UNAIDS/WHO WORKING GROUP ON LOBAL HIV/AIDS AND STI SURVEILLANCE

## WHO WORKING GROUP ON HIV INCIDENCE ASSAYS MEETING REPORT ESTIMATING HIV INCIDENCE USING HIV INCIDENCE USING HIV CASE SURVEILLANCE

10-11 DECEMBER 2015 GLION, SWITZERLAND





### UNAIDS/WHO Working Group on Global HIV/AIDS and STI Surveillance

Global surveillance of HIV and sexually transmitted infections is a joint effort of the World Health Organization (WHO) and the Joint United Nations Programme on HIV/AIDS (UNAIDS). The UNAIDS/ WHO Working Group on Global HIV/AIDS and STI Surveillance, initiated in November 1996, is the main coordination and implementation mechanism for UNAIDS and WHO to compile the best information available and to improve the quality of data needed for informed decision-making and planning at the national, regional and global levels.



**HIV/AIDS Programme** 

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# **ABBREVIATIONS**

AIDS	acquired immunodeficiency syndrome
ALPHA	Analysing Longitudinal Population-based HIV-AIDS data on Africa
ANC	antenatal clinic
ART	antiretroviral therapy
ARV	antiretroviral
CASCADE	Concerted Action on SeroConversion to AIDS and Deaths in Europe
CDC	Centers for Disease Control and Prevention
CEPHIA	Consortium for the Evaluation of the Performance of HIV Incidence Assays
CI	confidence interval
DBS	dry blood spot
DHS	Demographic Health Survey
DRC	Democratic Republic of the Congo
ECDC	European Centre for Disease Prevention and Control
EIA	enzyme immunoassay
EPP	Estimation and Projection Package
FIND	Foundation for Innovative New Diagnostics
FRR	false recent rate
GUM	genitourinary medicine
GUMCAD	genitourinary medicine clinic activity dataset
HIV	human immunodeficiency virus
ID	identity document
LAg	SEDIA HIV1 Lag-Avidity enzyme immunoassay
MDRI	mean duration of recent infection
MeSH	Measurement and Surveillance of HIV Epidemics
MPES	Multi-Parameter Evidence Synthesis
MSM	men who have sex with men
PEPFAR	President's Emergency Plan for AIDS Relief (United States)
PLHIV	people living with HIV
РМТСТ	prevention of mother-to-child transmission
PHE	Public Health England
PrEP	pre-exposure prophylaxis
PWID	people who inject drugs
RITA	recent infection testing algorithm
SOP	standard operating procedure
SWOT	strengths, weaknesses, opportunities and threats
ТРР	target product profile
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNSW	University of New South Wales
VL	viral load
WB	western blot

# **1. BACKGROUND**

In 2008, WHO established a Working Group on HIV Incidence Assays to look into the issues and challenges involved in assay-based estimation of HIV incidence (i.e. the number of new infections that occur in a population per period of time). The Working Group comprises epidemiologists, laboratory specialists and public health officials, and has worked to standardize terminology in the areas of assay calibration and validation.

Several meetings to advance the agenda have been held, and copies of reports are available on the Working Group's webpage.<sup>1</sup> The meetings have successfully brought together a wide group of assay users (in particular, from countries affected by the epidemic who may consider using HIV incidence assays in the future) and key experts in the field who apply laboratory-based methods for estimating HIV incidence. They have also highlighted the importance of HIV incidence as a key indicator of national programme success or failure. Clearly, ministries of health need to be aware of the complexities of producing estimates based on data generated by the currently available assays.

In collaboration with the Joint United Nations Programme on HIV/AIDS (UNAIDS) and the Centers for Disease Control and Prevention (CDC) in Atlanta, Georgia, the Working Group has:

- produced a guidance document on how to estimate HIV incidence at the population level using HIV incidence assays in cross-sectional surveys; and
- provided technical updates in the use of HIV incidence assays.

This information has been incorporated into the updated guidelines on monitoring the impact of the HIV epidemic using population-based surveys (1). In addition, UNAIDS/ WHO have produced regular technical updates.<sup>2</sup>

In many countries, surveillance of HIV infection relies mostly on HIV or AIDS case-based surveillance. Such surveillance is currently defined as a reporting system through which all new cases of HIV infection detected (i.e. diagnosed) at any stage are reported over time. HIV case notification makes reference to the methods used to capture information at the individual level about those diagnosed with HIV infection. However, the variable and often long time between infection and diagnosis means that HIV case surveillance does not directly reflect current patterns of virus transmission or incidence. Trends in the number of reported cases can result from changing patterns in HIV incidence, uptake of HIV testing or both. This limitation in the interpretation of diagnosis data underscores the need to measure HIV incidence to monitor HIV transmission.

Several methods for estimation of HIV incidence have been used in both developed and developing countries, including cohort studies, back calculation, modelling of repeated cross-sectional measures of prevalence, and cross-sectional use of biomarker assays for recent infection. The use of data from HIV case-based surveillance poses a new challenge to HIV-estimation methodology.

The United States and some European countries have developed and applied methods that use data from routine case-based surveillance to estimate HIV incidence. These approaches are promising and their implementation could be expanded to other developed countries.

An overview of the development of guidance for estimating HIV incidence with a recent infection testing algorithm (RITA) using case-based surveillance data was presented at the Working Group meeting in Barcelona in 2014. Consensus was reached during the meeting that the guidance should continue to be developed, because case reporting is becoming increasingly common in middle- and lower-income countries. In addition, WHO and partners are developing a guide to case surveillance and patient monitoring, to promote and improve HIV case reporting and the HIV national response in the health sector. These systems develop and link different databases; therefore, the UNAIDS/WHO Working Group on Global HIV/AIDS and STI Surveillance is exploring how these new information sources could be used in estimating incidence.

<sup>1</sup> http://www.who.int/diagnostics\_laboratory /links/hiv\_incidence\_assay/en/

<sup>&</sup>lt;sup>2</sup> http://www.who.int/hiv/pub/me/tech\_update\_0513/en/

# **2. OBJECTIVES, METHOD OF WORK AND EXPECTED OUTCOMES**

Incidence assays and other data collected in a casesurveillance system are used for two purposes: to identify new infections among diagnosed cases and to estimate HIV incidence at population level. The objectives of the workshop were to:

- review the different approaches used to estimate new infections and incidence in countries;
- agree on the inputs needed and the assumptions for new HIV infection cases, and how to estimate incidence using data collected by HIV case-reporting systems;
- agree on the methods and conditions for the application of the HIV incidence testing; and
- develop final recommendations on the methods and requirements for using HIV case-reporting data to estimate HIV incidence.

The 2-day meeting was dedicated to discussion of how to estimate HIV incidence using case reporting, and the methods used in some countries to achieve this. Expected outcomes were to:

- share progress on application of HIV incidence assays on HIV case reporting in different countries, and other methods such as CD4 count and back calculation; and
- provide a matrix of methods that can be used for HIV incidence estimation, with the parameters needed and the conditions under which to use such methods in countries with HIV case-reporting systems.

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