HIV policy in Italy and recommendations across the HIV care continuum

Massimo Galli[1,2], Marco Borderi[3], Pierluigi Viale[3]

[1]Department of Biomedical and Clinical Sciences "Luigi Sacco", University of Milan, Milan, Italy;
[2]III Division of Infectious Diseases, ASST Fatebenefratelli Sacco, Milan, Italy;
[3]Unit of Infectious Diseases, Department of Medical and Surgical Sciences, S. Orsola Hospital, "Alma Mater Studiorum" University of Bologna, Italy

SUMMARY

The HIV epidemic has not yet ended, and there are ever more challenges: the recent Italian National Plan of Interventions against HIV and AIDS (*Piano Nazionale di Interventi Contro HIV e AIDS (PNAIDS) 2017-2019*) was hailed for its comprehensiveness. Its likelihood of success across the HIV care continuum was therefore assessed. Awareness interventions are sporadic and continue to miss high risk populations; if effectively implemented, the prescriptive detail in PNAIDS may help address this. Combined prevention needs greater focus and investment. However, there has been recent progress: free anonymous testing is available at multiple settings although improvements to provide access to key vulnerable populations are needed. Clinical management is available to a high standard across the country, with some areas for improvement in ensuring equality of access. Long-term management of people living with HIV is often effective, but discrepancies exist across regions and settings of care. It is recommended to enable implementation of PNAIDS as a matter of urgency, develop integrated awareness and testing interventions for STIs and HIV, make condoms free for high-risk populations, and develop a network of multidisciplinary services for long-term holistic care of people living with HIV.

Keywords: PNAIDS, Recommendations, Policy assessment.

INTRODUCTION

Italy's response to the HIV epidemic has delivered good outcomes. Of the 110000 - 150000 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 treatment targets, resulting in the number of new infections broadly stabilizing 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. It's estimated that 11-13% of people living with HIV are undiagnosed. Each year over 3000 new HIV diagnoses are made, with persistently high rates of late diagnosis. There are more challenges, too: the changing epidemiology means the ageing cohort of people living with HIV are at greater risk of co- and multi-morbidities, 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 [1]. It promotes empowering and actively involving high risk populations in managing of

Corresponding author
Massimo Galli
E-mail: massimo.galli@unimi.it

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, we assessed each step across the HIV care continuum of Awareness, Prevention, Testing and Screening, HIV-specific Clinical Treatment and Long Term Holistic Health. We identified both areas of strength and those with room for improvement.

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

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

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

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.

HIV IN ITALY

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 suppressed. This is particularly relevant given the high proportion of people living with HIV who are diagnosed late. Italy's challenge lies with its undiagnosed population. Of the 130000 people estimated to be living with HIV in Italy, 11-13% or ~14000 are estimated to be unaware of their infection. Further, while incidence has stabilized, each year over 3000 new HIV diagnoses are made (3443 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

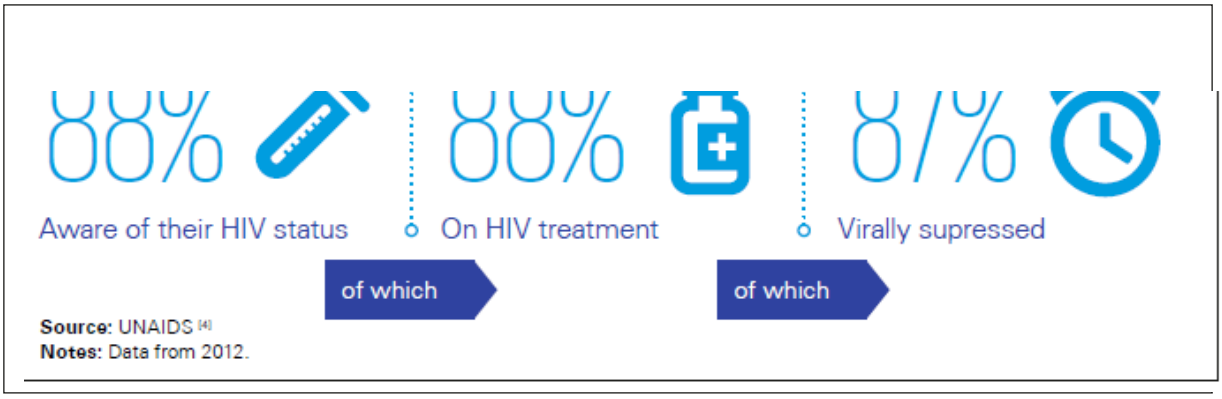

Figure 1 - Performance towards the 90-90-90- targets.

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, 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.

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 is 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, dictate that all citizens have equal social dignity and are equal before the law, without distinction of sex, race, language, religion, and 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 organize 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, including access to primary care services [9, 10].

3) *Decriminalization of behaviors 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 organized 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, stressing the urgent need to monitor this marginalized population, encouraging safe sex behaviors and promoting HIV-STI testing [14]. With regards to drug use, the Italian National Action Plan on Drugs (initially covering 2010-2013 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 programs (*e.g.*, needle and syringe dispensing machines and naloxone treatment). The positive impact of Italy's harm reduction policies is 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].

ASSESSMENT OF HIV POLICY

This chapter outlines the 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.

Overview of national HIV policy

Italy's detailed national strategy for HIV and AIDS, launched in 2016, remains unfunded to date. The renewed national plan, "Piano Nazionale di Interventi Contro HIV e AIDS" (PNAIDS) 2017-2019, is the first new plan in decades, integrating law 135/1990 which was in effect for more than 25 years [16]. PNAIDS outlines a detailed approach towards achieving the objectives indicated by UNAIDS and WHO 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 [16]. 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

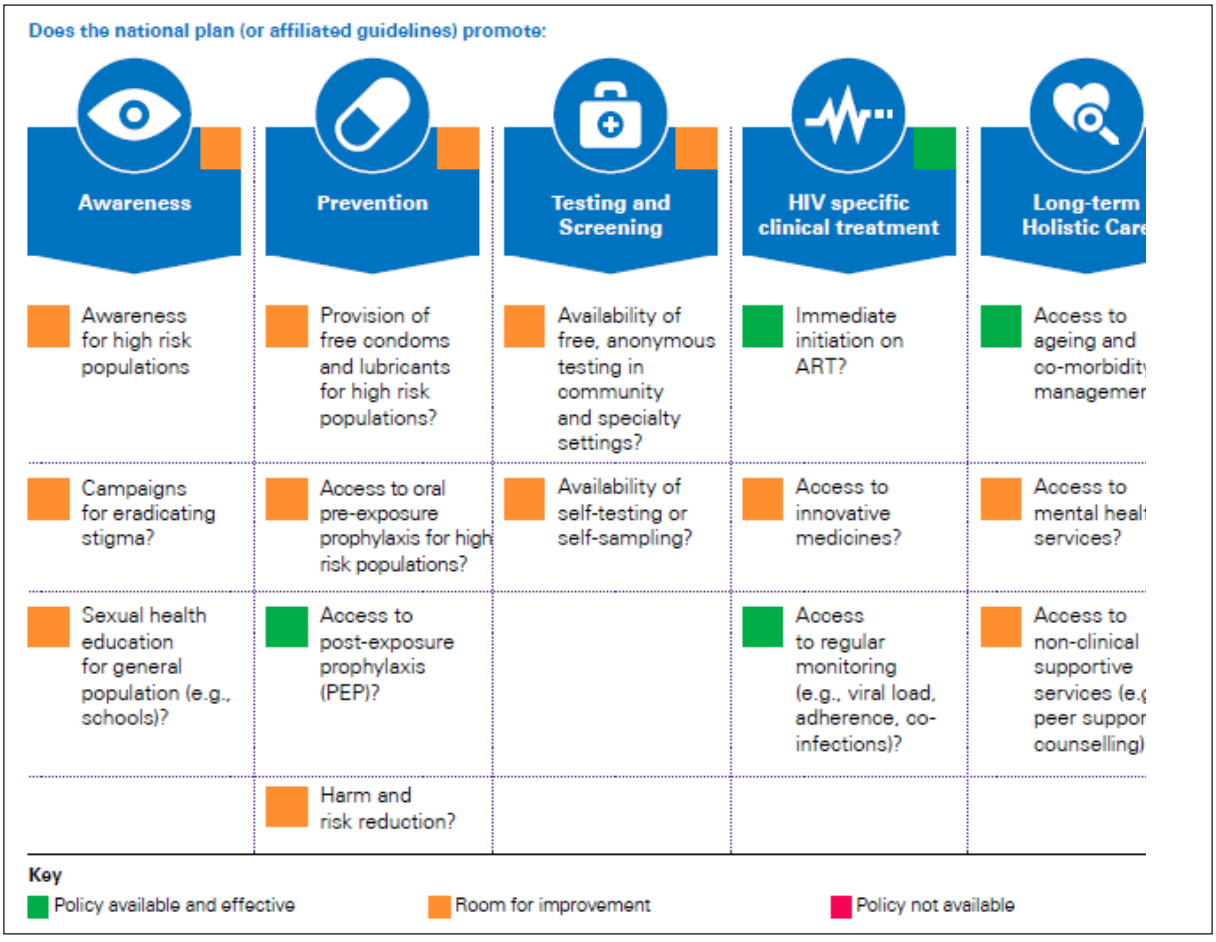

Figure 2 - Assessment of HIV policy in Italy.

curriculum, and also implement a wider sexual health program.

The plan is the result of a multi-stakeholder collaboration. Organizations including the Technical Health Committee (CTS), the National Institute of Health (ISS), scientific societies, voluntary associations, universities, research institutions and scientific care provided input. 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, we 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, we identified areas of strength and those with room for improvement. Figure 2 summarizes their findings.

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 research 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, 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 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]. 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].

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, 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.

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. 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 targeting 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].

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]. Recognizing 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 program 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 knowledge of HIV in Italy, which hinders and delays access to testing.

What happens in practice?
Sexual health education is totally lacking from school curriculums. Intermittent initiatives funded either by *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 3000 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.

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 minimizing the transmission of STIs including HIV [23]. The lack of safe behaviors 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]. 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].

PREVENTION

Combined prevention needs greater focus and investment; however, there has been recent progress:
- Condoms, PEP (Post-Exposure Prophylaxis) and harm/risk reduction are all stipulated in policy and implemented, although room for improvement exists.
- Questions remain over implementation of PrEP (Pre-Exposure Prophylaxis), although recent plants to initiate trials in larger cities are 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 recognized. 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 recognized, however explicit interventions are not outlined. References to PrEP in PNAIDS are limited. While it recognizes 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 recognized 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 programs in prisons, organized 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 2010-2013 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. Programs 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 [27-29]. 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 Contesta Rock Hair [24]. 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 nor 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, however, reports exist of current inaccessibility

Table 1 - PNAIDS and UNAIDS/WHO objectives.

resulting in procurement through such unofficial channels, or from abroad [30]. Recent news has indicated a number of planned PrEP feasibility studies may soon be commencing in large Italian cities, which is welcomed by experts. 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 centers 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]. Harm reduction programs 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 programs, take-home naloxone programs 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]. 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. 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 (counseling on risky behaviors). Further, skepticism 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 centers 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 counseling 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 counseling 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 20,00 [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 6347 in December 2016 to 3049 in April 2017, possibly highlighting a gap in continuous information campaigns to encourage uptake [38].

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 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 CD4+ count below 350/mm³ [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]. Current requirements for consent mean opportunities for testing are often missed. Enabling opt-out (*e.g.*, hospitals, STI or outpatient clinics and drug centers) where all those undergoing routine exams are tested for HIV may address this. 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.

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 centers 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 [39]. 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. 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.

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

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 recognize 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. Counseling 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 counseling 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 recognized, 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. Mental health care is available for severe cases, and more commonly found in urban areas. Good practices such as outpatient addiction treatment centers (SerT) provide integrated clinical and psychosocial support. Non-clinical support services (*e.g.*, counseling) are available, however these are sparse. Green Aid 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 counseling and extends to providing psychological accompaniment to hospital for test result confirmations, if required.

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). 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 suppression, is yet to be realized 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.

Conflicts of interest

none

REFERENCES

[1] LILA. Arriva il Piano Nazionale di interventi contro HIV e AIDS. La LILA: 'Documento innovativo e da attuare subito' ma i nodi sono quelli delle risorse e degli adeguamenti normativi. Available at: https://www.lila.it/it/lilanews/919-pna2017 [accessed 12 January 2020].

[2] Mammone A., Pezzotti P., Regine V., et al. How many people are living with undiagnosed HIV infection? An estimate for Italy, based on surveillance data. *AIDS.* 2016; 30 (7), 1131-6.

[3] Regine V., Pugliese L., Boros S., et al. Aggiornamento delle nuove diagnosi di infezione da HIV e dei casi di AIDS in Italia al 31.12.2017. Notiziario IST Super Sanità. 2018; 31, 1-51, 2016. Available at: http://www.salute.gov.it/imgs/C_17_notizie_3557_listaFile_itemName_0_file.pdf [accessed 12 January 2020].

[4] Joint United Nations Programme on HIV/AIDS, "UNAIDS Data 2017," Jt. United Nations Program. *HIV/AIDS.* 1-248, 2017. Available at: https://www.unaids.org/sites/default/files/media_asset/20170720_Data_book_2017_en.pdf [accessed 12 January 2020].

[5] Senato della Repubblica. The Constitution of the Italian Republic. 42, 4, 1948. Available at: https://www.senato.it/documenti/repository/istituzione/costituzione_inglese.pdf [accessed 12 January 2020].

[6] Piano degli interventi urgenti in materia di prevenzione e lotta all'AIDS (Gazzetta Ufficiale, n. 132, giugno 1990). vol. 2013, 1-6, 1991. Available at: https://www.gazzettaufficiale.it › eli › gu › 2018/12/03 › pdf [accessed 12 January 2020].

[7] Hammarin V. HIV/AIDS and the European Union. 2016. Available at: http://commons.lib.jmu.edu/cgi/viewcontent.cgi?article=1154&context=honors201019 [accessed 12 January 2020].

[8] European HIV Legal Forum (EHLF). Accessing HIV prevention, testing, treatment care and support in Europe as a migrant with irregular status in Europe: A comparative 16-country legal survey. 2018. Available at: https://www.aidsactioneurope.org/en/publication/accessing-hiv-prevention-testing-treatment-care-and-support-europe-migrant-irregular-0 [accessed 12 January 2020].

[9] ECDC. The status of the HIV response in the European Union/European Economic Area, 2016. 2017. Available at: https://www.ecdc.europa.eu/en/publications-data/status-hiv-response-european-unioneuropean-economic-area-2016 [accessed 12 January 2020].

[10] Fakoya I., Álvarez-Del Arco D., Monge Set, et al. HIV testing history and access to treatment among migrants living with HIV in Europe. *J. Int. AIDS Soc.* 2018; 21, e25123.

[11] Sexual Rights Database - Italy. Available at: http://sexualrightsdatabase.org/ map/21/Adult sex work/387/Italy. [accessed 12 January 2020].

[12] Abolizione della regolamentazione della prostituzione e lotta contro lo sfruttamento della prostituzione altrui. 75, 1958. Available at: https://www.gazzettaufficiale.it/atto/serie_generale/caricaDettaglioAtto/originario?atto.dataPubblicazioneGazzetta=1958-03-04&atto.codiceRedazionale=058U0075&elenco30giorni=false [accessed 12 January 2020].

[13] Sex, Poverty and Law Programme. Available at: http://spl.ids.ac.uk/sexworklaw [accessed 12 January 2020].

[14] Mulieri I, Santi F, **Colucci, Fanales Belasio E.,** et al. Sex workers clients in Italy: results of a phone survey on hiv risk behaviour and perception. *Ann. Ist. Super. Sanità.* 2014; 50, 4, 363-8.

[15] Dipartimento Politiche Antidroga. "Relazione sui

dati relativi allo stato delle tossicodipendenze in italia (Anno 2017). Anno 2017, 2018. Available at: http://www.politicheantidroga.gov.it/it/attivita-e-progetti/relazioni-annuali-al-parlamento/ [accessed 12 January 2020].
[16] Piano nazionale di interventi contro HIV e AIDS 2017-2019. Available at http://www.salute.gov.it/imgs/C_17_pubblicazioni_2655_allegato.pdf," 2016 [accessed 12 January 2020].
[17] Giornata mondiale aids. Al via campagna di comunicazione del ministero della salute. Available. at: http://www.salute.gov.it/portale/news/p3_2_4_1_1.jsp?lingua=italiano&menu=salastampa&p=comunicatistampa&id=5211 [accessed 12 January 2020].
[18] World Health Organization Regional Office for Europe. Compendium of good practices in the health sector response to HIV in the WHO European Region (2018). 2018. Available at: http://www.euro.who.int/en/publications/abstracts/compendium-of-good-practices-in-the-health-sector-response-to-hiv-in-the-who-european-region [accessed 12 January 2020].
[19] HIV - Proteggiamoci dal virus e dallo stigma, ancora tante iniziative in calendario per la Giornata mondiale contro l'AIDS – 1 dicembre 2017. Available at: https://www.cronacacomune.it/notizie/32363/aids-2017.html [accessed 12 January 2020].
[20] NPS Italia. Gli italiani e l'Aids: scarsa conoscenza della malattia e stigma ancora presente. Available at: https://www.npsitalia.net/gli-italiani-e-laids-scarsa-conoscenza-della-malattia-e-stigma-ancora-presente/ [accessed 12 January 2020].
[21] European Parliament Policy Department. Policies for Sexuality Education in the European Union. Available at: https://www.europarl.europa.eu/RegData/etudes/note/join/2013/462515/IPOL-FEMM_NT(2013)462515_EN.pdf [accessed 12 January 2020].
[22] L'Amore W. Available at: https://www.wlamore.it [accessed 12 January 2020].
[23] Suligoi B, Salfa MC. Le infezioni sessualmente trasmesse - Come riconoscerle e prevenirle. Ed Percorsi editoriale Carocci, 2018, Roma. Available at https://www.ibsafoundation.org/wp-content/uploads/2018/11/10-le-infezioni-sessualmente-trasmesse-suligoi.pdf [accessed 12 January 2020].
[24] LILA. Lo stato dell'HIV/AIDS in Italia: dati, diritti, persone, politiche di salute pubblica per sconfiggere l'HIV/AIDS entro il 2030. Available at: https://www.lila.it/it/news/1004-statohiv-aids-initalia-2017 [accessed 12 January 2020].
[25] Ministero della Salute Linee Guida Italiane sull'utilizzo dei farmaci antiretrovirali e sulla gestione diagnostico-clinica delle persone con infezione da HIV-1,2017. Available at: http://www.salute.gov.it/portale/documentazione/p6_2_2_1.jsp?lingua=italiano&id=2696 [accessed 12 January 2020].
[26] Dipartimento Politiche Antidroga. Piano di Azione Nazionale Antidroga 2010-2013. 2011. Available at: http://www.politicheantidroga.gov.it/it/attivita-e-progetti/le-pubblicazioni/ [accessed 12 January 2020].
[27] Preservativo gratis in Lombardia, tre motivi per cui è una rivoluzione per la salute pubblica. Available at: https://www.ilfattoquotidiano.it/2018/08/01/preservativo-gratis-in-lombardia-tre-motivi-per-cui-e-una-rivoluzione-per-la-salute-pubblica/4530455/[accessed 12 January 2020].
[28] Piemonte: pillola anticoncezionale e preservativi gratis a minorenni e disoccupate. Available at: https://www.fanpage.it/attualita/piemonte-pillola-anticoncezionale-e-preservativi-gratis-a-minorenni-e-disoccupate/ [accessed: 12 January 2020].
[29] Preservativi gratis nelle biblioteche di Milano: l'idea di un Municipio. Available at: http://www.milanotoday.it/attualita/preservativi-gratis-biblioteche.html. [accessed 12 January 2020]
[30] PLUS Onlus. Informazioni sull'uso di farmaci per prevenire l'HIV. Available at: http://www.prepinfo.it/prep-in-farmacia/ [accessed 12 January 2020].
[31] Prati G, Zani B1, Pietrantoni L1 et al. PEP and TasP Awareness among Italian MSM, PLWHA, and High-Risk Heterosexuals and Demographic, Behavioral, and Social Correlates. *PLoS One.* 2016; 11, 6, e0157339.
[32] European Monitoring Centre for Drugs and Drug Addiction. Italy Country Drug Report 2017. Available at: http://www.emcdda.europa.eu/countries/drug-reports/2017/italy/harm-reduction_en/ [accessed 12 January 2020].
[33] Cook C. Harm reduction investment in the European Union: Current spending, challenges and successes. 2017. Available at: https://www.hri.global/files/2017/04/25/HRWreportApril2017_web_1.pdf [accessed 12 January 2020].
[34] Documento di consenso sulle politiche di offerta e le modalità di esecuzione del test per HIV in Italia. 1-15. Available at: http://www.salute.gov.it/portale/documentazione/p6_2_2_1.jsp?lingua=italiano&id=1647 [accessed 12 January 2020].
[35] LILA. Il test per l'HIV. Available at: https://www.lila.it/it/infoaids/20-test [accessed 20 January 2020].
[36] Suligoi B, Luzi AM. Nuove linee di indirizzo per lo screening e la diagnosi delle principali patologie infettive correlate all'uso di sostanze nei servizi per le dipendenze. Available at: http://www.salute.gov.it/imgs/C_17_pubblicazioni_2767_allegato.pdf [accessed 12 January 2020].
[37] HIV self testing in Italy. Available at: http://hivst.org/blog/hiv-self-testing-in-italy. [accessed: 12 January 2020].
[38] Pittalis S, Orchi N, De Carli G, et al. HIV Self-Testing in Italy. *J. Acquir. Immune Defic. Syndr.* 2017; 76, 3, e84-e85.
[39] AIFA Publishes List of Innovative Drugs Regions Must Reimburse, with Type 2 Diabetes, Wet AMD and HIV/AIDS Drugs to the Fore. Available at: https://ihsmarkit.com/country-industry-forecasting.html?ID=1065928742 [accessed: 12 January 2020].