Demographics, Clinical Characteristics, and Treatment Patterns of People With HIV Who Are Virologically Suppressed Receiving Complex Regimens in Japan: A Real-World Database Study Using Electronic Medical Records

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Soodi Navadeh[1], Nao Taguchi[2], Jesse Najarro Cermeño[3], Reiko Yamaura[4], Siming Chen[4], Mellissa Williamson[1], Peter Sklar[1], Dai Watanabe[5]

[1]Gilead Sciences, Inc., Foster City, CA, USA; [2]Gilead Sciences K.K., Tokyo, Japan; [3]Gilead Sciences, Inc., Parsippany, NJ, USA; [4]IQVIA Solutions Japan, Tokyo, Japan; [5]AIDS Medical Center, NHO Osaka National Hospital, Osaka, Japan

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Conclusions

- **Prevalence.** In this retrospective Japanese hospital electronic medical record (EMR) analysis among people with HIV, 1 in 10 of those on treatment with an evaluable HIV-1 RNA result were virologically suppressed (VS) on a complex regimen (CR)
- **Regimens were heterogeneous but protease inhibitor (PI)–anchored.** Seventy distinct compositions across the VS on CR population; 82.7% of them were on a PI-based regimen and 40.6% on darunavir + cobicistat + emtricitabine + tenofovir alafenamide
- **Pill burden persists despite suppression.** 81.7% of the VS on CR population were on multiple-tablet regimens, receiving 2 pills per day on average
- **Adherence was high in this population.** Roughly 4 in 5 individuals from the VS on CR populations achieved 90% or higher proportion of days covered (PDC), with a median PDC of 100%
- These data describe a defined population in Japan for whom regimen optimization, such as the single-tablet approach evaluated in ARTISTRY-1, may be discussed on an individual basis

Plain Language Summary

- **Why we did this study.** Human immunodeficiency virus (HIV) is treated with medicines that help control the virus. People may be at different stages of treatment, from just starting treatment to having changed treatments several times. Some people take more complicated HIV treatments, such as taking several pills each day or taking medicine more than once a day. We wanted to learn how many people with HIV in Japan were taking these more complicated treatments, and to better understand their health and treatment history
- **What we did.** We reviewed hospital records from 7779 people with HIV in Japan, collected from 2019 to 2025. We did not give any new treatment. We looked only at the care people had already received
- **What we found.** Among people with HIV who were on treatment and had an HIV test, about 1 in 10 were taking a more complicated HIV treatment and had their HIV under control. Most took their medicines as prescribed. About 8 in 10 took two or more pills each day across 81 different treatments
- **What this means.** Many people kept their HIV under control but still needed to take several pills each day. Researchers have studied ways to reduce treatment to a single daily pill. However, each person and their doctor should decide whether this option is right for them

Introduction

- Many people with HIV still take complex multiple-tablet regimens, often due to viral resistance, intolerance, contraindications, or drug-drug interactions[1-3]
- These individuals may experience high pill burden and challenges with adherence and long-term HIV management, especially older people with multiple comorbidities and concomitant medications[4]
- As Japan's HIV population ages, rising comorbidities and polypharmacy are increasing treatment burden[5]
- Greater pill burden is linked to lower antiretroviral therapy (ART) adherence and persistence; 3.6% of people with HIV had limited treatment options in 2017 to 2022[6,7]
- Optimization is now evidenced; in ARTISTRY-1, people with HIV who were VS on CR who switched to single-tablet bictegravir/lenacapavir met the 4% noninferiority margin at Week 48 (difference: -0.3%, 95.002% CI: -2.3 to 1.8)[8]
- In a US cohort, 8% of people with HIV on ART were VS on CR, using a related but not identical definition.[9] The size and characteristics of this population have not been described in Japan (PubMed search current as of August 2026)
- Characterizing this group is an opportunity to identify unmet needs and to inform individual treatment optimization

Objectives

- To estimate the proportion of adults with HIV in Japan receiving a complex ART regimen and who are VS, using hospital EMR data
- To describe the demographic, clinical, laboratory, and treatment characteristics of this population

Methods

- Retrospective, noninterventional analysis of Japan's DATuM IDEA™ (TOPPAN Holdings Inc.) EMR database, covering 57 hospitals including major Regional Core Hospitals for HIV Care (54 in the National Hospital Organization)
- DATuM IDEA captures HIV-1 RNA and cluster of differentiation 4 (CD4) results for virologic status; core care facilities exclude people with HIV seen in smaller clinics or private practice
- Study period: January 1, 2019, to March 31, 2025; selection window: July 1, 2019, to September 30, 2024, allowing 6-month baseline and follow-up
- Adults aged ≥ 18 years at index with documented HIV and ≥ 1 DATuM IDEA record in selection window; no exclusions were applied
- Index: earliest date on a CR; baseline: the prior 6 months

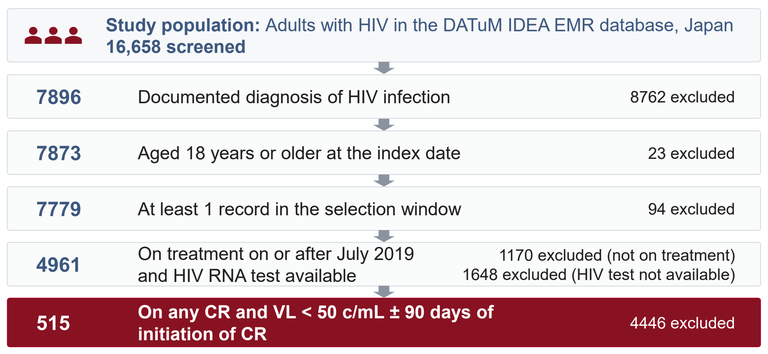
Complex Regimen: Meets Any One of Four Criteria

1) Two of three core classes (non-nucleoside/nucleotide reverse transcriptase inhibitor, PI, or integrase strand-transfer inhibitor) used concomitantly
2) Any boosted PI-based regimen
3) Dosing more frequently than once daily
4) Two or more pills per day, regardless of dosing frequency

- **Excluded:** Regimens representative of available single-tablet regimens; cabotegravir/rilpivirine or dolutegravir/rilpivirine given alone; and regimens containing ibalizumab, enfuvirtide, fostemsavir, or lenacapavir, indicated for heavily treatment–experienced persons (only lenacapavir approved in Japan)
- **Virologically suppressed:** HIV-1 RNA within < 50 copies/mL ± 90 days of index
- **Descriptive analyses:** Counts with percentages, medians with interquartile range, denominators stated on each row

Results

Figure 1. Study Population



Virologic status was assessed within 90 days either side of the index date.
c, copies; CR, complex regimen; EMR, electronic medical record; VL, viral load; VS, virologically suppressed.

Key Findings

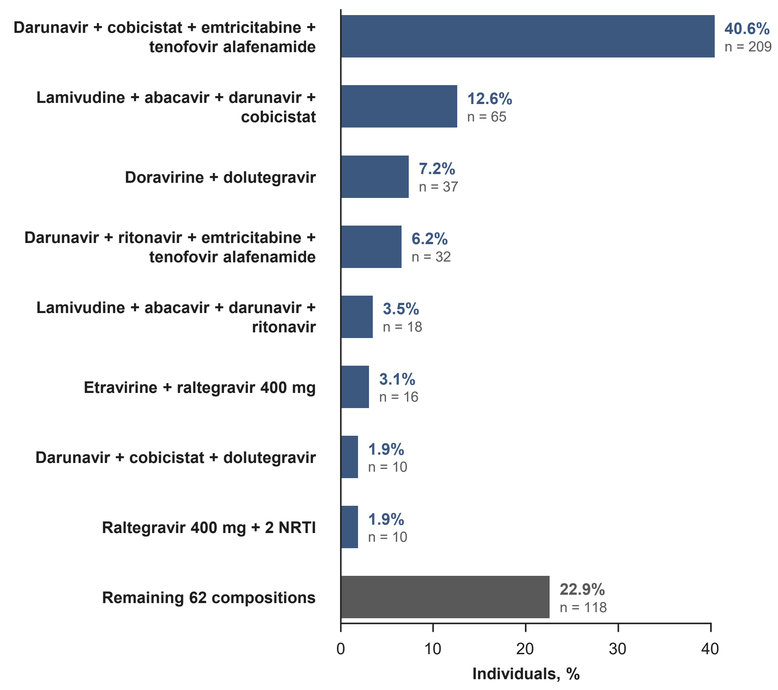
- Of 6609 (7779 - 1170) people with HIV on treatment, 515 were receiving a CR and were VS (**Figure 1**)

10.4% **of people with HIV on treatment with an evaluable HIV RNA result were VS on CR[a]**
515 of 4961

- **Regimens were heterogeneous.** There were 81 distinct compositions across all individuals on CR and 70 among the 515 VS on CR. Darunavir + cobicistat + emtricitabine + tenofovir alafenamide was most common, in 40.6% (**Figure 2**)
- **Most people with HIV were on a PI-based regimen,** with 82.7% of individuals VS on CR
- **A nucleoside/nucleotide reverse transcriptase inhibitor plus PI was the most common class pairing.** 70.5% of individuals VS on CR were receiving this combination (**Table 1**)
- **Most of those VS on CR remained on multiple-tablet regimens.** 81.7% (421/515) were taking a median of 2 pills per day and a maximum of 18 pills per day (**Table 1**, **Figure 3**)
- **Adherence was high.** 81.2% of VS on CR had a PDC of 90% or above, median 100% (**Table 1**)

[a]The denominator for 10.4% is the 4961 people with HIV on treatment with at least 1 evaluable HIV-1 RNA result within 90 days of the index date. Virologic status was assigned from that single result.

Figure 2. Most Common Complex Regimens



Regimen compositions are as recorded at the index date. Percentages are of the 515 individual who were VS on CR. Each of the 62 remaining compositions accounts for 8 or fewer of the 515.
CR, complex regimen; NRTI, nucleoside/nucleotide reverse transcriptase inhibitor; VS, virologically suppressed.

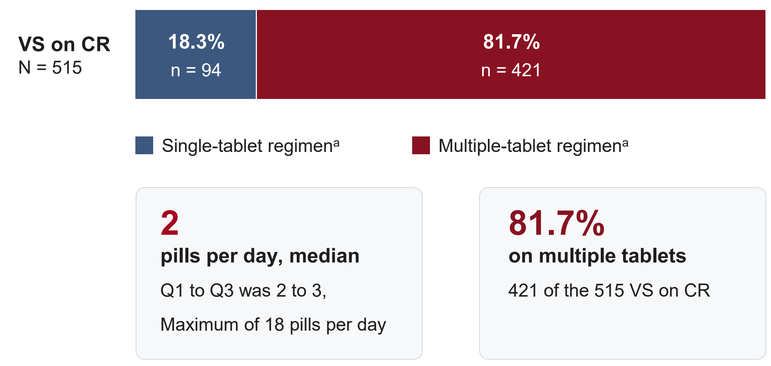
- Across the 515 individuals who were VS on CR, 70 distinct compositions were recorded
- The 8 most common account for 77.1% of the 515 individuals who were VS on CR
- 82.7% of the individuals who were VS on CR were on a PI-based regimen

Table 1. Demographic and Clinical Characteristics

	VS on a CR N = 515
Age at index date, years, median (Q1, Q3)	47.0 (41.0, 55.0)
Male, n (%)	485 (94.2)
BMI available, n	389
Overweight or obese (BMI ≥ 25 kg/m²), n (%)	132 (33.9)
eGFR available, n	180
eGFR < 60 mL/min/1.73 m², n (%)	53 (29.4)
Comorbidities at baseline, n (%)	
Sexually transmitted infections	88 (17.1)
Diabetes	54 (10.5)
Cardiovascular disease	26 (5.1)
Hyperlipidemia	23 (4.5)
Neuropsychiatric disorders	19 (3.7)
Antiretroviral classes at index date, n (%)	
NRTI + PI	363 (70.5)
NNRTI + INSTI	67 (13.0)
NRTI + PI + INSTI	16 (3.1)
Other	69 (13.4)
HIV regimen pill burden and adherence	
Pills per day, median (Q1, Q3)	2.0 (2.0, 3.0)
Single-tablet regimen, n (%)	94 (18.3)
Multiple-tablet regimen, n (%)	421 (81.7)
High adherence, PDC 90% or above, n (%)	418 (81.2)

BMI and eGFR rows are percentages of those with a value; all other percentages are of the column N.
CR, complex regimen; BMI, body mass index; eGFR, estimated glomerular filtration rate; INSTI, integrase strand-transfer inhibitor; NNRTI, non-nucleoside/nucleotide reverse transcriptase inhibitor; NRTI, nucleoside/nucleotide reverse transcriptase inhibitor; PDC, proportion of days covered; PI, protease inhibitor; Q, quartile; VS, virologically suppressed.

Figure 3. HIV Regimen Pill Burden



[a]A single-tablet regimen is 1 pill per day at the index date; a multiple-tablet regimen is 2 or more. A single tablet can meet the CR definition through its composition: all 94 here were boosted PI regimens.
CR, complex regimen; PI, protease inhibitor; Q, quartile; VS, virologically suppressed.

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Acknowledgments: We extend our thanks to the patients, their families, and all participating investigators. This study was funded by Gilead Sciences, Inc. Editing and production assistance were provided by IQVIA and Aspire Scientific Ltd (UK), and were funded by Gilead Sciences, Inc.

Disclosures: **SN**, **JNC**, **MW**, and **PS** are employees of, and own stock in, Gilead Sciences, Inc. **NT** is an employee of, and owns stock in, Gilead Sciences K.K.

Disclosures (cont.)**:** **RY** and **SC** are employees of IQVIA Solutions Japan. **DW** reports grants or contracts from AbbVie G.K., Cmic Co., Ltd, Gilead Sciences, Inc., GSK K.K., MSD K.K., and ViiV Healthcare K.K.; and honoraria from Gilead Sciences, Inc., MSD K.K., Shionogi & Co., Ltd, and ViiV Healthcare K.K.

Correspondence: Soodi Navadeh, soodi.navadeh@gilead.com.