

**European AIDS Clinical Society (EACS) Standard of Care Meeting on HIV and related co-infections: The Rome Statements**

European AIDS Clinical Society\*

*Running head: the Rome statements on HIV and coinfections*

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## **Abstract**

### Objective:

The objective of the 1<sup>st</sup> European AIDS Clinical Society (EACS) meeting on Standard of Care in Europe was to raise awareness about the European scenario and come to an agreement on actions that could be taken in the future.

### Methods:

Data driven presentations on specific topics followed by interactive panel discussions

### Results:

In Eastern European countries, the epidemic is largely driven by injecting drug use, in contrast with Western Europe where the infection mainly occurs through heterosexual contact. A high proportion of people living with HIV remain unaware of their infection. Substantial differences exist in Eastern Europe and Central Asia with respect to treatment coverage, regimen availability and continuity of drug supply. In 2012, tuberculosis case notification rates were five to ten times higher in Eastern Europe compared to Western Europe, with an alarming proportion of newly diagnosed multi-drug resistant cases. Hepatitis C is widespread among selected geographic areas and risk groups.

### Conclusions:

Key conclusions from the meeting were: a high priority group of actions, such as to increase HIV awareness and testing, to improve training for health care providers, to ensure equitable patient access to treatments and diagnostics for HIV and co-morbidities, to implement best practices in infection control and treatment of TB and HIV/HCV co-infected patients, should be considered for direct acting antivirals (DAA) treatment.

Key words: HIV, co-infections, access to care, treatment

## **Introduction**

The 1<sup>st</sup> European AIDS Clinical Society (EACS) meeting on Standard of Care in Europe was held in Rome during the Italian semester of the EU presidency. A number of renowned lecturers were asked to present cutting edge data on a range of important issues including epidemiology, patient access to treatments, standard of care and public health. Panellists interactively discussed the data presented, took up important remarks from the audience and addressed key points for each topic. Despite the lower participation of representatives from Eastern Europe, panellists from this region particularly felt that this 1<sup>st</sup> Meeting should trigger further regional activities on patient access and standard of care

## **Epidemiology and late presentation in the European region**

*Khouloud Porter (UCL, London,UK) and Amanda Mocroft (UCL, London, UK) illustrated European epidemiology.*

ECDC estimates that 2.4 million people are living with HIV in the WHO European area, the majority (1.5 million) being in eastern Europe (including central Asia) (1), which is the only region in the world with rising HIV incidence (1). Since the introduction of the combination antiretroviral therapy (cART) in the mid-1990s, the increase in average lifespan of HIV positive subjects resulted in a higher prevalence of HIV infection. However, HIV prevalence has steadily increased in the western region (including central Europe), whilst it has steeply increased in the Eastern countries. At present, prevalence rates differ significantly between the two regions, being 0.8% in the East and 0.2% in the West (1).

In the East, the epidemic is largely driven by injecting drug use, in contrast with the West where the infection mainly occurs through heterosexual contact. For instance, out of 90,190 new cases diagnosed in East Europe in 2010, 43% occurred in people who inject drugs, as compared to 4% of 28,137 new diagnoses in West Europe (2).

In 2004, the Dublin Declaration (3) stated an ambition of halting and reversing the increasing trend in HIV diagnosis in the European region; although, HIV diagnosis rates rose by 80% across the European region between 2004 and 2013. Up to 76 % of all newly HIV diagnosed cases in 2010 occurred in Eastern Europe, with 90% being in Russia and Ukraine (2).

Approximately half of total patients are diagnosed late according to the consensus definition in 2010 (4). Late diagnosis remains a key problem in Eastern Europe and Central Asia, and is also a critical issue for migrant populations. Particularly, undocumented migrants are at disadvantage: they do not have access to antiretroviral therapy in 12 EU states, mainly in Central Europe (5).

## **HIV testing**

*Amanda Mocroft, (UCL, London, UK) , Deniz Gökengin, (Ege University, Izmir, Turkey), Nikos Dedes, (EATG, Greece), Tamás Bereczky, (EATG, Hungary) discussed on HIV testing.*

The lack of further improvements in late presentation in Europe suggests that improving the coverage of voluntary counselling and testing will not produce substantial effects. A number of settings offer opportunities to target HIV testing to those at highest risk of exposure, including genitourinary medicine clinics, TB clinics, drug dependence clinics and antenatal care. Indicator-condition guided HIV testing also may help to identify undiagnosed individuals at high risk (6).

A high proportion of people living with HIV remain unaware of their infection, and the rates of undiagnosed cases range from 20% in Denmark, Sweden and Slovakia, and 30% in the United Kingdom, France and Germany, to as high as 50% in Poland and Latvia. Heterosexual men, older people, migrants and people living in areas with low HIV prevalence are more likely to remain undiagnosed (1).

Barriers to HIV testing may relate to patient, provider or structural issues. Knowing the different role of these barriers in the different scenarios is crucial to implement strategies for HIV testing (Table 1).

### **Key conclusions**

- A. The following key actions should be taken:
- To increase HIV awareness and testing:
  - To increase training for healthcare providers in order to improve their attitude towards HIV and confidence in conducting a test.
  - To intensify research for the development of successful models for community HIV testing.
  - To make every collaborative effort to reduce stigma around HIV testing and diagnosis aiming for 'normalization' of HIV- testing as a universal testing strategy.
  - To achieve consensus that verbal informed consent is acceptable.
  - To obtain brief post-test information from those testing negative
- B. To ensure patient access to care and follow up after HIV diagnosis, e.g. ensuring pathways to book appointments following test results, active follow-up of non-attenders, choice of providers and periodic evaluation of retention in care
- C. Five priorities identified by ECDC to reverse the increasing trend of HIV diagnosis (7, 8).

First: undertake appropriate targeted preventive measures for the key populations – men who have sex with men, people who inject drugs, migrants, prisoners and sex workers.

Second: increase coverage and frequency of HIV testing to reduce late diagnosis. Testing should be community-based and governments should look for innovative methods of expanding the uptake of testing, as well as targeting key populations.

Third: scale up antiretroviral treatment coverage in Eastern Europe and make antiretroviral therapies and care available to undocumented migrants. National programmes need to improve diagnosis rates and viral suppression in order to achieve the full impact of preventive treatment.

Fourth: promote large-scale financing, especially for civil society delivery of key prevention and harm reduction services.

Fifth: exert a strong political leadership, both at national and European level, in order to mobilise funding and change attitudes towards HIV.

### **Improving access to antiretroviral therapy**

*Martina Brostrom, UNAIDS, Geneva; Cristiana Oprea, Victor Babes Hospital, Bucharest, Romania; Andrea Antinori, Italy; Andrzej Horban, Warsaw, Poland; Teresa Branco, Portugal.*

Combined antiretroviral therapy (cART) coverage is encouraging in many low income countries - even in Africa (9); however, according to UNAIDS, treatment coverage has been estimated at 21% in Eastern Europe and Central Asia.

A survey on treatment access has been carried out on behalf of EACS by Cristiana Oprea and Deniz Gökingen in Eastern Europe and Central Asia, and substantial differences were observed within regional income bands in respect of treatment coverage, regimen availability and continuity of drug supply.

#### *Lower middle-income countries*

With the exception of Ukraine, these countries have low HIV prevalence and, in most cases, are highly reliant on support from international funds to provide cART. HIV epidemics appear to be concentrated in people who inject drugs (PWID) and heterosexuals. cART coverage is lower than 20%, and treatment is provided by infectious disease specialists. Preferred antiretroviral regimens are administered according to EACS or WHO guidelines, but single-dose combinations and newer antiretrovirals remain unavailable. Stock-outs of antiretroviral drugs have occurred in the past two years in most countries.

#### *Upper middle income countries (including Central and South-Eastern Europe)*

HIV prevalence is very low in these countries (<0.1%). Higher rates of HIV transmission were reported among PWID in Azerbaijan, Kazakhstan and Romania, and MSM in Serbia, Bulgaria and Hungary. cART initiation is recommended at 350 CD4 cells/mm<sup>3</sup>, although Hungary and Romania have moved to ART initiation at 500 CD4 cells/mm<sup>3</sup>. cART coverage ranges between 30%, 45% and 69% in Kazakhstan, Belarus and Romania, respectively. Preferred cART regimens reflect EACS guidelines. Newer agents and single-dose combinations are unavailable in most countries. Stock-outs have been reported in the past two years in Albania, Macedonia, Serbia and Romania.

#### *High-income countries (Russia & Central Europe)*

HIV prevalence is low with the exception of the Russian Federation (1%). HIV prevalence is high among PWID in Russia and Poland, and among MSM in Croatia, Czech Republic and Slovakia. cART initiation is recommended at 500 CD4 cell/mm<sup>3</sup> - save Russia, where treatment is started at 200 CD4 cells/mm<sup>3</sup>. cART coverage is equivalent to Western European levels (>60%) in all countries except Russia (20% - 34%). Preferred cART regimens are administered according to EACS guidelines (information unavailable for Russia). Newer agents and single dose combinations are available and preferred for first-line treatments in most countries. Only Russia has reported ART stock-outs in the past two years.

#### *Antiretroviral treatment in Western Europe*

In many European settings, cART prescribers face growing budgetary pressures to limit overall expenditure on cART and to consider the costs of individual agents. The introduction of generic antiretrovirals upon the expiry of patents between 2014 and 2018 is likely to force further consideration of prescribing costs.

#### *Migrants*

Forty per cent of HIV infections in the EU/EEA were diagnosed in migrants between 2007 and 2011. A survey by ECDC found that undocumented migrants are entitled only to emergency medical care in 20 E/EEA countries (10). Some countries do not collect surveillance data on country of origin of migrants and there has been little epidemiological analysis to determine whether migrants have been exposed to HIV in their country of origin or in destination countries.

#### **Key conclusions**

- The high cost of treatment, medicines and diagnostics for HIV and co-morbidities represents a significant barrier for full benefits of HIV treatment to prevent HIV-related illness, avert AIDS-related deaths and prevent new HIV infections.
- Governments and the EU should develop appropriate procedures aimed at providing equitable and affordable access to effective medicines and diagnostics for HIV and co-morbidities, ensuring sustainable national healthcare systems.
- This could be done by implementing cooperative strategies to effectively manage pharmaceutical expenditure, including issues related to affordable pricing through a unitary negotiation across Europe and the use of generic medicines. ~~compulsory licensing, medical across Europe devices, and small markets.~~

### **Improving retention and quality of care in particular in Eastern Europe**

*Cristina Mussini, University of Modena, Italy; Jens D. Lundgren, University of Copenhagen, Denmark.*

Comparative analysis of care and treatment cascades in the European region shows a variety of weaknesses in health system performance (Table 2).

Very high rates of viral suppression are being achieved in patients diagnosed and retained in care in Western Europe. Language and cultural barriers, as well as the burdens of economic recession, make it more likely that migrants will be lost to follow up or forced to move to seek work. Migrants represented 40% of HIV diagnoses in the European Union between 2007 and 2011, 92% of these in Western Europe. (10)

In Eastern Europe, the lack of HIV awareness and treatment, highly restrictive eligibility criteria and limited availability of treatments lead to very low rates of viral suppression. Antiretroviral coverage remains extremely low; only 35% of people eligible for treatment were receiving ART in 2012 -one of the lowest rate in the world.

Improving the quality of HIV care in Eastern Europe could avert at least 80,000 deaths a year. Close attention should be paid to the essential elements of care. Screening and management of lifestyle-related comorbidities and organ dysfunction is also desirable.

People who inject drugs need models of care which can address all their health needs at one site rather than to navigate multiple vertical services providing treatment for drug addiction, HIV, general medical care and TB.

Opioid substitution therapy (OST) is an crucial element of care for people who inject drugs. The proportion of people who inject drugs receiving OST is extremely low in Eastern Europe (<5% in Russia, Belarus, Ukraine) compared to Western Europe (50-60% in United Kingdom, Netherlands, Italy).

### **Key conclusions**

- Greater engagement with health care professionals in the region through invitations, support to international meetings and training courses will facilitate discussions with peers on best practices. Moreover, in order to limit expensive traveling, a program of e-learning run by EACS is in preparation.
- Political dialogue will be essential in order to ensure political leadership in Eastern Europe. G8-level Health Minister support, and dialogue between multilateral agencies and Health Ministries, will need to continue.

- In lower prevalence countries, EACS plays an important role in raising standards through training, research networks and in-country visits, and by advocating good practice also in harm-reduction policies through engagement with Health Ministries, who may be unaware of recent guidance.

## **Coinfections**

### ***HIV and tuberculosis***

*Enrico Girardi, National Institute for Infectious Disease L Spallanzani, Rome, Italy; Daria Podlekareva, Rigshospitalet, University of Copenhagen, Denmark.*

Tuberculosis (TB) case notification rates were five to ten times higher in Eastern compared to Western Europe in 2012 [11] and an alarming proportion of newly diagnosed cases are multi-drug resistant (MDR) (32-35% in Belarus in 2010-2012; 14.4% in Russia in 2010) [12-13]. TB incidence among people living with HIV (PLHIV) in Russia is one of the highest in the world, with an incidence rate of 1,600 cases per 100,000 inhabitants.

40% of subjects undergoing drug susceptibility testing (DST) in Eastern Europe had MDR-TB versus <5% in Western Europe, a low proportion of patients undergoing DST received a combination treatment with at least 3 active drugs, as per WHO recommendation [14-16]. Similarly, mortality among TB/HIV population was substantially higher in Eastern Europe than in the rest of Europe (33% vs 8-14% at 12 months). The increased risk of death was strongly associated with multi-drug resistance and disseminated disease [17, 18].

Regional variations in TB management and healthcare delivery, namely decentralised HIV and TB care, lack of anti-TB drugs, ARVs and susceptibility testing, as well as increased risk of nosocomial transmission during long-term hospitalisations, are likely to contribute to these poor outcomes.

### **Key conclusions**

- Integration of HIV and TB services, patient-oriented health care, social support and retention of patients in care
- Consistent implementation of best practice in TB and HIV infection control, and intensified case finding among key populations
- Availability of rapid TB diagnostic tests and DSTs
- Adequate adjustments of empiric TB treatment and subsequent treatments guided by DST results
- Unlimited availability of all TB drugs
- Appropriate treatment of HIV infection and unlimited cART coverage
- Improved TB and HIV surveillance and political will

### ***Hepatitis C & HIV coinfection***

*Antonella d'Arminio Monforte, University of Milan, Italy; Karine Lacombe, Hôpital St Antoine, Paris; Sanjay Bhagani, Royal Free Hospital, London, UK.*

HCV antibody prevalence among PLHIV is highest in Eastern Europe (57%), Central Europe (34%) and Southern Europe (29%) and is highly concentrated in urban populations [19]. HCV prevalence among injecting drug users has declined over time but an epidemic of HCV in MSM has emerged

in Western Europe [20-22]. The use of HCV screening in co-infected people remains variable, regardless of EACS guidance recommendations - particularly for MSM [23, 24]. Use of rapid tests for HCV and HIV antibody may improve screening rates [ 25].

Up to now, the proportion of co-infected patients treated for HCV infection remains very low, even if the risk of progression of liver disease is higher than in HIV-negative subjects, if left untreated (<5% per annum in the EuroSIDA cohort) [26, 27]. Fully suppressive antiretroviral therapies reduce the risk of progression in co-infected people; however, co-infected patients with a F4 fibrosis stage remain at high risk of decompensation [28, 29]. HIV/HCV co-infected patients should be considered as a high priority group for direct acting antivirals (DAA) treatment, as recommended in the AASLD 2014 and in EACS guidelines [30, 31]. Main barriers to hepatitis C treatment are listed in Table 3 [32, 33].

Cure rates of >90% have been reported in clinical trials conducted with co-infected patients treated with new interferon-free DAAs regimens [34-37].

Cost represents the most substantial barrier to hepatitis C treatment in all European countries.

European activists have called for an EU-wide strategic action plan to address HCV diagnosis and treatment, and a drug pricing for universal access to treatment. [38].

WHO is developing a global health sector strategy on viral hepatitis and will conduct European consultations during the first quarter of 2015.

### **Key conclusions**

Consensus discussion identified the following priority measures for action on HCV co-infection:

- Suboptimal treatment is unacceptable
- Support from clinical societies is needed
- Guidelines should be updated more frequently to take into account the rapidly evolving knowledge on HCV treatment
- More research is urgently needed to characterize patients at highest risk of liver decompensation and non-hepatic complications.

### **Conclusions**

Several actions need to be implemented in order to provide better clinical care and treatment of HIV and co-infections across Europe.

In particular, all reasonable efforts should be made to increase awareness on HIV testing and to reduce stigma around testing. Importantly, subjects diagnosed with HIV should be assured access to care and periodic evaluation of retention in care should be performed. Key populations, such as people who inject drugs, migrants, prisoners and sex workers deserve special attention for prevention.

Scaling up ART across Europe, particularly Eastern Europe, is crucial and migrants should also be assured both care and ART availability. The costs of ART and treating comorbidities, in particular

HCV and tuberculosis, should be negotiated with pharmaceutical companies both at national and European levels in order to guarantee access to care for every individual living in Europe. In this respect, the use of generic drugs could be taken into consideration once adequate combinations will be widely available.

Table 1: Barriers to HIV testing

Barriers to HIV testing		
Patient	Provider	Structural
<ul style="list-style-type: none"> <li>-</li> <li>- Low risk perception</li> <li>- Lack of awareness of HIV and treatment availability</li> <li>- Fear of HIV infection and its health consequences</li> <li>- Fear of disclosure (worries about stigma, discrimination and rejection by significant others)</li> <li>- Denial</li> <li>- Difficulty in accessing services, especially for migrant populations</li> </ul>	<ul style="list-style-type: none"> <li>○</li> <li>- Patient not perceived to be at risk</li> <li>- Insufficient time</li> <li>- Burdensome consent process</li> <li>- Lack of knowledge/training</li> <li>- Stereotyping – fear of appearing to discriminate</li> <li>- Pre-test counselling requirements</li> <li>- Reimbursement issues or lack of reimbursement incentives</li> <li>- In Eastern Europe also:</li> <li>- Corruption, including payments to health care providers for services</li> <li>- High prevalence of discriminatory attitudes towards key populations, sanctioned by authority</li> </ul>	<ul style="list-style-type: none"> <li>○</li> <li>- Lack of national policies on HIV testing</li> <li>- Lack of services that are friendly to key populations e.g. MSM, drug users, Africans</li> <li>- Regulatory and licensing systems that prevent all health care providers from offering a test</li> <li>- Medical device regulations that prevent the use of point of care tests</li> <li>- Lack of anti-discrimination laws</li> <li>- Criminalisation of people who inject drugs, sex workers and men who have sex with men</li> <li>- In Eastern Europe also:</li> <li>- Weak NGO sector</li> <li>- Lack of political pressure to provide HIV services</li> <li>- Political opposition to key populations at all levels</li> <li>- Widespread non-adherence to international guidance and standards of good practice</li> </ul>

Table 2. Comparative care and treatment cascades in Europe and Central Asia

	Estimated HIV	Diagnosed	Linked to care	Retained in care	On ART	Virally suppressed
France	149,000	81%	n/a	74%	16%	52%
Armenia	3700	44%	n/a	28%	16%	14%
Azerbaijan	9200	47%	n/a	28%	14%	10%
Belarus	24000	50%	n/a	41%	18%	13%
Georgia	4900	52%	44%	38%	26%	20%
Kyrgyzstan	7600	67%	n/a	28%	12%	?
Russia	1,360,000	49%	38%	35%	11.5%	9% (<1000)
Ukraine	237,000	86%	59%	?	?	17%

Table 3. Barriers to hepatitis C treatment

Patient barriers	Provider barriers
<ul style="list-style-type: none"> <li>- Lack of knowledge</li> <li>- Concern regarding treatment side effects and treatment efficacy claims</li> <li>- Socially and economically marginalised populations</li> <li>- Stigma</li> </ul>	<ul style="list-style-type: none"> <li>- Lack of treatment guidelines</li> <li>- Lack of awareness of HIV impact on the progression of HCV liver disease</li> <li>- Poor collaboration between infectious diseases specialists and hepatologists</li> <li>- Perception that co-infected patients are at high risk of non-adherence and re-infection</li> <li>- Concern regarding treatment efficacy and tolerability claims</li> <li>- Concerns about complexity of drug-drug interactions</li> <li>- Cost of treatment</li> </ul>

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Appendix:

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