# Real-world Treatment Experience of Treatment-naïve People Living with HIV who Initiated Treatment with Single-tablet Dolutegravir/Lamivudine in a Test and Treat Setting in the United States

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## Key Takeaways

- **TANDEM aimed to characterize real-world prescribing behaviors and treatment outcomes of DTG-based 2DR in the United States (US).**
- **Here we aim to describe the outcomes of those who initiated DTG/3TC in the Test and Treat (T&T) setting.**
- **After a median follow-up time of 1.3 years, >83% of treatment-naïve PLWH who initiated on DTG/3TC in a T&T setting experienced sustained virological suppression with few treatment discontinuations (<2%), irrespective of T&T status.**
- **TANDEM supports results from the STAT trial demonstrating DTG/3TC is a feasible, effective and well tolerated regimen when used in real-world T&T settings in treatment-naïve PLWH.**

## Introduction

- Dolutegravir/ lamivudine (DTG/3TC) is indicated as a two-drug regimen (2DR) for both treatment naïve and virally suppressed People Living With HIV (PLWH) [1].
- Use of DTG/3TC in these populations is supported by a strong recommendation (AI*) from the DHHS Clinical Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV, with some exceptions† [2].
- A Test & Treat (T&T) strategy has evolved in order to increase ART initiation rate and improve linkage of PLWH to healthcare systems [3-4].
- The feasibility, efficacy and safety of DTG/3TC use in a T&T setting has been demonstrated in the STAT trial. There is limited evidence with this approach in US-based real-world clinical settings [5].
- Here we describe outcomes of treatment-naïve (TN) PLWH that were initiated on DTG/3TC as part of a T&T strategy, defined as clinician attestation of treatment initiation shortly after diagnosis and in the absence of known lab-values for HIV-1 RNA viral load, CD4+ cell count and/ or HIV-1 resistance mutations.
  - Primary results for the TANDEM study have been presented previously [6-7]. Findings from TN PLWH with HIV RNA viral loads >100,000 copies/mL can be found at Poster 1278 at ID Week 2022.

## Methods

- TANDEM was a US-based, retrospective chart review. 24 sites abstracted clinical characteristic, treatment history, and post-initiation outcomes data from medical charts of PLWH who were initiated on DTG/3TC or dolutegravir / rilpivirine (DTG/RPV).
- Analyses were descriptive and no formal hypotheses were tested.
- Missing data were not imputed. Descriptive analyses were performed in IBM® SPSS® Data Collection Survey Reporter v7.5 software.
- Time to event outcomes were calculated using Kaplan-Meier estimators conducted in StataCorp, 2015. Stata statistical software: Release 16 (College Station, TX, StataCorp LP).

### Inclusion Criteria

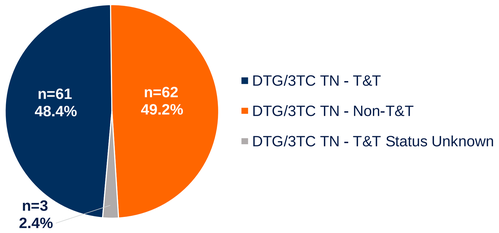
- ≥18 years old;
- Have a diagnosis of HIV-1 infection;
- Have a history of antiretroviral therapy (ART) consisting of the 2DR DTG/3TC or DTG/RPV as a single tablet regimen (STR);
- DTG/3TC cohort:
  - Must have been initiated on or after 1st May 2019 and before 30th September 2020;
  - Upon initiation, PLWH must have been either treatment-naïve (TN) to ART or virologically suppressed (i.e. stable switch [SS]) defined as having HIV-1 RNA <50 copies/mL, on a stable ART regimen for ≥3 months upon DTG-based 2DR initiation.
- Have at least 6 months of clinical follow-up after initiation of DTG-based 2DR which could include time post-discontinuation of either regimen.

*Rating for Recommendations = Strong (A) / Rating of Evidence = Data from randomized controlled trials (I)
†Exceptions in individuals with HIV RNA viral load >500,000 copies/mL, HBV coinfection, or in whom ART is to be started before the results of HIV genotypic resistance testing for reverse transcriptase or HBV testing are available

## Results

- From an overall sample of 469 PLWH, 151 received DTG/RPV and 318 received DTG/3TC, of which 126 were TN and 192 were virologically suppressed, switched from previous ART.
  - Almost half (48%) of the TN cohort received DTG/3TC as part of a T&T paradigm **(Figure 1)**, baseline demographics of this cohort are described in **Table 1**.

### Figure 1. Split of DTG/3TC Treatment Naïve (TN) Sub-Cohorts




### Table 1. Baseline Demographics of DTG/3TC TN Sub-Cohorts

| | T&T (n=61) | Non-T&T (n=62) |
|---|---|---|
| **Age (years)** | | |
| Mean (SD) | 34.4 (±9.97) | 40.3 (±14.32) |
| **Assigned Sex at Birth, n (%)** | | |
| Male | 58 (95.1) | 50 (80.6) |
| **Current Gender Identity, n (%)** | | |
| Cis-male | 52 (85.2) | 50 (80.6) |
| Cis-female | 3 (4.9) | 12 (19.4) |
| Trans-female | 3 (4.9) | 0 (0.0) |
| **Race, n (%)** | | |
| White/ Caucasian | 42 (68.9) | 33 (53.2) |
| Black | 12 (19.7) | 24 (38.7) |
| Mixed race | 2 (3.3) | 1 (1.6) |
| Pacific Islander | 2 (3.3) | 0 (0.0) |
| Asian | 1 (1.6) | 1 (1.6) |
| Not specified | 2 (3.3) | 3 (4.8) |
| **Ethnicity, n (%)** | | |
| Hispanic / Latinx | 28 (45.9) | 20 (32.3) |
| **Current Insurance Coverage, n (%)** | | |
| Employer provided/ sponsored insurance | 16 (26.2) | 17 (27.4) |
| Privately arranged insurance | 14 (23.0) | 8 (12.9) |
| Medicare | 1 (1.6) | 7 (11.3) |
| Medicaid | 5 (8.2) | 17 (27.4) |
| Health insurance exchange plan | 11 (18.0) | 5 (8.1) |
| AIDS Drug Assistance Program (ADAP) | 11 (18.0) | 8 (12.9) |
| No insurance coverage | 3 (4.9) | 0 (0.0) |
| **Started on free sample of DTG/3TC, n (%)** | 34 (55.7) | 6 (9.7) |

### Baseline Characteristics

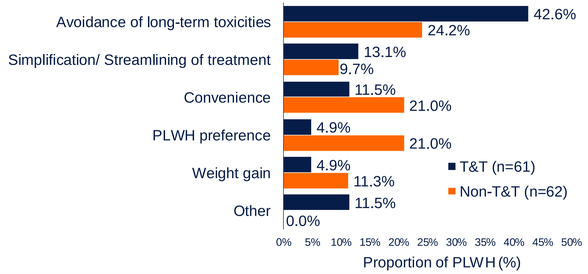
- Clinical characteristics are described in **Table 2**.
- Relevant treatment considerations were different for the two subgroups.
  - For the T&T subgroup, the main consideration was limited access to healthcare (n=12) and for the non-T&T it was comorbidities (n=10).
- In the T&T subgroup, the most common reasons for initiating DTG/3TC were avoidance of long-term toxicities (42.6%), followed by simplification/streamlining (13.1%) and convenience (11.5%) **(Figure 2).**

### Table 2. Baseline Clinical Characteristics

| | T&T (n=61) | Non-T&T (n=62) |
|---|---|---|
| **Time on DTG/3TC ongoing† (years)** | | |
| Median (IQR) | 1.3 (0.9, 1.7) | 1.2 (0.8, 1.8) |
| **Laboratory values prior to DTG/3TC initiation** | | |
| Median CD4 cell count, cells/mm$^3$ (IQR) | N/A | 366.5 (135, 594) |
| Median HIV viral load, copies/mL (IQR) | N/A | 44,522.0 (10,850, 128,814) |
| **Top Relevant Treatment Considerations, n (%)** | | |
| Limited access to healthcare | 12 (19.7) | 3 (4.8) |
| Mental health issues | 8 (13.1) | 1 (1.6) |
| Job instability | 6 (9.8) | 1 (1.6) |
| Health insurance issues/ changes | 3 (4.9) | 4 (6.5) |
| Comorbidities | 2 (3.3) | 10 (16.1) |
| No relevant treatment considerations identified | 32 (52.5) | 23 (37.1) |
| **Drug Resistance Testing Performed at DTG/3TC initiation, n (%)** | | |
| No resistance testing performed | 13 (21.3) | 20 (32.3) |
| Resistance testing performed; no resistance detected | 35 (57.4) | 28 (45.2) |
| Resistance testing performed; resistance detected | 7 (11.5) | 13 (21.0) |
| Information unknown | 6 (9.8) | 1 (1.6) |
| **Type of Drug Resistance Detected at DTG/3TC Initiation, n (%)** | **n=7** | **n=13** |
| NNRTI resistance* | 6 (9.8) | 10 (16.1) |
| PI resistance | 2 (3.3) | 5 (8.1) |
| NRTI resistance** | 0 (0.0) | 1 (1.6) |
| INI resistance*** | 0 (0.0) | 1 (1.6) |

†At the time of data abstraction, excludes PLWH who discontinued DTG/3TC, lost to follow-up or treatment status unknown.
*Most common NNRTI mutations detected overall were K103NS (n=6) and E138KAGQ (n=3).
**NRTI mutation detected was M41L (n=1); ***INI mutation detected was 'Not otherwise specified' (n=1).

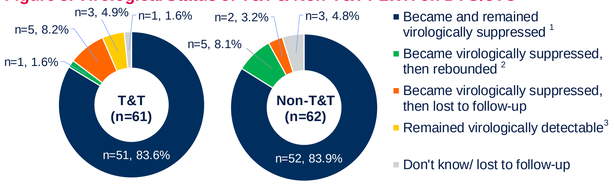
### Figure 2. Top HCP Reasons for Initiating TN PLWH on DTG/3TC




### Virological Outcomes

- At data cut-off, 57 (93.4%) of the T&T subgroup achieved virological suppression, 3 (4.9%) did not, and 1 (1.6%) was still unknown; in the non-T&T subgroup, 59 (95.2%) achieved virological suppression **(Figure 3)**.
- Median (IQR) time to virological suppression was 9.7 weeks (5.8, 17.7) in the T&T subgroup and 10.7 weeks (5.4, 19.3) in the non-T&T subgroup **(Table 3)**.
- Of the 3 individuals in the T&T subgroup who did not achieve viral suppression, 2 remained on DTG/3TC while 1 was switched to bictegravir/emtricitabine/tenofovir alafenamide.
- Virologic rebound occurred in 6 TN PLWH overall, with 1 of these occurring in the T&T subgroup.

### Figure 3. Virological Status of T&T & Non-T&T PLWH on DTG/3TC




[1] Virological suppression defined as a HIV-1 viral load of <50 copies/mL
[2] Rebound is defined as PLWH who had two consecutive viral load measurements of ≥200 copies/mL after previous reduction to <50 copies/mL.
[3] For non-T&T, 0 PLWH remained virologically detectable.

### Table 3. Virological Outcomes

| | T&T (n=61) | Non-T&T (n=62) |
|---|---|---|
| **Time to virological suppression following DTG/3TC initiation (weeks)** | | |
| Median (IQR) | 9.7 (5.8, 17.7) | 10.7 (5.4, 19.3) |
| **Time since virological suppression observed (weeks)** | | |
| Median (IQR) | 59.9 (33.3, 79.3) | 48.5 (29.8, 77.6) |
| % sustaining viral suppression to 24 weeks† | 48 (78.7) | 45 (72.6) |
| **Discontinuation Status, n (%)** | | |
| Discontinued DTG/3TC* | 1 (1.6) | 0 (0.0) |
| Ongoing DTG/3TC | 60 (98.4) | 60 (96.8) |
| Unknown/ lost to follow-up | 0 (0.0) | 2 (3.2) |

† All had at least 24 weeks of clinical follow-up post-initiation of DTG/3TC; n=3 T&T and n=7 non-T&T PLWH had remained virologically suppressed to data abstraction but had not yet reached 24 weeks suppressed.
*Primary reason for the n=1 discontinuation was due to 'persistent low-level viremia or viral blips'.

### Limitations

- TANDEM captured treatment outcomes up to and including virological rebound only; thus, there is no knowledge of outcomes post-rebound in the 6 who rebounded.
- TANDEM did not capture HepB status at baseline.
- Baseline VL was not captured in the T&T group.

## Conclusions

- TANDEM included treatment-naïve PLWH initiating onto DTG/3TC as part of a T&T strategy, a population in which there is limited reported real-world evidence.
- After a median follow-up time of 1.3 years, >83% of the treatment-naïve cohort who initiated on DTG/3TC experienced sustained virological suppression with few treatment discontinuations (<2%), irrespective of T&T status.
- TANDEM supports results from the phase IIIb STAT trial demonstrating DTG/3TC is an effective, feasible and well tolerated regimen when used in real-world settings in treatment-naïve PLWH that were initiated as part of a T&T strategy.

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**References: 1.** Centro, V and Perno, C. F., *J. Glob. Antimicrob. Resist.*, 2020;20:228-237. **2.** US Departments of Health and Human Services. *Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV.* Accessed March 2, 2022. **3.** Gibert, C.L. *et al., Fed. Pract.*, 2016;33(3):32-36. **4.** Perez-Gonzalez, A. *et al., Microorganisms, 2022;10(2):433.* **5.** Rolle, C.P., *et al., AIDS, 2021;35(12):1957-1965.* **6.** Schneider, S. *et al.*, IAS Conference 2022, Montreal; Poster # EPB147 **7.** Blick, G. *et al.*, AMCP Nexus Conference 2022, National Harbor

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