

## Legislation, policies and organization of community based Centers for HIV diagnosis and prevention in Piedmont Region.

### Author's Details:

<sup>(1)</sup>Tradori Vania <sup>(2)</sup>Biancone Paolo Pietro <sup>(3)</sup>Silvana Secinaro <sup>(4)</sup>Brescia Valerio

<sup>(1)</sup>Tradori V., University Researcher at the Department of Management, University of Turin <sup>(2)</sup>Biancone P.P., Full Professor at the Department of Management, University of Turin <sup>(3)</sup>Secinaro S., University Researcher at the Department of Management, University of Turin <sup>(4)</sup>Brescia V., PhD candidate at the Department of Management, University of Turin

**Corresponding Author:** Brescia V., Department of Management, University of Turin Corso Unione Sovietica 218 Bis, I – 10134 Turin

### Abstract:

*The article describes how the fight against AIDS is tackled, from an organizational and legislative point of view, especially with regard to HIV test offer to as many people as possible, with a focus on people with higher at-risk behaviors, in order to reduce the cases of immunodeficiency and unawareness of the serological state. The community-based services and the implementing policies of Piedmont Region answer to the need for integration already offered by the Regional Health Service. The features and results confirmed by a pilot project can be a useful reference for the activation of integrated services on the territory.*

**Key Words:** HIV, community-based, legislation, and organization of diagnosis centers.

### Introduction

#### Epidemiological situation

At the end of 2010, UNAIDS (Joint United Nations Programme on HIV/AIDS) estimated 33 million people living with HIV/AIDS worldwide. In 2009, 2.6 million new infections and 1.8 million deaths due to AIDS were reported. Sub-Saharan Africa is the most affected region, with 1.8 new cases per million inhabitants in 2009, followed by South-East Asia and Eastern Europe. The spread of the acquired immune deficiency virus in the European area has a strong geographical variability, mainly linked to economic and social differences. The number of AIDS and HIV notifications is high in Western Europe, but the trend is descending as a result of extensive access to antiretroviral therapy (effective in preventing clinical progression of infection) and of the successful outcome of prevention and information programmes. In Eastern Europe, there is a continuous increase in AIDS and HIV notifications due to the limits of the answer of health systems to HIV epidemic and to the reduced access to HAART. Central Europe countries, on the other hand, are less concerned about this epidemic. In Italy, data collection on AIDS cases started in 1982, and in June 1984 it was formalized in a National Surveillance System, according to which, in 2010, 4.0 new cases of HIV positivity were diagnosed every 100,000 Italian residents and 20.0 new cases of HIV positivity every 100,000 foreign residents. In 2010, almost one person out of three diagnosed as HIV positive had a foreign nationality. The incidence is higher in Center-North than in the South-islands. Over the past 10 years, there is a stabilization of the reports in the areas where the datum is available. People who discovered to be HIV positive in 2010 have a median age of 39 years old for males and 35 for females. The proportion of women has risen until the mid-1990s, and since 2003 it has been declining: the male/female ratio, which was 2.3 in 2003, became 3.2 in 2010.

Cases ascribable to heterosexual and homosexual contacts are increasing: in 2010 they accounted together for 80.7% of all reports. One-third of people with a new diagnosis of HIV is diagnosed at an advanced stage of illness, with a significant impairment of the immune system (number of CD4 lymphocytes less than 200 cells / mm<sup>3</sup>).

New AIDS cases per year continue to decrease mainly because of combined antiretroviral therapies (introduced in our country in 1996). Such therapies prolong survival and reduce the mortality of HIV-positive people, leading to a progressive increase in the number of people living with AIDS. The characteristics of people with AIDS have changed over the past 10 years: cases involving injective drug use decreased, the median age of people with AIDS increased, and cases of sexual contact increased (both

heterosexual and homosexual, with the first ones being on the rise). An increasing proportion of people find themselves to be HIV positive very late, concurrently with the diagnosis of AIDS. As a result of these late diagnoses, two-thirds of people diagnosed with AIDS from 1996 to 2010 did not benefit from antiretroviral therapies before such diagnosis.

### **Piedmont Region Prevention Plan 2014 – 2018**

The Regional Prevention Plan 2014-2018 (RPP) is designed to continue to respect the vision already enunciated in the National Plan for Prevention (NPP) and the principles that must be applied to public health:

- the centrality of health understood as a universal common good and therefore also as an inalienable right of every individual and interest of the community;
- social equity and equal health opportunities for everyone;
- the involvement of local authorities to make the best use of the health potential in all policies, even non-health ones;
- communication and listening;
- the integration of all the services of the socio-sanitary system and the collaboration with all the institutional components of the social fabric and volunteering;
- effectiveness and appropriateness, with rigorous application of the principles of scientific evidence, of action for health priority and transparency of choices;
- the sobriety and sustainability of interventions;
- the empowerment and participation of all operators.

The Plan sets common priority objectives in the NPP path, which answer to considerable health needs, identified at national and regional level.

These priority objectives are defined and explained through context analysis and identification of determinants / risk factors to:

- reduce the burden of disease by strengthening the health service's contribution to the welfare system. This is particularly true of the objectives connected to the reduction of premature mortality from non-transmissible chronic diseases, with the reduction of accidents and occupational diseases as well as with the promotion of active ageing;
- invest in the well-being of children and young people. It is a choice of strong formative and empowerment content that aims to promote, in a "life course" approach which favours early interventions, contexts favourable to the development of responsibility and personal skills that concern the proposal of healthy lifestyles, the pursuit of mental wellbeing, the adoption of behavioural rejection of dependencies and risk behaviours;
- strengthen and confirm the common heritage of effective preventive practices that have been consolidated over the years, even in relation to national planning acts (preventive interventions in life and workplaces, infectious disease prevention, vaccinations, food safety, etc.);
- strengthen and put at the system the focus on fragile groups;
- consider the individual and the populations in relation to their environment by promoting a healthy relationship between health and the environment and by developing the potential for the inter-institutional approach of health service;
- consider the interaction between socioeconomic and cultural conditions and personal lifestyle in a setting approach aimed at long-term organizational, cultural and health changes, with particular attention to the European strategies outlined in the WHO-Europe Action Plan NCD 2016/2020 regarding school environment (Network Schools for Health in Europe, SHE) and work environment (Network Workplace Health Promotion, WHP).

A key role in achieving these goals is played by awareness campaigns, which are applied in different contexts, such as in schools and communities. As far as resources are concerned, prevention activities are part of the healthcare services funded by the Health Fund and, as such, they must be included in the company's organization and in the action programmes of Prevention Department's Services and of Business Structures involved in the Local Preventive Plans. This means that the resources allocated for prevention (5% of NHF-National Healthcare Fund-+ Structured Funds) are actually used for preventive interventions which

burden on the functioning of weakened structures affected by the measures to reduce public spending and by the constraints imposed by the Plan of return.

Among the various programmes that are expected in order to reach the above goals, there is the one to reduce the frequency of infections / priority infectious diseases, including sexually transmitted infections and HIV, of which the Plan states: "In Piedmont, the total burden of sexually transmitted infections, including HIV infection, is such as to fully address their prevention and control among public health problems on which it is essential to intervene. "

In Piedmont, more than 3,000 people per year receive a diagnosis of sexually transmitted infection and about 300 Piedmontese find out that they contracted HIV infection (among them there is still a very high number of people arriving late to diagnosis when the immune system is already compromised or even when AIDS has already been developing).

Since the early 2000s, a network of 9 Centers has been active in Piedmont. It provides effective action to fight the spread of sexually transmitted infections by carrying out activities of surveillance, prevention, diagnosis and treatment of STIs in a homogeneous way and by adopting internationally recommended diagnosis and treatment protocols.

The Regional Prevention Plan 2014-2018 (RPP) is designed to continue to respect the vision already set out in the National Plan for Prevention (NPP) and the principles that must be applied to public health:

- the centrality of health understood as a universal common good and therefore also as an inalienable right of every individual and interest of the community;
- social equity and equal health opportunities for everyone;
- the involvement of local authorities to make the best use of the health potential in all policies, even non-health ones;
- communication and listening;
- the integration of all the services of the socio-sanitary system and the collaboration with all the institutional components of the social fabric and volunteering;
- effectiveness and appropriateness, with rigorous application of the principles of scientific evidence, of action for health priority and transparency of choices;
- the sobriety and sustainability of interventions;
- the empowerment and participation of all operators.

The Plan sets common priority objectives in the NPP path, which answer to considerable health needs, identified at national and regional level.

These priority objectives are defined and explained through context analysis and identification of determinants / risk factors to:

- reduce the burden of disease by strengthening the health service's contribution to the welfare system. This is particularly true of the objectives connected to the reduction of premature mortality from non-transmissible chronic diseases, with the reduction of accidents and occupational diseases as well as with the promotion of active ageing;
- invest in the well-being of children and young people. It is a choice of strong formative and empowerment content that aims to promote, in a "life course" approach which favours early interventions, contexts favourable to the development of responsibility and personal skills that concern the proposal of healthy lifestyles, the pursuit of mental wellbeing, the adoption of behavioural rejection of dependencies and risk behaviours;
- strengthen and confirm the common heritage of effective preventive practices that have been consolidated over the years, even in relation to national planning acts (preventive interventions in life and workplaces, infectious disease prevention, vaccinations, food safety, etc.);
- strengthen and put at the system the focus on fragile groups;
- consider the individual and the populations in relation to their environment by promoting a healthy relationship between health and the environment and by developing the potential for the inter-institutional approach of health service;
- consider the interaction between socioeconomic and cultural conditions and personal lifestyle in a setting approach aimed at long-term organizational, cultural and health changes, with particular attention to the European strategies outlined in the WHO-Europe Action Plan NCD 2016/2020 regarding school

environment (Network Schools for Health in Europe, SHE) and work environment (Network Workplace Health Promotion, WHP).

A key role in achieving these goals is played by awareness campaigns, which are applied in different contexts, such as in schools and communities. As far as resources are concerned, prevention activities are part of the healthcare services funded by the Health Fund and, as such, they must be included in the company's organization and in the action programmes of Prevention Department's Services and of Business Structures involved in the Local Preventive Plans.

This means that the resources allocated for prevention (5% of NHF-National Healthcare Fund+ Structured Funds) are actually used for preventive interventions which burden on the functioning of weakened structures affected by the measures to reduce public spending and by the constraints imposed by the Plan of return.

Among the various programmes that are expected in order to reach the above goals, there is the one to reduce the frequency of infections / priority infectious diseases, including sexually transmitted infections and HIV, of which the Plan states: "In Piedmont, the total burden of sexually transmitted infections, including HIV infection, is such as to fully address their prevention and control among public health problems on which it is essential to intervene.". As regards the fight against HIV, as recommended at international level (WHO, UNAIDS), it is essential to raise public awareness on the importance of sexual health and its value in terms of well-being and quality of life; the implementation of primary and secondary prevention interventions aimed at target groups at a higher risk. It is essential to ensure timely, correct and complete treatment in a homogeneous and accessible manner across the regional territory to achieve the therapeutic goal of a viral load under the measurable threshold in HIV positive patients."(REGIONAL PLAN FOR PREVENTION 2014-2018. Approval of prevention programmes for the period 2015-2018 "; Piedmont Region).

### **Late diagnosis and features of national regulations**

It is estimated that in Italy, similarly to other European countries, there is a significant proportion of people with HIV infection (about a third) who are unaware of their HIV status. In addition, it has been shown that approximately 30% of HIV infection diagnoses is conducted in people who are already at an advanced stage of disease (CD4 <200 / MMC lymphocytes and / or indicative AIDS pathologies) and, anyway, nearly 60% of AIDS diagnoses are made in people with late recognition of HIV infection. This phenomenon has several negative consequences. First, the person with late-diagnosed HIV does not have the opportunity to start antiretroviral therapy in the best periods and, on the one hand, has a higher risk of attaining a full-blown stage of the disease and, on the other hand, a reduced probability of a full immunological recovery once pharmacological treatment has started.

Secondly, lack of awareness of the state of infection may favor the further spread of the infection. It has been shown, indeed, that people with HIV infection reduce, in part or completely, the behaviors at risk of infection transmission once they are informed of their condition. Furthermore, there is evidence of the effectiveness of the prevention of infection spread addressed to people with known HIV infection.

Third, antiretroviral therapy, reducing viral load, can also help limit the infection spread. Indeed, a person aware of his / her HIV status receiving effective therapy has a very limited risk of transmitting the infection to others. Finally, pregnant women aware of having HIV infection can access maternal-fetal prophylaxis programmes that drastically reduce transmission of the virus to the unborn child. In view of the high number of seropositive people still unaware of their serological status, it is considered strategic, priority and urgent to recognize the importance and to activate early detection actions that allow early contact and early diagnosis of these individuals.

The data of the "Research project for the identification and the experimentation of intervention models to improve accession to the HIV screening test" (funded by the Ministry of Health, coordinated by the National Institute of Health and realized with the contribution of the Associations that are part of the AIDS Fighting Consultation) highlight a situation of extreme lack of homogeneity of the HIV test offer today in Italy.

Indeed, the results of the Project show how, in the Centers involved in the investigation, there is no common way of test execution, particularly with regard to gratuitousness, anonymity, and pre-and post-test counseling interview. In some regions, the objective scarcity of Centers where it is possible to access the test is reported, in some territorial realities, it is replaced by the access of the general population to the Transfusion Centers.

Data collected under another programme indicate that in many cases the test result is not withdrawn, in some contexts up to 25%. This document tries to emphasize the need to carry out the test, to propose unique ways of the provision of the test itself and of results' delivery across the national territory, to open the possibility of experimenting different test offer modes to ensure access and to identify intervention programmes aimed at bringing out the submerged.

### **Aim and methods**

The aim of the article is to assess whether regional policy meets organizational and epidemiological needs. To evaluate consistency with the established one, the case study of a pilot project realized by is used of Ody "Casa Arcobaleno." The analyzes are of a qualitative nature on the organization of the service and on the main characteristics by assessing the answer to the citizen's need through surveys. A quantitative statistical analysis was also conducted based on a survey that volunteers provided to users who identify behaviors and statistics of the same user by assessing whether more risk behaviors (dependent variables) are related to sexual behaviour (independent variable) and how the observable outcome corresponds to the epidemiological needs and to the regional trend already observed. All analyses were performed via STATA V.14,2 (Stata Corp., College Station, Texas, USA, 2013) with a  $p < 0.05$  considered significant for all analyzes.

### **Discussion**

#### **The offer of the HIV rapid test in Piedmont**

Since a long time, Piedmont Region Health Department promotes actions to facilitate access to the HIV test. With R.C.D. (Regional Council Decree) n. 54-12150 of 30/03/2004, the guidelines for the organization of the HIV test offer within the Regional Health Service were defined. In particular, indications about gratuitousness, anonymity, access to the test and the delivery of reports were given. After that, with note no. 14423 / 27,001 of October 12<sup>th</sup>, 2004, application clarifications related to the same measure were provided in terms of the definition of risk subjects, the management of the request for the execution of the test in anonymity by private facilities and the communication of the test result to subjects other than the person concerned.

During 2006, the Regional Hygiene Sector and Public Health promoted a training course about the aims, principles, and strategies of counseling intervention in HIV infection in which more than one hundred operators participated.

Subsequently, with R.C.D. no. 46-10149 of 24/11/2008 the *Regional Plan for the Spread of Sexually Transmitted Infections and HIV / AIDS* was approved. It includes, among the recommended actions, the development of interventions that can promote and facilitate access to the HIV test, reducing the latency period between infection and diagnosis.

In 2012, with R.C.D. no. 25 - 4082 Piedmont Region transposed the Agreement approved at the State-Regions Conference on the *Consent Document on the offer policies and the execution modes of the HIV test*. The national document outlines the general principles of the HIV test offered on the national territory, specifies in detail the organizational aspects, and the operating modalities which the diagnostic investigation facilities must follow identify the groups of the target population and indicate, among the technical tools, the procedures to conduct the test.

In Piedmont, over the years, many initiatives of active HIV test offer (mainly rapid test) have been carried out, in the framework of specific projects (Regional Project of rapid test offer in D.SER, Project of Aimed Health Research 2002 Challenge: Prevention of late HIV infection in populations difficult to be contacted) or within the routine activity of the RHS Services (Itinerant Dependency Service (CANGO), HIV Counselling Test Team Service, MISA (Migration and Health) Clinic, IST Clinic of Amedeo di Savoia Hospital LHA (Local Health Authority) TO2, Casa Verde of Volvera, D.SER of LHA TO3).

An important contribution has been provided by Volunteer Associations (Arcobaleno AIDS, Arcigay, LILA, Abele Group, Red Cross) which, over the years, have been conducting continuous projects and interventions of rapid HIV test offer in contexts other than those of RHS, always in collaboration and connection with specialists of health facilities.

### **Service organization**

RHS facilities offering HIV test must ensure the gratuitousness of the service, the direct access, and the anonymity to all the people who request it and they must provide appropriate procedures to maximize confidentiality of the result and of information about the person who requires the test.

RHS facilities that offer HIV test must guarantee, directly or indirectly through the connection with specialized centers, appropriate diagnostic procedures, prevention, treatment, and care, to facilitate timely taking-over in case of positivity. Preventive interventions are meant to be done, to provide rapid test offer in strategic contexts in order to increase early diagnosis and reach people who use health services with more difficulty. The HIV rapid active offer promoted by organizations outside the RHS (associations, third sector) must involve RHA specialized clinical centers (infectious diseases, IST centers). In particular, protocols and procedures must be prepared for the following aspects: training of staff involved in the test offer, communication of the test result, delivery of people found positive to infectious disease centers for confirmation of results (validation of disabled and positive results) and the taking-over, disposal of health biohazard waste. All RHS operators who come in contact with people who have high-risk sexual HIV behaviors must systematically propose HIV test. All people who go to regional IST centers must have actively and systematically offered the HIV test. The HIV test must be actively offered to all persons who have suffered sexual assault according to the criteria, timing, and modalities provided by protocols for the offer of post-exposure prophylaxis. The HIV test must be actively and systematically offered to all people:

- who used or use, even occasionally, injective and non-injective drugs;
- who is in charge of User (Dependence Public Services, or User: Drug Addiction);
- who are from high endemic HIV countries (prevalence > 1% - a reference to UNAIDS estimates) at the first occasion addressing RHS structures or health-care services, regardless of the risk behaviors reported;
- who show suggestive symptomatology of acute HIV infection;
- who have pathologies included in the definition of AIDS or associated with HIV infection; the test offer in these cases is highly recommended and must be systematic;
- who has a condition or pathology whose management can be influenced by the knowledge of the HIV serological status?

The HIV test must be offered to all women at pre-conception, at the time of pregnancy and subsequently during gestation if there is a risk exposure. Test offer in these cases is strongly recommended and must be systematic.

The HIV test must be offered to partners of pregnant women or of women who intend to start one. Test offer in these cases is strongly recommended and must be systematic. Healthcare staff assisting women in childbirth must check that HIV test has been conducted during pregnancy. If this is not the case, the test with urgency procedure must be offered in order to be able to make the appropriate decisions on the prophylaxis interventions to be done, including how to do the childbirth. The HIV test is mandatory for all blood donors, or blood components, of organs, tissues, and cells. The HIV test must be systematically offered to all people with accidental percutaneous exposure (knife wounds, puncture wounds, mucous and / or not intact skin contaminations), to potentially infected material according to the criteria, timing, and modalities provided in the protocols for post-exposure HIV prophylaxis. Fourth generation immunometric tests (first level tests) are the choice tests for HIV infection diagnosis, especially for cases of suspected acute or recent infection, and if the test is conducted for organ donation and of blood components. Immunometric tests must be used, which seek antibodies against HIV1 and HIV2 and which are sensitive to the subgroup or HIV-1. Positive results or doubts on first level tests must always be confirmed by Western Blot / Immunoblotting (second level or confirmation test) and / or HIV RNA. If the results of the serological tests are not conclusive, it is recalled that the search for HIV RNA is crucial; it is practicable in the reference laboratories. Laboratories conducting anti-HIV serological tests must preferentially work on a mother-test tube, incorporate internal quality control within each session and participate in a regional, national or international quality external assessment programme (QEA).

As regards the interpretation of the result and the report of the serological test for HIV antibodies:

- the negative result of the first level immunometric test (screening) indicates no HIV infection if conducted 3 months after the last potentially risk exposure;
- in case of reactivity of the first level immunometric test, the Western Blot and / or HIV RNA (second level test) must always be conducted;

- in case of discordant results (negative/undetermined reactive first level test/western blot/immunoblot), the HIV RNA execution is indicated by sending the sample to the reference laboratories. In case of suspected acute HIV infection, the choice test is HIV RNA ("window" phase);
- the report must indicate the test result as "positive" / "reactive" or "negative" / "non-reactive" along with information on the method used for test execution (ELISA, chemiluminescence, etc.);
- the reporting of a "positive" / "reactive" result must be made only after confirmation of the result to the immunometric first level test with Western blot / immunoblotting and / or HIV RNA confirmation test;
- test reporting times must usually be limited within one week;
- each HIV positivity/reactivity report must be delivered only to the person to whom the examination refers, with post-test counseling and contact with the Infectious Disease Center for patient submission.

With regard to rapid tests for anti-HIV antibodies:

- the properly trained professional (healthcare and non-healthcare) offering HIV rapid test must evaluate the risk of contracting the infection of the person undergoing the test;
- the HIV rapid test result must be communicated verbally during an interview and must be contextualized according to the evaluation of the risk of contracting the HIV infection from the person undergoing the test. When the person has reported dubious or known exposures in the three months before the test execution, the professional must propose the sending of the person to an infectious disease center and, if necessary, repeating the test at a distance of 3 months from the last exposure;
- the positivity of a rapid test must always be confirmed with other reference methods, according to the procedural algorithms for the conventional screening test (first level);
- the reactive result of the test can be interpreted as "preliminary positive," but it is always and in any case necessary to carry out a blood sample confirmation test and the taking-over of the person by the infectious disease center (Seremi, 2016).

### **Pilot project and results**

The delay in diagnosing HIV infection appears to be at least partially related to access barriers to test which affect some segments of the population. To counteract the phenomenon of late diagnosis of HIV infection, an important initiative is the one that focuses on HIV test offer in contexts other than services traditionally dedicated to this activity. In Europe, there are important experiences that demonstrate the potential effectiveness of these initiatives ([www.cobatest.org](http://www.cobatest.org)). Three projects achieved by Arcigay "Ottavio Mai" of Turin in collaboration with Odv "Casa Arcobaleno" cooperated in the evaluation of the acceptance of the salivary and drop blood test for HIV in a community based associative context with evidence of effectiveness in terms of new identified infections and people being treated (approximately two confirmed reactivities per 150 users, datum confirmed at national level through effectiveness data - efficiency of tests in Rome's Spallanzani and in the National Health Institute with a ratio of 1 to 200 users). All of the age subjects linked to the conduct locations selected during the study period were proposed to voluntarily undergo a fast-response HIV test on a sample of oral fluid or by blood drop. People with reactive test were sent with an easy course at the reference Care Center (Infectious Disease Department of the Amedeo di Savoia LHA TO 2 - Dr. Dal Conte Ivan) in order to conduct the confirmation test and for the clinical follow-up. In the three projects, 500 tests were carried out, very high datum towards the population "at risk, man has sex with a man," identifying 6 reactive cases confirmed through hematic tests and CD4 counting. The project identified as best practice tested 143 people (shown in Table 1 and 2).

This was possible thanks to the collaboration with FARMACIE COMUNALI SPA (Town Pharmacies SPA). The project documented the high ability of a community based association to ensure access to the test and link with clinical centers. The project is among the objectives set out at Piedmont Region Level - Prevention Plan 2014 - 2018, M09 Reduce the frequency of infections / priority infectious diseases Central Objectives 9.5 Reduce the risks of transmission from chronic or long-term infectious diseases, specific regional

objectives Reduce transmission risks from infectious diseases such as tuberculosis and HIV and IST infections. National Health Plan 2014 - 2018 2.9. Reduce the frequency of infections / priority infectious diseases - "SEXUALLY TRANSMITTED INFECTIONS; HIV, AIDS "Neisseria Gonorrhoea 2.2% in men, in 2011 half of the cases (56%) of new HIV diagnoses were already in AIDS, highlighting a delay in diagnosis. In 2011, the incidence of new HIV cases remained stable (5.8 / 100,000 residents). The structuring of a non-permanent community-based healthcare counter has been done, which facilitates access to early HIV diagnosis for the most vulnerable key populations, such as MSM, who may not actively seek test services and HIV counselling within the official health care system or find obstacles in doing so. The healthcare counter is a facility for rapid test in order to promote and raise awareness of the use of HIV test anonymously. This kind of service is already stably present in other European cities such as Barcelona, Lisbon, Athens, Belgrade and, in Italy, Bologna, but permanently in collaboration with public institutions. In addition to being a place where tests are conducted free, the activated counter has also become a meeting, information and documentation place about issues related to HIV and AIDS and other sexually transmitted diseases. The test offer took place between February and December 2016 at the associative seat of Turin and at the Right Village, which was set up for one month on the occasion of the Pride of Turin 2016. The project was realized thanks to material funding (purchase of tests) of FARMACIE COMUNALI (Town Pharmacies) and to the co-financing with the recognition of the hours of volunteers through a notice made by Vol.to Service Center of voluntary work won by the association. There were two doctors and 5 volunteers in the project execution, training was done both through plenary training on objectives, type of communication and information, type of test; and through the support of new volunteers with those already present in previous testing projects. The expected test course and the documentation may be represented by points: 1) reception of the person; 2) explanation of how the overall procedure and the test procedure work; 3) proposal to pen or sign informed consent for viewing; 4) if the proposal is accepted, produce the individual code to be attributed to the person in order to ensure anonymity and identify the subject without confusion 5) label with the individual code: a. the informed consent that remains to the association b. the informed consent given to the person c. the risk assessment questionnaire; 6) the compilation request of the questionnaire (almost always deferred to 20 minutes of waiting between the test and the result); 7) sending to the doctor with 2 labels with the individual code; 8) the doctor labels the test with 1 label, while he/she keeps the other one for a possible referral ticket; 9) the doctor fills up the internal form of the users-results. If the result is reactive (preliminarily positive) it is important to specify that the result is to be confirmed at the clinical center and is not to be understood as a definitive diagnosis; reassure the person in any case as for the possibility that it is confirmed to be positive and as for the manageability of this possibility (the person will still be worried about a possible confirmation, and we know that a confirmation is likely to be unless in unfortunate cases); ensure the referral, if possible also with accompaniment or otherwise facilitating direct contact with the clinical center (Amedeo di Savoia of Turin with which a Memorandum of Understanding has been defined). 10) At the end the subject fills up a questionnaire of satisfaction also to know the perception of the service and the perceived need to which he/she answers. The type of administered test is Alere determinants HIV 1 and 2 type, ag antigen detection and ab antibody on whole blood with reagent, otherwise on serum with anticoagulant reagent. From the analysis of risk assessment questionnaires administered by volunteers, it comes out that most of the sample is made up of men who have sex with men, of whom 18.5% had only one partner in the last year, 44.35% had 2 to 5, 22.58% had 6 to 10 and 14.52% had a number of partners over 10. It also turns out that men who have sex with men in the sample have a greater probability of having risk relationships, statistical regression between the men's variable who have sex with men compared to the rest of the sample and risk behaviours (unprotected sex) through linear regression has an odds ratio of 9.57, 95% confidence range varies between 2.7 and 33.89, while p-value is <0.001. After correcting for the age and number of education years, the fact of being (men who have sex with men) remains associated with a probability of 8.66 times higher than all those who are not (men who have sex with men) to have sex at risk. This makes it possible to state that the project answers to the regional need to intervene on those who have risk behaviours, identified in this case in men who have sex with men. The following question is interesting in the evaluation of the satisfaction expressed in the service: "Do you think that the service that you were offered is useful in supporting the service provided by the Public Bodies (Elisa test)?", the evaluation was collected with a scale from 1 to 10 where 1 matched with of little use and 10 matched with very useful, the average of the questions was 9.81 points average and the question "Do you think that the service you were



just offered is able to reach and guarantee the presence of all those users who cannot do the test on working hours?" where always in a scale from 1 to 10 where 1 is of little use and 10 very useful but sample average gives an evaluation of 9.54 points.

### **Conclusions**

The first possible observation from what is stated by data is that national regulations need the establishment and promotion of community-based early diagnosis services. The European Center for Disease Prevention and Control (ECDC) in the document HIV testing in Europe, published in September 2015, denounces that test offer programmes fail to reach a significant percentage of the most at risk groups and points out the need for more efforts to improve the spread of the test to reduce the percentage of HIV-positive people who do not know their status or who are diagnosed late. An effective programming aimed at early identification of HIV infections is a priority, essential and not desirable intervention today. Piedmont Region intends to fully integrate into policies against HIV the planning of an HIV test offer strategy that identifies the behaviors and conditions in which it is indicated, defining its frequency, locations, and modes, indicating the types of test and pre-and post-test counseling procedures and the return of the result. For the first time, it is about risk behaviors and not risk groups, although epidemiological analyses and national, regional and project statistics continue to confirm that the people more at risk of contagion are men who have sex with men. An immediate diagnosis will allow the reduction of new contagions and of costs associated with immunodeficiency treatments, due to late access to therapy because of the delay in diagnosis. The course structured in the pilot project, similar to what has already been done at national level through HIV salivary rapid tests (Ministry of Health, IRCCS -Recovery and Treatment Institute of Scientific Character-Spallanzani of Rome, 2015), is the most reliable at the moment and that best answers to the literature analysed before the implementation. The HIV rapid tests suggested by regional regulations with greater specificity and sensitivity are currently those of IV generation, but it is possible to take into consideration tests with different characteristics depending on the administration asset and on the window period of interest. Community-based services will be able to answer to the needs of the population, increasing what is already active as RHS and will be able to ensure greater effectiveness and efficiency of the diagnosis and treatment system.

### **Bibliography**

#### **Articles on magazines**

- i. *Smith MK, Rutstein SE, Powers KA, Fidler S, Miller WC, Eron JJ Jr, Cohen MS. The detection and management of early HIV infection: a clinical and public health emergency. J Acquir Immune Defic Syndr. 2013; 63 Suppl 2:S187-99*
- ii. *Cohen MS, Chen YQ, McCauley M, et al. Prevention of HIV-1 infection with early antiretroviral therapy. N Engl J Med 2011;365:493-505.*
- iii. *Rietmeijer CA, Kane MS, Simons PZ, et al. Increasing the use of bleach and condoms among injecting drug users in Denver: outcomes of a targeted, community-level HIV prevention program. AIDS 1996;10:291-8.*
- iv. *Rhodes F, Malotte CK. HIV risk interventions for active drug users. In: S.Oskamp, S.Thompson, eds. Understanding HIV risk behavior: safer sex and drug use. Thousand Oaks, CA: Sage Publications, 1996:297-36.*
- v. *Gibson DR, Lovelle-Drache J, Young M, Hudes ES, Sorensen JL. Effectiveness of brief counseling in reducing HIV risk behavior in injecting drug users: final results of randomized trials of counseling with and without HIV testing. AIDS and Behavior 1999;3:3-12.*
- vi. *Doll LS, O'Malley PM, Pershing AL, Darrow WW, Hessel NA, Lifson AR. High-risk sexual behavior and knowledge of HIV antibody status in the San Francisco City Clinic Cohort. Health Psychol 1990;9:253-65.*
- vii. *Cleary PD, Van Devanter N, Rogers TF, et al. Behavior changes after notification of HIV infection. Am J Pub Health 1991;81:1586-90.*
- viii. *Fox R, Odaka NJ, Brookmeyer R, Polk BF. Effect of HIV antibody disclosure on subsequent sexual activity in homosexual men. AIDS 1987;1:241-6.*
- ix. *Van Griensven GJP, de Vroome EMM, Tielman RAP, et al. Effect of human immunodeficiency virus (HIV) antibody knowledge on high-risk sexual behavior with steady and nonsteady sexual partners among homosexual men. Am J Epidemiol 1989;129:596-603.*

- x. Coates TJ, Morin SF, McKusick L. Behavioral consequences of AIDS antibody testing among gay men [Letter]. *JAMA* 1987;258:1889.
- xi. Wenger NS, Kusseling FS, Beck K, Shapiro MF. Sexual behavior of individuals infected with the human immunodeficiency virus: the need for intervention. *Arch Intern Med* 1994;154:1849–54.
- xii. Desenclos J-C, Papaevangelou G, Ancelle-Park R, for the European Community Study Group on HIV in Injecting Drug Users. Knowledge of HIV serostatus and preventive behaviour among European injecting drug users. *AIDS* 1993;7:1371–7.
- xiii. Dawson J, Fitzpatrick R, McLean J, Hart G, Boulton M. The HIV test and sexual behavior in a sample of homosexually active men. *Soc Sci Med* 1991;32:683–8.
- xiv. Otten MW Jr, Zaidi AA, Wroten JE, Witte J, Peterman TA. Changes in sexually transmitted disease rates after HIV testing and posttest counseling, Miami, 1988 to 1989. *Am J Pub Health* 1993;83:529–33.
- xv. Quinn TC, Wawer MJ, Sewankambo N, et al. Viral load and heterosexual transmission of human immunodeficiency virus type 1. *N Eng J Med* 2000;342:921–9.
- xvi. 18 CDC. [Cases of HIV infection and AIDS in the United States, 2004](#). *HIV/AIDS Surveillance Report* 2005;16:16-45.
- xvii. Tao G, Irwin KL, Kassler WJ. Missed opportunities to assess STDs in US adults during routine medical checkups. *Am J Prev Med* 2000;18:109–14.
- xviii. CDC. [HIV prevention practices of primary care physicians—United States](#), 1992. *MMWR* 1994;42:988–92.
- xix. Tiara DA, Safran DG, Seto TB, Rogers WH, Tarlov AR. The relationship between patient income and physician discussion of health risk behaviors. *JAMA* 1997;278:1412–7.
- xx. Schwartz JS, Lewis CE, Clancy C, Kinoshian MS, Radany MH, Koplan JP. Internists' practices in health promotion and disease prevention. *Ann Intern Med* 1991;114:46–53.
- xxi. Kassler WJ, Dillon GA, Haley C, et al. On-site, rapid HIV testing with same-day results and counseling. *AIDS*. 1997;11:1045–51.
- xxii. Horton T, Uniyal A, Smith LV, Curreri S, Kerndt P, Branson B. Feasibility of implementing rapid HIV testing in a community-based setting. *National HIV Prevention Conference; Atlanta GA; July 2003. Abstract T2-C1503.*
- xxiii. Luo W, Masciotra S, Delaney KP, Charurat M, Croxton T, Constantine N, et al. Comparison of HIV oral fluid and plasma antibody results during early infection in a longitudinal Nigerian cohort. *J Clin Virol*, 2013. 58 Suppl 1: e113-8.
- xxiv. Masciotra S, Luo W, Youngpairoj AS, Kennedy MS, Wells S, Ambrose K, et al. Performance of the Alere Determine HIV-1/2 Ag/Ab Combo Rapid Test with specimens from HIV-1 seroconverters from the US and HIV-2 infected individuals from Ivory Coast. *J Clin Virol*, 2013.
- xxv. Bert, F., Gualano, M. R., Biancone, P., Brescia, V., Camussi, E., Martorana, M., ... & Siliquini, R. (2016). HIV-screening in pregnant women: a systematic review of cost-effectiveness studies: Fabrizio Bert. *The European Journal of Public Health*, 26(suppl\_1), ckw174-023.
- xxvi. Girardi, E., Sabin, C. A., & Antonella d'Arminio Monforte, M. D. (2007). Late diagnosis of HIV infection: epidemiological features, consequences and strategies to encourage earlier testing. *JAIDS Journal of Acquired Immune Deficiency Syndromes*, 46, S3-S8.
- xxvii. Raimondo, M., Pasqualini, C., Ghisetti, V., Regine, V., Camoni, L., Salfa, M. C., & Suligo, B. (2010). Recent HIV infection among newly diagnosed with HIV cases in Turin, Italy. *Retrovirology*, 7(1), P98.
- xxviii. Camoni, L., Pasqualini, C., Regine, V., D'Amato, S., Raimondo, M., Pompa, M. G., ... & Suligo, B. (2012). An improved data-collection form for the surveillance of HIV infection in Italy. *Italian Journal of Public Health*, 7(1).
- xxix. Blystad H, Wiessing L. *Guidance on Provider-initiated Voluntary Medical Examination, Testing and Counselling for Infectious Diseases in Injecting Drug Users. Pre-final unedited version 5.5. EMCDDA. Lisbon: 2009.*
- xxx. Leaty S, Sherr L, Wells H, Evans A, Miller R, Johnson M, et al. Repeat HIV testing: high-risk behaviour or risk reduction strategy? *AIDS* 2000;14(5):547-52.
- xxxi. Fernyak SE, Page-Shafer K, Kellogg TA, McFarland W, Katz MH. Risk behaviors and HIV incidence among repeat testers at publicly funded HIV testing sites in San Francisco. *J Acquir Immune Defic Syndr*. 2002;31(1):63-70.
- xxxii. Hightow LB, Miller WC, Leone PA, Wohl DA, Smurzynski M, Kaplan AH. Predictors of repeat testing and HIV seroconversion in a sexually transmitted disease clinic population. *Sex Transm Dis*. 2004;31(8):455-9.
- xxxiii. MacKellar DA, Valleroy LA, Secura GM, Bartholow BN, McFarland W, Shehan D, et al. Repeat HIV testing, risk behaviors, and HIV seroconversion among young men who have sex with men: a call to monitor and improve the practice of prevention. *J Acquir Immune Defic Syndr*. 2002;29(1):76-85.

- xxxiv. *N.Lorente et All., Expanding Access to Non-Medicalized Community-Based Rapid Testing to Men Who Have Sex with Men: An Urgent HIV Prevention Intervention (The ANRS-DRAG Study), Plos One April 2013 vol.8 issue 4.*
- xxxv. *M. Meulbroeck et All, BCN Checkpoint, a community-based centre for men who have sex with men in Barcelona, Catalonia, Spain, shows high efficiency in HIV detection and linkage to care, British HIV Association, HIV Medicine 2013, supl. 3 25-28.*
- xxxvi. *Tavs Quist et All., High Linkage to Care in a Community-Based Rapid HIV Testing and Counseling Project Among Men Who Have Sex With Men in Copenhagen, Sexually Transmitted Diseases & Volume 41, Number 3, March 2014.*
- xxxvii. *A.D.Castel et All, Comparing Cost-Effectiveness of HIV Testing Strategies: Targeted and Routine Testing in Washington, DC, PLOS ONE | DOI:10.1371/journal.pone.0139605 October 14, 2015.*

#### **Acts and publications of Public Bodies**

- i. *CDC, Rapid HIV tests suitable for use in non-clinical settings (CLIA-waived), updates 11/07/2016*
- ii. *CDC. Monitoring selected national HIV prevention and care objectives by using HIV surveillance data—United States and 6 U.S. dependent areas—2011. HIV Surveillance Supplemental Report 2013;18(No. 5). Published October 2013.*
- iii. *CDC. Estimated HIV incidence in the United States, 2007–2010. HIV Surveillance Supplemental Report 2012;17(No. 4). Published December 2012.*
- iv. *SEREMI, HIV and AIDS in Piedmont. Update 2014 (ed. 2015), November 2015.*
- v. *REGIONAL PLAN FOR PREVENTION 2014-2018. Approval of prevention programmes for the period 2015-2018 "; Piedmont Region.*
- vi. *Consent Document on offer policies and test execution's modes of the HIV Test in Italy "; Ministry of Health, National AIDS Commission, year 2011.*
- vii. *Ministry of Health, IRCCS Spallanzani of Rome, rapid test Offer in unconventional contexts, November 30, 2015.*
- viii. *WHO, Consolidated guidelines on HIV testing services, July 2015.*
- ix. *ECDC GUIDANCE. HIV testing: increasing uptake and effectiveness in the European Union. December 2010*
- x. *ECDC Guidance: Prevention and control of infectious diseases among people who inject drugs (2011)*
- xi. *ECDC TECHNICAL REPORT Assessing the burden of key infectious diseases affecting migrant populations in the EU/EEA. May 2014.*
- xii. *HIV/AIDS Epi Update — Chapter 13: HIV/AIDS in Canada among people from countries where HIV is endemic Centre for Communicable Diseases and Infection Control Public Health Agency of Canada <http://www.phac-aspc.gc.ca/aids-sida/publication/epi/2010/chap13-eng.php>*
- xiii. *HIV Indicator Conditions: Guidance for Implementing HIV Testing in Adults in Health Care Settings. October 2012. [https://issuu.com/kandrup/docs/chip\\_guidance?e=4233206/1998749](https://issuu.com/kandrup/docs/chip_guidance?e=4233206/1998749)*
- xiv. *HIV testing in Europe. Monitoring implementation of the Dublin Declaration on partnership to fight HIV/AIDS in Europe and Central Asia. Progress report. February 2004.*
- xv. *POLICY BRIEF: WHO RECOMMENDS HIV TESTING BY LAY PROVIDERS, World Health Organization, July 2015*
- xvi. *SEREMI HIV TEST OFFER POLICIES IN PIEDMONT 2016", developed by the Piedmonte Health Department, year 2016.*

#### **Books**

- i. *Management of Health and Territorial Services, efficiency and social valorisation, Publiedit Editions, 2017 ISBN: 978-88-95425-09-2*

#### **Legislation**

- i. *HIV Test Offer in Piedmont, Piedmont Regional Health Direction, prot. 24314A1409A of November 30, 2016.*
- ii. *Consent to HIV test by the child. Annex DD 564 of October 1, 2009 Piedmont Region.*
- iii. *DGR 25 - 4082 of July 2, 2012. Transposition of the Agreement approved by the State-Regions Conference on "Consent Document on offer policies and test execution's modes of the HIV Test" Piedmont Region.*
- iv. *Consent Document on offer policies and test execution's modes of the HIV Test. Ministry of Health (GU General Series n.191 of 18-8-2011) Piedmont Region.*
- v. *DECISION OF THE PRESIDENT OF THE COUNCIL OF MINISTERS of January 12, 2017; President of the Council of Ministers: Gentiloni Silveri, Minister of Health: Lorenzin, Minister of Economy and Finance: Padoan; January 12, 2017.*