KPMG

Ending the epidemic

An assessment of HIV policy in Italy and recommendation to improve the lives of those living with, and at risk of HIV

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01 Executive summary

Italy's response to the HIV epidemic has delivered good outcomes. Of the 110,000 - 150,000 people estimated to be living with HIV, most are diagnosed, taking anti-retroviral therapy (ART), and are virally suppressed. Italy has made great progress towards international targets such as the UNAIDS 90-90-90 [1] treatment targets - resulting in the number of new infections broadly stabilising over time, although it is not yet decreasing.

But the epidemic is not yet ending. Italy still faces the key challenges of undiagnosed and late diagnosed HIV infections. Its estimated that 11-13% of people living with HIV are undiagnosed. Each year over 3,000 new HIV diagnoses are made, with persistently high rates of late diagnosis [2]. There are more challenges, too – the changing epidemiology means the ageing cohort of people living with HIV are at greater risk of co- and multimorbidities, and mental health issues. Some populations remain hard to reach. For example, newly arrived migrants, particularly women, often suffer intersecting stigmas and are reluctant to engage with state-run services.

Italy has a new strategy to tackle these challenges. The 'Piano Nazionale di Interventi Contro HIV e AIDS (PNAIDS) 2017 – 2019' is hailed for its comprehensiveness, is still unfunded to date of this report publication [3]. It promotes empowering and actively involving high risk populations in managing of their disease, reducing stigma, protecting social and working rights of people living with HIV as well as facilitating access to testing, prevention and treatment. For the first time, it also tackles the topic of sexual health education in schools.

To understand how successful Italy's new HIV strategy will be, the Steering Group [3] assessed each step across the HIV care continuum of Awareness, Prevention, Testing and Screening, HIV-specific Clinical Treatment and Long Term Holistic Health. They identified both areas of strength and those with room for improvement. [3]

1. The UNAIDS 90-90-90 targets set in 2014 are targets for the treatment of people with HIV – 90% of people with HIV will know their status, 90% of people diagnosed with HIV will be receiving ongoing antiretroviral therapy, and 90% of people with HIV on treatment will be virally supressed by 2020. These targets are based on the assertion that it is not possible to end the HIV epidemic without treating all of those with HIV that need it "Source: UNAIDS"
2. A 'late' diagnosis is one which is made at a point in time after which HIV treatment should have been started. Currently, a CD4 cell count below 350 cells/mm3 at time of diagnosis is considered 'late'. Source: UNAIDS
3. For full list of Steering Group members, see Methodology section, Table 1

Awareness

Interventions are available however may be sporadic and continue to miss high risk[4] populations. While PNAIDS tackles the issue of the lack of mandated sexual health education in schools, its implementation remains in question.

Testing and Screening

Free, anonymous testing is available at multiple settings, however, improvements that will enable access to key vulnerable populations are needed.

Prevention

Combined prevention needs greater focus and investment across behavioral interventions, risk and harm reduction in key populations, and pharmacological and structural interventions.

HIV-specific clinical treatment

Available to a high standard across the country. Improvements can be made in consistency of access to newly approved medication across the autonomous regions, a challenge also attributed to limited funding.

Long-term Holistic Care

Long-term management of people living with HIV is effective in specialist settings, but discrepancies exist across regions and settings of care.

4. See Methodology section, Figure 5 for full list of high risk populations

To drive improvements in the lives of those with, or at risk of HIV, the Steering Group put forward a number of recommendations:

- **Enable implementation of PNAIDS as a matter of urgency** – allocated dedicated funding and incorporate policies into Livelli Essenziali di Assistenza (or essential level of care, LEAs) to help ensure implementation and consistent resourcing across Italy
- **Develop integrated awareness and testing interventions for HIV and STIs** – combine broad awareness approaches with targeted campaigns for high risk populations to encourage testing
- **Make condoms free for high risk populations** - increase availability by approving the draft bill or by ministerial decree, to remove barriers to access for high risk populations, especially young people
- **Develop a network of multidisciplinary centres for long-term holistic care of people living with HIV** – enable consistent, high quality care of people living with HIV by establishing a broad network of centres, extending and linking to those currently embedded in specific areas of healthcare services such as geriatrics, mental health and cancer. Existing good practice can be studied and scaled up to ensure good models are put in place

02 HIV in Italy, the wider context

Brief epidemiology and 90-90-90 overview

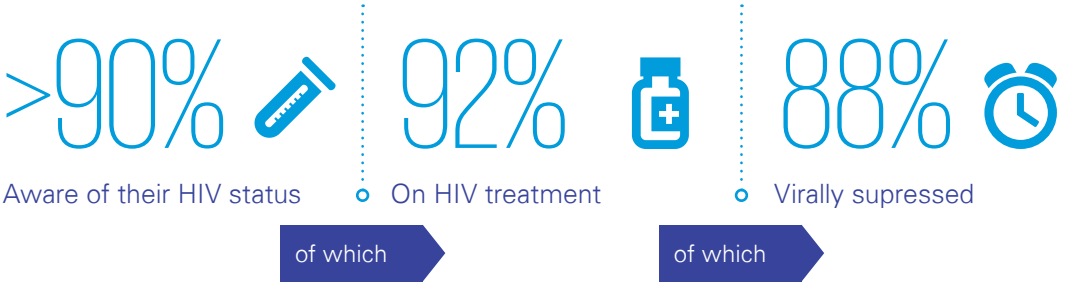
Italy has made great strides in tackling the HIV epidemic. It achieves good clinical outcomes, exemplified by its progress towards international targets such as the UNAIDS 90-90-90 (see Figure 1), indicating that once diagnosed, people living with HIV are successfully initiated on ART and virally supressed. This is particularly relevant given the high proportion of people living with HIV who are diagnosed late (see below).

Italy's challenge lies with its undiagnosed population. Of the 130,000 [111,000 - 150,000] people estimated to be living with HIV in Italy, 11-13% or ~14,000 are estimated to be unaware of their infection. Further, while incidence has stabilised, each year over 3,000 new HIV diagnoses are made (3,443 in 2017). A high rate of late diagnosis, known to be associated with higher mortality and morbidity. In 2017, the proportion of people newly diagnosed with HIV with CD4<350/mm^3 was 55.8%, and this rate has shown no change over time[2] [3].

Changing epidemiology of HIV, particularly the ageing cohort of people living with HIV, is another challenge. While Italy excels in ageing and co-morbidity management in general, combination of these services with the additional needs of people living with HIV (e.g., who suffer from a disproportionate burden of chronic and mental health conditions) has created capacity and funding pressures. The changing epidemiology is further exemplified by 2017 incidence data, which revealed highest number of new infections among people aged 25-29 years, indicating a potential high risk population targeted for combined awareness and prevention efforts.[3]

Demonstrating an on-going commitment from the government to the HIV response, a new national strategy for tackling HIV was launched in 2016 (see Chapter 3) - however its implementation remains in question. The wider legal and policy environment also continues to impact the current response, contributing towards the quality of life of people living with HIV and efforts to limit the spread of the epidemic (see Box 1).

Figure 1. Performance towards the 90-90-90 targets



Source: [44] [45]
Notes: Data for 1st 90 in Figure 1 is from 2013, and data for 2nd and 3rd 90 are from 2014. UNAIDS data from 2012 indicate 88%-88%-87%[4].

Box 1. The wider legal and regulatory landscape

As outlined in the Methodology section, a deep assessment of the wider legal and regulatory landscape and its impact on the HIV response is not within the scope of this project. However, indicated below are Italy's current position on three common potential barriers to the HIV response:

1) Legal protection against stigma and discrimination:

Antidiscrimination laws, based on Article 3 of the Italian Constitution, dictates that all citizens have equal social dignity and are equal before the law, without distinction of sex, race, language, religion, political opinion, personal and social conditions [5]. Further to this, the previous strategy for urgent action against AIDS & HIV details that the HIV infection cannot constitute for grounds for discrimination, in particular for school enrolment or access to employment[6]. Despite the laws, PNAIDS highlights stigma as an issue that is still present, proposing interventions aimed at monitoring stigma and reducing stigma in healthcare professionals and in the community. Research published by LILA and the University of Bologna in 2015 indicated 61% of people living with HIV kept their HIV positive status secret and more than half of the respondents with HIV reported unfair or different treatment because of their status [7]. Therefore, similar to other European countries included in this report, although legal protection is provided, a challenge exists in eliminating perceived or real discrimination against people living with HIV.

2) Free, non-discriminatory access to healthcare:

Italy's National Health Service (SSN) provides universal access to healthcare across the country for nationals, residents and regular migrants. It operates at three levels (central and regions, as required by constitution, and local) and is financed through general taxation (direct and indirect). While the State guarantees access to healthcare, it is the responsibility of regions to implement and organise the provision of care, which at times results in discrepancies and regional variations. Healthcare is available to undocumented migrants, through the "Testo Unico" law on immigration (established in 1998), and provides a number of services including prophylaxis, diagnosis and treatment of infectious diseases [8]. Evidence varies for how well this is implemented, with reports indicating challenges in provision of services to migrants at scale[9], including access to primary care services [10].

3) Decriminalisation of behaviours such as sex work and drug use:

While it is legal to be a sex worker in Italy, law dictates it is illegal to promote or profit from the prostitution of others and organised prostitution is prohibited, punishable with imprisonment and a fine[11][12]. Brothels have been banned since 1958 and prostitution in hotels, entertainment clubs and public areas is illegal[13]. While availability of data is limited, a study on sex worker clients indicated inadequate risk perception, condom use and HIV testing[14], stressing the urgent need to monitor this marginalised population, encouraging safe sex behaviors and promoting HIV-STI testing.

With regards to drug use, the Italian National Action Plan on Drugs (initially covering 2010-13 but currently in force) outlines objectives including demand reduction (e.g., prevention, treatment, rehabilitation) and supply reduction (e.g., evaluation, monitoring, legislation). Multiple harm reduction policies are in place and, although they are generally more extensive in the northern and central Italian regions, a range of services are available including mobile units, fixed sites and outreach programmes (e.g., needle and syringe dispensing machines and naloxone treatment) (see Chapter 2). The positive impact of Italy's harm reduction policies are seen in the latest data, in which only 96 new HIV infections were reported among people who inject drugs (PWID) (2016), with a decreasing trend between 2010 and 2016 [15].

03 Assessment of HIV policy in Italy

This chapter outlines the Steering Groups assessment of the current HIV policy in Italy, and its effectiveness in tackling the new and continuing challenges of the epidemic. It is broken down by stages of the HIV care continuum, covering Awareness, Prevention, Testing and Screening, HIV-specific Clinical Treatment and Long Term Holistic Health.

3.1 Overview of national HIV policy

Italy's detailed national strategy for HIV and AIDS, launched in 2016, remains unfunded to date[1]. The renewed national plan, *'Piano Nazionale di Interventi Contro HIV e AIDS'* (PNAIDS) 2017 – 2019[16], is the first new plan in decades, integrating law 135/1990 which was in effect for more than 25 years. PNAIDS outlines a detailed approach towards achieving the objectives indicated by UNAIDS and WHO[16], and aims to promote empowerment and active involvement of key populations in the management of their disease, the reduction of stigma, the protection of social and working rights of those living with HIV, along with facilitating access to testing, prevention and treatment.

Experts indicate a number of key strengths of PNAIDS:

- Focus on collaboration and intention to ensure complete involvement of high risk populations (including men-who-have-sex-with-men (MSM) sex workers and youth)
- Links to pre-existing clinical guidelines to ensure standards of care are met and are uniform across the country
- For the first time, addressing sexual health education, aiming to integrate it into the school curriculum, and also implement a wider sexual health program

The plan is the result of a multi-stakeholder collaboration. Organisations including the Technical Health Committee (CTS), the National Institute of Health (ISS), scientific societies, voluntary associations, universities, research institutions and scientific care provided input.

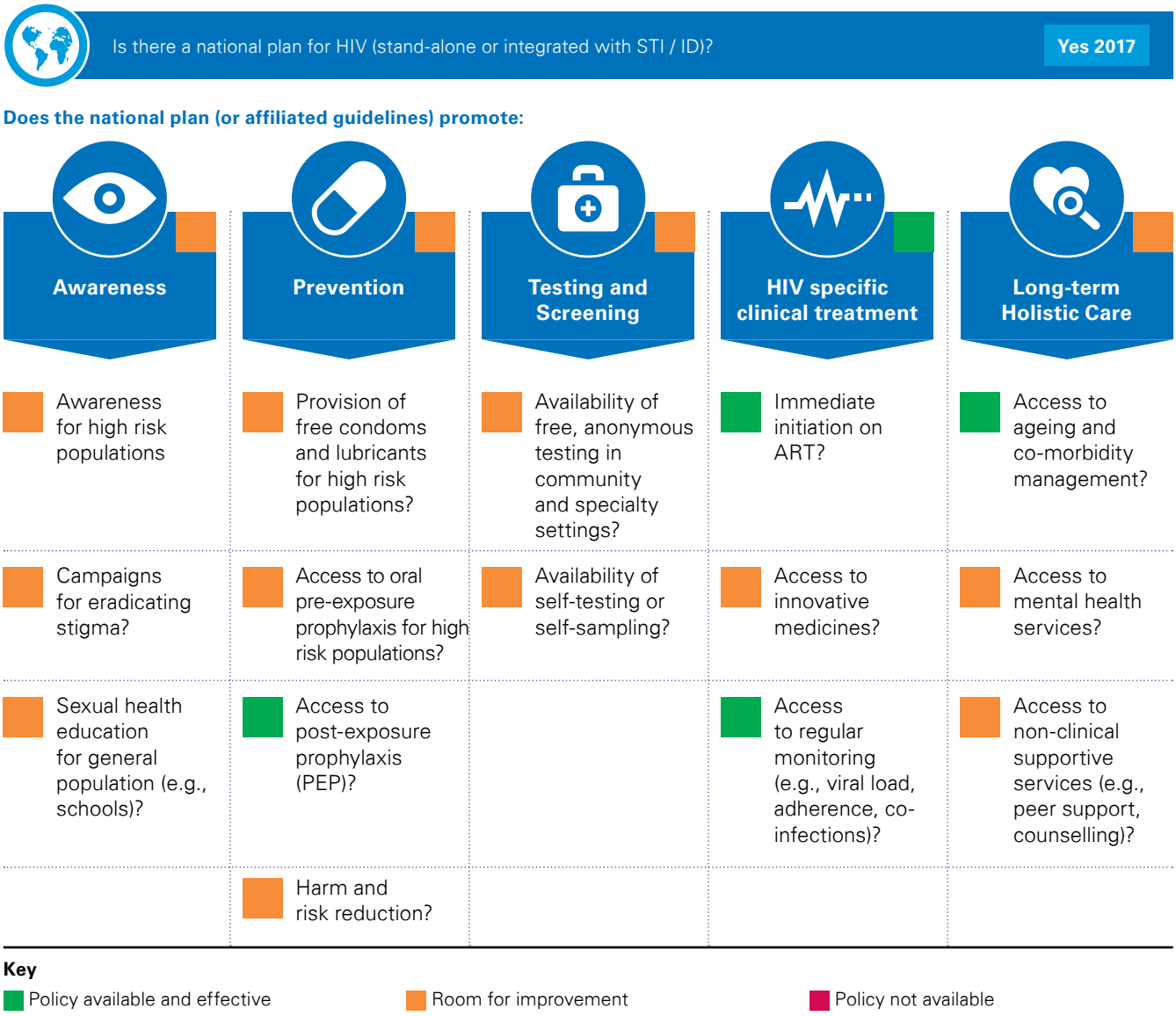
> "The national plan is quite comprehensive so we are satisfied. However, the issue is that funding hasn't been allocated so it's not possible to put it into practice. We are waiting for and pushing the government to implement it."
>
> **HIV NGO and policymaker, Italy**

Despite satisfaction over the potential of PNAIDS, experts remain concerned over the lack of dedicated funding to enable its implementation. It has been launched and approved in 2017 by the Ministry and Superior Council of Health, but not yet funded. While it has also approved by all 21 of the regions and autonomous provinces, it is yet to be ratified, fuelling further concern that discrepancies may emerge in the extent of its implementation.

To understand the ability of Italy's HIV strategy in tackling the new and emerging challenges of the epidemic, the Steering Group undertook an assessment. Going step by step across the HIV care continuum of Awareness, Prevention, Testing and Screening, HIV-specific Clinical Treatment and Long Term Holistic Health, they identified areas of strength and those with room for improvement.

Figure 2 summarises their findings, and further details on the policy position are available in chapter 5.

Figure 2. Assessment of HIV policy in Italy



Note on methodology: the assessment underlines the view of the Steering Group on current policy and its effectiveness, broken down by stage of the HIV care continuum. Additional in-country experts contributed (see Methodology section, Appendix 1), and findings were supplemented through secondary research. Full details of the policy, as related to stage of the HIV care continuum, is available in section 5.

Awareness

Awareness interventions are sporadic and continue to miss high risk populations. If effectively implemented, the prescriptive detail in PNAIDS may help address this.

- Interventions are intermittent and short-lived, and miss hard to reach populations (e.g., sex workers, migrants and women)
- There is a lack of continuous funding at the national, regional and local level

What is the policy position?

PNAIDS is prescriptive in its approach to raising awareness and tackling. Awareness interventions are broken down by key population (MSM, PWIDs, prisoners, youth, sex workers, transgender, migrants and people living with HIV partners), and indicators for measuring success are outlined. Regarding stigma, it proposes interventions such as stigma indicators for regular measurements and national campaigns [16], covering several high risk populations in detail (e.g., MSM, transgender and sex workers) [16].

Empowering the active involvement of civil society and groups associated with high risk populations is a key aspect of PNAIDS. For example, it details the need for community involvement to ensure interventions against MSM have the correct information and are credible [16].

What happens in practice?

National government-funded awareness campaigns for the general and high risk populations exist. The Ministry of Health re-launched a communication campaign in 2017, citing the need to continue attention on HIV. The campaign *'Con l'HIV non si scherza, proteggi te stesso e gli altri!'* (With HIV, do not mess around, protect yourself and others!) included TV commercials featuring Italian actors and broadcast on World AIDS Day, and an innovative campaign on YouTube featuring famous Italian YouTubers to target youth [17]. Initiatives extend to include a handbook 'La bussola' (the compass), aimed at providing practical information to guide people living with HIV in protecting their rights, and raising awareness of the tools available to them [18][42].

Campaigns against stigma are typically short-lived. Certain regions, such as Emilia-Romagna run campaigns around World AIDS Day, e.g., *'HIV - Proteggiamoci dal virus e dallo stigma'* (HIV - Protecting ourselves from the virus and the stigma) launched by Ferrara and the regional campaign *'Proteggersi sempre. Discriminare mai'* ('always protect yourself, never discriminate') [19].

> "You can see initiatives in areas, but they last for a year for example, are not continuous and should be implemented better."
>
> **HIV researcher, Italy**

What do the experts say?

While national and regional level campaigns exist, and initiatives such as Fast Track Cities are expected to make an impact (see case study), experts note more can be done to improve awareness and tackle stigma. While national-level campaigns exist, in general these are intermittent and short-lived. High risk populations, including migrants, sex workers and prisoners are often missed, and not enough emphasis is placed on gender specific campaigns. While efforts by the community (e.g., NGOs) exist, these are not sufficient to fill the gaps.

> "Sex workers are certainly one of the groups that are hard to reach so there are not many initiatives. For migrants, there are local initiatives but not everyone speaks Italian so there are limitations."
>
> **HIV researcher, Italy**

Lack of continuity is often attributed to an absence of sufficient dedicated funding for awareness and prevention, which does not exist at national level, or at the regional or provincial level, where responsibility for implementation is often devolved. Experts indicate investment in awareness is very small compared to amount of money devoted to other stages of the care continuum, e.g., treatment.

> "We need to devote a lot more funding to awareness and prevention."
>
> **HIV NGO, Italy**

Expert consensus is corroborated by evidence. A survey commissioned by Italian not-for-profit NPS Italia in 2016 showed only 50% of people were able to answer the question on what HIV is, highlighting the requirement for continuous awareness campaigns targetting general as well as high risk populations [20]. The same survey provided indicators of stigma, with 61% of young boys convinced that being HIV positive can result in rejection in a sexual relationship and 40% believed it can result in being insulted or denigrated [20].

PNAIDS tackles current lack of mandated

> "I think HIV has disappeared from the society, not only for high risk populations but for society. We need to improve awareness for everyone."
>
> **HIV policymaker, Italy**

sexual health education in schools, however, its implementation remains in question

What is the policy position?

Italy does not mandate sexual health education in schools. Its incorporation into the curriculum is at the discretion of each school, which results in a vast discrepancy across the country [21]. Recognising this, PNAIDS tackles this issue for the first time. It highlights the importance of incorporating sexual health education in schools in reducing the spread of HIV, and outlines a HIV and STI programme to be integrated into the school curriculum, addressing to students of all ages [16]. It extends to covering training programs addressed to teachers and implementation of an overall program of health education, in which themes of HIV and STI's are included [16].

PNAIDS also mentions insufficient sex education as one of the reasons behind the perceived lack of of knowledge of HIV in Italy, which hinders and delays access to testing.

> "We are convinced that prevention and sexual health education should be part of the curriculum in schools and not just something coming from doctors or available only on demand."
>
> **HIV policymaker, Italy**

What happens in practice?

Sexual health education is totally lacking from school curriculums. Intermittent initiatives, funded either by regional health services or NGOs exist, e.g., Project *'W L'amore'* ('Hurrah, Love!') which is a new sex-education manual launched across the northern Italian region of Emilia-Romagna. Within the first year, it was introduced to around 3,000 pupils across 19 districts [22].

The Ministries have come to an agreement, a critical first step: following the launch of PNAIDS, the Ministry of Health and the Ministry of Education reached a milestone decision to incorporate sex education into schools. However, no further implementation steps have yet been taken.

Sexual health education to the general public is provided by public STI clinics and family planning centres (consultorio Familiare) which are funded by regional health services. While these provide information and advice free of charge, many have seen a recent dismantling due to funding constraints.

What do the experts say?

Sexual health education must be implemented as a priority across Italy. There is a lack of awareness among youth in particular, which is detrimental in minimising the transmission of STIs including HIV. The lack of safe behaviours was demonstrated through a 2017 project commissioned by LILA in Cagliari, where as many as 74% of sexually active young adults (16-18) admitted to not using a condom consistently, or at all [24].

> "Prevention information is badly needed for HIV and STIs. We hope the situation will improve because there's a lot of ignorance in Italian youth."
>
> **HIV NGO, Italy**

Sexual health education must also be improved among the general population. A survey commissioned by NPS Italia identified that approximately only half of the individuals aged 25-34 can correctly identify ways in which HIV can be transmitted [20].

Case study: Fast Track Cities

What is it?

Fast Track Cities, launched in 2015 by a consortium composed of UNAIDS, the UN-Habitat organisations, the city of Paris and the International Association of Providers of AIDS Care (IAPAC). IT aims to support cities to achieve the 90-90-90 targets by 2020 as well as zero stigma and discrimination.

On 01 December 2018, the mayor of Milan, Guiseppe Sala, signed the Paris Declaration, thereby entering Milan into the Fast Track Cities network. This has been launched in partnership with The Bridge Foundation [43].

What are the key features?

A checkpoint at Casa dei Dritti containing:

- extra hospital space managed by 'peer' operators, psychologists and doctors
- free access to HIV tests
- systematic screening of various STIs (e.g., gonorrhoea, syphilis)
- access to PrEP (after screening and by appointment)
- Constant counseling services and referral to city's infectious disease centers in the case f positive diagnosis

Why is it a good practice?

- Enables convenient and accessible services to the public
- Ensures holistic care, through provision of counselling and other support (e.g., peer operators)
- Support good linkage to care through referrals to infectious disease centres in the case of a positive diagnosis

Prevention

Combined prevention needs greater focus and investment, however, there has been recent progress

- Condoms, PEP and harm / risk reduction are all stipulated in policy and implemented, although room for improvement exists
- Questions remain over implementation of PrEP, although recent plans to initiate trials in larger cities is welcomed as a move in the right direction

What is the policy position?

PNAIDS stipulates a combined prevention strategy: condoms, PrEP, PEP, and harm / risk reduction.

The role of condoms as an effective prevention tool is recognised. PNAIDS specifies the need for free condoms and lubricants to be distributed to MSM, sex workers and transgender populations through convenient routes (e.g., services they come in contact with or where they meet) [16]. The importance of condom use among other high risk populations, such as young people, is recognised, however explicit interventions are not outlined.

References to PrEP in PNAIDS is limited. While it recognises the need for antiretroviral drugs in prevention strategies (including PrEP), no explicit details are offered, referring instead to the guidelines. [16] The *Italian guidelines on the use of antiretroviral drugs and on diagnostic-clinical management of people infected with HIV-1* details the occurrences in which PrEP should be prescribed to high risk populations including MSM, heterosexuals and drug users [25].

They further detail dosage requirements, follow-up periods and providing all-round support for PrEP in terms of monitoring adherence and informing patients on the risk of acquiring other STIs [25].

PEP is recognised as an effective tool, and interventions are proposed to reduce barriers to access [16]. *The Italian guidelines on the use of antiretroviral drugs and on diagnostic-clinical management of people infected with HIV-1* refer to the use of PEP in both occupational and non-occupational settings, detailing different scenarios and recommendations for the use of PEP and timescales in which it must be administered and followed-up by an expert to re-evaluate the risk [25].

PNAIDS covers traditional harm reduction, with limited mention of emerging trends (e.g., chemsex). Extensive detail on PWIDs is available, denoting the need to promote harm and risk reduction - including replacement of sterile syringes and replacement therapy. The strategy extends to include similar promotion of prevention programmes in prisons, organised by the Ministry of Justice and Ministry of Health [16]. Harm reduction has recently been included in the LEA (essential levels of service) and so will be part of the health benefit package offered to all. The National Action Plan on Drugs 2010–13 also identifies and links the prevention and reduction of infectious disease transmission among drug users as one of its goals [26].

Chemsex is mentioned in PNAIDS as an activity drug users may partake in. However, no explicit interventions are proposed.

What happens in practice?

Regional discrepancies in free condom distribution schemes are common. Programmes exist, however, these are limited in nature. For example, Puglia, Lombardy, Piedmont and Emilia Romagna regions have approved free condom distribution, however these schemes are still not fully operational [27],[28],[29]. Privately funded campaigns around key dates such as World AIDS Day or through collaborations exist, e.g., the 'AIDS is not dead' campaign by LILA in partnership with hair brand ContestaRockHair [24].

> "Even though we can find some initiatives, the provision of condoms in high risk populations is not national and is very scattered."
>
> **HIV researcher, Italy**

Condoms can be purchased, however, barriers exist. Experts cite the high cost of condoms as a key obstacle, particularly for young people, along with psychological barriers such as embarrassment and shame of having to purchase from a pharmacy counter, and also a perception that condom use indicates a lack of trust in one's sexual partner.

PrEP is currently not widely available nor reimbursed through the National Health Service *(Servizio Sanitario Nazionale* (SSN)). Procuring PrEP at present requires a prescription from an infectious disease specialist, a visit to selected hospital pharmacies and payment for a generic form of the drug. Checkpoints such as Bologna provide information and assistance to users, however they do not provide the drug itself. Purchase of prescription drugs online (including PrEP for personal use) is illegal [30], however, reports exist of current inaccessibility resulting in procurement through such unofficial channels, or from abroad. Recent news has indicated a number of planned PrEP feasibility studies may soon be commencing in large Italian cities, which is welcomed by experts.

> "PrEP is not implemented at all – it's just mentioned in guidelines. We are far from using PrEP."
>
> **HIV policymaker, Italy**

The story is different with PEP, which has good availability. It can be accessed through hospitals, emergency rooms and infectious clinics across Italy, for free. While there can be some discrepancies (in waiting times, etc.) between centres that provide PEP, there are usually no restrictions to access. A study by LILA shows that more than 70% of the participants have basic knowledge of PEP [31].

> "The problem is prevention but once there is a problem [exposure to HIV], we can afford it and fix it."
>
> **HIV policymaker, Italy**

Harm reduction programmes are more common in the affluent north, and have suffered from funding cuts in recent times. According to the European Monitoring Centre for Drugs and Drug Addiction, Italy has needle and syringe programmes, take-home naloxone programmes and opioid substitution therapy in place. However, these are much more extensive in northern and central regions, and usually better located in larger cities [32]. Italy also lacks modern harm reduction services such as drug consumption rooms [32].

> "Harm reduction needs to improve. Services are present in the northern regions, with little or nothing in some regions in the south."
>
> **HIV NGO, Italy**

In addition, there have been funding cuts in harm reduction, resulting in some outreach services being closed and NSP coverage reducing from 24% to 15% from 2010 to 2014 [33].

Finally, there are very few interventions to tackle chemsex at present, with none that are done at a national scale.

What do the experts say?

Combined prevention requires improvements in both policy and implementation.

Condom use and access needs to be addressed through greater national-level awareness, distribution schemes and / or lowering the cost.

> "The price of condoms should be reduced, especially for young people, it's too expensive. There has been a request to the government already, but there has been no feedback."

HIV researcher and clinician, Italy

Key questions about PrEP need to be resolved. These include: funding (should PrEP be included in SSN), target populations (which subpopulations would want / should have access), routes of delivery (through hospital via infectious disease specialists or others, such as community based clinics) and provision of supportive services (counselling on risky behaviours). Further, scepticism among healthcare professionals needs to be addressed, through evidence-based discussions on its unintended consequences (e.g., increase of STIs). It is hoped the planned feasibility studies will provide insights to these questions, which in turn will inform an evidence-based PrEP policy.

Testing and screening

Free, anonymous testing is available at multiple settings however improvements to provide access to key vulnerable populations are needed

- Testing is efficient at specialty settings, however, requirements of opt-in means some opportunities are lost
- Community setting testing needs to be improved, to enable high risk populations (e.g., migrants, women, sex workers) to more easily access initial and repeat testing

What is the policy position?

Testing is regulated by law and policy in multiple settings. Law 135/1990 gives the right to all citizens (including undocumented migrants) to access testing, after having expressed consent to do so (opt-in testing) [6]. PNAIDS reiterates HIV testing must be made available, anonymous and free of charge, and actively offered to all those at high risk of infection (e.g., sex workers, MSM, migrants, PWID etc.) [16]. Access to HIV testing is restricted to unmarried minors, who require parental consent [34] [35]. PNAIDS highlights this barrier and aims to define procedures that allow minors to access the test without consent from parents. However, these have not been explicitly stated.

An absence of community-based 'non-health' setting testing is noted, and interventions targeting vulnerable populations are recommended, including involvement of such populations in the development of interventions. Guidelines on the *Use of antiretroviral drugs and on diagnostic-clinical management of people infected with HIV-1* further indicate tests must be offered to all those who present with STI's, Hepatitis or Tuberculosis [25]. New guidelines, developed by the National Institute of Health and the Drug Prevention Policy, also propose serological testing for related infections to PWID's, every 6-12 months [18][36].

PNAIDS and guidelines support self-tests, outlining recommendations on measuring impact and good practice in distribution (e.g., inclusion of informative briefs by pharmacies). While PNAIDS also mentions introducing self-sampling, no interventions are detailed to enable implementation.

What happens in practice?

Free, anonymous testing is available through hospitals and primary care. HIV tests require informed consent and unmarried youth under 16 require parental consent in addition. Limited screening, such as pre-natal is available and is well implemented.

Testing is also available in the community. This is often offered through infectious disease outpatient clinics, public drug treatment centres and government or self-funded NGO facilities. Efforts are made to engage with vulnerable communities and provide access to rapid tests as well as post-test counselling and follow-up, e.g., The National Institute for Health, Migration and Poverty (INMP) in Rome provides free outpatient care to vulnerable populations including undocumented migrants, the homeless and Roma people. Among their services are free, anonymous HIV rapid tests together with counselling and appointments for follow-up.

Self-tests have been available for purchase from pharmacies since 2016. They are available for adults, without a prescription for approximately EUR 20 [37]. Their introduction has been considered effective, with a study on new HIV diagnoses observed in the first 6 months following self-testing kits in Rome indicating that out of 39 new diagnoses observed, 9 (23%) had a first positive result with a self-test, all of which were MSM. Of the 9 patients, 6 were identified as those who had never had a HIV test before [38]. However, there has since been a decline in the number of self-tests sold, from 6,347 in December 2016 to 3,049 in April 2017 [38], possibly highlighting a gap in continuous information campaigns to encourage uptake.

What do the experts say?

Current policies together with implementation practices need to be improved to enable more effective testing. At present, Italy is struggling to achieve the first of the

> "Self-tests were announced in Italy in 2016, but should be more advertised. People who were not tuned into the news at the time simply do not know self-tests are provided in pharmacies."

HIV NGO, Italy

UNAIDS 90-90-90 targets, currently standing at 88%, and there still remains a high percentage of late diagnosis, with 55.8% of new diagnoses in 2017 diagnosed with a CD40 count below 350/mm^3 [3]. According to LILA, one in four people living with HIV are unaware of their HIV status, further demonstrating the extent to which testing efforts need to be amplified [24]

> "We won't be meeting 90-90-90 because there is not a sufficient effort on testing targeted at vulnerable groups."

HIV NGO, Italy

Current requirements for consent means opportunities for testing are often missed. Enabling opt-out (e.g., hospitals, STI or outpatient clinics and drug centres) where all those undergoing routine exams are tested for HIV may address this.

> "There is a strong need to try and promote opt-out testing in specific settings such as drug centres and STI clinics. There is also a misunderstanding on what opt-out might mean – people think it means imposing testing but it's not the same thing."

HIV researcher, Italy

Other challenges include regional / local discrepancies in number and type of community testing services, and lapse of knowledge on testing among other specialists and primary care physicians meaning opportunities to administer tests are often missed.

> "As you can imagine, after 28 years from the first law regulating the intervention on HIV, many things have changed. GP's, paediatricians and people representing the first line should be more familiar with HIV."

HIV policymaker, Italy

Case study: Bologna Checkpoint[39]

What is it?

'Bologna Checkpoint' is a community run rapid HIV and STI testing centre. Checkpoints exist in other European cities such as Barcelona, Lisbon, Athens and Belgrade but this is the first of its kind in Italy. The project is made possible by the contributions of the Municipality of Bologna, Local Health Unit Bologna, University Hospital of Bologna and various commercial businesses around the region.

What are the key features?

- The service offers free and fast tests in Hepatitis C and HCV tests with results in 20 minutes
- A sexual health test outside the hospital setting is often more accessible. In addition users can receive support and information from people like them in a "peer" approach

Why is it a good practice?

- Fulfils a part in a comprehensive approach to fighting the HIV epidemic, not just medically, but also socially by involving all social aspects of the virus such as support in dealing with fear, solitude, disclosure and stigma
- Allows testing to be more accessible as well as providing instant results that help with early medical intervention and the prevention of further transmission
- The approach is preventative in several ways, through educational events, distribution of free contraceptives and quick referral to Sant'Orsola hospital in Bologna

HIV-specific clinical treatment

Clinical management is available to a high standard across the country, with some areas for improvement in ensuring equality of access

- Immediate initiation on ART (regardless of CD4 count) is recommended and widely practiced, with examples of patients started on treatment within 3-5 days of diagnosis
- Access to medicine may be varied across the country, at times contributing to inequalities in the standard of care

What is the policy position?

PNAIDS and the Antiretroviral guidelines are comprehensive in management of patients in care, with a 'test and treat' approach. PNAIDS highlights the need to ensure access to treatment for all, and promotes maintenance in care of diagnosed and treated patients as a priority. It further proposes interventions to ensure adherence, e.g., proposing that treatment centres must be equipped with monitoring system to evaluate various metrics, such as the number of people living with HIV not yet on cART, rate of adherence and rate of follow-up [16]. Finally, PNAIDS also highlights co-infections, and proposes interventions to extend treatment to all people living with HIV with co-infections including HCV.

The guidelines provide further guidance. They indicate ART should be initiated immediately (in some cases without waiting for the outcome of the resistance test), outlines regimens in case of treatment failure, provides guidance on preferred drug combinations and recommends viral loads must be monitored in all patients from the moment they enter care [25].

The Italian Medicines Agency (AIFA) has also made efforts to reduce possible discrepancies in access to medicines. It reached an agreement with regions and autonomous provinces on a list of essential medicines that must be made available, which includes HIV medicines [40]. In 2017, AIFA released an 'innovation algorithm' to assess pharmaceutical products, to ensure quicker, equal access to cutting edge medicines. Medicines gaining approval through the algorithm may be eligible for additional funds (through the EUR 1 billion innovative drugs fund) and will be immediately included in all regional formularies.

What happens in practice?

Clinical treatment, follow-up visits and diagnostic tests are free-of-charge for all HIV-positive individuals, including irregular migrants and current intravenous drug users, through the National Health System (SSN). People living with HIV are exclusively managed by infectious disease specialists in Italy and the 'test and treat' approach is often followed, with patients initiating treatment within 3-5 days in many cases.

> "Treatment options are very good. There is a big push to put everyone in care with the best treatment available."
>
> **HIV NGO, Italy**

Innovative drugs are accessible, and supported by activities such as AIFA's 'innovation algorithm' and the government the 'Innovative Drug Fund'. The final decision on reimbursement and inclusion in formularies is devolved to regions and autonomous provinces, which may result in some variation in level of availability across the country.

Once in treatment, efforts are made to maintain patients in care. Viral load monitoring is effective, with people living with HIV closely monitored in the first 3 months to ensure viral suppression and adherence. Some variations may exist based on hospital and regions, with hospitals in the north often outperforming those in the south. Key co-infections (HCV, STIs) are routinely monitored, however, again regional variations may exist.

> "Viral load tests are not performed as frequently as they should be sometimes. People complain that they have viral load tests only once a year, when in the north, some hospitals offer it every 3-6 months."

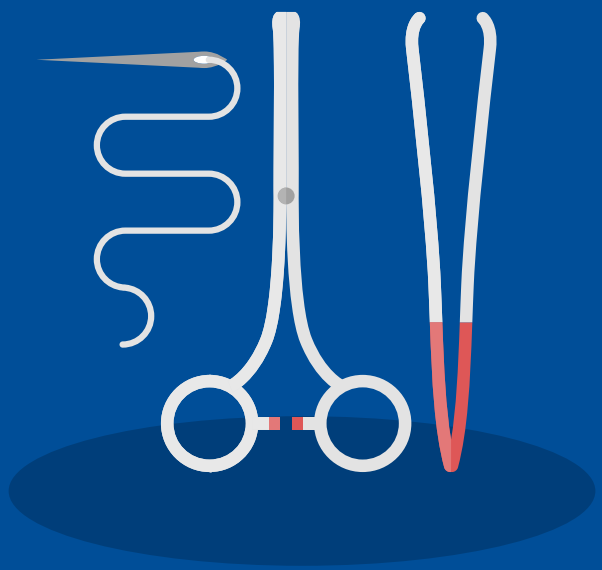
HIV NGO, Italy

What do experts say?

Experts agree Italy's HIV-specific clinical treatment is among the best in the world. This is particularly relevant given people living with HIV often enter care with low CD4 counts. While all medicines approved by AIFA should theoretically be available within all regions, expert consensus is that there may be delays and in some cases restrictions on availability of high priced medicines due to local budget constraints.

> "The process of approval at regional level is time consuming and decisions are delayed for budget reasons."

HIV NGO, Italy



Finally, the future of initiatives such as as the Innovative Drug Fund is uncertain, as experts note its continuity is not currently guaranteed.

Case study: Co-infection testing in public drug treatment centres[18]

What is it?

Certain groups, for example drug users, who are exposed to HIV are also likely to be exposed to other infectious diseases such as HBV and HCV. In Italy 70% of those who attend drug treatment services are not being tested for HIV, HBV and HCV, despite a high prevalence of these infections among drug users. The intention is to be actively testing within high prevalence groups in society as well as offer targeted pre- and post-test counselling, specific prevention measures, and follow-up treatment for those who need it.

What are the key features?

- New guidelines developed by the National Institute of Health and the Drug Prevention Policy Department are proposing to offer serological testing for related infections to people who use drugs, both new and old patients, every six to twelve months
- The new guidelines were published in March 2018, and full implementation across drug treatment facilities across Italy was expected within 2018

Why is it a good practice?

- Over the next few years the new guidelines will lead to reinforcement, at no cost, to obtain reliable epidemiological data on HIV and other drug-related infections. This leads to enhanced clinical management with regular testing to monitor infection rates in certain populations

Long-term holistic care

Long-term management of people living with HIV is often effective but discrepancies exist across regions and settings of care

- Co-morbidity management is outlined in policy, and is effective in hospital settings
- Focus on mental health, and person centered care, needs to be improved across all settings

What is the policy position?

PNAIDS and the Antiretroviral guidelines recognise the changing epidemiology of HIV. Together they cover ageing and co-morbidity care in great detail, proposing interventions to prevent co-morbidities and promoting the integration of care paths to ensure continuity [16] [25].

Clinical and non-clinical supportive services require a greater level of detail on policy, as well as associated funding. PNAIDS and the Antiretroviral guidelines cover the topics of mental health and psychiatric disorders, and suggest the need to extend clinical assessment behind strictly HIV aspects[16] and recommend performing periodic assessments for neurocognitive disorders. Counselling is mentioned as a proposed intervention when addressing high risk populations and providing access to tests, highlighting the need for CB-VCT (community-based voluntary counselling and testing) for all target populations. PNAIDS also highlights the importance of a social support network, to ensure continuity of care.

What happens in practice?

Management of long term health is primarily provided through infectious disease specialists in tertiary or secondary care settings. A move towards offering long-term care through outpatient clinics and primary care is recognised, however this has not yet been fully established.

Good practice examples of multi-disciplinary management of people living with HIV in outpatient settings are available (see case study). However, these are not common across the country.

> "If we don't move towards an outpatient approach, we will end up with lots of cost in the healthcare system, and at the same time, people will be suffering from a worse quality of life, and we may see more disability."
>
> **HIV activist, Italy**

Mental health care is available for severe cases, and more commonly found in urban areas. Good practices such as outpatient addiction treatment centres (SerT) provide integrated clinical and psychosocial support. Non-clinical support services (e.g., counselling) are available, however these are sparse. GreenAid Line is a government-funded communication channel to connect individuals with doctors and psychologists. Other government funded initiatives include community clinics such as Consultorio Familiare (Family Planning Clinics), however, funding has reduced in recent times resulting in many services being shuttered. Supportive services are also provided by NGOs and patient association groups, aiming to fill

gaps left by the health system. For example, LILA provides pre and post-test counselling and extends to providing psychological accompaniment to hospital for test result confirmations, if required.

> "Beyond people with strong symptoms of psychological disorders, mental health is not monitored. It is important to monitor it as it is linked to treatment adherence. There is also little done from an NGO stance – this requires medical expertise so NGO's can't do a lot in identifying cases."

HIV policymaker, Italy

What do the experts say?

Long-term holistic health of people living with HIV requires focus and funding, to enable the changing epidemiology of HIV to be adequately addressed. Experts note that Italy's infectious disease specialists are among the best in the world, and high quality management of co-morbidities is available. However, the health system continues to operate in 'silos', thereby causing challenges in managing patients who require greater co-ordination across settings of care. Experts indicate a lapse in HIV-specific knowledge among non-HIV specialists (e.g., family doctors, geriatricians) and a lack of required infrastructure to enable community-based care (e.g., primary care or outpatient setting).

> "Services must be in the community, not only in hospitals because it's the last place people want to go."

HIV policymaker, Italy

Clinical and non-clinical supportive services require greater focus. Similar to many countries in Western Europe, the shift from provision of care for HIV as a long term condition, rather than an acute event requiring infection control and viral supression, is yet to be realised in policy. Provision of services to enable a higher quality of life for people living with HIV is needed, requiring integration of long-term HIV-specific clinical management with social care and long term condition management management.

> "We have to go towards quality of life – the aim is not to survive but to survive with a good quality of life."

HIV NGO, Italy

Case study from other regions: Clinica Metabolica di Modena

What is it?

The Metabolic Clinic of the University of Modena and Reggio Emilia is a tertiary level referral centre, offering multidisciplinary consulting service including infectious disease physicians, nutritionists, personal trainers for physical activities, psychologists, cardiologist, nephrologists, endocrinologists and plastic surgeons for diagnosis and treatment of non-infectious co-morbidities.

What are the key features?

People attending the clinic are evaluated free of charge in one multidisciplinary assessment using a number of variables (selected only):

- Fasting biochemistry (e.g., total cholesterol, LDL, blood glucose, insulin, lactic acid, HBV, HCV)
- CD40 levels
- Endocrinology assessment
- Bone mineral density
- Cardiovascular risk factors

Through this, several outcomes are generated including ARV therapy, complementary drug exposure, metabolic syndromes etc., as well as subjective outcomes such as adherence questionnaires, back depression scores.

04 Recommendations

4.1 Enable implementation of PNAIDS as a matter of urgency

What is the issue?

PNAIDS is prescriptive and comprehensive, a result of multi-stakeholder collaboration; and seeks to address the existing challenges of HIV (targeting high risk populations, reducing the undiagnosed population, reducing rates of late diagnosis, and addressing the changing epidemiology of HIV). It was launched in 2017 and approved by the 21 regions and autonomous provinces. However, it remains unfunded to date of publication of this report.

What is the recommendation?

Dedicate specific funding for PNAIDS as a matter of urgency, and incorporate policies into LEAs *(Livelli Essenziali di Assistenza* or essential levels of care), to ensure consistent resourcing and guarantee uniformity of services across the country. Key areas for funding include awareness and testing, thereby enabling many more people living with HIV to engage with care.

4.2 Develop integrated awareness and testing interventions for STIs and HIV

What is the issue?

PNAIDS recognises there is a limited presence of community-based 'non-health' testing services that are required to reach highly vulnerable populations (e.g., newly arrived migrants, migrant women). This lack of access may be a driver of the undiagnosed population and persistent rates of late diagnosis (CD4<350/mm^3). Further, HIV as a topic has started to disappear from the public agenda, driven by complacency resulting from the view of HIV as a 'problem solved', contributing to the current lapse in awareness among the public.

What is the recommendation?

Enable convenient testing through integrated programmes for HIV and STIs that are available in the community. The broader focus will allow a greater population to be reached, particularly those who do not consider themselves to be at risk of HIV transmission (e.g., young people, older heterosexual men and women).

Testing can be enabled in a variety of community settings, taking lessons from Fast-Track Cities (e.g., Milan) and good practices from Italy and abroad, e.g., testing in high prevalence locations. Existing barriers, such as opt-in and requirements for parental consent for minors can be considered for removal / adaption. Targeted campaigns, developed with input from high risk populations and using appropriate channels (e.g., social media, Apps, YouTube) should be developed. Investment from the Ministry of Health and ASR will be required for long-term implementation.

4.3 Make condoms free for high risk populations

What is the issue?

Condom access is limited at present: free distribution schemes are sporadic, often focused on key dates and available only in certain regions. While available to purchase, the cost is considered prohibitive to a large proportion of the population, particularly the young. Finally, negative societal perceptions of use of condoms (e.g., a view that use of condoms indicates a lack of trust in one's partner) are also found, further limiting use.

What is the recommendation?

Make condoms free for high risk populations. Two approaches are available to enable this: parliamentary approval of existing draft law, or decree by the Ministry of Health. Further, while PNAIDS covers condom provision for MSM, sex workers and transgender populations this needs to be extended to include young people (e.g., under 25 years of age). Distribution schemes and infrastructure is required; one option would be to utilise existing infrastructure, e.g., Consultorio Familiare, NGOs and outpatient infectious disease clinics. Budget would need to be allocated.

4.4 Develop a network of multidisciplinary services for long-term holistic care of people living with HIV

What is the issue?

Long-term care of people living with HIV, who suffer a disproportionate volume of co- and multi-morbidities as well as psychological conditions requires a multidisciplinary effort. Currently, while management of people living with HIV by infectious disease specialists is very effective, challenges arise when co-ordination of care is required across specialties (e.g., geriatrics, mental health, and other non-communicable chronic conditions) and settings (e.g., primary or outpatient setting). There is a shortage of infrastructure, processes and skill sets that will enable long-term, holistic and person-centred care.

What is the recommendation?

Develop a network for the provision of multidisciplinary care to address the long term health of people living with HIV. These can incorporate specialty, outpatient and primary care settings, and put in place a series of processes to ensure continuity of care for people living with HIV. Good practice examples, such as Clinica Metabolica di Modena, should be studied and scaled up.

05 Policy Assessment

Is there a national plan for HIV? Yes

In 2016, Italy launched its renewed national level plan on HIV and AIDS, 'Piano Nazionale di Interventi Contro HIV e AIDS' (PNAIDS), covering the period 2017 – 2019. The plan aims to outline an approach to achieving the objectives indicated by UNAIDS and WHO [16]. In defining new intervention strategies to tackle HIV, PNAIDS aims to address unsolved issues concerning data collection, prevention, and access to testing and treatment.

PNAIDS follows law 135 published in 1990, which acted as the 'Plan for urgent action on prevention and fight against AIDS' *(Piano degli interventi urgenti in materia di prevenzione e lotta all'AIDS)*, operating under Italian policy for over 25 years [6]. PNAIDS proposes interventions based on scientific evidence and has been formed following integration from various organisations including the Technical Health Committee (CTS), the Higher Institute of Health (ISS), scientific societies, voluntary associations, universities, research institutions and scientific care [41].

PNAIDS is prescriptive and aims to formulate the best path to achieve objectives indicated by UNAIDS and WHO, prioritising objectives:

01 Outlining and implementing projects aimed at defining intervention models to reduce the number of new infections

02 Facilitating access to the test

03 Ensuring access to treatment for all

04 Promoting the maintenance in care of diagnosed patients

05 Coordinating intervention plans on the national territory

06 Improving the health and well-being of people living with HIV

07 Protecting the social and working rights of people living with HIV

08 Promoting the fight against stigma

09 Promoting empowerment and active involvement of high risk populations

Does the national plan (or affiliate guidelines) promote?

Awareness

Awareness for high risk populations?

PNAIDS recognises the importance of awareness campaigns on HIV & AIDS as part of Italy's national strategy, detailing the need of targeted awareness and communication campaigns for key population groups.

Policy is prescriptive, and breaks down the strategy in great detail for each key population (MSM, PWID prisoners, youth, sex workers, transgender, migrants and people living with HIV partners). It describes the type of campaigns required for each subpopulation, with descriptions on result indicators to measure success. Most interventions revolve around empowering the active involvement of social groups and organisations associated with high risk populations, in campaigns.

For example, for the MSM population, it details the need for programmes organised by the community and the need to promote empowerment and involvement through the MSM community to ensure information is credible[16].

Campaigns for eradicating stigma?

PNAIDS highlights the need for combined prevention programmes to reduce stigma and discrimination associated with HIV, citing it as an important issue among high risk populations.

It recognises the fight against stigma as a fundamental element of any policy to combat HIV, and proposes interventions such as stigma indicators (to measure the level of stigma regularly) and national campaigns to fight stigma against people living with HIV [16].

Several subpopulations are covered in detail, outlining the need for programmes to reduce homophobia across MSM populations, increase programs to tackle stigma in transgender populations and provide interventions aimed at social, health and police communities to break down stigma against sex workers [16].

Sexual health education for general populations (e.g., schools)?

At present, there is no mandated sexual health education in schools. It is at the discretion of each individual school on whether they wish to incorporate it into the curriculum, which results in a vast discrepancy across regions [21].

Recognising this, PNAIDS highlights the importance of incorporating sexual health education in schools as a key action in reducing the spread of HIV, and outlines a HIV and STI programme to be integrated into the school curriculum which addresses students of all ages [16]. It extends to covering training programs addressed to teachers and implementation of an overall program of health education, in which themes of HIV and STI's are included[16].

PNAIDS also mentions insufficient sex education as partly the reason behind the lack of knowledge of HIV in Italy, which hinders and delays access to testing.

Key

Policy available and effective | Room for improvement | Policy not available

Prevention

Harm and risk reduction (e.g., needle and syringe programmes (NSP), opioid substitution therapy (OST), chemsex)

PNAIDS extensively covers PWIDs as a key population, denoting the need to promote harm and risk reduction intervention programs including replacement of sterile syringes and replacement therapy.

The strategy extends to include similar promotion of prevention programs in prisons, organised by the Ministry of Justice and Ministry of Health [16].

Harm reduction has recently been included in the LEA (essential levels of service) and so will be part of the health benefit package offered to all.

Chemsex is mentioned in the national policy as an activity drug users may partake in. However, there is no explicit intervention proposed in order to reduce the risk.

The National Action Plan on Drugs 2010–13 also identifies and links the prevention and reduction of infectious disease transmission among drug users as one of its goals [26].

Provision of free condoms / lubricants for high risk populations?

PNAIDS highlights the correct use of condoms as an effective prevention tool, to be used in the general population and with particular attention to populations most at risk [16].

It goes further to recommend risk and harm reduction interventions in high risk populations through distribution of condoms and specifies the need for free condoms and lubricants to be distributed to MSM, sex workers and the transgender populations in areas where they meet and services they come in contact with [16].

With regards to other high risk populations such as young people, PNAIDS recognises the importance of using condoms, but doesn't explicitly specify interventions aimed at free condom distribution.

Access to oral PrEP for high risk populations?

PNAIDS recognises the need for prevention strategies to be based on the use of antiretroviral drugs (including PrEP) to limit the incidence of new infections, but does not explicitly detail any plans of rolling out the drug as part of the government's HIV prevention offering. The plan refers to guidelines to implement strategies for selected populations [16].

The *Italian guidelines on the use of antiretroviral drugs and on diagnostic-clinical management of people infected with HIV-1* details the occurrences in which PrEP should be prescribed to high risk populations including MSM, heterosexuals and drug users [25].

The guidelines go further in detailing the dosage requirements, follow-up periods and providing all-round support for PrEP in terms of monitoring adherence and informing patients on the risk of acquiring other STI's [25].

Key

Policy available and effective | Room for improvement | Policy not available

Access to post-exposure prophylaxis (PEP)?

PNAIDS recognises PEP as an effective role in limiting the incidence of new infections and proposes interventions based on reducing the access barriers and implementing an appropriate use based on clinical guidelines [16].

The *Italian guidelines on the use of antiretroviral drugs and on diagnostic-clinical management of people infected with HIV-1* refer to the use of PEP in both occupational and non-occupational settings, detailing different scenarios and recommendations for the use of PEP and timescales in which it must be administered and followed-up by an expert to re-evaluate the risk [25].

Testing and screening

Availability of free, anonymous testing in community and specialty settings?

In Italy, the HIV test is still regulated by law 135/1990 giving the right to all citizens to access a test, only after having expressed consent to do so (opt-in testing) [6]. PNAIDS reiterates that HIV testing must be made available, free of charge, anonymous and actively offered to all those at high risk of infection, paying particular attention to high risk populations including sex workers, MSM, migrants, drug users etc [16].

PNAIDS states that there's an absence or limited presence of community-based 'non-health' testing services required to reach target populations and so recommends interventions revolving around community-based testing, with involvement from target population representatives [16].

It also highlights the objective to launch testing programs in extra hospital settings, referring to international successes [16].

Italian guidelines on the use of antiretroviral drugs and on diagnostic-clinical management of people infected with HIV-1 emphasise the test must actively be offered in all clinical conditions that can be related to HIV infections, regardless of a behavioural risk assessment and must be offered to all those who turn to healthcare facilities for STI's, Hepatitis or Tuberculosis [25].

Access to HIV testing is restricted to unmarried minors, who require parental consent. PNAIDS highlights this barrier and aims to define procedures that allow minors to access the test without consent from parents. However, these have not been explicitly stated.

Availability of self-testing or self-sampling?

PNAIDS and Italian guidelines support the use of self-tests, detailing the requirement to evaluate the impact of dissemination of HIV self-tests. It goes further in requesting pharmacies to include informative briefs including time limits, reliability of the test and a toll-free number to the National Counselling Service [16].

PNAIDS mentions the introduction of self-sampling and details the role of non-healthcare settings must be redefined. However, no interventions have been detailed to introduce home sampling.

Key

Policy available and effective | Room for improvement | Policy not available

HIV specific clinical treatment

Immediate initiation on ART?

PNAIDS highlights the need to ensure connection to early treatment and suggests interventions to identify appropriate strategies to maximise the start of treatment with participation from all [16].

Ensuring access to treatment for all and promoting the maintenance in care of diagnosed and treated patients are highlighted as priority interventions in PNAIDS.

Italian guidelines on the use of antiretroviral drugs and on diagnostic-clinical management of people infected with HIV-1 refer to the initiation of cART as a crucial moment in the care pathway of people with HIV / AIDS, and suggest ART should be initiated immediately, (in some cases without waiting for the outcome of the resistance test) [25].

In an effort to reduce regional disparities in access to medicines, the Italian Medicines Agency (AIFA) reached an agreement with regions and autonomous provinces on a list of essential medicines that must be made available, which includes HIV medication [40].

Access to innovative medicine?

Italian guidelines on the use of antiretroviral drugs and on diagnostic-clinical management of people infected with HIV-1 mention second-line regimes, as an alternative if first line therapy fails and provides guidelines on preferred drug combinations and use of different therapies.

In 2017, AIFA released an 'innovation algorithm' to assess pharmaceutical products, to ensure quicker, equal access to cutting edge medicines. Medicines gaining approval through the algorithm may be eligible for additional funds (through the EUR 1 billion innovative drugs fund) and will be immediately included in all regional formularies. The government assignment of sufficient funds for innovative drugs remains a crucial issue.

Access to regular monitoring (e.g., viral load, adherence, co-infections)?

Adherence to drugs and maintenance in care are highlighted as crucial in PNAIDS to ensure the well-being of people living with HIV. It goes further to propose interventions aimed at ensuring adherence, such as ensuring treatment centers are equipped with monitoring systems to enable tracking of people living with HIV who are not yet on therapy, the rate of adherence, and rate of presence at check ups etc.[16]

Viral load monitoring is highlighted as primary importance in the guidelines on ART and clinical management, with strategies proposed aiming to zero viral load. *Italian guidelines on the use of antiretroviral drugs and on diagnostic-clinical management of people infected with HIV-1* emphasise viral loads must be monitored in all patients from the moment they enter care [25].

PNAIDS also highlights the issue of coinfections and proposes initiatives based on those with HCV co-infections, aiming to extend treatment for all people living with HIV co-infected with HCV.

Key

Policy available and effective | Room for improvement | Policy not available

Long-term holistic care

Access to ageing and co-morbidity management?

The national plan covers the issue of comorbidities and ageing in great detail, highlighting the need to develop new lines of intervention and extend clinical assessment behind strictly HIV aspects and include management of comorbidities, such as cardiovascular, renal, and neurological among others [16].

It goes further to propose interventions dedicated to the prevention and care of comorbidities and to promote integration paths in order to ensure continuity of care [16].

Italian guidelines on the use of antiretroviral drugs and on diagnostic-clinical management of people infected with HIV-1 corroborate, specifying actions to manage ageing and comorbidity care, including the need for dedicated clinical-care pathways and integration of resources between HIV and geriatric care [25].

Access to mental health services?

PNAIDS covers the issue of mental health disorders at a high level, highlighting the need to extend clinical assessment behind strictly HIV aspects and include neurological, cognitive and psychiatric diseases [16].

Italian guidelines on the use of antiretroviral drugs and on diagnostic-clinical management of people infected with HIV-1 refer to mental health and psychiatric disorders (ranging from depression and anxiety to Alzheimer's and dementia) as being more prevalent among people living with HIV and requires close monitoring. Guidelines suggest interventions such as performing periodic assessments for neurocognitive disorders.

Guidelines advise patients with psychiatric disorders to undergo specific, tailored therapy, which should be established with input from a psychiatrist, to manage drug interactions and possible side effects.

Access to clinical supportive services (e.g., peer support, counselling)?

PNAIDS highlights counselling must be provided in all occasions for those who are HIV positive. Counselling is mentioned as a proposed intervention when addressing high risk populations and providing access to tests, highlighting the need for CBVCT (community-based voluntary counselling and testing) for all target populations mentioned.

PNAIDS also highlights the importance of a social support network, to ensure continuity of care.

Key

Policy available and effective | Room for improvement | Policy not available

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