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Title: Variation in antiretroviral treatment (ART) coverage and virological suppression among three HIV key populations

Running head: Variation among HIV key populations

Authors:

Kamilla LAUT[1], Leah SHEPHERD[2], Magnus GOTTFREDSSON[3-4], Dalibor SEDLACEK[5], Brygida KNYSZ[6], Josip BEGOVAC[7], Roxana RADOI[8], Brigitte SCHMIED[9], Nikoloz CHKHARTISHVILI[10], Eric FLORENCE[11], Matti RISTOLA[12], Gerd FÄTKENHEUER[13], Fiona MULCAHY[14], Patrick SCHMID[15], Elena KUZOVATOVA[16], Dzmitry PADUTA[17], Jelena SMIDT[18], Pere DOMINGO[19], Janos SZLÁVIK[20], Jens LUNDGREN[1], Amanda MOCROFT[2], Ole KIRK[1] on behalf of the EuroSIDA study group

[1]CHIP, Centre of Excellence for Health, Immunity and Infections, Department of Infectious Diseases, Rigshospitalet, University of Copenhagen, Copenhagen, Denmark. [2]Centre for Clinical Research, Epidemiology, Modelling and Evaluation (CREME), Institute for Global health, UCL, London, UK ,[3]Faculty of Medicine, School of Health Sciences, University of Iceland, [4]Dept of Infectious Diseases, Landspitali University Hospital, Reykjavik, Iceland, [5]Charles University Hospital Plzen, AIDS Centre, Plzen, Czech Republic, [6]Medical University, Wroclaw, Poland, [7]University Hospital of Infectious Diseases, Zagreb, Croatia, [8]Clinical Hospital of Infectious Diseases Dr Victor Babes, Bucharest, Romania, [9]Pulmologisches Zentrum der Stadt Wien, Vienna,

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Austria, [10]Infectious Diseases, AIDS & Clinical Immunology Research Center, Tbilisi, Georgia, [11]Institute of Tropical Medicine, Antwerp, Belgium, [12]Helsinki University Hospital, Helsinki, Finland, [13]University Hospital Cologne, Cologne, Germany, [14]St James' Hospital, Dublin, Ireland, [15]Kantonsspital St Gallen, St Gallen, Switzerland, [16]Nizhny Novgorod Scientific and Research Institute of Epidemiology and Microbiology named after Academician I.N. Blokhina, Nizhny Novgorod, Russia, [17]Regional AIDS Centre, Svetlogorsk,Belarus, [18]Nakkusosakond Siseklinik, Kohtla-Järve, Estonia, [19]Hospital Sant Pau, Barcelona, Spain, [20]United Szent István and Szent László Hospital, Budapest, Hungary.

Corresponding author:

Kamilla Grønborg Laut

kamilla.groenborg.laut.01@regionh.dk

phone +45 60917252

Rigshospitalet, University of Copenhagen, CHIP, Department of Infectious Diseases, Section 2100

Blegdamsvej 9, DK-2100 Copenhagen Ø, Denmark

Email addresses for all other authors:

L.S.: leah.shepherd@ucl.ac.uk

M.G.: magnusgo@landspitali.is

D.S.: sedlacek@fnplzen.cz

B.K.: brygida.knysz@gmail.com

J.B.: josip.begovac@gmail.com

R.R.: dr_roxana_radoi@yahoo.com

B.S.: brigitte.schmied@wienkav.at

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N.C.: nikoloch@yahoo.com

E.F.: eflorence@itg.be

M.R.: matti.ristola@hus.fi

G.F.: g.faetkenheuer@uni-koeln.de

F.M.: fmulcahy@stjames.ie

P.S.: patrick.schmid@kssg.ch

E.K.: kouzovatova@yahoo.com

D.P.: ich@tut.by

J.S.: Jelena.Smidt@ivkh.ee

P.D.: pdomingo@santpau.cat

J.S.: doki@hivinfo.hu

J.L.: jens.lundgren@regionh.dk

A.M.: a.mocroft@ucl.ac.uk

O.K.: ole.kirk@regionh.dk

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Abstract:

Objectives: We assessed differences in antiretroviral treatment (ART) coverage and virological suppression across three HIV key populations, as defined by self-reported HIV transmission category: sex between men, injection drug use [IDU] and heterosexual transmission.

Design: Multinational cohort study

Methods: Within the EuroSIDA study, we assessed region-specific percentages of ART-coverage among those in care and virological suppression (<500 copies/mL) among those on ART, , and analyzed differences between transmission categories using logistic regression.

Results: Among 12,872 participants followed 01/07/2014 – 30/06/2016, the percentages of ART-coverage and virological suppression varied between transmission categories, depending on geographical region (global p for interaction: p=0.0148 for ART-coverage, p=0.0006 for virological suppression). In Western (adjusted odds ratio [aOR] 1.41 [95% confidence interval 1.14-1.75]) and Northern Europe (aOR 1.68 [1.25-2.26]) heterosexuals were more likely to receive ART than men who have sex with men (MSM), while in Eastern Europe there was some evidence that infection through IDU (aOR 0.60 [0.31-1.14]) or heterosexual contact (aOR 0.58 [0.30-1.10]) was associated with lower odds of receiving ART. In terms of virological suppression, people infected through IDU or heterosexual contact in East Central and Eastern Europe were around half as likely as MSM to have a suppressed viral load on ART, while we observed no differences in virological suppression across transmission categories in Western and Northern Europe.

Conclusions: In our cohort, patterns of ART-coverage and virological suppression among key populations varied by geographical region, emphasizing the importance of tailoring HIV programmes to the local epidemic.

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Keywords: HIV care continuum, key and vulnerable populations, public health, HIV, antiretroviral therapy, viral suppression

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Introduction:

While globally, there is promising progress towards the UNAIDS 90-90-90 goals, the WHO European and Central Asian region has not seen the same trends [1,2]. The goals launched by the Joint United Nations Programme on HIV/AIDS (UNAIDS) state that elimination of AIDS by 2030 will be possible if 90% of all people living with HIV are diagnosed, 90% of those diagnosed with HIV receive antiretroviral therapy (ART), and 90% of those on ART achieve virological suppression by 2020 [3]. However, ART-coverage and virological suppression among people on ART remain lower in Europe and Central Asia compared to the rest of the world, largely driven by low levels in Eastern Europe and Central Asia, where, simultaneously, the numbers of new HIV infections and AIDS-related deaths are still rising [1,2,4].

Curbing the HIV epidemic will not be possible without reaching key populations such as men who have sex with men (MSM), people who inject drugs, sex workers and other vulnerable populations, who carry the double burden of a higher risk of HIV infection and poorer access to HIV prevention and care [1,2,5,6].

However, a scarcity of data disaggregated by key population deprives programme implementers the possibility to target interventions that ensure the timely diagnosis, treatment and care needed to maximize individual health benefits and reduce the risk of onward transmission [7–11]. Previous EuroSIDA work showed country-level and regional variation in ART-coverage and virological suppression among people on ART [4]. We hypothesized that these estimates may mask differences between key populations, and aimed to assess regional variation in levels of ART-coverage and virological suppression among three key populations, as categorized by HIV transmission category: people infected through sex between men, heterosexual contact, or injecting drug use (IDU).

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Methods:

Patients:

People were included from the EuroSIDA cohort study which holds data from >23,000 people living with HIV followed at 100 collaborating clinics in 35 countries across Europe, Israel and Argentina. Further details are available at: https://www.chip.dk/Studies/EuroSIDA. Participants are consecutively enrolled into the study if they have a scheduled visit at any of the collaborating clinics. At enrolment into EuroSIDA, basic demographic characteristics are collected, including self-reported HIV transmission category (sex between men, IDU, heterosexual contact or other/unknown). People were characterized as MSM if they reported both sex between men and IDU as mode of transmission. Annual data collection includes clinic visit dates, data on ART (including start- and stop-dates) and all CD4 and HIV-RNA measurements since last follow-up. A range of other laboratory values, information about clinical AIDS- and non-AIDS-defining events, and causes of death, are also collected. Ethical approval is obtained by the principal investigator at each site, according to local and national regulations, and informed consent is obtained from all participants, as required. The EuroSIDA coordinating centre keeps a copy of the relevant approvals and documents.

As in other EuroSIDA studies, people were grouped into the following regions, based on country of residence: *Western Europe*: Austria, Belgium, France, Germany, Luxembourg, Switzerland. *Southern Europe*: Argentina, Greece, Israel, Italy, Portugal, Spain. *Northern Europe*: Denmark, Finland, Iceland, Ireland, Netherlands, Norway, Sweden, United Kingdom. *East Central Europe*: Bosnia-Herzegovina, Croatia, Czech Republic, Hungary, Poland, Romania, Serbia, Slovenia. *Eastern Europe*: Belarus, Estonia, Georgia, Latvia, Lithuania, Russia, Ukraine [4,12].

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Statistics:

In the period 01/07/2014 – 30/06/2016 EuroSIDA participants were considered "in care" if their first EuroSIDA visit occurred before the end of the period and their latest recorded visit or CD4 cell count or HIV-RNA measurement occurred after the start of the period. Participants were assessed for being "in care", "on ART" or "virologically suppressed" at the latest of a clinic visit, CD4 cell count or HIV-RNA-measurement, or at the midpoint of the period if all these dates were unavailable.In a cross-sectional analysis, we assessed the percentage receiving ART among those in care, and the percentage virologically suppressed among those on ART, stratified by HIV transmission category. ART was defined as receiving ≥3 antiretrovirals from any class, and virological suppression was defined as HIV-RNA below 500copies/mL at the most recent measurement within 12 months prior to assessment [4]. If participants in care had no available HIV-RNA-measurement in the period, they were considered unsuppressed (missing = failure).

Logistic regression modelled the odds ratio (OR) of receiving ART among those in care, and of being virologically suppressed among those on ART. We adjusted for factors hypothesized to vary across regions and transmission categories: current age, sex, CD4 at entry into EuroSIDA, and current hepatitis B (HBV) and hepatitis C (HCV) status. Formal tests for interaction were used to assess regional differences in the odds of receiving ART and being virologically suppressed by HIV transmission category.

Results:

We included a total 12,872 EuroSIDA participants in care between 01/07/2014 and 30/06/2016 (table 1). The predominant mode of HIV transmission was sex between men (37.3%), followed by heterosexual transmission (30.2%) and IDU (25.4%). Data from 924 (7.9%) people with

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other/unknown mode of HIV-transmission are included in overall estimates, but not shown separately because stratification yielded small numbers. The distribution of transmission categories differed by region: e.g. 55.9% of people included from Northern Europe were MSM, while half (49.0%) of those included in Eastern Europe were infected through IDU. Of the 3,507 females included, around two-thirds indicated heterosexual contact, and around one-third indicated IDU as the mode of transmission. The majority of people (86.4%) infected through IDU were co-infected with HCV, compared to 15.8% MSM and 21.1% in the heterosexual transmission category.

Regional variation among transmission categories

Overall estimates of ART-coverage and virological suppression by transmission category are presented in figure 1 in a cascade-like plot, using the same denominator (people in care) across both steps. In EuroSIDA as a whole, MSM had the highest levels of ART-coverage (crude estimate 80.8% [95% confidence interval (CI) 79.7-81.9%]) and virological suppression (93.3% [92.4-94.0]), while people infected through IDU had the lowest (74.5% [73.0-76.0] receiving ART, 81.3% [79.7-82.8] virologically suppressed on ART) (figure 1). However, these crude estimates varied by region (figure 2).

Figure 2 shows the percentage receiving ART among those in care and the percentage virologically suppressed among those on ART. This means that each step uses the previous step as denominator. As shown in figure 2a, estimates of ART-coverage among MSM varied across regions, while for virological suppression among those on ART, levels were generally high, and differences between regions smaller. The highest ART-coverage among MSM was observed in East Central Europe, where 87.2% (n=641) of those in care received ART, and of those, 91.6% (n=587) had a suppressed viral load. Among MSM, the lowest ART-coverage (73.6%), but the highest levels of virological

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suppression on ART (95.9%) were found in Western Europe, while the lowest level of virological suppression among MSM was observed in Eastern Europe (87.3%).

Differences across regions were more pronounced for people infected through IDU or heterosexual contact, and variation in the percentages reaching virological suppression was particularly large (figures 2b and 2c). Crude estimates of ART-coverage among IDU were at a lowest 67.0% in Western Europe ranging to a highest 85.7% in Northern Europe. Furthermore, in Eastern Europe, only 67.4% IDU receiving ART had a suppressed viral load, while as many as 96.4% of IDU living in Northern Europe reached virological suppression on ART. Heterosexuals in Northern Europe was the only category across all regions where more than 90% in care received ART (90.5%). By comparison, only 74.7% of the heterosexual transmission category in Eastern Europe received ART, while virological suppression in this group varied by region from 76.6% to 96.2%.

Within-region variation between transmission categories:

Our results showed that overall ART-coverage and virological suppression varied at the regional level. However, we also found regional differences across transmission categories, and formal tests for interaction between transmission category and region indicated that the size of these differences varied significantly by region (global p for interaction p=0.0148 for ART-coverage, p=0.0006 for virological suppression). Within-regional variation in the odds of receiving versus not receiving ART and in the odds of being virologically suppressed versus unsuppressed on ART are shown in figures 3 and 4, respectively.

For example, in Western Europe the adjusted odds of receiving ART were similar for a person infected through IDU and through sex between men (adjusted OR (aOR) 0.97 [95%CI 0.77-1.23].

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Conversely, a person infected through heterosexual contact in Western Europe had 41% higher odds of receiving ART compared to MSM (aOR 1.41 [1.14-1.75]) (figure 3a). We found no evidence of differences across transmission categories in Western Europe in the odds of being virologically suppressed (figure 4a). In Northern Europe, where ART-coverage was higher, people infected through heterosexual contact were also more likely to receive ART compared to MSM (aOR 1.68 [1.25-2.26]) (figure 3c). After adjustment, there was some evidence to suggest that people in this region infected through IDU were more likely than MSM to receive ART (aOR 1.40 [0.99-1.96]), whereas the odds of having a suppressed viral load on ART were similar across transmission categories in Northern Europe (figure 4c).

In Southern and East Central Europe, adjusted estimates showed no evidence of differences in ART-coverage across transmission categories (figures 3b and 3d). By contrast, after adjustment, there was evidence to suggest that those infected through heterosexual contact were significantly less likely to achieve virological suppression in both Southern and East Central Europe (figures 4b and 4d). In addition, IDU in East Central Europe were around half as likely as MSM to be virologically suppressed on ART (aOR 0.55 [0.37-0.80])

Eastern Europe exhibited the lowest overall levels of treatment coverage and virological suppression, and also had the largest heterogeneity across transmission categories. Thus, after adjustment, there was some indication that the odds of receiving ART were approximately 40% lower than that of MSM for IDU (aOR 0.60 [0.31-1.14]) and for heterosexuals (aOR 0.58 [0.30-1.10]) although this was not statistically significant (figure 3e). Furthermore, among those receiving ART in Eastern Europe, IDU and heterosexuals seemed to be around half as likely as MSM to be virologically suppressed (aOR 0.52 [0.25-1.06], aOR 0.57 [0.28-1.18] for IDU and heterosexuals,

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respectively) (figure 4e). Again, confidence intervals for these results were wide, which may partly be due to low numbers in this region.

Sensitivity analyses:

We assessed the effect of categorizing missing HIV-RNA as unsuppressed, and found that estimates did not change much when limiting analyses to those with available HIV-RNA measurements in the study period (figures 4a-4e). Thus, differences in the availability of HIV-RNA measurements did not account for the observed differences between transmission groups.

To account for possible collinearity between HCV-coinfection and the IDU transmission category, we also performed a post-hoc sensitivity analysis excluding HCV co-infection from adjusted models. When HCV-coinfection was not adjusted for, we no longer saw any differences between unadjusted and adjusted estimates among IDU; i.e. most of the difference between unadjusted and adjusted estimates was due to the inclusion of the HCV-variable. For MSM and heterosexuals, adjusted estimates remained the same as in the primary analysis.

Discussion:

We assessed variation in ART-coverage and virological suppression across key populations - as defined by self-reported HIV transmission categories - in a large, multinational cohort study. We found that the percentage receiving ART among those in care, the percentage virologically suppressed on ART, and the pattern of differences across transmission categories varied by geographical region. Within EuroSIDA as a whole, the highest heterogeneity for any transmission category was observed among those infected through IDU, whereas regional variation among MSM was less pronounced. However, we also found that members of different key populations may

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receive different care within the same region. In Western and Northern Europe, people infected through heterosexual contact were more likely than other transmission categories to receive ART, while MSM had the highest ART-coverage in Eastern Europe. Furthermore, we found no differences in the high levels of virological suppression across transmission categories in Western and Northern Europe, whereas the picture was more diverse in other regions.

Our findings highlight some important points: firstly, our data confirm the heterogeneity of the HIV epidemic, and underline the need to target and differentiate health services to fit the local epidemic [1,7,13]. Secondly, supporting the findings of others, it is possible to achieve equity in ART-coverage and virological suppression across transmission categories [14]. Thirdly – and further to our previous studies on regional differences [4] - this study shows that ART-coverage and virological suppression varied across transmission categories *within* each region. This indicates that variation in the continuum of HIV care may go beyond regional differences in economy and a limited supply of ART [15]. Our findings also highlight that some regions must focus on scaling up ART-programmes, while others may benefit from a particular focus on adherence counseling and support [1].

Achieving high levels of virological suppression among all living with HIV remains crucial; both for individual health benefits, and for reducing the risk of onward transmission. Our study illustrates that there are still opportunities to improve the virological response to ART. For example, ART-coverage was high and comparable across all transmission categories in East Central Europe, but levels of virological suppression were lower among people in the IDU and heterosexual categories than among MSM in this region. A similar pattern was observed among heterosexuals in Southern Europe.Importantly, sensitivity analyses showed that neither the observed disparities across transmission groups, nor regional differences in levels of virological suppression were explained by

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differences in the availability of HIV-RNA measurements. Our findings thus highlight the importance of increasing focus on differentiated treatment counseling and adherence support, targeting those who need it the most.

People infected through IDU were the least likely to receive ART and achieve virological control in our study. However, our estimates were higher than in some other studies [6,16,17], and it is important to keep in mind that there may be differences in testing and linkage to care across clinics and countries in EuroSIDA. A recent study found that IDU tended to be underrepresented in European cohorts when compared against a gold standard of ECDC surveillance data [18], and several studies have shown that both testing- and linkage rates are particularly low among people who inject drugs. Further, people enrolled into EuroSIDA must have had a visit to a collaborating clinic and must agree to participate in the cohort. EuroSIDA participants infected through IDU may therefore represent a selected population of the whole IDU-population in each country, characterized by a higher ability to remain in HIV care, and ultimately by better long-term clinical outcomes. Consequently, our data likely overestimate outcomes for people infected through IDU.

Our sensitivity analysis showed that adjusting for HCV-coinfection attenuated differences in ART-coverage and virological suppression between IDU and MSM. Because international treatment guidelines recommended early ART-initiation for HIV/HCV co-infected individuals throughout the study period, we find it unlikely that the lower odds of receiving ART among IDU were based on HCV-status [19,20]. Furthermore, a previous EuroSIDA study found no evidence that HCV-coinfection negatively affects the ability to suppress HIV-RNA [21]. We believe that IDU is more likely a shared risk factor for HCV-infection and poorer access to care, yielding poorer outcomes for people infected with HIV through IDU. However, due to collinearity of HCV-coinfection and

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IDU, we are unable to formally determine whether differences between IDU and MSM were driven primarily by transmission category or by differences in HCV-infection.

Even if our results cover large between-country and within-country differences, our regional estimates are helpful to highlight gaps in the quality of HIV care [1,4,22]. In this context, the climbing HIV epidemic in Eastern Europe should be mentioned. In line with our findings, surveillance data documented a substantial treatment gap in Eastern Europe [1,2], and levels of virological suppression that are comparable to our previous findings [4]. However, our study shows that a population average may mask substantial variation across key populations. People infected through IDU and heterosexual contact accounted for comparatively higher proportions of participants in Eastern Europe, at the same time that these people had the lowest levels of ART-coverage and virological suppression. Understanding how this incongruence may fuel the epidemic will be important. It is well-known that people with an active ilicit drug use have particularly poor access to integrated care and harm reduction services in some countries in Eastern Europe [23,24], which may contribute to the lower treatment- and suppression rates in this group. As for the heterosexual transmission category, people in some countries are predominantly migrants infected in high-endemic countries [25], while this group may include sex partners to people with IDU in other countries. Such regional diversity of the heterosexual category may partly explain why levels of ART-coverage and virological suppression for heterosexuals in Eastern Europe differed from other regions. Finally, we noticed that remarkably few MSM were included in Eastern Europe, which may be a reflection of the current epidemic in the region, but could also reflect misclassification due to fear of stigmatization or criminalization [17,26]. While the risk of such misclassification is inherent to self-reported data, we are not aware of other ways to collect information on transmission category.

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Some strengths of our study should be mentioned. While other studies have explored barriers to care for single key populations, this is one of few studies comparing differences between transmission categories in core HIV care parameters [6,7,11,27,28]. Furthermore, our study is among few European studies that hold some data on key populations, and is among the first to compare across regions of Europe [11,29–32]. Thirdly, our standardized data collection overcomes many of the problems, such as a lack of common definitions, often faced when trying to compare quality of care across countries [11,33]. EuroSIDA data is collected in a standardized manner at the individual level. This is in contrast to many existing studies (including surveillance data) that are the result of cross-sectional surveys often filled in by public health experts, or where data is merged from different data sources [2,11].

However, our study also has some limitations. Our cohort represents those diagnosed and linked to care, and it will be important to estimate the size of each key population, in addition to obtaining data on populations such as sex workers, prisoners, transgender people, and migrants, in order to tailor testing- and treatment strategies. These data are not routinely collected in EuroSIDA. Secondly, people's behaviours are fluid and the HIV-transmission category does not necessarily reflect current behavior. For example, we were not able to separate people who ever injected drugs from people with an ongoing use; people who may have very different lifestyles, and consequently very different needs. Thirdly, we did not adjust for differences in the type of ART-regimen, which may also affect the odds of having a suppressed viral load, e.g. due to well-known interactions between some ilicit drugs and antiretrovirals [20,34].

In our study we did not take varying local treatment threshold guidelines into account. While our data are new, progress is fast, and ART-coverage may have increased since our estimates, as

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countries increasingly adopt and implement new treatment strategies [1,35]. On the other hand, while differences in guidelines are likely reflected in our study, they are unlikely to explain the variation we saw between transmission groups. These differences may be explained by factors such as laws and policies criminalizing same-sex behavior or ongoing substance abuse, deferral of ART due to concerns about non-adherence, and various other structural and patient-related factors that we were not able to account for [7,16,24,36–38].

From previous studies we know that clustering of countries into regions may cover potentially large differences between countries in ART-coverage and virological suppression [4]. However, even in a cohort as large as EuroSIDA, it was not possible to present country-level data disaggregated by transmission category, which emphasizes the urgent need to increase the availability of data on key populations. It may be debated whether the grouping into five regions used in EuroSIDA is the most appropriate. On the other hand, similarities in both the epidemic, outcomes and health systems structure within regions account for the clustering [39,40,12]. Due to an extensive data quality assurance programme, data quality in EuroSIDA is high. Nonetheless, missing data, under-reporting or reporting delays may affect the data quality in any cohort, and could also affect our results. Finally, clinic characteristics and the number of people included in EuroSIDA vary by country, and EuroSIDA data may not be representative of HIV care within the individual countries. Work is ongoing to understand the representativeness of EuroSIDA data, and to explore how cohort data may supplement other data sources to facilitate longitudinal monitoring of HIV-programmes.

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Conclusions:

We found that levels of ART-coverage and virological suppression varied depending on HIV transmission category, both across and within regions. Overall, people infected through IDU were the least likely to receive ART and to achieve virological suppression on ART, but the pattern varied significantly by region of residence. Our results demonstrate that national estimates of ART-coverage and virological suppression may represent an average that covers large differences across key populations, highlight that a differentiated HIV-response remains crucial to reaching control of the HIV epidemic, and underline that high quality disaggregated data is needed to inform and strengthen interventions.

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Authorship:

K.G.L. contributed to the conception, design and interpretation of the study and drafted the article. O.K., A.M., L.S. and J.L. contributed to the conception of the work, design and the interpretation of data. L.S. performed the statistical analyses. All other authors contributed to data acquisition and provided intellectual input. All authors have read and approved the final manuscript.

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The EuroSIDA Study Group

The multi-centre study group, EuroSIDA (national coordinators in parenthesis).

Argentina: (M Losso), M Kundro, Hospital JM Ramos Mejia, Buenos Aires.

Austria: (B Schmied), Otto Wagner Hospital, Vienna; R Zangerle, Medical University Innsbruck, Innsbruck.

Belarus: (I Karpov), A Vassilenko, Belarus State Medical University, Minsk, VM Mitsura, Gomel State Medical University, Gomel; D Paduto, Regional AIDS Centre, Svetlogorsk.

Belgium: (N Clumeck), S De Wit, M Delforge, Saint-Pierre Hospital, Brussels; E Florence, Institute of Tropical Medicine, Antwerp; L Vandekerckhove, University Ziekenhuis Gent, Gent.

Bosnia-Herzegovina: (V Hadziosmanovic), Klinicki Centar Univerziteta Sarajevo, Sarajevo.

Croatia: (J Begovac), University Hospital of Infectious Diseases, Zagreb.

Czech Republic: (L Machala), D Jilich, Faculty Hospital Bulovka, Prague; D Sedlacek, Charles University Hospital, Plzen.

Denmark: G Kronborg, T Benfield, Hvidovre Hospital, Copenhagen; J Gerstoft, T Katzenstein, Rigshospitalet, Copenhagen; C Pedersen, IS Johansen, Odense University Hospital, Odense; L Ostergaard, Skejby Hospital, Aarhus, L Wiese, N Friis-Moller, Sjællands Universitetshospital, Roskilde; L N Nielsen, Hillerod Hospital, Hillerod.

Estonia: (K Zilmer), West-Tallinn Central Hospital, Tallinn; Jelena Smidt, Nakkusosakond Siseklinik, Kohtla-Järve.

Finland: (M Ristola), I Aho, Helsinki University Central Hospital, Helsinki.

France: (J-P Viard), Hôtel-Dieu, Paris; P-M Girard, Hospital Saint-Antoine, Paris; C Pradier, E Fontas, Hôpital de l'Archet, Nice; C Duvivier, Hôpital Necker-Enfants Malades, Paris.

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Germany: (J Rockstroh), Universitäts Klinik Bonn; G Behrens, Medizinische Hochschule Hannover; O Degen, University Medical Center Hamburg-Eppendorf, Infectious Diseases Unit, Hamburg; HJ Stellbrink, IPM Study Center, Hamburg; C Stefan, JW Goethe University Hospital, Frankfurt; J Bogner, Medizinische Poliklinik, Munich; G. Fätkenheuer, Universität Köln, Cologne.

Georgia: (N Chkhartishvili) Infectious Diseases, AIDS & Clinical Immunology Research Center, Tbilisi

Greece: (P Gargalianos), G Xylomenos, K Armenis, Athens General Hospital "G Gennimatas"; H Sambatakou, Ippokration General Hospital, Athens.

Hungary: (J Szlávik), Szent Lásló Hospital, Budapest.

Iceland: (M Gottfredsson), Landspitali University Hospital, Reykjavik.

Ireland: (F Mulcahy), St. James's Hospital, Dublin.

Israel: (I Yust), D Turner, M Burke, Ichilov Hospital, Tel Aviv; E Shahar, G Hassoun, Rambam Medical Center, Haifa; H Elinav, M Haouzi, Hadassah University Hospital, Jerusalem; D Elbirt, ZM Sthoeger, AIDS Center (Neve Or), Jerusalem.

Italy: (A D'Arminio Monforte), Istituto Di Clinica Malattie Infettive e Tropicale, Milan; R Esposito, I Mazeu, C Mussini, Università Modena, Modena; F Mazzotta, A Gabbuti, Ospedale S Maria Annunziata, Firenze; V Vullo, M Lichtner, University di Roma la Sapienza, Rome; M Zaccarelli, A Antinori, R Acinapura, M Plazzi, Istituto Nazionale Malattie Infettive Lazzaro Spallanzani, Rome; A Lazzarin, A Castagna, N Gianotti, Ospedale San Raffaele, Milan; M Galli, A Ridolfo, Osp. L. Sacco, Milan.

Latvia: (B Rozentale), Infectology Centre of Latvia, Riga.

Lithuania: (V Uzdaviniene) Vilnius University Hospital Santaros Klinikos, Vilnius; R Matulionyte, Centro poliklinika, Vilnius, Vilnius University Hospital Santaros Klinikos, Vilnius.

Luxembourg: (T Staub), R Hemmer, Centre Hospitalier, Luxembourg.

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Netherlands: (P Reiss), Academisch Medisch Centrum bij de Universiteit van Amsterdam, Amsterdam.

Norway: (DH Reikvam), A Maeland, J Bruun, Oslo University Hospital, Ullevaal

Poland: (B Knysz), J Gasiorowski, M Inglot, Medical University, Wroclaw; E Bakowska, Centrum Diagnostyki i Terapii AIDS, Warsaw; R Flisiak, A Grzeszczuk, Medical University, Bialystok; M Parczewski, K Maciejewska, B Aksak-Was, Medical Univesity, Szczecin; M Beniowski, E Mularska, Osrodek Diagnostyki i Terapii AIDS, Chorzow; T Smiatacz, M Gensing, Medical University, Gdansk; E Jablonowska, J Kamerys, K Wojcik, Wojewodzki Szpital Specjalistyczny, Lodz; I Mozer-Lisewska, Poznan University of Medical Sciences, Poznan.

Portugal: (L Caldeira), Hospital Santa Maria, Lisbon; K Mansinho, Hospital de Egas Moniz, Lisbon; F Maltez, Hospital Curry Cabral, Lisbon.

Romania: (R Radoi), C Oprea, Carol Davila University of Medicine and Pharmacy Bucharest, Victor Babes Clinical Hospital for Infectious and Tropical Diseases, Bucharest

Russia: (A Panteleev), O Panteleev, St Petersburg AIDS Centre, St Peterburg; A Yakovlev, Medical Academy Botkin Hospital, St Petersburg; T Trofimora, Novgorod Centre for AIDS, Novgorod, I Khromova, Centre for HIV/AIDS & and Infectious Diseases, Kaliningrad; E Kuzovatova, Nizhny Novgorod Scientific and Research Institute of Epidemiology and Microbiology named after Academician I.N. Blokhina, Nizhny Novogrod; E Borodulina, E Vdoushkina, Samara State Medical University, Samara.

Serbia: (D Jevtovic), The Institute for Infectious and Tropical Diseases, Belgrade.

Slovenia: (J Tomazic), University Clinical Centre Ljubljana, Ljubljana.

Spain: (JM Gatell), JM Miró, Hospital Clinic – IDIBAPS. University of Barcelona, Barcelona; S Moreno, JM Rodriguez, Hospital Ramon y Cajal, Madrid; B Clotet, A Jou, R Paredes, C Tural, J Puig, I Bravo, Hospital Germans Trias i Pujol, Badalona; P Domingo, M Gutierrez, G Mateo, MA

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Sambeat, Hospital Sant Pau, Barcelona; JM Laporte, Hospital Universitario de Alava, Vitoria-Gasteiz.

Sweden: (K Falconer), A Thalme, A Sonnerborg, Karolinska University Hospital, Stockholm; CJ Treutiger, Venhälsan-Sodersjukhuset, Stockholm; L Flamholc, Malmö University Hospital, Malmö.

Switzerland: (A Scherrer), R Weber, University Hospital Zurich; M Cavassini, University Hospital Lausanne; A Calmy, University Hospital Geneva; H Furrer, University Hospital Bern; M Battegay, University Hospital Basel; P Schmid, Cantonal Hospital St. Gallen.

Ukraine: A Kuznetsova, Kharkov State Medical University, Kharkov; G Kyselyova, Crimean Republican AIDS centre, Simferopol; M Sluzhynska, Lviv Regional HIV/AIDS Prevention and Control CTR, Lviv.

United Kingdom: (B Gazzard), St. Stephen's Clinic, Chelsea and Westminster Hospital, London; AM Johnson, E Simons, S Edwards, Mortimer Market Centre, London; A Phillips, MA Johnson, A Mocroft, Royal Free and University College Medical School, London (Royal Free Campus); C Orkin, Royal London Hospital, London; J Weber, G Scullard, Imperial College School of Medicine at St. Mary's, London; A Clarke, Royal Sussex County Hospital, Brighton; C Leen, Western General Hospital, Edinburgh.

The following centers have previously contributed data to EuroSIDA:

Infectious Diseases Hospital, Sofia, Bulgaria. Hôpital de la Croix Rousse, Lyon, France. Hôpital de la Pitié-Salpétière, Paris, France. Unité INSERM, Bordeaux, France. Hôpital Edouard Herriot, Lyon, France. Bernhard Nocht Institut für Tropenmedizin, Hamburg, Germany. 1st I.K.A Hospital of Athens, Athens, Greece. Ospedale Riuniti, Divisione Malattie Infettive, Bergamo, Italy. Ospedale di Bolzano, Divisione Malattie Infettive, Bolzano, Italy. Ospedale Cotugno, III Divisione Malattie Infettive, Napoli, Italy. Dérer Hospital, Bratislava, Slovakia. Hospital Carlos III, Departamento de

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Enfermedades Infecciosas, Madrid, Spain. Kiev Centre for AIDS, Kiev, Ukraine. Luhansk State Medical University, Luhansk, Ukraine. Odessa Region AIDS Center, Odessa, Ukraine.

The EuroSIDA Steering Committee

J Rockstroh (chair), R Paredes (vice chair), I Karpov, M Losso, J Lundgren, J Rockstroh, I Aho, LD Rasmussen, V Svedhem, G Wandeler, C Pradier, N Chkhartishvili, R Matulionyte, C Oprea, JD Kowalska, J Begovac, J Miro, G Guaraldi

Study Co-leads: A Mocroft, O Kirk

EuroSIDA staff

Coordinating Centre Staff: O Kirk, L Peters, A Bojesen, D Raben, D Kristensen, K Laut, JF Larsen, D Podlekareva, B Nykjær.

Statistical Staff: A Mocroft, A Phillips, A Cozzi-Lepri, L Shepherd, S Amele, A Pelchen-Matthews

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	Transmission category			
	Overall†	**MSM**	**IDU**	**Heterosexual**
Total number of people included, n (% of overall)	12,872 (100)	4,796 (37.3)	3,265 (25.4)	3,887 (30.2)
Number of people by region of residence, n (% of total in region)				
West	2,975 (100)	1,270 (42.7)	537 (18.1)	850 (28.6)
South	3,354 (100)	1,109 (33.1)	948 (28.3)	1,064 (31.7)
North	2,862 (100)	1,599 (55.9)	363 (12.7)	727 (25.4)
East Central	1,913 (100)	735 (38.4)	551 (28.8)	472 (24.7)
East	1,768 (100)	83 (4.7)	866 (49.0)	774 (43.8)
Current age in years,				

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median (IQR)	48.8 (40.7, 55.1)	50.7 (43.8, 58.1)	46.5 (38.4, 52.1)	47.6 (39.7, 54.8)
Median date of starting first ART, median (IQR)	06/2003 (03/1998-12/2008)	08/2001 (07/1997-05/2008)	09/2005 (02/1999-04/2010)	03/2004 (02/1998-03/2008)
Male, n (% of males)	9,365 (100)	4,774 (51.0)	2,294 (24.5)	1,632 (17.4)
Female, n (% of females)	3,507 (100)	-	971 (27.7)	2,255 (64.3)
CD4 at entry into EuroSIDA, median (IQR)	400 (250, 590)	408 (255, 592)	409 (254, 619)	390 (244, 563)
People on ART with no available HIV-RNA, by region of residence, n (% of transmission category on ART)	51 (2)	25 (3)	5 (1)	14 (2)

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West	301 (12)	70 (8)	96 (15)	118 (14)
South	97 (4)	54 (4)	11 (4)	24 (4)
North	157 (9)	35 (5)	79 (17)	30 (7)
East Central	137 (10)	3 (4)	90 (14)	41 (7)
East				
Known HBV positive, n (%)	606 (4.7)	258 (5.4)	158 (4.8)	145 (3.7)
Known HBV negative, n (%)	11,124 (86.4)	4,156 (86.7)	2,675 (81.9)	3,493 (89.9)
Known HCV positive, n (%)	4,737 (36.8)	758 (15.8)	2,821 (86.4)	820 (21.1)
Known HCV negative, n (%)	7,072 (54.9)	3,668 (76.5)	112 (3.4)	2,796 (71.9)

Table 1: Characteristics of people included by transmission category. MSM = men who have sex with men. IDU = injecting drug use. Heterosexual = heterosexual contact. †Data for 924 people with other/unknown transmission category are included in overall numbers, but are not shown separately due to small numbers.

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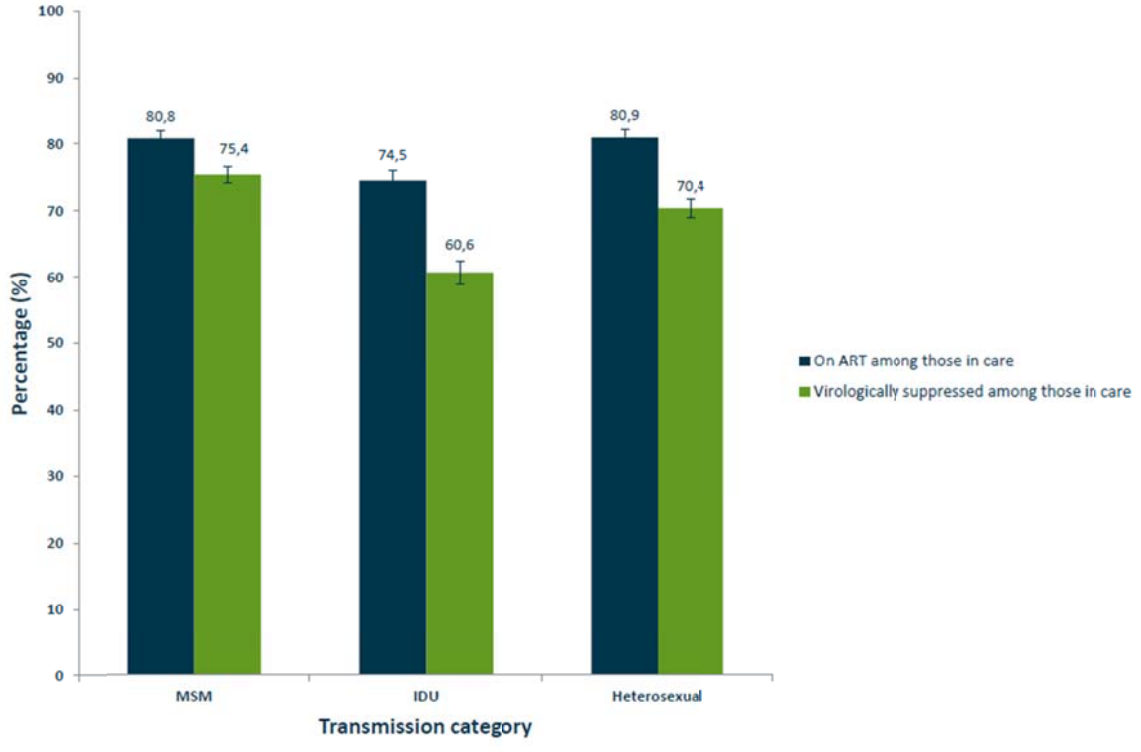

Figure 1: The treatment cascade for people in care in EuroSIDA, stratified by transmission category. The figure shows the overall crude percentages of people on antiretroviral therapy (ART) among those in care and virologically suppressed among those in care in EuroSIDA, stratefied by transmission category. This chart uses the same denominator (people in care) for both steps. MSM = men who have sex with men. IDU = injecting drug use. Heterosexual = heterosexual contact.

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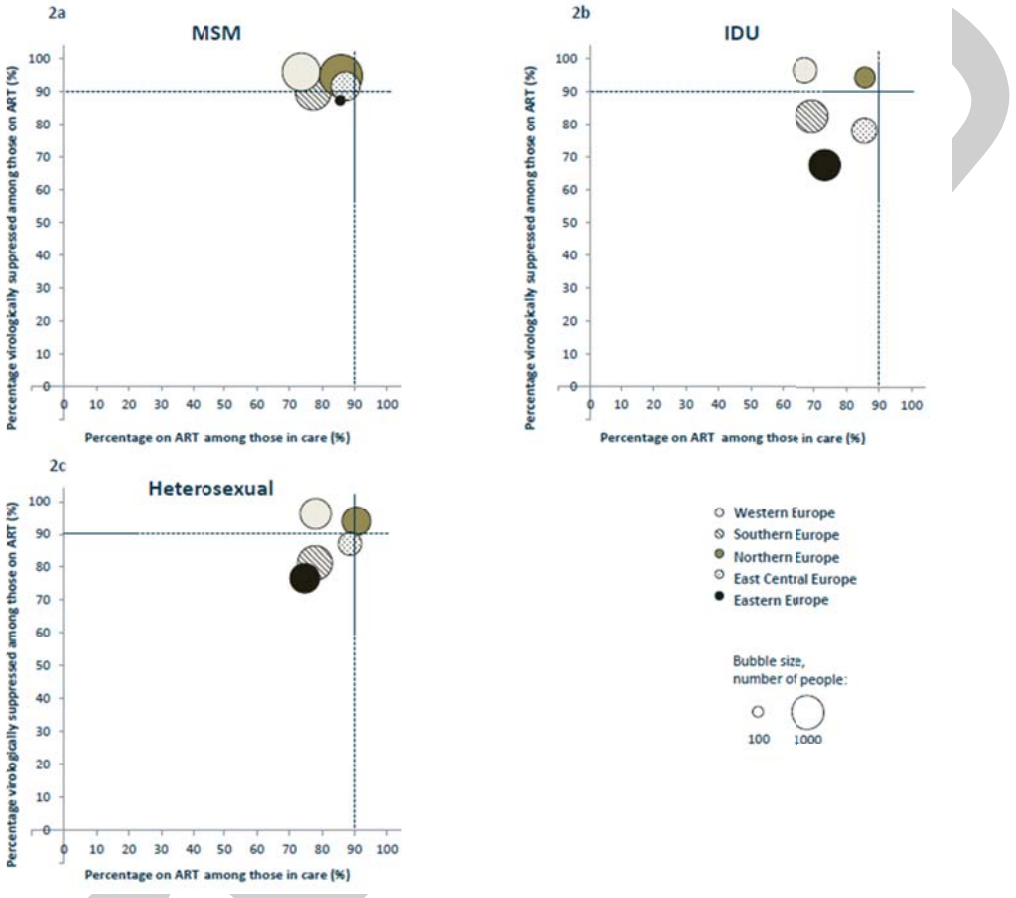

Figure 2: Crude estimates of the percentage on ART among those in care and virological suppression among those on ART by HIV transmission category and region. Each bubble represents a region, and the size of each bubble is proportional to the total number of people in care within a particular transmission category in that region. ART-coverage uses the number of people "in care" as denominator, while the estimate of virological suppression uses "on ART" as denominator. MSM = men who have sex with men. IDU = injecting drug use. Heterosexual = heterosexual contact.

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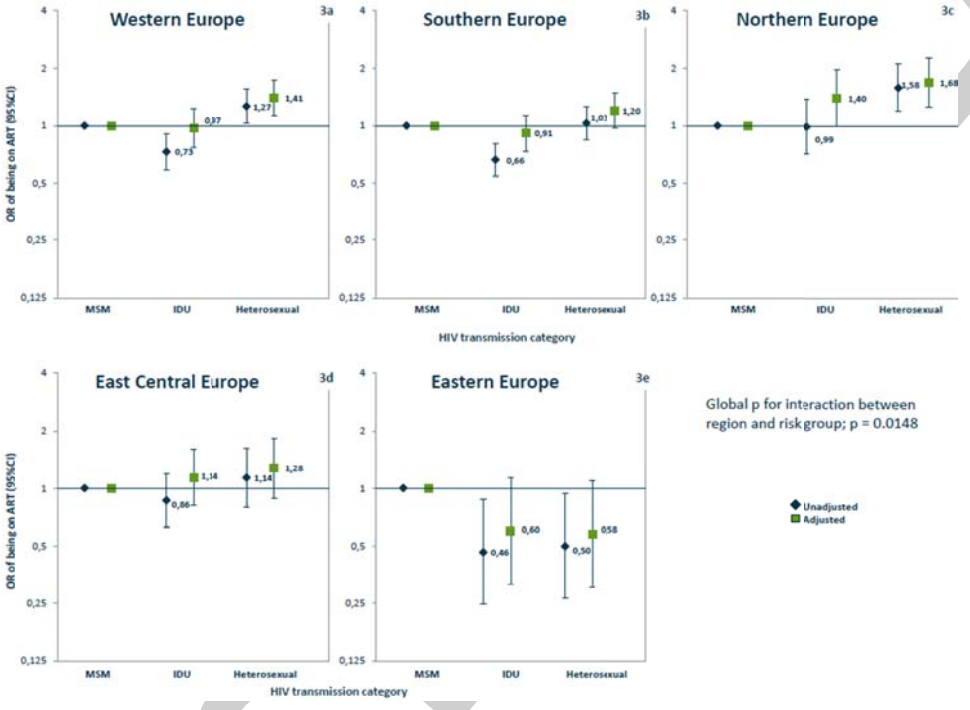

Figure 3: OR and aOR of being on ART among those in care, stratified by transmission category within each region. MSM reference. MSM = men who have sex with men. IDU = injecting drug use. Heterosexual = heterosexual contact. Adjusted for sex, current age, CD4 at entry into EuroSIDA, current HBV- and HCV-status.

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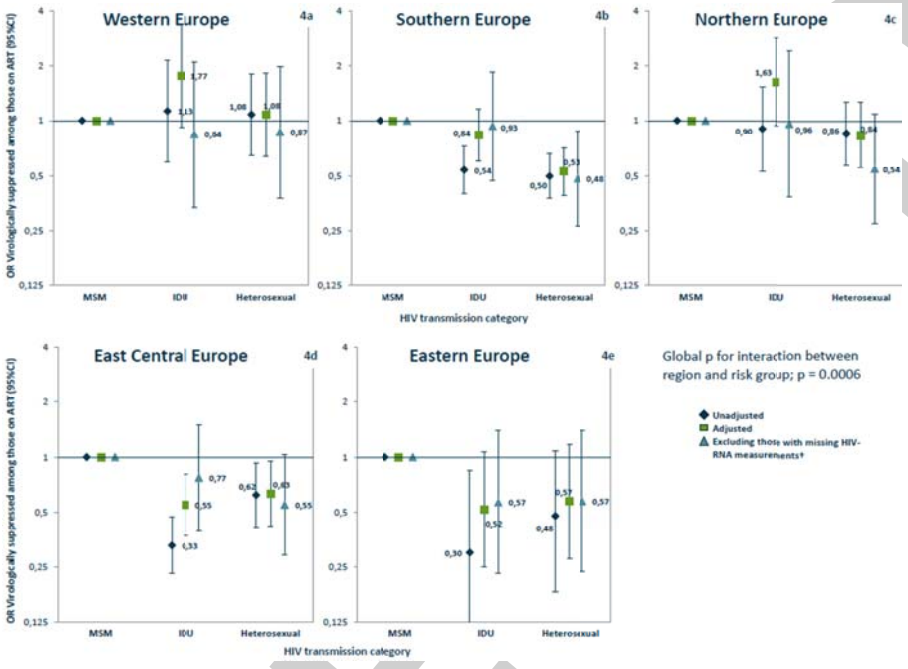

Figure 4: OR and aOR of being virologically suppressed among those on ART, stratified by transmission category within each region, and sensitivity analysis excluding those with no available HIV-RNA. MSM = men who have sex with men. IDU = injecting drug use. Heterosexual = heterosexual contact. Adjusted for sex, current age, CD4 at entry into EuroSIDA, current HBV- and HCV-status. †Based on only those with available HIV-RNA measurements in the study period, i.e. the denominator is different from the other estimates.

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