

Evolving Challenges in the Implementation of China's "Four Frees and One Care" Policy for HIV/AIDS

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Abstract: In response to the HIV/AIDS epidemic, China initiated the "Four Frees and One Care" policy in late 2003. This policy provided free counseling, testing, and antiretroviral treatment for people living with HIV, while also offering support to affected families. While instrumental in advancing HIV/AIDS prevention, the policy faces evolving challenges. This study aims to analyze this challenge from multiple dimensions and, based on this analysis, provide effective recommendations for the Chinese government to address it, promoting the sustainable development of the "Four Frees and One Care" policy. The research found that reduced government funding has led to the decline of grassroots organizations, creating a disconnect between administrative and treatment systems. Additionally, advancements in medical technology introduce new antiretroviral drugs, complicating their integration into the healthcare system. In the current healthcare reform, updating the list of free antiretroviral drugs proves challenging. Adapting the policy to contemporary HIV/AIDS prevention should be a priority for the Chinese government. Balancing financial constraints, organizational sustainability, and evolving medical technologies will be pivotal for the ongoing transformation of the "Four Frees and One Care" initiative.

Keywords: Four Frees and One Care, ART, PLHIV, China, HIV/AIDS policy

Introduction

To combat the HIV/AIDS epidemic, many countries have adopted and enacted policies to reduce its transmission and increase HIV-related service use.¹ The Chinese government initiated the "Four Frees and One Care" policy at the end of 2003.² The policy encompasses five key components: 1) providing free counseling and initial screening tests for individuals voluntarily seeking HIV counseling and testing, 2) offering free prevention of mother-to-child transmission (PMTCT) drugs to pregnant women living with HIV, 3) delivering free antiretroviral therapy (ART) drugs to low-income people living with HIV (PLHIV) in both rural and urban areas, 4) ensuring free access to education for children from HIV/AIDS-affected families, and 5) providing care and support to HIV/AIDS-affected families facing economic hardship. Undeniably, since the Chinese government implemented the "Four Frees and One Care" policy in 2003, there has been a significant increase in HIV testing rates in China, and the control of PLHIV condition and family care has improved significantly compared to before the policy was enacted. For instance, in 2013 alone, the number of voluntary HIV tests in China reached as high as 111 million person-times, with the proportion of pregnant women with HIV receiving PMTCT reaching 80.9%.³ In providing ART drugs for low-income PLHIV and offering family care, the "Four Frees and One Care" policy not only reduces the economic burden on PLHIV in treating the disease⁴ but also further reduces the HIV mortality rate in China⁵ and alleviates the psychological barriers faced by PLHIV due to illness.⁶ Over time, although the number of reported HIV cases in China remains substantial,⁷ the overall HIV epidemic has reached a low-prevalence level.⁸ However, the relatively rigid mode of the "Four Frees and One Care" policy also presents new challenges for its continued implementation. In fact, many countries have proposed similar policies and also encountered

various difficulties in their implementation. For example, South Africa has long implemented policies for voluntary HIV testing and the free provision of ART drugs. However, social gender norms can pose challenges to the effective implementation of these policies. In South Africa, influenced by cultural customs, men tend to avoid HIV testing as much as possible,⁹ while women, due to their lower social status, find it even more challenging to access effective assistance after HIV infection.¹⁰ Additionally, young people in Nigeria have a range of HIV testing preferences, which suggests that a “one-size-fits-all” approach to delivering such services to the youth may emerge as a challenging issue.¹¹ Government-funded assistance programs have an important role in most countries,¹² but the achievement of their objectives still face significant challenges.¹³ For example, in Kyrgyzstan, research shows several major state agencies exhibited some resistance or lack of initiative towards HIV/AIDS policies.¹⁴ Although Brazil began implementing HIV prevention and control policies as early as 1986, the uneven economic development levels among its regions have resulted in the policies not achieving the desired effectiveness.¹⁵ Furthermore, the sustainability of free drugs is affected by the resources and capabilities of various parties such as the government, medical systems and funders.^{16–18} For example, the Indian government began nationwide promotion of tuberculosis preventive therapy specifically targeting PLHIV in 2017. However, as a middle-to-low-income country, India still faces challenges with low coverage due to drug shortages.¹⁹ Similarly, Uganda faces challenges with HIV drug shortages stemming from suppliers’ failure to order drugs on time and a lack of accurate data on ART program, leading to inaccurate estimations of antiretroviral drug demand.²⁰

In China’s case, especially in the aspect of providing free ART drugs with nationwide coverage, the “Four Frees and One Care” policy has played a pivotal role in advancing efforts in HIV/AIDS prevention and control over the past two decades. With the continuous advancement of medical technologies and societal changes over the past 30 years, HIV has evolved from a disease associated with almost certain death into a manageable chronic condition.²¹ The treatment methods have also undergone corresponding changes. For example, the inclusion of emerging antiretroviral drugs in the free list of the “Four Frees and One Care” initiative is influenced by regional financial disparities and other factors.²² However, as China still has some distance to go before achieving the “95–95–95” target set by the Joint United Nations Programme on HIV and AIDS (UNAIDS) by 2025,²³ continuous improvements to HIV policies are necessary. Therefore, this study chooses to utilize systems analysis. Based on a comprehensive review of the content of the “Four Frees and One Care” policy and its alignment with the current HIV prevention and control situation in China, the study combines stakeholders’ organizational structures, HIV prevention and control policies, and updates on ART drugs. While identifying the challenges currently faced by this policy, it also provides corresponding recommendations to promote its sustainable development.

Organizational Structure and Challenges in “Four Frees and One Care” Policy Implementation

The implementation of the “Four Frees and One Care” policy involves a relatively diverse range of organizational structures. Generally, it is led and promoted by local health administrative departments, with cooperation and coordination from other relevant departments. For instance, providing free education to children from the families affected by HIV/AIDS and offering care and support to economically disadvantaged families require collaboration between the education and civil affairs departments. It is worth noting that the provision in the “Four Frees and One Care” policy ensuring free access to education for children from HIV/AIDS-affected families is actually integrated with China’s nine-year compulsory education system (specified by the Compulsory Education Law), which mandates “nine years of compulsory education for children and adolescents without charging tuition or miscellaneous fees”. Similarly, the provision of care and support to HIV/AIDS-affected families facing economic hardship is aligned with China’s minimum livelihood guarantee system (regulated by the Urban Residents Minimum Livelihood Guarantee Regulations), which states that “families with per capita income below the local minimum livelihood guarantee standard can apply for urban residents’ minimum livelihood guarantee funds”. Given that the nine-year compulsory education system and the minimum livelihood guarantee system are key components of China’s social security framework, the integration of these aspects with the “Four Frees and One Care” policy has resulted in relatively good operational effectiveness.

The health administrative departments consist of two subsystems: the administrative management system, represented by local Centers for Disease Control and Prevention (CDC), with a hierarchical structure; and the HIV/AIDS treatment system, represented by hospitals and other medical institutions. Both systems are under the leadership of the same-level health administrative department, and CDC can provide guidance and supervision to medical institutions for their specific tasks. For example, according to the “Notice on Launching the Information System for HIV/AIDS ART issued by the Ministry of Health”, health administrative departments at all levels are responsible for formulating detailed implementation rules for treatment information systems within their jurisdictions. They also organize the allocation of necessary resources and coordinate the cooperation of relevant departments to ensure the collection of treatment information for all PLHIV receiving ART in their jurisdictions and the proper operation of the treatment information system. Specifically, CDC and medical institutions are responsible for the collection, reporting, data quality control, and data quality assessment of medical information as well as business training and supervision. They work together to achieve these objectives.

Generally, when an individual’s initial HIV screening test is positive, they must visit the local CDC for confirmatory testing and simultaneously register in the corresponding health administrative management system. Subsequently, the individual can use the diagnosis certificate issued by the CDC to access free antiviral treatment at the designated medical institution in their locality. According to policy regulations, each region (district/county) in China must designate at least one hospital for treating PLHIV. These hospitals are responsible for antiviral treatment and admitting PLHIV with opportunistic infections, comorbid conditions, or complications.^{24,25} This strict administrative management system has also reduced the potential adverse impact of urban-rural differences on PLHIV to some extent. If an PLHIV needs to relocate for antiviral treatment, they must submit a change request within the CDC and the treatment institution systems to complete the process.

Furthermore, to leverage the significant role of grassroots organizations in HIV/AIDS prevention and control efforts, China established the Social Organization Participation in HIV/AIDS Prevention and Control Fund. Using a government procurement approach, this initiative collaborates with the PLHIV currently undergoing treatment, their peers, social volunteers, community workers, treatment support organizations, and other social groups to jointly promote HIV/AIDS prevention and control. These grassroots organizations are extensively involved in frontline activities, such as facilitating the transition from CDC to medical institutions and referrals between medical facilities.²⁶ For individuals, certain information barriers may arise during these processes,²⁷ and grassroots organizations, typically formed spontaneously by PLHIV, play a crucial role in bridging and coordinating these efforts.²⁸ Most of the designated healthcare institutions in China have social organizations stationed in them. They can tell PLHIV important information such as drug compliance in a more empathetic way, so as to improve the treatment effect. However, in recent years, funding support has been significantly reduced (by approximately 70% in 2023 compared with the last years), possibly influenced by government funding cuts²⁹ and advancements in HIV/AIDS medical technologies.³⁰ In our survey, many social organizations are even considering whether to withdraw from the HIV/AIDS prevention and control field.

The “Four Frees and One Care” policy, led by government agencies, has its advantages. For example, it can achieve comprehensive coverage by maximizing the administrative efficiency behind the policy implementation. However, due to its strict managerial nature, there is a noticeable deficiency in flexibility. In the past, China addressed this issue through extensive administrative procurement. Yet, as fiscal constraints lead to a decrease in government payment capabilities, the inherent limitations of social forces become more apparent and challenging to overcome.

Challenges to Voluntary Testing and Policy Conflicts in China’s HIV/AIDS Response

Since 2003, China has vigorously promoted and encouraged voluntary counseling and testing (VCT) within CDC and medical institutions. In 2007, it initiated a pilot program for provider-initiated testing and counseling in medical healthcare facilities, employing an “informed equals non-refusal” approach.³¹ However, in recent years, various forms of mandatory testing are prevalent in practice, including mandatory testing for pre-operative patients and occupational entrance examinations, exemplified by the standards for civil service physical examinations. Scholars have noted that

many groups, including travelers, certain industry workers, public service personnel, conscripts, civil service examination candidates, drug users, sex workers, blood donors, and organ donors, are subject to strict mandatory HIV testing.³² Although widespread mandatory testing provides robust support for the “early detection and treatment” of PLHIV, it has somewhat reduced the practice of VCT, as outlined in the “Four Frees and One Care” policy. Additionally, it has contributed to the proliferation of HIV-related stigma in society. In other words, the voluntary testing principle originally established within the framework of the “Four Frees and One Care” is facing erosion from conflicting policies.

The HIV/AIDS prevention and control grassroots organizations have significantly contributed to voluntary testing, especially among specific populations such as Men who have Sex with Men (MSM).² Through the coordinated efforts of various departments, the knowledge of HIV and utilization of preventive measures among the so-called “high-risk populations” have seen significant improvements in recent years.³³

If one were to assert that in the administrative system, the “Four Frees and One Care” policy is more constrained by financial austerity and falls short in terms of capability, then in the specified testing forms mandated by the policy, it is more subject to practical alienation. It is precisely for this reason that our standpoint is not advocating the complete abolition of the policy or solely addressing specific operational obstacles. Instead, it is about undertaking corresponding improvements based on its objectives in the context of societal changes. In this regard, we can further elaborate on the most crucial aspect of the “Four Frees and One Care” policy—the issue of the free antiretroviral drug list.

Evolving Landscape of ART Practices

Under the “Four Frees and One Care” policy, low-income PLHIV can receive ART drugs free of charge at designated healthcare institutions established in various regions. However, in practice, all individuals confirmed by CDC can benefit equally from this service without taking an income assessment. After an HIV diagnosis, designated healthcare institutions will conduct clinical and laboratory assessments for each PLHIV to determine their suitability for initiating ART. The cost of these assessments is generally borne by the individuals (approximately USD 100–140). Before initiating ART, healthcare institutions and social organizations emphasize the need for a high level of adherence to the treatment of PLHIV. Additionally, PLHIV must attend follow-up appointments to collect their medication within the prescribed time frame. Typically, healthcare institutions provide a three-month supply of medication per visit, possibly extending it to six months in special cases. However, in many regions, healthcare institutions may request that PLHIV undergo follow-up testing when receiving free ART drugs every turn. This practice aims to better monitor the antiviral effectiveness for PLHIV, enabling doctors to understand their physical condition and provide timely targeted medical advice. However, in practice, this requirement often becomes a prerequisite for PLHIV to receive free antiviral drugs, and the cost of this testing is usually borne by the PLHIV (approximately USD 30–50).

The Chinese CDC organizes centralized procurement of free ART drugs. The procurement funds come from the national budget for preventing and controlling major infectious diseases, specifically for the HIV/AIDS prevention and control project. The Chinese CDC conducts annual tenders for procurement, and various provincial drug regulatory agencies engage in decentralized procurement. These drugs are then distributed step by step to the designated healthcare institutions for ART and ultimately provided to PLHIV.²² In other words, apart from the drugs that the Chinese CDC centrally procures, the list of drugs available for free distribution by healthcare institutions may not be entirely consistent across different regions due to variations in local financial resources. One notable example of this discrepancy is the second-line treatment drug Dolutegravir (DTG).

The list of free ART drugs under the “Four Frees and One Care” policy has been continuously updated. In 2004, the free ART drugs mainly included domestically produced drugs such as Zidovudine (AZT), Stavudine (D4T) (subsequently removed), Didanosine (DDI) (subsequently removed), Nevirapine (NVP), and imported drugs such as Lamivudine (3TC), Efavirenz (EFV), and indinavir (IDV) (subsequently removed). By 2012, Fumarate (TDF) was introduced as a first-line treatment drug, and 3TC and EFV gradually entered domestic production. Free ART drugs fall into four categories: NRTIs, NNRTIs, PIs, and INSTIs. NRTIs include AZT/ZiDoVudine (ZDV), 3TC, TDF, Abacavir (ABC), and Emtricitabine (FTC); NNRTIs include EFV, NVP, and Rilpivirine (RPV); PIs include Lopinavir/ritonavir (LPV/r); and INSTIs include DTG. All first-line treatment regimens consist of three ART drugs: two NRTIs and one NNRTI. The preferred first-line treatment regimen is currently TDF+3TC+EFV, with an alternative regimen of TDF+3TC+RPV. AZT

Table 1 Free ART Regimen in “Four Frees and One Care” Policy

Original Treatment Regimen	Second-Line Recommended Regimen
TDF/AZT/ABC+3TC+NVP/EFV/RPV	TDF+3TC+DTG/LPV/r AZT+TDF+3TC+DTG/LPV/r

and ABC can be used as alternatives to TDF. New treatment initiators no longer choose NVP as the first-line treatment drug. Those previously on treatment can continue with NVP or switch to EFV or RPV after clinical assessment. In cases of treatment failure, second-line treatment regimens are available (Table 1).²² In addition, the treatment regimen for pregnant women is also TDF+3TC+EFV, which does not differ substantially from the treatment regimen for other PLHIV. However, doctors may adjust the treatment regimen to TDF+3TC+LPV/r or AZT+3TC+LPV/r based on clinical conditions. In other words, the subtle difference in treatment regimen for pregnant women may prioritize the use of LPV/r, originally part of the second-line recommended regimen, compared to other PLHIV. LPV/r, previously considered a second-line treatment drug, is not widely available in all regions. However, obtaining DTG for free is remains a challenge in China despite being included in the list of free ART drugs. With the advancement of medical technology, many new drugs, although not included in the list of free ART drugs in China, are available for purchase by individuals. Some of these drugs have also been gradually included in the medical insurance system in various regions. As of June 2023, drugs such as Azvudine (FNC), Ainovirine (ANV), Albuvirtide (ABT), Tenofovir alafenamide (TAF), and Emtricitabine (FTC) have entered the medical insurance system; self-funded drugs include Doravirine (DOR), Darunavir/Cobicistat (DRV/c), Raltegravir (RAL), Enfuvirtide (T-20), and a range of combination.²⁴ In other words, in addition to free ART drugs for HIV/AIDS, there are multiple channels for obtaining medication, including medical insurance and self-funded options. Some individuals may even resort to methods such as overseas purchasing, mainly from Indian generic drug manufacturers.²² Different channels can also be subject to cross-impacts in practice. For instance, although DTG has been included in the list of free ART drugs, it is also covered by medical insurance in many regions. This may be one of the reasons why various regions have no incentive mechanism to fully implement it as a free ART drug. It is worth noting that currently, PrEP and PEP drugs are not included in the “Four Frees and One Care” policy, but require personal purchase, which is also a major limitation of the current policy.

Recommendation

There is no doubt that the “Four Frees and One Care” policy has played a significant role in advancing HIV/AIDS prevention and control efforts in China over the past two decades. However, as the social context has evolved, the practical environment in which this policy is implemented has changed repeatedly. First, government leadership remains a necessary foundation for policy implementation. Nevertheless, with dwindling financial support, encouraging relevant social organizations to become self-sustaining has become a critical challenge. Many grassroots organizations have begun shifting their focus and actively engaging in certain medical support activities such as paid consultation to maintain operational sustainability. Second, mandatory testing, including standards such as those applied to civil service physical examinations, has somewhat deviated from the original principle of voluntary testing within the “Four Frees and One Care” policy. Although the motivations behind these approaches may differ, an excessive expansion of mandatory testing undoubtedly exacerbates the existing social stigma and discrimination. From a goal-oriented perspective, it will likely diminish the practical effectiveness of the “Four Frees and One Care” policy. Lastly, with advancements in HIV/AIDS medical technologies, coordinating the interaction between free ART drugs and medical insurance as well as the list of self-purchased drugs, poses a significant challenge for the future implementation of the policy. Despite the gradual inclusion of more ART drugs in the medical insurance system as part of China’s ongoing healthcare reforms,³⁴ the objective disparities between urban and rural areas persist along with wealth disparity. Thus, ensuring free access to ART remains essential for present-day HIV/AIDS prevention and control efforts.

Based on the aforementioned challenges, we believe that the “Four Frees and One Care” initiative should gradually shift its original mode of “universal coverage” to a bottom-line guarantee for economically disadvantaged PLHIV. For

instance, PLHIV could apply to receive free antiretroviral drugs. Given the trend of HIV/AIDS moving towards a chronic disease in the field of medicine,³⁵ relevant diagnostic and therapeutic activities should gradually integrate with the healthcare insurance system. This would also help reduce societal perceptions of HIV/AIDS as being treated as “special”. Of course, for the widespread practice of “informed refusal” testing, it should return to the voluntary orientation within the framework of the “Four Frees and One Care” initiative.

Finally, we recommend that the “Four Frees and One Care” policy should retain the provision of essential free antiretroviral drug combinations, or adopt a more standardized application system. For emerging antiretroviral drugs, better integration with the existing medical insurance system is advisable. This approach ensures that PLHIV in poverty can still benefit from free medication under the policy, while also encouraging regions to procure new antiretroviral drugs. After all, compared to the unconditional provision of free drugs, the medical insurance mechanism can alleviate the financial pressure on local public health expenditures.

Conclusion

As one of the primary policies in the field of HIV/AIDS in China, the “Four Frees and One Care” policy has made significant contributions to the country’s HIV/AIDS prevention and control efforts over the past twenty years. However, with the passage of time, it has also faced increasing obstacles and challenges in practice. Among them, the most notable is the reduction in funding leading to the shrinking of grassroots HIV/AIDS prevention and control social organizations, and the updating of the free ART drug list, both of which are closely related to the principle of voluntary testing. This study suggests alleviating the economic pressure of the “Four Frees and One Care” policy by incorporating antiviral drugs into the medical insurance system. Simultaneously, it recommends continuing funding for grassroots HIV/AIDS prevention and control social organizations to address these challenges. This policy shift not only helps adapt to the changing times in medical significance concerning HIV/AIDS but also greatly contributes to eliminating social stigma associated with HIV/AIDS.

Ethics Approval and Ethics statements

Ethical approval was not required for this study according to local law.

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Disclosure

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