PROPOSALS FOR AN INTEGRATED APPROACH TO HEALTH IN PEOPLE LIVING WITH HIV: 'HIV OUTCOMES ITALY'

December 2021

Summary

Premise

This document, result of a project to raise awareness, was created with the intention of representing to Italian institutions the state of the art of HIV care and the quality of life of HIV patients related to the recommendations recognized at European level elaborated by the European HIV Outcomes initiative.

HIV Outcomes is a multistakeholder[1] reality, represented by patient associations, clinicians, academics, public institutions and the pharmaceutical sector. The initiative, with the aim of improving the right global response to HIV, wants to highlight the relevance of the long-term health of people living with a HIV, in the view of the health systems sustainability[2].

The dossier, aimed at sharing information on critical issues and "best practices", represents only a first step towards the active involvement of institutional representatives to reflect, in terms of strategic and innovative opportunities, on how to better formalize proposals of change to integrate the health and social assistance components in the complex context of care and treatment of people living with HIV.

HIV Outcomes recommendations and the state of the art in Italy

In 2017 HIV Outcomes, drafted five recommendations to set the guidelines to achieve the objectives of the initiative and shared with the European Parliament, below:

1. Adopt an integrated approach based on long-term and patient-centered "outcomes".
2. Expand national monitoring of long-term care of people with HIV and outcomes.
3. Fund cohort studies to provide information on the long-term health of people living with HIV.
4. Contrast stigmas and discriminations in the health care system.
5. Increase and optimize community involvement in setting national priorities.

Through the objectives of involvement, awareness and communication towards institutions and political decision-makers, the Italian members of HIV Outcomes, supported by The Bridge Foundation, decided to activate a planning process of active debate among clinicians and communities to better understand the state of the art of HIV care in our health system in relation to the five recommendations.

A parallelism not to be forgotten

Before analyzing the results of the discussion among clinicians and the community, here it is important to highlight how, in many respects, the five recommendations made by the HIV Outcomes are going to be reflected at a regulatory level by the clear indications provided by our National AIDS Plan 2017-2019 (PNAIDS) which has never been fully activated by the individual regions. The Plan, even though it is expired, still deserves attention for its structural quality and the objectives listed there, being a document linking clinical, social and health considerations, with communication strategies.

The parallelism between the provisions of the PNAIDS and the considerations set out below as a development of the individual recommendations, could be an effective stimulus for the political decision makers to contribute to improving the quality of life of people living with HIV.

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[1] HIV Outcomes components list, in annex 1

[2] This objective can be achieved through different tools, e.g. activating "call to actions" at an EU parliament level, sharing best practices, emphasizing the relevance of therapeutic innovation and helping to implement health policies and clinical pathways that are linked to patients' needs.

1. TO ADOPT AN INTEGRATED APPROACH BASED ON LONG-TERM AND PATIENT-CENTERED OUTCOMES

The regionalization of the National Health Service and the qualitative disparity of services

Following the introduction of the Legislative Decree no. 502/1992, our Country started the process of regionalization of health care system, a process which, over the years - peaking with the reform of Title V of the Constitution - has entailed the need to maintain a difficult balance between the needs of universalism and equity dictated by our Health system and the intrinsic territorial diversities. The Constitutional Law n. 3/2001 made health care a matter of concurrent legislation between the State and the Regions: if the former determines the Essential Levels of Assistance (LEA), the latter have exclusive competence in the regulation and organization of health services and in the financing of Health Authorities (ASL).

If, in the intentions of the legislator, regionalization was designed to avert the fear that the centralization of the National Health Service could lead to a leveling of the quality of services downwards, the collateral result was that of constituting an uneven offer, with the coexistence of Regions of excellence, capable of extending the offer beyond the LEA, and of Regions, on the contrary, in serious economic difficulties, often subjected to external administrations. Qualitative disparity of the regional offer leads many people to move and opt for seeking healthcare services in different regions, regardless of distance.

Checkpoints and peer services[3]

In regards to HIV, based on the above mentioned disparity of services offered by the Regions, a role of primary relevance has been taken by the efforts of patient associations, able to decentralize some hospital functions, both in their own offices and in specialized structures such as Check Points[4], currently active only in very few Italian cities; among the services provided by the Check Points – as well as by other associations - there are rapid tests (i.e. for syphilis, HIV and hepatitis C), counseling, information exchange and provision of pre-exposure prophylaxis (PrEP), currently not recognized among the essential services offered by the National health care system.

These realities, as underlined, are still very limited in number and tend to be not always recognized and capitalized as fundamental resources by local institutions. Most of these associative realities are definitely confronted with a hospital-centred organization of HIV care, filling in, as far as possible and within the limits of their economic and staff capacity, those “gaps of proximity” which, regardless of urban realities, are typical of half of the Italian territory, made up of 53% internal, intermediate and ultra-peripheral areas.

Telemedicine

A further element to consider when talking about the long-term management of HIV is telemedicine which has become, thanks to the COVID-19 pandemic, a topic able to arouse enthusiasm in those who see it as a solution to the longstanding problem of distance from specialist services, which characterizes many Italian municipalities. However, it is necessary to carefully consider everything related to telemedicine, since, beyond the use of video-conferencing platforms, the core of the system still remains the possibility of data sharing between different points of the territorial network.

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[3] Peer support can be defined as an emotional and practical support mutually offered by people with a disease or disability to others in the same conditions.

[4] The Community Check Points are Centers managed by the Associations, in collaboration with the Municipalities and with the territorial Health Structures, dedicated to the prevention of HIV and other sexually transmitted infections.

Data and privacy

Related to the topic of data sharing and accessibility, the issue of privacy emerges, subject to a double code of interpretation: on the one hand the purely technical-legal one and on the other that of the public opinion, which do not always coincide. In particular it seems that at the level of common sense the issue of privacy coincides with the fear of violating information that could in fact be subject to social prejudice. This can affect both doctors, who in many cases avoid sharing information from department to department, thus adopting data collection systems unable to communicate with each other, but it can also affect patients, for whom the privacy overlaps with the desire to escape any kind of control by the State.

In concrete terms, this actually makes it impossible to effectively share information tranquilly, to be able to send it through official channels and allow it to be shared between clinicians and patients.

2. EXPAND NATIONAL MONITORING OF LONG-TERM CARE OF PEOPLE WITH HIV AND OUTCOMES

Regionalization and disparity of approaches

A first obstacle linked to a national monitoring of the long-term care of people with HIV is related to the meaning of the term “National” which refers to the need for a homogeneity of indicators, currently fragmented. Also in this case, in fact, in the framework designed by the LEA, Regions range from peaks of excellence to serious lacks; numerous frictions between different levels of “governance” shatter a systematic organization centered on the patient's needs.

New indicators for HIV aging population

While on the one hand we can consider the aging of the HIV population an undoubted success index of the Italian strategy on retention in care and viral suppression, on the other it is necessary to highlight the new priorities and emerging issues of people living longer lives and ageing with HIV. A life that, however, is often accompanied by comorbidities, which requires life-long treatment adherence and which, still today, suffers from very strong stigmatization.

A monitoring system that takes into account the aforementioned needs could be an excellent tool to improve care management, capturing those organizational junctions in which processes are blocked or duplicated, generating inefficiencies. In any case, it is necessary to estabilish from the beginning who is accountable for monitoring and controlling activities, choosing between a centralized approach (within the Ministry of Health or the National Health Institute, for example) or peripheral (Regions or Local health Authority -ASL-).

The role of scientific societies

Scientific societies, whose typically technical nature could guarantee the neutrality of the positions taken, can act as a stimulus in outlining the technical elements to define optimal long-term care management and the indicators to activate their monitoring.

Scientific Societies may interact with national institutions thus guaranteeing a spillover at the local level, being themselves organizations articulated in regional components. The discussion should take place at two levels: the first one related to the monitoring and reporting the actual services provided at the regional level, the second with the aim of boosting the quality of the services provided.

3. FUNDING COHORT STUDIES[5] TO PROVIDE LONG-TERM HEALTH INFORMATION ON PEOPLE WITH HIV

Among the largest Italian cohorts, the ICONA[6] cohort is the most internationally recognized thanks to its broadness and to the stratification by gender and territory reflecting data from the ISS[7] (National Health Institute) AIDS Operations Center (CoA). In addition to these large realities, it would be advisable to consider the possibility of carrying out studies and in-depth analysis at the local level, in individual clinical centers.

Italian cohorts are established and work thanks to European funding, and this protects their neutrality since any sponsorship from pharmaceutical companies only concerns the organization of events such as conferences, seminars or webinars. What needs to be highlighted is is the total absence or limited presence of a governmental (national) commitment to support research.

The lack of institutional interest is also shown in relation to the absence of a national strategy related to the circulation and processing of data collected from the studies or the possibility of adopting an integrated medical record for the enrolled patients.

The role of patient associations

From the comparison with clinicians and "community" representatives, came out the added value that patient associations could bring to research activities. It could be interesting to include in the cohorts a group of community members to participate in studies on various aspects of the quality of life, allowing the community to actively participate in the construction of specific indicators to detect the needs of patients.

4. COMBAT STIGMA AND DISCRIMINATION WITHIN HEALTH SYSTEMS

Missing or outdated knowledge

Discrimination can be defined *as a behavior that creates a fundamental prejudice against a minority or dominated group, or a behavior that harms the members of a minority or dominated social category by the mere fact of belonging to that category*[8]. As per HIV, if in the past in the clinical environment discrimination was widespread, systematic and obvious, today it exhibits through the absence of a widespread knowledge of some fundamental information for the management of patients, such as the notion of U = U (Undetectable = Untransmittable)[9].

Infectious disease clinicians and patient associations have clearly denounced the lack of awareness of internationally recognized axioms such as U = U by non-specialized doctors. To be noted is the inadequacy of university training and specialization courses that are not taking into consideration cross sectoral topics such as HIV.

Stigma and discrimination, however, are even stronger outside the health sector or, at least, outside the infectious disease centers, and this factor may refer to some concrete evidence:

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[5] By cohort study we mean an observational study that follows a group of patients (a cohort) for a very long period of time. Cohorts are made up of individuals who are selected on the basis of specific shared characteristics.

[6] "The ICONA study started in 1997 as an observational study on a large cohort of HIV-positive people. It is a study that has several elements of originality in it. Currently, ICONA's clinical records are made up of over 18,800 HIV-positive people. The only inclusion criterion is represented by having never taken antiretroviral drugs. Icon was designed as a national cohort of 'naive' subjects for antiretroviral therapy. " https://www.fondazioneicona.org/_new2/pages/publicArea/laCoorteICONA/

[7] The AIDS Operations Center (CoA) of the National Health Institute (ISS) since 1984 has been collecting data relating to AIDS notifications and since 2008, data on new diagnoses of HIV infection which since 2012 have been nationally covered.

[8] As defined in the glossary drawn up by the Human Rights Council of the Lombardy Order of Psychologists

[9] The acronym U = U stands for Undetectable = Untransmittable and indicates the clinical condition of those people who, under antiretroviral therapy, reached and durably kept, for at least six months, a non detectable viral load, making the risk of sexual transmission of HIV infection to their HIV-negative partner virtually nil.

- The absence of a political awareness movement on HIV shared by all key opinion leaders
- The difficulty of recruiting staff by patient organizations.
- The state of complete isolation in which many HIV-positive people find themselves, especially - but not only - within peripheral areas, far from metropolitan areas.

Proximity and needs

The search for proximity consists, on the one hand, in bringing the answers to needs physically closer to the place where they are expressed and, on the other, in making the relationship of listening, assistance and care of people living with HIV more and more horizontal, through a peer-oriented[10] approach. This approach is even more important for the so-called key population[11] who, often held back from seeking services for fear of a double stigma, are more subject to the risk of late diagnosis; moreover many PLWH do not belong to any specific category and this, may create further marginalization due to the absence of a reference community group[12].

There is therefore a need for a pluralistic type of associationism, which, while not losing its specific characteristics, matures an even greater ability to network its requests, in favor of a compact ecosystem of associations and informal groups.

5. INCREASE AND OPTIMIZE COMMUNITY INVOLVEMENT IN DEFINING PRIORITIES AT NATIONAL LEVEL

The need for a more institutional role

In relation to HIV, there are several international interventions sustaining the meaningful involvement of community representatives in defining the priorities of individual States, starting with what World Health Organization published in 2008[13]. In Italy there are some good practices, such as the annual ICAR convention (Italian Conference on AIDS and Antiviral Research), which has an active participation of the community within the organizational board, and the process of drafting the National 2017-2019 AIDS Plan, which integrates the point of view of associations with that of the clinical community.

However, in the institutional context, the difference in the perception of roles between community representatives and clinicians is still strong. For instance, the Technical Health Committee on HIV at the Ministry of Health, merged in 2 different sections[14] the functions of the National Commission fight against AIDS (CNA) and the Council of associations for the fight against AIDS; the reorganization has indeed brought the two entities closer to the Ministry of Health, yet without changing in their original tasks, it prevented them from acting in greater collaboration.

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[10] Refer to Note 2

[11] Also referred at as “target populations”, this term usually includes migrants, sex workers, the transgender population, people who use injectable drugs, men who have sex with other men and prisoners.

[12] Some patient associations, targeting specifically MSM population (Acronym for men having sex with other men), reached an excellent capacity of “minority influence” leveraging the peer approach, while other groups such as the female population are very underrepresented both at a political and social level.

[13] WHO, Operations Manual for Delivery of HIV Prevention, Care and Treatment at Primary Health Centres in High-Prevalence, Resource-Constrained Settings, 2008.

[14] Section L deals with monitoring the provision of assistance on the national territory, collects the needs and requests of people with HIV, coordinates the measures to contain the spread of the virus and defines priorities at the training and communication level; Section M deals with expressing opinions and formulating proposals, on the following topics: information-education, psycho-social, ethical, support and prevention.

The two souls of the community

At present, associations are having an informal role on whatever can be considered residual versus the role of hospitals and health authorities, i.e. prevention, psychological and social support, contact with the public opinion.

Despite that, the mandate that associations are giving themselves is much broader and, by comparing their founding statutes, their field of action is segmented into four main areas:

- political action, advocacy activities and monitoring of the quality of the services provided by the health and social system;
- cultural change, pursued through information and awareness-raising activities aimed at the general population or specific targets;
- professional activities, such as support and training services;
- charity, financing activities and projects both nationally and internationally.

The coexistence of political activities and the provision of services is a source of ambivalence for the entire Third Sector: creating integrated networks with local authorities, managing complex stakeholder platforms, building collaboration paths, is tough when it is not clear the role of the parties and when there is the risk of political manipulations.

A possible evolution of the current identity impasse may be a renewed declaration of intents making clear the main mandate that each association is choosing either political action or provision of services. However, such a strong dichotomy may result in a loss in terms of knowledge, since through the services provided associations can pinpoint people's priorities, their needs, and still unmet rights.

So, a valid alternative could be to clearly distinguish, within the same reality, the more politically oriented component from the one more oriented to providing services, thus maintaining the two souls and guaranteeing a circular relationship: the requests and asks instances gathered through the contact with public become demands brought to the political and institutional tables.

Raising funds: a constant issue

One of the most relevant problems for the associations operating in the HIV field is the raising of funds raising, coming from national tenders, either from local authorities or pharmaceutical companies. In the first scenario, the scarcity of the tenders and the amount of bureaucratic work required for participating in those is an issue; in the second scenario, local authorities may not be interested in financing HIV related projects. On the other hand, pharmaceutical companies promote projects that do not always correspond to local needs and which naturally tend to respond to their profit needs.

The power to concretely interact

Within the discussion with both clinicians and patient associations, the former perceive a stronger interaction with institutions, even though not always corresponding to an effective and systematic reception by the political decision-makers of the scientific indications provided, the community suffers from fewer opportunities to influence.

Against this, both entities could benefit from strategic alliances, to be established before attending any “political table”, to establish a single, coherent and compact front on relevant issues such as long-term management, management of therapies and the improvement of the quality of life of people living with HIV.

Obviously, the quality of participation, where it has official recognition by the institutions, must also correspond to an authentic sharing of decision-making powers. There have been several cases of regional or municipal tables that resulted in sporadic experiences of meeting between institutions and communities, unsatisfactory in their ability to influence decision-making processes. Influencing the decision making process is perceived as a concern by both clinicians and community organizations, noting that the technical-scientific opinion is not always decisive in political choices. Therefore, an effective change of pace is needed regarding the quality of democratic processes.

Attachments

Annex 1. Components of HIV Outcomes

HIV Outcomes Steering Group

- **Sini Pasanen |** AIDS Action Europe
- **Anke van Dam |** AFEW International
- **Vladimir Zhovtyak |** East Europe & Central Asia Union of PLWH (ECUO)
- **Mario Cascio |** European AIDS Treatment Group (EATG)
- **Jane Anderson *(Steering Group Co-Chair)* |** Homerton University Hospital NHS Foundation Trust, London
- **Nikos Dedes |** Positive Voice (*Greek association for PLHIV*)
- **Jeffrey Lazarus *(Steering Group Co-Chair)* |** ISGlobal, Hospital Clinic, University of Barcelona Richard Stranz - Coalition PLUS
- **Georg Behrens |** Hannover Medical School
- **Antonella d'Arminio Monforte |** University of Milan
- **Industry: Claire Albano |** Gilead Sciences and Rhon Reynolds | ViiV Healthcare

HIV Outcomes General Members

- **Adhara Asociación VIH/SIDA (ADHARA):** represented by Diego García and Alejandro Bertó Morán
- **Children's HIV Association (CHIVA):** represented by Amanda Ely and Amanda Williams
- **Correlation – European Harm Reduction Network [C-EHRN]:** represented by Roberto Pérez-Gayo
- **Dr Casper Rokx,** Erasmus MC
- **Dr Diana Barger,** University of Bordeaux
- **Dr Patrizia Carrieri,** French Institute of Health and Medical Research (INSERM)
- **GAMIAN-Europe:** represented by Nigel Olisa
- **Grupo de Ativistas em Tratamentos (GAT Portugal):** represented by Luis Mendão
- **Igor Gordon,** Eurasian Harm Reduction Association
- **Kelly Safreed Harmon,** ISGlobal
- **Maryan Said**
- **National AIDS Trust (NAT):** represented by Deborah Gold
- **National HIV Nurses Association (NHIVNA):** represented by Shaun Watson
- **Prof Alan Winston–Okeefe,** Imperial College London
- **Prof Anna Mia Ekström,** Karolinska Instituet
- **Prof Caroline Sabin,** University College London
- **Prof Giovanni Guaraldi,** University of Modena and Reggio Emilia (UNIMORE)

- **Prof Kyriakos Souliotis,** University of Peloponnese & Health Policy Institute
- **Prof Lars E Eriksson,** Karolinska Instituet
- **Prof Richard Harding,** King's College London
- **Sociedad Española Interdisciplinaria del SIDA (SEISIDA):** represented by Dr. María José Fuster-Ruíz de Apodaca
- **Supporting Women with HIV Information Network (SWIFT Network):** represented by Yvonne Gilleece
- **SKUK-Magnus:** represented by Miran Solinc
- **Terrence Higgins Trust (THT):** represented by Richard Angell

HIV Outcomes Observer Members

- **European Centre for Disease Prevention and Control (ECDC)**
- **Joint United Nations Programme on HIV/AIDS (UNAIDS)**
- **European AIDS Clinical Society (EACS)**
- **Fast Track Cities Europe**
- **UNITE Global Parliamentarians Network (UNITE)**

HIV Outcomes President

- **John Bowis**

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