

**UNFINISHED
BUSINESS:
A UNIFIED
VOICE DRIVING
INNOVATION
IN HIV**

2022

DISCLAIMER

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ViiV Healthcare is committed to the development of innovative solutions that can improve the health-related quality of life of people living with HIV and strives to improve access to prevention and treatment by engaging with communities and ensuring innovation addresses the unmet needs of at-risk and vulnerable population groups.

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TABLE OF CONTENTS

FOREWORD	05
-----------------------	----

Jean-Bernard Simeon,
Senior Vice President and Head of Europe, ViiV Healthcare

CONTRIBUTIONS	06
----------------------------	----

MEP Marc Angel
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Magdalena Ankersztejn-Bartczak,
CEO of the Foundation for Social Education in Poland

Dr Antonio Diniz,
Hospital Pulido Valente of Lisbon, Portugal

Erika Castellanos,
Global Action for Trans Equality

Sophie Strachan,
Sophia Forum

Dr Luz María Peña,
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Dr Matthew Weait,
Oxford University

SUMMARY OF POLICY RECOMMENDATIONS	21
--	----

REFERENCES

FOREWORD



JEAN-BERNARD SIMEON

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I am delighted to introduce this policy manifesto on HIV/AIDS which explores the importance of innovation to eliminate a leading global public health threat. The manifesto also underlines how a broad-based approach to innovation from science and medicines to HIV service delivery, access to justice and partnership working to transform the lives, livelihoods and living standards of people and communities living with and affected by HIV.

The broad theme of the manifesto is to understand: what are the remaining challenges in the fight against HIV/AIDS, and what the role of innovation is in accelerating progress towards the UN Global HIV targets?

We wanted to look at innovation in HIV/AIDS from multiple perspectives. Innovation has the potential to protect the most vulnerable against a leading chronic and infectious disease, to improve the health-related quality of life of people living with HIV, to make health systems more effective, and to deliver cost-savings in the long-term. The one overarching objective is innovation supports, ensuring people living with HIV are at the centre of the continuum of care and decision-making.

Given the significance of HIV innovation for people, communities, health systems and public health ViiV Healthcare has invited leading independent experts and opinion leaders to provide input and share evidence-informed insights which we have consolidated and published.

The powerfully made arguments for action are based on each author's own unique experiences and together represent a unified voice. While it would be impossible to truly include every voice across HIV communities, I believe that the diversity of the contributors to this manifesto demonstrates the importance of an innovative and transformative approach to ending the epidemic. I would therefore like to thank all the contributors for their invaluable efforts.

The manifesto concludes with a set of six policy recommendations for action at EU level, by both EU institutions and EU Member States, which also touches on actions that can be taken by countries more broadly.

I hope that you, the reader, find the policy manifesto informative, interesting and inspiring, and that you too can support the policy change that is needed.

MEP MARC ANGEL

Member of the European Parliament from Luxembourg, representing the Socialists and Democrats Group. He is also a UNAIDS Red Ribbon Leader on the 10-10-10 targets.



The United Nations Secretary General, in his 2021 report on HIV and AIDS, pointed out that there was an urgent need to “break out of the increasingly costly and unsustainable cycle of achieving some progress against HIV, but ultimately not enough to bring about an end to the pandemic”.

The report concluded that the world had failed to reach the global commitments for 2020, for reasons such as under-investment in the HIV/AIDS response. In 2019, funding for the HIV/AIDS response in low- and middle-income countries was 30% less than the USD 26 billion which the UN Member States committed to mobilise by 2020. In the past decade, low and middle-income countries increased their HIV/AIDS domestic resource allocation with 52%, representing the main source of funding for HIV/AIDS. In the same period, the share of HIV/AIDS funding from other bilateral governments, except the United States of America, has decreased from 11% to 2%.¹

Moreover, countries were insufficiently able to address the societal and structural barriers to an effective response. Falling short of the agreed commitments resulted in an additional 820,000 people dying from AIDS-related illnesses and an additional 3.5 million people acquiring HIV, requiring life-long antiretroviral treatment².

One key lesson learned from the HIV/AIDS response is that investing too little and too late has a huge cost for humanity, with millions of additional people requiring services, straining often fragile health care systems, and yielding more costly responses.

Recognising that this situation cannot continue, UN Member states have adopted the 2021 UN Political Declaration on HIV/AIDS, including bold targets for 2025, to get on track. The European Parliament, under the leadership of the Parliamentary Committee on Development, has been closely involved in this process, through its resolution on “Accelerating progress and tackling inequalities towards ending AIDS as a public health threat by 2030”³. The Resolution calls on the Commission to address AIDS as a global public health crisis and accelerate all efforts to meet the 2025 targets, including through scaling-up investments in UNAIDS and the Global Fund to Fight AIDS, Tuberculosis and Malaria, among others.

Yet, the 2020 funding gap for the HIV/AIDS response in low- and middle-income countries was close to USD 8 billion against the annual need of USD 29 billion by 2025. In terms of the cost of inaction, each year the world delays in fully funding the HIV response, at least USD 360 billion is lost, because of the economic cost of homophobia, due to stigma and discrimination; lost productivity, due to avoidable AIDS deaths; and lifetime costs of HIV treatment, from avoidable new HIV infections. Conversely, by investing now, 6.44 USD will save 12 USDs⁴. While adequate HIV/AIDS funding has become even more precarious in view of the earlier COVID-19 crisis and now the Ukraine war, the consequences of not investing in ending the AIDS pandemic are dire. We cannot allow the re-emergence of the HIV/AIDS pandemic.

A second key lesson, reflected in the UNAIDS Global AIDS Strategy, is that intersecting inequalities – such as social, economic, racial and gender inequalities, and restrictive social and legal environments - continue to drive the HIV/AIDS pandemic.

Many of the poorly performing HIV/AIDS responses are in settings where epidemics are heavily concentrated among key populations who disproportionately experience stigmatisation, social marginalisation and criminalisation that blocks their ability to access services. The people being left behind are those who disproportionately experience gender inequality, HIV-related stigma, social marginalisation and criminalisation.

An analysis, by [MM Kavanagh et al](#), shows that in countries where same-sex sexual acts were criminalised, the portion of PLHIV who knew their HIV status was 11% lower and viral suppression levels 8% lower. Sex work criminalisation was associated with 10% lower knowledge of status and 6% lower viral suppression. Drug use criminalisation was associated with 14% lower levels of both. Criminalising all three of these areas was associated with approximately 18%–24% worse outcomes. It is clear that we Parliamentarians have an important role to play in addressing inequalities, by driving law reforms and ensuring that national governments follow through on the commitments made.⁵

The third lesson is on the centrality of a human rights-based approach to create an enabling environment for successful HIV/AIDS responses and affirm the dignity of people living with, or vulnerable to, HIV, so that the world ends AIDS by 2030.

Despite being more than 40 years into the HIV/AIDS epidemic, continued human rights challenges, including stigma and discrimination, misuse of criminal law and punitive approaches, mandatory testing inequality and violence against women and girls, and denial of sexual and reproductive health and rights remain among the main barriers to effective HIV/AIDS responses. For example, 60% of the countries that report to UNAIDS still criminalise HIV exposure, non-disclosure and transmission; 37% criminalise same-sex sexual relations; and 40 countries still retain restrictions on entry and stay for people living with HIV⁶.

A community report on migrant sex workers in ten countries in Western and Central Europe, shows that nearly half of those interviewed experienced physical violence and more than a quarter faced sexual assault⁷. More than 25% of people aged 15 to 49 years reported holding discriminatory attitudes towards people living with HIV, as shown by recent population-based survey data.

It is for this reason that Luxembourg, a strategic partner of UNAIDS and a member of the UN Human Rights Council, has committed to join the Global Partnership for action to eliminate all forms of HIV-related stigma and discrimination”, as the first EU Member State.

POLICY RECOMMENDATIONS

1 **EU institutions and the Member States must scale up investments in the Global AIDS response to meet the 2025 commitments towards ending inequalities to end AIDS by 2030, equal to other global partners and entities, and in line with the Parliamentary Resolution on HIV/AIDS**

- Investment must be directed to HIV prevention, diagnosis and treatment; as well as in research by developing a vaccine against HIV/AIDS and more affordable health technologies, and sustainable funding for civil society and community organisations.
- The Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria must be funded to continue serving as a major financing partner for the national HIV/AIDS responses.
- UNAIDS must be enabled to continue its critical and unique scope of work, as thought-leader, coordinator of the UN Joint Programme on HIV and AIDS, strategic interlocutor on human rights violations with governments and country stakeholders, and guardian of strategic data for monitoring targets.

2 **The EU and Member States must tackle the human rights, stigma and discrimination aspects of HIV/AIDS, showing leadership both domestically and globally.**

- The EU in its entire entity must use the implementation of the EU Human Rights Action Plan and the Gender Action Plan III to address the human rights and gender inequality drivers of HIV/AIDS.
- The EU must work to meet the 10-10-10 targets. This requires prioritising the fight against stigma and discrimination, sexual and gender based violence, criminalisation of same-sex relations and other punitive and discriminatory laws and policies in order to contribute to universal access to sexual and reproductive health and rights, access to quality education, including comprehensive sexuality and relationship education age adapted, equitable and affordable access to healthcare, access to the labour market and the participation of affected communities in all spheres of public life.

3 **EU Member states, but also the EU itself, join the [Global Partnership for Action to eliminate all Forms of HIV-Related Stigma and Discrimination](#) as established in 2018 with the involvement of UNAIDS, UN Women, the United Nations Development Programme, the Global Network of People Living with HIV, the Programme Coordinating Board (PCB) NGO Delegation and the Global Fund to Fight AIDS, Tuberculosis and Malaria. The EU must leverage international platforms, including the UN General Assembly, to sustain focus on the HIV/AIDS pandemic as a global crisis, intersecting with existing and future pandemics, as shown by the COVID-19 crisis.**

- The EU must leverage its relevant committees and ensure inclusion of HIV/AIDS and related inequality issues within existing strategies and financing frameworks, such as the EU4Health Programme, to strategically ensure the achievement of the targets in the UN Political Declaration on HIV/AIDS.
- At the operational level, this would include support for HIV/AIDS prevention and linkage to care through joint action and projects, as well as earliest implementation of proven public health measures to prevent HIV, including: comprehensive harm-reduction services for drug users, treatment as prevention, condom use, pre-exposure prophylaxis and effective but also comprehensive sexual health and relationship education age adapted, particularly for marginalised and key populations at risk of HIV infection.

Dr MAGDALENA ANKIERSZTEJN-BARTCZAK, PHD

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Achieving the end of AIDS by 2030 should be within reach. The end of AIDS is possible. But to achieve it, we need to join forces between governments, civil society, business, industry and donors. Thanks to effective, modern therapies in many countries around the world, people living with HIV can live normal lives, have families, and do not have to worry about the risk of developing AIDS. These people have access to both care and diagnostics.

However, this **still does not apply to everyone**. In many countries, achieving the UNAIDS 95-95-95 targets is still a long way off, and adults and children are still dying of AIDS, even in Europe.

Access to HIV medical care in many countries, including European Member States, is not easy. In some countries HIV services are scarce and people need to travel long distances to access HIV prevention and care.

Treatment is prevention – every person on effective treatment. Yet, despite global and European standards for HIV monitoring, many people still do not have their viral load checked and under control.

Furthermore, **access to treatment does not equal good quality of life.** Medical advances in HIV are not matched by increased societal awareness and understanding of what living with HIV actually means. The U=U (Undetectable = Untransmittable) campaign is significantly changing the lives of people with HIV. **However, while HIV is one of many sexually transmitted diseases, it is still perceived and treated differently. HIV-related stigma and discrimination**

are still huge barriers to ending the epidemic. Fear of being stigmatised often prevents people living with HIV from disclosing their status, even to family or health care professionals. The criminalisation of HIV transmission, sexual and gender identity as well as sex work also still exist in many countries, including European Union member states.

When we think about HIV, focusing on treatment is not enough. Our focus should be on education and access to combination prevention which have a huge role to play to ensure the right to health of people living with HIV – or at risk of HIV transmission – is fully upheld. The end of AIDS is possible. Yet, why do we still have young people “finding out” about HIV, why are there so many late diagnoses, and why are people still dying of AIDS?

New epidemics and new crises must not be allowed to divert us from the important work that still needs to be done to end the HIV epidemic. **Scientific evidence, effective treatments, and proven methods to eliminate HIV are already available.** We should strive for long-term HIV education and prevention programmes, to be embedded in national healthcare policies and education systems.

The end of AIDS is possible, but only if we join forces and, together, benefit from the knowledge and experience of those countries that have succeeded. We need to be more attentive to those countries where the lack of access to treatment, standards of care, and epidemic surveillance are a daily reality. No one should be left behind.

CASE STUDY

Poland faced a new challenge after 24 February 2022 which has been to support and assist refugees from Ukraine displaced by war. In Poland, access to antiretroviral (ARV) treatment is unrestricted⁸. More than 15,000 people living with HIV in Poland are currently on ARV therapy. No one foresaw the situation of war across our border. However, everyone knew that no matter what the cost, help was needed. Providing ARV treatment for people from Ukraine was imperative. An international protocol allowed doctors from European countries to join forces with medics from Ukraine to enable access to the medical history of those fleeing Ukraine to facilitate the provision of high-quality care.

However, medicines alone are not enough. The sudden increase in the number of patients, the limited number of medical staff, and the language barrier was, and is, a huge challenge. For a few months, the number of children living with HIV in Poland almost doubled – and they all required specialist care and an appropriate medical support.

Thanks to interventions from the WHO and the Polish government, Poland received ARV drugs to provide treatment. Nonetheless, the growing numbers of adults and children require increasing staff levels to deliver people-centred care. We have many months of help and support ahead of us. Many people from Ukraine, who have found a safe haven in Poland, are still unable to return to their country.

This difficult time is a collective challenge for European countries. Poland has taken on the greatest burden, so also needs international support to ensure that displaced people are well cared for and supported.

POLICY RECOMMENDATIONS

- 1** Stop HIV criminalisation, stigma and discrimination.
- 2** Improve access to prevention, treatment and care by re-designing the provision of HIV services to introduce innovative delivery models which rely on the collaboration between healthcare systems and stakeholders.
- 3** Develop comprehensive prevention strategies, focused on combination prevention programmes, tailored to the needs of different communities.
- 4** Embed education and training on HIV prevention (and management) across national education systems - from school education to professional training for healthcare professionals.
- 5** Build on the UN Global AIDS Strategy⁹ to develop a set of specific actionable recommendations at EU level to guide countries in the implementation of targeted policy interventions at national and local level.

ERIKA CASTELLANOS

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After four decades of HIV, much has changed. New scientific breakthroughs have dramatically improved the outcome and life course of a person living with HIV. The challenges we faced in the early years of the epidemic: access to treatment, severe side effects, and access to diagnostics and prevention tools have changed in most countries. Unfortunately, some issues remain, and the lives of people living with HIV have faced emerging barriers regarding access to prevention tools, treatment, care, and retention.

Communities have historically been the driving force in the HIV response while governments remained passive or turned a blind eye to the epidemic. People living with HIV have played a key role in holding governments accountable and keeping them on track. In recent years we have seen a change in a once hostile political environment and an increase in corporate and political responsibility in the HIV response. But is it enough to end AIDS by 2030?

The epidemic's early days were characterized by a lack of empathy, confusion, fear, hate, and desperation. Religious leaders were telling their followers that HIV was a punishment from God. Friends and relatives turned their backs on their loved ones when they were diagnosed. We did not know what to believe or do with everything happening around us. It was hard to understand how governments and society might have remained unmoved by all the significant loss around us, the death of our friends, family, and lovers. We were afraid. Every day we woke up to sad news. Every day could be the last day for our loved ones, for us. And there was so little that could be done. Frequently we could hold the hands of the dying to at least provide them with a dignified death. Doctors refused to see us or even touch us. Hospitals refused to admit us; when they did, they placed labels on our beds for everyone to see. We were desperate and angry. People living with HIV were

losing everything: their houses, their jobs, their loved ones, and ultimately, their own lives.

From such a desperate situation emerged a strong community response. We came together and fought back. We organized ourselves and became experts in legal, human rights, health access, and antiretroviral treatment issues. We had no choice: it was a matter of survival. Perhaps the urgent need for survival was the driving force of our community response. We cared for each other, organized hospices to care for the dying, raised our voices, and lobbied politicians to engage in the HIV response. Over the years, we have successfully placed ourselves at the centre of the response. It was not granted to us, we had to fight for it, and many lives were lost in the process. Our community advocacy triggered the allocation of budgets, the development of national HIV strategies, and access to ARVs. We took the HIV response to the highest political platform- the United Nations. We made enormous contributions which delivered the creation of global response structures such as UNAIDS and the Global Fund. Overall, such key communities continue to be central to the HIV response, albeit the advocacy style and needs of people living with HIV have changed, at least in the biomedical field

I learnt of my diagnosis in December 1995. It was a very different experience from what a person recently diagnosed would encounter today. I had to be placed on a waiting list for treatment. I could only be treated when someone else living with HIV on the same treatment died. I started with monotherapy, and when it became available in my region, I started with what is famously known as a treatment cocktail, which obliged me to take up to 18 tablets and capsules. The side effects were severe and often felt worse than AIDS. Today, I take a very simplified treatment, and

for some people living with HIV adherence is as little as one pill daily. Today's experience is a universe away from the reality of the early 90s. Not only the number of pills for treatment, but the quality of medication has continued to improve over the years. Side effects that were common such as lipodystrophy¹⁰ and neuropathies are now rarely seen. Treatment innovations have allowed us to move away from an undignified mode of survival. My goal today is not to live to see another day but to live to see another day with a good quality of life.

While the biomedical response to HIV has surpassed all my expectations, sociocultural barriers have not only remained but - in some instances- even worsened. Stigma and discrimination are today as much a reality as they were in 1981. People living with HIV continue to be denied services and equal access to opportunities based on their serological status. For key populations they continue to be criminalized because of who we are, who we love, our actions, or our work. Now, we observe that resurgent hate trends add to the burden of stigma, discrimination, and violence we

continue to experience daily. Of considerable concern is the anti-gender rhetoric trying to erase trans identities and eradicate our socio-political gains. Therefore, despite progress, structural barriers to accessing HIV treatment and prevention still make our lives difficult and undermine our human rights. This continues to cause avoidable deaths from AIDS.

Governments have the responsibility to ensure we end AIDS by 2030. It is not only possible but necessary. As a person living with HIV, and while medically my life is easier than 10 years ago, averting all HIV transmission is a reality I aspire to see. To achieve the goal of ending AIDS, the social, political and legal space needs to replicate the rapid evolution witnessed in biomedical response. Our laws, public policies, and social protection schemes must align with innovations in HIV. Governments must guarantee protection from discrimination, guarantee access to treatment, and champion equal social opportunities.

POLICY RECOMMENDATIONS

- 1** Involve people living with HIV and members of key populations in decision-making. Top-down initiatives and strategies fail to understand beneficiaries' life experiences and needs. The direct input and participation of key populations in the development of programs and budgets will enrich policy initiatives and improve their effectiveness and impact on public health.
- 2** Enact laws and policies that protect people living with HIV from discrimination, creating specific mechanisms to hold both individuals and governments accountable when discrimination take place.
- 3** Develop initiatives that seek to de-criminalize key populations and improve access to and retention in services for communities most impacted by HIV . Policy measures should ensure the eradication of societal and legal obstacles so that those communities particularly hit by the epidemic can benefit from access to novel treatment and prevention tools.
- 4** Support a global HIV policy response instead of state-centric approaches. Policies developed in the last four decades have demonstrated greatest effect when developed in coordination with other governments and stakeholders at a multilateral level. Policymakers must continue follow a global approach to tackle an epidemic that does not respect borders.
- 5** Contribute to finance campaigns developed by communities. Civil society group-led responses continue to be essential to spotlight the challenges and needs of people living with HIV. Administrations should facilitate the continuation of the fight by communities as this response has demonstrated to uniquely benefit the overall governmental and societal response to the epidemic.

Dr ANTONIO DINIZ

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Innovation has been one of the dominant traits throughout the history of HIV. It was decisive in the successive advances in treatment, prevention (Pre-exposure prophylaxis (PrEP) or Post-exposure prophylaxis (PEP_) and diagnosis (e.g. point of care systems) that have allowed the transition from a fatal disease to a chronic disease and the rise of life expectancy seen in people with living with HIV, now close to that of uninfected people.

Innovation also covers the process of addressing HIV infection from the point of view of its organisational models (e.g. the joint approach to tuberculosis, drug use, hepatitis or STIs), and of linking care with other partners (health services with civil society organisations). Also, the role that, for the first time, patient organisations have developed as agents of change or influencers of health policies in relation to HIV and people living with HIV (PLHIV).

It is certain that there is still a way to go, namely the discovery of a vaccine that effectively prevents HIV transmission. In its absence and **given the efficacy of current therapeutic and prophylaxis regimens, we can easily achieve the elimination of HIV infection by 2030**, if we consider and implement the following points:

- Fight against inequalities (e.g. gender, ethnicity, sexual orientation, migration, age, poverty), that are the basis of failure in the prevention of infection. Facilitate the access to care and therapy is needed, especially in the most vulnerable subpopulations.
- Improve HIV information systems, as a basis for a better definition of regional, national, and local strategies, tailored to each of the most vulnerable subpopulations.

- Improve the cooperation between all different stakeholders with intervention in this area, concretely the articulation between health systems and the community and their community organizations.
- Focus the efforts on the second «95» of UNAIDS strategy 95-95-95: by 2025, 95% of diagnosed population should be on antiretroviral therapy. In my opinion, the hardest goal to achieve. To accomplish it, early diagnosis should be improved focusing on partnerships (NGOs and community pharmacies/ services) with faster referral process.

HIV infection is now a chronic disease and PLHIV have an average life expectancy much higher than a few years ago and that implies the reformulation of the models of health care that exist. This means considering, among others, the following points:

- Without forgetting the priorities of the strategy 95-95-95, consider the cross-cutting adoption of the fourth «95» and carry out its regular monitoring and evaluation with the direct participation of PLHIV and the different stakeholders.
- Foster, whenever possible and in accordance with PLHIV, the institution of the therapeutic regimen best adapted to their lifestyle.
- Where feasible, promote the integration of new partners (e.g. community pharmacies) and new functions in the provision of health care (e.g. drug delivery, new ways of drug administration)).

Community organizations and NGOs must be prepared to perform new tasks in multidisciplinary collaboration with health structures. National or regional health services, with the support of the private sector, must provide the resources, in particular financial so that these organizations can perform their function and acquire training to prepare themselves technically for these new tasks, mainly:

- Strengthening the role of prevention, referral, access, and retention in the healthcare system.
- Implementation/participation in adherence to treatment and healthcare programs.
- Where possible, participation in the delivery and administration of drug treatment/prophylaxis
- Participation in the HIV policy definition and programs.

POLICY RECOMMENDATIONS

- 1** Governments should improve the quality and access to databases both at national and regional level to monitor the evolution of HIV infection rates, particularly regarding the subpopulations most vulnerable to infection.
- 2** Reinforce the partnership with community organizations and other health system partners, such as pharmacies, to decrease the proportion of late diagnoses, especially for the most vulnerable populations.
- 3** Simplify and expedite the process of approval by health authorities of therapeutic innovation. This would accelerate the access to innovation for PLHIV and the access to it by PLHIV.

SOPHIE STRACHAN

CEO, Sophia Forum



As we enter the fifth decade of the HIV epidemic, HIV incidence remains highest amongst women and girls: 54% of the people living with HIV globally¹¹. Gender inequality is a key driver of the epidemic. It compounds inherent power inequalities between women and men as well as drives experiences of violence and harmful gender norms all of which contribute to increasing HIV vulnerability and limits women's access to HIV services, prevention or treatment technologies. Existing strategies do not adequately address these gender-driven barriers.

Wider inequalities have been laid bare across the over 40 years of the HIV epidemic and never more so than through the globalised experience of the COVID-19 pandemic. HIV transmission rates are still disproportionality affecting women from racially minoritised communities, especially Black African and Black Caribbean women in the UK and beyond. Whilst we have seen a reduction in new transmissions amongst gay and bisexual men, this decline has not been replicated for heterosexual women and men. The number of trans-people in the UK receiving treatment is currently around 151¹².

Barriers such as stigma, discrimination, criminalisation and inadequate health care structures drive these persistent inequalities. People who inject drugs, sex workers, people in prisons and transgender populations are more likely to face violence, stigma and laws that restrict access to services. Those most at risk of gender-based violence tend to be those least protected and supported by current efforts to prevent and tackle violence and other harm. This is compounded by the volatile political landscape perpetuating precarious migrant status, displacement, poverty, food and housing insecurity.

Intersectional feminism highlights the voices of those experiencing overlapping, concurrent forms of oppression to better understand the depths of the inequalities and the interconnected complexity this generates in any given context. Adopting this lens when reviewing and refining legal, public policy, clinical and financial responses to HIV is crucial. The potential vulnerabilities and challenges women may face are also dynamic across their life course and, therefore, these complexities need to be considered on an ongoing basis.

Within the UK alone there has been a ten-fold¹³ increase in the number of women living with HIV over the past ten years, with current models of care not actively responding to the gendered physical, psychological and social impact of ageing with HIV. The recent GROWS report¹⁴ highlighted a sense that there was insufficient information and resources in general for women, as well as for professionals providing health and social care for women living and growing older with HIV. As an example, women did not know where to find information about the menopause, bone health or heart health in the context of HIV. Public policy and service delivery interventions need to acknowledge such obstacles and build responses around evolving needs.

Significant progress has been made on advances in treatment for people living with HIV and for those at perceived risk. However, the disparity in access to newer prevention options such as PrEP has left women and minoritised groups behind. Despite data showing that women are attending sexual health services and have defined a need, this is not being identified by and responded to by clinicians. Therefore, many opportunities

to offer PrEP are being missed. To address this gap, training healthcare professionals to tackle such gender bias is an urgent priority. The eligibility criteria for PrEP has also facilitated barriers in uptake for women, alongside criminalisation of sex workers and drug users in some countries. Community activists are at the heart of informing and educating their communities. Yet, whilst there has been an increase in targeted approaches for women and other minoritized groups, this has not translated into access and uptake.

Equitable health outcomes for all self-identifying women perceived to be at risk of HIV and for women of all ages who are growing older with HIV can only be reached if we collaborate. Stakeholders such as governments, policymakers, health service providers, researchers, donors and civil society should jointly seek to fund and create partnerships, community mobilization to promote gender empowerment. Sexual, reproductive and post-reproductive health services and programs should be designed by, with and for women and girls. This will

directly contribute to achieving an accessible and enabling environment. It is critical to increase women's choices, giving us agency to exercise our rights and improving our quality of life by enhancing the robustness of health outcomes, as remarked in UN Global AIDS Strategy.

To achieve the 2030 targets and meet the needs of women living with, and at risk of HIV transmission we must stretch beyond efforts made to date. It is essential for future approaches to intentionally dismantle paternalistic, structural barriers and to tackle gender inequality from its root causes, by challenging and changing these gender norms.

We urge an intersectional feminist and human rights-based approach in the journey to 2030. Efforts should unapologetically listen to the perspectives, concerns and recommendations of women living with, and at risk of HIV transmission by:

POLICY RECOMMENDATIONS

- 1 Implementing gender responsive programs and activities following an intersectional, life-course approach.**
 - Policy initiatives should be designed considering the diverse needs of all self-identifying women, explicitly aiming to redress existing inequalities and health disparities based on gender.
- 2 Co-developing an aligned research agenda with women using social justice, intersectionality and anti-racism frameworks.**
 - Effectively coordinating research that explores and responds to lived experiences is essential to deliver actionable interventions to shift power dynamics and dismantle structural violence.
- 3 Commissioning peer-led services, which are essential in responding to the intersectional and dynamic needs of women across their life course.**
 - Working with peers has proved to be an effective tool to identify the needs and concerns of vulnerable populations. This will make significant contributes to address misrepresented challenges experienced by women ageing with HIV.
- 4 Ensure women's (cis and trans) needs are addressed in national HIV prevention guidelines to tackle existing gaps to accessing PrEP.**

LUZ MARÍA PEÑA- LONGOBARDO

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The economic burden that HIV has on societies overall is often unheard and unspoken of. As the considerable deterioration that the HIV causes in the quality of life, health and the wellbeing of the people who suffer from it, this disease has been one of the main concerns for public health since its discovery in 80s¹⁵⁻¹⁶. Therefore, HIV leads to serious socio-economic challenges for individuals, their families and governments. One of these challenges is related to the economic burden that HIV might have on society, as the health status of people living with this disease is worse than that of the general population¹⁷⁻¹⁸. This burden is mainly explained by the huge use of healthcare resources (based on drugs consumption, hospitalizations, visit to general practitioner and specialist, emergency visit, medical tests and so on) and by the labour productivity losses, derived from impaired ability to work and from potential premature deaths (occurring before 65 years).

Healthcare costs for people living with HIV are estimated to be seven times higher than healthcare spending for the general population. That means an estimated annual excess cost of 8,049€ per person¹⁹. Given the prevalence and incidence of the disease, this can cause a significant impact on the financial sustainability of national health systems.

However, the economic burden of HIV goes far beyond its direct medical costs. The impact of HIV on the labour market is one of the most tangible socio-economic consequences of the HIV epidemic – aggravated by the fact that the vast majority (almost 90% worldwide) of people living with HIV are of working age²⁰.

People living with HIV might experience an almost complete loss of or impaired ability to work due to the burden of the disease and its associated comorbidities. Evidence suggests that a person with HIV could experience on average an additional eight sick leave days annually compared with the general population, as well as a loss of economic productivity due to premature mortality. This translates into an annual productivity loss of up to 24,000€ per person living with HIV²¹.

In addition to a loss of productivity, people living with HIV usually experience higher rates of unemployment and job loss related to their condition – a factor that has a significant impact also on the individual socio-economic situation and overall well-being of people living with HIV over the life course. People with HIV are less likely to be employed than the general population²². Specifically, immunological status, source of infection and level of education play a relevant role among this population when comparing their labour participation with the general population. Additionally, an economic crisis or situations in which the economy could be harmed (as is happening with the COVID crisis) always has a greater effect on the employment prospects of people living with HIV than on the general population²³.

Scientific advancements that improve the health outcomes of people living with HIV have the potential to reduce the public health and socio-economic burden of the disease at societal level. When assessing the value of innovation in HIV prevention and care, it is essential to evaluate the wider socio-economic benefits that innovative prevention and treatment options can produce in the longer term.

Investments in prevention and innovative therapeutics support long-term population health and the overall resilience of healthcare systems and societies. The right balance should therefore be found between the need to ensure the sustainability of healthcare budgets in the short term, and the overarching goal of improving health outcomes, health related quality of life and societal cost savings in the longer term. Health-economic evaluation should play a role in assisting policymakers in the allocation of scarce health care resources.

This process should consider the opportunity cost of investing in prevention and screening as well as in innovating the overall HIV response²⁴⁻²⁵.

POLICY RECOMMENDATIONS

- 1** Ensure that HTA regulators take into account the overall public health and economic burden of the disease- including labour productivity losses- in the economic assessment of the value of prevention, testing and therapeutic innovation
- 2** Design holistic employment policies that take into consideration the needs of vulnerable populations and specifically of people living with chronic conditions, such as people living with HIV.
- 3** Reassess current recruitment and employment policies to ensure they do not have a negative impact on people living with HIV. Research shows a significant link between the clinical characteristics of people living with HIV and poorer work conditions.
 - Therefore, employment and social policies must address these challenges and take into account the specific needs of HIV-infected individuals as these will also entail positive benefits for both economies and healthcare systems.

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Law can make both a positive contribution to the eradication of HIV and ensuring that the human rights of people living with HIV and AIDS are respected, or it can do precisely the opposite: it can be the reason why people vulnerable to HIV transmission do not access, or are unable to access, prevention, why people with undiagnosed HIV do not get tested, or get tested late, and why people with diagnosed HIV from access treatment and care and support services. Countries with punitive laws that directly or indirectly impact on and discriminate against people with HIV – or vulnerable to HIV transmission – fuel HIV-related stigma and impede the global HIV response. On the other hand, countries that promote and effectively implement enabling laws benefit from a demonstrable reduction in their domestic HIV prevalence, contributing to efforts to end AIDS as a public health threat, and enabling all people – irrespective of their HIV status – to be treated with the dignity and respect.

Countries in all continents have punitive laws, and those in Europe are no exception. By punitive laws is legislation which establishes and sustains a hostile, unsupportive, legal environment in which coercive, restrictive, or discriminatory practices act as barriers to the provision of, or access to, HIV prevention, treatment, and care.

Criminalisation of drug use

HIV prevalence is increasing in Eastern Europe and Central Asia (EECA), driven in large part by injecting drug use.²⁶ Other than in the Czech Republic, countries

in EECA criminalise the possession of drugs for personal use and incarcerate those convicted. In addition, harm reduction facilities and provision are far from adequate. Although 26 out of 29 countries in this region make explicit and supportive reference to harm reduction in policy documents, none provides drug consumption rooms, only five provide a needle and syringe programme in at least one prison.²⁷ **There is strong and growing evidence that the decriminalization of drug use combined with more comprehensive provision of harm reduction services and anti-retroviral therapy would significantly reduce the incidence of HIV in these countries and ultimately lead to cost savings for healthcare systems overall.**²⁸

Criminalisation of sex work

Sex work is subject to different legal regimes across Europe. Where it is criminalised, alongside other structural and intersecting social factors, sex workers are at higher risk of HIV transmission, and prevalence rates are higher.²⁹

Criminalisation of HIV transmission

Many European countries criminalise people living with HIV for unintentionally exposing others through sexual transmission. Of 37 countries in Western and Central Europe for which data is available, only 10 countries have adopted a policy of non-criminalization, while 13 countries have not adopted this policy and 14 have partially adopted non-criminalisation.³⁰

There is no empirical evidence to indicate that criminalisation contributes to ending the epidemic.

On the contrary, there is evidence to suggest that it can disrupt the continuum of care, discourage testing, and reinforce HIV-related stigma (which in turn has a negative impact on health-seeking behaviour as well as the mental and physical wellbeing of people living with HIV). Even more perniciously, criminalisation can disproportionately impact women, who are more likely – through pre-natal and other forms of screening – to know their status compared to men, and as such are frequently blamed for HIV transmission. These examples offer compelling evidence of the negative impact that punitive laws can have on undermining an effective HIV response.

Law, health and a rights-based approach to public health is critical to progress the HIV response and end AIDS as a public health threat.

Not only should countries eliminate punitive and discriminatory laws because it is the right thing to do, but there is also growing evidence that doing so is efficient and has positive health outcomes.⁵ This has been recognised by UNAIDS, the Global Commission on HIV and the Law, and by numerous well-respected international bodies. But there is much yet to do.

POLICY RECOMMENDATIONS

- 1** Use robust evidence currently available to inform policy making, law-making, and legislative implementation and enforcement.
- 2** Work with, and not against, people living with HIV and key populations in the development of and roll-out of policy initiatives; ensure that their voices are not just heard but are heard where they need to be heard, and are acted on;
- 3** Recognise the importance of ensuring and promoting access to justice for people living with HIV and key populations, including support by states and donors for innovative, client-centred, legal and paralegal services and organizations.
- 4** Support inclusive policymaking frameworks and multistakeholder fora (e.g. the EU Civil Society Forum), to ensure different stakeholders - and especially people living with HIV and key populations - become key drivers of HIV policy shaping and their views are integrated into EU and national decision-making processes.
- 5** Repeal excessively broad and punitive laws aligning with the recommendations of the Global Commission on HIV and the Law. In addition adopt non-criminalisation policies towards people living with HIV and key populations.
- 6** Recognise that repealing punitive laws and introducing supportive legal environments is not in itself sufficient. It is essential to improve, and to provide, education and training for those responsible for law enforcement and adjudication, to effectively tackle HIV-related stigma, discriminatory practices and intersectional stigma.

OUTCOMES FROM THE EVENT UNFINISHED BUSINESS: A UNIFIED VOICE DRIVING INNOVATION IN HIV

on 17 November 2022

The policy manifesto has been informed by the outcome of the discussions during the event on “Unfinished business: a unified voice driving innovation in HIV” organised by ViiV Healthcare and hosted by MEP Nicolás González Casares (ES, S&D) and MEP Cyrus Engerer (MT, S&D) on 17 November 2022. The panel discussions featured the participation of the following speakers:

- JULIA DEL AMO, Director of the National AIDS Plan, Ministry of Health, Spain
- JANTINE JACOBI, Representative to the European Union, UNAIDS
- HELEN McDOWELL, Head of Government Affairs & Global Public Health, ViiV Healthcare
- STEFAN SCHRECK, Adviser for Stakeholder relations, DG SANTE, European Commission
- JEAN-BERNARD SIMEON, Senior Vice President and Head of Europe, ViiV Healthcare
- MARK VERMEULEN, Director, Aidsfonds – Soa Aids Nederland
- MATTHEW WEAIT, Director of the Department for Continuing Education, University of Oxford, United Kingdom

The discussions aimed to explore what innovation in the HIV response really means, not just from a biomedical point of view but also in terms of the wider challenges that the HIV community still faces – including psychological, social and legal challenges.

The panel explored how innovation can address these challenges holistically and how to ‘innovate’ the broader HIV response to ensure communities and healthcare systems can harness the full potential of bio-medical innovation.

Panellists agreed that:

- Innovation has a unique potential to deliver health-related quality of life and better outcomes for people living with HIV or at risk of HIV.
- While innovation is critical in ensuring access to HIV prevention, **it is vital to make innovation available to all those who need it in a timely and equitable way.**
- **Cost is a major challenge in making innovation available.** Increased funding to innovation is needed and the right balance should be struck between incentives to innovation and access.
- **HIV-related stigma and discrimination as well as punitive laws that criminalise HIV-related behaviours** (e.g., actions that pose a risk of HIV

transmission, including sex work, drug use etc.) **constitute huge barriers to access to HIV services**, especially by key populations, and pose a significant challenge to the attainment of the HIV elimination goals.

- **Policymakers must adopt an evidence-based approach to HIV prevention** and acknowledge that punitive laws that criminalise HIV-related behaviours are counterproductive and should be repealed.
- **A multi-sectoral approach, involving different stakeholders in the overall HIV response, is crucial** to reach the elimination targets and ensure no one is left behind.
- **Working with communities and investing in community-led responses is vital to ensure an effective HIV response**, tailored to the needs of the specific population groups.
- **Best practice sharing is a powerful instrument** through which the EU can intervene and advance the HIV response at Member State and regional level.
- The HIV elimination goals and a non-discrimination, rights-based approach should be embedded in the upcoming EU Global Health Strategy.

During the event, the attendees were asked to prioritise just one concrete policy action on HIV from the ones coming from the policy manifesto. This ranking was able through the Slido® webpage and had 35 votes from the audience. The results were:

29% Increase investment in HIV – including not only treatment, but also focusing on expanding the options available for the prevention of HIV

29% Repeal laws that criminalise key populations, and share best practices on innovative measures to mitigate the criminalisation of these populations, in particular sex workers, drug users and men who have sex with men

20% Strengthen national health systems for prevention and treatment of HIV, as well as investing in innovative community-led initiatives

17% Include ambitious action on HIV in the EU’s Global Health Strategy

6% Strengthen ECDC and national monitoring tools to expand and enhance collection of relevant data for HIV, in order to inform better decision making

0% Share best practices on supporting innovative delivery models, to ensure that no key population is left behind

SUMMARY OF POLICY RECOMMENDATIONS

Building on the UN Global AIDS Strategy, the EU should develop a set of actionable recommendations to guide member state implementation of targeted policy interventions at national and community level. This should enhance the important role of HIV/AIDS in existing EU initiatives; for example, HIV/AIDS and related inequality issues must feature in the EU4Health Programme*.

STRENGTHEN EUROPEAN CENTRE FOR DISEASE PREVENTION AND CONTROL AND NATIONAL MONITORING TOOLS TO EXPAND AND ENHANCE COLLECTION OF RELEVANT DATA FOR HIV, IN ORDER TO INFORM BETTER DECISION MAKING

EU and national policymakers and health authorities should make full use of existing data and evidence on HIV/AIDS to better inform policy and decision making. This should include information on HIV transmission rates, but also other aspects affecting health-related quality of life for people living with HIV. Furthermore, evidence and data gaps should be addressed, with further research being jointly developed with affected communities and supported by government funding mechanisms.

STRENGTHEN NATIONAL HEALTH SYSTEMS FOR PREVENTION AND TREATMENT OF HIV, AS WELL AS INVESTING IN INNOVATIVE COMMUNITY-LED INITIATIVES

Policymakers must work collaboratively with people living with HIV to ensure their efforts are not undermined. This requires partnership with community and peer-led organisations, among others, on programmes to strengthen access to innovative prevention, diagnosis and treatment. These must consider the differing needs of different affected (and marginalised) groups, including women and trans people.

REPEAL LAWS THAT CRIMINALISE KEY POPULATIONS, AND SHARE BEST PRACTICES ON INNOVATIVE MEASURES TO MITIGATE THE CRIMINALISATION OF THESE POPULATIONS, IN PARTICULAR SEX WORKERS, DRUG USERS AND MEN WHO HAVE SEX WITH MEN

EU and national policymakers should demonstrate leadership at home and globally by defending EU values of inclusion and anti-discrimination. This requires not only repealing punitive laws that uphold stigma, discrimination, and criminalisation of HIV/AIDS; it is also essential to establish a legal framework that actively protects those living with or affected by HIV. This includes, for example, ensuring access to the labour market through inclusive employment policies that recognise the workplace rights of vulnerable populations. Furthermore, comprehensive education and training is needed to ensure inclusive legal frameworks are implemented and enforced.

INCREASE INVESTMENT IN HIV – INCLUDING NOT ONLY TREATMENT, BUT ALSO FOCUSING ON EXPANDING THE OPTIONS AVAILABLE FOR THE PREVENTION OF HIV

It is essential to ensure the eradication of societal and legal obstacles, so that those communities particularly hit by the epidemic can benefit from access to novel treatment and prevention tools. Policy steps must also be taken to support access to prevention, treatment and care by re-designing the provision of HIV services and introducing innovative delivery models. The EU can be a key partner in directing and incentivising investment in HIV prevention, diagnosis and treatment; as well as in research to develop an HIV vaccine.

INCLUDE AMBITIOUS ACTION ON HIV IN THE EU'S GLOBAL HEALTH STRATEGY

HIV/AIDS is a global challenge, and therefore demands global policy action as well as action at the EU and national level. This is an opportunity for the EU to show leadership, which could include joining the Global Partnership for Action to eliminate all Forms of HIV-Related Stigma and Discrimination; being a financing partner for the global HIV/AIDS response, supporting the work of multilateral agencies focused on HIV such as UNAIDS and the Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria. In addition, the EU's advocacy and mobilisation voice on the international stage, such as at the UN General Assembly remain critical to end the epidemic.

*The EU4Health programme is an EU financial support programme providing funding in the health area.

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