



HIV/AIDS

An introduction to the current challenges and opportunities in the treatment of HIV.

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Introduction

Human immunodeficiency virus (HIV) is the virus that is responsible for Acquired Immune Deficiency Syndrome (AIDS). This is caused when the virus attacks the immune system, particularly CD4 T lymphocytes. The destruction conferred to these cells by HIV can weaken a person's immunity against many different infections.

HIV continues to be a major global public health issue having claimed the lives of 36.3 million people so far, according to World Health Organization (WHO).

Currently, there is no cure for HIV infection. However, thanks to the increasing access of patients to effective HIV prevention, treatment and care, HIV has become a manageable chronic health condition and therefore, people who have access to medication can live long, healthy lives. According to WHO, at the end of 2020, there were an estimated 37.7 million people living with HIV globally, two thirds of whom were in the WHO African Region.

Challenges, trends and opportunities

Sustained access to combination antiretroviral therapy (cART) has been deemed crucial in reducing mortality rates of people with HIV infection. The early initiation of cART and subsequent suppression of the plasma viral load can contribute towards reduced mortality and HIV transmission rates and a better quality of life.

Towards that direction, the Joint United Nations Program on HIV/AIDS (UNAIDS) has proposed the 90-90-90 and 95-95-95 targets which state that, by 2020 and 2030, respectively, at least 90% and 95% of all people with HIV should be diagnosed, at least 90% and 95% of those diagnosed should be treated with cART, and at least 90% and 95% of those treated with cART should be virologically suppressed.

The progress made so far has been encouraging. However, a considerable number of countries have not reached the 90-90-90 targets.

There are many challenges that need to be addressed to bridge the gaps in prevention, diagnosis, and treatment.

Challenges have risen in HIV prevention and care over the last years in many countries. These challenges are rooted in societal and psychological factors, such as poor social support, gender-based violence, stigma, discrimination, and poverty. Therefore, successful prevention programs should target gender inequality and economic issues.

37.7 million

The total number of people living with HIV globally at the end of 2020.





Furthermore, sexual health and condom promotion, HIV testing and counselling, supportive local and national legal policy environments, treatment as prevention (TasP) and voluntary male medical circumcision (VMMC) seem to be effective prevention measures.

The costs of diagnosis and access to care constitute another important challenge. Access to care should be cheap and non-discriminating worldwide to reach the goals set by UNAIDS. In terms of diagnosis, while some regions of the world have been successful in reaching high

numbers of diagnosed HIV-positive individuals, other areas, such as sub-Saharan Africa, estimated the number of diagnosed HIV-positive people at 45%.



Proactive testing, such as door-to-door testing, instead of passive testing, where individuals test voluntarily, could be the answer. Treatment and retention in care are the next steps towards the control of HIV infections.

The health systems should ensure that medicines are provided free of charge and that a good stock is maintained, so that the medicines are widely available. Additionally, the removal of policies and laws that discriminate against certain population groups and HIV-positive individuals and have a negative impact on testing and treatment of HIV is crucial.

The third challenge is associated with the HIV treatment. Currently, the antiviral drugs used to treat HIV include nucleoside reverse transcriptase inhibitors (NRTIs), non-nucleoside reverse transcriptase inhibitors (NNRTIs), protease inhibitors (PIs), fusion inhibitors, CCR5 antagonists, integrase strand transfer inhibitors (INSTIs), attachment inhibitors, post-attachment inhibitors, pharmacokinetic enhancers and combination HIV medicines.

While, so far, a significant decrease in HIV-associated morbidity and mortality rates has been achieved, alongside a reduction in the HIV transmission rate and the improvement of quality of life of people living with HIV, cART is still unable to eradicate HIV infections and, thus, has to be taken for life.

Interruption of cART is associated with viral rebound even when cART has been started very soon after HIV infection. Current treatments are unable to cure HIV infection. Rather than eliminating HIV, a functional cure that ensures a durable viral suppression in the absence of cART is more likely to be found first.

Finally, despite the significantly improved safety profiles of current HIV treatments, compared to older ones, the use of antiretroviral drugs is associated with certain adverse effects that may have an impact on patients' quality of life. These include weight gain that can lead to obesity, drug-related hepatitis linked to the use of NNRTIs and protease inhibitors, as well as certain rare adverse effects, such as hypersensitivity reactions caused by certain NRTIs or less commonly with some NNRTIs, or bone and renal issues linked to the use of certain NRTIs. Even though the adverse effects associated with cART are generally not serious, new under-development assets for HIV treatment should demonstrate improved safety profiles, compared to current or older treatment choices.

Other co-existing diseases and aging are also factors that need to be considered. The presence of other diseases on top of the HIV infection and/or adverse effects from the long-term administration of antiviral drugs can contribute to increased morbidity and mortality rates of patients with HIV. Additionally, interactions of antiviral drugs with drugs administered to patients to treat other co-existing diseases can lead to safety issues. Finally, lifestyle-associated risk factors, such as smoking, obesity and substance abuse are more prevalent among HIV-positive people.



**\$28.79
billion**

was the global
HIV drugs market
value in 2020



HIV is still a dynamic field with room for innovation

AIDS is considered one of the most serious and chronic diseases: there is still no treatment that can eradicate HIV.

To date, the main treatment target is to obtain a functional cure where a durable suppression of HIV can be maintained in the absence of cART. Towards that end, experimental strategies target the HIV replication cycle (gene therapy, latency reversal agents), provide HIV-specific immune response (T-cell vaccines, broadly neutralising monoclonal antibodies), or modulate the immune response (anti-inflammatory drugs, immune checkpoint inhibitors).

Additionally, due to safety and tolerability issues regarding the long-term administration of antiviral drugs, companies are currently researching and implementing simplified antiretroviral dosing regimens, such as two-drug single-tablet regimens or long-acting injectable formulations of existing drugs.

Apart from HIV treatment, pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) are other dynamic areas in the HIV field. PrEP is medicine that can significantly reduce the chances of healthy individuals contracting HIV. PrEP medicines are available as tablets, as well as a recently approved long-acting injectable formulation. PEP is medicine that is used only in emergency situations and should be initiated within 72 hours of a potential high-risk exposure to HIV to prevent the virus from taking hold in the human body.

Globally, the HIV drugs market was \$28.79 billion in 2020 and is anticipated to grow over the forecast period 2021 - 2028 (Fortune Business Insights, June 2021).



The growth is fuelled by the increase in HIV prevalence and the increase in the rate of care diagnoses, combined with an increasing number of new product launches and rising drug approvals.

The continuous growth of the HIV market, the ongoing research on the field and the innovation potential render HIV a dynamic therapeutic area of interest where companies will keep competing for market share in the coming years.

What does this mean for patients?

HIV diagnosis and treatment become increasingly available to patients, irrespective of their background and country of residence, and their quality of life has significantly improved.

The regulatory approval and commercialisation of new drugs and therapies could further improve the patients' quality of life through simplified antiviral drug dosing regimens, the potential future capability to stop the administration of cART after certain time of treatment, and the long-term goal of eradicating HIV.

Appendix

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