

**Original Article** 

# Partial Achievement of the 90-90-90 UNAIDS Target in a Cohort of HIV Infected Patients from Central Italy

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Abstract. *Background:* Despite progress in the prevention and treatment of HIV, persistent issues concerning the evaluation of continuum in care from the serological diagnosis to virologic success remains. Considering the 2020 UNAIDS target 90-90-90 for diagnosis, treatment, and viral suppression of people living with HIV (PLWH), our purpose was to verify if, starting from new diagnoses, the viral suppression rate of our cohort of new PLWH satisfied the second and the third steps.

*Methods:* This retrospective study regards all patients aged ≥15 undergoing HIV test at our clinic between January 2005 and December 2017. We evaluated the second and the third '90 UNAIDS targets and the unclaimed tests, linkage to care, retention in ART, and the viral suppression at 1 and 2 years. Logistic regression (odds ratio, 95% confidence interval) was performed.

*Results:* We observed 592 new diagnoses for HIV infection: 61.4% on Italians, 38.5% on foreigners. An antiretroviral treatment was started on 78.8% of the new diagnoses (467/592) (second UNAIDS target), and a viral suppression was obtained at 2 years on 82% of PLWH who had started ART (383/467) (third UNAIDS target), namely only 64.7% of the new diagnoses instead of the hoped-for 81% of the UNAIDS target. Logistic regressions demonstrated that second and third '90 UNAIDS targets were unrelated to sex, nationality, CD4 cells count, HIV-RNA and CDC stage (p>0.05). The age class 25-50 years (OR=2.24; 95% CI = 1.06-4.37; p=0.04) achieves more likely viral suppression when compared with patients <25 years. Considering the continuum of care, 88 (15%) PLWH were lost to engagement in care (55 unclaimed tests and 33 unlinked to care), 37 didn't start ART, 51 were LFTU at 2 years.

*Conclusions:* UNAIDS goal was far to be reached. The main challenges were unreturned tests as well as the retention in ART. Rapid tests for a test-treat strategy and frequent phone communications in the first ART years could facilitate UNAIDS target achievement.

Keywords: UNAIDS endpoint; HIV; Engagement in care; Foreigners.

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**Introduction.** Despite progress in the prevention and treatment of HIV, persistent issues remain concerning

continuum in care: late diagnosis, weak linkage, and retention in care, limited engagement in therapy and/or

treatment adherence. To address these issues UNAIDS, in 2016, proposed the "90-90-90" target (to ensure that 90% of people with HIV (PLWH) be diagnosed, 90% of these be treated with ART, and 90% of those on ART should achieve an undetectable viral load (VL).<sup>1</sup> The continuum in care starts with HIV testing, progresses through to linkage to care, retention in care, engagement in ART until achieving sustained viral suppression, and then finishes with the maintenance of the status.<sup>2</sup>

A systematic analysis of national data showed that diagnosis (target one-90%) ranged from 87% (the Netherlands) to 11% (Yemen). Treatment coverage (target two-81% on ART) ranged from 71% (Switzerland) to 3% (Afghanistan). Viral suppression (target three-73% virally suppressed) was between 68% (Switzerland) and 7% (China).<sup>3</sup> In Italy, in 2017, were reported 3.443 new HIV diagnoses, equaling an incidence of 5.7 per 100.000 residents. HIV incidence in Italy is similar to the average incidence observed in the European region (5.8 new cases x 100.000),<sup>4</sup> and it is estimated that 139.000 people are living with HIV and 11% of these are undiagnosed.<sup>5</sup> Based on the results of a recent cohort study, 83% of patients are linked to care and 87% of treated one's achieved viral suppression.<sup>6</sup>

It was estimated that in Italy, in 2017, 34.3% of people with a new HIV diagnosis were from a foreign country. The proportion of foreigners among new diagnoses has increased from 28.6% in 2010 to 34.4% in 2017.<sup>4,5,7</sup> However, in our region, Umbria, in 2017, the incidence of new diagnoses of HIV infection was 6.7 x 100.000 residents,<sup>4</sup> up to 40% of the new HIV diagnoses regarded foreign-born individuals in 2016-17.<sup>8</sup> Foreigners are disproportionately affected by HIV compared to natives; they still face barriers in attending the public health care system, in initiating ART, and are at increased risk of virologic failure. This type of risk is particularly high for unemployed and irregular immigrants.<sup>7</sup>

Other studies on the continuum in care about small Italian cohorts have found that risk factors for unretention and virological failure were: nationality, age, and CD4 cells counts.<sup>9,10</sup>

The aim of this retrospective study was to compare 2005-2017 data collected at the Perugia Infectious Diseases Clinic with the 2020 UNAIDS 90 targets for treatment and viral suppression and to identify risk factors that could be associated with failure to reach these targets.

## Materials and Methods.

*Clinical Setting.* The Infectious Disease Clinic of Perugia follows about two thirds of all Umbrian patients with HIV infection (PLWH), and at its day hospital, it is possible to take the test for HIV infection anonymously and free of charge. Moreover, in its laboratories, the confirmative assay of all HIV positive screenings from the medical area around Perugia is carried out; the medical staff of the Clinic personally returns the positive results to facilitate a link to care and rapid access to therapies. At the time of anonymous HIV screening, the nursing staff is responsible for registering gender, age, and country of origin of all test takers. For patients linked to care, data regarding demographic issues, medical history, sexual behavior, comorbidities, immune-virological profile, current medications and other risk factors are inserted into an electronic database system (NETCARE).

*Data collection.* This retrospective study was performed compiling data from anonymous nurse records and from NETCARE (only demographic issues, immune-virological profile, current medications) in an excel file for processing. All data up to 24 months of follow up for each patient were collected. The study was approved by our local ethics committee on June13<sup>th</sup> 2019 (protocol number 16566/19/ON) and according to the Declaration of Helsinki.

Data Definitions. We included all patients aged  $\geq 15$ undergoing an HIV test at our clinic between January 2005 and December 2017. The following definitions were used: Unclaimed Tests: HIV positive results not collected. Linked to care: patients attending one visit where blood samples are taken to determine the viral load and CD4+ T cell count. Retained in ART for one and two years: PLWH receiving therapy for one and two years. Virologic responder: HIV viral load < 50 copies/mL after 6 months of ART. Lost to Follow Up (LTFU): linked to care but subsequently lost to follow up.<sup>11,12</sup>

### Primary outcomes.

- Accordingly with the aim of the study, to compare observed 2020 UNAIDS 90 targets for treatment and viral suppression *vs* expected one, we calculate:
- Proportion of patients treated at our clinic compared to all new diagnoses of HIV infection.
- Proportion of virologic suppressed patients one and two years after starting ART.
- The proportion of virologic suppressed
- Patients respect to the new diagnoses.

#### Secondary outcomes.

- We investigated factors that could be associated with failure to reach 2020 UNAIDS 90 targets.
- Proportion of patients with unclaimed tests,
- Proportion of patients linked to care,
- Proportion of patients retained in ART after two years.

*Statistical analyses*. <u>Study design</u>: retrospective mono center cohort study.

Categorical variables were described as frequency (%, with a 95% confidence interval, CI) and continuous variables were described as mean (± standard deviation, SD). In the crude analysis, we used Pearson or Mantel-Heaenzel chi square test (as appropriate) to assess the association between categorical variables. Age at the diagnosis was categorized into three levels (< 25, 25-50 and > 50-year olds) using the stratum of < 25 as a reference category. CD4 cells was also categorized into four class variables as <200, 200-350, 350-500 and >500 cells/mmc. Logistic regression (odds ratio, 95% confidence interval) was used to account for differences among the groups when comparing patients diagnosed that were on ART vs. patients who were off ART, and patients on ART that were virally suppressed at 24 months vs. unsuppressed and patients lost to follow-up. Variables included in the analysis are: age strata, gender, nationality, CD4 cells count strata, HIV-RNA, CDC stage.

Data analysis was conducted using the statistical software SPSS release 22.0 (SPSS Inc, Chicago III).

## **Results.**

Characteristics of diagnosed subjects. Between 2005 and 2017, 592 new diagnoses for HIV infection were made at our laboratories: 364 on Italian-natives (61.4%), 228 on foreigners (38.5%). Overall, 454 were men (30.3% foreigners), 138 women (65% foreigners). The mean age was 40 (range 18-78), 9 % were aged <25, 72.6 % were aged 25-50 and 18.2 % were aged >50. Noteworthy, foreigners were more numerous than Italians in the < 25 year olds category (27 vs. 22), while they were very poorly represented over 50 (12 vs 104 subjects).

From diagnosis to ART: second "90"UNAIDS target. Four hundred sixty-seven out of 592 (78.8%) PLWH started an ART. Out of 125 PLWH not treated, 88 (54 Italians and 34 foreigners) were lost to engagement in care (55 didn't withdraw the test, 33 didn't attend the first visit) and 37 didn't start therapy. Of the 37 PLWH linked to care, who didn't start ART, 6 didn't initiate ART within two years (all before year 2009 and all with CD4 T cell counts > 350/mmc), 7 died before, 3 moved to other centers, 1 was HIV-2 positive and 20 were lost to follow up. Three out of the 20 LFTU were <25 year olds, 14 were aged 25-50, 3 patients were over 50. Demographic characteristics of new diagnoses, of treated and not treated PLWH are shown in **Table 1**. No significant differences between patients on ART and off ART for nationality, gender and age were observed (**Table 1**).

From ART to viral suppression: third "90"UNAIDS target. An antiretroviral therapy was prescribed to 467 PLWH. The virologic response at 12 and 24 months after starting ART was observed in 339 (72.6 %) and 383 (82%) patients respectively. Demographic and immunological characteristics of PLWH starting ART, of whose achieving or not the third UNAIDS target are reported in **Table 2**. Logistic regressions demonstrated that second and the third '90 UNAIDS targets were unrelated to sex, nationality, CD4 cells count, HIV-RNA and CDC stage (p>0.05). The age class 25-50 years (OR=2.24; 95% CI = 1.06-4.37; p=0.04) achieves more likely viral suppression than patients <25 years (**Table 2**).

Overall 64.7% patients were virally suppressed at 24 months respect to 592 new diagnoses. At 24 months 51 PLWH were LTFU (32 within the first year), 33 didn't achieve a sustained viral suppression. Considering only the 435 patients with available viral load at 12 months, a viral suppression was obtained in 88% at 24 months.

The cascade of continuum in care from diagnoses to viral suppression in all patients and in Italian and foreigners is illustrated in **figure 1**. Finally, we

	New diagnosis <i>n</i> = 592 n (%)	Patients on ART <i>n</i> = 467 <b>n</b> (%)	Patients off ART <i>n</i> = 125 n (%)	р	Odds Ratio (95%CI)
Nationality				0.61	1.12(0.72-1.74)
Italians	364 (61.5)	290 (62)	74 (59.2)		
Foregneirs	228 (38.5)	177 (38)	51 (40.8)		
Gender				0.78	1.07(0.66-1.74)
Male	454 (76.7)	360 (77)	94 (75.2)		
Female	138 (23.3)	107 (33)	31 (24.8)		
Age					
< 25 yrs	54 (9.1)	39 (8.4)	15 (12)	0.40	Reference cat.
25-50 yrs	430 (72.6)	344 (73.7)	86 (68.8)	0.56	0.79(0.37-1.72)
> 50 yrs	108 (18.2)	84 (18)	24 (19.2)	0.50	1.19(0.70-2.04)

 Table 1. Achievement of second UNAIDS Target (start of ART). Demographic characteristics of new diagnoses, of treated and not treated

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Legend: ART: antiretroviral therapy; yrs: years.

Table 2. Achievement of third UNAIDS Target (viral suppression). Demographic and immunological characteristics of patients who started
ART.

	Pts in ART n= 467 n (%)	Achieved n= 383 n (%)	Not achieved n= 84 n (%)	р	Odds Ratio (95%CI)
Nationality					
Italians	290 (62)	240 (62.6)	50 (59.5)	0.72	0.91(0.53-1.55)
Foregneirs	177 (38)	143 (37.3)	34 (40.5)		Reference cat.
Gender					
Male	360 (77)	295 (77)	65 (77.4)	0.77	1.09(0.59-1.99)
Female	107 (33)	88 (23)	19 (22.6)		Reference cat.
Age					
<25 yrs	39 (8.4)	27 (7)	12 (14.3)	0.11	Reference cat.
25-50 yrs	344 (73.7)	287 (75)	57 (67.9)	0.04*	2.24(1.06-4.37)
>50 yrs	84 (18)	69 (18)	15 (17.9)	0.12	2.06(0.82-5.15)
CD4 cells/ml					
< 200	181 (38.7)	145 (37.9)	36(42.9)	0.85	Reference cat.)
200-350	83 (17.8)	70 (18.3)	13(15.5)	0.82	0.88(0.29-2.69)
350-500	178 (38.4)	148 (38.6)	30 (35.7)	0.77	1.18(0.37-3.78)
>500	25 (5.3)	20 (5.2)	5 (6)	0.82	1.13(0.39-3.29)
HIVRNAcp/ml > 500.000	94 (20)	80 (20.8)	14 (16.7)	0.29	1.40(0.74-2.68)
CDC C	98 (21)	78 (20.4)	20 (23.8)	0.81	0.92(4.68-1.81)

Legend: ART: antiretroviral therapy; Pts: patients; yrs: years; cp/ml: copies/ml.



Figure 1. The cascade of continuum in care from diagnoses to viral suppression at 24 months. Legend: ART: antiretroviral therapy.

compared the observed UNAIDS target with the expected one, the result is shown in **figure 2**. The second and the third '90 UNAIDS targets obtained was significantly lower than expected (p<0.001).

True loss to follow up, and deaths. Overall, we observed 64 PLWH true LTFU (20 before ART, 27

during the first year and 27 in the second one), 6 PLWH moved to other centers (3 before ART) and 11 patients who died (7 before and 4 after ART), all for malignancies. No differences were observed between Italians and foreigners or gender or age classes neither in the withdrawal of the test nor in the linkage to care (data not shown).



**Figure 2.** The 2020 UNAIDS 90 targets for treatment and viral suppression, expected vs observed in the study population.

**Discussion.** Considering the UNAIDS identified target 90-90-90 for 2020, the main characteristic of our study was of being able to follow the entire clinical pathway of PLWH from serological diagnosis to ART prescription, as well as to virologic suppression (i.e., second and third target), given that for the diagnosis of HIV infection all confirmatory tests from the medical area of Perugia were carried out in our laboratories and positive assays were always returned by our medical staff. Indeed, our surveillance concerns a very high prevalence of foreign-born HIV-infected subjects (38.5%), which significantly differs from general national data: 17.3%<sup>13</sup> and from those reported in Genoa: 19%<sup>9</sup> and Florence: 27%<sup>10</sup> experiences. In fact, other studies on the continuum in care have been published in Italy about single hospital cohorts and, recently, from the ICONA Foundation Study Cohort, all regarding the retention to care and the virologic success on patients linked to care.9,10,14

In this study, the UNAIDS goal was far to be reached; antiretroviral treatment was started only on 78.9% of the new diagnoses (second 90 UNAIDS target) and viral suppression was obtained only on 82% of PLWH who had started ART (third 90 UNAIDS target). Overall, only 64.7% of the new diagnoses achieved sustained viral suppression instead of the hoped-for 81% of the UNAIDS target (90% of the new diagnoses treated, 90% of treated under viral control).

The failure in achieving the second target was partly determined by fifty five subjects who didn't claim the test, that is 9.2% despite being tested, 33 who didn't link to care (5.6%), and 20 who were true LTFU before starting ART (3.96%). This is a very worrying data, indicative of a substantial share of persistent undeclared or untreated. Indeed, excluding patients not treated on the basis of contemporary guidelines, those who moved to other centers and those who didn't withdraw the results, the second UNAIDS target was close to being reached (89.6%). The failure to achieve viral suppression (third UNAIDS target) in our cohort regarded, without any difference, both gender and

nationality, unlike Prinapori and Lagi<sup>9,10</sup> who observed that being foreign born patients was statistically significant for failed retention in care. Conversely, we observed, like Lagi<sup>10</sup> a higher risk of failure in achieving the third target for younger PLWH (**Table 2**). The failure was not associated with ineffective drug regimens but, instead, with a high LFTU on ART. Whether the analysis had been performed from linkage to care, our results would have been in agreement with the above studies. Prinapori reported a 75.8 %<sup>9</sup> and Lagi of 67.4%<sup>10</sup> of virologic control compared to our 76% (383/504 PLWH linked). The national data from the ICONA Foundation Study Group was very higher,

patients from the ICONA cohort gave written informed consent to the study group participation, thus effectively creating a bias in favor of retention in ART compared to real life. Eventually, our virologic success in retained patients (92.3 %) was similar to the studies mentioned above (97.6% and 95% respectively), but with a higher rate of foreign people included. Regarding the durable viral suppression, it's worthy of consideration it was mainly achieved in the second year, although without substantial changes in the proposed regimens, index of initial inadequate adherence. Indeed, we observed a high rate of true LFTU (excluding deaths) throughout the 24 months observation period, 64.5 x 1000 person-years and 39.1x1000 person-years in the first and second year, respectively. These results require a clinical strategy aimed at fostering the linkage to care and retention in ART.

In order to improve the engagement in care, considering the anonymity and the reluctance to provide a telephone number, we intend to activate a strategy, particularly on test-treat vulnerable populations, in line with the most recent World Health Organization (WHO) treatment guidelines.<sup>15</sup> In addition to blood specimens drawn for routine HIV test, we want to get a rapid HIV test on oral fluid and then, if positive, to start ART immediately. The rapid test checks IgM and IgG antibodies to HIV-1 and HIV-2 (sensitivity is 99.3%, specificity is 99.8%)<sup>16</sup> and gets results within 30-40 minutes. Rapid ART could improve the uptake of the therapy by reducing the number of LTFU from diagnosis to ART initiation<sup>17,18</sup> and the spread of HIV infection. In this regard, the San Francisco RAPID program addressed to vulnerable subjects might constitute a valid example of interventions.<sup>19</sup> A rapid HIV test on oral fluid and immediate treatment can be useful strategies to improve the achievement of ART start.

Moreover, to foster adherence we want to be focused on frequent health care workers interactions and communications with PLWH by phone in agreement with recent tips and advice,<sup>20</sup> focused not only on the several aspects of ART but also on their wellbeing, in order to achieve a higher virologic success and decrease the LTFU.

Strengths of our work are the follow up starting from serological diagnosis and the high prevalence of foreign born PLWH.

Limitations are the limited number of subjects enrolled, the data collection from a single clinical center, the absence of data about socio-economic status, education, sex behavior, and about the follow up of PLWH moved to other centers.

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**Conclusions.** The UNAIDS goal was far from being reached. The main challenges were unreturned tests as well as the retention in ART, particularly for younger PLWH. Rapid tests for a test-treat strategy and frequent phone communications in the first ART years could facilitate UNAIDS target achievement.

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