therapy, 22% started DTG-based therapy and 24% started BIC/F/TAF. 36 discontinued INSTI-based therapy early yielding an incidence rate of 0.17 DCs per person-years (PPY) among RAL patients, 0.14 DCs PPY among EVG/c patients, 0.22 DCs PPY among DTG patients, and 0 DCs PPY among BIC patients, p=0.006. Treatment-related AEs occurred in 27% of RAL patients, 42% of EVG/c patients, 50% of DTG patients, and 43% of BIC patients p=0.607; and were responsible for early DC rates of 0.022 in 3 EVG/c patients and 0.075 in 5 DTG patients. No treatment-related early DCs occurred among RAL or BIC patients. No evaluated factor was significantly associated with early INSTI DC, however DTG use was significantly associated with treatment-related AEs (aOR 3.46, 95% confidence interval: [1.20; 10.82]).

Table 1. Risk factors for early integrase inhibitor discontinuation and treatment-related adverse events

Characteristic	Early INSTI DCs (n=36) N (%)	Unadjusted OR for early INSTI DC (CI)	Adjusted OR for early INSTI DC (CI)	Treatment-related AEs (n=141) N (%)	Unadjusted OR for treatment-related AE (CI)	Adjusted OR for treatment-related AE (CI)
Age	N/A*	1.01 (0.98; 1.04)	0.99 (0.96; 1.03)	N/A*	1.01 (0.99; 1.03)	1.01 (0.99; 1.04)
Gender						
Male	30/285 (11)	Ref	Ref	128/294 (44)	Ref	Ref
Female	6/37 (16)	1.64 (0.58; 4.03)	1.62 (0.52; 4.58)	13/37 (35)	0.70 (0.34; 1.41)	0.59 (0.27; 1.23)
INSTI						
RAL	4/26 (15)	Ref	Ref	7/26 (27)	Ref	Ref
EVG/c	18/149 (12)	0.76 (0.25; 2.80)	1.26 (0.38; 5.06)	63/151 (42)	1.94 (0.80; 5.23)	2.48 (0.94; 7.16)
DTG	14/74 (19)	1.28 (0.41; 4.90)	1.98 (0.53; 8.57)	37/74 (50)	**2.71 (1.06; 7.66)**	**3.46 (1.20; 10.82)**
BIC	0/73 (0)	NA	NA	34/80 (42)	2.01 (0.78; 5.63)	2.76 (0.9; 9.08))
NRTI Backbone						
F/TDF	21/120 (18)	**2.64 (1.31; 5.45)**	1.64 (0.72; 3.78)	50/120 (42)	0.94 (0.60; 1.48)	1.02 (0.57; 1.80)
F/TAF	15/202 (7)	Ref	Ref	91/211 (43)	Ref	Ref
Baseline HIV-1 RNA (copies/mL)						
<100,000 copies/mL	18/210 (9)	Ref	Ref	82/216 (38)	Ref	Ref
≥100,000 copies/mL	18/111 (16)	**2.08 (1.02; 4.17)**	1.62 (0.71; 3.68)	58/114 (51)	**1.69 (1.07; 2.68)**	1.57 (0.93; 2.65)
Baseline CD4⁺ count (cells/mm³)						
≥200 cells/mm³	19/230 (8)	**0.39 (0.19; 0.80)**	0.82 (0.07; 11.37)	94/237 (40)	0.64 (0.39; 1.04)	1.06 (0.18; 6.11)
<200 cells/mm³	17/91 (19)	Ref	Ref	47/93 (51)	Ref	Ref
HIV Disease Status						
Asymptomatic	14/193 (7)	Ref	Ref	77/198 (39)	Ref	Ref
Symptomatic	5/40 (12)	1.83 (0.56; 5.12)	1.19 (0.35; 3.49)	18/41 (44)	1.23 (0.62; 2.42)	1.38 (0.67; 2.83)
AIDS	17/89 (19)	**3.02 (1.42; 6.54)**	1.54 (0.13; 20.75)	46/91 (51)	1.61 (0.97; 2.66)	1.31 (0.23; 7.61)

Note. Significant p-values (<0.05) have been **bolded** for ease of interpretation
Abbreviations. OR, odds ratio; INSTI, integrase strand transfer inhibitor; DC, discontinuation; CI, confidence interval; AE, adverse event; RAL, raltegravir; EVG, elvitegravir; c, cobicistat; DTG, dolutegravir; NRTI, nucleoside reverse transcriptase inhibitor; F/TDF, emtricitabine/tenofovir disoproxil fumarate; F/TAF, emtricitabine/tenofovir alafenamide
*Age was analyzed as a continuous variable

Conclusion. In this cohort, early DCs occurred in 11% initiating INSTI-based therapy, however of these only 2% were treatment-related. These data support use of INSTI-based regimens as preferred options for treatment-naïve patients living with HIV due to their favorable safety and tolerability profiles.

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890. Evaluation of Association Among Integrase Inhibitors for HIV Treatment, Weight Gain, and Body Image

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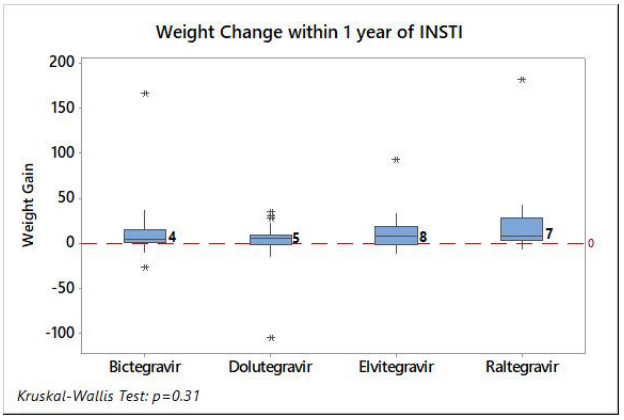
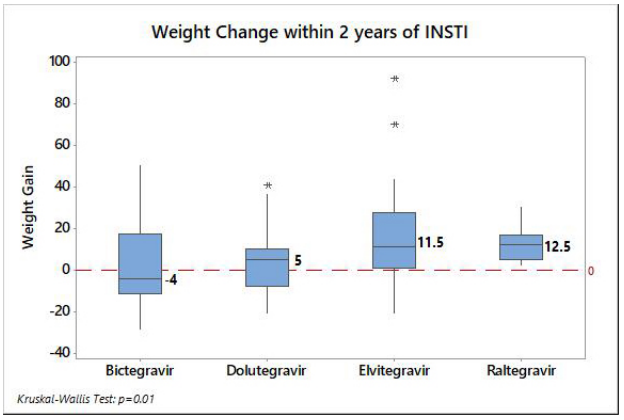
Session: P-51. HIV: Treatment

Background. Integrase inhibitors (INSTIs) are preferred antiretroviral agents for people living with HIV (PLWH). Recent studies suggest that INSTIs may contribute to weight gain and the development of metabolic syndrome. A lack of knowledge remains about how INSTIs affect metabolic parameters that contribute to weight gain as well as the impact of weight gain on medication adherence and body image in PLWH.

Methods. We conducted a retrospective chart review along with a real time survey of PLWH who are receiving HIV care at UConn Health. Participants who were switched to or added an INSTI to their ART regimen between 2012 - 2020 were included (n=204). Patient weight was recorded in 3-month intervals for two years prior to and two years after INSTI initiation. Lipid profile parameters and hemoglobin A1c were noted pre and post INSTI switch. A survey was administered to rate perception of weight gain, body appearance, and medication adherence on a five-point Likert scale. Statistical methods included Chi-square test and Fisher's Exact test for categorical data, and T-test or Kruskal-Wallis test for continuous data.

Results. Patients started on or switched to any INSTI regimen experienced a mean weight gain of 5 and 7 pounds at 12 and 24 months, respectively ($p < 0.001$). Weight gain was greatest with raltegravir and elvitegravir (Figure 1,2). Bictegravir regimens resulted in a 4 pound weight loss at 24 months. An INSTI switch increased cholesterol by a mean of of 7.9mg/dL (p=0.05), with no effect on other parameters. A switch to Bictegravir increased HDL by 4mg/dL (p=0.04) and decreased triglycerides by 35mg/dL (p=0.04). Survey results showed that 100% of patients denied missing ART doses despite 69% mentioning weight gain due to ART. 97% of patients were satisfied with their ART regimen, with the majority disagreeing that their body image was negatively affected.





Conclusion. We demonstrate a link between INSTI use and weight gain up to two years following INSTI initiation, with the most weight gained within the first 12 months. Elvitegravir and raltegravir are associated with greater weight gain whereas bictegravir demonstrates weight loss and beneficial effects on lipid profile. Despite weight gain, most patients remained adherent and satisfied with their medication and denied negative perceptions of body image.

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891. Minimum Manufacturing Costs and National Prices for Weight Loss Treatments, as Potential Mitigation for Anti-Retroviral Related Weight Gain in HIV

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Session: P-51. HIV: Treatment

Background. Weight gain is being observed for a wide range of antiretroviral treatments. Weight gains are higher for people taking first-line integrase inhibitor based treatments, especially those including TAF/FTC. Weight gains are higher for women and people of colour. Clinical obesity increases the risks of cardiovascular disease, diabetes, adverse birth outcomes and could lower survival rates. Anti-obesity treatments are needed to supplement lifestyle interventions and counteract progressive weight gains, but are not routinely provided as part of HIV care.

Methods. Costs of production for FDA-recommended weight loss treatments and anti-diabetic medications (orlistat, naltrexone-bupropion, topiramate, phentermine, semaglutide, liraglutide and metformin) were estimated using an established and published methodology based on costs of active pharmaceutical ingredients (API), extracted from the global shipping records database Panjiva. This was compared with national drug list price data from a range of low, medium, and high-income countries.

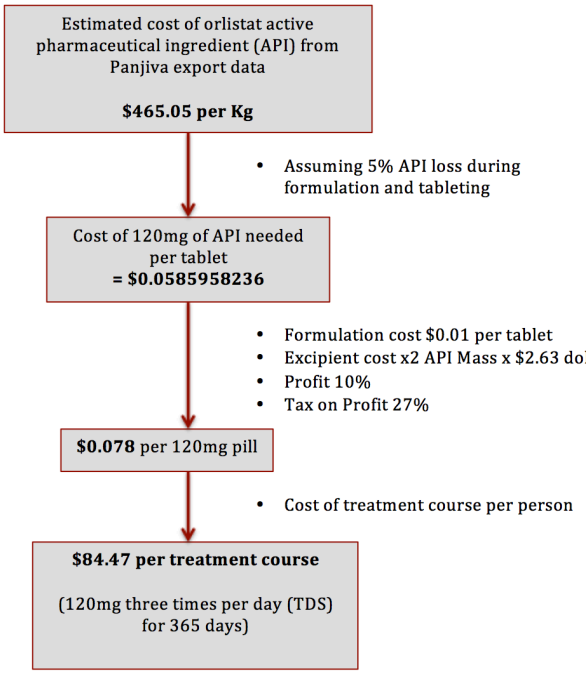

Figure 1. Example of methodology for calculating the estimated minimum cost of production for orlistat

Results. Weight loss and anti-diabetic treatments can be generically manufactured at low per-course costs, e.g. $85 per person per year for oral treatments such as orlistat and $1 per person per month for metformin. However, prices for a year of treatment with orlistat are as high as $1,205 in the USA and as low as $11 in Vietnam. In comparison, a month of ARV treatment costs about $15 via global health institutions like CHAI. Price for injectable (subcutaneous) treatments were higher, ranging from $1,985 for liraglutide in USA to $330 in Morocco, whilst they could potentially be profitably sold for $155 for a 12-week course. No export price data was available for semaglutide. When compared against international list prices, we found wide variations between countries.

Table 1. Summary of drug prices and minimum cost estimates

Drug, route (Course duration and dose)	**Highest course list price** (Country)	**Lowest course list price** (Country)	**Estimated minimum cost course** (USD)
Metformin (PO) (2g/day for 30 days)	$0.72 (USA)	$0.01 (Kenya)	$1.03
Topiramate (PO) (92mg/day for 30 days)	$27 (Peru)	$0.70 (Kenya)	$0.86
Phentermine (PO) (15mg/day for 30 days)	$1.53 (USA)	$0.64 (Kenya)	$0.53
Topiramate-phentermine (PO) (92/15mg/day for 30 days)	$137 (USA)	$137 (USA)	$4.78
Semaglutide (PO) (14mg/day for 30 days)	$578 (USA)	$97 (UK)	NA
Orlistat (PO) (120mg TDS for 360 days)	$1,205 (USA)	$11 (Vietnam)	$85
Liraglutide (S/C) (1.5mg OD for 84 days)	$1,985 (USA)	$330 (Morocco)	$155
Naltrexone-bupropion (PO) (8mg/90mg QDS for 365 days)	$3,918 (USA)	$1,156 (UK)	$655

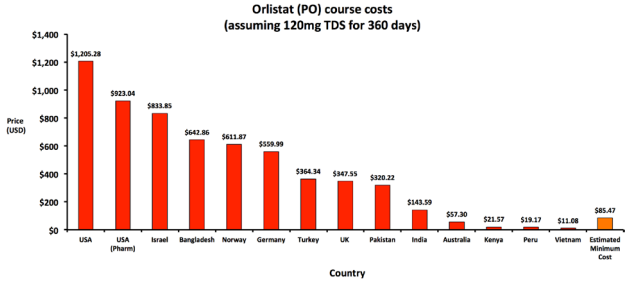

Figure 2. Orlistat course costs in a range of countries, compared with estimated minimum cost

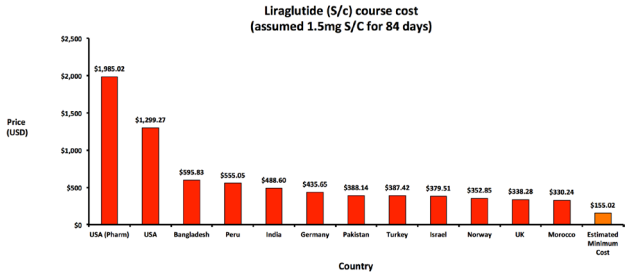

Figure 3. Liraglutide course costs in a range of countries, compared with estimated minimum cost

Conclusion. We show that weight loss treatments can be manufactured and sold profitably for low prices, but have a wide price range between countries. Government and non-governmental healthcare systems should be evaluating weight loss agents for inclusion within ART programmes.

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892. Determination of the Unavailability of Alternative Antiretroviral Formulations

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Session: P-51. HIV: Treatment

Background. Many pediatric and some adult people living with HIV (PLWH) are unable to swallow tablets and require alternative antiretroviral formulations (ARVF) such as liquids, chewable tablets, or powders for suspension. A growing number of issues with the timely procurement of alternative ARVF have been reported; the full scope of this problem is unknown. Without access to appropriate treatment, PLWH are at increased risk of poor disease outcomes. This study's objective was to determine the scope of availability issues of ARVF and its potential impact on patient care.

Methods. An online survey invitation was sent to members of AAHIVM and the ACCP HIV PRN. Data collection included provider demographics, number of issues related to ARVF availability, time spent procuring ARVFs, and identification of unavailable formulations. To determine potential impact on clinical care and cost of care the time required to resolve shortages was summarized.

Results. The analyzable sample was 154, a majority of whom were pharmacists or physicians (n=132, 85.7%; Figure 1), in a clinical role (n=134, 87.0%), and serve pregnant patients (n=121, 79.2%). 85 (55.2%) practice at sites that provide care to > 300 PLWH, 81 (52.6%) practice at sites that did not serve pediatric patients. 525 instances of gaps in care due to ARVF unavailability were reported. In 283 instances, a more complex regimen was prescribed due to first-choice ARVF unavailability. Providers also reported 186 situations in which a less optimal regimen was used and 140 cases of treatment delays. The average time spent to resolve such issues was 2.7 hrs (CI: 1.3 – 4.2). The longest time reported was 72 hrs; most providers spent 1 hr or less. The most common unavailable ARVF were branded ritonavir 80 mg/mL solution (n=12), zidovudine 50 mg/5 mL syrup (n=11), raltegravir 100 mg chewable tablets (n=11), and raltegravir 100 mg granules for suspension (n=10). Branded nevirapine 50 mg/5 mL suspension (n=7) and generic nevirapine 50mg/5ml powder for suspension (n=11) were also reported more frequently.

Distribution of Respondents by Provider Type