



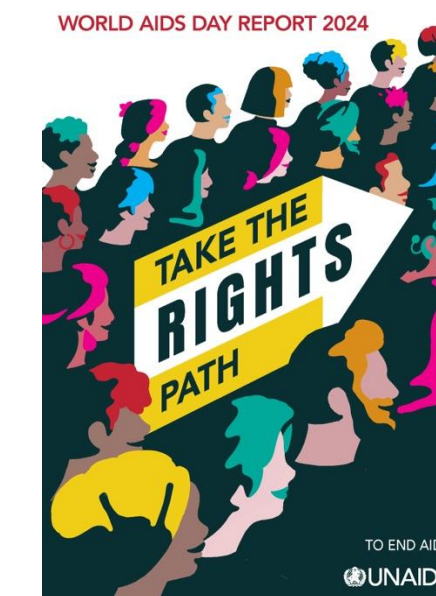
HIV: la pandemia silenziosa

Andrea Antinori
Dipartimento Clinico e di Ricerca Malattie Infettive
Istituto Nazionale per le Malattie Infettive
Lazzaro Spallanzani IRCCS, Roma



Global HIV statistics

- **39.9 million** [36.1 million–44.6 million] people globally were living with HIV in 2023.
- **1.3 million** [1 million–1.7 million] people became newly infected with HIV in 2023.
- **630 000** [500 000–820 000] people died from AIDS-related illnesses in 2023.
- **30.7 million** people [27–31.9 million] were accessing antiretroviral therapy in 2023.
- **88.4 million** [71.3 million–112.8 million] people have become infected with HIV since the start of the epidemic.
- **42.3 million** [35.7 million–51.1 million] people have died from AIDS-related illnesses since the start of the epidemic.



Global HIV data , 2000-2023

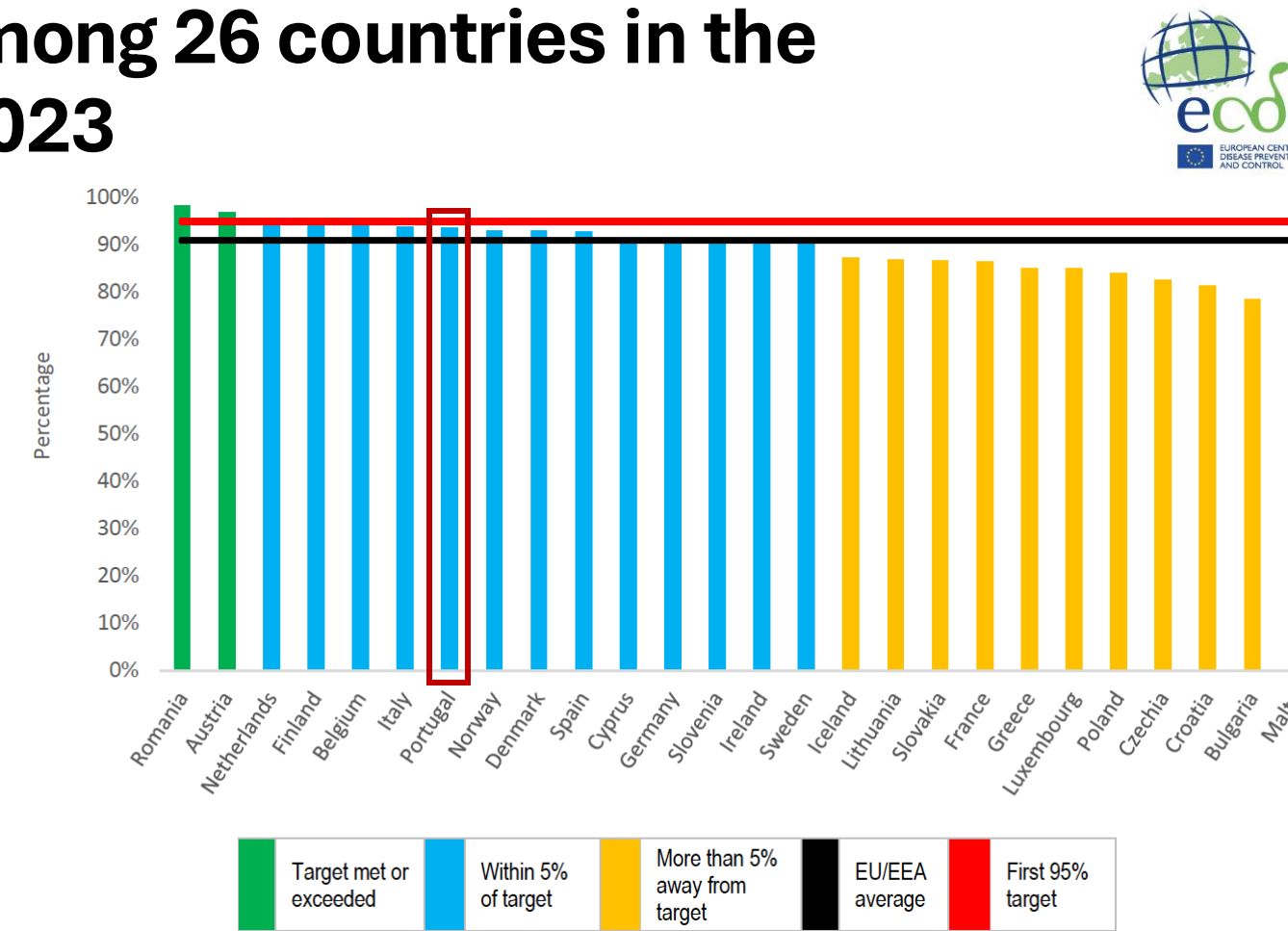


	2000	2005	2010	2020	2022	2023
People living with HIV	27.2 million [24.6 million–30.4 million]	29.4 million [26.6 million–32.9 million]	32 million [29.0 million–35.8 million]	38.7 million [35.0 million–43.2 million]	39.5 million [35.8 million–44.2 million]	39.9 million [36.1 million–44.6 million]
New HIV Infections	2.8 million [2.3 million–3.6 million]	2.5 million [2.0 million–3.2 million]	2.1 million [1.7 million–2.7 million]	1.5 million [1.2 million–1.9 million]	1.4 million [1.1 million–1.7 million]	1.3 million [1.0 million–1.7 million]
AIDS related deaths	1.8 million [1.4 million–2.3 million]	2 million [1.6 million–2.6 million]	1.3 million [1.0 million–1.7 million]	730 000 [570 000–940 000]	670 000 [530 000–870 000]	630 000 [500 000–820 000]
New HIV Infections (Adults, aged 15+)	2.3 million [1.9 million–3.0 million]	2 million [1.6 million–2.6 million]	1.8 million [1.5 million–2.4 million]	1.3 million [1.1 million–1.7 million]	1.2 million [980 000–1.6 million]	1.2 million [950 000–1.5 million]
New HIV Infections (Children, aged 0–14)	530 000 [380 000–760 000]	470 000 [340 000–680 000]	300 000 [220 000–440 000]	150 000 [110 000–210 000]	130 000 [94 000–190 000]	120 000 [83 000–170 000]
People accessing antiretroviral therapy	510 000 [450 000–530 000]	1.9 million [1.7 million–2.0 million]	7.7 million [6.7 million–8.0 million]	26.2 million [23.1 million–27.3 million]	29.3 million [25.7 million–30.4 million]	30.7 million [27.0 million–31.9 million]
Resource availability	US\$ 5.1 billion	US\$ 9.3 billion	US\$ 16.7 billion	US\$ 21.5 billion	US\$ 20.8 billion	US\$ 19.8 billion



Estimated number of PLHIV among 26 countries in the EU/EEA, based on data as of 2023

Countries	PLHIV
Austria	7 732
Belgium	19 177
Bulgaria	3 199
Croatia	1 795
Cyprus	1 354
Czechia	3 983
Denmark	7 100
Finland	3 532
France	178 700
Germany	90 800
Greece	17 175
Iceland	368
Ireland	7 200
Italy	140 730
Lithuania	3 626
Luxembourg	1 455
Malta	814
Netherlands	24 110
Norway	4 572
Poland	18 923
Portugal	45 532
Romania	18 221
Slovakia	19 415
Slovenia	898
Spain	148 371
Sweden	9 455
TOTAL	778 237



Proportion of PLHIV who had been diagnosed in 26 countries of the EU/EEA, based on data as of 2023

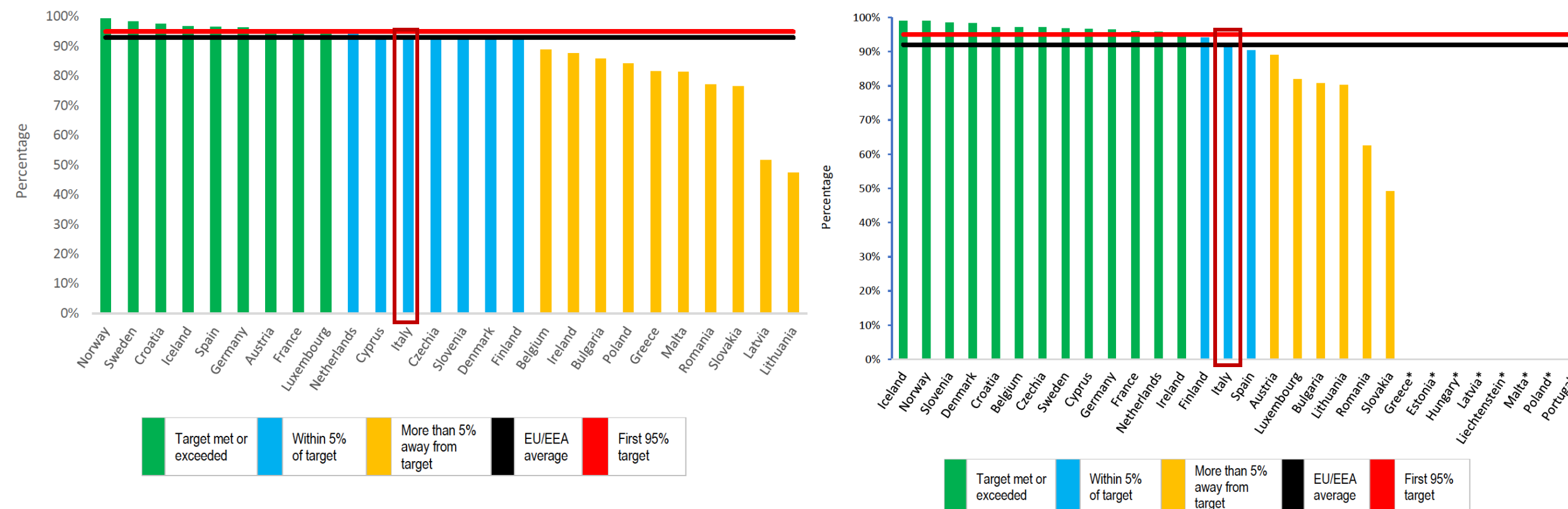
In Italy, by 2023 data, a total of 140,730 PLWH were estimated, with 132,098 PLWH diagnosed (94%).

European Centre for Disease Prevention and Control. Continuum of HIV care. Monitoring implementation of the Dublin Declaration on partnership to fight HIV/AIDS in Europe and Central Asia: 2023 progress report. Stockholm: ECDC; 2024.

Proportion of diagnosed PLHIV who were on treatment and people on treatment achieving viral suppression in 26 countries in the EU/EEA, based on data as of 2023

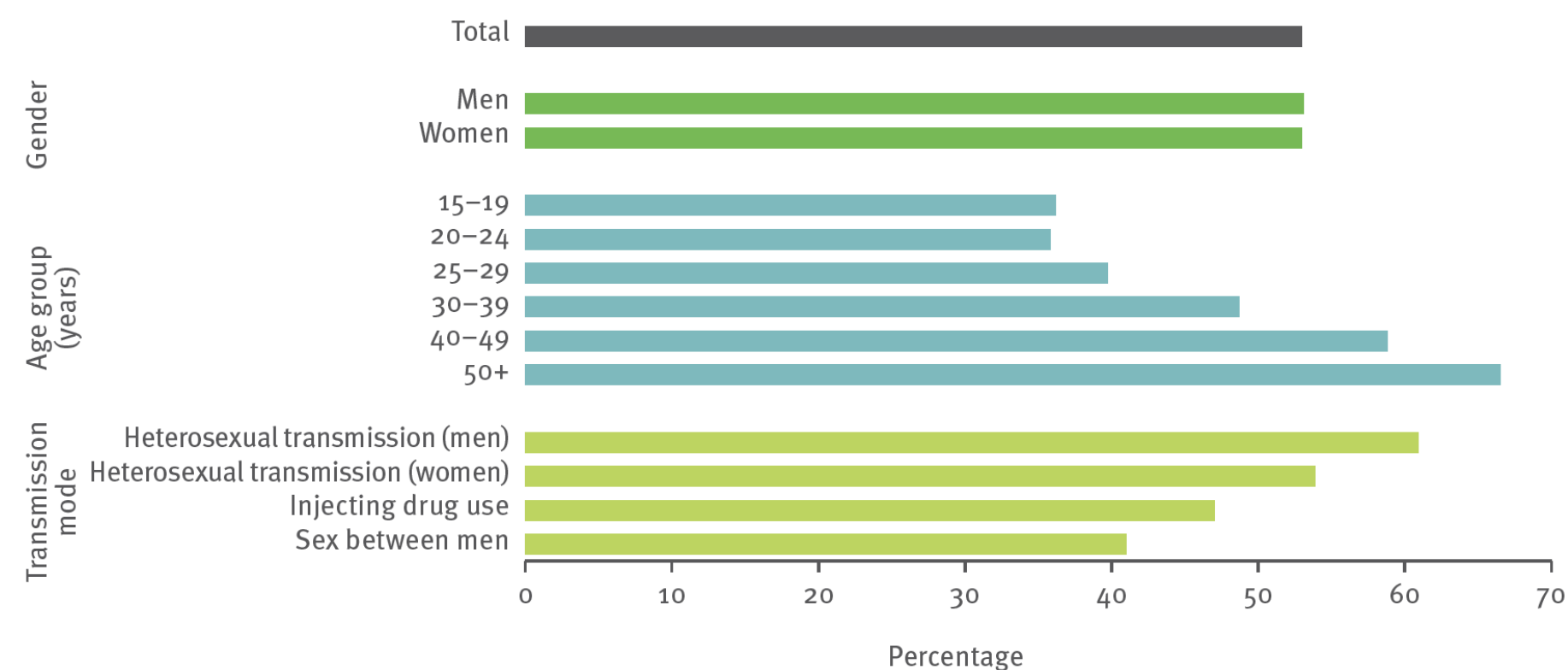


In Italy, by 2023 data, among 132,098 PLWH diagnosed, 123,359 were estimated to be treated (93%), with 113,430 of PLWH treated who have achieved viral suppression (92%).



European Centre for Disease Prevention and Control. Continuum of HIV care. Monitoring implementation of the Dublin Declaration on partnership to fight HIV/AIDS in Europe and Central Asia: 2023 progress report. Stockholm: ECDC; 2024.

**Proportion of people diagnosed late (CD4 cell count < 350 per mm³)
 by gender, age and transmission
 WHO European Region, 2022 (n = 28,718)**



Note: Cases with unknown CD4, acute cases, and previous positives are excluded from this figure. CD4 data from the Russian Federation was excluded as it did not include age, sex, and transmission route breakdowns

European Centre for Disease Prevention and Control/WHO Regional Office for Europe. HIV/AIDS surveillance in Europe 2023 – 2022 data. Stockholm: ECDC; 2023.

Persistent poor clinical outcome of PLWH presenting with AIDS and late HIV diagnosis. Italy, 2009-2022



Of **6813 participants** (2448 non-LD, 3198 LD asymptomatic, and 1167 LD-AIDS), **161 (2.4%) died after ART initiation**. A higher probability of all-cause mortality has been identified for LD than non-LD ($P < 0.001$) and within the former, for LD-AIDS over LD asymptomatic ($P < 0.001$). After adjusting for confounders, **LD showed a higher risk of all-cause mortality** (vs non-LD **aHR 5.51**, $P < 0.001$) and, in particular, being an **AIDS presenter predicted a greater risk of all-cause** (**aHR = 4.42**, $P < 0.001$), AIDS-related (**aSHR = 16.86**, $P < 0.001$), and **non-AIDS-related mortality** (**aSHR = 1.74**, $P = 0.022$) than the rest of the late presenters.

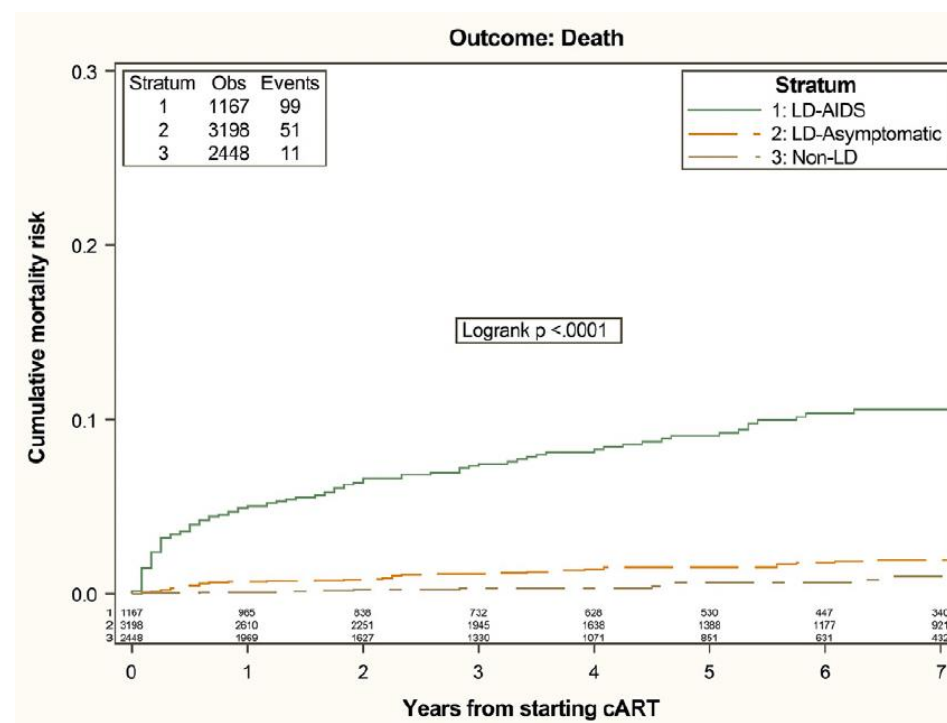


Table 2
HR and aHR for all-cause mortality (non-LD vs LD [Table 3a] and non-LD vs LD-asymptomatic vs LD-AIDS [Table 3b]) and SHR and aSHR for specific-cause mortality (AIDS-related [Table 3c] and non-AIDS-related mortality [Table 3d]) associated with LD.

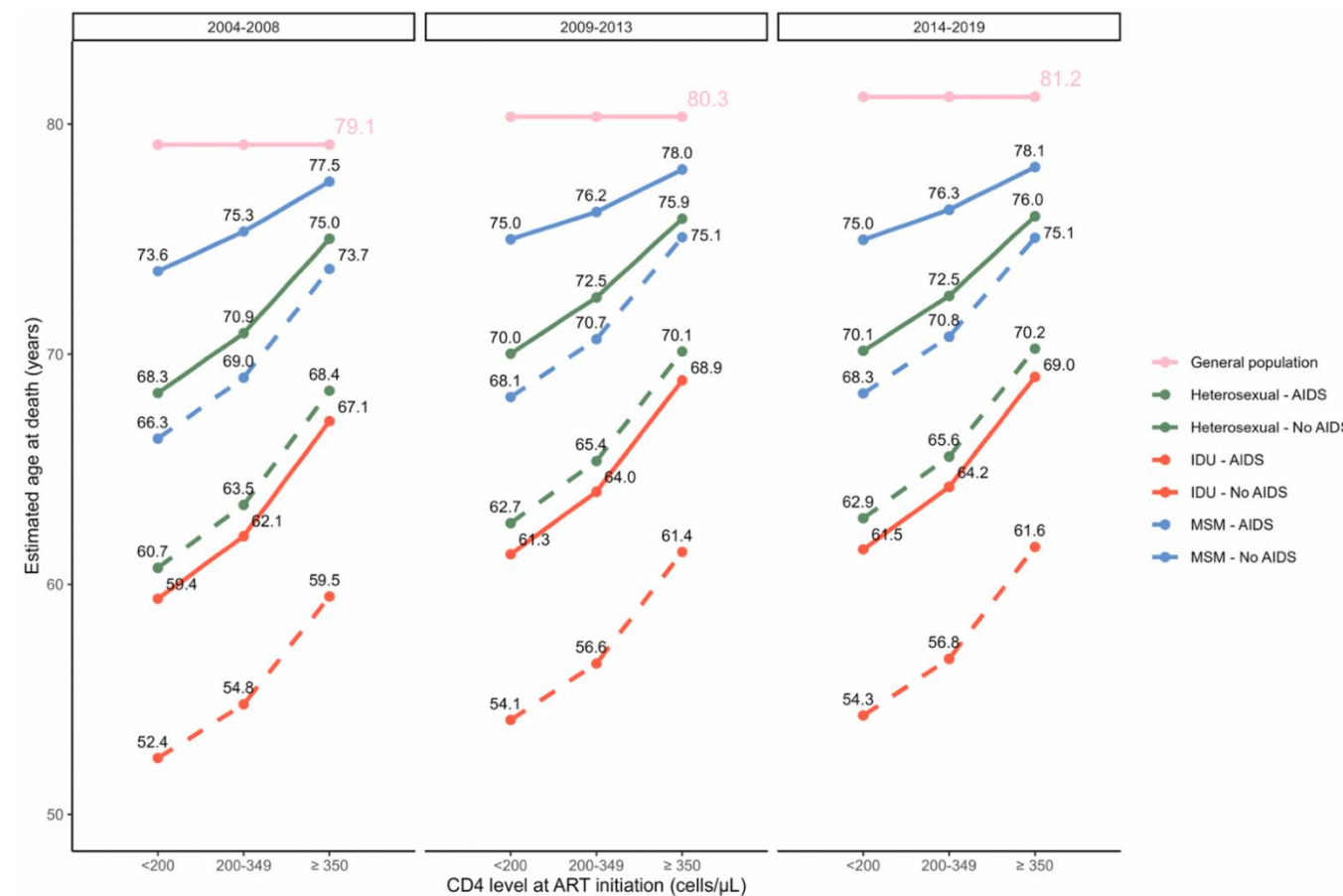
	HR	95% CI	P-value	aHR ^a	95% CI	P-value
Table 2a. All-cause mortality^b						
Non-LD	1	-	-	1	-	-
LD	6.86	3.72-12.67	<0.001	5.51	2.87-10.60	<0.001
X interaction test exposure group and calendar year of ART start: $P = 0.41$						
Table 2b. All-cause mortality^b						
LD-asymptomatic	1	-	-	1	-	-
LD-AIDS	5.19	3.70-7.28	<0.001	4.42	3.14-6.22	<0.001
Non-LD	0.31	0.16-0.60	<0.001	0.35	0.17-0.69	0.002
X interaction test exposure group and calendar year of ART start: $P = 0.07$						
Table 2c. AIDS-related mortality^c						
LD-asymptomatic	1	-	-	1	-	-
LD-AIDS	19.13	9.52-38.42	<0.001	16.86	8.24-34.46	<0.001
Non-LD	-	-	-	-	-	-
X interaction test exposure group and calendar year of ART start: $P = 0.42$						
Table 2d. Not AIDS-related mortality^c						
LD-asymptomatic	1	-	-	1	-	-
LD-AIDS	2.09	1.32-3.33	0.002	1.74	1.08-2.78	0.022
Non-LD	0.42	0.22-0.82	<0.001	0.53	0.26-1.11	0.093
X interaction test exposure group and calendar year of ART start: $P = 0.65$						

^a Adjusted for age, sex, mode of HIV transmission, nationality, calendar year for ART initiation, hepatitis coinfection, and type of ART regimen;
^b standard Cox regression model;
^c Fine-Gray Cox regression model. Abbreviations: aHR, adjusted hazard ratio; aSHR, adjusted sub-hazard ratio; ART, antiretroviral therapy; HR, unadjusted hazard ratio; CI, confidence interval; LD, late diagnosis; non-LD, non-late diagnosis; SHR, sub-hazard ratio.

Mondi A, et al. International Journal of Infectious Diseases 142 (2024) 106995

CoRIS Cohort

Gap of the age at death of PLWH compared to the general population correlates with advanced HIV infection



Jarrin I, et al. AIDS, 2023

Among the 16,759 participants included in the CoRIS cohort between January 1, 2004 and November 30, 2019, **14,194 who started ART aged ≥ 20 years were included in the study.**

Of them, 84.7% were men and the most frequent mode of HIV acquisition was **MSM (60.0%)**.

The median age at starting ART was 37 (IQR: 30-44) years, 41.3% started ART with CD4 ≥ 350 cells/μL and 13.0% had a previous AIDS diagnosis.



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Advanced HIV as a Neglected Disease

Nathan Ford, D.Sc., Peter Ehrenkranz, M.D., and Joseph Jarvis, M.B., B.S.

In the early decades of the global response to HIV/AIDS, the focus was on saving lives. And rightly so: without antiretroviral treatment (ART), people lived less than a year, on average, from the time they developed AIDS. But over the past 15 years, the focus has shifted to virologic control. Since modeling and trials have shown that treating HIV could not only benefit the infected person but also eliminate transmission, viral suppression has become the main measure of success for HIV programs. Global targets have focused attention on the numbers of

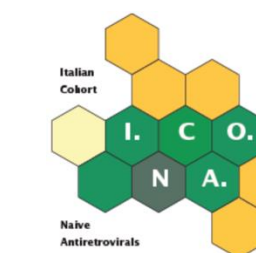
people who are tested, who begin receiving treatment, and in whom viral suppression is achieved. Reducing mortality is no longer a central metric.

For many years, HIV treatment was given only to people with a low CD4 count, who were at the highest risk for severe illness and death. In 2015, two large randomized trials showed that treatment should be started as soon as possible after infection. These results led to a rapid global shift in policy and funding, with the goal of getting as many people on treatment as early as possible. This

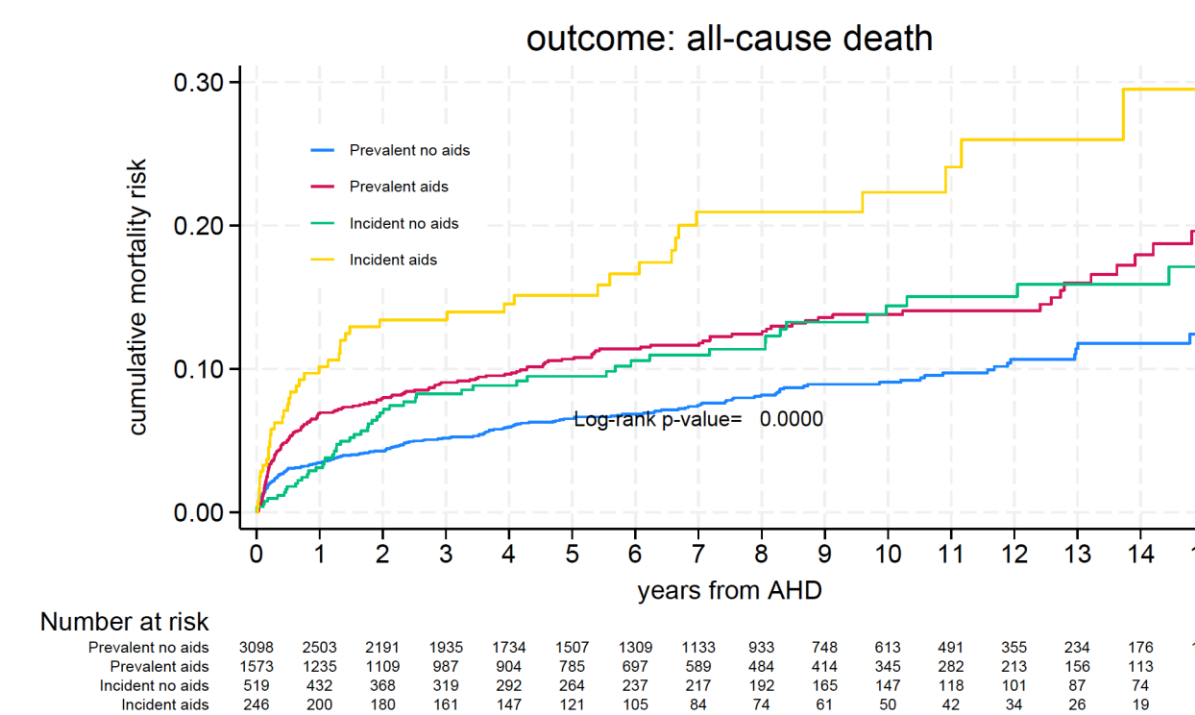
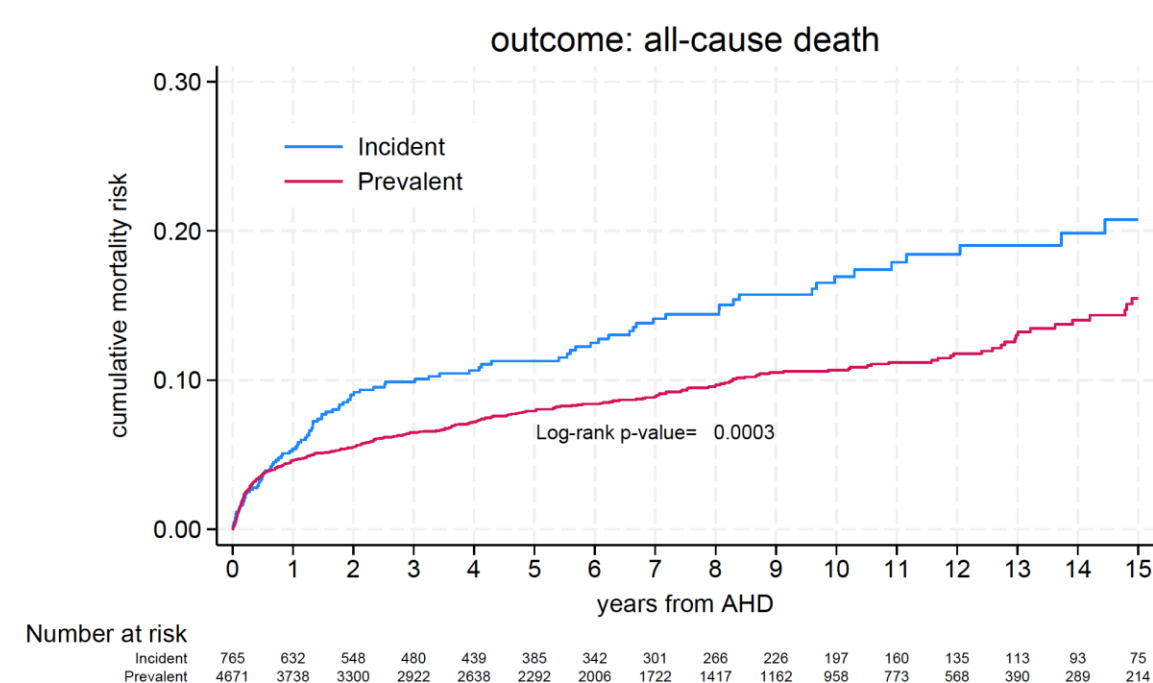
change led to the perception that CD4 testing was no longer essential. To help pay for increased treatment coverage and assessment of its impact on virologic outcomes, donors and countries reduced their support for CD4 testing, and testing rates within ART programs declined rapidly. This shift occurred despite consistent inclusion of CD4 testing in clinical guidelines from the World Health Organization (WHO) and other leading authorities, who deemed it essential at baseline and when a patient returned to care.

Although treatment coverage

Advanced HIV disease in individuals already in care: incidence and comparison with late presentation

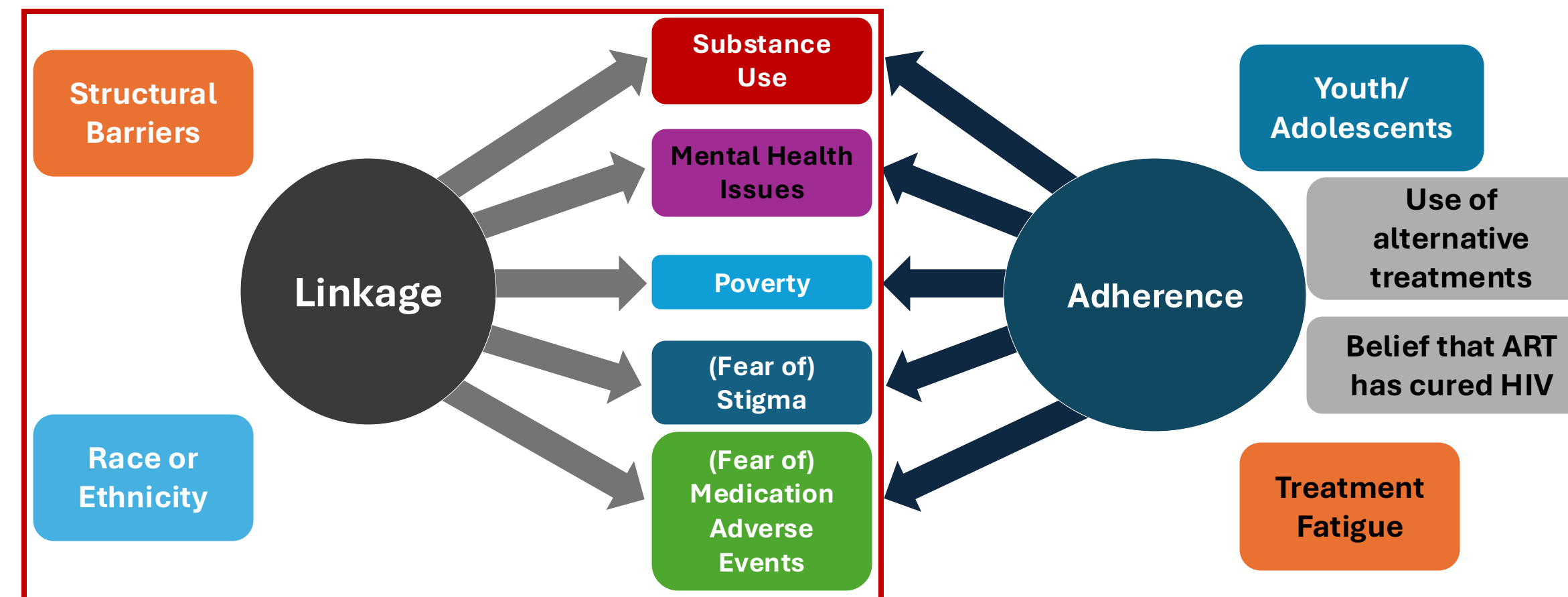


PWH enrolled in the Icona Foundation Study cohort with a first diagnosis of AHD (CD4<200cells/mm³ or AIDS-defining event [ADE]) between January 1, 2004, and December 31, 2023, were included. Participants were classified as having either a **prevalent AHD (pAHD: AHD diagnosed at the time of starting ART)** or an **incident AHD (iAHD: AHD diagnosed >3 months after starting ART)**, which was the main exposure of interest. **iAHD, compared to pAHD, showed worse clinical outcomes for a given set of risk factors for death.**



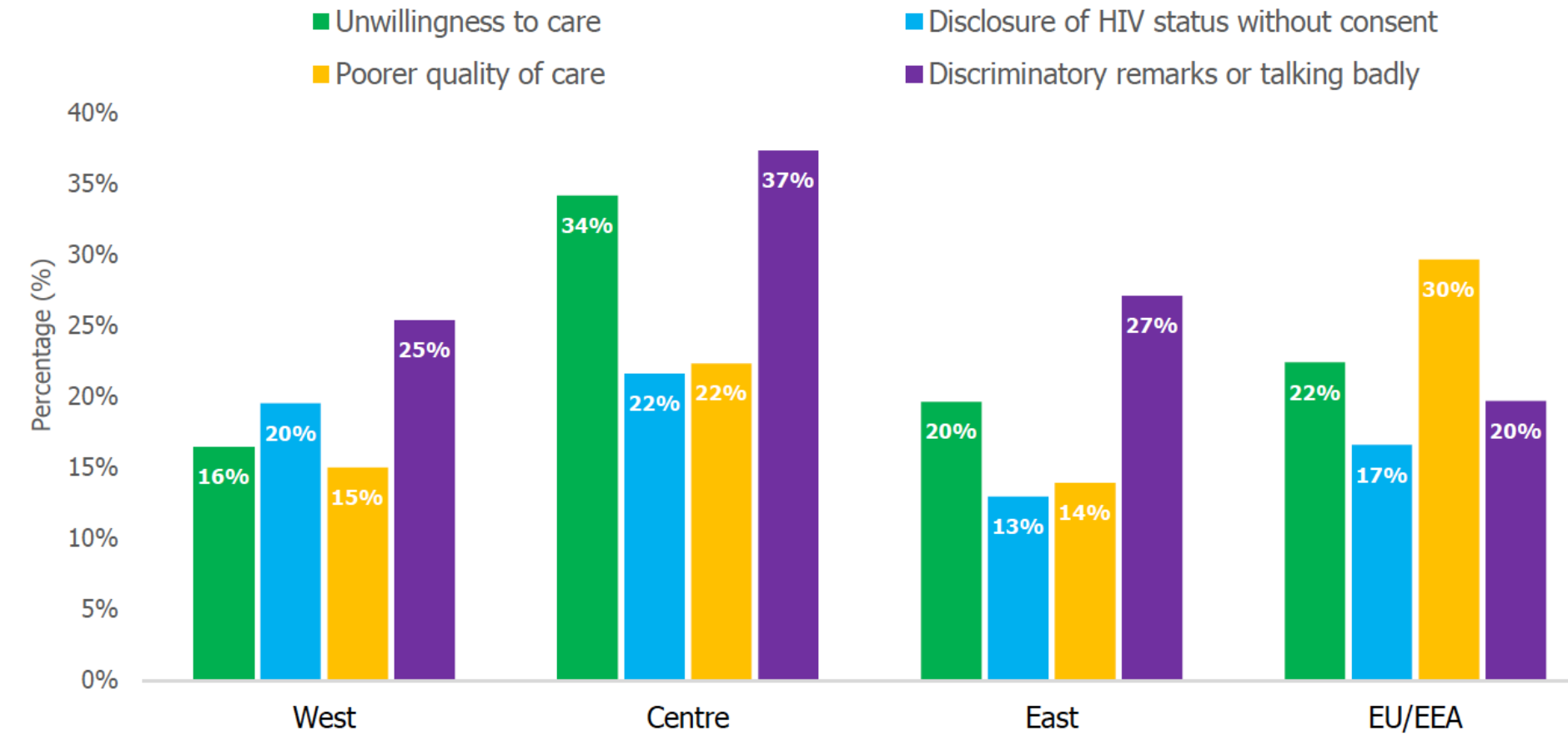
Mondi A, et al. CROI 2025; San Francisco (CA); March 9-12, 2025.

Factors That Predict Delayed Care Linkage and Inconsistent HIV Care and Treatment



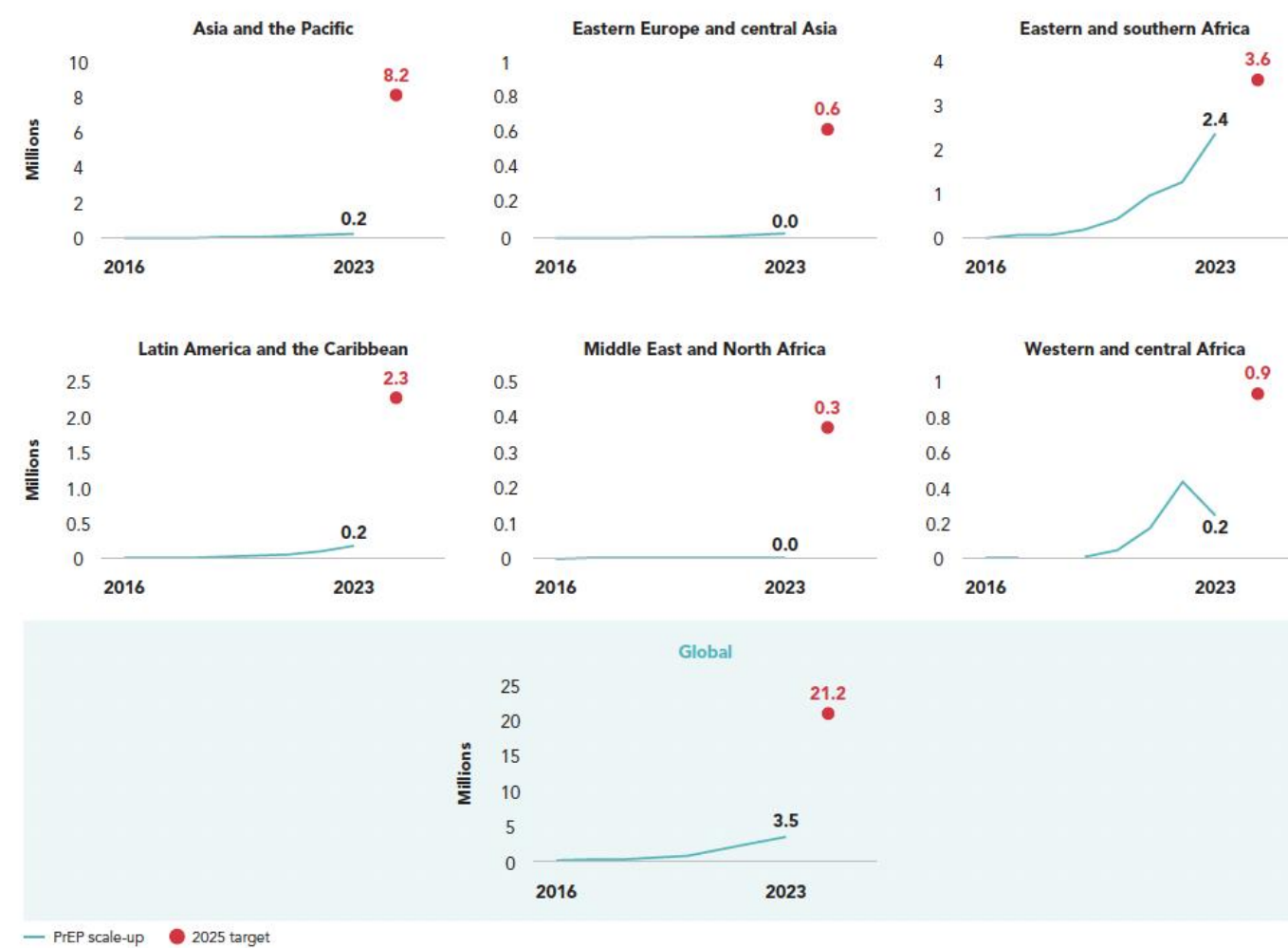
Camlin. AIDS. 2016;30:495. CDC. HIV Surveillance Suppl Report 201. Dombrowski. AIDS Patient Care STDS. 2015;29:279. Giordano. Top Antivir Med. 2011;19:12. Mayer. Clin Infect Dis. 2011;52(Suppl 2):S205.

Proportion of HCPs who have observed different forms of stigma and discrimination towards PLWH at their workplace during the past 12 months, by geographical region



European Centre for Disease Prevention and Control. HIV stigma in the healthcare setting. Monitoring implementation of the Dublin Declaration on partnership to fight HIV/AIDS in Europe and Central Asia. Stockholm: ECDC; 2024.

Scale-up in the number of people who received pre-exposure prophylaxis (PrEP) at least once during the reporting period, by region, 2016–2023 (blue), and 2025 target (red)



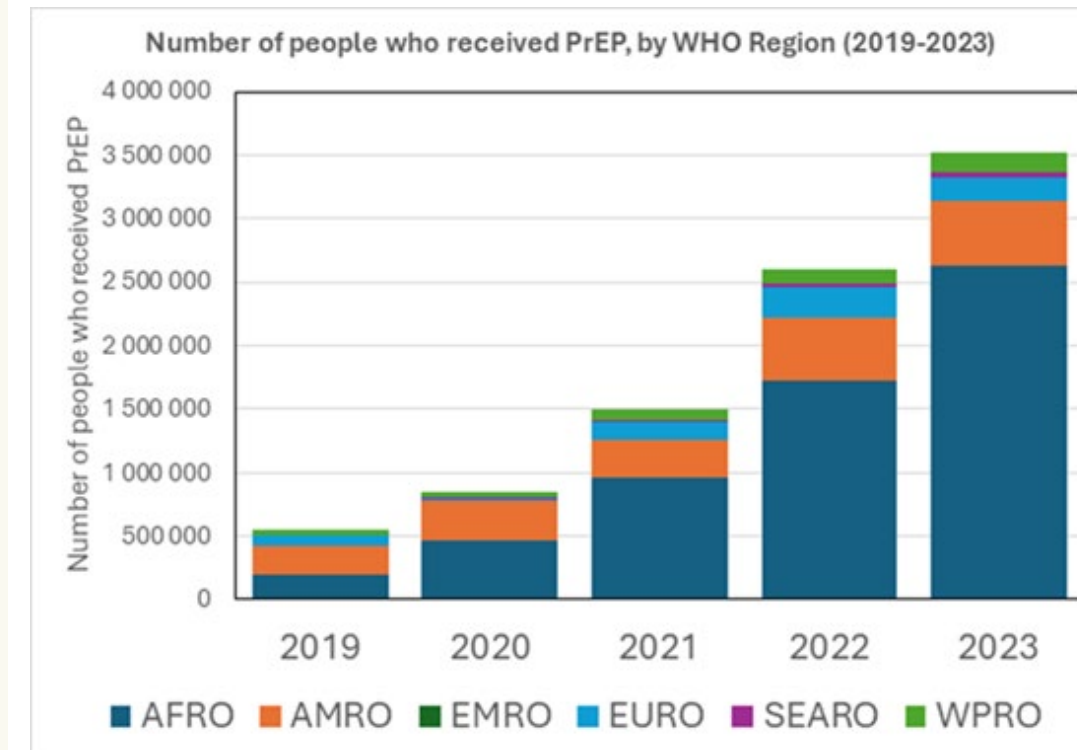
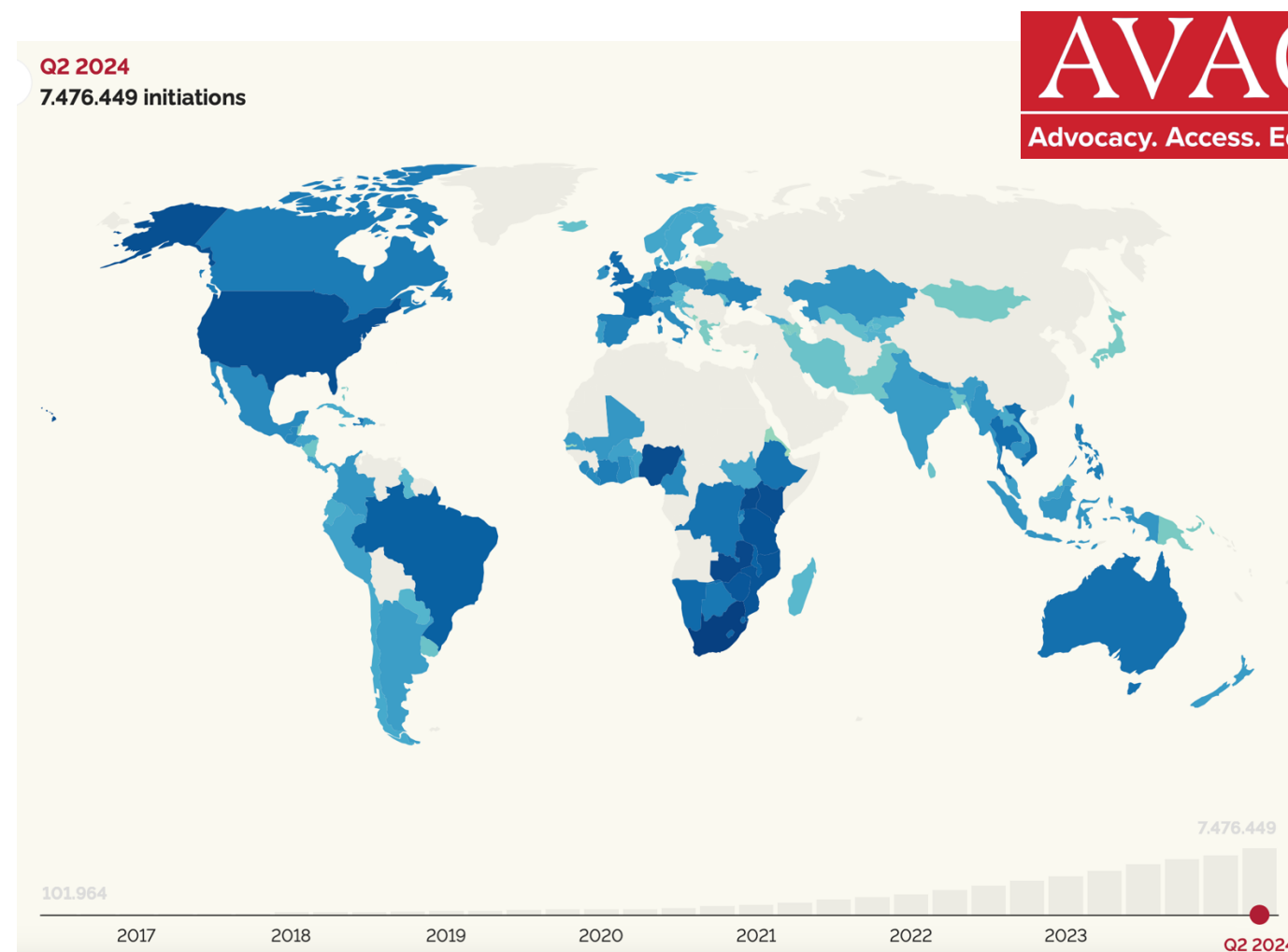
The total number of people using oral PrEP has risen from a little over 200 000 in 2017 to about 3.5 million in 2023 (Figure 2.15), but this remains far short of the 10 million target set for 2025 (this target is adjusted to reflect the number initiating PrEP at least once during the year). In 2023, only about 15% of the estimated need for this powerful prevention option was being met. Expanded access to PrEP is still limited to a small number of countries and is not reaching regions where PrEP need is predominantly among people from key populations.

2025 TARGET

21.2 million people using PrEP at least once during the past year

The urgency of now: AIDS at a crossroads. Geneva: Joint United Nations Programme on HIV/AIDS; 2024. Licence: CC BY-NC-SA 3.0 IGO.

How many people are in PrEP?



The urgency of now: AIDS at a crossroads. Geneva: Joint United Nations Programme on HIV/AIDS; 2024. Licence: CC BY-NC-SA 3.0 IGO.

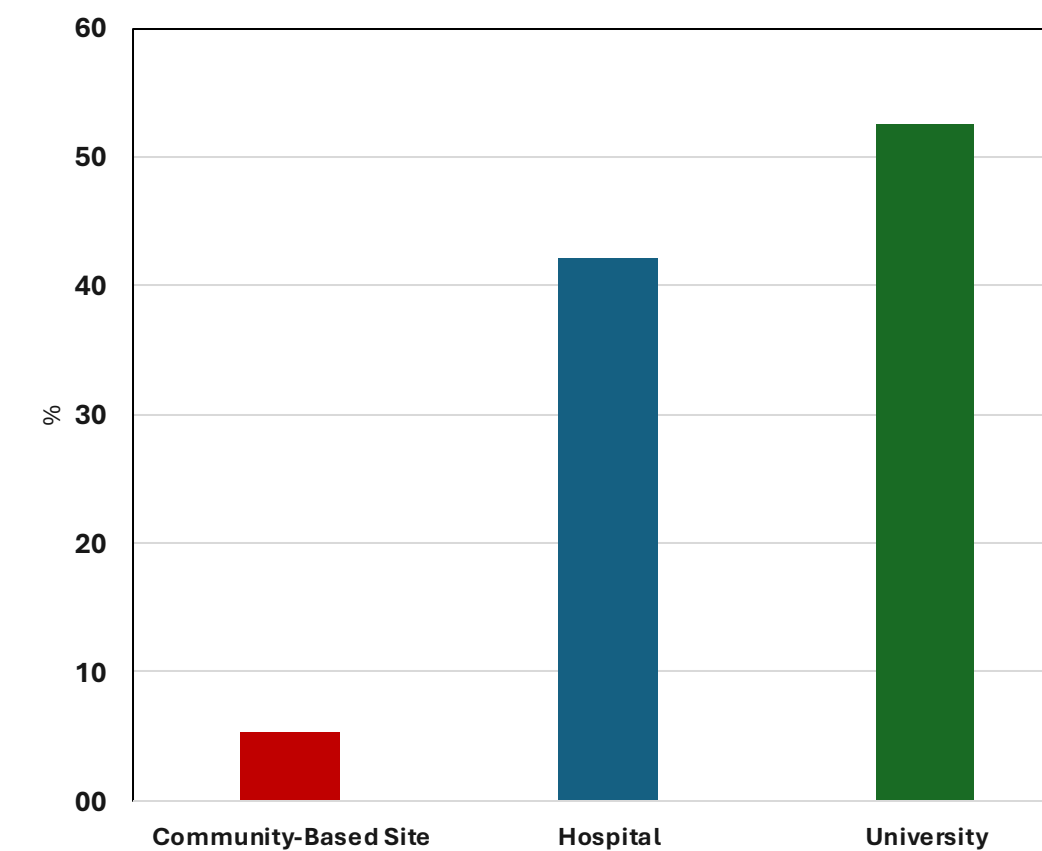
PRIDE Prevention Icona Dedicated Ensemble



57 Centers (53 ID Clinics of the Icona network, 4 Checkpoints)

- N. of high-risk people starting PrEP overall = 11,325
- **N. of PrEP users in active FU on the end of 2023 = 9,001**
- N. of new PrEP users in 2023 = 4,176

What is the quantitative target of PrEP users achievable in Italy?



Nozza S, et al. ICAR 2024; Nozza S, et al. HIV Therapy, Glasgow, 2024

ItaPrEP (2017-2023) Main characteristics of study participants



Total of participants	1,758
Gender, n(%)	
Male	1,731 (98.5%)
Female	14 (0.8%)
Transgender (MtF)	13 (0.7%)
Age, years, median (IQR)	
36.0 [31.0 44.0]	
Class of age	
<25	87 (4.9%)
25-39	1,050 (59.7%)
>40	621 (35.3%)
Italian Nationality	
No	300 (17.1%)
Yes	1,450 (82.9%)
Sexual orientation, n(%)	
MSM	1,599 (91.2%)
Heterosexual	35 (2.0%)
Bisexual	114 (6.5%)
Unknown	6 (0.3%)

Educational level, n(%)	
Primary school	5 (0.3%)
Junior high school	49 (3.0%)
High school	487 (30.2%)
University	1,071 (66.4%)
Job status, (%)	
Employed	1,370 (87.4%)
Unemployed	168 (10.7%)
Student	29 (1.9%)
Sex worker	
No	1,438 (97.0%)
Yes	44 (3.0%)
Criteria for starting PrEP	
inconsistent use of condom	1,216 (73.5%)
Previous STI	445 (29.0%)
Previous PEP	232 (15.0%)
Chemsex use	274 (17.8%)
Number of High-risk defining criteria	
0	270 (18.3%)
1	670 (45.5%)
2	380 (25.8%)
3	124 (8.4%)
4	28 (1.9%)
Median follow up in months	14.0 [5.9 27.6]

Mazzotta V, et al. 5th HIVR4P 2024; Lima, Peru. Abstr OA1006



Grazie per l'attenzione!