugs. The government is playing with our lives."

Moreover, Kaletra, a crucial reagent used when testing for HIV in children, is also unavailable in some parts of Kenya.

Ms Asero said efforts to seek answers from several government offices, including the Differentiated Service Delivery unit under the Ministry of Health, which ensures those infected receive supplies of between three and six months, have been futile.

Margaret Wendo, 23, was born with HIV. She knows what it means to be a student living with HIV in a Kenyan secondary school. She had managed to keep her status private until her yellow card, which indicates the dates of your next appointments with your doctor, amount of drugs you should be given and tests that should be done to analyse the viral load and CD4 levels, was exposed.

She said most classmates stopped talking to her and her desk mate moved. The stigmatisation that came from unplanned disclosure of her health status affected her to the extent that she stopped taking ARVs for three and a half years. Her viral load, previously at zero, shot up to over one million.

Now a peer counsellor who helps HIV-positive youths, she understands students' fear of stigmatisation should they have to keep asking for permission to go check if their ARVs have arrived. Most shy from having their drugs delivered by parcel as they may land in the wrong hands.

Africa

Lawyer Timothy Wafula. Photo credit: Steve Otieno | Nation Media Group

"In this case, it is the government that is charged with ensuring their medical needs are met and now that they cannot access ARVs, the government is failing them."

He also called on the government to account for every shilling spent in the acquisition of ARVs and make public how they are distributed.

As of three weeks ago, Ritonavir, a drug used to increase the levels of HIV protease inhibitors and reduce the risk of virologic failure and HIV drug resistance, was out of stock in several hospitals and pharmacies across the country.

"I have just been informed that Ritonavir is out of stock when I went to my usual centre to check whether the ARVs have arrived. I have been told to buy for myself. I sent someone in Nairobi to go get them where it is always available (Coptic Hospital) and they have told me that it is also out of stock," a source told Nation.Africa.

Government responds

Contacted for comment by Nation.Africa, Nascop, through its head of programme Catherine Ngugi, said the pandemic came with

Africa

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PHARMACY AND POISONS BOARD (https://web.pharmacyboardkenya.org/)

(tel:+1-800-456-478-23)

Have Any Questions?
(tel:+1-800-456-478-23)
+254 709 770 100

Report Adverse Events & Poor Quality Medicines (https://pv.pharmacyboardkenya.org/)

Submit Complaints (https://complaints.pharmacyboardkenya.org)

This is Exhibit marked AMS 7 referred to in the Annexed affidavit/Declaration of ANN MAKETH
Sworn/Declared before me on this 21st day of September 2023 at NAIROBI in the Republic of Kenya
Commissioner for Oaths

Products Recalled in 2022

S/N	Date recall was initiated	Product Name/ Product Category	INN Name (s)	Batch Number(s)	Name of Manufacturer	Reasons for recall
11	14/12/2022	Famcal tablets	Calcium citrate maleate with Cholecalciferol	FDF1AD3B	Indoco Remedies Limited, Industrial area, M.DI.D.C, Thane Belapur Road, Mumbai	Out of specification of results of assay testing on stability studies program at 9M time point
10	13/12/2022	Umbicare gel	Chlorhexidine Gluconate Gel 7.1% w/w	UAM1IC1B	Indoco Remedies Limited, Industrial area, M.DI.D.C, Thane Belapur Road, Mumbai	Out Of Specification results on testing of related substances

9	07/12/2022	Tenofovir Disoproxil Fumarate/ Lamivudine / Dolutegravir (300/300/50mg) tablets	Tenofovir Disoproxil Fumarate/ Lamivudine/ Dolutegravir (300/300/50mg) tablets	Several	Universal Corporation Limited	Market complaints on Discoloration of induction seal, broken tablets and black spots on the tablets
8	12/09/2022	Biodine mouth gargle	Povidone Iodine mouth gargle	0122081, 0122082, 0322054, 0322056 and 0322057	Biodeal Laboratories Ltd	Market complaint on discoloration of the products and review of retained and stability samples
7	01/07/2022	Rocephin I g Injection	Ceftriaxone 1 g injection	B0752B04	Siegfried Hameln in Germany manufactured for ROCHE	Detection of pinholes in 10 mL Water for Injection (WFI) ampoules used in Rocephin 1.000 g finished products

6	24/06/2022	EEATM Auto SutureTM Circular Stapler with DST SeriesTM Technology 25mm	Intraluminal circular stapler	All		Covidien llc 15 Hampshire Street Mansfield, USA	A complaint was received for EEATM AutosutureTM Circular Stapler with DST SeriesTM Technology (EEAXL2535) reported as "Staples Did Not Deploy". According to the reporter, during laparoscopic procedure the circular stapler was able to fire, but the staples did not deploy when attempting to staple a small bowel segment to the gastric pouch. Further tissue dissection and manipulation was required to recreate tissue and the gastric pouch for anastomosis. The case was completed by using another stapler. The surgical time was extended by at least 2 hours and hospitalization for 1 day. One EEAXL2535 instrument was received at Medtronic manufacturing for evaluation of the reported conditions of "Staples Did Not Deploy" and "Disengaged Staple Guide". The staple guide was not attached to the instrument, and it was not received for evaluation. The weld witness marks were not observed at the inner area of the shell, which is an indication of improper staple guide assembly.
5	24/06/2022	Dawaflox DPS suspension 100ML	Flucloxacillin	2006121, 2012085		Dawa Lifesciences Ltd	Failure of assay during stability studies
4	06/04/2022	Biodopa 250mg tablets	Methyldopa	0321077 and 0421112		Biodeal Laboratories Ltd	Discoloration of the tablets
3	07/03/2022	Vasofix certo G24X19MM yellow	Peripheral vascular infusion catheter	20A19G8334, 20A21G8381		B.Braun Melsungen AG (BBMAG)	A defect on the injection port that may result in potentially critical clinical consequences for the patient e.g blood loss, underdosage or delay of therapy. Third party are at risk being inContact with patients fluids.

2	21/02/2022	ALKAR-UR effervescent granule satchets	Sodium bicarbonate 1.76g, Tartaric acid 0.890g, Citric acid anhydrous 0.720g and trisodium citrate anhydrous	3620100	National Pharmaceutical Industries Co. (SAOC), Sultanate of Oman	Sachets bloated and powder agglomerated
1	14/01/2022	Pregsmile tablets 3 *10s	Doxylamine/Pyridoxine / Folic acid	EKE-235	Corona Remedies Pvt.Ltd, India	Mix up (found to contain blister of Rosuvastatin)

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eenya.org/careers
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(mailto:maxbizz@mail.com)

Mail Us (mailto:maxbizz@mail.com)

General Information: info@pharmacyboardkenya.org

Pharmacovigilance: pv@pharmacyboardkenya.org Website and Portals: webmaster@pharmacyboardkenya.org

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OFFICE OF THE COUNCIL OF GOVERNORS
22 NOV 2022
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P O. Box 40401-00100, NAIROBI

MINISTRY OF HEALTH
OFFICE OF THE DIRECTOR GENERAL FOR HEALTH

Telephone:(020) 2717077
Fax: (020) 2713234
Email: dghealth2019@gmail.com
When replying please quote

AFYA HOUSE
CATHEDRAL ROAD
P. O. Box 30016 – 00100
NAIROBI

Ref: MOH/NASCOP/HIVC/VOL.1 (25)

22nd November 2022

All County Directors for Health

Thro'

Chief Executive Officer
Council of Governors
Delta House-Westlands
P.O. Box 40401
NAIROBI

VOLUNTARY RECALL AND QUARANTINE OF TLD PRODUCTS MANUFACTURED BY UNIVERSAL CORPORATION LIMITED AND GUIDANCE ON SERVICE CONTINUITY

The Ministry of Health through the National AIDS & STI Control Program (NASCOP) and Pharmacy and Poisons Board (PPB) has received reports of and complaints on discoloration of Tenofovir/Lamivudine/Dolutegravir 300/300/50mg (TLD) tablets and bottle covers specific to the brand supplied by Universal Corporation Limited (UCL) through the Kenya Medical Supplies Authority (KEMSA). Following these complaints and engagement by PPB, a decision on voluntary recall of all the TLD products manufactured by UCL was communicated to UCL on 16th November 2022 by KEMSA.

A stakeholders meeting communicating the same and key actions expected was convened on 17th November 2022 by NASCOP. To ensure the continuity of services for recipients of care during this phase of quarantine and recall of the affected TLD products (manufactured by UCL), please note the following as communicated in the meeting: -

1. Only the TLD manufactured by UCL is affected by this quarantine and recall.
2. There are sufficient national stocks (> 6months) of TLD from other manufacturers other than UCL.
3. Facilities are instructed to;
    a. Quarantine all TLD Tablets manufactured by UCL.
    b. Accept all UCL TLD tablets returned by clients.

c. Counsel all clients on the need to maintain adherence to treatment as other brands of TLD are not affected.
d. Replace and issue clients with TLD tablets from other manufacturers.
e. Fill out the stock status of the TLD tablets via an e-tool. https://enketo.ona.io/x/9VFt9tHM

4. Details of the reverse logistics i.e. how the quarantined stocks at facility level will get back to the manufacturer are being coordinated by KEMSA and PPB.
5. In line with its mandate, PPB is following up with the quality analysis of the TLD product manufactured by UCL, and will share the outcome including the cause of the reported discoloration and any implication on clients' safety.
6. Consequently, as we await the results of the quality analysis, we urge recipients of care to seek assistance from their health care providers.

By this letter all County Directors for Health (CDHs) are directed to:

a) Cascade this communication to all your facilities to ensure that the agreed actions are followed and that any hitches in service continuity is addressed and or escalated for action.
b) Work with stakeholders at your level including communities of Persons Living with HIV (PLHIVs) and implementing partners in addressing any emerging issues with regard to this exercise.

For further clarification please contact Head NASCOP on head@nascop.or.ke.

Dr. Patrick Amoth, EBS.
Ag. DIRECTOR GENERAL FOR HEALTH

47 A

REPUBLIC OF KENYA

IN THE HIGH COURT OF KENYA AT KISUMU

CONSTITUTIONAL AND HUMAN RIGHTS DIVISION

PETITION NO OF 2023

IN THE MATTER OF ARTICLES 1, 2, 3, 10, 19, 20(1) & (4), 21, 22, 23, 24, 25, 26(1), 27, 28, 29, 35, 43(1)(a), 47, 53 (1)(c), 165, 232(1), 258 AND 259 OF THE CONSTITUTION OF KENYA, 2010

AND

IN THE MATTER OF SECTIONS 4 (b), (c), (d), (e), (f), (h), (i), (l) (n) AND (m), 14 (f), 20, 24,32, AND 33 (2) AND (5) OF THE EAST AFRICAN COMMUNITY HIV AND AIDS PREVENTION AND MANAGEMENT ACT, 2012

AND

IN THE MATTER OF SECTIONS 4, (c) (d) 5, 8, (c) (d) 15 OF THE HEALTH ACT, 2017

AND

IN THE MATTER OF SECTION 19 OF THE HIV PREVENTION AND CONTROL ACT

AND

IN THE MATTER OF SECTIONS 8, 9, 10 AND 16, OF THE CHILDREN ACT, 2022

BETWEEN

FA……..1ST PETITIONER

(Suing on her own behalf and as mother and next friend of DM (A minor)

BK……2ND PETITIONER

CNN……3RD PETITIONER

PATRICIA ASERO OCHIENG……4TH PETITIONER

AMBASSADOR FOR YOUTH AND ADOLESCENTS

REPRODUCTIVEHEALTHPROGRAM(AYARHEP)..5TH PETITIONER

KENYA LEGAL AND ETHICAL

ISSUES NETWORK ON HIV/AIDS (KELIN)……6TH PETITIONER

KATIBA INSTITUTE……7TH PETITIONER

VERSUS

THE HON. ATTORNEY GENERAL……1ST RESPONDENT

CABINET SECRETARY FOR HEALTH……2ND RESPONDENT

KENYA MEDICAL SUPPLIES AUTHORITY……3RD RESPONDENT

CERTIFICATE OF AUTHENTICITY

(Under section 78 and 106B of the Evidence Act. Cap 80 of the Laws of Kenya)

I, **ALLAN ACHESA MALECHE, OF P.O BOX 112-00202 NAIROBI,** a Kenyan male adult of sound mind residing and working for gain in Nairobi Cunty within the Republic of Kenya, and the Executive Director of the 6th Petitioner herein whose address for purposes of this petition is

A7 C

care of KENYA LEGAL AND ETHICAL ISSUES NETWORK ON HIV AND AIDS, Kuwinda Lane, off Langata Road, Karen C, P O Box 112 - 00202 KNH Nairobi, do hereby make a solemn oath and states as follows;

1. **THAT** I am an advocate of the High Court of Kenya and the Executive Director of the Kenya Lega and Ethical Issues Network of HIV and Aids (KELIN) .
2. **THAT** on the 20th day of September 2023 while preparing an Affidavit by KELIN I used my laptop to take a screenshot from the Pharmacy and Poisons Board website: (https://web.pharmacyboardkenya.org/products-recalled-in 2022/) at 2.42 PM.
3. That I have annexed this printout from the website to the affidavit sworn by Allan Achesa Maleche sworn on 21st September 2023 Marked **AM2**.
4. **THAT** I took the screen shot using my laptop; Think pad type number 21B6-SOTN00 ;service tag/ serial number S/N PW 05R9XJ which was in good working condition and operated and performed the actions described above seamlessly and without any technical difficulties.
5. **THAT** I printed the documents using printer Kyocera model number TA2553d; serial number RFM9Z24946 which was in good working condition and operated and performed the actions described above seamlessly and without any technical difficulties.
6. **THAT** at the time of my use, the laptop and printer which I used to

6. **THAT** at the time of my use, the laptop and printer which I used to access and print the information were both functioning correctly to the best of my knowledge.
7. **THAT** I therefore certify that the printed copies of the electronic documents I have produced before the court are authentic. I have also produced a certificate of authentication.

CERTIFIED at NAIROBI this 2nd day of September 2023

By the said

Allan Achesa Maleche

Drawn and Filed By:

Nyokabi Njogu, Advocate,

C/O Kenya Legal and Ethical

Issues Network on HIV & AIDS (KELIN)

Kuwinda Lane, off Langata Road, Karen C

P.O Box 112-00202 KNH Nairobi

Tel: 0790 111578

Email: litigation@kelinkenya.org

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This is Exhibit marked "ATM 8"
referred to in the Annexed affidavit/Declaration
of Abdi Mahamud
Sworn/Declared before me on this 21st
day of September 2021
at Nairobi in the Republic of Kenya
Commissioner for Oaths

COUNCIL OF GOVERNORS

21st May, 2021

PRESS STATEMENT ON ISSUES AFFECTING COUNTY GOVERNMENTS

Today the Council of Governors held an extra-ordinary meeting to discuss issues affecting County Governments and we would like to address you on the resolutions from the meeting.

1. Impeachment of Governors

The Council has taken note of the trend of impeachments of Governors over the last one year, specifically in Kiambu County, Nairobi City County and now Wajir County.

While we appreciate the fact that impeachment is both a legal and a political process, the rule of law should prevail while undertaking the same. All the bodies involved should ensure that they are guided by the Constitution and the principles laid down by the courts on the threshold of impeachment.

The Council assures the public that it values integrity and accountability in the running of public affairs in the Counties. Nevertheless, oversight bodies must remain cognizant of the legal principles surrounding impeachment so that the exercise is not abused. The Council shall engage relevant institutions with a view to streamlining court pronouncements with the law so that the impeachment process can be anchored in legitimacy and impartiality.

2. Approval of the NHIF Report on gazettement of County Health Facilities

The Council has had previous discussions with the Ministry of Health on the NHIF cover as part of the UHC agenda, specifically refunds to the County Health facilities which was low and sometimes non-existent. An agreement was reached with the Ministry of Health and NHIF on this matter.

In this regard, County Governments have reviewed the list of NHIF contracted Health facilities with a view to verify that indeed they are County facilities as well as updating the existing list to include the new facilities which were unlisted with NHIF. These facilities will be instrumental in the implementation of Universal Health Coverage.

The list of health facilities from the Counties will be forwarded to the NHIF to ensure that they are contracted in the exercise that is set to begin on **1st July 2021.**

3. Provision of ARVs Drugs to Counties

Over the past 20 years, HIV commodities have significantly been supported by US Government and the Global Fund. These Commodities include ARVs, laboratory consumables, reagents, and HIV testing kits. There is likelihood of a looming shortage of these commodities from **1st July 2021,** posing a potential crisis in continuity of HIV care and treatment of **1.1 Million** Kenyans living with HIV. This therefore means that their health will be compromised and they risk dying due to increased HIV related infections and massive drug resistance.

As a matter of urgency, we call upon the Ministry of Health and USAID to immediately procure a third-party agent to handle the warehousing and distribution of the health commodities that are stuck at the port. Further, they are to distribute these commodities to all County facilities before **20th June 2021.**

However, both the National Government and the County Governments should have a candid conversation around how the country can move towards self-reliance in the purchase of HIV and TB drugs. In the long-term, both levels of government need to discuss sustainable HIV interventions and how we can reduce dependence on donors on such critical matters. We need to look internally and begin to rely on ourselves in the procurement of these critical commodities.

We assure the public of the Council's commitment to support devolution.

Asanteni sana.

Signed

H.E James Ongwae, EGH,CBS ,EBS
Vice-Chair, Council of Governors

NATIONAL EMPOWERMENT NETWORK OF PEOPLE LIVING WITH HIV/AIDS IN KENYA (NEPHAK)

P.O Box 75654-00200 Nairobi, Kenya Tel: +254 – 020 - 3875917 / 3862271
Telfax: + 254 02 3861376, Mobile: +254 720 209 694 / 734 685 607.
Email: info@nephak.or.ke
www.nephak.or.ke

05.05.21.

Hon. Sen. Mutahi Kagwe, EGH.
Cabinet Secretary for Health
Afya House, Cathedral Road,
P.O. Box: 30016-00100,
Nairobi.

RE: STALEMATE ON DISTRIBUTION OF ARVS & INVOLVEMENT OF PLHIV IN DISCUSSIONS

We, the undersigned, individuals, organizations and associations, are representatives of people living with and affected by HIV, health and human rights civil society and non-governmental and community-based organizations. We write this letter pursuant to our constitutional mandate under Articles 3, 10 and 35 of the Constitution on the responsibility to defend and protect the Constitution, the right to participate in matters concerning us and to access public information, respectively.

We refer to an earlier letter from the National Empowerment Network of People Living with HIV/AIDS in Kenya (NEPHAK) dated 4th March 2021. We note with regret that the letter has never been responded to. Not even an acknowledgement of receipt of the letter was provided. The ARVs stalemate is still on and people living with HIV remain anxious some having to make frequent visits to health facilities and mothers having to share their medicine with children infected with HIV.

Although we have held virtual meeting with the head of NASCOP, the discussions did not adequately address the concerns, anxiety and fears from the PLHIV community. We are especially disappointed that the voice of people living with HIV is not being considered on a matter that impacts their life. This is not in line with the provisions of Article 10 of the Kenyan Constitution that makes it an obligation for our government to facilitate public participation in decision making processes. Further it doesn't augur well with the international principles including the Principle of the Greater Involvement of People Living with HIV (GIPA), as espoused in the 1994 Paris AIDS Summit. The non-engagement of people living with HIV in the on-going discussions is already impacting negatively because the community do not know what to believe. The irreducible basis of GIPA Principle is that PLHIV engage through their networks and leadership identified by themselves: Nothing for Us Without Us.

From the media reports *(quoting the CS – National Treasury)*, we understand that half (50%) of the tax required by the KRA was waivered; and with that; the Laboratory

commodities were immediately released. We do not understand the difficulty in extending the waiver to cover ARVs. We are yet to be informed of any other issue causing this stalemate.

We take this opportunity to remind the Ministry of Health of its obligation to promote, protect, respect and fulfil the right to the highest attainable standard of health as provided for in Articles 43(1) a and 53(1) c. As such the Ministry is under an obligation to take measures to achieve the progressive realization of the right to health for adults, and the immediate realization of the right to health for children. The continued threat to the disruption in access to life-saving medicines for people living with HIV constitutes a violation of the rights to health.

We welcome the investigation that is ongoing to determine how drug combinations that were phased out made their way to a facility in Siaya county. Our members are keen to participate in this process to ensure comprehensive information is provided. We are also keen to understand how the KEMSA is having in their warehouse an ARVs regimen that was phased out months ago.

We, therefore, demand that the Ministry of Health, as per its constitutional obligation, ensures ARVs are immediately made available and accessible to PLHIVs in Kenya either by ending the stalemate with USAID and or finding an alternative that will ensure we revert to the multi-month dispensing especially during this surge of the COVID-19.

People living with HIV also recommend that the Kenya government should take up the role of procuring ARVs to those in need and leave partners to engage in other areas of the HIV response. This can only be possible with increased domestic HIV financing. The government should also explore other possibilities such as local production of medicines, including ARVs.

More importantly, we reiterate that any initiative and/or intervention aimed at improving the health and wellbeing of the PLHIV community should be people-centred and have the community (PLHIV) at the centre. In that way, the Ministry of Health will be able to sustainably act in the best interest of PLHV

Signed

i. National Empowerment Network of people living with HIV in Kenya (NEPHAK)
ii. Women Fighting AIDS in Kenya (WOFAK)
iii. The Organization of young people living with HIV in Kenya (Y+)
iv. Tuberculosis Survivors Support Group
v. Pamoja TB Group
vi. Network of TB Champions - Kenya
vii. International Community of Women Living with HIV (ICW-Kenya)
viii. Discordant Couples Organization in Kenya (DISCOK)
ix. Indigenous Muslim Women living with HIV in Kenya
x. Positive Families Network
xi. Faws Women Group
xii. KELIN

xiii. WACI Health
xiv. Health GAP
xv. AfroCAB Treatment Access Partnership
xvi. AIDS Healthcare Foundation – Kenya (AHF – Kenya)
xvii. Health Options for Young Men on HIV/AIDS
xviii. Positive Young Women Voices (PYWV)
xix. Kenya Network of HIV Positive Teachers (KENEPOTE)
xx. Movement of Men Against AIDS in Kenya (MMAAK)
xxi. Network of Men living with HIV in Kenya (NETMA+)
xxii. Lean on Med Foundation
xxiii. Most at Risk Young Mothers and Teenage Girls living with HIV (MOYOTE)
xxiv. Mombasa PLHIV Support Network (MOPESUN)
xxv. WOTE Youth Development Program
xxvi. AYARHEP
xxvii. Coalition of people Fighting HIV/AIDS and TB in Migori
xxviii. ITPC – EA
xxix. Reach-Out Centre
xxx. Kenya Sex Workers Alliance (KESWA)
xxxi. Kenya NGOs Alliance Against Malaria (KeNAAM)
xxxii. Kilifi County PLHIV Network
xxxiii. Kobat Youth Group
xxxiv. Changu ni Chema Network
xxxv. OPAHA - Wajir
xxxvi. OPHAHA – Mandera
xxxvii. KENEPOTE – Nakuru
xxxviii. Operation Hope Organization
xxxix. Bomet Shine Group
xl. Kwazi Youth Group
xli. CCC Men Support Group – Nakuru
xlii. Fountain of Hope CBO
xliii. Mother Francisca Muungano – Nandi
xliv. WEFKO CBO Garissa
xlv. Focus on Families
xlvi. Vihiga Health Centre Support Group
xlvii. South Imenti HIV Action Group
xlviii. KENEPOTE Marsabit
xlix. Nyabende Support Program – Kisumu

l. Restoration of Hope – Marsabit
li. Dandora Community AIDS Support Association (DACASA)
lii. Bar Hostess Empowerment Support Program (BHESP)
liii. Umoja ni Nguvu Self Help Group
liv. Stigma Sportsmen Fighting HIV and TB in Kenya (SPOFA)
lv. Centre for Integrated Community Empowermet (CICE)
lvi. Nelson Mandela TB/HIV Community information CBO
lvii. Mwea Hope in Life – Embu
lviii. Nyeri PLHIV Network (NYEPLWA)
lix. KISWA
lx. Sister Vision Support Group
lxi. PIPE
lxii. Stress Free Support Group
lxiii. Jowakawaka Self Help Group
lxiv. Love and Hope Centre - Nakuru
lxv. Umbrella Women Group
lxvi. Smart Widows Support System (SWISS)
lxvii. Network of Post est HIVand AIDS Community Organization (NEPOTECH)
lxviii. Network of Key Populations Affected with HIV
lxix. Nyandarua Network of PLHA
lxx. KENAPA
lxxi. SUNRISE SUPPORT
lxxii. KENEPOTE Narok
lxxiii. Kosor Gaa
lxxiv. Marigat Support
lxxv. Laikipia East AIDS Support Group (LEISU)
lxxvi. Coalition Against Stigma
lxxvii. Tumaina Support Group – Baragoi
lxxviii. Association of PLHA in Kuria (APAK)
lxxix. UCODEV – Migori
lxxx. Kericho Shine SG
lxxxi. Tujipende Support Group
lxxxii. Yes Support Group
lxxxiii. Jikaze Support Group
lxxxiv. Echami Support Group - Maralal
lxxxv. Muital Care and support Group
lxxxvi. Cicapao Suppurt Group
lxxxvii. Mwangaza disabled shg
lxxxviii. Toretgei Support Group

lxxxix. Kimusor Support Group
xc. Kalawa People with HIV support group
xci. Kangundo Positive Teachers
xcii. Mbone Ngwone Support Group
xciii. Ambassadors of Hope CBO
xciv. Apame Support Grioup
xcv. Ambassadors of Hope Support Group
xcvi. FAWS
xcvii. Nakuru Drop In Online Centre
xcviii. DIPADS HOPE Group - Kiambaa
xcix. Iturkana Support Group
c. Kisii Township PLHIV Network
ci. Nyamira Change and live SG
cii. Himwaneti support group
ciii. Vivasile support group
civ. TESO men living with HIV
cv. Busia Children Rehabilitation Center
cvi. AnyolebekhoyeSupport Group
cvii. VHC support group - Vihiga
cviii. Pole Pole SG – Kakamega
cix. Nyamira Post HIV Test SHG

CC: Jackline Mogeni, CEO - Council of Governors
Dr. Medhin T, UNAIDS Country Coordinator, Kenya

To: The National Tuberculosis, Leprosy and Lung Disease Program (NTLD-P)

1ST Floor, Afya Annex, Kenyatta National Hospital

Hospital Grounds

Nairobi, Kenya

26th July 2023

This is Exhibit marked "AM 4" referred to in the Annexed affidavit/Declaration of ALLAN MALEH Sworn/Declared before me on this 21st day of September 2023 in NAIROBI in the Republic of Kenya

Commissioner for Oaths

Dear Dr. Immaculate Kathure, Head of Program,

Subject: Petition to Address Tuberculosis (TB) Drug Stock-Outs and Ensure Uninterrupted Treatment Access

We, The Network of TB Champions Kenya, Representing TB Affected Communities in all 47 Counties in collaboration with other CSOs, are writing to express our profound concern regarding the current issue of DS TB drug stock-outs, which severely hampers access to life-saving medications for tuberculosis clients, which is a violation of the Constitution of Kenya Article 43 which states. "Every person has the right to the highest attainable standard of health, which includes the right to health care services, including reproductive health care."

The government has the ethical and legal responsibility to ensure free and appropriate treatment is available to every single person affected by TB.

Tuberculosis continues to be a significant health challenge in Kenya, affecting millions of lives yearly. Timely and consistent access to anti-TB medications is crucial to achieving successful treatment outcomes and preventing the development of drug-resistant strains. However, the current DS TB drug stock-out situation is getting out of hand, contributing to clients interrupting treatment and delaying the initiation of life-saving DS TB treatment for others. If not resolved soonest, the current situation will reverse the gains in ending TB in Kenya.

The Network of TB Champions Kenya , its constituents' members and collaborators acknowledge the National TB Programs efforts to ensure TB Clients receive the necessary treatment. We understand that some factors to the DSTB drug Stock out situation are beyond the control of the National TB Program , and we stand in solidarity with the efforts made to mitigate the problem . however, we believe immediate action is required to prevent further harm to TB Clients, unnecessary suffering and deaths due to interrupted and delayed treatment while safeguarding the progress made in Ending TB in Kenya.

We, therefore, petition for the following actions to be taken:

1. Financial Support: Allocate sufficient funding and resources to support TB programs, including procurement and distribution of medications, to avoid stock-outs.
2. Emergency Stockpile: Create emergency stockpiles of essential TB drugs at national and regional levels as a buffer during unforeseen circumstances and prevent stock-outs.
3. Data Transparency: Ensure transparency in drug stock levels, communication, and distribution data for effective advocacy, accountability, and resource allocation.
4. Collaboration with Pharmaceutical Companies: Engage in dialogue and collaboration with pharmaceutical companies to address manufacturing and distribution challenges that may contribute to drug shortages.
5. Early Warning Systems: Develop and implement early warning systems to detect potential drug stock-out situations in advance, allowing for timely interventions and preventing treatment disruptions.

6. Contingency Planning: Develop contingency plans at national and regional levels to swiftly respond to TB drug stock-outs and minimize their impact on patient care.
7. Monitoring and Supply Chain Strengthening: Implement robust monitoring systems to track drug stocks at all Levels (National , County , Sub -County and health facilities) and strengthen supply chains to ensure an uninterrupted flow of TB medications to facilities within the country, Build Capacity of all level providers on TB Commodity Monitoring and Accurate reporting.

By addressing the issue of TB drug stock-outs, we can safeguard the health and well-being of TB clients, prevent treatment interruptions, and make significant progress in our fight against tuberculosis.

We urge you to treat this matter with the utmost urgency and dedication it deserves. Together, we can work towards a Kenya where no individual battling tuberculosis faces unnecessary obstacles in their journey toward recovery.

We also hope that the government will issue a statement clarifying how it will be tackling this issue urgently.

Thank you for your continued support to the TB Affected communities and Commitment to Ending TB in Kenya.

Signed By:

Network of TB Champions Kenya -NTBC-K.

Stop TB Partnership Kenya.

The Kenya Legal & Ethical Issues Network on HIV and AIDS – KELIN

National Empowerment Network of People Living with HIV/AIDS in Kenya - NEPHAK .

Pamoja TB Group .

Wote Youth Development .

Y+Kenya.

Ambassadors for Youth and adolescents Reproductive Health Programme – AYARHEP.

Kenya Network of HIV Positive Teacher – KENEPOTE.

Disease Eradication Civil Society Assemblies – DECSA

Arid Land Action Forum – ALAF

Kitale HIV and Aids Positive People Survival - KHAPPS

Nelson Mandela TB HIV Information CBO

Envisioned Youths and Adolescent Ambassadors on Move - EYAAM

Trust Five Self Help Group

SWISS CBO

Youths Advocating Positive Behavior Change

Uzalendo Social Justice Center Vihiga County

KENEPA- Elgeyo Marakwet

Isiolo County Tuberculosis , HIV/AIDS and Mental Health Champions – ITAMEC

Masculinity Institute Kenya

Globe Institute of Grassroots Initiative – GIGI

Nyando Social Justice

Vision Makers CBO

Mambokaje CBO

Most at Risk Young Mothers and Teenage girls living with HIV Initiative - MOTOTE

MINISTRY OF MEDICAL SERVICES

MINIMUM PACKAGE OF CARE IN HIV SERVICES PROVISION

1.0 Introduction

1.1 Background

The Ministry of Health through NASCOP has continued to provide HIV care and treatment services to people living with HIV with the aim of achieving quality HIV care and increased access to treatment. In line with the current KNASP III, NASCOP has continued to spearhead the scale up of HIV care and treatment services in the country. In the past 7 years HIV treatment in the country has seen rapid scale up and increased access to care and treatment for persons living with HIV. There were 482,000 patients active on antiretroviral therapy as at May 2011.

The Government of Kenya in collaboration with key development and implementing partners has continued to support HIV services in terms of client level services and health system level support that include capacity building, HIV commodities and infrastructure. Variations have been witnessed in support of both technical and non-technical areas. This has led to disparities in provision of HIV services and support at facility and regional level. In view of this there is need to guide and coordinate HIV services and support more effectively while creating a better system of accountability.

Through various formal assessments, gaps have been identified in the provision of HIV care and treatment services. These gaps are mainly in the provision of standardized care

and treatment services, data management, commodity and information flow, as wel commodity management practices at decentralized levels.

A comprehensive care package defining client level services and the correspondi health systems support has been compiled. This will give guidance to all stakeholders HIV service provision regarding the type of support to be provided at all levels. Th standardization enables all stakeholders identify opportunities for improvement in HI care and treatment service provision

1.2 Definition of terms

Patients in HIV care – This refers to a HIV positive client registered at a comprehensive care clinic for purposes of accessing care, treatment and support services. This includes all enrolled whether on ART or not and excludes HIV exposed children and Post Exposure prophylaxis clients until their status is confirmed to be positive.

Patients on antiretroviral therapy (ART) – This refers to a HIV positive client who is already registered at a comprehensive care clinic and is on antiretroviral therapy for treatment purposes, it excludes those on ARVs for prophylaxis such as PMTCT or PEP.

2.0 The minimum package of care

The package defines the minimum set of HIV services that every PLHIV visiting a health facility should access.

It is presented in two levels:

- Client level
- Health systems level

2.1 Client level support

At the client level, all PLHIV should have access to a set of services that are known to promote health, improve the quality of life, prevent further HIV transmission and delay HIV disease progression and prevent mortality. These may vary depending on the age of the patient. These services have been divided into the following categories:

1. Paediatric
2. Adolescent
3. Adult

2.1.1 Paediatric care and treatment services

This covers children in the age bracket 0 to 14 years. There are two groups of children with respect to HIV management:

a) The HIV exposed child.

This is a child who is born to a mother known to be HIV positive and /or has a positive rapid HIV antibody test result. Confirmation of HIV status of a child <18 months of age is by DNA PCR test.

Component	Services
HIV Diagnosis	1. Screening for exposure using rapid antibody tests for those whose exposure status is unknown.
	2. Early infant diagnosis (early testing for HIV infection:(Dry blood spots (DBS) for DNA PCR at 6 weeks of age or earliest contact thereafter.)
	3. Repeat HIV rapid antibody tests at 9 and 18 months of age for DNA PCR negative infants. Confirmatory PCR for those who have a positive HIV antibody test at nine months
	4. Provider Initiated Testing and Counselling (PITC) for children older than 18 months

HIV Exposed Infant	1. Regular follow-up and documentation using the HEI register and card

	2.Infant feeding options and ARV prophylaxis for the exposed child as per guidelines
	3. Cotrimoxazole preventive therapy from 6 weeks of age

b) HIV infected child (child whose HIV status is confirmed positive

Both HIV Exposed and Infected child	1. Growth and development monitoring at every clinic visit
	2. Immunization as per EPI guidelines
	3. Nutritional assessment, counselling and support
	4. TB screening for all HIV exposed and infected children on every visit
	5. Regular presumptive deworming every 6 months
	5. Health education & counselling of the child's caregiver on: o Infant feeding o HIV related symptoms o Adherence: appointments and medication (Cotrimoxazole prophylaxis, ARVs and where relevant anti-TB/ Isoniazid prophylaxis)

HIV Infected child	1. Timely enrolment into care
	2. Immediate initiation of HAART for all HIV infected children under 2 years
	3. Timely determination of treatment eligibility and initiation of HAART for all HIV infected children above two years of age
	4. Treatment preparation(Counselling for and providing antiretroviral therapy)
	5. Dose evaluations and adjustments as per weight at every visit
	6. Prompt treatment of infections including opportunistic infections
	7. Cotrimoxazole Preventive Therapy (CPT)
	8. Prevention of tuberculosis through Isoniazid Preventive Therapy (IPT)
	9. Clinical and laboratory monitoring o Routine screening for OIs and their management o Routine screening and monitoring for adverse drug reactions o Routine CD4 , targeted viral load and resistant testing where necessary o Outcome and treatment response monitoring
	10. Psychosocial support

	11. Providing comprehensive care for other family members ○ Family testing ○ Harmonizing appointments for families
	12. Planning for/providing long-term HIV care and follow up including community support
	13. Defaulter tracking systems: identification and tracking mechanisms
	14. Routine follow-ups for all on care through scheduled visits

2.1.2 Adolescent HIV care and treatment services

The World Health Organisation defines adolescence as the age range from 10 to 19 years. The term "young people" refers to individuals aged 10-24 years. Young people aged 15-24 years account for 63% of PLHIV in Sub-Saharan Africa. There are two groups of the HIV infected adolescent:

a) Long term survivors of perinatally acquired HIV (vertically acquired HIV infection)

b) Adolescents infected during childhood or adolescence (horizontally acquired HIV infection)

Adolescent HIV care and treatment package	
Component	**Services**
HIV Diagnosis	Confirmation/documentation of HIV infection
Initial clinic visits	1. Staging of HIV disease

	2. Ensure immunization is up to date and educate on appropriate vaccine schedules
	3.Treatment preparation (clinical and laboratory assessment and psychosocial counselling)
	4. Immediate ART initiation for those who are eligible

All visits	1. Growth and development assessment and monitoring(physical, emotional and cognitive)
	2. Prompt treatment of infections including opportunistic infections
	3. Cotrimoxazole Preventive Therapy (CPT)
	4. TB screening at all clinic visits
	5. Prevention of tuberculosis through Isoniazid Preventive therapy (IPT)
	6. Nutritional assessment, counselling and support
	7. Psychosocial assessment and counselling - disclosure, alcohol and substance abuse
	8. Health education includes : Developmental changes, Sexuality, Basic facts of HIV and AIDS, Primary and secondary abstinence and safer sex practices, hygiene and sanitation, malaria prevention
	9. Prevention with Positives (PWP)
	10. Sexual and reproductive health care: For pregnant adolescent(Refer to PMTCT package), STI screening and treatment, Family planning services, Cervical cancer screening
	11. Clinical and laboratory monitoring o Routine screening for OIs and their management o Routine screening and monitoring for adverse drug reactions o Routine CD4 , targeted viral load and resistant testing where necessary o Outcome and treatment response monitoring
	12. Providing comprehensive care for other family members o Family testing o Harmonizing appointments for families

	13. Planning for/providing long-term HIV care and follow up including community support
	14. Defaulter tracking systems: identification and tracking mechanisms
	15. Routine follow-ups for all on care through scheduled visits

2.1.3 Adult HIV care and treatment services

Adult HIV care and treatment package	
Component	**Services**
HIV Diagnosis	Confirmation/documentation of HIV infection

Initial clinic visits	1. Staging of HIV disease
	2. Treatment preparation (clinical & laboratory assessment and adherence counselling)
	3. Immediate ART initiation for those who are eligible

All visits	1. Cotrimoxazole Preventive Therapy (CPT)
	2. Prompt treatment of infections including opportunistic infections
	3. Screening and management of co-morbidities
	4. TB screening at all clinic visits
	5. Prevention of tuberculosis through Isoniazid preventive therapy (IPT)
	6. Nutritional assessment, counselling and support
	7. Psychosocial assessment and counselling - disclosure, alcohol and substance abuse
	8. Health education
	9. Prevention with Positives (PWP) (disclosure status, partner testing, Family planning, alcohol abuse assessment, condom use)
	10. Sexual and reproductive health care: PMTCT package for pregnant women, STI screening and treatment, Family planning services, cervical, breast and prostate cancer screening,

	11. Clinical and laboratory monitoring o Routine screening for OIs and their management o Routine screening and monitoring for adverse drug reactions o Routine CD4 , targeted viral load and resistant testing where necessary o Outcome and treatment response monitoring
	12. Providing comprehensive care for other family members o Family testing o Harmonizing appointments for families
	13. Planning for/providing long-term HIV care and follow up including community support
	14. Defaulter tracking systems: identification and tracking mechanisms
	15. Routine follow-ups for all on care through scheduled visits

Additional services for PMTCT

- Health talks to ANC mothers on Pregnancy, Nutrition, FP and birth plan, infant follow-up after delivery, infant feeding.
- Mother baby booklet at ANC for follow up
- Long Lasting Insecticide Treated Nets (malaria endemic zones)
- ARV prophylaxis or treatment as indicated
- Skilled and safe delivery, strengthening referrals from the existing community midwives where they exist.
- Newborn care- specialized care for sick and preterm infants

2.1.4 HIV Care and Treatment: Requirements for Client Service provision

Client Level services	Policy/ Guidelines	Infrastructure/ equipment	Commodities and information Support	M&E requirements

HIV Care & Treatment including pregnant women	Guidelines
	• HTC
	• Antiretroviral therapy and Care
	• Opportunistic infections management
	• TB/HIV
	• Pharmacovigilance
	• RH/STI guidelines
	• HTC, PMTCT, PWP
	• Decentralization
	• Mentorship
	• Nutrition and HIV
	• IYCF in HIV guidelines
	
	Job AIDS and SOPs
	• dosing charts, testing algorithms, nutrition charts, FP/RH, TB screening, WHO Staging charts, counseling
		• Running water,
		• Spacious well ventilated and lit room
		• BP machines, glucometers
		• Diagnostic set
		• Stethoscopes
		• Thermometers
		• Anthropometric equipment (Height measuring boards/meters, BMI wheel/chart, weight charts ,MUAC tapes and weighing scales)
		• Examination couches , speculums ,
			• ARVs available at facility
			• OI medicines
			• Nutrition commodities
			• BCP commodities
			• Demonstration models
			• FP commodities
			• Ca Cervix screening
			• STI medicines
			• INH
			• Condoms
			
			Tools
			• National data capture and reporting tools
			  ○ For ARVs and OIs
			  ○ Laboratory test kits
			  ○ Nutrition
				National Data collection and reporting tools (manual or electronic)
				• Patient CCC card (MOH 257)
				• HEI follow up cards and registers(MOH 408)
				• TB ICF cards
				• CCC Daily activity registers (MOH 366)
				• pre-ART and ART registers (MOH 361 A & B)
				• Cohort monitoring tools
				• ARVs dispensing - DAR/ADT (MOH 367 A&B) and reporting tools CDRR (MOH 730 A&B) MAPs(MOH 729 A&B)
				• Monthly reporting (MOH 711/731)
				• ANC, maternity , post natal registers (MOH 405)

	tools • Client education and literacy materials	examination lamps	supplies	• Adverse events reporting forms • Nutrition registers and monthly summary sheets
Lab evaluation and support (HIV testing , CD4, Viral load, chemistry, hematology)	• National Treatment guidelines • National testing guidelines • Job AIDS and SOPs , • SOPs on equipment maintenance	• Running water spacious well ventilated and lit room • Functional laboratory equipments(Micro scopes, CD4 machines, Hematology and biochemistry analyzers, autoclave, fridges, machines) • Lab networks for sites without equipment	• Appropriate vaccutainer tubes and lab supplies • HIV test kits and consumables • Lab Reagents for CD4, blood chemistries and hematology investigations • Consumables such as gloves etc	• Appropriate and standard laboratory requisition and report forms available • Logistic tools (data collection and reporting tools) manual or electronic
EID	• EID testing algorithm • EID SOPs and JOB AIDs • HEI package of Care	• Functional Sample /results transportation networks	• Filter paper and DBS consumables(desiccant, glycine envelopes, lancets, capillary tubes	• EID lab requisition form • HEI register • Facility laboratory register (for sites using lab as collection or

			humidity indicators and swabs), • Rapid Antibody test kits	dispatch point)

2.2 SYSTEMS SUPPORT

Support Area	MOH Support – National	MOH Support- Regional	Partner Support
Policy/guidelines	• Develop and review guidelines • Develop and review training materials develop and review job aids and SOPs • Monitoring of guidelines implementation • Disseminate guidelines to regional levels • Ensure availability of guidelines	• Disseminate guidelines to facilities • On job training and mentorship of health care workers- Coordination of all activities in the program at regional level • Monitoring of guidelines implementation • Ensure availability of guidelines	• Support dissemination of guidelines, job aids , SOPs • On job training and mentorship of health care workers • Ensure availability of guidelines
Infrastructure/equipment	• Define infrastructure requirements and standards (equipments, furniture, buildings, space) • Support procurement of equipment and setting up of infrastructure • Mapping , Identify gaps and	• Mapping , Identify gaps and needs • Support rational allocation of resources at regional level • Mobilize resources • Maintain infrastructure and equipment	• Support procurement of equipment and setting up of infrastructure • Participate in mapping , Identify gaps and needs • Support maintenance of infrastructure and equipment • Support establishment and

	needs • Mobilize resources • Maintain infrastructure and equipment	• Establishment and management of efficient and functional networks for lab services and commodities	management of efficient and functional networks for lab services and commodities
Commodities Support	• National forecasting and quantification, and supply for ARVs and lab, nutrition commodities Product selection , procurement , warehousing and distribution • Commodity stocks monitoring • Ensure adequate national stock levels • Quality control and assurance(external and internal) • Set up logistics management systems (tools, commodity and information flow, databases)	• Regional/district/county forecasting and Quantification, and for ARVs and lab, nutrition commodities • Support distribution /re-distribution of commodities • Set up of adequate storage facilities of commodities for decentralized sites • Support Logistics information systems (dissemination of tools , OJTs, promote data use for decision making) • Consolidation of commodity requirements for district /county , placement of orders to national level supply chains (e.g. central site to satellites) • Mentorship on supply chain • Supportive supervision • Monitoring of short dated stocks and	• Support distribution and redistribution of commodities • Support Logistics information systems (dissemination of tools , OJTs, promote data use for decision making) • Promote rational drug use • Support mentorship , OJT for commodity management • Support computerizing of data collection and reporting at site level and maintenance of data electronic systems • Ensure logistics data quality at facility level • Participate in joint supportive supervision • Ensure facilities have adequate stocks (min-max) and no stock outs

		re-distribution • Facilitate disposal of damaged and expired commodities • Promote rational drug use • Ensure facilities have adequate stocks (min-max) and no stock outs • Support computerizing of data collection and reporting at site level and maintenance of data electronic systems • Ensure logistics data quality at facility level	•

M&E Support	• Develop and design standard data capture and reporting tools for use at facility , district, provincial and national levels (both manual and electronic) • Monitor utilization of standard national tools • Develop and implement national surveillance and evaluation agenda • Set National targets for all program areas • Develop denominators at national and regional level to monitor program implementation • Provide guidance on the roll out and use of electronic medical records for HIV management • Custodian of national data • Collate , compile national data , generate reports and feedback to various levels	• Mentorship of MOH staff on available M&E structures • Disseminate , distribute data capture and reporting tools to facilities • Improve data capture and reporting and communication from various service delivery points/units within facilities • Ensure data uniformity between service statistics and logistics data (e.g. ART Patient numbers reported from pharmacy and CCC) • Conduct routine data quality checks , mentorship on use of tools • Ensure use of data for decision making • Collate , compile regional data , generate reports and feedback to various levels and stakeholders • Develop joint plans (MOH and partners) • Performance monitoring of work plans for regions and stakeholders • Promote use of national standard tools	• Participate in Joint AOP planning at the facility, district and provincial levels • Support use of MOH tools and registers • support dissemination , distribution of MOH data capture and reporting tools to facilities • Support Performance monitoring of work plans as well report on performance • Support data review meetings at the district and province/county levels • Support DHMT and PHMT to conduct DQAs, mentorship on use of standard tools • Support lower levels to collect and report data on service delivery • Support quality measurement and improvement by using data • Support the implementation of electronic medical records in all facilities that meet the set criteria • Ensure use of data for decision

	and stakeholders • Conduct periodic/regular data audits • Integrate and linkage M and E systems (HIS , LMIS) • Develop joint plans (MOH and partners) • Performance monitoring of work plans for , national level, regional and stakeholders		making • Support compilation of reports at site and regional level • Promote use of national standard tools

Other Cross cutting Program support Areas

Support Area	MOH Support – National	MOH Support- Regional	Partner Support
Referral and Linkages	• Give guidance on referral	Defines referral systems	Support strengthen referral systems (downward, upwards)
Decentralization of HIV Care and Treatment	• Provide guidelines on decentralization • Disseminate decentralization guidelines	• Plan and implement rational decentralization of quality services (this should include mapping and identification of sites for scale up) as per national guidelines • Conduct periodic needs assessment for continued scale up of service points • Support commodity and information flow for decentralized levels • Ensure delivery of quality services at decentralized levels through mentorship and on job training • Update national level on a regular basis on scale up of service delivery points	• Support planning and implementation of decentralization of quality services • Support commodity and information flow for decentralized levels • Ensure delivery of quality services at decentralized levels through mentorship and on job training

Capacity Building (Training and mentorship)	• Provide Guidelines, Training materials and curricula
	• Dissemination of guidelines
	• Training of Trainers
	• Mentoring of mentors
	• Establish and Maintain national training database
		• JOINT planning for training and mentorship programs (MOH and partners)
		• Coordinate regional training
		  ○ Having training plans
		  ○ Training needs identification
		  ○ Rationalize number of trainings
		  ○ Ensure selection of appropriate trainees
		• Plan and implement routine mentorship programs at decentralized levels
		• Identify appropriate mentors and approach for various areas or disciplines
		• Monitor the progress of trainings and mentorship activities (MOH and partners) against work plans
		• Establish and Maintain regional training database
		• Compile reports on trainings and mentorship and progress
		• Monitor impact and quality improvement as a result of trainings and mentorship (MOH and partners)
			• JOINT planning for training and mentorship programs (MOH and partners)
			• Provide technical, financial support for trainings and mentorship
			  ○ Provide financial support for mentorship visits by regional teams
			  ○ Provide technical experts to conduct **JOINT** MOH-Partner mentorship visits to sites
			• Monitor the progress of trainings and mentorship activities (MOH and partners) against work plans
			• Monitor impact and quality improvement as a result of trainings and mentorship (MOH and partners)

Supportive	• Develop checklists and	• Constitute multidisciplinary teams and	• Constitute multidisciplinary

Supervision	reporting tools • Constitute multidisciplinary teams and Jointly Supervise regions and partners • Facilitate MOH regional supportive supervision • Compile reports and provide feedback to relevant persons and institutions	Jointly Supervise decentralized levels and facilities (MOH and partners) • Ensure supervision of all relevant HIV programmatic areas (e.g. clinical , commodity, lab, nutrition etc) • Develop and implement action plans following supervision • Compile reports and provide feedback to relevant persons and institutions	teams and Jointly Supervise decentralized levels and facilities (MOH and partners) • Provide financial support for supervision • Develop and implement action plans • Compile reports and provide feedback to relevant persons and institutions

Integration	• Provide guidance on integration of services at facility
	  • MCH and child and maternal HIV care
	  • TB/HIV
	  • RH/HIV
	  • Lab services
	• Identify various appropriate models for integration
		• Jointly plan and implement recommended integration models(MOH and Partners)
		• Provide technical support required for implementation
		• Monitor integration of services
			• Jointly plan and implement recommended integration models(MOH and Partners)
			• Provide technical and financial support required for implementation
			• Monitor integration of services

	• Monitor integration of services		
Human resource	• Define competencies (knowledge, skills and attitudes)required for HIV management • Dissemination of updates	• Rational deployment of staff • Regularly update the HR database as per defined competencies Capacity build newly deployed staff • Dissemination and implementation of updates	• Supplement technical staff • Support capacity building newly deployed staff • Dissemination and implementation of updates
Quality of Care	• Define the key quality of care indicators e.g. o Continuum of care o Retention rates o Dose adjustments o Return of results o Regimen switch • Monitor implementation of quality improvement programs i.e. HIV DR EWI, HIV QUAL, Pharma-covigilance, QA/QI(Nutrition, Lab)	• Jointly monitor longitudinal monitoring and outcomes at facility level(MOH and Partners) • Capacity Build Facilities on use of data for decision making e.g. defaulter rates, ADR monitoring, appointment keeping, delayed initiation of treatment, failure to adjust doses • Support and implement Quality Improvement interventions (i.e. HIV DR EWI, HIV QUAL, Pharma-covigilance, QA/QI (Nutrition, Lab) • Monitor implementation of quality improvement programs	• Jointly monitor longitudinal monitoring and outcomes at facility level Use of data for decision making • Capacity build facilities on use of data for decision making e.g. defaulter rates, ADR monitoring, appointment keeping, delayed initiation of treatment, failure to adjust doses • Support and implement Quality Improvement interventions i.e. HIV DR EWI, HIV QUAL, Pharma-

			covigilance, QA/QI, (Nutrition ,Lab) • Monitor implementation of quality improvement programs

REPUBLIC OF KENYA

IN THE HIGH COURT OF KENYA AT KISUMU

CONSTITUTIONAL AND HUMAN RIGHTS DIVISION

PETITION NO OF 2023

IN THE MATTER OF ARTICLES 1, 2, 3, 10, 19, 20(1) & (4), 21, 22, 23, 24, 26(1), 27, 28, 29, 35, 43(1)(a), 47, 53 (1)(c), 165, 232(1), 258 AND 259 OF THE CONSTITUTION OF KENYA, 2010

AND

IN THE MATTER OF SECTIONS 4 (b), (c), (d), (e), (f), (h), (i), (l) (n) AND (m), 14 (f), 20, 24,32, AND 33 (2) AND (5) OF THE EAST AFRICAN COMMUNITY HIV AND AIDS PREVENTION AND MANAGEMENT ACT, 2012

AND

IN THE MATTER OF SECTIONS 4, (c) (d) 5, 8(c) (d) 14, 15 OF THE HEALTH ACT, 2017

AND

IN THE MATTER OF SECTION 19 OF THE HIV PREVENTION AND CONTROL ACT

AND

IN THE MATTER OF SECTIONS 4, 5, 6, 8, 9, 16AND 38(g) OF THE CHILDREN ACT, 2022

BETWEEN

FA.....1ST PETITIONER

(Suing on her own behalf and as mother and next friend of Baby DM (A minor)

BK.....2ND PETITIONER

CN.....3RD PETITIONER

PATRICIA ASERO OCHIENG.....4TH PETITIONER
AMBASSADOR FOR YOUTH AND ADOLESCENTS
REPRODUCTIVE HEALTH PROGRAM (AYARHEP).....5TH PETITIONER
KENYA LEGAL AND ETHICAL
ISSUES NETWORK ON HIV/AIDS (KELIN).....6TH PETITIONER
KATIBA INSTITUTE.....7TH PETITIONER

VERSUS

THE HON. ATTORNEY GENERAL.....1ST RESPONDENT
CABINET SECRETARY FOR HEALTH.....2nd RESPONDENT
KENYA MEDICAL SUPPLIES AUTHORITY.....3RD RESPONDENT

PETITION

A. INTRODUCTION

1. This humble Petition is filed by the 1st - 6th Petitioners, whose address of service is Nyokabi Njogu and Kenneth Otieno Advocates, C/O KELIN, Kuwinda Lane, off Lang'ata Road, Karen C, P.O. Box 112-00202, Nairobi; and the 7th Petitioner, whose address of service is Emily Kinama, Advocate, C/O Katiba Institute, 5 The Crescent, Off Parklands Road, Westlands, P.O. Box 26586-00100, Nairobi.

B. THE PARTIES

2. The 1st Petitioner, FA, is a Kenyan woman living and working for gain in Kisumu County within the Republic of Kenya. She is a person living with HIV and takes ARV medication as prescribed. She sues in her name, as well as on behalf of her son, DM, a minor child aged 7 years old, who also lives with HIV.

3. The 2nd Petitioner, BK, is a Kenyan woman working in a health facility in Nakuru county. She is a person living with HIV and is a mother to a young child. She works within Nakuru County as a mentor mother who offers adherence counselling as well as guidance and health talks to HIV positive mothers.

4. The 3rd Petitioner, CN, is a Kenyan woman working in a public health facility in Nakuru County as a HIV testing services provider. She is a person living with HIV and takes her ARV medication as prescribed.

5. The 4th Petitioner, Patricia Asero Ochieng is a woman who is living with HIV. She is the Coordinator of Dandora Community AIDS Support Association (DACASA) Kenya, the current Chair of the International Community of Women living with HIV East Africa. She was a fellow of the International Treatment Preparedness Coalition and has more than 20 years of experience and knowledge on HIV issues surrounding treatment and access to care. She is a staunch advocate of the right of persons living with HIV to access quality treatment and service.

6. The 5th Petitioner, Ambassador for Youth and Adolescents Reproductive Health Program (AYARHEP) is an adolescent and youth reproductive health rights organization whose main purpose is to mitigate the impact of HIV and AIDS, promote healthcare, reproductive health and human rights.

7. The 6th Petitioner, Kenya Legal and Ethical Issues Network on HIV and AIDS (KELIN), is a non-partisan, non-profit and non-governmental organisation duly registered under the Non-Governmental Organisations Act, working to protect and promote health-related human rights in Kenya

8. The 7th Petitioner, Katiba Institute, is a constitutional research, policy and litigation institute established to promote the Constitution of Kenya, 2010 and to develop a culture of constitutionalism in Kenya.

9. The 1st Respondent is the Principal Legal Adviser to the Government and the person authorized by Article 156(4)(b) of the Constitution of Kenya to represent the National Government in proceedings to which it is a party and named in that capacity.

10. The 2nd Respondent is the Cabinet Secretary in charge of the Ministry of Health who has various responsibilities in the management, prevention and control of HIV in Kenya.

11. The 3rd Respondent is the Kenya Medical Supply Authority, a state corporation under the Ministry of Health established under the Kenya Medical Supplies Authority Act, 2013 whose role includes the procurement and distribution of drugs and medical supplies for public health programs.

C. THE FACTS

HIV Prevalence in Kenya

12. Kenya has the fifth-largest number of persons living with HIV(PLHIV) in the world, and HIV continues to be a leading cause of adult morbidity and mortality.[1]

13. By the end of 2021, it was estimated by the National Syndemic Diseases Control Council (NSDCC) that there were 1,122,334 Kenyans were living with HIV.[2] In 2021, the number of new HIV infections increased by 7.3%.[3] Women and girls are

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[1] National AIDS and STI Control Programme (NASCOP), *Preliminary KENPHIA 2018 Report* (NASCOP, 2020), p.1. Available at https://phia.icap.columbia.edu/wp-content/uploads/2020/04/KENPHIA-2018_Preliminary-Report_final-web.pdf

[2] National Syndemic Diseases Control Council, *It's a Race against Time World Aids Day Report 2022* (NSDC, 2022), P. 3. Available at https://nsdcc.go.ke/wp-content/uploads/2022/12/WAD-Report_F4-1.pdf

[3] *See* PEPFAR, *Kenya: Country Operational Plan 2022 Strategic Direction Summary* (2022), p. 11. Available at https://www.state.gov/wp-content/uploads/2022/09/Kenya-COP22-SDS-.pdf

disproportionately affected by HIV.[4] Of these new infections, it is estimated that at least 70% of the infections occurred among women and girls, with 8 out of every 10 new infections occurring among adolescent girls and young women aged 15-24 years.[5]

14. Despite the fact that there are a number of children who continue to be infected with HIV, the 2nd Respondent notes that there are significant gaps in treatment and management of HIV among children and young people. At least 32% or some 34,337 children living with HIV were not on anti-retroviral treatment (ART) treatment by the end of 2019. The 2nd Respondent further notes that among those on treatment, only 51% were virally suppressed leaving at least half of children prone to HIV related co-morbidities and ill health.[6] These figures are mirrored by NSDCC 2022 Report which states that as of 2021, the country lost 4,098 children and adolescents below 18 to AIDS related deaths, attributed to low diagnosis and treatment coverage.[7]

15. The NSDCC has also noted that while the number of people living with HIV has increased, there has been a decrease in resources for the procurement of commodities. As a result of these gaps in the provision of anti-retroviral treatment or therapy, positive health outcomes for at least 68% of persons living with HIV (PLHIV) remain elusive. In addition, the 2nd Respondent notes that there are a number of people who are not aware of their HIV status.[8]

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[4] ibid, at p.11 (Noting that "females are disproportionately affected, with a prevalence more than double that of men, at 5.4% versus 2.6%, respectively, for ages 15-49. Forty-two percent of adult new infections are found among the age band 15-24 years, with AGYW aged 15-24 years contributing 47% of all new infections among women aged 15 years+, reinforcing the need to actively prevent new infections by strengthening programs which decrease AGYW vulnerability." *See also* Joint United Nations Programme on HIV/AIDS, *UNAIDS Data 2022*, (Geneva, 2022), p. 28. Available at https://www.unaids.org/sites/default/files/media_asset/data-book-2022_en.pdf

[5] National Syndemic Diseases Control Council, *It's a Race against Time World Aids Day Report 2022* (n 2 above).

[6] The Second Kenya AIDS Strategic Framework 2020/21-2024/25 p. 10 available at https://nacc.or.ke/wp-content/uploads/2021/01/KASFII_Web22.pdf

[7] National Syndemic Diseases Control Council *It's a Race against Time World Aids Day Report 2022* (n 2 above)., at p. 8.

[8] Ibid p.13

16. The 2nd Respondent has committed to the provision of antiretroviral treatment and noted that the success of ART programmes among children aged between 0-14yrs is largely dependent on early diagnosis and prompt ART initiation.[9]

17. Despite knowledge that success of ART treatment success being dependent on early diagnosis, the National Government through the Ministry of Finance and the National Treasury as well as the 2nd Respondent failed to establish mechanisms to avail the treatment and management commodities and admitted on various occasions that treatment for HIV in the form of ARVs is not funded through resources from the republic of Kenya. The 2nd Respondent has also admitted at least 75% of all interventions and programmes on HIV are funded by external donors. As of 2021, Kenya's response to the HIV epidemic was predominantly reliant on external (non-State) funding, constituting 76.3% of the total funding to HIV responses. These external funding included funding by international donors, households, and corporations, whereas the Government's contribution amounted to a mere 23.6%.[10]

Stockouts on ARVs and commodities used in the management of HIV

18. Since January 2021, PLHIV in Kenya have experienced delays in accessing lifesaving HIV medicines and other treatment in public health facilities.

19. The interruptions in the supply of essential antiretroviral drugs were said to have been caused by a stalemate between the Respondents on one hand, and the United States Agency for International Development (USAID) on the other hand, which saw donations of ARVS as well as essential commodities required for the detection of HIV stuck at the Port of Mombasa for several weeks.

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[9] Ibid p. 12.

[10] *See* Health Policy Plus, *Trends in Public Sector Investments in HIV in Kenya* (October 2022), Available at https://pdf.usaid.gov/pdf_docs/PA00ZRZV.pdf; PEPFAR, *Kenya Country Operational Plan 2022: Strategic Direction Summary*, Available at https://www.state.gov/wp-content/uploads/2022/09/Kenya-COP22-SDS-.pdf.

20. From the reports made public in national media, it is apparent that:

    a. The 2nd Respondent relies solely on donations to meet its obligations in terms of access to essential medicines and treatments for PLHIV.

    b. The main donors include international aid agencies such as USAID and are distributed by the 3rd Respondent on behalf of the 2nd Respondent.

    c. There have been numerous instances of corruption and mismanagement at the 3rd Respondent, all of which have gone unaddressed by the 1st and 2nd Respondents, which has led mistrust by international agencies in relation to distribution of their donations.

    d. This mistrust has led to international aid agencies opting to use their own distribution channels to distribute essential stocks of ARVs and commodities.

21. Due to the delay in resolving this standoff, public health facilities in various counties, among them Kisumu, Nakuru, Makueni, Machakos and Nairobi experienced severe stock outs of essential drugs as well as commodities for the treatment of HIV. In particular, the stock outs experienced were in relation to:

    a. Kaletra LPV/r Syrup used to manage HIV in children, and which has been out of stock with most children being given the pellets instead.

    b. Kaletra LPV/r Pellets which have been out stock with children having to be dispensed with crushed LPV/r 100/25mg tablets as a substitute.

    c. Paediatric Kaletra in syrup form, an ARV that is used for the management and treatment of HIV infection in children which since January 2021 is completely unavailable.

d. Viral Load reagents and technologies that are used to carry out sample collection. It was therefore impossible to carry out viral load testing for persons living with HIV.

e. Supply of early infant diagnosis sample collection kits has been low with total shortage starting in June 2021. All the counties were therefore unable to carry out early infant diagnosis testing.

f. Essential HIV treatment drugs called Tenofovir, Lamivudine and Dolutegravir (TLD) and Kaletra Syrup for children have since January 2021 been unavailable in most parts of the country, and especially in Kisumu County where the 1st Petitioner resides.

g. A lack of Nevirapine and Septrin syrup which is used as a prophylactic medication for children who are breastfed by mothers living with HIV.

h. Testing kits and cartridges used to detect the presence and strain of tuberculosis in patients.

22. In the few public health facilities where the drugs were available, they could only be dispensed in small quantities, with PLHIV forced to take enough for only two weeks while prior to the stalemate, essential drugs were dispensed with a patient given enough for three to six months, and only those patients who required closer follow ups were required to visit health care facilities for follow up.

23. In 2021, the 2nd Respondent then indicated that PLHIV could access drugs distributed by the Universal Corporation. However, these drugs were discoloured and the 2nd Respondent eventually, in November 2022, directed that they be returned to the health facilities as they were contaminated.

24. At the time of the recall of the drugs, many PLHIV had already consumed the drugs.

25. While the toll on the health of individual PLHIV is unknown, this has resulted in interrupted treatment of PLHIV, as seen in the case of the 1st Petitioner's son, as well as irregular courses of treatment that caused them to fall ill and has reversed their progress made in suppressing HIV replication.

26. These interruptions to provision of ARVs goes contrary to the patient centred approach which is outlined in the Differentiated Service Delivery (DSD) model published by the 2nd Respondent. This approach is meant to simplify access to treatment for PLHIV by reducing unnecessary visits to healthcare facilities and improve adherence to treatment.

Access to Essential Medicines for 1st Petitioner and Baby DM

27. The 1st Petitioner FA is a Kenyan woman living with HIV. She has a minor son, DM aged 7 years, who is also living with HIV. They are both on ARV therapy. DM has been taking Septrin, Nevirapine and Paediatric Kaletra in syrup form since July 2018.

28. In February 2021, FA went to pick up medication for DM from Liverpool Voluntary Counselling and Testing Tivoli Health Centre where she and DM attend follow up and care. However medical personnel at the facility informed her that there was no Kaletra syrup available, and they gave her Kaletra tablets for DM instead.

29. The Kaletra tablets are big in size, and the child was unable to swallow them. She was advised by medical personnel to crush the tablets and dissolve them in water, which she then forced DM to drink.

30. Even after crushing the drugs and dissolving them in water, DM was still unable to keep the drugs down as they are very bitter. He would therefore vomit anytime he would take his medicine in this form.

31. FA was thereafter asked by the medical personnel to put the medication in pellet form in DM's food. This had the effect of making the food very bitter and he was unable to eat.

32. DM was therefore unable to keep any food or drink down as long as it has been mixed with the Kaletra tablets or pellets. This meant that between February 2021 and August 2022, he was not on consistent treatment or nutrition.

33. In any case, according to the Ministry of Health Guidelines,[11] Kaletra tablets ought to be swallowed whole and are ineffective if administered otherwise.

34. As a result of the inconsistent medication and nutrition, DM was getting very ill with swellings on his neck, infections in his ears and suffering from severe weakness.

35. DM continues to suffer from ill health to date and continues to exhibit symptoms that he developed in the period that he was on inconsistent medication.

Unavailability of Early Infant Diagnostic testing, Viral Load Testing and Prophylaxis treatment for the 2nd and 3rd Petitioners and their infant children

36. The 2nd Petitioner is a woman living with HIV who gave birth to her second child in July 2020. Until December 2021, she had not had any viral load testing since before she gave birth, yet she had been breastfeeding her child until November 2021.

37. The 2nd Petitioners infant child was put on prophylaxis treatment from six weeks as a measure to prevent parent to child transmission.

38. The Septrin medication that the 2nd Petitioners' child had been on has previously been provided by the government free of charge. However, after the stock out of ARVs and

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11 Guidelines for antiretroviral therapy in Kenya 4th Edition 2011 http://guidelines.health.go.ke:8000/media/Final_guidelines_re_print_11-09-2012.pdf

other commodities, she was forced to purchase the medication for herself in the private sector; this has not always been possible because sometimes it is not available.

39. She has been unable to keep up with the intermittent supply of the drugs. It was also very expensive to purchase the drug for herself.

40. Moreover, she had been unable to access viral load testing for herself and remained unaware if her ARV regimen was effective and if it was safe to continue breastfeeding.

41. All her efforts to determine the HIV status of her child by having the infant undergo diagnostic testing in the period that she was breastfeeding were not fruitful, and she remained in fear that she had transmitted the virus to her child through breastfeeding.

42. She therefore decided to stop breastfeeding her child at the age of one year despite the fact that she is aware that for the health and development of the child it is best to breastfeed until the age of two years.[12]

43. The 3rd Petitioner gave birth to twin boys in 2021, just as the shortage of anti-retroviral medication and commodities for testing had begun to emerge. This shortage included a stockout of filter papers used for sample collection for infants. During the course of her pregnancy, she never underwent viral load testing as part of her antenatal care because of the lack of testing kits.

44. After her children were born in 2021, they did not undergo early infant diagnostic testing because of the lack of testing kits. They only underwent testing when they were four months old, and these results took an inordinately long time to be released because there were no reagents to perform the tests.

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[12] Ministry of Health National Policy Maternal, Infant and Young Child Nutrition available at http://www.nutritionhealth.or.ke/wp-content/uploads/Downloads/MIYCN%20Policy%20Summary%20Statement%20-%20March%202019.pdf

Interrupted supply of essential medication and commodities to adolescents and young mothers and their infant children

45. For over a year, between February 2021 and August 2022, persons living with HIV could not reliably or consistently access life and health saving medication.

46. Those who could get access to medication were not given the full dose of medication and were given medication in inappropriate containers such as brown paper bags.

47. In addition, there continues to be reports of unavailability of early infant diagnostic testing, as well as commodities such as condoms in various parts of the country.

D. PARTICULARS OF CONSTITUTIONAL VIOLATIONS

Violation of the Right to Health as enshrined under Article 43(1)(a) and 53 (1)(c) of the Constitution, as read together with the Health Act, the Children Act and the East African Community HIV and AIDS Prevention and Control Act

48. Every person has the right to the highest attainable standard of health care. This is an immediate right for children guaranteed under Article 53(1)(c).

49. As at August 2021, many health facilities around the country did not have adequate supplies of ARVs that PLHIV can access. This was a violation of Article 43(1)(a) and 53(1)(c) of the Constitution of Kenya, 2010.

50. The 2nd Respondent has no implementation plan to procure and distribute ARVs, which saw a lack of supply of essential medication used for the treatment and management of children. In particular:

a. There was a lack of paediatric Kaletra which meant that children living with HIV, like DM, had to use make use of Kaletra tablets which they are not able to swallow.

b. As the children are unable to swallow the Kaletra tablets, their mothers were forced to crush the tablets and mix with food contrary to the Ministry of Health guidelines and which form renders the medicine ineffective.

c. Within health facilities, there are concerns of resistance occurring due to low absorption of the therapies.

d. Where children such as DM are given the medication dissolved in water or mixed in with food, they were unable to keep the food down which deprived them of adequate nutrition in addition to depriving them of life saving medication.

e. The lack of ARVs and other essential medication has resulted in severe illness in DM whose immunity has become very low and who continues to suffer from illnesses and various opportunistic infections.

f. The suffering of DM has greatly affected the mental health of 1st Petitioner who was helpless and without options to procure treatment for her son.

51. The 2nd Respondent failed to procure and distribute ARVs and laboratory commodities for the testing and management of HIV. This meant that early infant detection and viral load testing which are integral to the management of HIV stopped altogether. In addition, viral load sample collection was halted in all counties due to shortages of sample collection tubes.

52. The lack of early infant diagnostic testing and viral load testing meant that the 2nd and 3rd petitioners, as well as other breastfeeding mothers were not able to ascertain their health status or that of their children.

53. Due to a lack of prophylaxis for children who are breastfeeding, the 2nd and 3rd Petitioners were forced to stop breastfeeding their children early, exposing them to reduced immunity and an increase in childhood ailments. It was also an additional hardship where they would be forced to procure alternative forms of nutrition including formula milk and clean water for preparation.

54. The reduced availability of ARVs and essential commodities have meant that persons living with HIV have been forced to share the available medicines, with it given in brown paper bags or ziplock bags. The removal of ARVs from their appropriate packaging reduces their effectiveness.

55. The lack of ARVs and laboratory commodities that are used for the treatment and management of HIV has been detrimental to the mental and physical health of adolescents and young people, and to other persons living with HIV.

56. By failing to ensure provision of ARVs, care and support to PLHIV, the 2nd and 3rd Respondents have failed in their mandate to respect, protect, promote and fulfil the right to the right to the highest attainable standard of health per Section 4 of the Health Act.

57. The 2nd and 3rd Respondents failed to give information to communities of PLHIV on their enquiries into the plans and safeguards in place to ensure continuous and uninterrupted access to ARVs and laboratory commodities contrary to Section 10 of the Health Act.

58. In furtherance to a child's immediate right to health services under Article 43 of the Constitution and as also spelt out at Section 16 of the Children Act, the 2nd and 3rd

Respondents have failed in their duty to ensure the survival and development of children living with HIV with the interests of the children as the primary consideration.

Violation of the East African Community HIV and AIDS Prevention and Management Act, 2012 and the HIV Prevention and Control Act

59. The 2nd Respondent is responsible for preventing and controlling HIV transmission and promoting and protecting the rights of PLHIV.

60. The 2nd Respondent has failed to facilitate and promote access to essential medicine, strengthen institutions working with PLHIV or affected by HIV and make budgetary provisions and/or avail adequate funding for HIV and AIDS programmes and provide care and support to PLHIV in violation of Section 4 of the Act.

61. Additionally, the 2nd Respondent failed to provide the requisite resources, including test kits and reagents necessary to facilitate prevention of mother-to -child transmission of HIV.

62. The 2nd and 3rd Respondents have also not made available health commodities for HIV testing and especially to persons who are required to undergo HIV testing which failure runs afoul Section 20 of the Act.

63. The Respondents' failure to undertake their mandatory obligations has led to PLHIV not getting access to quality healthcare services and specifically in the failure to provide sustainable treatment, care and support to PLHIV including access to affordable anti-retroviral therapy and other medicine as prescribed under Section 32 of the Act.

Violations of the Right to Life

64. Article 26 of the Constitution guarantees the right to life.

65. PLHIV rely on essential ARVs for their survival and wellbeing. By failing to provide essential drugs and commodities to treat and manage HIV, the Respondents have threatened the right to life for PLHIV.

66. The life of DM is at risk should he not receive appropriate paediatric ARVs to preserve his health.

67. Through their inaction, the Respondents endangered the lives of FA, DM and other PLHIV by failing to provide with life saving information on where they can obtain clinically appropriate anti-retroviral therapy or management of HIV.

68. The quality of life for DM has been severely affected as he continues to suffer from illnesses that he contracted in the period when he could not access life saving medication.

69. Despite that many children and PLHIV require immediate treatment through life saving medication, the respondents have not indicated how they intend to address the lack of commodities required for treatment and management of HIV to ensure that stockouts as previously witnessed do not occur again.

Violation of the Right to Access Information

70. Communities of persons living with HIV, among them the Petitioners, wrote to the 2nd and 3rd Respondents seeking a resolution of the situation and a means to chart a plan that would ensure continuous and uninterrupted access of ARVs and laboratory commodities. These letters have gone unanswered, denying these communities information on life saving health related information as well as an opportunity to participate in the resolution of a dispute that would see them access lifesaving treatment.

71. The Respondents continually refused to proactively provide information to PLHIV as to the public health facilities where they can access either essential medicines or attend for the purpose of management.

Violation of the Right to equal protection, equal benefit of the law and the freedom from non-discrimination

72. The 1st Petitioner is a woman living with HIV and has limited means. The 2nd Respondent has a positive obligation to ensure that vulnerable people, such as the 1st Petitioner and DM, access lifesaving treatment for themselves and their dependents. The failure of the 2nd Respondent to meet its positive obligation is a violation of her right to protection of the law.

73. The 2nd and 3rd Petitioners were forced to withdraw from breastfeeding of their children because of an economic inability to provide medication to their infant children. The 5th Petitioner also had reports of PLHIV who were forced to make repeated trips to health care facilities and where this was not possible were forced to forego treatment. This constitutes a violation of the right to access essential medication based on vulnerability and lack of economic ability which also constitutes a form of discrimination.

74. The 6th and 7th Petitioners have noted concerns around the disproportionate effect the lack of essential medicines, particularly those who cannot pay for these essential medicines or procure them from private health facilities suffer. This is discrimination based on economic status.

Violation of the Right of the right to human dignity

75. Article 28 guarantees human dignity and the right to have dignity respected and protected.

76. The failures by the government to provide essential medicines and life saving essential commodities to vulnerable people, such as the Petitioners, have led to the violation of the right to dignity, and the right of PLHIV to access treatment in a manner that is free from cruel, inhuman and degrading treatment, which are inextricably linked to the right to life and health.

E. PRAYERS FOR RELIEF

77. Based on the Constitutional and statutory violations suffered, your Humble Petitioners pray for the following reliefs:

a. A declaration that the right to nutrition and health care for children living with HIV is immediate and not progressive under Article 53 of the Constitution

b. A declaration that the failure of the 2nd Respondent to make provision for the continuous and uninterrupted supply of ARVs and commodities for the management of HIV in health facilities is a violation of Articles 26, 27, 28, 43(1)(a),43(2), 53 and 232 of the Constitution of Kenya

c. A declaration that the Respondent's failure to proactively provide information to the public, and the Petitioners on the availability of essential ARVs is a violation of Article 35 of the Constitution and the right to health as guaranteed under Article 43(1)(a) of the Constitution.

d. An order that the 2nd respondent pays general damages to the 1st petitioner and her son, the 2nd and 3rd Petitioners for the physical,

psychological and mental distress suffered as a result of the violations of their constitutional rights.

e. A declaration that the 2nd Respondent has a constitutional obligation to ensure the accessibility, availability, acceptability and quality health services to PLHIV.

f. An order of mandamus compelling the 2nd and 3rd Respondents to publish and publicise within 30 days of this order, information, broken down by county, on:

i) The measures to be taken by the government to ensure that antiretroviral medication and essential commodities for the detection, testing and management of HIV are available for use for all persons who require and may require such medication and commodities.

ii) The availability of ARVs and viral load testing and availability of commodities for the treatment and/or management of HIV for persons living with HIV in all public health facilities in the country.

g. An order requiring the 2nd Respondent to make public the reforms undertaken at the 3rd Respondent agency and its suitability to receive and distribute essential medicines.

h. The 2nd Respondent do, within 45 days of this judgment, and working together with the 4th, 5th ,6th and 7th Petitioners, as well as communities of persons living with HIV, as well as state

i. That the Respondents, within thirty days from the date of the order, and every thirty days thereafter, file affidavits with the Court detailing their progress in compliance with these orders.

j. Costs of this Petition

k. Any other just and expedient order the Court may deem fit to make.

DATED at KISUMU this 21st **day of** September **2023**

NYOKABI NJOGU AND KENNETH OTIENO

ADVOCATE FOR THE 1ST – 6TH PETITIONERS

Kinama

EMILY KINAMA

ADVOCATE FOR THE 7TH PETITIONER

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REPUBLIC OF KENYA

IN THE HIGH COURT OF KENYA AT KISUMU

CONSTITUTIONAL AND HUMAN RIGHTS DIVISION

PETITION NO OF 2023

IN THE MATTER OF ARTICLES 1, 2, 3, 10, 19, 20(1) & (4), 21, 22, 23, 24, 26(1), 27, 28, 29, 35, 43(1)(a), 47, 53 (1)(c), 165, 232(1), 258 AND 259 OF THE CONSTITUTION OF KENYA, 2010

AND

IN THE MATTER OF SECTIONS 4 (b), (c), (d), (e), (f), (h), (i), (l) (n) AND (m), 14 (f), 20, 24,32, AND 33 (2) AND (5) OF THE EAST AFRICAN COMMUNITY HIV AND AIDS PREVENTION AND MANAGEMENT ACT, 2012

AND

IN THE MATTER OF SECTIONS 4, (c) (d) 5, 8(c) (d) 14, 15 OF THE HEALTH ACT, 2017

AND

IN THE MATTER OF SECTION 19 OF THE HIV PREVENTION AND CONTROL ACT

AND

IN THE MATTER OF SECTIONS 4, 5, 6, 8, 9, 16AND 38(g) OF THE CHILDREN ACT, 2022

BETWEEN

FA.....1ST PETITIONER

(Suing on her own behalf and as mother and next friend of Baby DM (A minor)

BK.....2ND PETITIONER

CN.....3RD PETITIONER

PATRICIA ASERO OCHIENG.....4TH PETITIONER

AMBASSADOR FOR YOUTH AND ADOLECSENTS

REPRODUCTIVE HEALTH PROGRAM (AYARHEP)....5TH PETITIONER

KENYA LEGAL AND ETHICAL

ISSUES NETWORK ON HIV/AIDS (KELIN).....6TH PETITIONER

KATIBA INSTITUTE.....7TH PETITIONER

VERSUS

THE HON. ATTORNEY GENERAL.....1ST RESPONDENT

CABINET SECRETARY FOR HEALTH.....2ND RESPONDENT

KENYA MEDICAL SUPPLIES AUTHORITY.....3RD RESPONDENT

AFFIDAVIT OF FA IN SUPPORT OF THE PETITION

I, **FA,** a resident and citizen of the Republic of Kenya, do solemnly make oath and state as follows:

1. I am the 1st Petitioner herein and therefore competent to swear this affidavit.

2. I am a woman living with HIV living and working for gain as a food vendor working within Kisumu County and I earn a profit of approximately Kshs 500 a month.
3. I am the mother of DM, a boy who was born on 18th December 2016.
4. Sometime in July 2018, DM begun to fall very ill; he was vomiting and losing weight. I had been taking him to the clinic, but they would only measure his weight and were unable to diagnose what was ailing him.
5. Around the same time, during a common walk through the estate where I live, two nurses from Liverpool Voluntary Counselling and Testing (LVCT) in Kisumu at Tivoli Centre, visited my house and noticed that DM was weak and in poor health.
6. They examined DM and recommended that I visit LVCT for further examination.
7. When we visited LVCT both I and the child were tested for HIV. The tests came out positive. It was at this point that I found out the HIV status for both myself and DM. We were both put on medication. DM was put on Septrin and I was advised that we should both immediately visit Jaramogi Oginga Odinga Teaching and Referral Hospital (JOOTRH) which we did.
8. At Jaramogi Oginga Odinga Teaching and Referral Hospital (JOOTRH), also known as Obama Hospital (previously known as Russia Hospital) both DM and I were examined. DM was found to be

in very poor health. The medical personnel administered a HIV test on DM, and this test confirmed that he was positive for HIV.

9. DM was then admitted to hospital for further treatment. He remained here for a period of two months. When he was discharged, he was on Nevirapine and Kaletra syrup which I routinely picked at LVCT.
10. On or about February 2021, there was a shortage of drugs at LVCT; the personnel there informed me that Kaletra syrup in particular was in short supply in most health facilities and advised me to give the child Kaletra tablets. However, the child was unable to take the drugs which would force me to have to crush and dissolve them in water.
11. Even after crushing the drugs and dissolving them in water, DM was still unable to keep the drugs down as they are very bitter. He would therefore vomit anytime he would take his medicine.
12. Due to the shortage that went on for some time, DM switched between the syrup and the Kaletra tablets which had adverse effects on the baby's health. DM became weak, developed skin rash, body swelling and severe cough. He also continued to have a very high viral load.
13. He started developing rashes again and developing big pimples all over his body, especially his thighs.
14. I explained this to medical personnel at Tivoli Centre who gave me the medicine in pellet form and advised me to mix the medicine in with fruit juice.

15. Sometimes I did not have money for juice and would look for powder juice to put the medicine in, but DM would still vomit the mixture.
16. The personnel at LVCT then gave me the medicine in pellet form and told me to mix it in his food. This had the effect of making the food very bitter and he was unable to eat.
17. As a result of the difficulties of DM keeping the dissolved Kaletra tablets and his inability to eat food that has been mixed up with Kaletra pellets, DM has been unable to keep any food down and has been unable to properly ingest his ARVs.
18. As a result, DM has not been on effective ARV treatment, including food or nutrition) since February 2021 until August 2022. As a result, DM became very sick. He had rashes on his neck, swellings on his neck, infections on his ears and was very weak. He was coughing severely as well.
19. I also took DM to Jaramogi Oginga Odinga Hospital where I was informed that his condition was as a result of lack of medication. DM was given medicine for the infections, but his anti-retroviral regimen was not changed.
20. Eventually I sought help through the 6th Petitioner and visited Optimum Health Consultants in Kisumu to have the child examined. He was diagnosed as having allergic cough due to underlying HIV disease.

(Annexed hereto and marked FA1 is a medical report from Optimum Health Consultants)

21. This lack of medication for my son, and his illness led to me becoming very distraught. Moreover, there was a significant financial strain on me as I would have to provide additional food and juice every time DM would vomit.

22. Eventually, DM was started on Dolutegravir in January 2023 which he is now currently taking.

23. I have brought this Petition because my son got very ill during the time he was not on regular medication. He became very ill and continues to have symptoms of illness. To date, DM still has rashes, he still has a severe persistent cough, and he cannot run for a long time like other children his age.

24. Even still, it has been difficult to get him viral load testing because DM continues to be very weak and his veins are undetectable.

25. I am afraid that if this Court does not direct the 2nd respondent to ensure the availability of suitable drugs for children living with HIV, or any other appropriate drug that my 5-year-old son can take without vomiting, then he risks losing his life. I therefore ask the Court to intervene to ensure that the shortage of essential medication does not occur again.

25. What I have deponed to is true to the best of my knowledge, information and belief, save for information whereof sources of information have been disclosed.

SWORN in KISUMU this 21st day of September 2023

By the said FA) FA
) DEPONENT
)
BEFORE ME)
)
)
COMMISSIONER FOR OATHS)

DRAWN & FILED BY:-
Nyokabi Njogu, Advocate,
C/O KELIN
Kuwinda Lane, off Langata Road, Karen C
P O Box 112 - 00202 KNH Nairobi
Mobile: 0790 111578
E-mail: litigation@kelinkenya.org

This is Exhibit marked "FA-1"
referred to in the Annexed affidavit/Declaration
of FA
Sworn/Declared before me on this 21st
day of September 2023
at NAIROBI in the Republic of Kenya
Commissioner for Oaths

Patient Name	: DESMOND MARCEL
Sex	: MALE
Clinic No	: 4050
Date of Birth	: 18/12/2017
Date reviewed	: 13/01/2022

"I declare that I have no conflict of interest in compiling this medical report. I freely give my professional opinion without influence, coercion nor bias. The report is based upon my personal review of all available documentation, clinical interviews and patient examination."

Attending Doctor JOSEPHINE OJIGO
Date: 14/01/2022

Clinical Summary

Patient was seen at my clinic accompanied by the mother who was the informant on the 13th of January 2022 with a long-standing cough for the past 2 years. He had been treated severally as an outpatient for the same. Cough worse at night or evening when it is cold and when the child is involved in vigorous play. No difficulty in breathing, fevers, weight loss or night sweats. Patient actively plays.

He is known to have HIV infection diagnosed at the age of 2 years at Liverpool VCT where he had previously presented with reduced play, poor feeding, weight loss and delayed walking. He had an admission then for treatment for severe malnutrition for 2 months with outpatient nutrition rehabilitative services follow-up for 5 more months after discharge. ARV therapy was started at the same time and is currently on ABC/3TC tablets twice a day (dose unknown) and LPV/r 2 capsules in food once a day. No treatment records/summary availed by the mother. Child is unable to take food containing the pellets hence the mother doesn't give this. He has been treated thrice as an outpatient for cough, ear discharge and swelling behind the ears. Antenatally, the mother attended clinic once where she was diagnosed with HIV but did not attend follow-up clinics due to psychosocial issues.

On Examination

Stable, not pale, no jaundice, well hydrated, generalized papular pruritic eruptions, generalized lymph node enlargement prominent at the pre- and post-auricular, occipital, cervical and axillary areas.

Temp 36.5 C	RR 22Bb/m	PR 97	WT 15kg	Height 94cm

Systemic Exam:
Per Abdomen- normal fullness, soft, non-tender, reducible umbilical hernia about 5cm diameter, no hepatomegaly or splenomegally
Cardiovascular –normoactive precordium, normal heart sounds
CNS – alert, normal tone
Respiratory – Not in distress, bilateral clear air entry, no wheeze or rhonchi
ENT: Bilateral non-tender parotid enlargement, normal ears and throat.

Investigations:
None

Diagnosis
1. Allergic cough in underlying HIV disease WHO clinical stage 2
2. Poor adherence to LPV/r pellets due to the unpalatable taste

Medication
Syrup cetirizine 5mg once daily for 2 weeks

Recommendations
- Mother to come with a comprehensive summary of treatment, follow-up and investigations done with the results from their primary clinic (LVCT) for review and forwarding to the Nyanza Western HIV TWG for discussion on possible change of LPV/r to DTG paediatrics formulation to improve on adherence and for way forward on follow-up investigations.

Dr. Josephine Ojigo - Consultant Pediatrician

REPUBLIC OF KENYA

IN THE HIGH COURT OF KENYA AT KISUMU

CONSTITUTIONAL AND HUMAN RIGHTS DIVISION

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THE HON. ATTORNEY GENERAL.....1ST RESPONDENT

CABINET SECRETARY FOR HEALTH.....2ND RESPONDENT

KENYA MEDICAL SUPPLIES AUTHORITY.....3RD RESPONDENT

AFFIDAVIT OF BK IN SUPPORT OF THE APPLICATION AND PETITION

I, **BK,** a female adult of sound mind and disposition of P.O Box 13088 Nakuru, do solemnly make oath and state as follows:

1. I am the 2nd Petitioner in this case and competent to swear this Affidavit.
2. I swear this Affidavit in support of the Notice of Motion and the Petition, including the prayers that the Petition be certified urgent and that I be granted leave to prosecute the application and the petition using my initials BK.
3. I am a mentor mother who offers adherence counselling to HIV positive mothers as well as guidance and health talks and working in a private health facility in Nakuru County.
4. I am a mother of two children aged nine years and three years respectively.
5. I was diagnosed with HIV in the year 2012 during my first pregnancy when I had my first antenatal clinic visit.
6. I was given the necessary medical advice and attention including administration of ARV's and health information on prevention of mother-to child transmission. Additionally, my child was put on nevirapine and Zidovudine. When I gave birth, tests were undertaken on my child at 6 weeks and 6 months respectively.
7. In 2019, I conceived my second child and after delivery in August 2020 my child was tested at 6 weeks and put on Nevirapine and Zidovudine medication.
8. My child was later tested when he turned 1 year in August 2021. Being a mentor mother and clinician with experience in HIV testing, I was

able to tell that the filter paper that was used to collect my child's sample had expired but was nevertheless still put to use.

9. From the experience gained from my work, I am aware that samples collected by the use of expired filter papers ought to be rejected. Surprisingly, the sample was not rejected and the results were indicated as negative.

10. To this date, I am uncertain of whether the results shared are a true reflection of my child's HIV status as the sample was collected using an expired filter paper.

11. Unfortunately, my child was the last to be tested as that was the last filter paper in stock. Consequently, all mothers who delivered their babies during the period of stock out did not have their babies tested at 6 weeks and 6 months as they are required to be tested as outlined in the Guidelines for Antiretroviral Therapy in Kenya. **A copy of the said guidelines is annexed hereto and marked BK1.**

12. It was only until November 2021 that the government supplied a limited number of filter papers most of which had a short expiry date. Personnel were therefore forced to prioritise testing for children of 6-8

weeks meaning that other children were entirely left out of the testing exercise.

13. My child has been on septrin medication that was provided to us by the government free of charge but unfortunately, this too has been out of stock.

14. I have since been forced to buy septrin for my child with one bottle of 100ml going for Kshs. 250. This has become quite expensive and financially strenuous as a child requires about 10ml of the medicine per single dosage.

15. As a result of the lack of availability of the septrin syrup and my inability to buy the medicine consistently, I was forced to abandon administering septrin syrup to my young child which puts the child's health at great risk.

16. Eventually I opted to withdraw from breastfeeding my child as I was uncertain of my health and the child's status and the risks involved.

17. I am also aware that in order to prevent mother-to-child HIV transmission, it is important that the mother's viral load be closely monitored with breastfeeding mothers being tested for their viral loads every 6 months.

18. The higher a mother's HIV viral load, the greater the risk is of her transmitting HIV to her infant via breastmilk. Viral load monitoring helps healthcare workers to tell if the ARVs the mother is taking are effective in suppressing the virus to levels that reduce or eliminate the risk of transmission. If the viral load shows that the treatment is not sufficiently effective, the healthcare workers will need to determine why this is so, and make adjustments to her treatment plan accordingly. It follows, that if healthcare workers cannot test a mother living with HIV's viral load, they are essentially "flying in the dark" with no insight to enable informed decision-making to prevent mother-to-child-transmission.

19. Additionally, lack of HIV care commodities impedes routine health checks that is essential for persons living with HIV. This 3TC results to diagnostics of kidney and liver failure only realised when they have significantly progressed.

20. I was only able to get certain health checks due to pregnancy complications and not as a routine test for a HIV patient.

21. I swear this affidavit to demonstrate the urgent need to provide adequate support to prevent mother-to-child transmission.

22. What I have deponed to is true to the best of my knowledge, information and belief, save for information whereof sources of information have been disclosed.

SWORN in NAIROBI)
this 21st day of September 2023)
)
By the said BK) _____
) **DEPONENT**
)
BEFORE ME)
)
)
COMMISSIONER FOR OATHS)

LYDIA W. MWANGI COMMISSIONER FOR OATHS P.O. Box 25315-00100, NAIROBI

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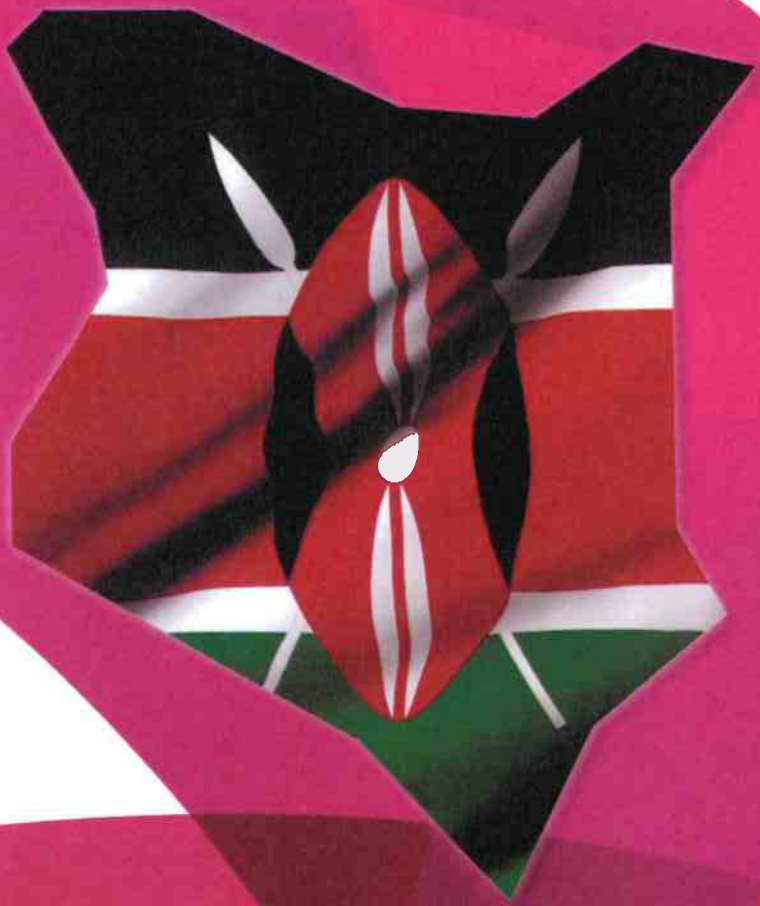

BK-1

Guidelines for antiretroviral therapy in Kenya

4th edition 2011 (Re-print)

This is Exhibit marked BK-1
referred to in the Annexed affidavit/Declaration
of BK-1
Sworn/Declared before me on this 21st
day of September 2023
at NAIROBI in the Republic of Kenya

Commissioner for Oaths

Guidelines for antiretroviral therapy in Kenya

4th edition 2011

These evidence-based guidelines reflect emerging clinical and scientific advances in HIV Prevention, Care and Treatment and related specialties as of the date issued. All reasonable precautions have been taken by NASCOP to verify the information in this publication. For any clarification contact National AIDS and STI Control Program (NASCOP) on P.O. Box 19361, Nairobi, Kenya, Tel: 254 20 2729502, 2714972, Email: info@nascop.or.ke, Website: www.nascop.or.ke

Citation for the guidelines should be as follows:
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Re-print

Foreword

Since the publication of the third edition of the national guideline on antiretroviral therapy in Kenya in 2005, new evidence on more efficacious, durable and tolerable HIV care and treatment options has emerged; culminating in the publication, in 2010, of World Health Organization (WHO) updates on prevention and treatment of HIV infection. The WHO recommendations, however, retained emphasis on a public health approach to the scaling up of HIV care and treatment services.

The fourth edition of the Guideline on antiretroviral therapy in Kenya has adopted these recommendations which are in line with international best practice. In addition, the Guideline provides specific emphasis on efficient and effective delivery of HIV prevention, care and treatment services. It outlines the health systems pillars that are essential to the delivery of quality HIV care and treatment services. Key areas covered include HIV diagnosis, antiretroviral therapy for adults, adolescents and children including special populations, prevention of mother-to-child transmission of HIV infection and prevention and management of common opportunistic infections as well as chronic non communicable diseases among PLHIV.

This Guideline is an important tool for use by multi-disciplinary teams of health care professionals providing care and treatment to PLHIV including doctors, clinical officers, nurses, pharmacists, pharmaceutical technologists, nutritionists, social workers and laboratory technologists among other service providers. In addition, it is presented in a simplified manner and provides a sound knowledge base for health care professionals involved in caring for PLHIV.

The development of this 4th edition of the Guideline has been done through extensive consultations and the commendable effort of multiple stakeholders, individuals and institutions led by the Ministries of Medical Services and Public Health & Sanitation.

It is our hope that this Guideline will add impetus to the rapid scale up of comprehensive HIV prevention, care, treatment and support and contribute to the achievement of universal access to quality HIV care and treatment services in Kenya.

Dr. Francis Kimani
Director of Medical Services
Ministry of Medical Services

Dr. S.K. Sharif
Director of Public Health & Sanitation
Ministry of Public Health & Sanitation

November 2011

Table of contents

1. Overview of recommendations for standard prevention, care and treatment of HIV infection in Kenya

1.1 Introduction

This section contains succinct information on recommendations made throughout the "Guidelines" for quick reference. In the 4th revision of the national guidelines, emphasis has been laid on

- earlier initiation of antiretroviral treatment initiation and improved criteria for ART switching
- the use of the most potent, effective and feasible first-line, second-line and subsequent treatment regimens applicable to the majority of populations,
- the optimal management of pregnant women for their own health and for prevention of mother-to-child transmission
- the management of HIV-exposed infants including feeding options
- the management of TB/HIV and HIV/HBV co-infections as well as common chronic noncommunicable conditions in HIV infection.

1.2 Essential package of care for People living with HIV

Knowledge of HIV status is essential for one to access HIV care services. Therefore HIV testing should be offered at all service points and appropriate referrals made.

The essential package of services should be provided to all PLHIV; it includes

- Counselling and psychosocial support
- Prevention with positives
- Potrimoxazole prophylaxis
- Tuberculosis prevention and treatment among PLHIV
- Sexually transmitted and other reproductive tract infections
- Screening for cervical cancer
- Preventing malaria
- Vaccination and immunization
- Reproductive health and family planning
- Nutrition

1.3 Antiretroviral therapy (ART) in adolescents and adults

1.3.1 Recommendations for antiretroviral therapy in adults and adolescents

When to start ART

Antiretroviral therapy (ART) is indicated in all HIV-positive adults and adolescents with the following:

- WHO clinical stage 1 or 2 and a CD4 count ≤ 350 cells/mm^3,
- WHO clinical stage 3 or 4 regardless of CD4 count,
- HIV and TB co-infection regardless of the CD4 count,
- Patients with HIV/HBV co-infection with evidence of active liver disease (elevated ALT), cirrhosis or other evidence of chronic liver disease.

What antiretroviral agents (ARVs) to start with

The recommended **first-line antiretroviral regimens** in treatment naïve adults and adolescents are:

TDF + 3TC + EFV or NVP	OR	AZT + 3TC + NVP or EFV

In pregnant women, AZT based ART is preferred due to the long experience of AZT in pregnancy and its well documented efficacy in preventing mother-to-child transmission of HIV.

As much as possible, fixed dose ARV drug combinations should be used to reduce the pill burden and encourage optimum adherence.

Stavudine phase out - patients already on a stavudine-based first-line regimen should be evaluated for adverse effects and where indicated, therapy changed appropriately. Patients who have been on stavudine for more than 6 months and are experiencing toxicity should have a viral load assessment to exclude treatment failure and to guide choice of appropriate regimen.

Recommended second-line regimens for adults and adolescents

In patients failing first-line therapy, the recommended second-line regimens are as shown in Table 1.1

Table 1.1 Recommended second-line regimens for adults and adolescents

First-line regimen	Second-line regimen
TDF + 3TC + EFV or NVP	AZT + 3TC + LPV/r or ATV/r*
AZT + 3TC + EFV or NVP	TDF + 3TC + LPV/r or ATV/r*
d4T + 3TC + EFV or NVP	TDF + 3TC + LPV/r or ATV/r*

*ATV/r is a suitable substitute when LPV/r is not tolerated.

1.4 Antiretroviral therapy in children

1.4.1 Diagnosis of HIV infection in infants and children

- All infants and young children whose exposure status is not known at the time of the first visit to a health facility should have their exposure status established through
  - counselling and then testing the mother for HIV or
  - testing the infant using an antibody test where the mother is not available or unwilling to be tested.
- All HIV -exposed infants (HIV antibody test positive/child born to HIV infected mother) should be offered routine HIV DNA PCR testing (early infant diagnosis) at the 6 weeks visit or at the earliest opportunity for infants seen after 6 weeks of age
- All HIV-exposed infants (HIV antibody test positive/child born to HIV-infected mother) should be offered cotrimoxazole preventive therapy from age 6 weeks till their HIV status is established. HIV-infected children should receive life-long cotrimoxazole prophylaxis unless contraindicated.

1.4.2 Recommendations for antiretroviral therapy in infants and children

When to start ART

- All children aged less than 24 months, confirmed HIV-infected; should be initiated on ART regardless of CD4 cell count, CD4 percentage or WHO clinical stage.
- In children older than 24 months of age, initiation of ART should be based on WHO stage and/or CD4 cell count or percentage as shown in Table 1.2 below

Table 1.2 Criteria for initiation of ART in children

Age	WHO clinical stage	CD4%	CD4 count (cells/mm³)
<24 months	All	All	All
24–59 months	3 or 4	<25%	<1000
5–12 years	3 or 4	<20%	<500

Recommended first-line ART for infants and children

The choice of the ART regimen for use in a child is based on whether the child was exposed to nevirapine during PMTCT. The recommended first-line regimen in children depending on NVP exposure status is shown in Table 1.3.

Table 1.3 Recommended first-line ART in infants and children

Child characteristics	Recommended regimen	
A. Child previously exposed to infant or maternal nevirapine for PMTCT (failed prophylaxis)		
All ages	Preferred	ABC + 3TC + LPV/r
	Alternative	AZT + 3TC + LPV/r
B. Child previously NOT exposed to Nevirapine for PMCT HIV transmission		
Age below 3 years or weight <10 kg	Preferred	ABC + 3TC + NVP
	Alternative	AZT + 3TC + NVP
Age above 3 years and weight >10 kg	Preferred	ABC + 3TC +NVP/EFV
	Alternative	AZT + 3TC + NVP/EFV

1.4.3 Prevention of mother-to-child transmission of HIV infection (PMTCT)

- All pregnant women should be encouraged to start attending antenatal care (ANC) early (as soon as they know they are pregnant; and preferably in the first trimester)
- All pregnant women should be offered HIV counselling and testing during their first ANC visit in line with testing and counselling guidelines. Those who are HIV-negative should be re-tested every 3 months until delivery.
- All pregnant women who are not tested, and opt-out or decline HIV testing during the initial ANC visit should be offered HIV counselling and testing at subsequent visit(s).
- Encourage mothers attending ANC to bring their partners for counselling and testing (couple counselling).
- Test sexual partners and children of all HIV-positive women identified at ANC.
- All HIV-positive pregnant women should be screened for TB, STIs, cervical cancer, and initiated on cotrimoxazole prophylaxis.
- All HIV-positive pregnant women should be evaluated for eligibility for ART during the first ANC visit; clinically, using WHO staging and CD4 cell count where available.
- All HIV-positive pregnant women in WHO stage 1 or 2 and with a CD4 cell count ≤ 350 cells/mm^3 or in WHO stage 3 or 4 irrespective of CD4 count should be started on life-long ART as soon as possible irrespective of the gestational age.
- All HIV-positive pregnant women with CD4 cell count >350 cells/mm^3 and with WHO clinical stage 1 or 2 should be provided with efficacious antiretroviral prophylaxis to prevent mother-to-child transmission of HIV infection but may be considered for lifelong ART where feasible.

All women, of unknown HIV status presenting in labour or after delivery should be offered HIV counselling and testing and managed as per the PMTCT recommendations
All HIV-exposed infants should be started on NVP prophylaxis from birth regardless of infant feeding option. Duration of NVP in the infant depends on whether the mother is on ART and whether the infant will be breastfed as follows:
  - for infants whose mothers are on HAART or those who are not breastfed at all regardless of mother's treatment/PMCT intervention; NVP should be continued for 6 weeks only;
  - for breastfeeding infants whose mothers are not on HAART, NVP should be given continuously from birth and continued throughout the duration of breastfeeding then stopped 1 week after complete cessation of breastfeeding.

  All HIV-exposed breastfeeding infants whose mothers are not on HAART, presenting for the first time in the post-partum period up to 6 weeks of age, should be started on nevirapine prophylaxis upon presentation at the health facility. Diagnostic HIV DNA PCR testing of these infants should be done at 6 weeks of age or at the earliest opportunity thereafter. Infants with PCR negative result should be continued on nevirapine prophylaxis while those with PCR positive results should be initiated on ART.
- All HIV-exposed breastfeeding infants whose mothers are not on HAART, presenting for the first time in the post-partum after 6 weeks of age, should start on cotrimoxazole prophylaxis and have a diagnostic DNA – PCR done at the first visit. Infants with a positive PCR results should start ART while those with negative PCR results should start nevirapine prophylaxis.
- Breastfeeding infants of mothers who start ART during the post-natal period should continue nevirapine prophylaxis till one week after cessation of breastfeeding.
- Infants with a positive PCR result should have the nevirapine prophylaxis discontinued and instead started on full ART, (Refer to table 1.3 above).

1.4.4 Infant and young child feeding in the context of HIV infection

- All mothers who are HIV-negative or are of unknown HIV status should be encouraged and supported to exclusively breastfeed for the first 6 months and continue breastfeeding with appropriate complementary feeds introduced thereafter.
- All HIV-positive mothers should be given accurate information on available infant feeding options including the challenges and benefits of each option in order to help them make an informed decision on which infant feeding option best suits their circumstances.

For majority of HIV-positive mothers, breastfeeding with infant ARV prophylaxis is the best option. They should be encouraged and supported to exclusively breastfeed for the first 6 months and continue feeding with appropriate complementary feeds thereafter. Infants of these mothers should receive Nevirapine prophylaxis throughout breastfeeding and until one week after complete cessation of breastfeeding.

All HIV-positive mothers who choose not to breastfeed should be counselled and supported to provide exclusive replacement feeding for the first 6 months and appropriate complementary feeds introduced thereafter. Infants of these mothers should be provided with Nevirapine prophylaxis from birth until 6 weeks of age.

Micronutrient deficiency disorders such as anaemia are also categorized into different grades of severity based on cut-off points or type of the signs observed. Generally, they are graded as mild, moderate or severe. In the case of anaemia, Hb less than 11 g/dl indicates mild anaemia, while Hb less than 7g/dl severe anaemia.

Table 9.1 Reference values for anthropometric measurements

Diagnosis/classification	Adults (not pregnant) BMI (kg/m²)	Adults (not pregnant) MUAC (cm)	Pregnant and early postpartum MUAC (cm)[1]
Severe acute malnutrition	<16	<16 cm	<19 cm
Moderate acute malnutrition Mild acute malnutrition	16–17 17.1–<18.5	16.0–18.5 cm 18.5–23 cm	19–<22 cm 22–23 cm
Normal	18.5–<25	_	_
Overweight	25–30	_	_
Obese	>30	_	_

1 Early post-partum in this context is the first 6-8 weeks.
The diagnostic category should trigger specific actions (counselling, nutritional treatment and referral services) through specific pre-determined eligibility (entry and exit) criteria for therapeutic or supplemental nutritional therapy and support services such as food assistance.

9.3.3 Management

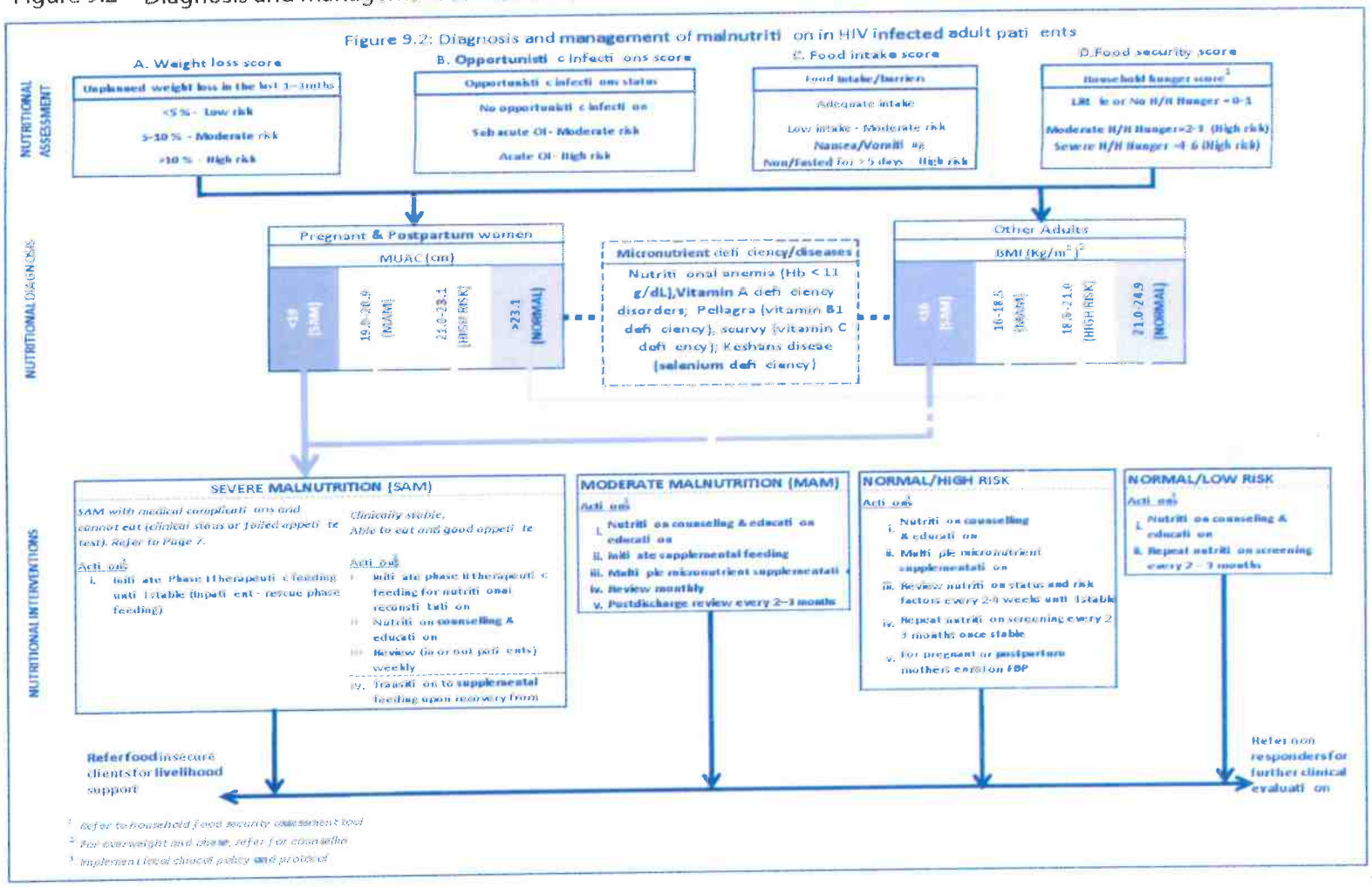
All stable PLHIV and their care givers, irrespective of nutrition status (normal, malnourished or over nourished) should received quality nutrition counselling and education. Clinically malnourished patients and their care givers should also receive specific nutritional therapies and adherence counselling.

Nutrition counselling – critical nutrition practices

The following key nutrition counselling and education messages should be provided to influence individual or family nutrition practices:

1. The patient should have periodic (every 2-3 months) nutritional status assessments, especially weight.
2. The patient has increased energy needs depending on the disease stage. To achieve required energy, the patient should eat sufficient amounts of balanced foods in three meals and one or more snacks between meals per say.
3. The patient should maintain high levels of sanitation, food hygiene and use safe water at all times.
4. The patient should practice positive living behaviours, including safe sex practices, avoidance of alcohol and tobacco, avoidance or moderation in consumption of high fat, refined foods and seek help in management of stress and depression.

Figure 9.2 Diagnosis and management of malnutrition in HIV infected adult patients



5. Physical activity is important to strengthen or build muscles and increase appetite and improve health. Progressive resistance exercise is required for recovery of malnourished patients.
6. Recommend drinking of plenty of clean, safe water (at least 8 glasses of filtered and boiled or treated water) and using the same to swallow medicines, preparation of juices and cleaning of fruits and salads before eating.
7. The patient should seek prompt treatment for all opportunistic infections and other diseases, and manage mild symptoms with dietary practices, especially for illnesses that may interfere with food intake, absorption and utilization.
8. If the patient is on medicine, such as ARV agents, manage drug-food interactions and diet-related side-effects. Encourage patients taking traditional herbs or nutritional supplements to inform the clinician.

Nutritional treatment

The aim of treating clinical malnutrition is to stop further weight loss, facilitate weight gain and nutritional reconstitution. Overall, management of clinical malnutrition requires supplemental or therapeutic interventions depending on the severity. Patients with severe malnutrition and life threatening medical complications; or unable to feed orally are managed as inpatients. Stabilization of hypoglycaemia, hypothermia, dehydration, electrolytes balance and infection control is required before in addition to nutrition therapy. Appropriate hospital feeding protocols and feeds should be used to ensure gradual increase in energy intake to allow the patient to physiologically stabilize before full loading with energy and nutrient requirements (Refer to Guidelines on Integrated Management of Acute Malnutrition, 2009).

Stable in-patients with uncomplicated severe malnutrition are managed with oral nutrition therapeutic or supplemental regimens of ready to use therapeutic food (RUTF) which are continued at home upon discharge. These foods are lipid based pastes, powders or bars and may be combined with supplemental food formulations to improve acceptability. Commonly available formulations include, lipid based peanut-milk powder paste and cereal-milk powder and plant protein based solid bars. Supplemental food formulations are nutrient dense fortified blended foods (FBF) or composites of staple foods.

Majority of adult patients with severe acute malnutrition weigh less than 45 kg. The recommended energy intake should be gradually increased from 25-30 kcal/kg body weight/ day over a period of 5-10 days to help normalize the physiologic and biochemical body functions. Patients in this phase of treatment should receive 100 mg of thiamine (vitamin B1) along with complete multi-micronutrients in the therapeutic food. Thiamine plays an important role in the regulation of glucose metabolism and pancreatic beta-cell functioning. Patients entering the rehabilitation phase should be provided with full loading of therapeutic food regime to meet about 100% energy, proteins, lipids and micronutrients requirements and extra to enhance repletion (Section 9.2). Patients should be encouraged

to eat normal foods with or after therapeutic food to facilitate transition to regular home diets upon recovery. With good adherence, patients should reach the exit cut-off point for moderate malnutrition shown in Table 9.1 in 4 to 8 weeks. Upon reaching moderate malnutrition stage, patients should be transitioned to oral supplemental food prescriptions alone.

Supplemental foods such as FBF and ready to use supplemental foods (RUSF) are designed to provide about 50% of energy (section 9.2), over 70% of whole protein and lipids along with approximately one recommended dietary allowance (RDA) of key micronutrients.

An RDA is the average daily dietary intake of a nutrient that is sufficient to meet the requirement of nearly all healthy persons. Oral supplemental foods are used for stable patients with moderate and mild acute malnutrition in out-patient and inpatient settings. Oral nutrition therapeutic and supplemental regimens are currently provided under food by prescription (FBP) programme and outpatient therapeutic programme (OTP) protocols in some settings. Alternative supplemental food formulations are required for diabetic patients.

Oral nutrition therapeutic foods provide therapeutic/pharmacological doses of multi-micronutrients to restore physiological levels and replenish body stores (Table 9.2). Oral nutrition supplemental foods contain levels of multi-micronutrients formulations at approximately one RDA to correct mild deficiencies and prevent development of deficiencies in moderately and mildly malnourished patients. Patients whose diet is not adequate with respect to recommended daily allowances and patients who have borderline nutrition status (high risk) are also supplemented with one RDA multi-micronutrients formulations until their dietary intake is considered adequate and stable.

Table 9.2 Nutritional composition multi-micronutrient formulations

Nutrients	Therapeutic (multiply by number of grams prescribed per day)[1]	Daily (1 RDA)
Vitamins		
Vitamin A	0.8 to 1.1 mg/100 g	700-900 µg
Vitamin D	15 to 20 µg/100 g	10 µg
Vitamin E	20 mg/100 g minimum	10 mg
Vitamin C	50 mg/100 g minimum	60 mg
Vitamin K	15 to 30 µg/100 g	80 µg
Vitamin B1 (thiamine)	0.5 mg/100 g minimum	1.5 mg
Vitamin B2 (riboflavin)	1.6 mg/100 g minimum	1.7 mg
Vitamin B 3 (niacin)	5 mg/100 g minimum	2.0 mg
Vitamin B6 (pyridoxine)	0.6 mg/100 g minimum	2.0 mg
Vitamin B12 (coalmine)	1.6 µg/100 g minimum	1.7 µg
Folic acid	200 mcg/100 g minimum	193 µg
Pantothenic acid	3 mg/100 g minimum	2.85 mg
Biotin	60 µg/100 g minimum	60 µg
Minerals		
Iron	10 to 14 mg/100 g	18 mg
Zinc	11 to 14 mg/100 g	15 mg
Copper	1.4 to 1.8 mg/100 g	2.0 mg
Selenium	20 to 40 µg	70 µg
Iodine	70 to 140 µg/100 g	150 µg
Sodium	290 mg/100 g maximum	<276 mg
Potassium	1100 to 1400 mg/100 g	1022 mg
Calcium	300 to 600 mg/100 g	276 g
Phosphorus	300 to 600 mg/100 g	276 g
Magnesium	80 to 140 mg/100 g	84.6 mg

1 Source: World Health Organization/World Food Programme/United Nations System Standing Committee on Nutrition/The United Nations Children's Fund, 2007

To overcome acute persistent barriers to oral intake of food requires clinical assessment to establish underlying causes. In addition to psychosocial support, symptoms such as acute anorexia, nausea and vomiting, pain from oral-pharyngeal lesions, pharmacological treatments is required. For patients who do not have heart ailments, diabetes and chronic bronchitis, short course of metopine a non-hormonal anabolic, 3-5 mg in 5-10 ml oral suspension before main meals is useful. Metopine is combined with the B-complex vitamins and amino acids lysine and carnitine to enhance carbohydrate metabolism. Relief to persistent nausea and vomiting may be provided through short course of antiemetics. Oral sores should be treated promptly by use of antifungal agents (for oral thrush), antiviral agents (viral infections) and local analgesics (aphthous ulcers). Adjunctive nutrition actions shown in Table 9.3 are key to successful management of mild barriers to adequate food intake and prevention of malnutrition.

Table 9.3 Nutritional management of common symptoms of HIV/AIDS

Symptom	Nutritional management	Things to avoid
Anorexia	• Eat foods high in fibre content • Drink plenty of fluids	Processed or refined foods
Nausea or vomiting	• Eat small quantities of food at frequent intervals • Drink after meals, limit drinking fluids with meals • Eat dry foods • Avoid spicy/salty foods • Take sips of ORS if vomiting occurs • Rest between meals	Avoid staying with an empty stomach
Diarrhoea	• Drink plenty of fluids (clean, boiled/treated water) • Prepare and drink ORS regularly • Take soluble fibre foods (like oranges and mangoes) • Seek medical advice if diarrhoea is severe or if there is blood in stool)	Foods cooked in plenty of oil Fried foods
Dry mouth	• Rinse mouth with warm water, a pinch of salt may be added • Maintain good oral hygiene • Seek medical advice if there is pain on swallowing or there are oral sores or spots	Very hot or spicy foods Excess caffeine beverages such as tea or coffee and effervescent drinks
Fever	• Drink plenty of fluids • Eat energy and nutrient rich foods • Eat small but frequent meals • Seek medical advice	
Change or loss of taste	• Chew food well and move it around in the mouth • Eat flavoured foods (spicy) as tolerated.	

11. Overview of HIV in children

11.1 Introduction

Globally, 3.2 million children live with HIV infection; and approximately 1500 children are born with HIV infection daily. More than 90% of HIV-infected children live in sub-Saharan Africa. Most children acquire HIV infection in-utero, during delivery or through breastfeeding. For most infants who acquire HIV infection in-utero or around delivery, disease progression occurs rapidly in the first few months of life, often resulting in severe opportunistic infections, failure to thrive and death. By two years of age, more than 50% of perinatally HIV-infected children have died. Improving access to optimal interventions that prevent mother-to-child HIV transmission has the potential to reduce transmission from 40% to less than 2%, and contribute to the eventual elimination of paediatric HIV infection.

In Kenya, an estimated 70 000 to 100 000 infants are exposed to HIV (born to HIV-infected mothers) every year. With current coverage of interventions to prevent mother-to-child HIV transmission (PMTCT), there are still an estimated 7000–10 000 children newly infected with HIV in Kenya each year.

11.2 Package of care for the HIV-exposed and the HIV-infected child

There are two groups of children with respect to HIV infection:
(a) HIV-exposed children: children born to HIV-infected mothers but the HIV status of the child is not yet known
(b) HIV-infected children: child whose HIV infection is confirmed

Services to prevent HIV infection for HIV-exposed children start before conception though to the childhood. The following 10 steps summarizes the package of care to be provided to HIV-exposed children:

1. Provision of essential prenatal, delivery and postnatal care for women
2. Provision of ARV to mother and child for prevention of mother-to-child transmission of HIV
3. Early infant diagnosis (early testing for HIV infection)
4. Health education and counselling of the child's caregiver on:
   a. Infant feeding
   b. HIV-related symptoms
5. Preventing opportunistic infections through co-trimoxazole and isoniazid prophylaxis
6. Monitoring growth and development

7. Immunization
8. Nutritional care, supplementation and advice
9. Regular presumptive de-worming every 6 months
10. Regular follow-up, with a clearly communicated a follow up schedule – birth, week age 2, 6, 10, 14 weeks, then monthly in the first year, quarterly in second year, 6 monthly thereafter or at least annually till age 5 years) and on regular basis for all HIV-positive children.

The impact of HIV infection on child survival can be minimized through these additional pillars of care:

- Confirmation / documentation of HIV infection
- staging of HIV disease
- Prompt treatment of infections including opportunistic infections
- Cotrimoxazole preventive therapy
- Prevention of tuberculosis through isoniazid prophylaxis counselling for and providing antiretroviral therapy
- Providing comprehensive care for the child, mother and other family members.
- Planning for/providing long-term HIV care and follow up including community support

11.3 Diagnosis and staging of HIV infection in infants and children

Diagnosis of HIV infection in a child often means that the mother is HIV-infected and her partner and other siblings may be HIV-infected as well. This provides an opportunity to provide counselling and support to the family and to link infected family members to care and treatment services.

11.3.1 Identification of the HIV-exposed child

Routine HIV testing should be universal in all well child clinic settings (during routine immunization and growth monitoring visits), as well as for all sick child settings, such as paediatric wards and paediatric out-patient settings (casualties, maternal and child health, sick child visits, paediatric out-patient clinics and TB clinics) in order to maximize opportunities for early HIV diagnosis. Parents with TB or with HIV infection should be encouraged to bring their children for HIV testing.

All infants and young children of unknown HIV-exposure status at the time of the first visit to a health facility should have their exposure status established through:

- Counselling and HIV antibody testing of the mother and/or
- Testing the infant using a HIV antibody test where the mother is unavailable or unwilling to be tested

A positive HIV antibody test of mother and/or child confirms that the child is HIV-exposed.

Children exposed to HIV infection should be identified as early as possible to enable interventions to prevent MTCT or to allow entry into care.

11.3.2 Diagnosis of the HIV-infected child

I. HIV diagnosis in children 18 months and older

The diagnosis of HIV infection in children who are 18 months and older is confirmed by a positive HIV antibody test (rapid test). Refer to the national HIV testing and counselling guidelines for the rapid HIV testing algorithm.

II. HIV diagnosis in children younger than 18 months (refer to figure 11.1)

Children under 18 months have maternal HIV antibodies passively transferred to them in utero, which persist in infant blood for 9–18 months. In this age group a positive HIV serological test detects HIV antibody, however it is not possible to determine if this is maternally transferred antibody, or antibody generated by the infant. The positive antibody test before age 18 months therefore does not confirm HIV infection, but is an indication of maternal HIV infection and therefore HIV exposure of the child.

In order to confirm HIV diagnosis in children <18 months of age it is necessary to perform a test that detects HIV virus using "virologic tests" such as HIV DNA PCR assay. A positive HIV PCR test confirms that the child is HIV-infected.

A virological test at 6 weeks of age identifies more than 95% of infants infected in utero and in the peri-partum period.

HIV diagnosis in a child under 18 months is confirmed through two steps:

1. A positive HIV antibody test (shows HIV exposure)
2. A confirmatory positive virologic test such as HIV DNA PCR (or HIV RNA PCR) assay.

- All HIV-exposed children under 18 months (infant or mother positive by HIV antibody test) should be offered routine confirmation of HIV diagnosis using HIV DNA PCR testing at the 6 week immunization visit or at the earliest opportunity for infants seen after 6 weeks of age.
- For those children who present sick to health services and are not yet tested for HIV, should be offered HIV diagnostic testing as a routine test through provider initiated testing and counselling (PITC).
- This early infant diagnosis enables any infected child less than 18 months to access life-saving antiretroviral therapy and other aspects of comprehensive HIV care.
- Failure to diagnose and treat HIV early results in 50% of these infected infants dying before age 2 years.

In the absence of virologic tests, a presumptive HIV diagnosis can be made by using a combination of laboratory and clinical criteria.

Table 11.1 Diagnosis of HIV-infection in infants and children

Age	HIV diagnosis confirmed as follows
18 months and older	Positive HIV antibody test (rapid HIV antibody test)
Below 18 months	Positive HIV PCR after age 1 month
Below 18 months *If HIV DNA PCR not available*	Presumptive HIV diagnosis as shown in Table 11.2

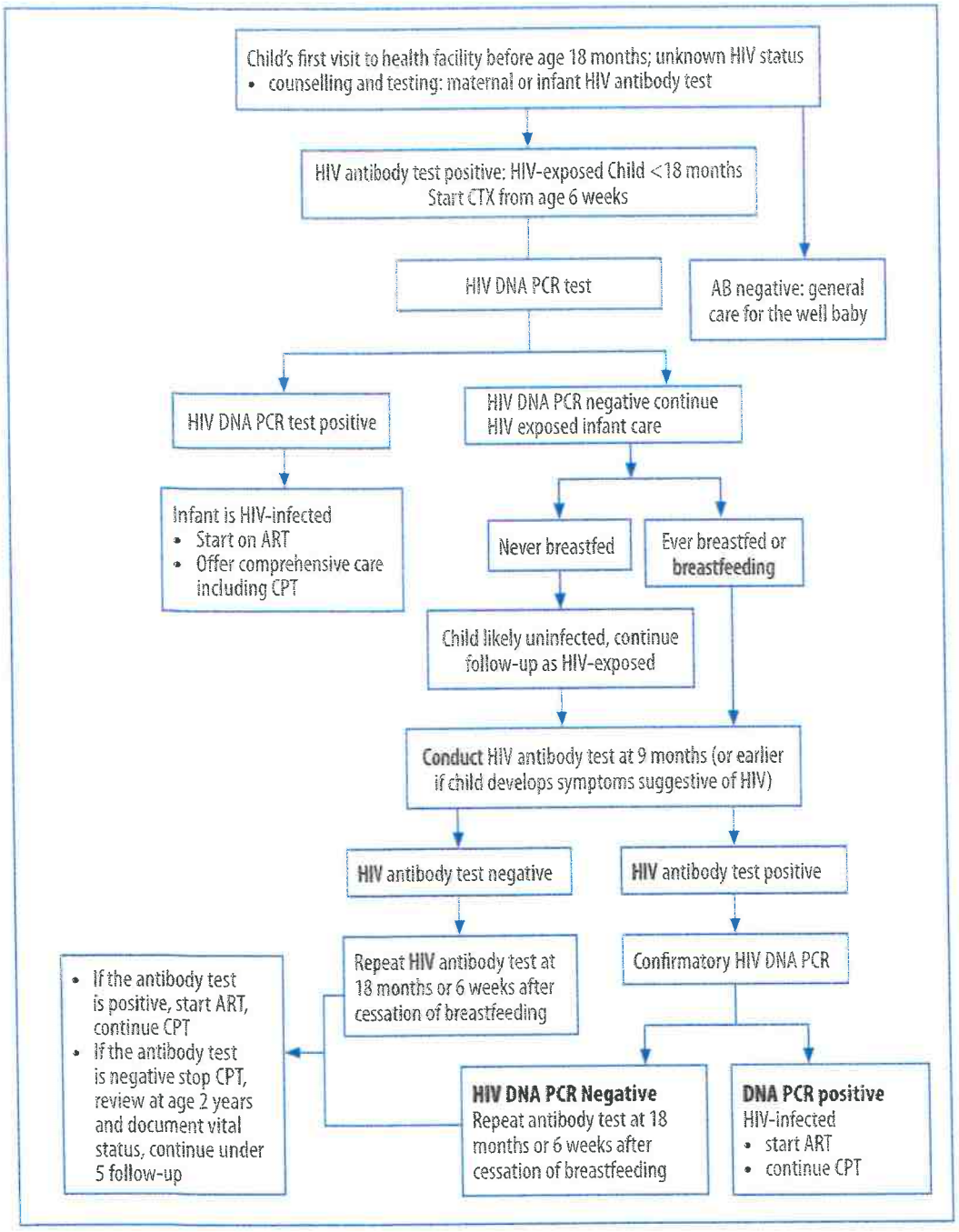
* Available HIV PCR tests: (i) HIV DNA PCR (test reported as positive or negative for HIV DNA), (ii) HIV RNA PCR which reports viral load (reports number of copies of virus/ml of blood).

III. Diagnosis of HIV infection in breastfeeding infants

An HIV-exposed breastfeeding infant is at risk of HIV infection throughout the breastfeeding period. A positive HIV DNA PCR test at any age is indicative of HIV infection. On the other hand, a negative HIV DNA PCR test does not constitute a final diagnosis, as the infant continues to be at risk of HIV transmission through ongoing breast milk exposure.

This risk is <5% if ARV prophylaxis is given either to the baby or to the mother throughout breastfeeding to prevent breast milk transmission. In these infants, the final diagnosis is determined 6 weeks after cessation of all breastfeeding, at which time a final PCR test should be done (or if the child is already above 18 months, an antibody test). Only then can a negative HIV test be indicative of no HIV infection in the infant or child.

Figure 11.1 Early infant diagnosis of HIV infection before age 18 months



Presumptive diagnosis of severe HIV disease in children less than 18 months – when a virologic HIV test is not readily available

Occasionally, children less than 18 months of age will present to healthcare facilities with severe disease suggestive of HIV infection. In some cases lack of immediately available virologic test confirmation of HIV infection could result in undue delay in instituting life-saving ART. In such cases, **a presumptive diagnosis of severe HIV disease** should be made based on the criteria in Table 11.2 below, and prompt ART initiated. However, the diagnosis should be confirmed by HIV DNA PCR (or serological tests for children >18 months of age) as soon as is feasible.

Table 11.2 Presumptive diagnosis of severe HIV disease in children under 18 months

Presumptive diagnosis of severe HIV disease in children less than eighteen months old where virologic confirmation of HIV infection is not readily available
Child < 18 months of age; HIV antibody test positive and symptomatic with: 2 or more of the following: • oral candidiasis/thrush • severe pneumonia • severe sepsis OR An AIDS defining condition* Other factors that support the diagnosis of clinical stage 4 HIV infection in this infant are recent maternal death or advanced HIV disease in mother; and/or child's CD4% <20%

* AIDS defining conditions include any of the diseases listed in the WHO clinical stage 4 in the Appendices Table 20.17.

11.3.3 Staging of HIV infection in infants and children

The next step in management of the child in whom HIV infection has been diagnosed, is to stage how advanced the child's disease progression is. This is done through history, and physical examination, and where necessary through a few simple laboratory assays. Disease is staged using a World Health Organization (WHO) staging system into asymptomatic, mild, moderate or severe HIV disease (Table 11.3 and table 2.2)

Table 11.3 World Health Organization clinical staging of HIV disease in children

Severity of HIV clinical disease	WHO clinical stage
Asymptomatic	1
Mild	2
Advanced	3
Severe	4

REPUBLIC OF KENYA

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AND

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AND

IN THE MATTER OF SECTIONS 4, (c) (d) 5, 8(c) (d) 14, 15 OF THE HEALTH ACT, 2017

AND

IN THE MATTER OF SECTION 19 OF THE HIV PREVENTION AND CONTROL ACT

AND

IN THE MATTER OF SECTIONS 4, 5, 6, 8, 9, 16AND 38(g) OF THE CHILDREN ACT, 2022

BETWEEN

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(Suing on her own behalf and as mother and next friend of Baby DM (A minor)

BK.....2ND PETITIONER

CN.....3RD PETITIONER

PATRICIA ASERO OCHIENG.....4TH PETITIONER

AMBASSADOR FOR YOUTH AND ADOLECSENTS

REPRODUCTIVE HEALTH PROGRAM (AYARHEP)....5TH PETITIONER

KENYA LEGAL AND ETHICAL

ISSUES NETWORK ON HIV/AIDS (KELIN).....6TH PETITIONER

KATIBA INSTITUTE.....7TH PETITIONER

VERSUS

THE HON. ATTORNEY GENERAL.....1ST RESPONDENT

CABINET SECRETARY FOR HEALTH.....2ND RESPONDENT

KENYA MEDICAL SUPPLIES AUTHORITY.....3RD RESPONDENT

AFFIDAVIT OF CN IN SUPPORT OF THE APPLICATION AND PETITION

I, **CN,** a female adult of sound mind of P.O Box 100 Gilgil, do solemnly make oath and state as follows:

1. I am the 3rd Petitioner in this Petition and competent to swear this Affidavit.

2. I swear this Affidavit in support of the Notice of Motion and the Petition, including the prayers that the Petition be certified urgent and that I be granted leave to prosecute the application and the petition using my initials CN.

3. I am a HIV testing services provider at a public health facility within Nakuru County.

4. I am a mother of four children aged twenty-four years, twenty-one years and twins of two years.

5. I was diagnosed as HIV positive in the year 2003 but was only put on medication in the year 2011 because my CD4 level went below 250 counts.

6. I had a breastfeeding child when I was diagnosed in 2003. At the time there were no medications for children and I breastfed my child up until she turned two years and five months.

7. Before I conceived my twin children in 2020, I checked my viral load in line with medical advice. This enabled me to see that my ARVs at the time were effectively suppressing the virus in my body and to confirm that there was a low risk of HIV transmission to my babies.

8. However, after birth, I had difficulty getting viral load testing during pregnancy and after birth because there was a shortage of testing kits and reagents.

9. Even after the birth of my twins, there was still a shortage of reagents and testing kits and as a result, my children were neither tested at birth nor at six weeks. They were only tested at 4 months.

10. I am aware, because of the work I am engaged in that from 2020, there was a lack of anti-retroviral drugs, testing kits and reagents amongst other commodities used in the testing, treatment and management of HIV. In particular I am aware that items such as filter papers for the testing kits were in short supply, and that what was coming had very short expiry times.

11. Early viral load testing for both myself and my then infants would have greatly assisted me to make an informed decision on the safety and timing of exclusive breastfeeding and weaning. It would also have reduced my psychological stress and anxiety.

12. My children had initially been on septrin medication that was provided to us by the government free of charge but unfortunately, this too went out of stock.

13. I was then forced to use septrin for my children with one bottle of 100ml going for Kshs. 250. This became quite expensive and financially strenuous as a child requires about 10ml of the medicine per single dosage.

14. As a result of the lack of availability of the septrin syrup and my inability to buy the medicine consistently, I was forced to abandon administering septrin syrup to my young children which I know put the children's health at great risk.

15. As a result of not knowing what my viral load was and my children's health status, as well as my inability to buy them septrin, I developed severe anxiety leading to diminished production of breastmilk. This was heightened by the fact that it took over several months for me to receive my children's early infant diagnostic test results.

16. The situation became even more difficult for me as there were no support groups available for me to seek peer-to-peer support and general psycho-social assistance.

17. The unavailability of reagents left me in mental anguish as I was uncertain of my health status and that of my children due to the risk of mother-to-child transmission.

18. I am aware due to my engagements in my employment as a public health worker that there was and continues to be lack of consistent viral load testing due to insufficient reagents and testing kits. This has been worrying because there are just three laboratories in Kisumu, Kericho and Nairobi to process viral load tests as well as children's tests. This can lead to a delay in receiving results and affects the treatment one receives.

19. The effect of this means that even children who do contract HIV from their mothers are not being diagnosed early enough and may miss an opportunity to be initiated on the correct treatment in time.

20. I am aware through my work that people living with HIV also experienced a stock-out of ARVs that saw medical facilities reduce the quantity of medicine given to clients. Dosage was reduced to just two weeks which distribution required that the medicine be removed from their packaging and be handed over to each patient in zip lock bags.

21. The removal of the drugs from their packaging meant that their quality was compromised as the alternative packaging in zip lock bags exposed them to light and moisture.

22. Despite news reports that the situation on the drugs and availability of commodities being available, I myself have been unable to consistently monitor my viral load due to lack of reagents at the testing facilities. The last time I accessed viral load testing was in early 2023. I am now due for testing but have been unable to access it due to a lack of reagents.

23. I am also aware that there continues to be lack of information around the quantity and quality of ARVs that are available; some of the drugs provided were discoloured and information reaching people living with HIV, including myself, that some drugs might be expired and should be returned to facilities.

24. Other persons living with HIV, including myself have been experiencing some side effects after taking the drugs that are now provided to us. These complaints presented include nausea, itching, bloating and general body discomfort.

25.I am experiencing some of these side effects including headaches, bloating and itching. When this is reported to the health facility where I undertake my follow up, I underwent a test to determine if there was an issue with my kidneys but luckily this turned negative. I was then informed that the reaction was due to the medication I am taking.

26.I am aware that there is urgent need to provide adequate support to HIV patients including provision of ARVs, routine testing, psycho-social services and prevention of mother-to-child transmissions. However, this sort of support is rarely available.

27.This is despite that ARVs, while life saving and life-sustaining, can have severe and dangerous side effects that need to be monitored regularly.

28.I therefore ask this court to intervene and grant the orders sought in the Petition so that persons living with HIV can access essential life saving medication.

29. What I have deponed to is true to the best of my knowledge, information and belief, save for information whereof sources of information have been disclosed.

SWORN in NAIROBI)
this 21st day of September 2023)

By the said CN) _____
) **DEPONENT**
)
BEFORE ME)
)
)
COMMISSIONER FOR OATHS)

LYDIA W. MWANGI COMMISSIONER FOR OATHS P.O. Box 25315-00100, NAIROBI

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KENYA MEDICAL SUPPLIES AUTHORITY……3RD RESPONDENT

AFFIDAVIT OF JEROP LIMO IN SUPPORT OF THE APPLICATION AND PETITION

I, **JEROP LIMO**, a resident of Nairobi within the Republic of Kenya do hereby make a solemn oath and swear as follows;

1. I am the Executive Director of the Ambassador for Youth and Adolescent Reproductive Health Programme (AYARHEP), the 5th Petitioner herein and thus competent to swear this affidavit.

2. I am conversant with the contents of the Petition and I fully understand the issues in question and I further adopt the contents of the Petition filed herein as if the same were set out *seriatim.*

3. The 3rd Petitioner is a non-governmental organisation registered in Kenya working to mitigate the impact of HIV and AIDS and promote healthcare, reproductive health and human rights. ***(A copy of the 3rd Petitioner's registration certificate is attached and marked as JL-1)***

4. I have been involved in campaigning for the provision of ARVs and HIV commodities to the benefit of adolescents and young women in my personal capacity and in collaboration with networks such as Ambassador for Youth and Adolescent Reproductive Health Program (AYARHEP).

5. In the course of my work, I witnessed the dwindling supply of ARVs and HIV commodities to persons living with HIV (PLHIV) through 2020 and 2021 and its specific adverse effects on infants and children as well as adolescents and young people who I work with.

6. I am aware that since February 2020, before the COVID-19 pandemic in Kenya, there have been severe challenges in accessing ARVs for persons living with HIV. In addition, there has been a lack of access to HIV commodities such as viral load testing kits as well as laboratory reagents that are needed for use in early infant diagnosis.

7. Before the shortage, persons seeking treatment would receive multi-month prescription of ARVs for up to 6 months, in line with guidelines on differentiated service delivery. However, during the shortage, the supply of these drugs was then reduced to 2-week dosages.

8. Before the shortage, there had also been prompt testing of pregnant mothers for HIV which led to early infant diagnosis and treatment therapies to prevent transmission in newborn children. However, due to lack of reagents, and even testing kits, I am aware that there was no early infant diagnosis taking place in hospitals.

9. I know this through interacting with adolescents and young people who would visit AYARHEP for support. Many of these people reported receiving their medication in low (few) doses, in brown paper bags, as opposed to properly labelled medicine packs as well as not receiving enough medication to last for a month.

10. Some pregnant women also informed us that they had not received any viral load testing prior to giving birth or even after giving birth. A number of young mothers also visited our offices and reported that they were unable to get early infant diagnostic testing or prophylaxis for their newborn children and they were afraid of breast feeding their children. This posed a challenge because they were unable to afford formula milk.

11. Concerned that adolescents and young women were not receiving their ARVs and that efforts towards prevention of parent to child transmission were being undermined, I, in collaboration with other organizations working to agitate for the rights of persons living with HIV tried to engage the Ministry of Health to try and get to the root cause of the stockouts.

12. All we received was contradictory information from the Ministry of Health and the National AIDS and STIs Control Programme on the availability and distribution of ARVs and other HIV commodities.

13. We also wrote various letters requesting the Ministry of Health, the Office of the President and to Parliament to address the issue of shortages of ARVs and HIV Commodities in the country but none of these letters was ever responded to. (***Annexed hereto and marked JL2 are copies of letters written to various state actors with regard to the shortage of ARVs and HIV commodities.)***

14. Due to the non-responsiveness of the Ministry, my colleagues and I from AYARHEP alongside other civil society organizations organized a demonstration that I participated in a demonstration at the offices of the Ministry of Health in Nairobi on 9th November 2021.

15. After the demonstration, together with others, we sought to speak with the then Cabinet Secretary for Health. However, we could not gain access and were received by a gentleman only identified as Dr. Mulwa, to whom we explained our grievances. Dr Mulwa promised that early infant diagnostic testing would resume by December 2021, while the supply of 3 to 6-month ARV dosages would resume by February 2022.

16. However, this did not happen, and all through 2022, supply of ARVs continued to be erratic. In particular, young mothers who we work with have continued to express a shortage of viral load testing for themselves as well as early infant diagnostic testing for their children.

This has led to sever anxiety for these women as they have no means to provide alternative forms of feeding to their children.

17. I believe the lives of undiagnosed and untreated children continue to be at risk. I am aware that scientific evidence proves that of children at risk of contracting HIV should be provided with anti-retroviral medications that prevent the risk of transmission of HIV through breastmilk, and those who have HIV should be initiated on treatment as soon as they are diagnosed to prevent the risk of severe illness or death.

18. I am also aware that there continue to be reports of a lack of other commodities that are used in the treatment and management of HIV, including reagents for conducting viral load testing for women living with HIV as well as condoms.

19. Should this Court not intervene and grant the orders sought, there is a risk that another stockout of these essential medications is likely to happen and this puts the lives of persons living with HIV at risk. I therefore swear this affidavit in support of the Notice of Motion seeking urgent relief as well as the Petition herein.

20. I swear this affidavit in support of this petition and attest that what is deponed to herein is true to the best of my knowledge, information and belief.

SWORN at **NAIROBI** by the said)
JEROP LIMO)
) **DEPONENT**

This 21st day of September 2023)
BEFORE ME)
)
)
COMMISSIONER OF OATHS)

LYDIA W. MWANGI COMMISSIONER FOR OATHS P.O. Box 25315 00100 NAIROBI

DRAWN & FILED BY:

Nyokabi Njogu

C/O KELIN

Karen C, Kuwinda Lane, Off Langata Road.

P O Box 112 - 00202 KNH

NAIROBI

Tel: 0790 111 578

TO BE SERVED UPON: -

The Hon. Attorney General,

The State Law Office

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Form 5 (r.11)

REPUBLIC OF KENYA

OP.218/051/16-058/10265

THE PRESIDENCY

MINISTRY OF DEVOLUTION AND PLANNING

This is Exhibit marked "..." referred to in the Annexed affidavit/Declaration of ... Sworn/Declared before me on this ... day of ... 20... at ... in the Republic of Kenya ... Commissioner for Oaths

CERTIFICATE OF REGISTRATION

I, FAZUL YUSUF MAHAMED, Executive Director of the Non-Governmental Organizations Board, certify that xxx AMBASSADOR FOR YOUTH AND ADOLESCENT REPRODUCTIVE HEALTH PROGRAM xxx has this day been registered under section 10 of the Non-Governmental Organizations Co-ordination Act as applied for.

Dated 4TH MAY, 2016

FAZUL Y. MAHAMED

Executive Director of the Board

OPEN LETTER TO THE PRESIDENT

A LETTER OF APPEAL

This is Exhibit marked "IL 2"
referred to in the Annexed affidavit/Declaration
of JOSEPH LIMO
sworn at the Republic of Kenya
day of September 2023
at NAIROBI in the Republic of Kenya
Commissioner for Oaths

H.E. Uhuru Muigai Kenyatta, C.G.H
President of the Republic of Kenya
Commander in Chief of the Defence Forces of The Republic of Kenya
Nairobi, Kenya
info@president.go.ke

Dear H.E. President Uhuru Kenyatta,

We, the undersigned, individuals, organizations, and associations, are representatives of people living with and affected by HIV including children and adolescents, health and human rights civil society and non-governmental and community-based organizations. We write this letter, pursuant to our constitutional mandate under Articles 3, 10, 43(1)a and 53(1)c of the Constitution on the responsibility to defend and protect the Constitution, the right to participate in matters concerning us and to access public information, respectively.

This is an urgent appeal that you take action and resolve commodity and supplies shortages plaguing the HIV response in the country. As matters stand now, over 1.3 million adults and children living with HIV risk losing their lives.

Mr. President, Kenya has faced an erratic supply of ARVs and acute stock-outs of laboratory supplies since February 2021. We have reached out to the Cabinet Secretary, Ministry of Health on this matter and the head of National AIDS and STI Control Programme our correspondences to them remain an unanswered. See: https://nephak.or.ke/wp-content/uploads/2021/ARVs-Stalement-MoH.pdf Despite verbal assurances from some of the Ministry of Health officials the dire situation has persisted, and now many people living with HIV and especially children continue to miss out on life saving treatment. This has dire consequences to the lives of people living with HIV but also the gains made in the fight against HIV stand to be eroded.

Kenyans have become aware of the importance of knowing their HIV status but at the moment, people visiting health facilities cannot be tested due to lack of testing kits and laboratory reagents. PLHIV who previously received a three-month supply of ARVs are now receiving as little as two weeks' supply. Worse, the standard of care for PLHIV has been compromised. Some PLHIV are being issued ARVs well past their expiration dates and in some instances, drugs have been dispensed in unlabeled plastic bags.

The situation for children is worse. The country has run out of pediatric diagnostic and viral load test kits and reagents. Children are being turned away without tests, resulting in inexcusable and dangerous delays in initiating HIV positive children onto life-saving treatment. This is the emergency we are now facing as we approach nearly a year without testing infants and children exposed to HIV.

On HIV treatment, a limited supply of pediatric Dolutegravir received from PEPFAR is now at extreme risk of expiring rather than keeping children healthy. This is due to an arbitrary and non-evidence-based Ministry of Health circular issued on 9th September 2021 that unnecessarily require viral load tests be done before initiating HIV positive children on this optimal, preferred line of pediatric treatment. With no viral load test kits available, the circular amounts to a ban on dispensing the life-saving medicines and means children with HIV will suffer unnecessarily.

We are appalled that your government has made a decision to uphold long procurement processes above the lives of people living with HIV and are disturbed by the refusal by the government to offer tax waivers to donors bringing in life-saving medication. We are not able to wait for months while the government haggles with donors at the expense of the lives of PLHIV.

We are appalled that your government has made a decision to uphold long procurement processes above the lives of people living with HIV and are disturbed by the refusal by the government to offer tax waivers to donors bringing in life-saving medication. We are not able to wait for months while the government haggles with donors at the expense of the lives of PLHIV.

People living with HIV, including children are no longer realizing their constitutional right to health as stipulated in Articles 43(1)(a) and 53(1)c of the Constitution of Kenya. Our lives are at risk your Excellency and we urgently need your intervention on this matter.

We request that you, in exercise of your responsibilities as the Head of Government:

1. *Acknowledge that it is the responsibility of the GOK through the Ministry of Health to provide essential medications and medical supplies for Kenyans under strategic health programs including TB and HIV.*
2. *Direct the MOH to procure and deliver sufficient quantities of ARVs and other medicines for treatment of HIV infection for both children and adults to avert the ongoing suffering of recipients of HIV care.*
3. *Direct the National Treasury to facilitate an emergency procurement for urgently needed HIV medicines and supplies by among other things providing the required funds and waiving the cumbersome importation taxes*
4. *Urgently direct the relevant government agencies to utilize the waiver provision of the procurement law to speed up the processes as demanded by this emergency. People with HIV cannot wait for a nine-month procurement process to play out when critical medicines and commodities are out of stock.*
5. *Direct the Ministry of Health and National Treasury to set-aside the importation taxes on donated essential medical supplies and medicines imported by recognized UN Agencies and NGOs registered in Kenya for "FREE DISTRIBUTION" in Kenya.*
6. *Direct the Ministry of Health to provide and publicize a procurement plan and budget that results in the replenishment of the full nine-month supply buffer stock of ARVs, HIV test kits and Viral load test reagents for both adults and children.*
7. *Direct the Ministry of Health to overturn the 9th September 2021 circular and remove the arbitrary and reckless requirement for viral load tests before initiating children on better, safer and well tolerated ARV when there are no pediatric viral load test kits available.*
8. *As this is a matter affecting both the National and County governments, we humbly request that you urgently convene an Extra-Ordinary Session of the National and County Government Coordination Summit to address this critical issue and agree on a joint direction on how to resolve it.*

People living with HIV, including children are no longer realizing their constitutional right to health as stipulated in Articles 43(1)(a) and 53(1)c of the Constitution of Kenya. Our lives are at risk your Excellency and we urgently need your intervention on this matter.

SIGNED:

This letter is endorsed by ninety eight other organisations

REPUBLIC OF KENYA

IN THE HIGH COURT OF KENYA AT KISUMU

CONSTITUTIONAL AND HUMAN RIGHTS DIVISION

PETITION NO OF 2023

IN THE MATTER OF ARTICLES 1, 2, 3, 10, 19, 20(1) & (4), 21, 22, 23, 24, 26(1), 27, 28, 29, 35, 43(1)(a), 47, 53 (1)(c), 165, 232(1), 258 AND 259 OF THE CONSTITUTION OF KENYA, 2010

AND

IN THE MATTER OF SECTIONS 4 (b), (c), (d), (e), (f), (h), (i), (l) (n) AND (m), 14 (f), 20, 24,32, AND 33 (2) AND (5) OF THE EAST AFRICAN COMMUNITY HIV AND AIDS PREVENTION AND MANAGEMENT ACT, 2012

AND

IN THE MATTER OF SECTIONS 4, (c) (d) 5, 8(c) (d) 14, 15 OF THE HEALTH ACT, 2017

AND

IN THE MATTER OF SECTION 19 OF THE HIV PREVENTION AND CONTROL ACT

AND

IN THE MATTER OF SECTIONS 4, 5, 6, 8, 9, 16AND 38(g) OF THE CHILDREN ACT, 2022

BETWEEN

FA.....1ST PETITIONER

(Suing on her own behalf and as mother and next friend of Baby DM (A minor)

BK.....2ND PETITIONER

CN.....3RD PETITIONER

PATRICIA ASERO OCHIENG.....4TH PETITIONER

AMBASSADOR FOR YOUTH AND ADOLECSENTS

REPRODUCTIVE HEALTH PROGRAM (AYARHEP)...5TH PETITIONER

KENYA LEGAL AND ETHICAL

ISSUES NETWORK ON HIV/AIDS (KELIN).....6TH PETITIONER

KATIBA INSTITUTE.....7TH PETITIONER

VERSUS

THE HON. ATTORNEY GENERAL.....1ST RESPONDENT

CABINET SECRETARY FOR HEALTH.....2ND RESPONDENT

KENYA MEDICAL SUPPLIES AUTHORITY.....3RD RESPONDENT

AFFIDAVIT OF ALLAN ACHESA MALECHE IN SUPPORT OF THE PETITION

I, **ALLAN ACHESA MALECHE,** of **P.O. BOX 112 – 00202, Nairobi,** a male adult Kenyan of sound mind residing and working for gain in Nairobi

County within the Republic of Kenya do hereby make oath and state as follows;

1. I am an advocate of the High Court of Kenya and the Executive Director of the Kenya Legal and Ethical Issues Network of HIV and AIDS (KELIN), the 6th petitioner and thus competent to swear this Affidavit.

2. I have the authority of the Board of Directors to swear this Affidavit on behalf of KELIN herein.

3. I am conversant with the contents of the Petition, I have interacted with the Petitioners, I fully understand the issues in question, and I further adopt the contents of the Petition filed herein as if the same were set out *seriatim*.

4. KELIN is a non- partisan, non-profit making, and non- governmental organization duly registered under the Non-Governmental Organizations Act, working to protect and promote health-related human rights in Kenya. **(Annexed and marked "AAM1" is a copy of KELIN's registration certificate).** The mandate of KELIN is achieved by facilitating access to justice for those who have faced human rights violations, creating partnerships with key stakeholders, building capacities of communities to know their rights and analysing laws and policies to ensure they integrate human rights principles.

5. KELIN's vision is the full enjoyment of health-related human rights for all while its mission is to promote and protect health-related rights for all.

6. KELIN has received complaints from various individuals such as the 1st Petitioner who are unable to access ARV medication and who have reported that they are unable to access testing for HIV at public health facilities.

7. The 1st, 2nd and 3rd Petitioners approached KELIN because they had been unable to find suitable paediatric medication for their children. They have also been unable to access early infant diagnosis to establish the health status of their children and viral load testing for themselves.

8. Through its internal advocacy processes, the 6th Petitioner also became aware that since January 2021, there has been stark stock outs of ARVs and other essential commodities used in the detection and management of HIV.

9. KELIN later came to learn through the media that the reason for the stock out of ARVs was as a result of a stalemate between the Kenya Medical Supplies Authority (the 3rd Respondent herein) and the United States Agency for International Development (USAID) that negatively affected the distribution of essential medicines and commodities used in the management of HIV.

10. The reason for this stalemate as widely reported was the rampant corruption and mismanagement that has pervaded the 3rd Respondent. (**Annexed hereto and marked AAM2 are copies of media reports demonstrating the lack of accountability highlighted by USAID in the distribution of ARVs)**

11. Due to this dispute, and further because of the 2nd Respondent's lack of a plan to procure essential medicines for its population of PLHIV, including the 1st Petitioner and her son are unable to access ARV medication which is necessary for their health and to preserve their lives.

12. It has also come to our attention that not only is there a lack of ARVs, but there has also been a shortage of viral load testing reagents as well as early infant diagnostic tests which are used to detect HIV in persons who present themselves for testing.

13. This resulted in interruptions in care for PLHIV, who as part of management of infection have to undergo regular testing to ensure that therapy is working as indicated. This has meant that their lives and health have been threatened.

14. KELIN with other stakeholders and communities living with HIV wrote to the 2nd Respondent asking it to fast-track resolution or to be included in the resolution of the stalemate and highlighting that various persons living with HIV have not been receiving their ARVS.

(Annexed and Marked AAM3 is the multi-Stakeholder letter dated 5th May 2021).

15. We have tried to engage the relevant state agencies, in particular the 2nd and 3rd Respondent through our network of PLHIV to address the cause of the stock outs but this has borne no fruit.

16. Some of the efforts that we have undertaken to try and get the 2nd Respondent to honour its obligations and commitment in the provision of access to medicines for PLHIV include:

a. Three letters to the Cabinet Secretary of Health by civil society have gone un-responded.

b. Three virtual meetings with PEPFAR, USAID, NACC, NASCOP and KEMSA and none which yielded any meaningful information.

c.Twitter chats and press conferences through which awareness on the issue has been raised.

d. Engagements with various parliamentary committees to seek a resolution of the issue but there has been none (when, at whose invitation?

Annexed hereto and marked AAM4 is a bundle of documents detailing the various interventions made KELIN and other civil society partners)

17. I am aware that even though the 2nd Respondent reported that the stalemate between itself and USAID had been resolved, this is in fact not the case as children living with HIV still cannot access Kaletra, a child-friendly paediatric ARV. **(Annexed hereto and marked AAM5 is a copy of a feature done on NTV demonstrating the lack of the essential drug in Kisumu County.)**

18. There is a continuing violation of the right to life and the right to health because persons living with HIV continue to be denied access to health care services, particularly to access to medicines as which is a violation of their rights to health, dignity and life.

19. This in fact not the only time that the 2nd Respondent has failed in its obligation to provide continuous and uninterrupted access to essential medication for HIV treatment and management. **Annexed hereto and marked AAM6 are news reports from 2014 to date demonstrating that Kenya regularly suffers from stockouts of ARVs that continue to put the lives and health of PLHIV in danger.**

20. The 2nd Respondent has acknowledged in various documents that it has published that there continues to be gaps in the provision of ARVs and essential commodities for the management of HIV. **(Annexed hereto and marked AAM7 is a report by the Senate Standing Committee on Health of the 2nd Respondent acknowledging the shortage of ARVs)**

21. The National Government through the Ministry of Finance and the National Treasury as well as the 2nd Respondent have admitted on various occasions that treatment for HIV in the form of ARVs is not funded through resources from the republic of Kenya. The 2nd Respondent has also admitted 75% of all interventions and programmes on HIV are funded by external donors.

(Annexed hereto and marked AAM8 is a copy of the Ministry of Health, Health Sector Working Group Report Medium Term Expenditure Framework (MTEF) For the Period 2018/19 to 2020/21 demonstrating funding for HIV and AIDS management).

22. This demonstrates a lack of appreciation of the obligation placed on the 2nd Respondent in the provision of access to essential medicines which will preserve the life and health of PLHIV. Should the 2nd respondent fail in securing access to essential medicines there is a likelihood and threat that another stockout will occur and needless severe illness and death.

23. Given the foregoing, and in the interest of safeguarding the Constitutional rights of health and life for PLHIV, I pray this Honourable Court to grant the orders set out in the Petition.

24. What is deponed to in this affidavit is within my knowledge save for information the sources whereof are otherwise disclosed.

SWORN in **NAIROBI** this 21st day of September 2023
By the said
ALLAN ACHESA MALECHE)
) **DEPONENT**
BEFORE ME)
)
)
COMMISSIONER FOR OATHS)

LYDIA W. MWANGI
COMMISSIONER FOR OATHS
P.O. Box [illegible] NAIROBI

DRAWN & FILED BY: -
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C/O KELIN
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Mobile: 0790 111578
E-mail: litigation@kelinkenya.org

AAM1
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FORM 5

REPUBLIC OF KENYA

OP.218/051/2002/0155/2233

OFFICE OF THE PRESIDENT

CERTIFICATE OF REGISTRATION

I, PROF. WILSON KIPNG'ENO KOECH, Chairman of the Non-Governmental Organizations Board, certify that the xxx KENYA LEGAL AND ETHICAL ISSUES NETWORK ON HIV/AIDS xxx has this day been registered under section 10 of the Non-Governmental Organizations Co-ordination Act as applied for.

This is Exhibit marked "AAM1" referred to in the Annexed affidavit/Declaration of ALLAN MAKOTSE
Sworn/Declared before me on this 21st day of September 2023
at NAIROBI in the Republic of Kenya
Commissioner for Oaths

Dated 20TH DECEMBER, 2001.

W. K. KOECH
Chairman of the Board

GPK 3004—200—1/2002

devex
Do Good. Do It Well.™

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INSIDE DEVELOPMENT | HIV/AIDS

This is Exhibit marked AAM 2
referred to in the Annexed affidavit/Declaration
of A.A. [illegible]
Sworn/Declared before me on this 21st
day of September 2023
at NAIROBI in the Republic of Kenya
Commissioner for Oaths

Supplies run low as Kenya and US standoff over HIV drugs

By ***Sara Jerving*** *// 21 April 2021*

Protestors gathered in downtown Nairobi to demand ARV drug release from the Port of Mombasa in Kenya. Photo by: Sara Jerving / Devex

Levi Knowles has lived with HIV for 13 years but manages it through medication. He typically receives a three-to-six-month supply of antiretroviral therapy. But in recent months, the clinic has only given him enough drugs to last about a week.

This is because the Kenyan government has been in a stand-off with the U.S. Agency for International Development over a large batch of ARV doses and other donated health supplies that have been stuck at the port of Mombasa since mid-January.

Because of this, antiretroviral treatment in the country, which is needed for the 1.2 million HIV-positive people, is running "dangerously low," according to civil society organizations. Treatment for children and lab reagents for testing HIV in babies are already completely out of stock. Most counties also don't have tuberculosis tests.

As a result of the shortages and rationing Knowles has resorted to skipping doses as he can't afford to go to the clinic every week.

"I'm playing with my immunity," he said. "I don't want to gamble with my life — but the government is gambling with my life."

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'Holding us hostage'

Jane Gotiangco, a spokesperson for the U.S.-based private firm Chemonics explained that at the end of a five-year contract between USAID and the Kenya Medical Supplies Authority, USAID instead asked the Global Health Supply Chain-Procurement and Supply Management — implemented by Chemonics and a consortium of partners — to procure HIV, malaria, and family planning commodities for Kenya.

Civil society organizations in Kenya speculate that USAID decided to not use the Kenya Medical Supplies Authority for this shipment because of allegations of corruption and mismanagement of COVID-19 funds.

> *"[The standoff] risks rolling back decades of long gains made in the fight and management of HIV/AIDS."*
>
> *— Diana Gichengo, campaigns manager, Amnesty International Kenya*

In response, the Kenyan government initially demanded 90 million Kenyan shillings ($832,000) in importation taxes on the drugs, saying it wasn't a tax-exempt government to government donation, but has since waived these taxes. But according to a statement from local civil society organizations, the government is still insisting the drugs be delivered through its own system and not USAID's private partner.

A U.S.-based health expert from a civil society organization operating in Kenya, who wished to remain anonymous, said the matter is at a standstill as the new U.S. administration sees this as a diplomatic issue, adding that the U.S. President's Emergency Plan For AIDS Relief refused to address the issue at the country's operational planning meeting for Kenya on Tuesday citing the same reason.

"For civil society that's a slap in the face, because it's literally people's lives. Access to your drugs right now — and we aren't going to talk about it because it's a diplomatic issue? No, it's a life and death issue," the source said.

A USAID spokesperson said the agency has "been working on this jointly with the Government of Kenya and other international donors ... In order to achieve this, we are having urgent and ongoing diplomatic conversations with [Government of Kenya] representatives. We do not discuss diplomatic conversations publicly."

As a stop-gap measure, the Kenyan government made an arrangement with the Global Fund to Fight AIDS, Tuberculosis and Malaria to support the country with drugs for the next three months, these shipments started this week.

Levi Knowles holds up his empty bottle of ARV pills at a protest in Nairobi, Kenya. Photo by: Sara Jerving / Devex

At a press conference in Nairobi on Tuesday, representatives from over a dozen civil society groups and people living with HIV said this recent shipment of drugs is only a bandaid to a larger problem, as it's unlikely to lead to multi-month supplies and will continue to result in people skipping doses.

"They take today, they skip tomorrow, so that they can extend the days before they go back to the clinic," said Bernard Baridi, chief executive officer at Blast, an organization for young people living with HIV.

They emphasized that many people will likely skip doses because it's impractical for them to go to the clinic every week amid COVID-19 movement restrictions, taking time off of work, paying for transport each way, and risking COVID-19 exposure. People often travel long distances for their ARVs to avoid bumping into people they know at a clinic, because of the stigma surrounding HIV.

The CSOs warned that missed doses could increase mother-to-child transmission of HIV and sexual transmission of the disease. Interrupted treatment can also lead to opportunistic infections, such as tuberculosis, and HIV drug resistance.

They called upon the Kenyan Ministry of Health to inform the public about any reforms on government "leakages" and "wastages" to "restore donor confidence." They also pleaded with USAID to immediately release the drugs to credible organizations operating in Kenya like NGOs or faith-based organizations. 175

"They are holding us hostage," said Patricia Asero, treatment advocate and chairperson of the International Community of Women Living with HIV in Kenya.

Kenya's faith leaders preach knowledge about HIV

The Kenya National AIDS Control Council has drawn on religious texts to help faith leaders deliver science-based messages about HIV prevention, treatment, and stigma to their congregations.

In a press release issued Tuesday, Amnesty International's Kenya office said it was "deeply concerned" about the drug shortages and the "lack of accountability" at Kenya Medical Supplies Authority.

The situation "risks rolling back decades of long gains made in the fight and management of HIV/AIDS," said Diana Gichengo, campaigns manager for the organization.

Difficult memories

Shortages of HIV drugs in Kenya remind 24-year-old Queenter Mugweru of a darker time in the country's history. Both her parents are HIV positive and the disease was passed along to her at birth.

When she was young, her parents didn't have access to HIV drugs. At one point, her mother got very sick. Her parents would attend support groups preparing them to die. They wrote her a book of memories to remember them by, expecting they wouldn't be around to raise her.

Thankfully, her parents survived, but her 1-year-old sibling died from the disease, making her an only child.

"I don't want us to go back to where we once were. When I look at my parents, they look much better in comparison to those days," Mugweru said. "HIV should not be

something that keeps you in bed ... not with all of the technology and where we are today."

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Global Health | Funding | Trade & Policy | Humanitarian Aid | United States | Kenya

ABOUT THE AUTHOR

Sara Jerving

sarajerving

Sara Jerving is a Senior Reporter at Devex, where she covers global health. Her work has appeared in The New York Times, the Los Angeles Times, The Wall Street Journal, VICE News, and Bloomberg News among others. Sara holds a master's degree from Columbia University Graduate School of Journalism where she was a Lorana Sullivan fellow. She was a finalist for One World Media's Digital Media Award in 2021; a finalist for the Livingston Award for Young Journalists in 2018; and she was part of a VICE News Tonight on HBO team that received an Emmy nomination in 2018. She received the Philip Greer Memorial Award from Columbia University Graduate School of Journalism in 2014.

REPUBLIC OF KENYA

DATE: 8/7/2021
TABLED BY: Sen. Mary Seneta
COMMITTEE: Health
CLERK AT THE TABLE: Kavuti Mbiyuka

TWELFTH PARLIAMENT (FIFTH SESSION)

THE SENATE

STANDING COMMITTEE ON HEALTH

REPORT ON THE STALEMATE BETWEEN THE GOVERNMENT OF KENYA AND THE UNITED STATES AGENCY FOR INTERNATIONAL DEVELOPMENT (USAID) ON HIV/AIDS COMMODITIES

Rt. Hon. Speaker
You may approve for tabling!
25/05/21

CDS
Recommended & Forwarded
24/05/2021
For DC-EG.

Clerk's Chambers,

First Floor,

Parliament Buildings,

NAIROBI.

21st May, 2021

Approved
25/5/2021

ABBREVIATIONS

MOH	-	Ministry of Health
NT	-	National Treasury
PPB	-	Pharmacy and Poisons Board
PSK	-	Pharmaceutical Society of Kenya
USAID	-	United States Agency for International Development

LIST OF ANNEXURES

1. ***Annex 1:*** Minutes of the stakeholder meetings.
2. ***Annex 2:*** Kenya Population-based HIV Impact Assessment (KENPHIA) 2018 Report.
3. ***Annex 3:*** Report by the Kenya Revenue Authority (KRA) to the National Assembly Departmental Committee on Health on the ARVs Consignment at the Port of Mombasa.
4. ***Annex 4:*** Statement by the Ministry of Health (MoH) on the Alleged Stalemate on HIV/AIDS Commodities with United States Agency for International Development (USAID).
5. ***Annex 5:*** Statement by the Ministry of National Treasury and Planning on the Alleged Stalemate on HIV/AIDS Commodities with United States Agency for International Development (USAID).
6. ***Annex 6:*** Global Fund Investigation Report on Nigeria Supply Chain: Sub-contractor invoice fraud resulted in substantial overcharging.
7. ***Annex 7:*** Request for documentation from USAID.

TABLE OF CONTENTS

PREFACE

Mr. Speaker Sir,

The Senate Standing Committee on Health is established under standing order 218(3) of the Senate Standing Orders and is mandated to, *"consider all matters relating to medical services, public health and sanitation."*

Committee Membership

The Membership of the Committee is composed of the following:

1. Sen. (Dr.) Michael Mbito, MP.
2. Sen. Mary Seneta, MP.
3. Sen. Beth Mugo, EGH, MP.
4. Sen. Beatrice Kwamboka, MP.
5. Sen. (Prof.) Samson Ongeri, EGH, MP.
6. Sen. (Dr.) Abdullahi Ali Ibrahim, CBS, MP.
7. Sen. Fred Outa, MP.
8. Sen. Ledama Olekina, MP.
9. Sen. Millicent Omanga, MP.

Mr. Speaker,

According to the Kenya Population-based HIV Impact Assessment (KENPHIA) 2018 report, Kenya had 1.3 million adult Kenyans (15-64 years) and 139,000 children (0-14 years) living with HIV in 2018. Of these, the report estimated that 79.4% of adults infected with HIV knew their status (that is, approx. 1,032,000). And of those who knew their status, 95.7% were receiving antiretroviral (ARV) treatment (or approx. 987,816 children and adults).

It is noteworthy that, Kenya has, and continues to be heavily reliant on donors for ARV medication and other HIV/AIDS commodities, particularly the United States Agency for International Development (USAID) and Global Fund.

Mr. Speaker,

The attention of the Committee was first drawn to the looming ARV crisis in Kenya following various media reports published on diverse dates between March and April, 2021 regarding an acute shortage of ARV medication. The shortage of ARVs in the country was reported to have been triggered by an alleged tax row between the Government of Kenya (GoK) and the United States Agency for International Aid (USAID). As a result, public hospitals in the counties were reported to have started rationing dwindling HIV supplies while a consignment of ARVs worth KShs. 1.1 billion was reported to have been stuck at the port of Mombasa since 18th January, 2021. Further, there were unsubstantiated media reports of the Government releasing phased out ARV drugs (that is, Zidovudine/Lamivudine/Nevirapine) to counties ostensibly in response to the ongoing shortage.

Mr. Speaker,

Consequent to the above, at a sitting of the Committee held on Wednesday, 14th March, 2021, the Committee deliberated on the alleged stalemate between the GoK and USAID and resolved to invite the Ministry of Health (MoH) and the Ministry of National Treasury and Planning to a meeting to apprise it on the following:

1. The terms and conditions of the USAID grant for HIV/AIDS antiretroviral (ARV) commodities, and other essential drugs such as antimalarials, anti-tuberculosis treatment etc;
2. Relevant information regarding existing donor financing arrangements between the GoK and development partners, particularly, USAID and Global Fund on the provision of ARVs and other essential medical commodities;
3. A chronology of the events and circumstances that had led to the stalemate between GoK and USAID with regards to the HIV/AIDS antiretroviral (ARV) crisis;
4. What had triggered the impasse, and what remedial and/or mitigating actions the GoK had taken to try and prevent it;
5. What actions/interventions the Government had taken to address the ARV crisis when it occurred, and whether they constituted a stop-gap measure or permanent solution;
6. What actions the GoK had taken, if any, to reduce donor dependency on ARVs and other essential medical commodities; and

7. What remedial legislative measures or interventions may have been required to avoid similar occurrences in the future, not only for ARVs, but also other essential medical commodities such as antimalarials, anti-TB treatment etc.

Mr. Speaker,

The Committee subsequently met with the Cabinet Secretaries of Health and National Treasury and Planning on Friday, 30th April, 2021 and Monday, 3rd May, 2021 respectively.

This report details the responses received from the Ministry of Health and the Ministry of National Treasury and Planning on the alleged stalemate. It further details the Committee's observations and recommendations based on the responses received, and other information available within the public domain.

Mr. Speaker Sir,

It is now my pleasant duty and privilege to present this report of the Standing Committee on Health, for consideration and approval by the House pursuant to Standing Order No. 226(2) of the Senate Standing Orders.

Signed..... .....

Date.....**21/05/2021**.....

SEN. MBITO MICHAEL MALING'A, MP

CHAIRPERSON, STANDING COMMITTEE ON HEALTH

ADOPTION OF THE REPORT OF THE STANDING COMMITTEE ON HEALTH OF THE SENATE

We, the undersigned Members of the Standing Committee on Health of the Senate, do hereby append our signatures to adopt the Report-

1. Sen. (Dr.) Michael Mbito, MP ....
2. Sen. Mary Seneta, MP ....
3. Sen. Beth Mugo, EGH, MP .....
4. Sen. Beatrice Kwamboka, MP ....
5. Sen. (Prof) Samson Ongeri, EGH, MP ....
6. Sen. (Dr) Abdullahi Ali Ibrahim, MP ....
7. Sen. Fred Outa, MP ....
8. Sen. Millicent Omanga, MP ....
9. Sen. Ledama Olekina, MP .....

CHAPTER ONE

INTRODUCTION

A. Establishment, Mandate and Membership of the Committee

The Senate Standing Committee on Health is established under standing order 218(3) of the Senate Standing Orders and is mandated to, *"consider all matters relating to medical services, public health and sanitation."*

The Membership of the Committee is composed of the following:

1. Sen. (Dr.) Michael Mbito, MP.
2. Sen. Mary Seneta, MP.
3. Sen. Beth Mugo, EGH, MP.
4. Sen. Beatrice Kwamboka, MP.
5. Sen. (Prof.) Samson Ongeri, EGH, MP.
6. Sen. (Dr.) Abdullahi Ali Ibrahim, CBS, MP.
7. Sen. Fred Outa, MP.
8. Sen. Ledama Olekina, MP.
9. Sen. Millicent Omanga, MP.

B. Background

According to various media reports published on diverse dates, Kenya faced an acute shortage of ARV medication from March, 2021, following an alleged tax dispute between the Government of Kenya (GoK) and the United States Agency for International Aid (USAID) over a consignment of ARVs worth KShs. 1.1 billion at the port of Mombasa.

As a result of the impasse between the GoK and USAID and ensuing shortages in ARVs, public hospitals in the country were reported to have started rationing dwindling HIV supplies to patients leading to public alarm and anxiety. Further, there were unsubstantiated media reports of the Government releasing phased out ARV drugs (that is, Zidovudine/Lamivudine/Nevirapine) to counties ostensibly in response to the ongoing shortage.

To note, Kenya has, and continues to be heavily reliant on donors for ARV medication and other HIV/AIDS commodities, particularly the United States Agency for International Development (USAID) and Global Fund.

i) HIV Data and Statistics

According to the Kenya Population-based HIV Impact Assessment (KENPHIA) 2018 report, Kenya had 1.3 million adult Kenyans (15-64 years) and 139,000 children (0-14 years) living with HIV in 2018. Of these, the report estimated that 79.4% of adults infected with HIV knew their status (that is, approx. 1,032,000). And of those who knew their status, 95.7% were receiving antiretroviral (ARV) treatment (or approx. 987,816 children and adults) ***(please see Annex 2).***

The KENPHIA 2018 report further noted that HIV prevalence was highest in Kisii (6.1%), Turkana (6.8%), Busia (9.9%), Siaya (15.3%), Kisumu (17.5%), Homabay (19.6%) and Migori (13.0%).

ii) HIV Commodities Tax Dispute between the GoK and USAID

According to a report by the Kenya Revenue Authority (KRA) to the National Assembly Departmental Committee on Health on the ARVs Consignment at the port of Mombasa ***(please see Annex 3),*** the total volume of the consignment of HIV/AIDS commodities being held at the port of Mombasa as of 30th April, 2021 was thirteen (13) forty-foot containers broken down as follows:

a) Eight (8) forty-foot containers containing 520,750 HIV self-tests;
b) Three (3) forty-foot containers containing ARVs (Dolutegravir, Lamivudine and Tenofovir Disoproxil Fumarate tablets); and
c) Two (2) containers containing ARVs (Atazor-R and Atazanavir 300mg + Ritonavir 100mg tablets).

According to the report, the MoH *vide* a letter, Ref: MOH/MED/11/3/1, dated 31st March, 2021, requested the Ministry of National Treasury and Planning (NT&P) to issue an undertaking to KRA on its behalf to pay taxes for the consignment amounting to KShs. 45,825,875.15.

Consequently, according to KRA, *vide* a letter, Ref: DFN 415/232/011, dated 6th April, 2021, the Ministry of NT&P undertook to pay the taxes, Railway Development Levy (RDL) and Import Declaration Fees (IDF) for the thirteen (13) containers. However, despite the undertaking by the Ministry of NT&P, KRA reported that owing to delays in the issuance of a permit by the Pharmacy and Poisons Board, and releases by Port Health, the consignment was yet to be cleared from Customs.

To note, prior to the above, KRA reported that since January, 2021, it had cleared seventy-eight (78) forty-foot and one (1) twenty-foot containers of medical supplies consigned to Ms. Chemonics on behalf of USAID.

iii) Evolution of the Dispute

Notwithstanding the aforementioned interventions by the MoH, Ministry of NT&P and KRA to waive taxes on the HIV commodities consignment, according to media reports, USAID is alleged to have subsequently declined to release the HIV commodities to the Kenya Medical Supplies Agency (KEMSA) for warehousing and distribution citing issues with corruption and mismanagement.

C) Methodology

Its attention having been drawn to the looming ARV crisis in the country, at a sitting of the Committee held on Wednesday, 14th March, 2021, the Committee deliberated on the alleged stalemate between the GoK and USAID and resolved to invite the Ministry of Health (MoH) and the Ministry of National Treasury and Planning to a meeting to apprise it on the following:

1. The terms and conditions of the USAID grant for HIV/AIDS antiretroviral (ARV) commodities, and other essential drugs such as antimalarials, anti-tuberculosis treatment etc;
2. Relevant information regarding existing donor financing arrangements between the GoK and development partners, particularly, USAID and Global Fund on the provision of ARVs and other essential medical commodities;
3. A chronology of the events and circumstances that had led to the stalemate between GoK and USAID with regards to the HIV/AIDS antiretroviral (ARV) crisis;

4. What had triggered the impasse, and what remedial and/or mitigating actions the GoK had taken to try and prevent it;
5. What actions/interventions the Government had taken to address the ARV crisis when it occurred, and whether they constituted a stop-gap measure or permanent solution;
6. What actions the GoK had taken, if any, to reduce donor dependency on ARVs and other essential medical commodities; and
7. What remedial legislative measures or interventions may have been required to avoid similar occurrences in the future, not only for ARVs, but also other essential medical commodities such as antimalarials, anti-TB treatment etc.

The Committee subsequently met with the Cabinet Secretaries of Health and National Treasury and Planning on Friday, 30th April, 2021 and Monday, 3rd May, 2021 respectively. A summary of the Committees' findings, observations and recommendations arising from this exercise has been captured in subsequent sections of this report.

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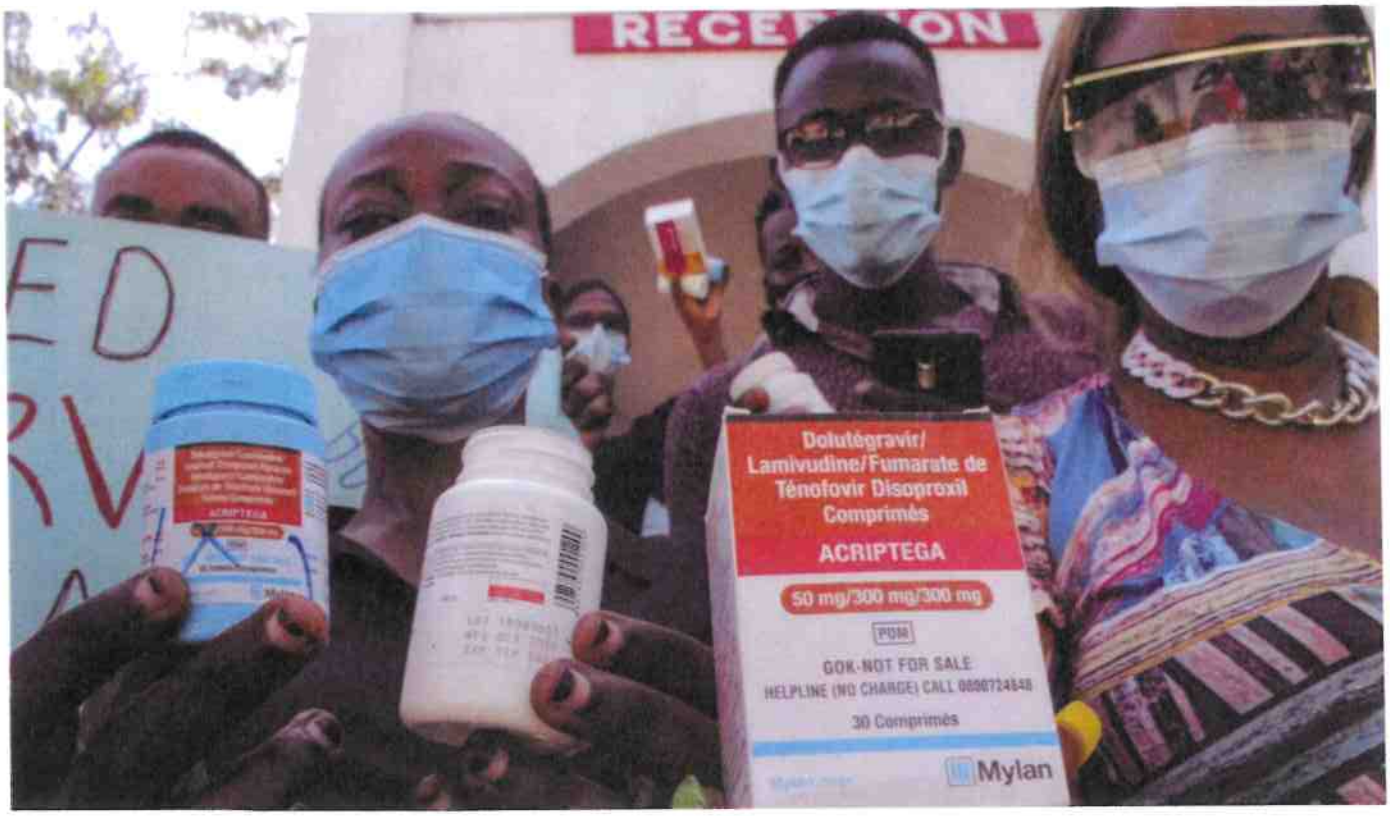
HIV drugs run short in Kenya as people say lives at risk



BY TOM ODULA
Published 10:42 AM GMT+3, April 24, 2021

NAIROBI, Kenya (AP) — Kenyans living with HIV say their lives are in danger due to a shortage of anti-retroviral drugs donated by the United States amid a dispute between the U.S. aid agency and the Kenyan government.

The delayed release of the drugs shipped to Kenya late last year is due to the government slapping a $847,902 tax on the donation, and the U.S. aid agency having "trust" issues with the graft-tainted Kenya Medical Supplies Authority, activists and officials said.

Activists on Friday dismissed as "public relations" the government's statement on Thursday that it had resolved the issue and distributed the drugs to 31 of Kenya's 47, counties. The government said all counties within five days will have the drugs needed for 1.4 million people.

"We are assuring the nation that no patient is going to miss drugs. We have adequate stocks," Kenya Medical Supplies Authority customer service manager Geoffrey Mwagwi said as he flagged off a consignment. He said those drugs would cover two months.

OTHER NEWS

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The Justice Department says there's no valid basis for the judge to step aside from Trump's DC case

England wins the toss and bowls first against New Zealand in final ODI. Ben Stokes is rested

Germany faces call to rethink sports system after World Cup-winning basketball team defies rankings

The U.S. is by far the largest donor for Kenya's HIV response.

Kenya's health minister, Mutahi Kagwe, told the Senate's health committee earlier this week that USAID had released the drug consignment that had been stuck in port. Patients are expected to receive them during the

week.

He said USAID had proposed using a company called Chemonics International to procure and supply the drugs to Kenyans due to "trust issues" with the national medical supplies body.

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Bernard Baridi, chief executive officer of Blast, a network of young people living with the disease, said the drugs would last for just a month.

He said the delay in distributing the drugs, in addition to supply constraints caused by the coronavirus pandemic, meant that many people living with HIV were getting a week's supply instead of three months.

Many of those who depend on the drugs travel long distances to obtain them and may find it difficult to find transport every week, and if they fail to take them they will develop resistance, Baridi said.

"Adherence to medication is going to be low because of access. ... If we don't get the medication, we are going to lose people," he said.

According to Baridi, children living with HIV are suffering the most due to the shortage of a drug known Kaletra, which comes in a syrup form that can be taken more easily. Parents are forced to look for the drug in tablet form, crush it and mix it with water, and it's still bitter for children to ingest.

Baridi urged Kenya's government and USAID to find a solution on who should distribute the drugs quickly, for the sake of the children.

On Thursday, about 200 people living with HIV in Kisumu, Kenya's third largest city, held a peaceful protest wearing T-shirts reading "My ARV's My Life" and carrying posters that read "A sick nation is a dead nation" and "A killer government."

Some 136,000 people live with HIV in Kisumu, or about 13% of the city's population, said local rights activist Boniface Ogutu Akach.

"We cannot keep quiet and watch this population languish just because they can't get a medicine that is lying somewhere, and that is happening because the government wants to tax a donation," he said.

Erick Okioma, who has HIV, said the government's attention has been diverted by the COVID-19 pandemic, which has affected even community perception.

"People fear even getting COVID than HIV," Okioma said, asserting that local HIV testing and treatment centers were empty.

OPEN LETTER TO THE PRESIDENT

A LETTER OF APPEAL

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AA M3

This is Exhibit marked "..."
referred to in the Annexed affidavit/Declaration
of ALHAN MALECHE
Sworn/Declared before me on this 21st
day of September 2023
at NAIROBI in the Republic of Kenya
Commissioner for Oaths

H.E. Uhuru Muigai Kenyatta, C.G.H
President of the Republic of Kenya
Commander in Chief of the Defence Forces of The Republic of Kenya
Nairobi, Kenya
info@president.go.ke

Dear H.E. President Uhuru Kenyatta,

We, the undersigned, individuals organizations, and associations, are representatives of people living with and affected by HIV including children and adolescents, health and human rights civil society and non-governmental and community-based organizations. We write this letter, pursuant to our constitutional mandate under Articles 3, 10, 43(1)a and 53(1)c of the Constitution on the responsibility to defend and protect the Constitution, the right to participate in matters concerning us and to access public information, respectively.

This is an urgent appeal that you take action and resolve commodity and supplies shortages plaguing the HIV response in the country. As matters stand now, over 1.3 million adults and children living with HIV risk losing their lives.

We are appalled that your government has made a decision to uphold long procurement processes above the lives of people living with HIV and are disturbed by the refusal by the government to offer tax waivers to donors bringing in life-saving medication. We are not able to wait for months while the government haggles with donors at the expense of the lives of PLHIV.

Mr. President, Kenya has faced an erratic supply of ARVs and acute stock-outs of laboratory supplies since February 2023. We have reached out to the Cabinet Secretary, Ministry of Health on this matter and the head of National AIDS and STI Control Programme our correspondences to them remain an unanswered. See https://nephak.or.ke/wp-content/uploads/2021/ARVs-Statement-MoH.pdf Despite verbal assurances from some of the Ministry of Health officials the dire situation has persisted, and now many people living with HIV and especially children continue to miss out on life saving treatment. This has dire consequences to the lives of people living with HIV but also the gains made in the fight against HIV stand to be eroded.

Kenyans have become aware of the importance of knowing their HIV status but at the moment, people visiting health facilities cannot be tested due to lack of testing kits and laboratory reagents. PLHIV who previously received a three-month supply of ARVs are now receiving as little as two weeks' supply. Worse, the standard of care for PLHIV has been compromised. Some PLHIV are being issued ARVs well past their expiration dates and in some instances, drugs have been dispensed in unlabeled plastic bags.

The situation for children is worse. The country has run out of pediatric diagnostic and viral load test kits and reagents. Children are being turned away without tests, resulting in inexcusable and dangerous delays in initiating HIV positive children onto life-saving treatment. This is the emergency we are now facing as we approach nearly a year without testing infants and children exposed to HIV.

On HIV treatment, a limited supply of pediatric Dolutegravir received from PEPFAR is now at extreme risk of expiring rather than keeping children healthy. This is due to an arbitrary and non-evidence-based Ministry of Health circular issued on 9th September 2021 that unnecessarily require viral load tests be done before initiating HIV positive children on this optimal, preferred line of pediatric treatment. With no viral load test kits available, the circular amounts to a ban on dispensing the life-saving medicines and means children with HIV will suffer unnecessarily.

We are appalled that your government has made a decision to uphold long procurement processes above the lives of people living with HIV and are disturbed by the refusal by the government to offer tax waivers to donors bringing in life-saving medication. We are not able to wait for months while the government haggles with donors at the expense of the lives of PLHIV.

People living with HIV, including children are no longer realizing their constitutional right to health as stipulated in Articles 43(1)(a) and 53(1)c of the Constitution of Kenya. Our lives are at risk your Excellency and we urgently need your intervention on this matter.

We request that you, in exercise of your responsibilities as the Head of Government:

1. *Acknowledge that it is the responsibility of the GOK through the Ministry of Health to provide essential medications and medical supplies for Kenyans under strategic health programs including HIV and other*
2. *Direct the MOH to procure and deliver sufficient quantities of ARVs and other medicines for treatment of HIV infection for both children and adults to avert the ongoing suffering of recipients of HIV care.*
3. *Direct the National Treasury to facilitate an emergency procurement for urgently needed HIV medicines and supplies by among other things providing the required funds and waiving the cumbersome importation taxes*
4. *Urgently direct the relevant government agencies to utilize the waiver provision of the procurement law to speed up the processes as demanded by this emergency. People with HIV cannot wait for a nine-month procurement process to play out when critical medicines and commodities are out of stock.*
5. *Direct the Ministry of Health and National Treasury to set-aside the importation taxes on donated essential medical supplies and medicines imported by recognized UN Agencies and NGOs registered in Kenya for "FREE DISTRIBUTION" in Kenya.*
6. *Direct the Ministry of Health to provide and publicize a procurement plan and budget that results in the replenishment of the full nine-month supply buffer stock of ARVs, HIV test kits and Viral load test reagents for both adults and children.*
7. *Direct the Ministry of Health to overturn the 9th September 2021 circular and remove the arbitrary and reckless requirement for viral load tests before initiating children on better, safer and well tolerated ARV when there are no pediatric viral load test kits available.*
8. *As this is a matter affecting both the National and County governments, we humbly request that you urgently convene an Extra-Ordinary Session of the National and County Government Coordination Summit to address this critical issue and agree on a joint direction on how to resolve it.*

People living with HIV, including children are no longer realizing their constitutional right to health as stipulated in Articles 43(1)(a) and 53(1)c of the Constitution of Kenya. Our lives are at risk your Excellency and we urgently need your intervention on this matter.

SIGNED:

KANCO KATIBA KELIN KENYA

This letter is endorsed by ninety eight other organisations

AMM4
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PRESS RELEASE

Kenya and US Governments Resolve Stalemate on ARVs in Kenya

Kenya has made significant progress in the HIV response. Out of the estimated 1.5 million People Living with HIV, 1.2 million are currently on long-term lifesaving antiretroviral drugs (ARVs).

However, the country recently experienced a temporal disruption in the commodity supply chain that affected the seamless distribution of ARVs to people living with HIV. As a result, eligible persons living with HIV have been receiving less than the 3-months' supply of medications. The hitch arose due to a disruption of the supply chain following misunderstanding between the Government of Kenya and United States Agency for International Development (USAID), a key donor of the HIV commodities.

To unlock the impasse, the Principal Secretary, Ministry of Health, Susan Mochache, appointed a committee on May 11, 2021 to work on modalities of resolving the stalemate. The committee drew representatives from the Ministry of Health, National AIDS Control Council (NACC), National AIDS and STI Control Programme (NASCOP), Malaria Programme, Kenya Medical Supplies Authority (KEMSA), Pharmacy and Poisons Board and the Council of Governors.

The Committee, convened by the NACC, held a series of meetings with US representatives where all outstanding issues were resolved. The resolutions include the signing of a framework and implementation letter to facilitate tax and fee waivers, and distribution of the USAID-purchased commodities. These commodities are now cleared and ready for distribution.

The NACC appreciates the long standing partnership with the US Government and will continue to work with all stakeholders to address gaps and challenges in the HIV response including the issues affecting the commodities supply chain. The Council also thanks PS Susan Mochache for her leadership to resolve this matter.

The Council looks forward to continued access to safer and efficacious drugs by People Living with HIV and the resumption of dispensation of multiple months' supply of ARV drugs as guided by Differentiated Service Delivery Model developed by NASCOP.

Dr. Ruth Laibon-Masha (PhD)
Chief Executive Officer
National AIDS Control Council

June 30, 2021

This is Exhibit marked "AMM4"
referred to in the Annexed affidavit/Declaration
of ALLAN MABEYA
Sworn/Declared before me on this 21st
day of September 2023
at NAIROBI in the Republic of Kenya

Commissioner for Oaths

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COUNCIL OF GOVERNORS

21st May, 2021

PRESS STATEMENT ON ISSUES AFFECTING COUNTY GOVERNMENTS

Today the Council of Governors held an extra-ordinary meeting to discuss issues affecting County Governments and we would like to address you on the resolutions from the meeting.

1. Impeachment of Governors

The Council has taken note of the trend of impeachments of Governors over the last one year, specifically in Kiambu County, Nairobi City County and now Wajir County.

While we appreciate the fact that impeachment is both a legal and a political process, the rule of law should prevail while undertaking the same. All the bodies involved should ensure that they are guided by the Constitution and the principles laid down by the courts on the threshold of impeachment.

The Council assures the public that it values integrity and accountability in the running of public affairs in the Counties. Nevertheless, oversight bodies must remain cognizant of the legal principles surrounding impeachment so that the exercise is not abused. The Council shall engage relevant institutions with a view to streamlining court pronouncements with the law so that the impeachment process can be anchored in legitimacy and impartiality.

2. Approval of the NHIF Report on gazettement of County Health Facilities

The Council has had previous discussions with the Ministry of Health on the NHIF cover as part of the UHC agenda, specifically refunds to the County Health facilities which was low and sometimes non-existent. An agreement was reached with the Ministry of Health and NHIF on this matter.

In this regard, County Governments have reviewed the list of NHIF contracted Health facilities with a view to verify that indeed they are County facilities as well as updating the existing list to include the new facilities which were unlisted with NHIF. These facilities will be instrumental in the implementation of Universal Health Coverage.

The list of health facilities from the Counties will be forwarded to the NHIF to ensure that they are contracted in the exercise that is set to begin on **1st July 2021.**

3. Provision of ARVs Drugs to Counties

Over the past 20 years, HIV commodities have significantly been supported by US Government and the Global Fund. These Commodities include ARVs, laboratory consumables, reagents, and HIV testing kits. There is likelihood of a looming shortage of these commodities from **1st July 2021,** posing a potential crisis in continuity of HIV care and treatment of **1.1 Million** Kenyans living with HIV. This therefore means that their health will be compromised and they risk dying due to increased HIV related infections and massive drug resistance.

As a matter of urgency, we call upon the Ministry of Health and USAID to immediately procure a third-party agent to handle the warehousing and distribution of the health commodities that are stuck at the port. Further, they are to distribute these commodities to all County facilities before **20th June 2021.**

However, both the National Government and the County Governments should have a candid conversation around how the country can move towards self-reliance in the purchase of HIV and TB drugs. In the long-term, both levels of government need to discuss sustainable HIV interventions and how we can reduce dependence on donors on such critical matters. We need to look internally and begin to rely on ourselves in the procurement of these critical commodities.

We assure the public of the Council's commitment to support devolution.

Asanteni sana.

Signed

H.E James Ongwae, EGH,CBS ,EBS
Vice-Chair, Council of Governors

NATIONAL EMPOWERMENT NETWORK OF PEOPLE LIVING WITH HIV/AIDS IN KENYA (NEPHAK)

P.O Box 75654-00200 Nairobi, Kenya Tel: +254 – 020 - 3875917 / 3862271
Telfax: + 254 02 3861376, Mobile: +254 720 209 694 / 734 685 607,
Email: info@nephak.or.ke
www.nephak.or.ke

05.05.21.

Hon. Sen. Mutahi Kagwe, EGH.
Cabinet Secretary for Health
Afya House, Cathedral Road,
P.O. Box: 30016-00100,
Nairobi.

RE: STALEMATE ON DISTRIBUTION OF ARVS & INVOLVEMENT OF PLHIV IN DISCUSSIONS

We, the undersigned, individuals, organizations and associations, are representatives of people living with and affected by HIV, health and human rights civil society and non-governmental and community-based organizations. We write this letter pursuant to our constitutional mandate under Articles 3, 10 and 35 of the Constitution on the responsibility to defend and protect the Constitution, the right to participate in matters concerning us and to access public information, respectively.

We refer to an earlier letter from the National Empowerment Network of People Living with HIV/AIDS in Kenya (NEPHAK) dated 4th March 2021. We note with regret that the letter has never been responded to. Not even an acknowledgement of receipt of the letter was provided. The ARVs stalemate is still on and people living with HIV remain anxious some having to make frequent visits to health facilities and mothers having to share their medicine with children infected with HIV.

Although we have held virtual meeting with the head of NASCOP, the discussions did not adequately address the concerns, anxiety and fears from the PLHIV community. We are especially disappointed that the voice of people living with HIV is not being considered on a matter that impacts their life. This is not in line with the provisions of Article 10 of the Kenyan Constitution that makes it an obligation for our government to facilitate public participation in decision making processes. Further it doesn't augur well with the international principles including the Principle of the Greater Involvement of People Living with HIV (GIPA), as espoused in the 1994 Paris AIDS Summit. The non-engagement of people living with HIV in the on-going discussions is already impacting negatively because the community do not know what to believe. The irreducible basis of GIPA Principle is that PLHIV engage through their networks and leadership identified by themselves: Nothing for Us Without Us.

From the media reports *(quoting the CS – National Treasury)*, we understand that half (50%) of the tax required by the KRA was waivered; and with that; the Laboratory

commodities were immediately released. We do not understand the difficulty in extending the waiver to cover ARVs. We are yet to be informed of any other issue causing this stalemate.

We take this opportunity to remind the Ministry of Health of its obligation to promote, protect, respect and fulfil the right to the highest attainable standard of health as provided for in Articles 43(1) a and 53(1) c. As such the Ministry is under an obligation to take measures to achieve the progressive realization of the right to health for adults, and the immediate realization of the right to health for children. The continued threat to the disruption in access to life-saving medicines for people living with HIV constitutes a violation of the rights to health.

We welcome the investigation that is ongoing to determine how drug combinations that were phased out made their way to a facility in Siaya county. Our members are keen to participate in this process to ensure comprehensive information is provided. We are also keen to understand how the KEMSA is having in their warehouse an ARVs regimen that was phased out months ago.

We, therefore, demand that the Ministry of Health, as per its constitutional obligation, ensures ARVs are immediately made available and accessible to PLHIVs in Kenya either by ending the stalemate with USAID and or finding an alternative that will ensure we revert to the multi-month dispensing especially during this surge of the COVID-19.

People living with HIV also recommend that the Kenya government should take up the role of procuring ARVs to those in need and leave partners to engage in other areas of the HIV response. This can only be possible with increased domestic HIV financing. The government should also explore other possibilities such as local production of medicines, including ARVs.

More importantly, we reiterate that any initiative and/or intervention aimed at improving the health and wellbeing of the PLHIV community should be people-centred and have the community (PLHIV) at the centre. In that way, the Ministry of Health will be able to sustainably act in the best interest of PLHV

Signed

i. National Empowerment Network of people living with HIV in Kenya (NEPHAK)
ii. Women Fighting AIDS in Kenya (WOFAK)
iii. The Organization of young people living with HIV in Kenya (Y+)
iv. Tuberculosis Survivors Support Group
v. Pamoja TB Group
vi. Network of TB Champions - Kenya
vii. International Community of Women Living with HIV (ICW-Kenya)
viii. Discordant Couples Organization in Kenya (DISCOK)
ix. Indigenous Muslim Women living with HIV in Kenya
x. Positive Families Network
xi. Faws Women Group
xii. KELIN

xiii. WACI Health
xiv. Health GAP
xv. AfroCAB Treatment Access Partnership
xvi. AIDS Healthcare Foundation – Kenya (AHF – Kenya)
xvii. Health Options for Young Men on HIV/AIDS
xviii. Positive Young Women Voices (PYWV)
xix. Kenya Network of HIV Positive Teachers (KENEPOTE)
xx. Movement of Men Against AIDS in Kenya (MMAAK)
xxi. Network of Men living with HIV in Kenya (NETMA+)
xxii. Lean on Med Foundation
xxiii. Most at Risk Young Mothers and Teenage Girls living with HIV (MOYOTE)
xxiv. Mombasa PLHIV Support Network (MOPESUN)
xxv. WOTE Youth Development Program
xxvi. AYARHEP
xxvii. Coalition of people Fighting HIV/AIDS and TB in Migori
xxviii. ITPC – EA
xxix. Reach-Out Centre
xxx. Kenya Sex Workers Alliance (KESWA)
xxxi. Kenya NGOs Alliance Against Malaria (KeNAAM)
xxxii. Kilifi County PLHIV Network
xxxiii. Kobat Youth Group
xxxiv. Changu ni Chema Network
xxxv. OPAHA - Wajir
xxxvi. OPHAHA – Mandera
xxxvii. KENEPOTE – Nakuru
xxxviii. Operation Hope Organization
xxxix. Bomet Shine Group
xl. Kwazi Youth Group
xli. CCC Men Support Group – Nakuru
xlii. Fountain of Hope CBO
xliii. Mother Francisca Muungano – Nandi
xliv. WEFKO CBO Garissa
xlv. Focus on Families
xlvi. Vihiga Health Centre Support Group
xlvii. South Imenti HIV Action Group
xlviii. KENEPOTE Marsabit
xlix. Nyabende Support Program – Kisumu
l. Restoration of Hope – Marsabit
li. Dandora Community AIDS Support Association (DACASA)
lii. Bar Hostess Empowerment Support Program (BHESP)
liii. Umoja ni Nguvu Self Help Group
liv. Stigma Sportsmen Fighting HIV and TB in Kenya (SPOFA)
lv. Centre for Integrated Community Empowermet (CICE)
lvi. Nelson Mandela TB/HIV Community Information CBO
lvii. Mwea Hope in Life – Embu
lviii. Nyeri PLHIV Network (NYEPLWA)
lix. KISWA
lx. Sister Vision Support Group
lxi. PIPE
lxii. Stress Free Support Group
lxiii. Jowakawaka Self Help Group
lxiv. Love and Hope Centre - Nakuru
lxv. Umbrella Women Group
lxvi. Smart Widows Support System (SWISS)
lxvii. Network of Post est HIVand AIDS Community Organization (NEPOTECH)
lxviii. Network of Key Populations Affected with HIV
lxix. Nyandarua Network of PLHA
lxx. KENAPA
lxxi. SUNRISE SUPPORT
lxxii. KENEPOTE Narok
lxxiii. Kosor Gaa
lxxiv. Marigat Support
lxxv. Laikipia East AIDS Support Group (LEISU)
lxxvi. Coalition Against Stigma
lxxvii. Tumaina Support Group – Baragoi
lxxviii. Association of PLHA in Kuria (APAK)
lxxix. UCODEV – Migori
lxxx. Kericho Shine SG
lxxxi. Tujipende Support Group
lxxxii. Yes Support Group
lxxxiii. Jikaze Support Group
lxxxiv. Echami Support Group - Maralal
lxxxv. Muital Care and support Group
lxxxvi. Cicapao Suppurt Group
lxxxvii. Mwangaza disabled shg
lxxxviii. Toretgei Support Group

lxxxix. Kimusor Support Group
xc. Kalawa People with HIV support group
xci. Kangundo Positive Teachers
xcii. Mbone Ngwone Support Group
xciii. Ambassadors of Hope CBO
xciv. Apame Support Griоup
xcv. Ambassadors of Hope Support Group
xcvi. FAWS
xcvii. Nakuru Drop In Online Centre
xcviii. DIPADS HOPE Group - Kiambaa
xcix. Iturkana Support Group
c. Kisii Township PLHIV Network
ci. Nyamira Change and live SG
cii. Himwaneti support group
ciii. Vivasile support group
civ. TESO men living with HIV
cv. Busia Children Rehabilitation Center
cvi. AnyolebekhoyeSupport Group
cvii. VHC support group - Vihiga
cviii. Pole Pole SG – Kakamega
cix. Nyamira Post HIV Test SHG

CC: Jackline Mogeni, CEO - Council of Governors
Dr. Medhin T, UNAIDS Country Coordinator, Kenya

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HEALTH
Living with HIV/AIDS
Watch Video

JESSE CHENGE November 30, 2022 News

This is Exhibit marked "AAMS" referred to in the Annexed affidavit/Declaration of ALLAN MALECHE. Sworn/Declared before me on this 21st day of September 2022 at NAIROBI in the Republic of Kenya
Commissioner for Oaths

Lack of HIV test kits hits counties ahead of Wold AIDS Day

Shortage of HIV/AIDS testing kits and condoms has hit several counties across Kenya.

In Bungoma county, officials say the shortage has lasted for over eight months, forcing medics to do targeted testing.
Kennedy Bomji County AIDS coordinator said kits donors have urged counties to do independent planning for the commodities as they are now redistributing the ones available to different countries.

Bomji said Bungoma County hit 30,644 HIV cases in 2022.

He noted that the HIV cases are going high attributing it to the three triple threat (gender-based violence, teenage pregnancy and Female genital mutilation).

He says that Kanduyi Constituency is leading in HIV/AIDS cases because it is a cosmopolitan followed by the Webuye West constituency.

He also decried the low use of condoms in the County saying that it is a major threat to the spread of HIV.

"If young girls are exposed to early sex with older men they risk getting both STI's, HIV and teenage pregnancy," he said.
Dr. Antony Akot the chairman KMPDU Western region has said that the HIV situation in the country is facing a huge challenge.

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AMM 6

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To: The National Tuberculosis, Leprosy and Lung Disease Program (NTLD-P)

1ST Floor, Afya Annex, Kenyatta National Hospital

Hospital Grounds

Nairobi, Kenya

This is Exhibit marked "AMM 6" referred to in the Annexed affidavit/Declaration of ALLAN MALEH
Sworn/Declared before me on this 21st day of September 2023 at NAIROBI in the Republic of Kenya
Commissioner for Oaths

26th July 2023

Dear Dr. Immaculate Kathure, Head of Program,

Subject: Petition to Address Tuberculosis (TB) Drug Stock-Outs and Ensure Uninterrupted Treatment Access

We, The Network of TB Champions Kenya, Representing TB Affected Communities in all 47 Counties in collaboration with other CSOs, are writing to express our profound concern regarding the current issue of DS TB drug stock-outs, which severely hampers access to life-saving medications for tuberculosis clients, which is a violation of the Constitution of Kenya Article 43 which states. "Every person has the right to the highest attainable standard of health, which includes the right to health care services, including reproductive health care."

The government has the ethical and legal responsibility to ensure free and appropriate treatment is available to every single person affected by TB.

Tuberculosis continues to be a significant health challenge in Kenya, affecting millions of lives yearly. Timely and consistent access to anti-TB medications is crucial to achieving successful treatment outcomes and preventing the development of drug-resistant strains. However, the current DS TB drug stock-out situation is getting out of hand, contributing to clients interrupting treatment and delaying the initiation of life-saving DS TB treatment for others. If not resolved soonest, the current situation will reverse the gains in ending TB in Kenya.

The Network of TB Champions Kenya , its constituents' members and collaborators acknowledge the National TB Programs efforts to ensure TB Clients receive the necessary treatment. We understand that some factors to the DSTB drug Stock out situation are beyond the control of the National TB Program , and we stand in solidarity with the efforts made to mitigate the problem . however, we believe immediate action is required to prevent further harm to TB Clients, unnecessary suffering and deaths due to interrupted and delayed treatment while safeguarding the progress made in Ending TB in Kenya.

We, therefore, petition for the following actions to be taken:

1. Financial Support: Allocate sufficient funding and resources to support TB programs, including procurement and distribution of medications, to avoid stock-outs.
2. Emergency Stockpile: Create emergency stockpiles of essential TB drugs at national and regional levels as a buffer during unforeseen circumstances and prevent stock-outs.
3. Data Transparency: Ensure transparency in drug stock levels, communication, and distribution data for effective advocacy, accountability, and resource allocation.
4. Collaboration with Pharmaceutical Companies: Engage in dialogue and collaboration with pharmaceutical companies to address manufacturing and distribution challenges that may contribute to drug shortages.
5. Early Warning Systems: Develop and implement early warning systems to detect potential drug stock-out situations in advance, allowing for timely interventions and preventing treatment disruptions.

6. Contingency Planning: Develop contingency plans at national and regional levels to swiftly respond to TB drug stock-outs and minimize their impact on patient care.
7. Monitoring and Supply Chain Strengthening: Implement robust monitoring systems to track drug stocks at all Levels (National , County , Sub -County and health facilities) and strengthen supply chains to ensure an uninterrupted flow of TB medications to facilities within the country, Build Capacity of all level providers on TB Commodity Monitoring and Accurate reporting.

By addressing the issue of TB drug stock-outs, we can safeguard the health and well-being of TB clients, prevent treatment interruptions, and make significant progress in our fight against tuberculosis.

We urge you to treat this matter with the utmost urgency and dedication it deserves. Together, we can work towards a Kenya where no individual battling tuberculosis faces unnecessary obstacles in their journey toward recovery.

We also hope that the government will issue a statement clarifying how it will be tackling this issue urgently.

Thank you for your continued support to the TB Affected communities and Commitment to Ending TB in Kenya.

Signed By:

Network of TB Champions Kenya -NTBC-K.

Stop TB Partnership Kenya.

The Kenya Legal & Ethical Issues Network on HIV and AIDS – KELIN

National Empowerment Network of People Living with HIV/AIDS in Kenya - NEPHAK .

Pamoja TB Group .

Wote Youth Development .

Y+Kenya.

Ambassadors for Youth and adolescents Reproductive Health Programme – AYARHEP.

Kenya Network of HIV Positive Teacher – KENEPOTE.

Disease Eradication Civil Society Assemblies – DECSA

Arid Land Action Forum – ALAF

Kitale HIV and Aids Positive People Survival - KHAPPS

Nelson Mandela TB HIV Information CBO

Envisioned Youths and Adolescent Ambassadors on Move - EYAAM

Trust Five Self Help Group

SWISS CBO

Youths Advocating Positive Behavior Change

Uzalendo Social Justice Center Vihiga County

KENEPA- Elgeyo Marakwet

Isiolo County Tuberculosis , HIV/AIDS and Mental Health Champions – ITAMEC

Masculinity Institute Kenya

Globe Institute of Grassroots Initiative – GIGI

Nyando Social Justice

Vision Makers CBO

Mambokaje CBO

Most at Risk Young Mothers and Teenage girls living with HIV Initiative - MOTOTE

REPUBLIC OF KENYA

DATE: 8/7/2021
TABLED BY: Sen. Mary Seneta
COMMITTEE: Health
CLERK AT THE TABLE: Kavuti Mbiyuka

TWELFTH PARLIAMENT (FIFTH SESSION)

THE SENATE

STANDING COMMITTEE ON HEALTH

REPORT ON THE STALEMATE BETWEEN THE GOVERNMENT OF KENYA AND THE UNITED STATES AGENCY FOR INTERNATIONAL DEVELOPMENT (USAID) ON HIV/AIDS COMMODITIES

Rt. Hon. Speaker
You may approve for tabling!
25/05/21

CDS
Recommended & Forwarded
24/05/2021
For DC - EG

Clerk's Chambers,

First Floor,

Parliament Buildings,

NAIROBI.

21st May, 2021

25/5/2021

PREFACE

217B

Mr. Speaker Sir,

The Senate Standing Committee on Health is established under standing order 218(3) of the Senate Standing Orders and is mandated to, "*consider all matters relating to medical services, public health and sanitation.*"

Committee Membership

The Membership of the Committee is composed of the following:

1. Sen. (Dr.) Michael Mbito, MP.
2. Sen. Mary Seneta, MP.
3. Sen. Beth Mugo, EGH, MP.
4. Sen. Beatrice Kwamboka, MP.
5. Sen. (Prof.) Samson Ongeri, EGH, MP.
6. Sen. (Dr.) Abdullahi Ali Ibrahim, CBS, MP.
7. Sen. Fred Outa, MP.
8. Sen. Ledama Olekina, MP.
9. Sen. Millicent Omanga, MP.

Mr. Speaker,

According to the Kenya Population-based HIV Impact Assessment (KENPHIA) 2018 report, Kenya had 1.3 million adult Kenyans (15-64 years) and 139,000 children (0-14 years) living with HIV in 2018. Of these, the report estimated that 79.4% of adults infected with HIV knew their status (that is, approx. 1,032,000). And of those who knew their status, 95.7% were receiving antiretroviral (ARV) treatment (or approx. 987,816 children and adults).

It is noteworthy that, Kenya has, and continues to be heavily reliant on donors for ARV medication and other HIV/AIDS commodities, particularly the United States Agency for International Development (USAID) and Global Fund.

Further, indicating that the country also expected to receive a further donation of 20 million doses from COVAX, plus 11 million of self-procured vaccines, he stated that Kenya expected to fully vaccinate its entire adult population by the end of June, 2022.

MIN. NO. SCH2/051/2020 STATEMENT BY THE CABINET SECRETARY OF HEALTH ON THE ALLEGED STALEMATE ON HIV/AIDS COMMODITIES WITH USAID

Hon. Mutahi Kagwe, Cabinet Secretary, the Ministry of Health (MoH) updated the Committee on the alleged stalemate between the Government of Kenya and USAID on HIV commodities as summarized below:

According to the CS Health, the overall framework guiding donations of HIV commodities from USAID were contained in an annual agreement between the GoK and the United States Government referred to as Kenya's Country Operational Plan (COP).

With specific regards to the terms and conditions for the management of USAID donations of HIV/AIDS ARV commodities and other essential drugs (e.g. antimalarials and anti-TB treatment), the CS stated that they were outlined in a contractual arrangement known as the Medical Commodities Program (KEMSA MCP) between USAID and KEMSA for the procurement, warehousing and distribution of medical supplies.

He further stated that the first KEMSA MCP was executed on 1st October, 2015 and was scheduled to run up to 25th September, 2020. It was the flagship framework contracting KEMSA for the procurement, warehousing and distribution of medical supplies donated through USAID.

According to the CS Health, the flagship KEMSA MCP was first scheduled to lapse on 24th September, 2020. However, before it lapsed, it was extended to 24th December, 2020 under the same terms of procurement, warehousing and distribution by KEMSA.

Subsequently, on the request of USAID, a close-out plan with KEMSA was negotiated whereby USAID reviewed the contractual terms prior to the lapse of the extension period to include warehousing and distribution and exclude procurement. Further to this, the extension period was revised to 23rd April, 2021.

On 17th March, 2021, following reports of a stalemate over HIV/AIDS commodities at the port of Mombasa, the CS Health submitted that he requested a meeting with representatives of the US

This is Exhibit marked "AMM-1" referred to in the Annexed affidavit/Declaration of ALLAN MALECHE
Sworn/Declared before me on this 21st day of September 2023 at NAIROBI in the Republic of Kenya
Commissioner for Oaths

Government and the Ministry of Foreign Affairs. During the meeting, he stated that it was established that the said consignment had been imported into the country using a private company. This had been done without the Ministry's prior knowledge and outside of the agreed framework.

He further stated that during the said meeting, USAID elaborated on its intention to review its existing collaboration with KEMSA and to use a third party for purposes of providing ARV commodities to the country. At the request of the MoH, a technical meeting to develop a framework to support this was proposed. This led to a meeting on 19th April, 2021.

That notwithstanding, he noted that the matter was still under discussion between the MoH and the US Government. He further indicated that he had urged the US Embassy to revert to using KEMSA noting that the MoH was willing to take the necessary remedial actions to increase transparency and accountability at the agency.

With regards to what factors had triggered the impasse between the GoK and USAID, the CS health cited the following:

i. Lack of communication from USAID on their intention to shift the procurement, warehousing and distribution of HIV commodities from KEMSA;
ii. A unilateral decision by USAID to procure their commitment of donations to Kenya without prior notice to the MoH thereby attracting taxes and other levies; and
iii. Failure by the USAID to communicate on a delay in the consignment of ARVs that were expected by October, 2020 as stipulated in the annual forecasting and quantification frameworks.

The CS Health further noted that despite citing various challenges with KEMSA, the undiplomatic manner in which USAID executed its decision to shift to a private third-party was unwarranted.

He further stated that the MoH had remained pro-active in its attempts to help resolve the challenges cited by USAID. For example, he stated that the MoH had initiated communications and extended invitations to USAID in an effort to understand the challenges that they were facing with regards to KEMSA. However, he reported that USAID delayed in honoring these invitations until a meeting held on 26th January, 2021 and a letter dated 29th January, 2021 whereby he was duly informed of the Agency's challenges in clearing taxes at the port.

Following receipt of the letter, the CS reported that the MoH initiated a budgetary approval process through the National Assembly Departmental Committee on Health in February, 2021 for the clearance of the consignment from USAID. Following approval by the National Assembly, the MoH requested the Ministry of National Treasury & Planning to undertake to pay taxes worth KShs. 45, 825,875 being the taxable amount for the commodities that were being held at the port as per invoices provided by USAID. The MoH further directed KEMSA to expedite distribution of the commodities once released by USAID.

Further, he stated that to prevent a recurrence of the matter, the MoH took the following actions:

- Guided USAID to sign a contractual framework that allows for tax exemptions in line with Kenya taxation policies;
- Advised USAID to change its consignee to the MoH and other relevant agencies in order to enable swift customs clearance; and
- Initiated reforms of KEMSA through the establishment of a KEMSA Reforms Committee with the support of development partners, including USAID.

In addition, in order to avert the ARV crisis, the CS Health stated that MoH had:

- Issued guidelines for shorter-term drug prescriptions aimed at averting total stock outs at patient level;
- Called down other consignments funded by Global Fund and the GoK in an effort to re-stock and solve the temporary ARV crisis;
- Initiated and sustained constant discussions with USAID aimed at ensuring that they were facilitated to clear the consignment of donations of ARVs and essential commodities; and
- Recommended long-term solutions aimed at avoiding similar occurrences in the future e.g. securing and ring-fencing domestic resources for the procurement of the life-saving commodities, expediting plans for local production of health products for purposes of promoting self-sufficiency, and donor diversification.

Noting that Kenya had over the years relied on traditional bilateral and multilateral agreements for off-budget arrangements that were subject to conditionalities and manipulations that undermined institutional capacity-building, the CS Health outlined the following actions that had been taken by the MoH to reduce donor dependency on ARVs and other essential medical commodities:

- Enhanced domestic resource mobilisation in anticipation of reductions in external resources for the HIV response.
- Enhanced efficiency and effectiveness in resource utilisation through the restructuring of strategic health programs to create synergies, eliminate duplication and gain efficiencies.

- Development of a Health Financing Transition Plan aimed at providing short- and long-term options for resource mobilisation.

The CS Health further called for the development of a legal framework to ring-fence funding for strategic health programs at National and County level, particularly with regards to health products.

MIN. NO. SCH2/051/2020 **ADJOURNMENT**

There being no other business, the meeting was adjourned at 5.25 pm.

SIGNED:.....

(CHAIRPERSON)

10/5/2021

DATE:.....

REPUBLIC OF KENYA

Ministry of Health

HEALTH SECTOR WORKING GROUP REPORT

MEDIUM TERM EXPENDITURE FRAMEWORK (MTEF) FOR THE PERIOD 2018/19 to 2020/21

This is Exhibit marked "AAM 8"
referred to in the Annexed affidavit/Declaration
of ALLAN MALECHE
Sworn/Declared before me on this 21st
day of September 2023
at NAIROBI in the Republic of Kenya
Commissioner for Oaths

November 18, 2017

FOREWORD

The Health sector developed the Kenya Health Policy, 2014–2030, which outlines the direction that the Ministry will take to ensure significant improvement in the overall status of health in Kenya in line with the Constitution of Kenya 2010, the country's long-term development agenda, Vision 2030 and global commitments such as the Sustainable Development Goals (SDGs). The Kenya Health Policy 2014-2030 demonstrates the health sector's commitment, under the government's stewardship, to ensuring that the country attains the highest possible standards of health, in a manner responsive to the needs of the population.

The Kenya Constitution (2010), gives Kenyans the right to life and the highest attainable standard of health, which includes the right to quality health care services, reproductive health, emergency care, clean, safe and adequate water for all Kenyans, reasonable standards of sanitation, food of acceptable quality and a clean healthy environment. The Constitution further obligates the State and every State organ to observe, respect, protect, promote, and fulfil the rights in the Constitution and to take "legislative, policy and other measures, including setting of standards to achieve the progressive realisation of the rights guaranteed in Article 43."

The Health Sector is responsible for the provision and coordination of the health policy formulation, ensuring quality of service delivery and regulation and control of health care. The responsibility should be guided by the understanding that good health ensures a robust population able to contribute to productivity, and overall economic development thus contributing directly to the achievement of the national poverty reduction as outlined in the Sessional Paper No. 10 of 2012 of Kenya Vision 2030.

The Health Sector recognizes the importance of efficiency and effectiveness in service delivery. However, there is need for attention to be directed at ways of measuring and documenting the resource flows, allocation and management of resources. This is effectively undertaken through public expenditure review which focuses on the following areas;

- Examination of the Government of Kenya's (GoK) policies and objectives in the health sector, and the broad programmes and activities put in place to achieve these over the next three years, annually.
- Evaluation the public health expenditures against budgetary allocations with emphasis on the composition of expenditure;
- Identification of budget related constraints and resource use;
- Review the effectiveness of expenditures;
- Assessment of the extent to which the expenditures are aligned to policies and objectives in the health sector,
- Setting out the broad annual financing requirements to implement planned activities using existing facilities and capacity, but removing short-term constraints while working to eliminate long- term constraints; and
- Establishing priorities in recognition that there are constraints of financial, technical and physical nature that must be addressed if the country is to improve its health outcomes.

The Health Sector Medium Term Expenditure Framework (MTEF) for the period 2018/19-2020/21is guided by; the Third Medium Term Plan (2018 – 2022) of Vision 2030; the Kenya Health Policy 2014 – 2030; The Health Sector Strategic Plan 2013 – 2017 and; The Constitution of Kenya 2010.

ACKNOWLEDGEMENTS

The main purpose of the Health Sector Working Group (SWG) Report is to provide legislators, policy makers, donor agencies and other stakeholders with key information on the performance of the Sector for the MTEF period that will enable them to make appropriate policies and funding decisions

The preparation of the Medium-Term Expenditure Framework (MTEF) 2018/19–2020/21) would not have been possible without the support, hard work, and endless efforts of a large number of individuals and institutions. The Team worked tirelessly to ensure the Report was completed on time.

The Health Sector comprises of the Ministry of Health and seven Semi-Autonomous Government Agencies (SAGAs) namely, Kenyatta National Hospital (KNH), Moi Teaching and Referral Hospital (MTRH), Kenya Medical Research Institute (KEMRI), Kenya Medical Supplies Authority (KEMSA), Kenya Medical Training College (KMTC), National Aids Control Council (NACC), and National Health Insurance Fund (NHIF).

The compilation of this Report would not have been successful without the professional input and dedication on the part of those involved. The MTEF preparation process was coordinated by the Offices of the Senior Chief Finance Officer (Division of Finance) and the Chief Economist (Division of Policy and Planning). We are particularly grateful to the entire MTEF Report Writing Team whose members were drawn from the National Treasury, Ministry of Devolution and Planning (State Department of Planning) and National Ministry of Health and its SAGAs.

I wish to thank all those who participated in the preparation of this Health Sector Report and whose diverse contributions made this exercise a success.

Julius Korir, CBS
PRINCIPAL SECRETARY

LIST OF ABBREVIATIONS

ACT	Artemether Combination Therapy
AIA	Appropriation in Aids
AIDS	Acquired Immuno Deficiency Syndrome
AIE	Authority to Incur Expenditures
ALARM	Advanced Labour and Risk Management
ALOS	Average Length of Stay
AMR	Antimicrobial Resistance
AMREF	African Medical and Research Foundation
ARV	Anti-Retroviral
ASAL	Arid and Semi-Arid Lands
AU	African Union
AYP	Adolescents and Young People
CAPR	Community AIDS Programme Reporting system
CASPs	County AIDS Strategic Plans
CBA	Collective Bargaining Agreement
CDC	Centre for Disease Control
CHMTs	Community Health Management Teams
CLTS	Community Lead Total Sanitation
COBPAR	Community Based Programme Activity Reporting Tool
COFOG	Classification of the Functions of Government
COG	Council of Governors
CRWPF	Central Radioactive Waste Processing and temporary storage Facility
CSOs	Community Service Organizations
E&PWSD	Elderly and Persons With Severe Disabilities
ETAT	Emergency Triage Assessment and Triage
FBOs	Faith Based Organizations
FKF	Federation of Kenya Football
FY	Financial Year
GAMR	Global AIDS Monitoring Report
GAVI	Global Alliance on Vaccines and Immunization
GDP	Gross Domestic Product
GF	Global Fund
GOK	Government of Kenya
HAIs	Hospital Acquired Infections
HISP	Health Insurance Subsidy Program
IAEA	International Atomic Energy Agency
ICT	Information, Communication and Technology
IPC	Poor Infection Prevention Control
IPPD	Integrated Payroll and Personnel Database
JICA	Japanese International Cooperation Agency
KAIS	Kenya AIDs Indicator Survey
KDHS	Kenya Demographic and Health Service

KEMRI	Kenya Medical Research Institute
KEMSA	Kenya Medical Supplies Authority
KHP	Kenya Health Policy
KHSSP	Kenya Health Sector Strategic Plan
KICD	Kenya Institute of Curriculum Development
KIPPRA	Kenya Institute of Public Policy Research and Analysis
KMTC	Kenya Medical Training College
KNBS	Kenya National Bureau of Statistics
KNH	Kenyatta National Hospital
KQMH	Kenya Quality Model for Health
KSh	Kenya Shilling
LDCs	Least Developed Countries
LMIC	Lower Middle-Income Country
LMIS	Logistics Management Information System
MCP	Medical Commodities Program
MDAs	Ministry, Department and Agency
MES	Managed Equipment Service
MHM	Menstrual Hygiene Management
MOE	Ministry of Education
MOH	Ministry of Health
MTEF	Medium Term Expenditure Framework
MTP	Medium-Term-Plan
MTRH	Moi Teaching and Referral Hospital
NACC	National Aids Control Council
NASCOP	National AIDS and STDs Control Programme
NBTS	National Blood Transfusion Services
NCD	Non-Communicable Diseases
NEPHAK	Network for Empowerment of People Living with HIV in Kenya
NGOs	Non-Governmental Organizations
NHIF	National Health Insurance Fund
NMR	Neonatal Mortality Rate
NPHL	National Public Health Laboratories
NSSF	National Social Security Fund
O&M	Operations and Maintenance
OBA	Output Based Approach
ODF	Open Defecation Free
PDQ	Process Data Quickly
PE	Personnel Emolument
PFM	Public Financial Management
PLHIV	Persons Living with HIV/AIDs
PPP	Public Private Partnership PPP
RDI	Training, Research, Development & Innovation
RH	Reproductive Health
RMNCAH	Reproductive Maternal Neonatal Child and Adolescent Health
SAGA	Semi-Autonomous Government Agency

SGDs	Sustainable Development Goals
SIAs	Supplementary Immunization Activities
SIDs	Small Inland Developing States
SLA	Service Level Agreement
SRC	Salaries and Revenue Commission
SRH	Sexual Reproductive Health
SUPKEM	Supreme Council of Kenya Muslim
SWG	Sector Working Group
TB	Tuberculosis
THP	Traditional Health Practitioner
THS-UC	Transforming Health Systems for Universal Care
TRIPS	Trade Related Intellectual Properties
UHC	Universal Health Coverage
WASH	Water, Sanitation and Hygiene
WB	World Bank
WHO	World Health Organization
WRA	Women of Reproductive Health

Table of Contents

Executive Summary

Under the Constitution of Kenya, Kenyans have the right to life and the highest attainable standard of health, which includes the right to quality health care services, reproductive health, emergency care, clean, safe and adequate water for all Kenyans, reasonable standards of sanitation, food of acceptable quality and a clean healthy environment. Constitution further states that a person shall not be denied emergency medical treatment and that the State shall provide appropriate social security to persons who are unable to support themselves and their dependants.

The Kenya Health Policy, 2014–2030 gives direction to ensure significant improvement in the overall status of health in Kenya in line with the Constitution of Kenya 2010, the country's long-term development agenda, Vision 2030 and global commitments such as the Sustainable Development Goals (SDGs). It demonstrates the health sector's commitment, under the government's stewardship, to ensuring that the country attains the highest possible standards of health, in a manner responsive to the needs of the population.

The Ministry in line with the Government pronouncement on the implementation of the Big Four Initiatives of which Universal Health Care is one of them has prepared the implementation plan for rolling out the Universal Health Care program from 2017/18 financial year to 2021/22 financial year.

The preparation of the Health Sector Working Group (SWG) Report for MTEF period 2018/19 - 2020/21 was undertaken by a team comprising the Ministry of Health and its seven SAGAs namely; Kenyatta National Hospital (KNH), Moi Teaching and Referral Hospital (MTRH), Kenya Medical Research Institute (KEMRI), Kenya Medical Supplies Authority (KEMSA), Kenya Medical Training College (KMTC), National Health Insurance Fund (NHIF), and National Aids Control Council (NACC). The Report spells out the Sector performance, achievements, key priorities and the resource requirements for the period 2018/19 - 2020/21.

Health Performance by Programmes

Preventive and Promotive and RMNCAH Services Programme

The achievements of this programme are dependent on both the National and County Governments allocating resources and delivering fully on their respective mandates through the five sub-programmes: (i) Communicable Diseases Prevention and Control, (ii) Non-Communicable Diseases Prevention and Control, (iii) Radioactive Waste Management (iv) Reproductive Maternal Neonatal Child and Adolescent Health (v) Environmental Health. The section below highlights some of the key achievements during the period 2014/15 - 2016/17.

Communicable Diseases Prevention & Control

HIV and AIDS Control

The health sector has continued to undertake interventions aimed at controlling the spread of HIV/AIDS in the country. As a result, considerable achievements have been made within the sector. The number of persons tested for HIV have risen from 7.5 million (2014/15) to 10.9

million (2015/16) and 13.4 million (2016/17). From the numbers of newly identified PLHIVs, an incremental number of PLHIVs have been initiated on life – saving antiretroviral therapy from 850,000 (2014/15) through 947,000 (2015/16) to 989,280 (2016/17). After the introduction of the new HIV Care and Treatment guidelines, all newly diagnosed PLHIVs are initiated to antiretroviral therapy immediately. These interventions have cumulatively averted over 400,000 HIV/ AIDS related deaths. In addition, the proportion of HIV positive pregnant women receiving ARVs to prevent-mother-to-child-transmission of HIV have improved from 82.2% (2014/15) through 94.1% (2015/16) to 95.3% (2016/17), leading to reduction in the number of mother – to – child transmission of HIV by half.

The key challenges facing HIV and AIDS control is dependence on donor funding as 75% of the funds spent on HIV and AIDs come from donors. The donors are not scaling up their financial support, due to other competing priorities/needs. The shrinking donor support calls for sustainable and innovative financing of HIV and AIDS from domestic sources. This is further aggravated by rebasing of the economy in September 2014 when Kenya became a Lower Middle-Income Country (LMIC) and is therefore expected to contribute more funding to HIV and AIDS. Two to three years down the line, the country may not be able to procure ARVs and related commodities using the pre-negotiated prices of poor countries.

Malaria Control

Nearly half of the population (47.3%) live in areas with a parasite prevalence of 5-10% and 18% live in areas with a parasite prevalence of 20-40%. Routine data on malaria cases shows a similar picture with majority of the cases from the malaria endemic zone and the lowest cases in the low endemic areas[1]. Malaria control interventions undertaken have led to a gradual drop in the proportion of suspected malaria cases in the outpatient attendance. The interventions undertaken include:

a) Distribution of an average of 6 million long lasting insecticide treated bed nets in the last three fiscal years. These prevention efforts have led to a gradual reduction in the burden of malaria.
b) Distribution of an average of 11 million doses of artemether combination treatment (ACT) in 2014/15, 2015/16 and 2016/17. These were accompanied by a similar amount of rapid diagnostic test kits (RDTs).

Tuberculosis Control

Kenya has made great strides in the control and prevention of tuberculosis. The proportion of successfully treated notified tuberculosis cases has hit a plateau of 89% (2014/15), 90% (2015/16) and 90% (2016/17). This has surpassed the WHO global targets of successfully treating 85% of the notified cases.
These achievements can be attributed to uninterrupted availability of anti-TB medicines, successful roll-out and implementation of high impact interventions for TB control. Moving forward, enhanced diagnosis and treatment of drug resistant TB, TB/HIV and Diabetes Mellitus integration will be critical.

[1]Revised Kenya national Malaria Strategy 2009-2018

Non-Communicable Diseases (NCDs) Prevention and Control

In Kenya, NCDs accounts for more than 50% of total hospital admissions and over 40% of hospital mortality. With projections indicating that the morbidity from HIV/AIDS, TB and other infectious diseases declining, NCDs and Injuries will be the major health burden by 2030 in Kenya.

The major NCDs of concerns in Kenya include cardiovascular diseases, cancers, diabetes mellitus, chronic respiratory diseases, injuries, alcohol and substance abuse ailments and a battery of small but very significant diseases like epilepsy, sickle cell anaemia, nutritional and birth defects all of which confer long term complications and disabilities. Towards monitoring progress to combating NCDs, the country was able to screen 127,859 (2012/13), 178,474 (2013/14) and 291,318 (2014/15) women of the reproductive age group for cervical cancer.

Radioactive Waste Management

Radioactive sources and nuclear materials are widely used in the various sectors of our economy – in medicine, road construction, industry, research, water/mineral/oil/gas exploration, power (electricity) generation, etc. Such uses generate radioactive or nuclear waste which may (inadvertently or by deliberate action) contaminate the environment thereby affect the health, safety and security of the people and destroy their property. Safe management and physical security of radioactive sources and radioactive waste are therefore mandatory requirements.

Kenya is a member State of the International Atomic Energy Agency (IAEA), a specialized Agency of the United Nations, and subscribes to IAEA's published Safety Standards on radiation and nuclear safety, nuclear security and nuclear safeguards. It is against this background and specific recommendations by the IAEA that Kenya embarked on the development of the Central Radioactive Waste Processing and temporary storage Facility (CRWPF) to ensure the safety and security of radioactive sources and intercepted nuclear materials in illicit trafficking.

There were increasing public health and environmental concerns with respect to the increasing use of radioactive materials, abandoned and illicit radioactive sources and nuclear materials, and the wastes arising there from. The Radiation Protection Board advised the Ministry of Health on a national strategy for the security of disused, illicit and orphan radioactive sources and nuclear materials as well as the associated radioactive/nuclear waste.

In 2006, the Government approved the development of the CRWPF as a national health and security project in Oloolua forest in Ngong, next to the Institute of Primate Research. The purpose is to:

- ensure safety and physical security of disused/illicit/orphan radioactive sources and nuclear materials
- safely and securely process, and temporarily store, radioactive waste for eventual disposal in a near surface repository
- prevent environmental contamination with radioactive sources/waste
- To be a knowledge transfer centre for radioactive and nuclear materials, nuclear security and safeguards.

- safeguard radioactive and nuclear materials against acts of terror

The development of the CRWPF was to be constructed in three (3) integrated Phases.

Phase I: Interim underground secure storage bunker with associated health physics and chemistry laboratories for waste processing facility.

Phase II: Environmental radiation and nuclear forensic laboratories, and offices.

Phase III: Near Surface Repository away from the CRWPF site where processed and packaged radioactive/nuclear waste would be stored for a long time.

Note: Only Phase I has been completed to date.

Currently, the CRWPF facility holds solid and liquid radioactive materials (Caesium-137, Tritium and others) warranting security against unauthorized access, theft, transfer or sabotage. The decommissioned teletherapy unit from the Kenyatta National Hospital, a Category I security risk radioactive Cobalt-60, is also currently housed at this facility. In the near future, the facility will store radioactive waste from major users in the country, disused radioactive sources, intercepted radioactive and nuclear materials which are currently stored at a radiation bunker within the current premises of the National Radiation Protection Laboratory.

Reproductive Maternal Neonatal Child and Adolescent Health

The general objective of this sub – programme is 'to reduce maternal and child mortality' that is to be achieved through Family Planning Services, Maternity and Immunisation, and requires full participation of the County Governments.

According to the KDHS 2014, infant mortality rate stands at 39 per 1000 live births, a decline from the previous rate of 52 per 1000 live births (2012/13). This decline is driven mainly by utilization of mosquito nets, increases in antenatal care, skilled attendance at childbirth and postnatal care, as well as overall improvements in other social indicators such as education and access to water. However, reduction in neonatal mortality rate (NMR) was much slower during the same period (from 31 to 22 per 100,000 live births).

The proportion of Women of Reproductive Health (WRA) using contraceptives has gradually improved from 40.7% (2014/15), through 47.4% (2015/16) to 44.9% (2016/17) as captured by routine data. In addition, the fourth ante-natal clinic coverage has also registered improvement from 51.7% (2014/15), 51.9% (2015/16) to 52.2% (2016/157). This has been matched by an even remarkable improvement in the births by skilled attendants in health facilities from 73.7% (2014/15), 77.4% (2015/16) to 77.4% (2016/17). This could largely be attributed to the implementation of the Free Maternity Services, which has been transformed to Linda Mama Program.

Immunization

Immunization services have been adversely affected by the numerous industrial action by health workers since the advent of devolution. The fully immunized child coverage has been fluctuating around 71% (2014/15), 68.5% (2015/16) and 71.7% (2016/17). During this period, a number of new antigens (vaccines) have been introduced including Rota virus, Measles – Rubella vaccine, Inactivated Polio Vaccine. In addition, the Ministry in close collaboration with all stakeholders conducted a number of successful Supplementary Immunization Activities (SIAs) in high risk regions.

Nutrition

Since 2012, there has been an enhanced policy environment to guide implementation of nutrition Programmes. Some of the achievements include development of policy and guidelines from 2012 to 2014 this includes: The National Food and Nutrition Security Policy launched October 2012, Breast Milk and Substitutes Act (2012), Mandatory fortification of flour and oils (2012), MIYCN Policy and Strategy and operational guidelines (2013), Urban Nutrition Strategy (2013–2017). Dissemination and sensitisation of the counties in the relevant policies was done in 2014/2015 financial year.

The nutrition sector has sustained some of the achievements over the three (3) years such as enhanced coordination at both national and county governments through nutrition technical forums, increased surveillance through the Months DHIS monitoring, annual SMART surveys in ASAL areas, Seasonal Assessment; and continuous capacity building of health workers on high impact nutrition interventions.

Environmental Health

The water, sanitation and hygiene (WASH) programme was implemented during the period under review. However, basic sanitation services are not yet accessible to the majority of the population with Open Defecation rates at about 14% but with regional disparities. At the same time, a real-time monitoring and evaluation system was developed for use in monitoring rural sanitation and hygiene interventions in the country. 37 counties are implementing the Community Lead Total Sanitation (CLTS) and have adopted strategies to realize an Open Defecation Free Kenya. A total of 69,250 villages have been mapped across the country out of which 4,000 have been certified as Open Defecation Free as at June 2017 in line with SDG 6.2.1 which aims at eradication of Open Defecation by 2020.

An open defecation free road map has been developed to eradicate open defecation by the year 2020; Menstrual Hygiene Management (MHM) Policy is in the final stages of finalization; 70 TOTs on menstrual hygiene management have been trained and are building capacity of County Teams on the same and together with the Ministry of Education, a teacher's handbook on MHM has been developed. Next steps will include launch and implementation of the MHM Policy and strategy, organizing more MHM trainings for counties, integrating and mainstreaming MHM in all the sectors, leveraging on the work done to mobilize for resources to support MHM activities and follow up and reporting of MHM activities in Kenya.

Poor management of health care waste potentially exposes health care workers, waste handlers, patients and the community at large to infection, toxic effects and injuries, and risks polluting the environment. The 20% of the total waste is considered hazardous material that may be infectious, toxic or radioactive. The infections, toxic effects and pollution are reduced by proper waste management. In a bid to improve medical waste management, diesel fire incinerators were installed and commissioned at Kiambu, Nyamira, Mpeketoni, Siaya, Malindi, Nakuru and Vihiga county hospitals 2014. In addition, 669 health workers from 25 health facilities were trained on medical waste management in 2014.

National Referral and Rehabilitative Services Programme

To improve curative health services there has been increased access to curative and rehabilitative emergency care. Several programs have also been undertaken to improve the health care services to the public. In the period under review, the following achievements were made.

Mental Health Hospital

Psychiatric services have been expanding rather slowly in Kenya mainly due to lack of trained staff and funds for expanding the services however, there has been efforts by the medical schools and nursing to train students to meet the national needs of our manpower r requirements. There are 8 psychiatric units established and some of them have qualified psychiatrists running these services. These are in Nakuru, Nyeri, Murang'a, Machakos, Kisumu, Kakamega, Mombasa and Kisii.

Mathari hospital remains the hub of the psychiatric services. It acts as the major referral Hospital in Kenya. Mathari Hospital is a mental hospital operating under the Mental Health Act Chapter 248 of the Laws of Kenya with a mandate of providing specialized mental health care including drug rehabilitation services, integrated preventive and curative services, forensic services for legal purposes, offer training and conduct research in mental health.

The hospital has a bed capacity of 700 and 650 available beds. In the last 3 years 2013/14 - 2015/16, the average daily inpatient was 730 patients and 266,551 patients annually, translating to 126% bed occupancy. The average annual outpatient workload for the last 3 years 2013/14 - 2015/16 was 64,842 patients. In 2015/16 alone 91,049 cases were reported, of which 85% were 5 years and older. During the period under review a Mental Health Policy was developed.

The main challenges are inadequate number of trained personnel in psychiatry, inadequate availability of the physical health infrastructure to care for mental health cases and lack of data on mental health case prevalence. The hospital is the only facility that caters for inmates who suffer from mental illness or who have committed crimes as a result of insanity. The facility however is in a dilapidated state and requires urgent attention to improve on the infrastructure.

Forensic and Diagnostic Services

Kenya National Blood Transfusion Service (KNBTS) is mandated under the National Government to ensure provision of adequate safe blood for the country. In order to achieve this KNBTS carries out its mandate through a network of Regional and satellite blood transfusion

centres strategically located in the country. KNBTS currently operates six regional and seventeen satellite centres.

International best practices and World Health Organization as well as Kenya blood policy recommends that patients should be transfused with the component of blood he/she requires as opposed to universally giving all of them whole blood. It has also been shown that close to 95% of all transfusions require blood components and only about 5% require whole blood. It has also been observed that one third of all transfusions go to children who require smaller blood volumes as compared to adults. In order to comply with best practices, KNBTS converts a certain percentage of whole blood units collected into various blood components namely packed red cells, platelets, fresh frozen plasma and cryoprecipitate. It also prepares small packs for children This process requires dedicated skilled staff, special blood bags, appropriate infrastructure including transport and blood storage equipment.

Kenya has approximately 480 transfusing facilities (GOK, Faith based and Private) of which about 350 do get blood from KNBTS; however, KNBTS is only able to meet 52% of their total needs. We are therefore proposing that with adequate support in capacity building, resources and political good will, KNBTS should be able to progressively upscale its activities and meet the County's blood in the next three years.

Managed Equipment Services

The health care infrastructure has seen unprecedented expansion and improvements with an increase in the number of health facilities from just about 9,000 before devolution to 10,000, increasing the national average facility density from 1.9 to 2.2 health facilities per 10,000 populations. About 80 percent of these facilities are at Levels 2 and 3, focused on primary health care, and include community health facilities, dispensaries and health centres. Levels 4 and 5 comprise secondary health facilities which provide specialized services. Level 6 facilities are highly-specialized tertiary hospitals (referral hospitals) and provide health care, teaching, training and research services. This classification is in accordance with the Kenya Essential Package of Health.

One of the main priority investment areas outlined in KHSSP 2014-2018 is Health Infrastructure whose aim is to ensure the complementarities of private sector investment and increase the capital investment on upgrading of existing facilities to fill the gap between what is available and required as per standard, especially the rehabilitation of 100 existing level IV facilities.

During the MTP II MOH undertook the following infrastructure projects: Construction and equipping of a Maternity block at Likoni Sub-County Hospital; construction of a 30 bed Maternity ward and Theatre at Ngong County Hospital; equipped 40 Hospitals under Managed Equipment Services Project; constructed 98 classrooms for the Medical Training College (MTC), constructed Central Radioactive Waste Processing Facility (CRWPF); Upgrading of the Health facilities in the slum areas, initiating the construction of the East Africa's Centre of excellence for skills & tertiary Education; and construction of the burns unit at Kenyatta National Hospital amongst others, construction of Neuro-Surgery Centre at Moi Teaching and Referral Hospital amongst others.

The Managed Equipment Service (MES) programme helped to embark on a comprehensive programme to upgrade 98 public hospitals, 2 in each of 47 Counties (94) and 4 National hospitals with a view to improve access to specialized services countrywide. The equipment under this project is categorized into 7 Lots; Lot 1 Theatre, targeted 98 hospitals; Lot 2 surgical and CSSD targeted 98 hospitals, Lot 5 renal, targeted 49 hospitals; Lot 6 ICU, targeted former 11 national and provincial hospitals and Lot 7 Radiology, targeted 86 hospitals. In 2015/2016 the Ministry had completed about 76% of the project, managing to fully equip 40 hospitals. For each 5 categories which included; LOT 1: Theatre equipment, 69 hospitals had been installed; LOT 2: 87 hospitals had been equipped with surgical instruments and 86 CSSD machines; LOT 5: 26 hospitals equipped with Renal equipment; LOT 6: 3 hospitals equipped with ICU equipment and LOT 7: 84 hospitals equipped with Radiology equipment. The private sector (Equipment manufacturers) has been contracted to service equipment, train equipment users and biomedical engineers for seven years.

Health Products and Technologies

The Major achievements in the period under review for KEMSA in the delivery of outputs include the following:

KEMSAs order fill rate has improved over the years under review with the ERP and LMIS. The trend has moved from 85%-2014/15 and 87% 2015/16, to the current achievement for FY 2016/17 of 85%. The management targets an order fill rate of 95% in 2017/18 and it hopes to maintain the target up to 2018/2019 through the improved efficiency in automation of all operation activities.

The order turnaround time has increased customer satisfaction. Training of over 3,000 health facilities workers on the Logistics Management Information System (LMIS) has boosted medical commodities order turnaround and has helped KEMSA address the challenges experienced in inaccuracy of quantity ordered, forecasting reduce paper work and building a data bank where facilities quantify volumes of drugs they consume. As a result, the order turnaround time has reduced from 10 days in 2014/15 to 9 days in 2015/16. However, in FY 2016/17 there was slight decline in performance to 12 days against a target of 10days. This decline was attributed to the doctors/nurses' strike experienced the better half of the financial year. Notwithstanding, the Authority targets an order turnaround of 7days in FY 2018/19.

Health Research and Development Programme

Training

Major achievements during the period 2014/2015 to 2016/2017 are as indicated below

- Infrastructural developments were undertaken that increase training opportunities. This led to increased number of campuses from 45 to 65 within the period under review
- Students admission grew from 6,500 to 12,600 during the same period
- Research projects undertaken grew from 6 to 14
- Compensation to employees grew from KSh2.09 Billion to Kshs3.01Billion in 2016/2017

REPUBLIC OF KENYA

Ministry of Health

HEALTH SECTOR WORKING GROUP REPORT

MEDIUM TERM EXPENDITURE FRAMEWORK (MTEF) FOR THE PERIOD 2018/19 to 2020/21

November 18, 2017

FOREWORD

The Health sector developed the Kenya Health Policy, 2014–2030, which outlines the direction that the Ministry will take to ensure significant improvement in the overall status of health in Kenya in line with the Constitution of Kenya 2010, the country's long-term development agenda, Vision 2030 and global commitments such as the Sustainable Development Goals (SDGs). The Kenya Health Policy 2014-2030 demonstrates the health sector's commitment, under the government's stewardship, to ensuring that the country attains the highest possible standards of health, in a manner responsive to the needs of the population.

The Kenya Constitution (2010), gives Kenyans the right to life and the highest attainable standard of health, which includes the right to quality health care services, reproductive health, emergency care, clean, safe and adequate water for all Kenyans, reasonable standards of sanitation, food of acceptable quality and a clean healthy environment. The Constitution further obligates the State and every State organ to observe, respect, protect, promote, and fulfil the rights in the Constitution and to take "legislative, policy and other measures, including setting of standards to achieve the progressive realisation of the rights guaranteed in Article 43."

The Health Sector is responsible for the provision and coordination of the health policy formulation, ensuring quality of service delivery and regulation and control of health care. The responsibility should be guided by the understanding that good health ensures a robust population able to contribute to productivity, and overall economic development thus contributing directly to the achievement of the national poverty reduction as outlined in the Sessional Paper No. 10 of 2012 of Kenya Vision 2030.

The Health Sector recognizes the importance of efficiency and effectiveness in service delivery. However, there is need for attention to be directed at ways of measuring and documenting the resource flows, allocation and management of resources. This is effectively undertaken through public expenditure review which focuses on the following areas;

- Examination of the Government of Kenya's (GoK) policies and objectives in the health sector, and the broad programmes and activities put in place to achieve these over the next three years, annually.
- Evaluation the public health expenditures against budgetary allocations with emphasis on the composition of expenditure;
- Identification of budget related constraints and resource use;
- Review the effectiveness of expenditures;
- Assessment of the extent to which the expenditures are aligned to policies and objectives in the health sector,
- Setting out the broad annual financing requirements to implement planned activities using existing facilities and capacity, but removing short-term constraints while working to eliminate long- term constraints; and
- Establishing priorities in recognition that there are constraints of financial, technical and physical nature that must be addressed if the country is to improve its health outcomes.

The Health Sector Medium Term Expenditure Framework (MTEF) for the period 2018/19-2020/21is guided by; the Third Medium Term Plan (2018 – 2022) of Vision 2030; the Kenya Health Policy 2014 – 2030; The Health Sector Strategic Plan 2013 – 2017 and; The Constitution of Kenya 2010.

ACKNOWLEDGEMENTS

The main purpose of the Health Sector Working Group (SWG) Report is to provide legislators, policy makers, donor agencies and other stakeholders with key information on the performance of the Sector for the MTEF period that will enable them to make appropriate policies and funding decisions

The preparation of the Medium-Term Expenditure Framework (MTEF) 2018/19–2020/21) would not have been possible without the support, hard work, and endless efforts of a large number of individuals and institutions. The Team worked tirelessly to ensure the Report was completed on time.

The Health Sector comprises of the Ministry of Health and seven Semi-Autonomous Government Agencies (SAGAs) namely, Kenyatta National Hospital (KNH), Moi Teaching and Referral Hospital (MTRH), Kenya Medical Research Institute (KEMRI), Kenya Medical Supplies Authority (KEMSA), Kenya Medical Training College (KMTC), National Aids Control Council (NACC), and National Health Insurance Fund (NHIF).

The compilation of this Report would not have been successful without the professional input and dedication on the part of those involved. The MTEF preparation process was coordinated by the Offices of the Senior Chief Finance Officer (Division of Finance) and the Chief Economist (Division of Policy and Planning). We are particularly grateful to the entire MTEF Report Writing Team whose members were drawn from the National Treasury, Ministry of Devolution and Planning (State Department of Planning) and National Ministry of Health and its SAGAs.

I wish to thank all those who participated in the preparation of this Health Sector Report and whose diverse contributions made this exercise a success.

Julius Korir, CBS
PRINCIPAL SECRETARY

LIST OF ABBREVIATIONS

ACT	Artemether Combination Therapy
AIA	Appropriation in Aids
AIDS	Acquired Immuno Deficiency Syndrome
AIE	Authority to Incur Expenditures
ALARM	Advanced Labour and Risk Management
ALOS	Average Length of Stay
AMR	Antimicrobial Resistance
AMREF	African Medical and Research Foundation
ARV	Anti-Retroviral
ASAL	Arid and Semi-Arid Lands
AU	African Union
AYP	Adolescents and Young People
CAPR	Community AIDS Programme Reporting system
CASPs	County AIDS Strategic Plans
CBA	Collective Bargaining Agreement
CDC	Centre for Disease Control
CHMTs	Community Health Management Teams
CLTS	Community Lead Total Sanitation
COBPAR	Community Based Programme Activity Reporting Tool
COFOG	Classification of the Functions of Government
COG	Council of Governors
CRWPF	Central Radioactive Waste Processing and temporary storage Facility
CSOs	Community Service Organizations
E&PWSD	Elderly and Persons With Severe Disabilities
ETAT	Emergency Triage Assessment and Triage
FBOs	Faith Based Organizations
FKF	Federation of Kenya Football
FY	Financial Year
GAMR	Global AIDS Monitoring Report
GAVI	Global Alliance on Vaccines and Immunization
GDP	Gross Domestic Product
GF	Global Fund
GOK	Government of Kenya
HAIs	Hospital Acquired Infections
HISP	Health Insurance Subsidy Program
IAEA	International Atomic Energy Agency
ICT	Information, Communication and Technology
IPC	Poor Infection Prevention Control
IPPD	Integrated Payroll and Personnel Database
JICA	Japanese International Cooperation Agency
KAIS	Kenya AIDs Indicator Survey
KDHS	Kenya Demographic and Health Service

KEMRI	Kenya Medical Research Institute
KEMSA	Kenya Medical Supplies Authority
KHP	Kenya Health Policy
KHSSP	Kenya Health Sector Strategic Plan
KICD	Kenya Institute of Curriculum Development
KIPPRA	Kenya Institute of Public Policy Research and Analysis
KMTC	Kenya Medical Training College
KNBS	Kenya National Bureau of Statistics
KNH	Kenyatta National Hospital
KQMH	Kenya Quality Model for Health
KSh	Kenya Shilling
LDCs	Least Developed Countries
LMIC	Lower Middle-Income Country
LMIS	Logistics Management Information System
MCP	Medical Commodities Program
MDAs	Ministry, Department and Agency
MES	Managed Equipment Service
MHM	Menstrual Hygiene Management
MOE	Ministry of Education
MOH	Ministry of Health
MTEF	Medium Term Expenditure Framework
MTP	Medium-Term-Plan
MTRH	Moi Teaching and Referral Hospital
NACC	National Aids Control Council
NASCOP	National AIDS and STDs Control Programme
NBTS	National Blood Transfusion Services
NCD	Non-Communicable Diseases
NEPHAK	Network for Empowerment of People Living with HIV in Kenya
NGOs	Non-Governmental Organizations
NHIF	National Health Insurance Fund
NMR	Neonatal Mortality Rate
NPHL	National Public Health Laboratories
NSSF	National Social Security Fund
O&M	Operations and Maintenance
OBA	Output Based Approach
ODF	Open Defecation Free
PDQ	Process Data Quickly
PE	Personnel Emolument
PFM	Public Financial Management
PLHIV	Persons Living with HIV/AIDs
PPP	Public Private Partnership PPP
RDI	Training, Research, Development & Innovation
RH	Reproductive Health
RMNCAH	Reproductive Maternal Neonatal Child and Adolescent Health
SAGA	Semi-Autonomous Government Agency

SGDs	Sustainable Development Goals
SIAs	Supplementary Immunization Activities
SIDs	Small Inland Developing States
SLA	Service Level Agreement
SRC	Salaries and Revenue Commission
SRH	Sexual Reproductive Health
SUPKEM	Supreme Council of Kenya Muslim
SWG	Sector Working Group
TB	Tuberculosis
THP	Traditional Health Practitioner
THS-UC	Transforming Health Systems for Universal Care
TRIPS	Trade Related Intellectual Properties
UHC	Universal Health Coverage
WASH	Water, Sanitation and Hygiene
WB	World Bank
WHO	World Health Organization
WRA	Women of Reproductive Health

Table of Contents

Executive Summary

Under the Constitution of Kenya, Kenyans have the right to life and the highest attainable standard of health, which includes the right to quality health care services, reproductive health, emergency care, clean, safe and adequate water for all Kenyans, reasonable standards of sanitation, food of acceptable quality and a clean healthy environment. Constitution further states that a person shall not be denied emergency medical treatment and that the State shall provide appropriate social security to persons who are unable to support themselves and their dependants.

The Kenya Health Policy, 2014–2030 gives direction to ensure significant improvement in the overall status of health in Kenya in line with the Constitution of Kenya 2010, the country's long-term development agenda, Vision 2030 and global commitments such as the Sustainable Development Goals (SDGs). It demonstrates the health sector's commitment, under the government's stewardship, to ensuring that the country attains the highest possible standards of health, in a manner responsive to the needs of the population.

The Ministry in line with the Government pronouncement on the implementation of the Big Four Initiatives of which Universal Health Care is one of them has prepared the implementation plan for rolling out the Universal Health Care program from 2017/18 financial year to 2021/22 financial year.

The preparation of the Health Sector Working Group (SWG) Report for MTEF period 2018/19 - 2020/21 was undertaken by a team comprising the Ministry of Health and its seven SAGAs namely; Kenyatta National Hospital (KNH), Moi Teaching and Referral Hospital (MTRH), Kenya Medical Research Institute (KEMRI), Kenya Medical Supplies Authority (KEMSA), Kenya Medical Training College (KMTC), National Health Insurance Fund (NHIF), and National Aids Control Council (NACC). The Report spells out the Sector performance, achievements, key priorities and the resource requirements for the period 2018/19 - 2020/21.

Health Performance by Programmes

Preventive and Promotive and RMNCAH Services Programme

The achievements of this programme are dependent on both the National and County Governments allocating resources and delivering fully on their respective mandates through the five sub-programmes: (i) Communicable Diseases Prevention and Control, (ii) Non-Communicable Diseases Prevention and Control, (iii) Radioactive Waste Management (iv) Reproductive Maternal Neonatal Child and Adolescent Health (v) Environmental Health. The section below highlights some of the key achievements during the period 2014/15 - 2016/17.

Communicable Diseases Prevention & Control

HIV and AIDS Control

The health sector has continued to undertake interventions aimed at controlling the spread of HIV/AIDS in the country. As a result, considerable achievements have been made within the sector. The number of persons tested for HIV have risen from 7.5 million (2014/15) to 10.9

million (2015/16) and 13.4 million (2016/17). From the numbers of newly identified PLHIVs, an incremental number of PLHIVs have been initiated on life – saving antiretroviral therapy from 850,000 (2014/15) through 947,000 (2015/16) to 989,280 (2016/17). After the introduction of the new HIV Care and Treatment guidelines, all newly diagnosed PLHIVs are initiated to antiretroviral therapy immediately. These interventions have cumulatively averted over 400,000 HIV/ AIDS related deaths. In addition, the proportion of HIV positive pregnant women receiving ARVs to prevent-mother-to-child-transmission of HIV have improved from 82.2% (2014/15) through 94.1% (2015/16) to 95.3% (2016/17), leading to reduction in the number of mother – to – child transmission of HIV by half.

The key challenges facing HIV and AIDS control is dependence on donor funding as 75% of the funds spent on HIV and AIDs come from donors. The donors are not scaling up their financial support, due to other competing priorities/needs. The shrinking donor support calls for sustainable and innovative financing of HIV and AIDS from domestic sources. This is further aggravated by rebasing of the economy in September 2014 when Kenya became a Lower Middle-Income Country (LMIC) and is therefore expected to contribute more funding to HIV and AIDS. Two to three years down the line, the country may not be able to procure ARVs and related commodities using the pre-negotiated prices of poor countries.

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a) Distribution of an average of 6 million long lasting insecticide treated bed nets in the last three fiscal years. These prevention efforts have led to a gradual reduction in the burden of malaria.
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There were increasing public health and environmental concerns with respect to the increasing use of radioactive materials, abandoned and illicit radioactive sources and nuclear materials, and the wastes arising there from. The Radiation Protection Board advised the Ministry of Health on a national strategy for the security of disused, illicit and orphan radioactive sources and nuclear materials as well as the associated radioactive/nuclear waste.

In 2006, the Government approved the development of the CRWPF as a national health and security project in Oloolua forest in Ngong, next to the Institute of Primate Research. The purpose is to:

- ensure safety and physical security of disused/illicit/orphan radioactive sources and nuclear materials
- safely and securely process, and temporarily store, radioactive waste for eventual disposal in a near surface repository
- prevent environmental contamination with radioactive sources/waste
- To be a knowledge transfer centre for radioactive and nuclear materials, nuclear security and safeguards.

- safeguard radioactive and nuclear materials against acts of terror

The development of the CRWPF was to be constructed in three (3) integrated Phases.

Phase I: Interim underground secure storage bunker with associated health physics and chemistry laboratories for waste processing facility.

Phase II: Environmental radiation and nuclear forensic laboratories, and offices.

Phase III: Near Surface Repository away from the CRWPF site where processed and packaged radioactive/nuclear waste would be stored for a long time.

Note: Only Phase I has been completed to date.

Currently, the CRWPF facility holds solid and liquid radioactive materials (Caesium-137, Tritium and others) warranting security against unauthorized access, theft, transfer or sabotage. The decommissioned teletherapy unit from the Kenyatta National Hospital, a Category I security risk radioactive Cobalt-60, is also currently housed at this facility. In the near future, the facility will store radioactive waste from major users in the country, disused radioactive sources, intercepted radioactive and nuclear materials which are currently stored at a radiation bunker within the current premises of the National Radiation Protection Laboratory.

Reproductive Maternal Neonatal Child and Adolescent Health

The general objective of this sub – programme is 'to reduce maternal and child mortality' that is to be achieved through Family Planning Services, Maternity and Immunisation, and requires full participation of the County Governments.

According to the KDHS 2014, infant mortality rate stands at 39 per 1000 live births, a decline from the previous rate of 52 per 1000 live births (2012/13). This decline is driven mainly by utilization of mosquito nets, increases in antenatal care, skilled attendance at childbirth and postnatal care, as well as overall improvements in other social indicators such as education and access to water. However, reduction in neonatal mortality rate (NMR) was much slower during the same period (from 31 to 22 per 100,000 live births).

The proportion of Women of Reproductive Health (WRA) using contraceptives has gradually improved from 40.7% (2014/15), through 47.4% (2015/16) to 44.9% (2016/17) as captured by routine data. In addition, the fourth ante-natal clinic coverage has also registered improvement from 51.7% (2014/15), 51.9% (2015/16) to 52.2% (2016/157). This has been matched by an even remarkable improvement in the births by skilled attendants in health facilities from 73.7% (2014/15), 77.4% (2015/16) to 77.4% (2016/17). This could largely be attributed to the implementation of the Free Maternity Services, which has been transformed to Linda Mama Program.

Immunization

Immunization services have been adversely affected by the numerous industrial action by health workers since the advent of devolution. The fully immunized child coverage has been fluctuating around 71% (2014/15), 68.5% (2015/16) and 71.7% (2016/17). During this period, a number of new antigens (vaccines) have been introduced including Rota virus, Measles – Rubella vaccine, Inactivated Polio Vaccine. In addition, the Ministry in close collaboration with all stakeholders conducted a number of successful Supplementary Immunization Activities (SIAs) in high risk regions.

Nutrition

Since 2012, there has been an enhanced policy environment to guide implementation of nutrition Programmes. Some of the achievements include development of policy and guidelines from 2012 to 2014 this includes: The National Food and Nutrition Security Policy launched October 2012, Breast Milk and Substitutes Act (2012), Mandatory fortification of flour and oils (2012), MIYCN Policy and Strategy and operational guidelines (2013), Urban Nutrition Strategy (2013–2017). Dissemination and sensitisation of the counties in the relevant policies was done in 2014/2015 financial year.

The nutrition sector has sustained some of the achievements over the three (3) years such as enhanced coordination at both national and county governments through nutrition technical forums, increased surveillance through the Months DHIS monitoring, annual SMART surveys in ASAL areas, Seasonal Assessment; and continuous capacity building of health workers on high impact nutrition interventions.

Environmental Health

The water, sanitation and hygiene (WASH) programme was implemented during the period under review. However, basic sanitation services are not yet accessible to the majority of the population with Open Defecation rates at about 14% but with regional disparities. At the same time, a real-time monitoring and evaluation system was developed for use in monitoring rural sanitation and hygiene interventions in the country. 37 counties are implementing the Community Lead Total Sanitation (CLTS) and have adopted strategies to realize an Open Defecation Free Kenya. A total of 69,250 villages have been mapped across the country out of which 4,000 have been certified as Open Defecation Free as at June 2017 in line with SDG 6.2.1 which aims at eradication of Open Defecation by 2020.

An open defecation free road map has been developed to eradicate open defecation by the year 2020; Menstrual Hygiene Management (MHM) Policy is in the final stages of finalization; 70 TOTs on menstrual hygiene management have been trained and are building capacity of County Teams on the same and together with the Ministry of Education, a teacher's handbook on MHM has been developed. Next steps will include launch and implementation of the MHM Policy and strategy, organizing more MHM trainings for counties, integrating and mainstreaming MHM in all the sectors, leveraging on the work done to mobilize for resources to support MHM activities and follow up and reporting of MHM activities in Kenya.

Poor management of health care waste potentially exposes health care workers, waste handlers, patients and the community at large to infection, toxic effects and injuries, and risks polluting the environment. The 20% of the total waste is considered hazardous material that may be infectious, toxic or radioactive. The infections, toxic effects and pollution are reduced by proper waste management. In a bid to improve medical waste management, diesel fire incinerators were installed and commissioned at Kiambu, Nyamira, Mpeketoni, Siaya, Malindi, Nakuru and Vihiga county hospitals 2014. In addition, 669 health workers from 25 health facilities were trained on medical waste management in 2014.

National Referral and Rehabilitative Services Programme

To improve curative health services there has been increased access to curative and rehabilitative emergency care. Several programs have also been undertaken to improve the health care services to the public. In the period under review, the following achievements were made.

Mental Health Hospital

Psychiatric services have been expanding rather slowly in Kenya mainly due to lack of trained staff and funds for expanding the services however, there has been efforts by the medical schools and nursing to train students to meet the national needs of our manpower r requirements. There are 8 psychiatric units established and some of them have qualified psychiatrists running these services. These are in Nakuru, Nyeri, Murang'a, Machakos, Kisumu, Kakamega, Mombasa and Kisii.

Mathari hospital remains the hub of the psychiatric services. It acts as the major referral Hospital in Kenya. Mathari Hospital is a mental hospital operating under the Mental Health Act Chapter 248 of the Laws of Kenya with a mandate of providing specialized mental health care including drug rehabilitation services, integrated preventive and curative services, forensic services for legal purposes, offer training and conduct research in mental health.

The hospital has a bed capacity of 700 and 650 available beds. In the last 3 years 2013/14 - 2015/16, the average daily inpatient was 730 patients and 266,551 patients annually, translating to 126% bed occupancy. The average annual outpatient workload for the last 3 years 2013/14 - 2015/16 was 64,842 patients. In 2015/16 alone 91,049 cases were reported, of which 85% were 5 years and older. During the period under review a Mental Health Policy was developed.

The main challenges are inadequate number of trained personnel in psychiatry, inadequate availability of the physical health infrastructure to care for mental health cases and lack of data on mental health case prevalence. The hospital is the only facility that caters for inmates who suffer from mental illness or who have committed crimes as a result of insanity. The facility however is in a dilapidated state and requires urgent attention to improve on the infrastructure.

Forensic and Diagnostic Services

Kenya National Blood Transfusion Service (KNBTS) is mandated under the National Government to ensure provision of adequate safe blood for the country. In order to achieve this KNBTS carries out its mandate through a network of Regional and satellite blood transfusion

centres strategically located in the country. KNBTS currently operates six regional and seventeen satellite centres.

International best practices and World Health Organization as well as Kenya blood policy recommends that patients should be transfused with the component of blood he/she requires as opposed to universally giving all of them whole blood. It has also been shown that close to 95% of all transfusions require blood components and only about 5% require whole blood. It has also been observed that one third of all transfusions go to children who require smaller blood volumes as compared to adults. In order to comply with best practices, KNBTS converts a certain percentage of whole blood units collected into various blood components namely packed red cells, platelets, fresh frozen plasma and cryoprecipitate. It also prepares small packs for children This process requires dedicated skilled staff, special blood bags, appropriate infrastructure including transport and blood storage equipment.

Kenya has approximately 480 transfusing facilities (GOK, Faith based and Private) of which about 350 do get blood from KNBTS; however, KNBTS is only able to meet 52% of their total needs. We are therefore proposing that with adequate support in capacity building, resources and political good will, KNBTS should be able to progressively upscale its activities and meet the County's blood in the next three years.

Managed Equipment Services

The health care infrastructure has seen unprecedented expansion and improvements with an increase in the number of health facilities from just about 9,000 before devolution to 10,000, increasing the national average facility density from 1.9 to 2.2 health facilities per 10,000 populations. About 80 percent of these facilities are at Levels 2 and 3, focused on primary health care, and include community health facilities, dispensaries and health centres. Levels 4 and 5 comprise secondary health facilities which provide specialized services. Level 6 facilities are highly-specialized tertiary hospitals (referral hospitals) and provide health care, teaching, training and research services. This classification is in accordance with the Kenya Essential Package of Health.

One of the main priority investment areas outlined in KHSSP 2014-2018 is Health Infrastructure whose aim is to ensure the complementarities of private sector investment and increase the capital investment on upgrading of existing facilities to fill the gap between what is available and required as per standard, especially the rehabilitation of 100 existing level IV facilities.

During the MTP II MOH undertook the following infrastructure projects: Construction and equipping of a Maternity block at Likoni Sub-County Hospital; construction of a 30 bed Maternity ward and Theatre at Ngong County Hospital; equipped 40 Hospitals under Managed Equipment Services Project; constructed 98 classrooms for the Medical Training College (MTC), constructed Central Radioactive Waste Processing Facility (CRWPF); Upgrading of the Health facilities in the slum areas, initiating the construction of the East Africa's Centre of excellence for skills & tertiary Education; and construction of the burns unit at Kenyatta National Hospital amongst others, construction of Neuro-Surgery Centre at Moi Teaching and Referral Hospital amongst others.

The Managed Equipment Service (MES) programme helped to embark on a comprehensive programme to upgrade 98 public hospitals, 2 in each of 47 Counties (94) and 4 National hospitals with a view to improve access to specialized services countrywide. The equipment under this project is categorized into 7 Lots; Lot 1 Theatre, targeted 98 hospitals; Lot 2 surgical and CSSD targeted 98 hospitals, Lot 5 renal, targeted 49 hospitals; Lot 6 ICU, targeted former 11 national and provincial hospitals and Lot 7 Radiology, targeted 86 hospitals. In 2015/2016 the Ministry had completed about 76% of the project, managing to fully equip 40 hospitals. For each 5 categories which included; LOT 1: Theatre equipment, 69 hospitals had been installed; LOT 2: 87 hospitals had been equipped with surgical instruments and 86 CSSD machines; LOT 5: 26 hospitals equipped with Renal equipment; LOT 6: 3 hospitals equipped with ICU equipment and LOT 7: 84 hospitals equipped with Radiology equipment. The private sector (Equipment manufacturers) has been contracted to service equipment, train equipment users and biomedical engineers for seven years.

Health Products and Technologies

The Major achievements in the period under review for KEMSA in the delivery of outputs include the following:

KEMSAs order fill rate has improved over the years under review with the ERP and LMIS. The trend has moved from 85%-2014/15 and 87% 2015/16, to the current achievement for FY 2016/17 of 85%. The management targets an order fill rate of 95% in 2017/18 and it hopes to maintain the target up to 2018/2019 through the improved efficiency in automation of all operation activities.

The order turnaround time has increased customer satisfaction. Training of over 3,000 health facilities workers on the Logistics Management Information System (LMIS) has boosted medical commodities order turnaround and has helped KEMSA address the challenges experienced in inaccuracy of quantity ordered, forecasting reduce paper work and building a data bank where facilities quantify volumes of drugs they consume. As a result, the order turnaround time has reduced from 10 days in 2014/15 to 9 days in 2015/16. However, in FY 2016/17 there was slight decline in performance to 12 days against a target of 10days. This decline was attributed to the doctors/nurses' strike experienced the better half of the financial year. Notwithstanding, the Authority targets an order turnaround of 7days in FY 2018/19.

Health Research and Development Programme

Training

Major achievements during the period 2014/2015 to 2016/2017 are as indicated below

- Infrastructural developments were undertaken that increase training opportunities. This led to increased number of campuses from 45 to 65 within the period under review
- Students admission grew from 6,500 to 12,600 during the same period
- Research projects undertaken grew from 6 to 14
- Compensation to employees grew from KSh2.09 Billion to Kshs3.01Billion in 2016/2017

	Delivery Unit	Key Outputs	Key Performance Indicators	Target 2016/17	Actual Achievements 2016/17	Target (Baseline) 2017/18	Target 2018/19	Target 2019/20	Target 2020/21
	and Epidemic Response	increased (polio surveillance)							
SP.1.2: Non-Communicable disease prevention & control	Division of NCD Control Unit	Cancer prevention interventions in women enhanced	No. of Women of Reproductive Age (WRA) screened for cervical cancer	325,000	310,677	350,000	400,000	425,000	450,000
		Establish 4 new comprehensive regional cancer treatment centres in Kisii, Mombasa, Nakuru and Nyeri	Number of cancer centres established	NA	NA	1	1	1	1
SP1.3: Radioactive waste management	Radiation Protection Board	Radiation safety enhanced	Percentage of Radiation sources monitored for safety	100%	100%	100%	100%	100%	100%
		Radiation safety enhanced	Completion of Central Radioactive Waste Processing Facility	87%	85%	90%	100%	N/A	N/A
SP.1.4: RMNCAH	Division of Family Health	Access to and uptake of FP services improved	Proportion of WRA receiving FP commodities	45%	44.9%	47%	49%	50%	51%
	Division of Family Health	Increased deliveries conducted by skilled birth attendants	% of deliveries conducted by skilled birth attendants in health facilities	78%	77.4%	79%	80%	81%	81%
	National Vaccines and Immunization Programme	Pentavalent 3 vaccination coverage increased	Proportion of children immunized with DPT/ Hep + HiB3 (Pentavalent 3)	90%	79%	90%	90%	90%	90%
		Cold Chain	Number of health facilities with on-grid cold chain equipment	N/A	N/A	N/A	400	280	25
	Dietetics & Nutrition Unit	Vitamin A supplements coverage increased	Proportion of Children aged 6-59months given 2 doses of Vitamin A supplement annually	60%	41%	70%	80%	80%	80%
SP.1.5: Environmental Health	Environmental Health Unit	Environmental Health strengthened	Number of counties implementing The Kenya Open defecation free (ODF) strategy	47	47	47	47	47	47
Programme 2: National Referral and specialized health Services ***Programme Outcome: provision of specialized services improved***									
SP2.1: Specialized Health Services	KNH	Quality of specialized care services improved	ALOS for trauma patients' days	33	39	35	32	28	26
			Average waiting time (monthly) for	7 Month	1 month	27 days	24 days	21 Days	19 days

	Delivery Unit	Key Outputs	Key Performance Indicators	Target 2016/17	Actual Achievements 2016/17	Target (Baseline) 2017/18	Target 2018/19	Target 2019/20	Target 2020/21
			radiotherapy(cancer)						
		increased specialized services	Number of Open Heart surgeries	78	61	67	74	81	89
			Number of Renal Transplant	15	7	15	20	25	30
			Number of minimally invasive surgeries done	720	456	479	503	528	554
	MTRH	Increased specialized services.	Number of specialised Laboratory investigations	553,562	553,562	581,240	610,302	640,817	672,857
			Number of Orthopaedic Surgeries Done	2,084	2,084	2188	2,297	2,413	2,534
			Number of Minimally Invasive Surgeries	1,041	1,041	1093	1,148	1,205	1,265
			ALOS for Trauma Patient Days	15	15	14	13	12	12
			Number of Mental Health Patients Treated	3,583	3,762	3,950	4,147	4,355	4,573
			No. of Radiological investigations	31,790	31,790	33,380	35,049	36,800	38,641
	Mathari Hospital	Access to specialized health services improved	No of patients receiving in-patient mental health services	3,000	2,819	3,000	3,100	3,300	3,450
	National Blood Transfusion Services	National demand for blood and blood products met	Number of units of Blood demand met	250,00	158,378	280,000	300,000	320,000	330,000
			Percentage of whole blood units collected converted into components	80%	69%	85%	90%	95%	95%
SP2.5: Health Products &Technologies	Kenya Medical Supplies Authority	Availability of Health Products & technologies	% order refill rate for HPTs	90%	85%	95%	95%	95%	95%
			Order turnaround time	10	12	7	7	7	7
		National Commodities Storage centre	% completion rate	40%	40%	60%	90%	100%	N/A
Programme 3: Health Research and Development									
Programme Outcome: Increased knowledge and innovation for effective health delivery									
SP3.1: Pre-Service and In-Service Training	Kenya Medical Training College	Health professionals graduating from KMTCs	Number of pre-service middle level health professionals graduating from KMTCs	7,629	8,534	8,731	9,481	10,421	11,351
			Number of in-service middle level health professionals graduating from KMTCs	413	423	469	519	579	649
		Increased number of training opportunities	Number of new intake	12,000	12,600	12,800	13,000	13,200	13,400
		Policy document	Research projects	8	14	16	18	20	22
SP3.2: Health Research	Kenya Medical Research	Innovative research finding in	Number of policy contributions	3	5	1	1	1	1

	Delivery Unit	Key Outputs	Key Performance Indicators	Target 2016/17	Actual Achievements 2016/17	Target (Baseline) 2017/18	Target 2018/19	Target 2019/20	Target 2020/21
	Institute	application.							
		response to national health research priorities	New research protocols developed & approved	200	199	215	220	225	230
			Completed Research Projects	10	35	10	12	14	16
		production and utilisation of research	Published Papers	216	280	280	290	300	310
			Hold Scientific & Health Conferences	2	2	2	2	2	2
		support of counties health research	Counties supported	5	5	47	47	47	47
		Critical mass of human resource developed	Number of graduate researchers enrolled	75	36	40	40	40	40
Programme 4: General Administration & Support Services ***Programme Outcome: Responsive health leadership and administration***									
SP4.1: General Administration	General Administration	Customer satisfaction index	Customer satisfaction index	1	0	1	1	1	1
	Human Resource	Reviewed Schemes of service	No of Schemes of service submitted for approval	3	9	3	3	3	2
		Incentive frameworks finalized	finalized frameworks	2	2	2	2	2	2
		Staff sensitized on performance appraisal System	Sensitization report	1	1	1	1	1	1
		Staff with PWD mapped	No of staff with PWD appropriately mapped	N/A	100%	100%	100%	100%	100%
	Management & Development	Enhanced capacity building & competency development	No. MoH staff projected and trained	100	180	100	100	100	200
		Health workers from national and county level seeking further training supported	Number of health workers supported	1350	1350	1350	1350	1350	1350
		Health workers proceeding on retirement undergo pre-retirement training	% of retirees trained	100	100	100	100	100	100
	ICT Unit	ICT Services strengthened	Ratio of staff to computers (Technical % Non-Technical).	1:1 & 1:10	1:1 &1:10	1:1 & 1:10	1:1 & 1:10	1:1 & 1:10	1:1 & 1:10
	Department of Inter-	Major intergovernmental	No. of forums planned and held	4	4	4	4	4	4

	Delivery Unit	Key Outputs	Key Performance Indicators	Target 2016/17	Actual Achievements 2016/17	Target (Baseline) 2017/18	Target 2018/19	Target 2019/20	Target 2020/21
	Governmental Affairs & Coordination	health system policy issues discussed							
	General Administration	Refurbishment of Afya House and replacement of Lifts		N/A	N/A	0%	30%	30%	40%
SP4.2: Financing and planning	Finance division, planning and M&E	Financial resources efficiently utilized	percentage absorption of budgeted funds	100%	89%	100%	100%	100%	100%
		Increased public health sector financial resources	Total of A-in-A collected by the Ministry	10.4 Billion	8.6 Billion	10.6Billion	10.8 Billion	11.0 Billion	11.5 Billion
		Quarterly review reports	Performance review reports developed	4	4	4	4	4	4
			No. of strategies, plans and guidelines developed	2	3	2	2	2	3
Programme 5: Health Policy, Standards and Regulations ***Programme Outcome: Strengthened policy and population***									
SP5.1: Health Policy	Division of Health Policy; Division of Health Financing	Dissemination of the Kenya Health Policy 2014-2030	No. of counties	N/A	N/A	N/A	47	NA	NA
		Development of the Kenya Health Sector Strategic Plan 2018-2023	Health Sector Strategic Plan Document	N/A	N/A	N/A	1	NA	NA
		Development of the Ministerial Strategic Plan 2018-2022	Ministerial Strategic Plan Document	N/A	N/A	N/A	1	NA	NA
SP5.2: Social Protection in Health	Division of Health financing	Increased access to health services through subsidies	No of vulnerable persons accessing subsidized health insurance	160,710	171,800	180,000	180,000	180,000	N/A
			No of elderly persons accessing subsidized health insurance	42,000	42,000	42,000	181,000	200,000	250,000
		Policy framework developed for UHC	Health Financing Strategy	Strategy	Draft Strategy	Final Strategy	Legislation	Legislation	N/A
SP5.3: Health Standards & regulations	Dept. of Health Standards, Quality Assurance and Regulation	Quality standardized care is provided by all health facilities and registered/ licensed health professionals	% of health facilities meeting defined minimum standards	N/A	N/A	50%	60%	70%	80%
		ISO Certification	Attainment of ISO 9001-2015	ISO 9001-2008	ISO 9001-2008	ISO 9001-2008	ISO 9001-2015	ISO 9001-2015	

3.1.3 Programmes by order of ranking

To achieve maximum outcome from the sector investments, the programmes have been ranked using the following criteria;

1. Preventive, Promotive and RMNCAH
2. National Referral and Specialized Services
3. Health Policy, Standards and Regulations
4. Health Research and Development
5. General Administration & Support Services

3.2 Criteria for programme prioritization

In ranking the Programs, reference was made to the **Treasury Circular No 9/2017 (Ref No. ES 1/03)** dated **30th August 2017** that states the below mentioned Criteria to be used for prioritisation/ranking: -

1 Programme Performance Review findings of the on-going programmes;
2 Linkage of the programme with the objectives of the Medium-Term Plan of Kenya Vision 2030 for the period 2013 – 2017;
3 Linkage of the programme to the Jubilee administration flagship projects/interventions;
4 Degree to which a programme addresses core poverty interventions;
5 Degree to which the program is addressing the core mandate of the Ministry, Departments and Agencies;
6 Expected outputs and outcomes of the program;
7 Linkage of a program with other programmes;
8 Cost effectiveness and sustainability of the programme;
9 Immediate response to the requirements and furtherance of the implementation of the Constitution.

Scoring Method

- All the above criteria carry an equal score of 1 mark.
- A programme that meets the above 9 criteria scores 9 marks
- Degree to which the programme meets criteria is awarded 0.25, 0.5, 0.75 or 1 marks

3.3 Analysis of Resource Requirement versus Allocation

The requirement for the period 2018/19 is KSh.115.9 billion compared to a resource allocation of KSh.70.36 billion. Further, requirements are KSh.124.4 billion and KSh.134.3 billion for the 2019/20 and 2020/21 respectively. The Sector's resource requirements are guided by the sector policy commitments as broadly articulated in the Vision 2030 and more specifically in the third Medium Term Plan (2018 – 2022) while ensuring alignment of the Health Sector policies.

Table 3.2.1 Recurrent requirement versus allocation

Category		REQUIREMENT (KSh. Millions)			ALLOCATION (KSh. Millions)		
	2017/18 estimates	2018/19	2019/20	2020/21	2018/19	2019/20	2020/21
Gross	**30,722**	**44,657**	**45,633**	**45,882**	**35,680**	**33,624**	**33,908**
AIA	3,978	3,978	3,978	3,978	3,978	3,978	3,978
NET	26,744	40,679	41,655	41,904	31,702	29,646	29,930
Compensation to Employees	6,959	12,461	13,645	13,570	8,668	7,383	7,604
Transfers	21,989	24,333	23,678	23,678	22,180	21,332	21,312
Other Recurrent	1,774	7,863	8,309	8,634	4,832	4,910	4,992

Table 3.2.2 Development requirement versus allocation

Category		REQUIREMENT (KSh. Millions)			ALLOCATION (KSh. Millions)		
	2017/18 Estimates	2018/19	2019/20	2020/21	2018/19	2019/20	2020/21
Gross	**30,979**	**71,198**	**78,812**	**88,420**	**34,679**	**35,119**	**35,843**
GOK	13,023	53,448	61,062	70,670	16,929	17,369	18,093
Loans	6,877	7,727	7,727	7,727	7,727	7,727	7,727
Grants	11,078	10,023	10,023	10,023	10,023	10,023	10,023
Local AIA	-	-	-	-	-	-	-
Other Development	-	-	-	-	-	-	-

Table 3.2.3: Summary of Big Four Intervention: DRIVERS

PROGRAMMES/ PROJECTS	Output	Target					Estimated Cost	Baseline Allocation 2017/18			Allocation 2018/19			2019/20	2020/21
		Baseline 2017/18	2018/19	2019/20	2020/21	2021/22		GOK	PPP/Donor	Total	GOK	PPP/Donor	Total	Gross Projection	
PROGRAMME 1: PREVENTIVE, PROMOTION AND R.M.N.C.A.H							**62,436**	**1,689**	**5,470**	**7,159**	**1,725**	**7,004**	**8,729**	**15,569**	**15,569**
Establisment of Six new comprehensive cancer centres	No. of cancer centres established		1	2	2	1	17,000	400	-	400	400	-	400	5,400	5,400
Health Sector Development (Rep. Health and HIV/AIDS) Commodity - KFW	No. of women of reproductive age (WRA) reclining family planning commodities	30%					45,436	-	270	270	-	270	270	270	270
Health System Management (GAVI)	Proportion of children immunized with DPT/Hep +HiB3	90%	90%	90%	90%	90%		-	2,600	2,600	-	2,600	2,600	2,600	2,600
Procurement of Family Planning & and Reproductive Health Commodities	No. of women of reproductive age (WRA) reclining family planning commodities							73	-	73	64	-	64	64	64
Vaccines and Immunizations (GOK)	Proportion of children immunized with DPT/Hep +HiB3	90%	90%	90%	90%	90%		703	-	703	703	-	703	703	703
HIV/AIDS Round 7 (Global Fund)	No of People living with HIV on ARVs	1,234,875	1,369,731	1,302,303				-	760	760	-	1,095	1,095	2,095	2,095
Tuberculosis Round 6 (Global Fund)	No of first line anti TB medicine Doses Distributed	87,471	86,597	90,000				403	200	603	403	605	1,008	1,749	1,749
Malaria Round 10 (Global Fund)	No. Artemether Combination Therapy (ACT) Doses Distributed	12M	12M	12M	12,M	12,M		-	1,200	1,200	-	1,200	1,200	1,200	1,200
Procurement of Ant TB Drugs not Covered under Global Fund	No of first line anti TB medicine Doses Distributed	87,471	86,597	90,000				110	-	110	155	-	155	155	155

(GOK)																
Nutrition (UNICEF)	Proportion of children with severe and moderate malnutrition receiving treatment	80%	90%	90%	90%	90%		-	68	68	-	860	860	960	960
Environmental Health Services (UNICEF)	No. of Counties implementing the Kenya Open Defecation	47	47	47	47	47		-	50	50	-	50	50	50	50
Food and Nutrition Support for Vulnerable Populations Affected by HIV (WFP)	No. of vulnerable persons affected by HIV/AIDs accessing Nutritional feeds as prescribed	250,000	250,000	250,000	250,000	250,000		-	324	324	-	324	324	324	324
Programme 2: NATIONAL REFERRAL & RAHABILITATIVE SERVICES								**95,442**	**5,000**	**-**	**5,000**	**9,400**	**-**	**9,400**	**19,421**	**24,421**
Managed Equipment Services (MES)	No. of Hospitals equipped	98	119	119	119	119		45,442	5,000	0	5,000	9,400	-	9,400	9,421	9,421
Establish 10 new Referral Hospitals	No. of Referral Hospitals established		2	2	3	3		50,000	-	-	-	-	-	-	10,000	15,000
Programme 4: GENERAL ADMINISTRATION AND SUPPORT SERVICES								**55,550**	**7,009**	**1,755**	**8,765**	**9,618**	**2,995**	**12,613**	**12,684**	**12,390**
Sub-Activity 1.3 : Pensioners	No. of People covered		300,000	360,000	432,000	480,000		-	0	-	-	-	-	-	-	-
Activity 3: Removal of user fees	No. of outpatient attendance	45,000,000	55,000,000					-	-	-	-	900	-	900	900	900
Activity 4: Informal Sector (Voluntary)	No. of Informally employed	3,140,202	4,710,303	6,594,424	9,232,194	12,001,852		-	-	-	-	-	-	-	-	-
Activity 5: Formal Sector	No. of formally employed	3,800,000	3,800,000	3,925,400	4,054,938	4,188,751		-	-	-	-	-	-	-	-	-
Support to Universal Health Coverage - DENIDA									-	855	855	-	1,095	1,095	1,024	-
Wavers and Exemptions	No. of Patients Exempted/							1,200	-	-	-	-	-	-	300	300

staff attain mandatory retirement age. Upon settling of the unpaid pension, the financial implication annually is will be expected to be KSh 100 Million.

4. **Research funding**

KEMRI was allocated KSh.224M during the financial year 2014/2015 and 2015/2016 and KSh 260M in 2017/18 for the purpose of conducting research on identified national and county priority areas. During this period major research undertakings included research on the affects Khat (Miraa) on human health and welfare, research on pyrethrum and research on cancer and other non-communicable diseases, as well as other health challenges of national concern. Investment in health research will enhance Kenya's economic development and growth. In consideration of the enormous challenges and research needs, KEMRI requires funds in the amount of **Kes.480, 000,000/=** in financial 2017/2018 for continuity and to ensure sustainable support for research within the institute. An annual commitment to support research through exchequer funding will go a long way in enhancing research capacity at KEMRI for national development.

B. Capital Funding

1. **Construction of research infrastructure**

KEMRI being a national Health research institution has research facilities in Nairobi, Kilifi, Kisumu and Busia. In order to realize its mandate, the institute aims at upgrading research infrastructure for conducting research that will provide evidence- informed policies and interventions aimed at reduction of disease burden and supporting the achievements of the highest level of health as envisioned in Kenya's vision 2030. This is in response to the increasing demand for KEMRI to build research capacities to address the local (county specific) health needs through involvement of communities in the management of research and health research services/ activities. The research infrastructure is expected to maintain high levels of biosafety standards and international standards. The following is a breakdown of infrastructure to undertaken:

1. sample storage and management facility – **KSh 40 million**
2. Construction of research laboratories – **KSh 55m**
3. Construction of research regulation and coordination facility – **KSh 250m**
4. ICT infrastructure and automation – **KSh 65m**
5. Construction of research administration and conference block - **KSh 300m**
6. Rehabilitation of sewer lines and waste treatment ponds in Busia – **KSh 40m**

3.4 Analysis of Funding for Capital projects

There was a total of 76 capital projects at various stages of completion in the sector as at FY 2017/18 as listed in Annex III. These capital projects were allocated a total of KSh. 31 Billion during the financial year 2017/18, comprising of KSh. 18 Billion from development partners (57.7%) and KSh. 13 billion from the GOK (42.3%). The amounts are projected to increase to KSh 55 Billion, reducing to KSh 45 Billion and KSh. 37 Billion in financial years 2018/19, 2019/20, 2020/2021 respectively.

During the financial year 2017/18, health policy standards and regulations program received a total of KSh. 10 Billion, national referral and rehabilitative services a total of KSh 23.8 Billion and preventive promotive & RMNCH receiving KSh. 14 Billion. Capital projects receiving funding priority in the financial year 2017/18 were Free Maternity Project (KSh 3.8 Billion, GOK) and Transforming Health systems for Universal Care (THS-UC) (KSh. 4.2 Billion, WB) Managed Equipment Service-Hire of Medical Equipment (KSh. 5 Billion, GOK) all under health policy standards and regulations program.

Some of the challenges experienced by the sector include lack of sufficient funds especially counterpart funding, slow disbursement of funds by development partners, litigation issues and cost overrun among others.

In the next MTEF period the Sector was given GOK ceilings of KSh.16.9 billion, KSh.17.3 billion and KSh.18.0 billion in the FY 2018/19,2019/20 and 2020/21 respectively for Capital Projects. From the amount allocated in 2018/19 KSh.14.6 billion was for Strategic Intervention Projects namely Managed Equipment Service-Hire of Medical Equipment for 120 Hospitals, Free Maternity Program, Cancer Institute, Purchase of the Teaching Equipment – KMTC and Up Grade of Health Centres in slums and KSh.2.3 billion was for other projects.

The Ministry of Health Headquarters received the highest allocation out of the government sharable financing at KSh.1.6 Billion, while the Moi Teaching and Referral Hospital received KSh.30 Million, The National Aids Control Council KSh.66.4 Million, Kenya Medical Training College Kshs.197.6 Million, Kenya Medical Research Institute KSh.229 Million, Kenya Medical Supplies Authority KSh.94Million and Kenyatta National Hospital KSh.40 Million. Details are as in Annex III.

3.5 Resource Allocation criteria

The sector adopted the following criteria in the allocation of resources for the financial year 2018/2019

Table 5: Resource Allocation Criteria- Health Sector, Mombasa retreat 6-19November2017

S/NO	CRITERIA	CRITERIA INDICATORS	EVIDENCE
1	Personnel emoluments Annual increment	• Salaries for MOH establishment • Signed CBAs • SRC upgrades	• Supported by IPPD, Treasury authority to recruit • CBA
2	GOK Counterpart Financing	• GOK Counterpart Financing	• Contract details
3	On-going projects	• Status of implementation and absorption capacity of the project	• Implementation Status
4	O & M (Utilities e.g. Rent and rates, electricity parking)	• Lease agreement	• Lease agreement •
5	Statutory obligations and membership subscriptions	• Subscriptions and dues to International organisations	• Demand notes and payment trends
6	Transfers (SAGAs) Annex 5 of the guidelines	• Current and Capital Grants to Parastatals	• Payment trends
7	Achievability/Sustainability	• Project design including feasibility studies, Land availability, Environmental Impact Assessment • Source of funding identified - GoK, /DONOR, PPP, AIA and GoK counterpart funding	• Donor agreement, PPP and MOU's • Availability of the fiscal space
8	Alignment and harmonisation to government development agenda	• Consistency with government transformation agenda, vision 2030, Consistency with MTP III • Addressing core mandate of the Subsector/Ministry and poverty intervention	• Captured in MTP and Sectoral reports
9	Approved by Project Committee	• Constitution of the Project Committee by the Subsector • Project concept note	• Minutes of approvals by the PC members • Concept notes for projectsSubmitted to the SWG

3.6 Linkage of the Health Sector to the 'Big Four'

One of the 'Big Four' priorities of Government during the period, 2018 to 2022 is the achievement of Universal Health Coverage. This prioritization is in line with the Constitution, the Kenya Vision 2030, the Kenya Health Policy, 2014 to 2030 and sector strategies.

Universal Health Coverage entails guaranteeing access to all necessary services to everyone while providing protection against financial risk. This implies that three main dimensions of health have to be addressed, namely:

iv). The whole population is covered, especially the poor and vulnerable populations;
v). That there is access to quality health services;
vi). There is financial protection against out of pocket expenditure as a barrier to access.

It is noted in the foregoing that although a lot of progress has been achieved in meeting various health targets, there are differentials in the country in terms of population covered with health services within a radius of 5 kilometres, with the hard to reach areas most disadvantaged. The differentials also include access to health facilities, access to services, the distribution of health workers and the access to health commodities and technologies. Inequalities are also experienced in terms of out of pocket expenses when paying for services provided. Evidence indicates that one third of all health financial resources in the sector are contributed through out of pocket expenditure. Government financing of health also stands at just about 7 per cent (national and county budgets) – which is way below the global targets, including the African commitment (Abuja target of 15%). All these factors contribute to inadequate access to quality health services. Besides, the quality of services is also affected. Evidence further shows that close to 1 million people fall below the poverty line as a result of catastrophic health expenditure arising from a major illness in the family.

Medium Term Objectives and outputs on UHC

The Government's objective in both the medium to long term is to ensure that universal health coverage is fully achieved in Kenya by 2022. Although all the priorities outlined in **Section 3.1** of this report are aligned and linked to the achievement of UHC, the programming and targets will be fast tracked to achieve universal health coverage by 2022.

The overall objective on UHC is to cover 100 per cent of the population with access to quality health services while ensuring that they are financially protected against prohibitive financial costs. The priorities and outputs to be achieved for UHC by 2018/19 will include:

i). Implementing targeted financial health protection initiatives, including Linda Mama (free maternity health services for about 1.2 million mothers that will now include ante and post-natal services and care for infants), subsidies through the NHIF for about 350,000 poor and vulnerable households, about 1 million elderly (aged 70+ years) and about 300,000 people with severe disabilities.
ii). Increasing the proportion of government budget going to the health sector so as to gradually reach the Abuja target
iii). Scale up the health insurance cover through the National Hospital Insurance Fund (NHIF) from the current 36 per cent to 100 per cent of the population through the use of legislative reforms, financial agency and digital systems, community based approaches

and advocacy. Besides, NHIF will roll out a multi-tier insurance plan that will provide Kenyans with a choice of affordable insurance plans that will suit their needs.

iv). Strengthening the primary healthcare system through empowerment of communities, equipping of primary healthcare facilities and recruitment of additional health workers;

v). Strengthening the provision of secondary and tertiary healthcare services through extending of the Managed Equipment Services Project (MES) to 21 more sites, increasing the number of referral health facilities and use of e-health systems in delivering health care. The construction of a new 2,000 bed multi-speciality hospital will be commissioned under the Moi Teaching and Referral Hospital in Eldoret.

vi). Expanding the provision of specialized health services, including the establishment of additional surgical, 6 cancer centres and one new centre of excellence in renal services;

Promoting the use of alternative sources of financing health care and the role of the private sector in healthcare.

REPUBLIC OF KENYA

IN THE HIGH COURT OF KENYA AT KISUMU

CONSTITUTIONAL AND HUMAN RIGHTS DIVISION

PETITION NO OF 2023

IN THE MATTER OF ARTICLES 1, 2, 3, 10, 19, 20(1) & (4), 21, 22, 23, 24, 26(1), 27, 28, 29, 35, 43(1)(a), 47, 53 (1)(c), 165, 232(1), 258 AND 259 OF THE CONSTITUTION OF KENYA, 2010

AND

IN THE MATTER OF SECTIONS 4 (b), (c), (d), (e), (f), (h), (i), (l) (n) AND (m), 14 (f), 20, 24,32, AND 33 (2) AND (5) OF THE EAST AFRICAN COMMUNITY HIV AND AIDS PREVENTION AND MANAGEMENT ACT, 2012

AND

IN THE MATTER OF SECTIONS 4, (c) (d) 5, 8(c) (d) 14, 15 OF THE HEALTH ACT, 2017

AND

IN THE MATTER OF SECTION 19 OF THE HIV PREVENTION AND CONTROL ACT

AND

IN THE MATTER OF SECTIONS 4, 5, 6, 8, 9, 16AND 38(g) OF THE CHILDREN ACT, 2022

BETWEEN

FA.....1ST PETITIONER

(Suing on her own behalf and as mother and next friend of Baby DM (A minor)

BK.....2ND PETITIONER

CN.....3RD PETITIONER

PATRICIA ASERO OCHIENG.....4TH PETITIONER

AMBASSADOR FOR YOUTH AND ADOLESCENTS

REPRODUCTIVE HEALTH PROGRAM (AYARHEP)....5TH PETITIONER

KENYA LEGAL AND ETHICAL

ISSUES NETWORK ON HIV/AIDS (KELIN).....6TH PETITIONER

KATIBA INSTITUTE.....7TH PETITIONER

VERSUS

THE HON. ATTORNEY GENERAL.....1ST RESPONDENT

CABINET SECRETARY FOR HEALTH.....2ND RESPONDENT

KENYA MEDICAL SUPPLIES AUTHORITY.....3RD RESPONDENT

AFFIDAVIT OF PATRICIA ASERO OCHIENG

I, **PATRICIA ASERO OCHIENG**, a female adult of sound mind living within the Republic of Kenya do hereby make oath and solemnly state as follows:

1. I am a Kenyan woman living with HIV and have been involved in advocating for the rights of persons living with HIV since 1990.

2. I currently work as a community health activist with the Dandora Community Aids Support Association (DACASA) and also serve as the Chairperson of the International Community of Women Living with HIV Kenya Chapter, and as a board member of the International Community of Women Living with HIV East Africa Chapter. I am also a member of the International Treatment Preparedness Coalition.

3. I am conversant with the matters raised in the petition and therefore competent to swear this affidavit.

4. Due to my experience and through my activism which spans a period of over 25 years, I am aware that the wholesome and effective diagnosis and management of HIV requires that there be proper testing and diagnosis of the virus; that the person tested be linked to medical care; that such person actually receives proper medical care; that the person be retained in medical care and eventually viral suppression be achieved and maintained.

5. The HIV medicine that is administered to patients retained and maintained under medical care is called antiretroviral therapy (hereinafter interchangeably referred to as "ART"). The medication does not cure HIV, but with proper administration and medical

care, controls the virus.

6. Further, patients' care and support are important outside of the regular administration of ART to facilitate immediate access to treatment when a person is diagnosed with HIV, to support adherence to treatment in order to attain viral suppression for persons living with HIV, to enhance the prevention and management of HIV-related infections and to enhance coping with the challenges of living with HIV.

7. Between February and June 2021, all public health facilities witnessed stock-outs of antiretroviral drugs (ARVs). The stock was replenished sometime in June 2021 but was only able to last till September 2021 between then and now, there have been intermittent supplies of ARVs in public health facilities.

8. As a matter of practice, patients are given between one month and three-month supplies of ARVs to reduce transport and related costs. This approach has been found to promote adherence of persons living with HIV to treatment.

9. In addition, this approach helps to offload the facilities where care is given, by reducing the number of patients visiting the facility, and

give health care workers attend to all patients. This model, called Differentiated Delivery had been in use in the country and is part of the policy direction taken by the Ministry of Health to promote adherence.

10. As a result of the subsisting stock out of ARVs, patients would only receive medication for just two weeks or at most a month. Many persons living with HIV were then faced with economic and logistical challenges as they had to visit the facility more frequently, dedicating more time and money to the same as opposed to once every six months.

11. During the period of the stockouts the drugs out of stock included Dolutegravir (DTG) and zidovudine/ lamivudine (AZT/3TC). Normally, ARVs work as a combination of three drugs. However, it was not possible to attain the triple availability thereby forcing health workers to improvise and use other drugs such as Septrin (CTX).

12. Additionally, infants born to mothers living with HIV were at an extremely high risk of infection due to the unavailability of the nevirapine drug which was completely unavailable due to the stockout.

13. In the case of children under five (5) years) they risk developing advanced HIV disease or acquired immunodeficiency syndrome (AIDS) and dying from complications should they not get prophylactic treatment or be put on treatment protocols as soon as possible. I believe the lives of undiagnosed and untreated children to be at risk as scientific evidence proves that if children are not treated early enough, they die by their second birthday.

14. As part of the medical care for persons living with HIV, viral load tests ought to be conducted on the patients periodically. However, reagents required to conduct the test were out of stock and it was therefore impossible to monitor patients' viral load. This continued up until early 2023.

15. Adherence to treatment means taking ARVs at the right time, at the right dosage and in the right way. People living with HIV are generally counselled about how important it is to adhere to ARVs. This is because non-adherence and inconsistent adherence have dire consequences for both personal and public health. Amongst others:

    a. Poor adherence leads to the medication being less effective. The result is that the virus is allowed to replicate and the person's viral load increases.

b. For the person living with HIV, this weakens their immune system, which in turn leads to higher rates of secondary infections and disease. Simply put, people get sicker and weaker.

c. An increased viral load also means that the person is at higher risk of transmitting HIV. Treatment adherence is therefore important to HIV prevention.

d. Inconsistent adherence to ARVs has an additional danger to both the individual and public health as it risks a person developing drug resistance.

e. For an individual, drug resistance means that the treatment becomes less effective. It can also lead to people having to change medications to ones that are more expensive, that may be more burdensome to take, or that may risk worse side effects. Sometimes drug resistance can make an entire class of ARVs ineffective.

f. From a public health perspective, drug resistance is a problem for a number of reasons. One reason is that drug resistance

increases the costs on the healthcare system in identifying and providing effective treatment to people living with HIV.

g. Another reason relates to the risk that people with drug-resistant HIV may transmit drug-resistant HIV to others. In simple terms, this will mean that there are more people in the community who have a strain of HIV that is difficult to treat.

16. Ascertaining HIV viral load is critical in the medical management and care of persons living with HIV. It allows healthcare professionals to determine whether a patient is responding to ART positively, has developed drug resistance or is failing treatment. This information allows healthcare providers to make decisions on whether a modification of treatment or change in the combination of medication is required. This has not been possible with the lack of reagents for the test thereby leading to the non-responsive patients wasting away.

17. Children, adolescents, sex workers and pregnant women (who are at risk of transmitting the virus during birth) who require special assistance and ought to be tested on their viral loads regularly have equally not been tested to determine the viral load on account of the lack of reagents.

18. The combination of poor access to ARVs and viral load testing is particularly dangerous. Healthcare providers are unable to identify when people are developing drug resistance or failing on their treatment and cannot respond properly when this occurs by modifying their treatment.

19. There has also been a shortage of HIV testing kits. Prior to the shortage, persons who visited testing centers would be advised to visit the facility after 3 months for a confirmation test. However, for the entire duration of the stockout, this was not possible with people being advised to visit the testing centers after one year so as not to "misuse" the kits.

20. In the period of the stockout, for one to be tested, their free will was no longer enough. People presenting themselves to health facilities for testing were required to qualify why they required the test in order to ensure that the test kits were not used up rapidly.

21. The lack of test kits has also been of great consequence to the health of infants born of mothers living with HIV. This is because six weeks, six months, one year and one and a half years after birth, it is required that the infants be tested to ascertain whether there was mother-to-child viral transmission. However, this came to a

complete stop during the period of the stockout and persisted until early 2023.

22. The dire situation that was created around the shortage of ARVs and the lack of testing kits and early infant diagnostic kits has been admitted by the Ministry of Health. As recently as April 2023, the Ministry of Health has noted that in the period May 2021 and December 2022, commodity shortages and missed opportunities in maternal ART and early infant diagnosis led to at least 3793 infants not provided with prophylaxis, 3493 HIV positive mothers not provided with maternal ART and at least 32, 249 early infant diagnostic tests not done. In addition, there were at least 9,268 children and adolescents not provided with the DTG-based regimen ***(annexed hereto and marked PAO1 is a copy of a presentation made by the Ministry of Health at PMTCT/Pediatric Catch-Up Plan 13th March 2023.***

23. I am aware that in some areas, there are still some stockouts, and the Kenyan government has not taken concrete steps to ensure that a stockout of ARVs, or other commodities required for the treatment and management of HIV are not out of stock again.

24 I swear this affidavit in support of this petition and attest that what is deponed to herein is true to the best of my knowledge, information and belief.

25 What is deponed herein is true to the best of my knowledge and belief save where based on information and advice the sources and grounds whereof have been duly disclosed and specified respectively.

SWORN in NAIROBI)
this 21st day September 2023)
By the said **PATRICIA ASERO)** _____
) DEPONENT
BEFORE ME)
)
)
COMMISSIONER FOR OATHS)

LYDIA W. MWANGI COMMISSIONER FOR OATHS P.O. Box 112-00202 KNH NAIROBI

DRAWN & FILED BY: -

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National AIDS and STI and Control Program

PMTCT/Pediatric Catch-Up Plan

13th March 2023

This is Exhibit marked "PAD1" referred to in the Annexed affidavit/Declaration sworn/affirmed before me on this 24

Presentation Outline

- Background
- Overview of the RRI
- Objectives
- Steps of implementation
- Implementation model
- Timelines

NASCOP

Background

- Kenya is among the first countries to shape the Global Alliance to end AIDS in children by 2030
- NASCOP conducted a desk review of missed opportunities among children and pregnant mothers of the period ending December 2022
- Triggers:
  - Post-Covid performance evaluation in CALHIV and PMTCT
  - Commodity shortage impacting VL, EID testing and patient outcomes

Summary of missed opportunities May 2021 to April 2022

Gap	Number
Missed opportunities in pregnant women (positive mothers –maternal ART)	3493
Missed opportunities in infants (Positive mothers –infant prophylaxis)	3793
EID tests not done	32,249
Number of CALHIV not a DTG based regimen	9,268

- Main interventions
  - Validation exercise
  - Cluster meetings
  - Commodity availability
  - KMMP supervision
  - DQA

NASCOP

Rapid Result Initiative(RRI)

Rapid Result Initiative(RRI)

Need to identify and reduce missed opportunities in PMTCT and CALHIV care cascades and implement appropriate intervention through an RRI

RRI will focus on saturating **client-centred intervention** at the **facility** and **community** levels across the **47 counties** while ensuring stakeholder engagement

Proposed implementation dates are March 13th to 4th July 2023(100 days RRI)

Main support from the Global fund Covid-19 reinvestment grant

NASCOP

Focus areas of the RRI

- The Rapid Result Initiative (RRI) will focus on the following:
  - Capacity building of healthcare workers,
  - Supply chain optimization,
  - Strengthening of the data management system,
  - Client-centred interventions,
  - Advocacy and demand creation up to the community level

Objectives

Broad Objective: Reduce by 80% missed opportunities as of December 2022 for HIV interventions targeting pregnant & Breastfeeding women, children, and adolescents

Specific Objectives :

- To increase HIV testing among children and pregnant women from 76% and 82%, respectively, to 95% by May 2023
- To increase infant prophylaxis coverage from 75% to 100% by May 2023
- To increase Maternal ART from 85% to 100% by May 2023
- To improve viral load monitoring among CALHIV and PMTCT

NASCOP

Specific objectives

To increase coverage for EID testing among HIV-exposed infants from 63% to 100% by May 2023

To mop up treatment optimization among children & adolescents from 88.7% to 100% by May 2023.

To ensure continuous facility-level commodity alignment of HIV diagnostic, ART, and treatment monitoring commodities.

To strengthen the capacity of communities to participate in HIV prevention and treatment, including PMTCT, Nutrition and VMMC, through advocacy and demand creation and recruitment and facilitation of community own-resource persons.

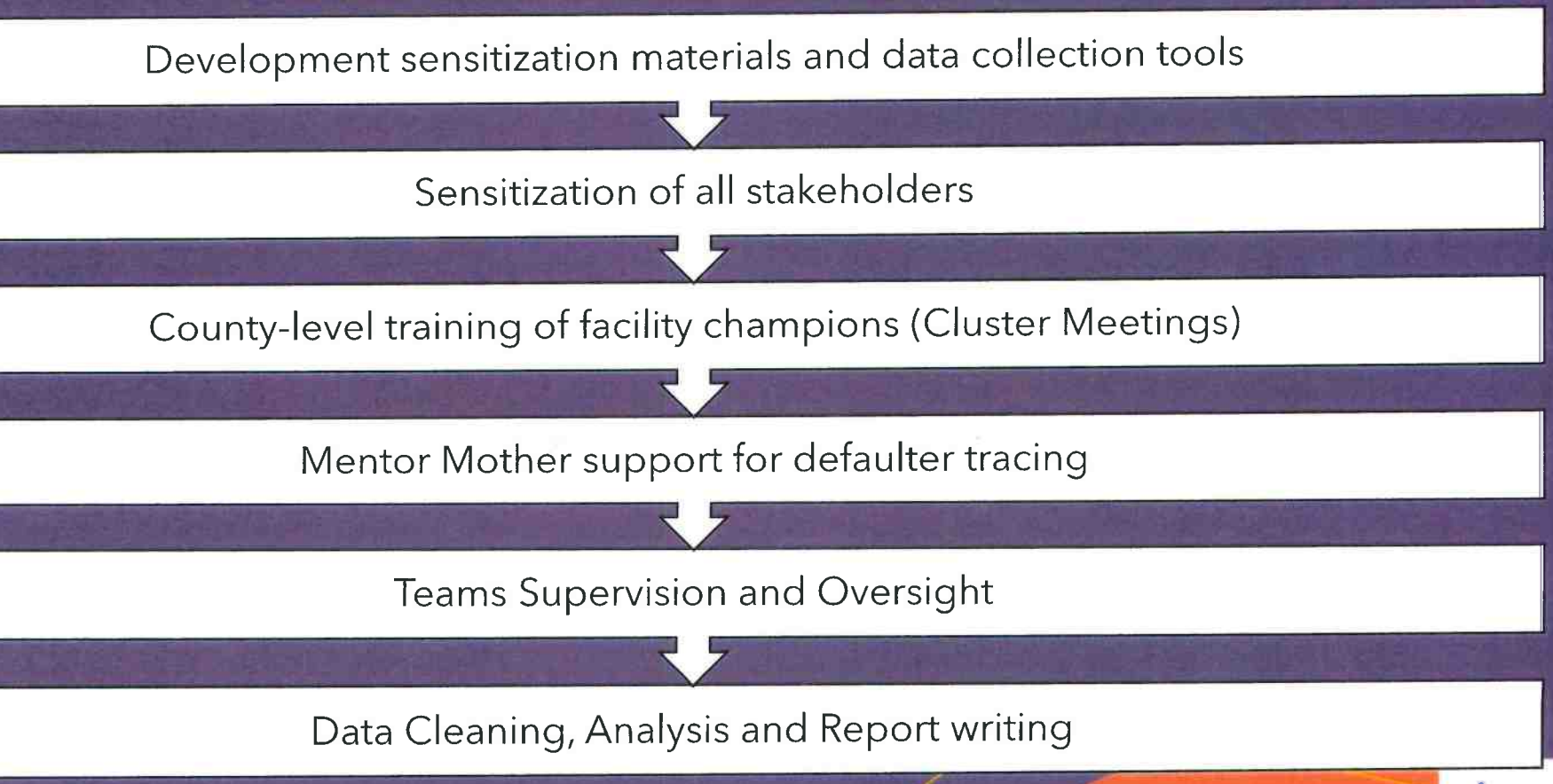
To improve data quality and completeness for PMTCT and CALHIV

To improve utilization of PrEP and FP use in 800 MNCH facilities across the 47 counties

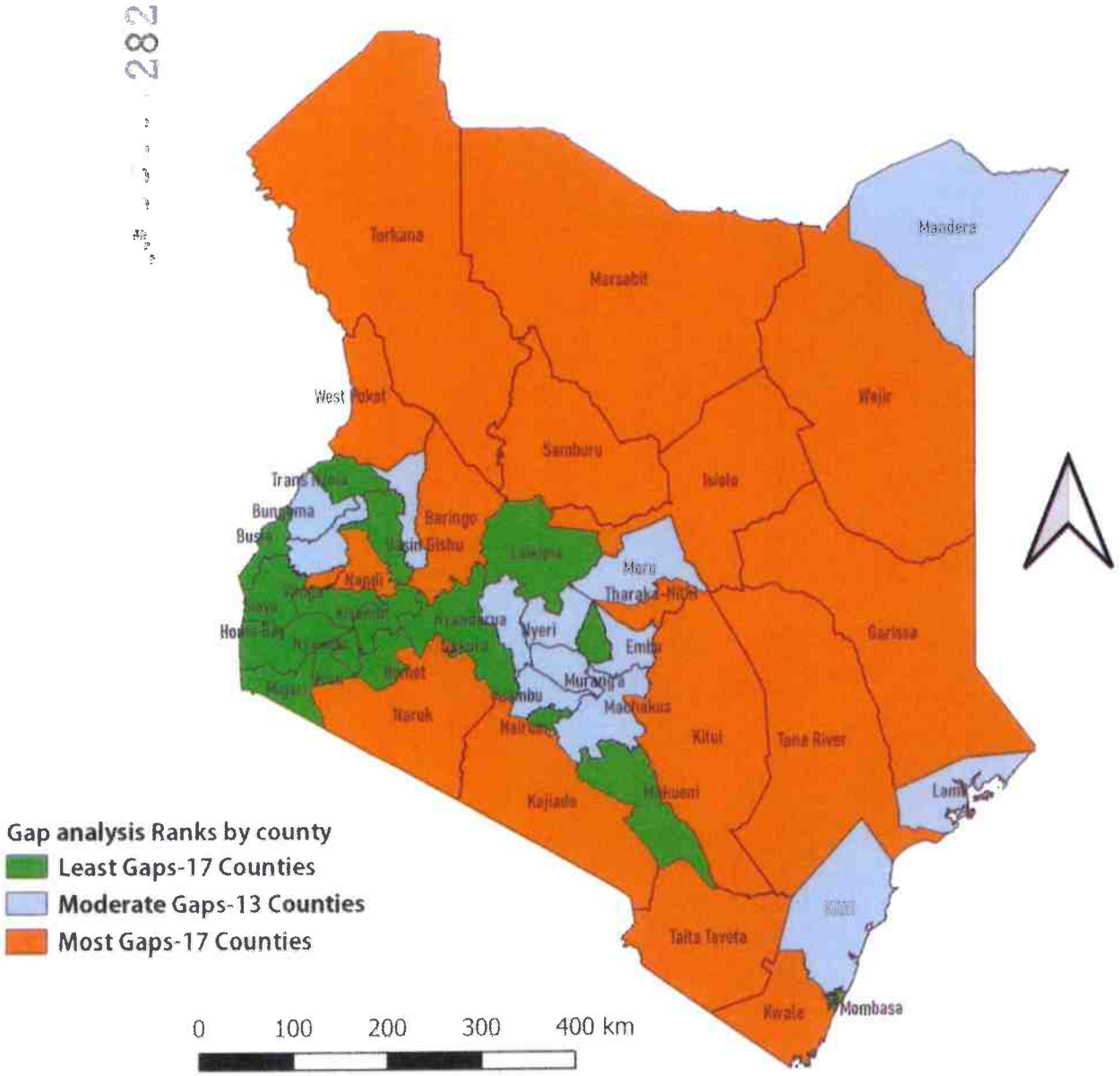
To use community linkages for advocacy and demand creation for HIV service

NASCOP

Steps of implementation



NASCOP



County categorization Variables

- Ranking was done from 1-3, with 3 being counties having the most gaps in the variables selected and 1 being the least missed opportunities.
- Variables used:
  - Viral load unsuppression 0-14
  - Gap in EID testing
  - Gap in Maternal HAART
  - Gap in DTG optimization and
  - Gap in infant prophylaxis

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Process of facility identification and ratification

Virtual sensitization

Proposed date 9th March 2023

- -CASCO
- -PMTCT focal persons
- -Pediatric Focal Persons
- -CHRIO
- -County pharmacists
- -CMLT
- -IPs

County categorization matrix

Variables of interest

- -Gap in Maternal testing
- -Gap in EID testing
- -Gap in Maternal HAART
- -Viral load unsuppression 0-14
- -Gap in DTG optimization
- -Gap in infant prophylaxis

-Facility gap analysis

-Nominated facility champions

-Line list for LTFU

Ratification and collation of facility-level data

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Implementation model

National level-NASCOP and Partners

- Technical Assistance
- Capacity Building
- Monitoring role

47 County leadership &IPs

- Supervisory role
- Monitoring Targets

Facility Level (821 sites, 1408 HWs as champions, >1000 mentor mothers engaged)

- Implementation of intervention
- Cascading capacity building
- Community level engagement

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Commodity security and supply chain optimization

National Level

- Update on the commodity status needed to implement the catch-up plan as an RRI
- Focus on Diagnostic capacity, HIV prevention, ART treatment and treatment monitoring
  - EID commodities, VL commodities, HIV testing commodities, ART regimen for CALHIV and Pregnant women

County-level

- Facility-level commodity status update with forecasting in recognition of the catch-up plan implementation
- Commodity status will be based on gap analysis by the counties based on the line list provided

Facility Level

- Special Order Management on Treatment and diagnostic commodities(Lab capacity)

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Facility selection criteria

- All National Referral Facilities-6
- All County referral Facilities-47
- All sub-county facilities-290
- 1 FBO per county(based on gap analysis) -47
- 1 private facility per county(based on gap analysis) -47
- 1 health center per sub-county (based on gap analysis) -290
- 2 dispensaries per county (based on gap analysis)-94
- **All facilities 821**

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Facility Champions to be trained

- From all selected facilities= 821 healthcare workers
- All sub-county AIDs and STI(SCASCO) and Sub-county pharmacists=580
- Total to be trained 1408

Facility-level champions criteria

- 1 Champion per facility selected.
- Criteria for selecting facility-level champion:
  - Must be working in a service delivery point, preferably MNCH clinic, CCC clinic, YFC or PrEp clinic and seeing patients daily.
  - Must be a GoK healthcare worker
  - Must be a nurse, clinical officer, medical officer, or laboratory officer
  - Must be passionate about HIV and have some basic knowledge of HIV care

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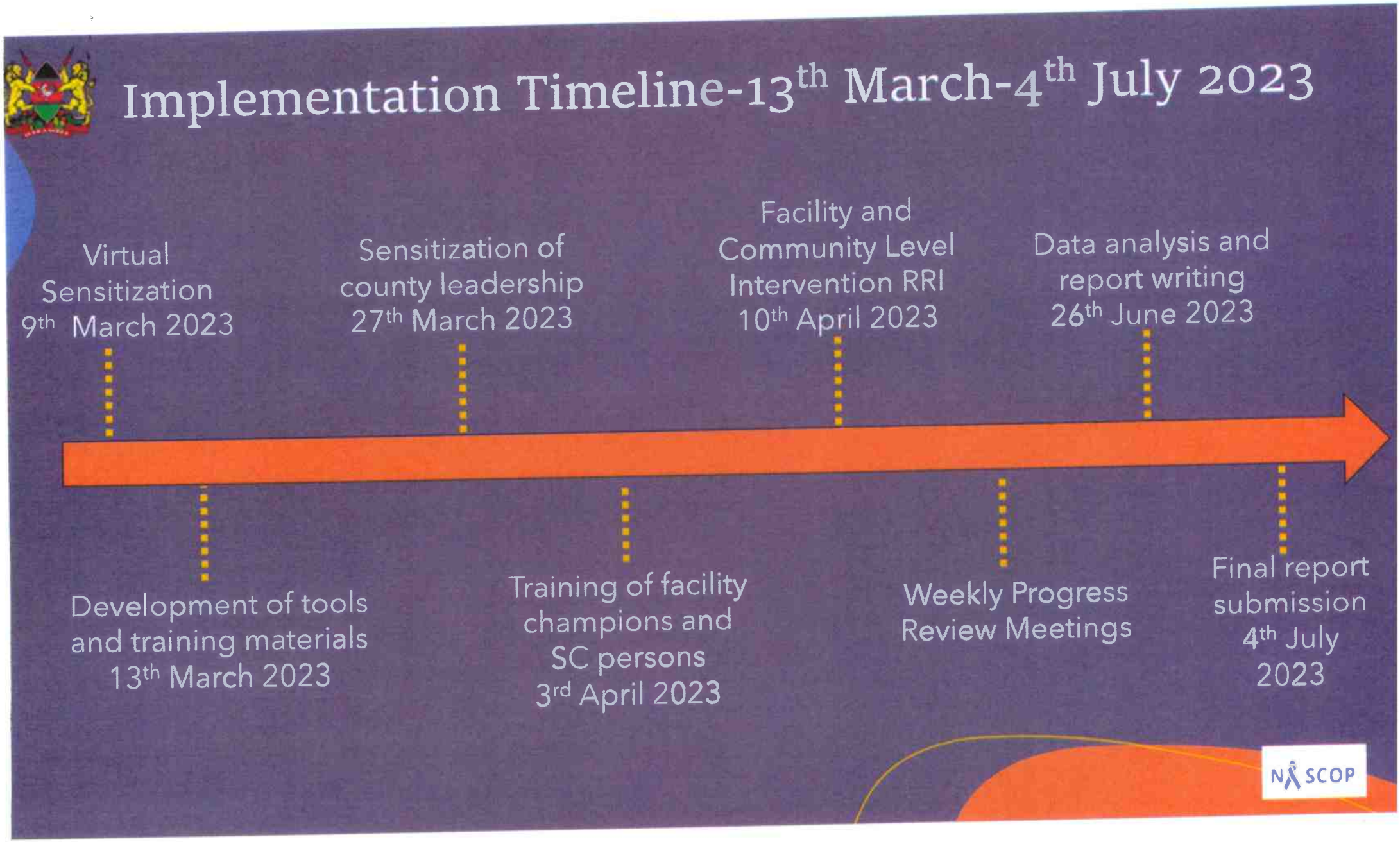
Implementation Timeline-13th March-4th July 2023
Virtual Sensitization 9th March 2023
Development of tools and training materials 13th March 2023
Sensitization of county leadership 27th March 2023
Training of facility champions and SC persons 3rd April 2023
Facility and Community Level Intervention RRI 10th April 2023
Weekly Progress Review Meetings
Data analysis and report writing 26th June 2023
Final report submission 4th July 2023
NASCOP

Indicator based Targets

	Indicator	Current	Target
1	Missed HIV testing at ANC	291,385	256,419
2	Missed Syphilis testing at ANC	218,000	191,840
3	Maternal HAART Gap	956	956
4	Missed infant prophylaxis	556	556
5	Missed EID testing	19,846	19,846
6	Gap in DTG optimization 1st line	3,805	3,805
7	Unsuppressed PMTCT	4,465	3,572
8	Unsuppressed CALHIV 0-9	4,017	3,214
9	Unsuppressed CALHIV 10-14	4,084	3,267

NSCOP

Thank you

REPUBLIC OF KENYA

IN THE HIGH COURT OF KENYA AT KISUMU

CONSTITUTIONAL AND HUMAN RIGHTS DIVISION

PETITION NO OF 2023

IN THE MATTER OF ARTICLES 1, 2, 3, 10, 19, 20(1) & (4), 21, 22, 23, 24, 26(1), 27, 28, 29, 35, 43(1)(a), 47, 53 (1)(c), 165, 232(1), 258 AND 259 OF THE CONSTITUTION OF KENYA, 2010

AND

IN THE MATTER OF SECTIONS 4 (b), (c), (d), (e), (f), (h), (i), (l) (n) AND (m), 14 (f), 20, 24,32, AND 33 (2) AND (5) OF THE EAST AFRICAN COMMUNITY HIV AND AIDS PREVENTION AND MANAGEMENT ACT, 2012

AND

IN THE MATTER OF SECTIONS 4, (c) (d) 5, 8(c) (d) 14, 15 OF THE HEALTH ACT, 2017

AND

IN THE MATTER OF SECTION 19 OF THE HIV PREVENTION AND CONTROL ACT

AND

IN THE MATTER OF SECTIONS 4, 5, 6, 8, 9, 16AND 38(g) OF THE CHILDREN ACT, 2022

BETWEEN

County. I am fully conversant with the facts of this case, thus competent to swear this Affidavit.

2. I am conversant with the contents of the Petition, I fully understand the issues in question and I further adopt the contents of the Petition filed herein as if the same were set out seriatim.

3. WOYDEP's objectives include enhancing knowledge skill, practices and behaviour on HIV and AIDS as a means of prevention of the spread of HIV

4. Through the work that I do, I am aware that since 2020, there has been a nationwide stock outs of essential health commodities for People living with HIV/AIDS and People Living with TB. These commodities include cartridges used for TB testing, HIV testing kits, condoms, HIV viral load testing kits and early infant diagnosis kits.

5. The major supplier of these commodities is the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), which procures them through the Kenya Medical Supplies Authority (KEMSA).

6. These stock outs have been caused by the fact that there is no buffer of ARVs or HIV Commodities at KEMSA or at the county level.

7. The stockouts had the greatest impact in Makueni County between 2020 and 2021, when there were no ARVS in County Hospitals for a period of about 6 months. As a result of the stockout persons living with HIV who required antiretroviral medication started collecting drugs from catholic churches and private facilities, which also had limited stocks.

8. As a practice, when PLWHIV collect ARVs from public institutions, they are given a dosage for 3 months at a time. This allows them to carry on with their daily activities without having to constantly visit the hospital for medication. With the continuing stockouts, persons living with HIV could only collect (from private institutions) medication with a dosage to last 2-3 weeks only.

9. The shortage of health commodities has adversely affected people living with HIV in at least the following ways:

    a) Pregnant women living with HIV did not have access to viral load testing and medicine to suppress their viral load. This increased the risk of transmission to newborns.

b) Further, children born to persons living with HIV were left vulnerable to the virus since there were no early infant diagnosis tests. Therefore, children who had just been born could not be adequately attended to medically.

c) Children born to persons living with HIV were left exposed to the HIV virus because their mothers did not know their viral loads hence, they did not know how to feed the children. Breastfeeding mothers with HIV have to have viral tests and their viral load suppressed to enable the child to breastfeed. However, these testing kits were not available and ARVs were contaminated and recalled. It cannot be said that the Ministry has undertaken several campaigns to encourage mothers to breastfeed their children because of the benefits of breast milk.

d) Lastly, patients with HIV who get TB suffer greater deficiencies in quality health services due to lack of testing cartridges for molecular testing. The importance of this mode of testing is that it not only tests for the presence of TB but also reveals the type of TB one has. This further helps in issuing the correct medication. Currently, TB patients are given general TB medicine that may not address the type of TB they have. After a period of taking this TB medicine for 6 months and it does not

work, they are subjected to start the process afresh with different medication until it works. This trial-and-error process weakens vital body organs.

10. As of December 2022, there was still a stock out in the essential health commodities such as HIV testing kits, condoms, HIV viral load testing kits and early infant diagnosis kits.

11. More children continue to be exposed to HIV at birth, people living with HIV who depend on ARVs for survival are continuing to suffer.

12. I believe that the Ministry of Health failed to act on time to address the stock outs and the contamination of the ARVs and this has affected millions of Kenyan lives.

13. I am aware that at the beginning of 2021, the government made a decision to procure ARVs from an entity known as the Universal Corporation in an effort to deal with the stockout challenge.

14. Many of the people living with HIV realised that the ARVs Universal Corporation ARVs supplied to them (through county hospitals) were contaminated. Discoloration occurred on some tablets, and mold

developed on others. The community of people living with HIV reported this to the Government on 8th November 2021.

15. The government did not address the issues raised with regard to contaminated ARVs until the community led petitions and demonstrations against the government was the drug recalled from the market in late November 2022. By this time, a majority of the people living with HIV had consumed the contaminated drug.

16. Following the recall of the Universal Corporation ARVs, people living with HIV were advised by the Government to return certain bottles with certain identifying marks to the health facilities in exchange for different medicine.

17. A number of issues arose as a result of the Government's directive requiring return of the contaminated ARV drugs. First, stockout of HIV medicine and commodities has persisted, and the contaminated drugs would not be replaced with appropriate doses. Secondly, the Government's directive was only given to the National Empowerment Network of People living with HIV and AIDS in Kenya (NEPHAK), with no corresponding instructions to County pharmacies.

18. In addition, there has been insufficient communication regarding the recall of the contaminated drugs. While the government's recall directive was communicated through newspapers, television, and radio, many PLHIV live in rural areas without access to these mediums. Consequently, many PLWIV did not learn about the recalled contaminated ARVs in a timely manner.

19. As a result of the foregoing, some of the PLHIV only learnt of the recall after they returned to empty bottles for replacement. The imaginable anguish and panic wrought by this discovery is damning to a patient whose life depends on taking ARV medication.

20. In addition, the Ministry of Health's recall directive was confusing—even to PLHIV who had timeous access to the recall directive. Although the directive referred to ARVs packed in Universal Corporation bottles, it emerged that some of the bottles had labels completely erased, making it almost impossible to identify their manufacturers. The Ministry's further attempt to clarify the directive—by making reference to batch numbers starting with "58"—

only created further confusion among the PLHIV community because it was not easy to know which bottles the Ministry was referring to.

21. After the Ministry's recall directive, the Ministry failed to communicate on what would happen to those who had taken the contaminated drugs.

22. The Ministry also failed to communicate the results from the tests conducted on the contaminated drugs. It is not even clear whether any tests have been conducted on the drugs. This resulted in general uncertainty and unease in the PLHIV community.

23. I am afraid that if this Honourable Court does not direct the Ministry of Health to ensure the availability of essential health commodities for HIV and TB, persons living with HIV/TB will suffer dire health consequences and there will be an increase in the number of new and preventable HIV/TB infections.

24. I swear this affidavit in support of the Petition and the prayers particularized therein.

What I have deponed to is true to the best of my knowledge, information and belief, save for information whereof sources of information have been disclosed.

SWORN in NAIROBI)
this 21st day September 2023)
By the said **Peter Owiti**)
)
) DEPONENT
BEFORE ME)
)
)
COMMISSIONER FOR OATHS)

LYDIA W. M. WANGI COMMISSIONER FOR OATHS P.O. Box 25315-00100, NAIROBI

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