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## Late diagnosis of HIV: an updated consensus definition

**Short title:** Late HIV diagnosis consensus definition update

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## **ABSTRACT**

**Introduction:** In recent years, HIV testing frequency has increased, resulting in more people being diagnosed during seroconversion with a temporarily low CD4 count. Using the current consensus definition of late HIV presentation (“presenting for care with a CD4 count <350 cells/ $\mu$ l or an AIDS-defining event, regardless of CD4 count”) these individuals would be incorrectly assigned as being diagnosed late.

**Methods:** In Spring 2022, a European expert group convened to revise the current late HIV presentation consensus definition. A survey on data availability to apply this revised definition was sent to nominated European focal points responsible for HIV surveillance (n=53).

**Results:** Experts agreed the updated definition should refer to late HIV diagnosis rather than presentation and include the following addition: People with evidence of recent infection should be reclassified as ‘not late’, with evidence of recent infection considered hierarchically. The individual must have: i) laboratory evidence of recent infection; ii) a last negative HIV test within 12 months of diagnosis; or iii) clinical evidence of acute infection. People with evidence of being previously diagnosed abroad should be excluded.

Eighteen countries responded to the survey; 83% reported capturing CD4 count and/or AIDS at diagnosis through national surveillance, 67% last negative test and/or previous HIV diagnosis, 61% seroconversion illness at diagnosis and 28% incident antibody results.

**Conclusions:** Accurate data on late diagnosis are important to describe effects of testing programmes. Reclassification of individuals with recent infection will help to better identify populations most at risk of poor HIV outcomes and areas for intervention.

## **MANUSCRIPT**

### **INTRODUCTION**

Late HIV diagnosis is associated with poor outcomes, an increased risk of ongoing HIV transmission and high healthcare costs.(1, 2) As such, late diagnosis remains a key public health metric in assessing the success of HIV testing programmes. In 2010, a consensus statement was published in which late presentation of HIV was defined as presenting for HIV care having a CD4 count <350 cells/ $\mu$ L or with an acquired immunodeficiency syndrome (AIDS)-defining event.(3) This definition was endorsed by the European Centre for Disease Prevention and Control (ECDC) and the World Health Organization (WHO) Regional Office for Europe and has been used across Europe for clinical research and public health monitoring for more than 10 years. Completeness of HIV surveillance data on CD4 count at diagnosis is now high for most countries reporting to ECDC and WHO.(4)

In recent years, testing for HIV has expanded and frequency has increased across some populations and regions, particularly in relation to the roll out of pre-exposure prophylaxis (PrEP) programmes. This has resulted in an increasing number of people, particularly men who have sex with men (MSM), being diagnosed with HIV during seroconversion, when their CD4 count may be temporary low, (known as the 'seroconversion effect' (5, 6)). Using the current definition of late HIV presentation, these individuals are incorrectly assigned as being diagnosed late. This issue of overestimation has already been raised by research groups in Belgium,(7) Sweden (8) and the United Kingdom (UK).(9) This has led to correction factors being applied to the late diagnosis rate of specific subgroups. The magnitude of these correction factors depends on the reclassification criteria, population, country, and study period, but was estimated to be as high as 9% in Belgium.(7)

Therefore, a working group established under the EuroTEST Initiative, with the support of the ECDC, WHO Regional Office for Europe and European AIDS Clinical Society (EACS), decided to revisit this definition, reviewing the feasibility of incorporating data on markers of recent infection to enable better distinction between people diagnosed with HIV late and people recently acquiring HIV.

### **MATERIALS AND METHODS**

The EuroTEST Initiative convened a working group of experts in HIV from Europe, including clinicians, epidemiologists, public health professionals and civil society, to review the existing late HIV diagnosis definition in January 2022. Multiple meetings were held for stakeholders to discuss possible updates to the definition based on previous research.(7-9) The full list of experts consulted can be found in Appendix 1.

In May 2022, a short survey was developed by the EuroTEST HIV Late Diagnosis Definition Working Group and sent to all 53 national surveillance contact points for HIV in the WHO European Region by the ECDC and WHO (one per country). Responses were entered onto the Research Electronic Data Capture (REDCap) online tool, hosted at the Centre of Excellence for Health, Immunity and Infections (CHIP).(10, 11) The main aim of this survey was to better understand the availability and flow of data on recent infection needed to be able to re-classify late HIV diagnoses and to monitor the modified late diagnosis indicator at a national and European level. Respondents were asked about baseline assessments carried out when people are diagnosed with HIV, data collection, data caveats and whether there are currently any adjustments made to national late HIV diagnosis figures to account for recent infection in their country. Submitted data was validated by the ECDC, where applicable. The full survey can be found in Appendix 2.

## **RESULTS**

### **Definition**

Late HIV diagnosis: A person first diagnosed with HIV with a CD4 count <350 cells/ $\mu$ l or with an AIDS-defining event, regardless of the CD4 cell count.

People with evidence of recent infection (i.e. being diagnosed during seroconversion) should be reclassified as 'not late'. Evidence of recent infection should be considered hierarchically; the individual must have either: i) laboratory evidence of recent infection (recent infection testing algorithm (RITA), p24 antigen), ii) a last negative HIV test within 12 months of HIV diagnosis or iii) clinical evidence of acute infection (e.g. seroconversion illness). People with evidence of being previously diagnosed, either abroad or elsewhere, should be excluded from the calculation of the proportion of the population diagnosed late.

This definition has been adapted from the previously published definition (3) to describe late HIV diagnosis rather than late presentation, to focus on people newly diagnosed with HIV. Twelve months was chosen as a pragmatic cut-off for timing of last negative HIV test to broadly align with current HIV testing recommendations.(12) It is also known that most people who are seroconverting recover their CD4 count within a year,(13) typically within six months, and those who do not could rather be considered as 'fast progressors'.(6, 14, 15) Furthermore, research from the UK and Sweden shows that among people newly diagnosed with HIV with a negative test recorded, the vast majority had their last negative test within the most recent year, so lengthening the cut-off would have minimal effect.(9, 16) The 12-month cut-off was endorsed by members of the EACS Governing Board and antiretroviral therapy (ART) panel group.

We recommend people with evidence of being previously diagnosed with HIV should be excluded from the late diagnosis calculation as their current positive test is not their first and thus, they are not being newly diagnosed.

### **Survey to European countries**

Overall, the response rate for the survey was relatively low, with respondents from only 18 countries participating: Albania, Belgium, Denmark, France, Georgia, Germany, Greece, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Netherlands, Serbia, Slovakia, Spain, Sweden and the United Kingdom (UK). All questions were answered by respondents from all countries.

Baseline assessments at presentation: In all 18 countries, the standard of care for people newly diagnosed with HIV is to have a CD4 count taken and be asked about previous HIV diagnosis elsewhere (e.g. abroad). Seventeen (94%) respondents reported that people are assessed for clinical symptoms of AIDS-defining illnesses (clinical judgement based on symptoms and medical history), 16 (89%) that HIV testing history information is collected, 16 (89%) that the individual is assessed for clinical symptoms of seroconversion illness and 14 (78%) that laboratory testing for evidence for seroconversion (HIV polymerase chain reaction (PCR) or antigen positive but HIV antibody negative) is carried out. Only six (38%) country respondents reported people newly diagnosed with HIV are tested for recent infection (e.g. avidity testing).

Clinical data flows: Not all country respondents reported being able to capture data needed to re-classify late HIV diagnoses at a national level (Table 1); 15 (83%) reported AIDS at diagnosis is able to be captured through national surveillance mechanisms, 15 (83%) CD4 count at diagnosis, 12 (67%) last negative HIV test, 12 (67%) previous HIV diagnosis, 11 (61%) information on seroconversion illness at diagnosis and only five (28%) incident HIV antibody test results. While the respondent for Belgium reported that laboratory findings of seroconversion are collected as part of national HIV surveillance with a coverage of almost 100%, the respondent for Ireland reported that all avidity testing has been paused due to resourcing issues. In Georgia, RITA surveys are conducted periodically, dependent on funding, but are not part of routine surveillance. In Sweden, incidence HIV antibody results are only available from HIV clinical cohort study data from Stockholm and Gothenburg. Only respondents from three countries, France, Ireland and the UK, reported that all surveyed indicators needed to apply the revised late HIV diagnosis definition are captured nationally. Most respondents who reported at least one data item not being available at a national level, indicated that these data were available either locally (nine countries) or through cohort

studies (three countries), highlighting potential for expanding data collection nationally and opportunities for collaboration.

Data caveats: Respondents for each country were asked what data caveats would need to be considered if HIV surveillance data indicating recent infection were used to adjust late diagnosis figures at a national level. In terms of incident antibody testing, seven respondents reported testing was not carried out in their country, while five indicated the testing results were not collected centrally, one reported there was a significant reporting delay in receiving the results, one reported incomplete linkage between datasets and four that the data source did not cover all cases. The most common reasons for difficulty in providing last HIV test information were significant missing data (10 respondents), incomplete coverage (five respondents) and incomplete linkage between datasets (five respondents). Significant missing data was also a barrier reported by 10 respondents in collecting data on seroconversion illness; a further five respondents reported seroconversion illness data are not currently collected centrally.

Respondents from Spain, the UK, Denmark, France and Belgium reported that late HIV diagnosis figures are adjusted for recent infection in their country. The respondent from the Netherlands reported that figures had been adjusted previously and the respondent from Serbia reported that adjustments had been attempted previously. Fourteen respondents expressed an interest in being involved in future work to attempt to quantify the 'seroconversion effect' correction factor for MSM diagnosed late in their countries.

## **DISCUSSION**

We present a revised consensus definition of late HIV diagnosis, in which people known to be diagnosed during seroconversion are reclassified as 'not late'. This represents a pragmatic approach to take into account observed increases in HIV testing frequency in Europe and this revision will ensure continued relevance of this longstanding key HIV metric for public health monitoring.

The application of this definition by national public health agencies and institutions is recommended but it is acknowledged this is dependent on reporting of surveillance data relating to late HIV diagnosis (CD4 count and AIDS at diagnosis) and evidence of recent infection (presence of seroconversion illness, last negative HIV test date or incident antibody testing). Our survey findings show this is currently only possible in some countries. However, it is important to note that respondents from only 18 countries responded to the survey, likely due to competing priorities, including coronavirus and monkeypox virus, with limited representation from Eastern European countries. Expansion of HIV surveillance

mechanisms to facilitate data collection of these markers is essential to ensure uptake is comprehensive across Europe. In some circumstances, collaboration with HIV clinical cohort studies of people with HIV may be able to fill data gaps. Analyses from Spain and France show that in the absence of surveillance data, the use of cohort data is feasible for identifying the prevalence of recent infection at national level.(17, 18)

This consensus definition of late HIV diagnosis has been endorsed by the EACS and adopted by the ECDC and WHO Regional Office for Europe. The European Surveillance System (TESSy) for HIV currently includes a variable on acute HIV infection,(19) which will be adapted based on this work. This will facilitate comparisons between countries and assessment of trends over time across Europe where possible. It will also allow for a more accurate assessment of the effectiveness of national HIV testing programmes in reaching people who are underserved.

Respondents from some Western European countries reported already adjusting their national late HIV diagnosis figures for recent infection.(7-9) With regard to the extent that these adjustments have been found to affect late HIV diagnosis rates, there was variation by country and sub-population. A study from Belgium, showed that, in 2012, late HIV diagnosis dropped by 9%, from 42%, to 33%, after reclassification based on reported recent infection by clinicians.(7) In the UK, late HIV diagnosis dropped by 7%, from 49% to 42% in 2019, following reclassification based on RITA testing and/or a negative test within the last 24 months.(9) In both Belgium and the UK, reclassification was more frequent among MSM compared to people who acquired HIV through heterosexual contact.(7) Data from the national Swedish InfCareHIV registry between 2017 to 2021, showed that late HIV diagnosis dropped from 55% to 52% after reclassification of people with primary HIV infection and evidence of a negative HIV test within one year of HIV diagnosis to 'not late'.(16, 20)

In conclusion, adoption of this revised consensus definition of late HIV diagnosis by national health agencies, institutions and researchers is needed to ensure consistent monitoring of access to HIV testing. Reclassification of individuals with recent infection will help to reduce overestimation of late HIV diagnosis estimates and better identify populations most at risk of poor HIV outcomes and areas for intervention, to further expand and target HIV testing in the era of elimination of HIV transmission. International public health bodies, such as the ECDC and WHO, should continue to work with countries to improve reporting of data needed to reclassify late HIV diagnoses. Furthermore, collaboration between agencies responsible for national HIV surveillance and HIV clinical cohorts should be strengthened to try to address gaps in data availability.



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## **AUTHOR CONTRIBUTIONS**

All authors were involved in the development of the survey on late HIV diagnosis and contributed important intellectual content to this manuscript. All authors commented on the manuscript and approved the final draft. SC was responsible for creating the survey and carried out data analysis with LC and ARS. SC also drafted the manuscript, incorporated author comments, and was responsible for the final draft to be published. LC created the

survey in REDCap. ARS and DR were responsible for convening the expert group on behalf of EuroTEST. VCD and DR contributed to the study conception. AS, DVB, GK, VD, AP, SC and TN provided public health and surveillance expertise; AS, SG, OK, EG and JB provided clinical input. DS and ND provided a community perspective.

## **DATA AVAILABILITY STATEMENT**

The data that support the findings of this study are available on reasonable request from the corresponding author. The data are not publicly available due to privacy restrictions.

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## **DECLARATIONS OF INTEREST**

SC, ARS, LC, JVL, JB, ND, SG, GK, AP, TN, DR, DS, AKS, DVB and VCD report no conflicts of interest to disclose. JKR reports honoraria for consulting or speaking at educational events from Abivax, Boehringer, Galapagos, Gilead, Janssen, Merck, Theratechnologies and ViiV, outside the submitted work. EG received grants support from Gilead Sciences and Mylan, and speaker's honoraria from Gilead Sciences, outside the submitted work. OK reports a research grant from Gilead, and non-financial support from Merck, outside the submitted work.

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