HEALTHCARE RESOURCE CONSUMPTION AND RELATED COSTS IN PATIENTS UNDER ANTIRETROVIRAL THERAPIES: FINDINGS FROM REAL-WORLD DATA IN ITALY

Acceptance Code: EE366

Valentina Perrone¹, Melania Dovizio¹, Diego Sangiorgi¹, Margherita Andretta², Fausto Bartolini ³, Arturo Cavaliere⁴, Andrea Ciaccia⁵, Alessandro Chinellato⁶, Alberto Costantini⁷, Stefania Dell'Orco⁸, Fulvio Ferrante⁹, Simona Gentile¹⁰, Antonella Lavalle¹⁰, Rossella Moscogiuri¹¹, Elena Mosele¹², Cataldo Procacci¹³, Davide Re¹⁴, Fiorenzo Santoleri⁷, Alessandro Roccia¹⁵, Franco Maggiolo⁶, Luca Degli Esposti¹

¹CliCon S.r.I. Società Benefit - Health, Economics & Outcomes Research, Bologna, Italy; ²Azienda ULSS 8 Berica Vicenza, 36100, Italy; ³USL Umbria 2 Terni, Italy; ⁴ASL Viterbo, Viterbo, Italy; ⁵Servizio Farmaceutico Territoriale ASL Foggia Foggia, Italy; ⁶PharmaD Azienda ULSS 3 Serenissima Mestre (VE), Italy; ⁷ASL Pescara, Pescara, 65100, Italy; ⁸ASL Roma 6, Albano Laziale, Italy; ⁹ASL Frosinone Frosinone, Italy; ¹⁰Direzione Generale per la Salute Regione Molise Campobasso, Italy; ¹¹ASL Taranto, Taranto, Italy; ¹²UOC Assistenza Farmaceutica Territoriale Azienda ULSS 7 Pedemontana Bassano del Grappa (VI), Italy; ¹³Dipartimento Farmaceutico ASL BAT Trani, Italy; ¹⁴ASL Teramo Teramo, Italy; ¹⁵Gilead Sciences Srl Milano, Italy; ¹⁶MD ASST Papa Giovanni XXIII Bergamo, Italy

CLICON S.R.L. SOCIETÀ BENEFIT, HEALTH, ECONOMICS & OUTCOMES RESEARCH

ISPOR EUROPE 2022, VIENNA (AUSTRIA), 6-9 NOVEMBER 2022



The introduction of antiretroviral therapies (ARTs) and then the availability of combination ARTs in the clinical practice has dramatically changed the course of HIV infection, from an acute to a chronic disease [1]. Among the most widely used ART combinations, Tenofovir Alafenamide (TAF) regimen has been shown to achieve a successful viral load suppression [2,3].

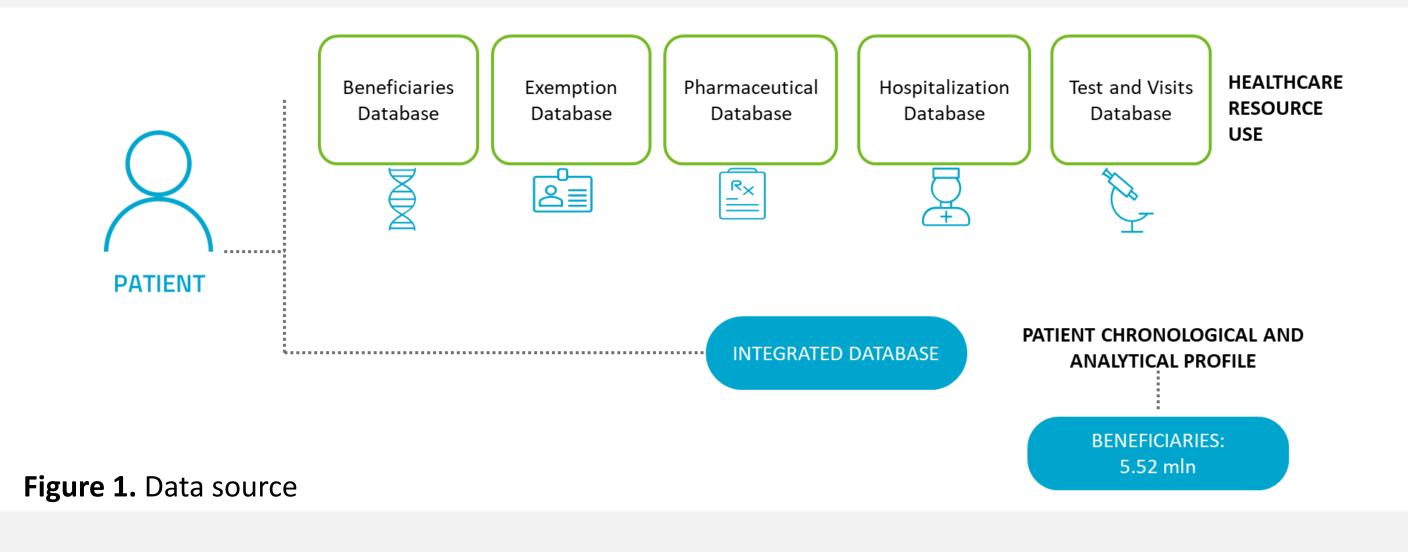
MEAN ANNUAL DIRECT COSTS IN TAF-TREATED PATIENTS

The <u>mean annual direct costs for the INHS</u> averaged $15,493 \in (2017)$, $12,060 \in (2018)$, and $10,216 \in (2019)$. ART-related cost was the most relevant item with $10,685 \in 9,474 \in 0.017 \in 0.017$, for 2017, 2018, and 2019, respectively (Figure 2).

This real-world analysis was aimed at evaluating TAF-based regimens in terms of persistence on therapy and the resulting impact on healthcare resource consumption and related direct healthcare costs for Italian National Health Service (INHS).



A retrospective analysis was conducted on administrative databases of Italian geographically distributed entities covering 5.52 million health-assisted individuals, during 2015-2019 (Figure 1).



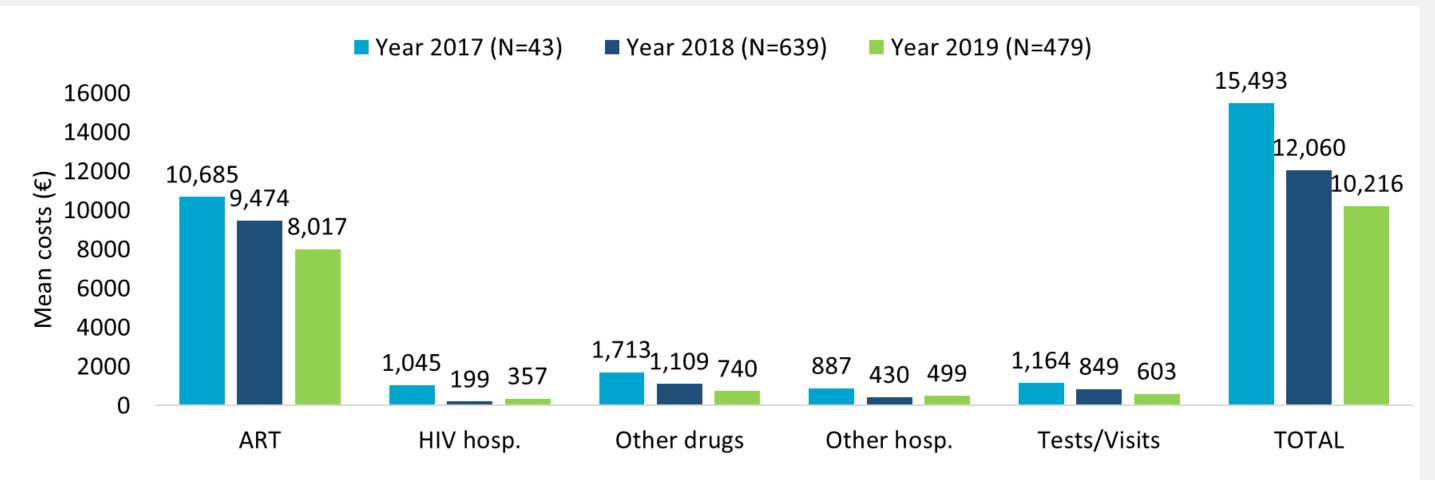
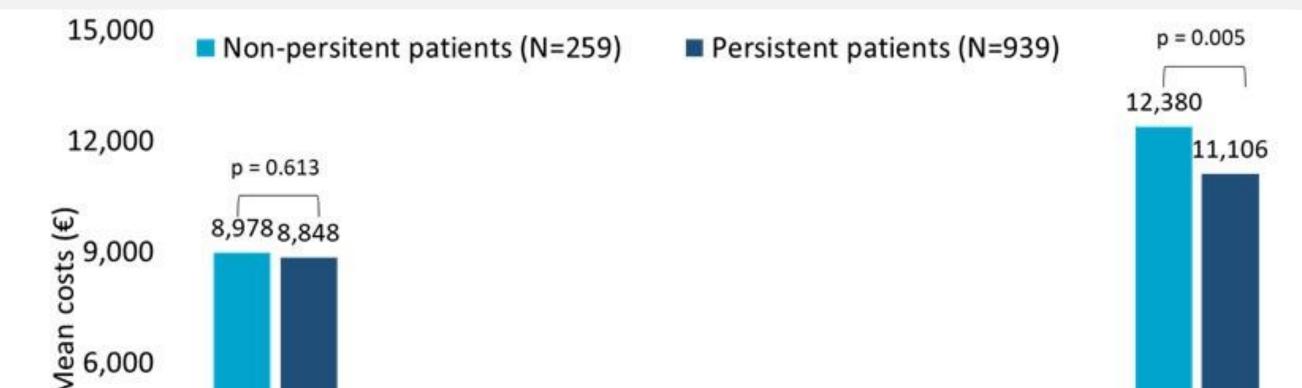


Figure 2. Mean annual health care costs (€) in patients with TAF-based regimen during first year of follow-up for the inclusion years 2017-2018-2019.

<u>Persistence on treatment</u>. Persistent patients were characterized by lower total costs versus non-persistent (11,106€ vs 12,380€, P=0.005), mostly due to the reduction of HIV-hospitalizations, non-ART drugs and test/visits costs (Figure 3).



DESIGN OF THE ANALYSIS

Study population: between 2015 and 2019 (identification period), all adults with TAFbased therapies were identified by presence of the following drugs: TAF (ATC code J05AF13); emtricitabine and tenofovir alafenamide (ATC code J05AR17); emtricitabine, tenofovir alafenamide, elvitegravir and cobicistat (ATC code J05AR18); emtricitabine, tenofovir alafenamide and rilpivirine (ATC code J05AR19); emtricitabine, tenofovir alafenamide and bictegravir (ATC code J05AR20); emtricitabine, tenofovir alafenamide, darunavir and cobicistat (ATC code J05AR22). Patients had to be continously enrolled during study period.

The first TAF prescription was the index-date, and patients were followed-up for at least 1 year after index date.

Persistence on therapy was calculated as presence of ART prescription during last trimester of each calendar year.

Healthcare resource consumptions related to ART prescriptions, other-drugs (non-ART), HIV-related and other cause-hospitalizations, laboratory tests/outpatient visits, were calculated over one-year follow-up and reported as mean±SD. Moreover, **direct costs** related to healthcare resource consumptions were estimated as total costs and those related to drug consumptions, hospitalizations and test/outpatient visits. Direct healthcare costs were reported as mean annual cost/patient. A generalized linear model (GLM) was applied to evaluate predictors of non-ART total costs.

3,000 p = 0.004 p = 0.004 p = 0.004 p = 0.425 $1,181 \ 921$ $597 \ 445$ $1,038 \ 686$ 0ART HIV hosp. Other drugs Other hosp. Tests/Visits TOTAL

Figure 3. Mean annual health care costs (€) during first year of follow up for patients with TAF-based regimen based on persistence.

<u>Multivariate analysis</u>. The GLM model (Table 2) showed that non-ART costs increased with older age (patients aging 35 years as reference), +1,360 \in in those ranging 51-65 years (P<0.001) and +2,264 \in in >65, (P=0.079) and to the Charlson Comorbidity Index (+1,736 \in for unit increment, P=0.027).

| Table 2. GLM analysis | β (€) | 95%CI | | P value |
|----------------------------|---------|---------|--------|---------|
| Age 35 | REF. | | | |
| Age 35-50 years | 415.3 | -291.3 | 1121.8 | 0.249 |
| Age 51-65 years | 1363.6 | 557.5 | 2169.6 | 0.001 |
| Age >65 years | 2265.2 | -260.6 | 4791.0 | 0.079 |
| Male gender | -62.0 | -675.1 | 551.2 | 0.843 |
| Year 2017 | REF. | | | |
| Year 2018 | -1229.3 | -4141.3 | 1682.7 | 0.408 |
| Year 2019 | -1829.8 | -4731.9 | 1072.3 | 0.217 |
| Charlson Comorbidity Index | 1733.8 | 195.7 | 3271.8 | 0.027 |

RESULTS

HEALTHCARE RESOURCE CONSUMPTIONS BETWEEN 2017 AND 2019

The analysis identified 1,198 TAF-treated patients meeting the inclusion criteria. Focusing on the last 3-year period 2017-2019, the mean number per patient of ART prescriptions decreased from 8.0 \pm 2.4 to 7.7 \pm 2.4, those for non-ART prescriptions from 4.4 \pm 5.0 to 3.4 \pm 4.0, HIV- hospitalizations from 0.2 \pm 0.5 to 0.1 \pm 0.4, and diagnostic tests/visit prescriptions from 8.5 \pm 7.6 to 5.9 \pm 7.6 (Table 1).

Table 1. Healthcare resource consumptions by year (focus in 2017-2019)

| Year | 2017 | 2018 | 2019 |
|--------------------------------------|---------------|---------------|---------------|
| Patients, n | 43 | 639 | 479 |
| ART prescriptions | 8.0 ± 2.4 | 7.9 ± 2.5 | 7.7 ± 2.4 |
| HIV hospitalizations | 0.2 ± 0.5 | 0.1 ± 0.3 | 0.1 ± 0.4 |
| Number of other drugs | 4.4 ± 5.0 | 3.8 ± 3.9 | 3.4 ± 4.0 |
| Other hospitalizations | 0.1 ± 0.5 | 0.1 ± 0.4 | 0.1 ± 0.4 |
| Specialistic visits/diagnostic tests | 8.5 ± 7.6 | 6.7 ± 6.7 | 5.9 ± 7.6 |



Seguiti C, et al. J Patient-Rep Outcomes. 2022;6(1):27. doi:10.1186/s41687-022-00423-4
 Carpenter CC, et al. JAMA. 1998 Jul 1;280(1):78-86. doi: 10.1001/jama.280.1.78. PMID: 9660368.
 Linee Guida Italiane sull'utilizzo della Terapia Antiretrovirale e la gestione diagnostico-clinica delle persone con infezione da HIV-1. https://www.salute.gov.it/imgs/C_17_pubblicazioni_2696_allegato.pdf

DISCLOSURE: Gilead Sciences Srl purchased the study report that is the basis for this poster presentation. This poster was developed with Gilead Sciences Srl and CliCon S.r.l. Società Benefit. The views expressed here are those of the authors and not necessarily those of the supporters. VP, MD, DS, MA, FB, ACavaliere, ACiaccia, Achinellato, Acostantini, SDO, FF, SG, AL, RM, EM, CP, DR, FS, FM report no other conflicts of interest in this work. The agreement signed by Clicon S.r.l. and Gilead Sciences Srl does not create any entityship, joint venture or any similar relationship between parties. Clicon S.r.l. is an independent company. Neither CliCon S.r.l. nor any of their representatives are employees of Gilead Sciences Srl for any purpose. AR is employees of Gilead Sciences Srl.

CONCLUSIONS

This real-world analysis in TAF-treated patients showed that healthcare total costs were mainly driven by ART-related costs, which represent almost 70% of the total expenditure. TAF persistence was associated with cost saving, due to a reduction of total healthcare cost related to HIV- hospitalizations, non-ART drug prescriptions, outpatient visits and specialist services.