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ORIGINAL RESEARCH

European AIDS Clinical Society Standard of Care meeting on HIV and related coinfections: The Rome Statements

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Objectives

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

Methods

Data-driven presentations were given 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 5–10 times higher in Eastern Europe compared with Western Europe, with an alarming proportion of newly diagnosed multi-drug-resistant cases. Hepatitis C is widespread in selected geographical areas and risk groups.

Conclusions

The key conclusion from the meeting was that a high-priority group of actions could be identified, including: increasing HIV awareness and testing, improving training for health care providers, ensuring equitable patient access to treatments and diagnostics for HIV and comorbidities, and implementing best practices in infection control and treatment of HIV-infected patients coinfected with tuberculosis and hepatitis C virus, for whom direct acting antiviral treatment. should be considered.

Keywords: access to care, coinfections, HIV, treatment

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Introduction

The 1st 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 first meeting should trigger further regional activities related to patient access and standard of care.

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Epidemiology and late presentation in the European region

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European Centre for Disease Prevention and Control (ECDC) estimates that 2.4 million people are living with HIV in the World Health Organization (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 a rising HIV incidence [1]. Since the introduction of combination antiretroviral therapy (cART) in the mid-1990s, the increase in the average lifespan of HIV-positive subjects has resulted in a higher prevalence of HIV infection. However, the prevalence of HIV infection has steadily increased in the Western region (including Central Europe), while 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 Eastern Europe in 2010, 43% occurred in people who inject drugs, as compared with 4% of 28 137 new diagnoses in Western 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. Seventy-six per cent of all newly diagnosed cases of HIV infection in 2010 occurred in Eastern Europe, with 90% of these being in Russia and Ukraine [2].

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

HIV testing

Amanda Mocroft (University College London, London, UK), Deniz Gökengin (Ege University, Izmir, Turkey) and Nikos Dedes (EATG, Athen Greece) and Tamás Bereczky (EATG, Budapest, Hungary)

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, tuberculosis (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 (PLHIV) remain unaware of their infection, and the rates of undiagnosed cases range from 20% in Denmark, Sweden and Slovakia, and 30% in the UK, 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. Knowledge of the different roles of these barriers in the different scenarios is crucial for implementing strategies for HIV testing (Table 1).

Key conclusions

(A) The following key actions should be taken:

- Increase HIV awareness and testing.
- Improve training for health care providers in order to improve their attitude to those with HIV infection and increase their confidence in conducting a test.
- Intensify research into the development of successful models for community HIV testing.
- Make every collaborative effort to reduce the stigma around HIV testing and diagnosis with the aim of 'normalization' of HIV testing as a universal testing strategy.
- Achieve a consensus that verbal informed consent is acceptable.
- Obtain brief post-test information from those testing negative.

(B) Patient access to care and follow-up after HIV diagnosis should be ensured. For example, there should be pathways for booking appointments following test results, active follow-up of nonattenders, a choice of providers and periodic evaluation of retention in care.

(C) Five priorities were identified by ECDC to reverse the trend of an increasing number of HIV diagnoses [7,8].

(1) Undertake appropriate targeted preventive measures for the key populations – men who have sex with men (MSM), people who inject drugs, migrants, prisoners and sex workers.

(2) Increase the 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.

(3) 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

Table 1 Barriers to HIV testing

Patient	Provider	Structural
• Low risk perception • Lack of awareness of HIV and treatment availability • Fear of HIV infection and its health consequences • Fear of disclosure (worries about stigma, discrimination and rejection by significant others) • Denial • Difficulty in accessing services, especially for migrant populations	• Patient not perceived to be at risk • Insufficient time • Burdensome consent process • Lack of knowledge/training • Stereotyping – fear of appearing to discriminate • Pre-test counselling requirements • Reimbursement issues or lack of reimbursement incentives In Eastern Europe, also: • corruption, including payments to health care providers for services; • high prevalence of discriminatory attitudes towards key populations, sanctioned by authority	• Lack of national policies on HIV testing • Lack of services that are friendly to key populations, e.g. MSM, drug users and Africans • Regulatory and licensing systems that prevent all health care providers from offering a test • Medical device regulations that prevent the use of point-of-care tests • Lack of anti-discrimination laws • Criminalization of people who inject drugs, sex workers and MSM In Eastern Europe, also: • weak NGO sector; • lack of political pressure to provide HIV services; • political opposition to key populations at all levels; • widespread nonadherence to international guidance and standards of good practice

MSM, men who have sex with men; NGO, nongovernmental organization.

viral suppression in order to achieve the full potential impact of preventive treatment.

(4) Promote large-scale financing, especially for civil society delivery of key prevention and harm reduction services.

(5) Exert strong political leadership, both at national and European level, in order to mobilize funding and change attitudes towards HIV infection.

Improving access to antiretroviral therapy

Martina Brostrom (UNAIDS, Geneva, Switzerland), Cristiana Oprea (Victor Babes Hospital, Bucharest, Romania), Andrea Antinori (National Institute for Infectious Disease L Spallanzani, Rome, Italy), Andrzej Horban (Warsaw Medical University and Hospital of Infectious Diseases, Warsaw, Poland) and Teresa Branco (Department of Centro Hospitalar, Lisbon, Portugal)

Combination antiretroviral therapy 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 < 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 2 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 a CD4 count of 350 cells/μL, although Hungary and Romania have moved to ART initiation at 500 cells/μL. cART coverage is 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. Stocks-outs have been reported in the past 2 years in Albania, Macedonia, Serbia and Romania.

High-income countries (Russia and Central Europe)

HIV prevalence is low in these countries, 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 cells/μL, save for Russia,

where treatment is started at 200 cells/μL. 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 2 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/European Economic Area (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 EU/EEA countries [10]. Some countries do not collect surveillance data on the 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 infection and comorbidities represents a significant barrier to achieving the full benefits of HIV treatment to prevent HIV-related illness, AIDS-related deaths and 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 infection and comorbidities, ensuring sustainable national health care 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.

Improving retention and quality of care in particular in Eastern Europe

Cristina Mussini (University of Modena, Modena, Italy) and Jens D. Lundgren (University of Copenhagen, 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 EU 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 rates 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 for and management of lifestyle-related comorbidities and organ dysfunction are also desirable.

People who inject drugs need models of care that can address all their health needs at one site rather than having to navigate multiple vertical services providing treat-

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

	Estimated number infected with HIV	Diagnosed (%)	Linked to care (%)	Retained in care (%)	On ART (%)	Virally suppressed (%)
France	149 000	81	NA	74	16	52
Armenia	3700	44	NA	28	16	14
Azerbaijan	9200	47	NA	28	14	10
Belarus	24 000	50	NA	41	18	13
Georgia	4900	52	44	38	26	20
Kyrgyzstan	7600	67	NA	28	12	?
Russia	1 360 000	49	38	35	11.5	9 (<1000)
Ukraine	237 000	86	59	?	?	17

ART, antiretroviral therapy; ?, not known; NA, not available

ment for drug addiction, HIV infection and TB, and general medical care.

Opioid substitution therapy (OST) is a crucial element of care for PWID. The proportion of PWID receiving OST is extremely low in Eastern Europe (<5% in Russia, Belarus and Ukraine) compared with Western Europe (50–60% in the UK, the Netherlands and Italy).

Key conclusions

- Greater engagement with health care professionals in the region through invitations to, and support for attendance at, international meetings and training courses will facilitate discussions with peers on best practices. Moreover, in order to limit expensive travel, a programme 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 arm-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) and Daria Podlekareva (Rigshospitalet, University of Copenhagen, Copenhagen, Denmark)

TB case notification rates were five to ten times higher in Eastern compared with 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 PLHIV in Russia is one of the highest in the world, with an incidence rate of 1600 cases per 100 000 inhabitants.

Forty per cent of subjects undergoing drug susceptibility testing (DST) in Eastern Europe had MDR TB, *vs.* <5% in Western Europe, and a low proportion of patients undergoing DST received combination treatment with at least three active drugs, as per the WHO recommendation [14–16]. Similarly, mortality among the TB/HIV-coinfected population was substantially higher in Eastern Europe than in the rest of Europe (33% *vs.* 8–14%, respectively, 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 health care delivery, with problems of decentralized HIV and TB care, lack of anti-TB drugs, antiretrovirals and susceptibility testing, and increased risk of nosocomial transmission during long-term hospitalizations, are likely to contribute to these poor outcomes.

Key conclusions

- Priorities should include integration of HIV and TB services, patient-oriented health care, social support and retention of patients in care.
- There should be consistent implementation of best practice in TB and HIV infection control, and intensified case finding in key populations.
- Increased availability of rapid TB diagnostic tests and DSTs is needed
- There should be adequate adjustments of empirical TB treatment and subsequent treatments guided by DST results.
- Unlimited availability of all TB drugs is required
- Appropriate treatment of HIV infection and unlimited cART coverage are also required
- There should be improved TB and HIV surveillance, and the political will to implement these changes is crucial

Hepatitis C virus (HCV) and HIV coinfection

Antonella d'Arminio Monforte (University of Milan, Milan, Italy), Karine Lacombe (St Antoine Hospital, Paris, France) and Sanjay Bhagani (Royal Free Hospital, London, UK)

Hepatitis C virus 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 infection in MSM has emerged in Western Europe [20–22]. The use of HCV screening in coinfected people remains variable, regardless of EACS guidance recommendations, particularly for MSM [23,24]. Use of rapid tests for HCV and HIV antibodies may improve screening rates [25].

To date, the proportion of coinfected patients treated for HCV infection remains very low, although 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

Table 3 Barriers to hepatitis C treatment

Patient barriers	Provider barriers
Lack of knowledge	Lack of treatment guidelines
Concern regarding treatment side effects and treatment efficacy claims	Lack of awareness of HIV impact on the progression of HCV liver disease
Socially and economically marginalized populations	Poor collaboration between infectious diseases specialists and hepatologists
Stigma	Perception that coinfected patients are at high risk of nonadherence and re-infection
	Concern regarding treatment efficacy and tolerability claims
	Concerns about complexity of drug–drug interactions
	Cost of treatment

HCV, hepatitis C virus.

therapies reduce the risk of progression in coinfected people; however, coinfected patients with fibrosis stage F4 remain at high risk of decompensation [28,29]. HIV/HCV-coinfected patients should be considered as a high-priority group for direct acting antiviral (DAA) treatment, as recommended in the American Association for the Study of Liver Diseases (AASLD) 2014 guidelines and the EACS guidelines [24,30]. The main barriers to hepatitis C treatment are listed in Table 3 [31,32].

Cure rates of >90% have been reported in clinical trials conducted with coinfected patients treated with new interferon-free DAA regimens [33–36].

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 drug pricing for universal access to treatment [37].

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 coinfection.

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

Conclusions

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

In particular, all reasonable efforts should be made to increase awareness regarding 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 PWID, migrants, prisoners and sex workers, warrant special attention for prevention.

Scaling up ART across Europe, particularly in Eastern Europe, is crucial and migrants should also be assured both care and ART availability. The costs of ART and treatment of comorbidities, in particular HCV and TB, 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 are widely available.

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Appendix :

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