All scientific posters have been arranged into the following categories and numbers:

Category	Poster number
ARV-based prevention	P001–P002
Clinical pharmacology	P003
Co-morbidities and complications and disease and/or treatment	P004–P007
HIV/hepatitis co-infection	P008–P009
HIV and women including MTCT	P010–P016
HIV and vulnerable populations	P017–P027
Models of care/scale-up of treatment	P028–P033
Non-AIDS morbidity and mortality, and ageing	P034–P036
Treatment strategies and outcomes	P037–P044
Viral hepatitis	P045–P049
Virology and immunology	P050

O224 **ART initiation rates and first-line regimens in Latin America remain a challenge for WHO recommendations**
Isabel Cassetti[*1]; Pablo Parenti[2]; William Lenis[3]; Rosa Teran[4]; Alberto Castillo[4]; Ana Belen Arauz[5]; Miguel Morales[6]*
[1]Latin American HIV Workshop Study Group, AIDS, Buenos Aires, Argentina; [2]Latin American HIV Workshop Study Group, AIDS, Rosario, Argentina; [3]Latin American HIV Workshop Study Group, AIDS, Cali, Colombia; [4]Latin American HIV Workshop Study Group, AIDS, Quito, Ecuador; [5]Latin American HIV Workshop Study Group, AIDS, Panama City, Panama; [6]Latin American HIV Workshop Study Group, AIDS, Caracas, Venezuela

P001 **Use of social networking applications (apps) and meeting sites in patients with acute HIV infection in a specialized clinic in Mexico City**
Cruz, JB; Hirata, AH; Vega, EH; Ferreya, VD; Rocabert, C; Rodriguez, V; Gonzalez, A (Mexico City, Mexico)*

P002 **Sexual risk behaviours among MSM with HIV in acute infection in a specialized clinic in Mexico City**
Hirata, AH; Cruz, JB; Vega, EH; Ferreya, VD; Rocabert, C; Rodriguez, V; Gonzalez, A (Mexico City, Mexico)*

P003 **A randomized, double-blind comparison of Tenofovir Alafenamide (TAF) vs. Tenofovir Disoproxil fumarate (TDF), each co-formulated with elvitegravir, cobicistat, and emtricitabine (E/C/F) for initial HIV-1 treatment: week 96 results**
Wohl, D; Oka, S; Clumeck, N; Clarke, A; Brinson, C; Tashima, K; Arribas, J; Chéret, A; Brunetta, J; Sax, P; Zhong, L; Das, M; Laurido, M; Fordyce, M (Foster City, USA)*

P004 **Influence of age on outcomes in HIV-infected adults initiating tenofovir alafenamide fumarate (TAF) versus tenofovir disoproxil fumarate (TDF) with elvitegravir, cobicistat, and emtricitabine (E/C/F/TAF vs. E/C/F/TDF)**
Andrade Villanueva, J; Daar, E; Trottier, B; Clarke, A; Parks, D; Brinson, C; Martin, H; Guo, S; Friborg, S; Laurido, M; Fordyce, M (Guadalajara, Mexico)*

P006 **Co-morbidities in a sample of HIV-positive adults in Puerto Rico**
Rodriguez-Diaz, CE; Santana, J; Santiago-Rodriguez, El; Jovet-Toledo, GG; Irizarry-Gonzalez, L; Ron-Suarez, Y; Orengo, JC; Arbelaez, Felipe; Monsanto, H (San Juan, Puerto Rico)*

P007 **Baseline characteristics of a prospective cohort of adult HIV positive patients in Latin America (LATINA)**
Rodriguez Loria, G; Losso, M; Mosqueda, L; Viloria, G; Alave, J; Andrade Villanueva, J; De Paz, M; Laplume, H; Belloso, W (Buenos Aires, Argentina)*

P008 **Ledipasvir/sofosbuvir is safe and effective for the treatment of patients with genotype 1 chronic HCV infection in both HCV mono-and HCV/HIV coinfected patients**
Santana, J; Sulkowski, M; Cooper, C; Kwo, P; Kowdley, K; Kleinstein, SE; Cheinquer, N; Naik, S; Wolf, J; Natha, M; German, P; Stamm, L; Brainard, D; Naggie, S (San Juan, Puerto Rico)*

*Indicates presenting author.

POSTER PRESENTATIONS (continued)

P010 **Improved safety and efficacy of TAF vs. TDF single-tablet regimen in HIV-1 treatment-naïve women through week 48**
Koenig, E; Orkin, C; Clarke, A; Podzamczer, D; Clotet, B; Callebaut, C; SenGupta, D; Das, M; Silva, A; Fordyce, M (Santo Domingo, Dominican Republic)*

P011 **Pregnancies in adolescents infected with HIV in the state of São Paulo, Brazil: Challenges to avoid mother-to-child transmission of HIV and keep these adolescents alive**
Silva, MA; Domingues, CSB; Tayra, A (São Paulo, Brazil)*

P012 **Case investigation protocol and committee as strategies to reduce and eliminate mother-to-child transmission of HIV: Experience of the state of São Paulo, Brazil**
Domingues, CSB; Silva, MA; Tayra, A; Gianna, MC; (São Paulo, Brazil)*

P013 **Long term follow-up of HIV-infected mothers from Perinatal and LILAC studies in Buenos Aires, Argentina**
Gladstone, D; Ivalo, S; Nachman, S; Losso, M (Buenos Aires, Argentina)*

P014 **Implementation gaps for interventions to prevent mother to child transmission of HIV in Mexico during 2014**
Villafuerte Garcia, A; Rivera Reyes, MdP; Uribe Zúñiga, P; Magis Rodríguez, CL (Mexico City, Mexico)*

P016 **HIV testing, prenatal care and diagnosis in pregnant women hospitalized in a public hospital in Buenos Aires**
Ivalo, S; Bulló, M; Hakim, A; Scalise, C; Losso, M; Terwel, S (Buenos Aires, Argentina)*

P017 **HIV/STI testing among MARPs in Mexico City: a key first step to improve the cascade of care**
Ruiz, V; Medina, Y; Iracheta, P; Macias, I; Juarez, L; Rodriguez, E; Niño, R; Diaz, S; Gonzalez, A (Mexico City, Mexico)*

P018 **Implementation of new strategies for timely HIV diagnosis in Mexico City's Prison System and its impact on the continuum of care**
Vargas González, H; Badial Hernandez, F; Gras Allain, N; Pineirua Menendez, A; Casillas Rodriguez, J; Gonzalez Rodriguez, A; Jimenez Munguia, LM; Cid Vasque, H (Mexico City, Mexico)*

P019 **Incidence and time-varying predictors of HIV and sexually transmitted infections (STIs) among male sex workers in Mexico City**
Ganley, KY; Zullo, AR; Sosa-Rubi, SG; Conde-Glez, CJ; Lurie, MN; Marshall, BDL; Operario, D; Mayer, K; Galarraga, O (Providence, USA)*

P020 **Changes in renal laboratory parameters and bone mineral density in treatment-naïve HIV-1-infected adolescents initiating therapy with INSTI-based single-tablet regimens containing tenofovir alafenamide (TAF) or tenofovir disoproxil fumarate (TDF)**
Koenig, E; Gaur, A; Kizito, H; Prasitsuebsa, W; Rakhmanina, N; Chokephaibu, K; Fourie, J; Bekker, L-G; Shao, Y; Bennett, S; Silva, A; Quirk, E (Santo Domingo, Dominican Republic)*

P023 **Prevalence of HIV infection among imprisoned women in Brazil: a cross-sectional survey in the State Prison System of São Paulo**
Souza, TRC; Ramos Jr, AN; Sparinger, WdA; Santos, MTF; Silva, MA; Placco, AL; Lamastro, SM; Pongelupi, SM; Domingues, CSB; Gianna, MC (São Paulo, Brazil)*

P024 **HIV Cascade of Care and viral load suppression in trans-Women (TGW) and men who have sex with men (MSM) populations in the Dominican Republic**
Paulino, R; Rodriguez-Lauzurique, M; Domingo, R; Tapia, L; Peña, P; Duran, JA (Santo Domingo, Dominican Republic)*

P026 **Prevalence of elevated depression symptoms and key associated factors among female sex workers and women living with HIV/AIDS in the Dominican Republic**
Rael, C; Davis, A (New York, USA)*

P027 **Trends of the HIV/AIDS epidemic in men who have sex with men (MSM) in the state of São Paulo, Brazil**
Tancredi, MV; Domingues, CSB; Tayra, A; Polon, MC; Gianna, MC (São Paulo, Brazil)*

*Indicates presenting author.

P029 **Assessing mental health among recently diagnosed HIV patients at Condesa Clinic in Mexico City**
Vega-Ramirez, EH; Rodriguez, V; Cruz, JB; Ferreya, D; Rocabert, C; Hirata, H; Gonzalez-Rodriguez, A (Mexico City, Mexico)*

P030 **High rate of linkage to care and antiretroviral therapy initiation in Haiti, and improvements over time**
Dorvil, N; Hennessey, K; Guiteau, C; Rivera, V; Devieux, J; McNairy, M; Severe, P; Marcelin, A; Julma, P; Attwood, S; Koenig, S; Pape, JW (Port-au-Prince, Haiti)*

P031 **Median CD4 count increase at ART initiation in Ministry of Health of Mexico between 2010 and 2015**
Valenzuela-Lara, M; Magis Rodríguez, C; Becerril-Vargas, E; León Juárez, EA (Mexico City, Mexico)*

P033 **Care model for HIV-positive pregnant women**
Cabrera López, TdJ; Ramos Alamillo, U; Langarica Naves, E; Badial Hernandez, F; Piñeirua, A; Cruz Islas, JB; Díaz, S; Gónzalez Rodríguez, A (Mexico City, Mexico)*

P034 **Are we doing enough preventive primary care for older HIV positive patients? A survey in a third level hospital in Mexico City**
Crabtree-Ramirez, B; Sierra-Madero, J; Madrigal-Iberri, C; Reyes-Fentanes, MJ; Caro-Vega, Y (Mexico City, Mexico)*

P035 **Human papilloma virus and anal associated lesions in men who have sex with men, HIV and non HIV-infected. First cross-sectional study in Uruguay**
Frantchez, V; Arteta, Z; Albora, C; Ruchansky, D; Caserta, B; Cabrera, A; Cabrera, S (Montevideo, Uruguay)*

P036 **Analysis of HIV/AIDS mortality in Mexico by state and municipal level from 2003 to 2013**
Bravo-García, E; Ortiz-Pérez, H (Mexico City, Mexico)*

P037 **Significant increase in new HIV infections among young adults in Latin America**
Gallo, C; Lopez, O; Chahin, C; Marincovich, B; Zitko, P; Beltran, C (Santiago, Chile)*

P038 **Presentation to care with advanced HIV disease is still a problem in Latin America**
Celi, AP; Greco, M; Martinez, E; Vargas, C; Belaunzaran, F; Mejia, F (La Plata, Argentina)*

P040 **Clinical monitoring system of people living with HIV/AIDS (SIMC): Brazilian strategy to reduce GAP treatment**
Moura, M; Kolling, A; Freitas, M; Pascom, AR; Benzaken, A; Mesquita, F (Brasilia, Brazil)*

P041 **Low level viremia in people living with HIV at antiretroviral therapy**
Valenzuela-Lara, M; Magis-Rodríguez, C; Becerril-Vargas, E; León Juárez, EA (Mexico City, Mexico)*

P042 **Persistency of first-line ART in a real-world setting in a cohort of HIV-positive patients from Santiago, Chile**
Chanqueo, L; Bernal, F; Vásquez, P; Gutierrez, C; Giadalah, C; Serri, M (Santiago, Chile)*

P043 **48 weeks CD4 cell recovery in HIV infected patients on effective antiretroviral treatment**
Viloria, GA; Kundro, MA; Toibaro, JJ; Losso, MH (Buenos Aires, Argentina)*

P044 **Prevalence of HIV-1 drug resistance associated mutations in patients experiencing first-line antiretroviral therapy failure in a cohort of HIV-positive patients from Santiago, Chile, 2012 to 2014**
Bernal, F; Chanqueo, L; Gutierrez, C; Vásquez, P (Santiago, Chile)*

P045 **Ledipasvir/sofosbuvir (LDV/SOF) for 8W in genotype 1 treatment-naïve (TN) noncirrhotic (NC) patients with viral load (VL) <6 million IU/ML; a comparative analysis of the ION-3 data to real work effectiveness**
Feld, J; Buggisch, P; Peterson, J; Mauss, S; Kowdley, K; Curry, M; Ruane, P; Ain, D; Tsai, N; Lee, Y; Eggleton, E; Natha, M; Kretter, B; Brainard, D; Cheinquer, N; Ingiliz, P (Toronto, Canada)*

P046 **Characterization of a large hepatitis C patients cohort in a reference center in Brazil: a descriptive cohort study**
Quiroga, R; Luiz, AM; Odongo, FCA; De Matos, MLM; Nastri, AC; Campos, AF; Capuani, L; Mendes-Correa, MC (São Paulo, Brazil)*

P050 **Integrated analysis of emergent drug resistance through 96 & 144 weeks from clinical studies of HIV-1 treatment-naïve subjects receiving dolutegravir based regimens**
Aboud, M; Demarest, J; Quercia, R; Zolopa, A; St Clair, M; Wynne, B; Underwood, M; Granier, C (Brentford, UK)*

*Indicates presenting author.

ART initiation rates and first line regimens in Latin America remain a challenge for WHO recommendations

Cassetti, Isabel ; Parenti, Pablo ; Lenis, William ; Teran, Rosa ; Castillo, Alberto ; Arauz, Ana Belén ; Morales, Miguel

on behalf of the Latinamerican Workshop Study Group

Abstract Text

Background: WHO Consolidated Guidelines released in November 2015 recommend ART initiation in all adults living with HIV regardless of clinical stage and at any CD4 count. The preferred first line regimen is TDF -- 3TC (FTC) -- EFV with NVP, EFV 400 mgs and DTG as alternative regimens as well as AZT -- 3TC in place of TDF -- 3TC. Latin-American countries follow local specific guidelines, each one recommending different approaches for time and ART combinations for ART initiation. The aim of this study is to determine how often ART is initiated in new HIV cases and what antiretroviral combinations are used in clinical practice in countries from Latin America. **Materials and methods:** The Latin-American Workshop Study Group is an expanding network of 38 HIV Care Centers form 11 countries of South America, Central America, the Caribbean and Mexico with clinical data from 73,431 patients up to September 2015. We identified 9,979 cases of ART initiation in 2013 -- 2014 in 8 countries. Statistical analysis by chi square test and confidence intervals. **Results**: Globally 81% of newly diagnosed HIV cases initiated ART during the first year of follow up. Mexico, Dominican Republic and Argentina were the only countries with rates of ART initiation of 90% or higher while rates of ART initiation were 64% to 74% in most South American countries. Only 16% of patients initiated TDF -- 3TC/FTC -- EFV. AZT -- 3TC is still the preferred backbone (52.2%) while TDF -- 3TC/FTC is the second preferred backbone (24.1%) with large differences in NRTI use between countries; less to 25% in Costa Rica and Peru to over 90% in Ecuador and Mexico. EFV is the third drug in 65.4% of therapies initiated in 2013 -- 2014, protease inhibitors in 18.3% of cases and Raltegravir in 2.4%. **Conclusions:** In Latin America some countries adopted ART initiation regardless of CD4 count while most South American countries show ART initiation rates around 70%. Regimens selected for first line therapy are diverse between countries and WHO recommended regimen is not preferred in most countries. AZT -- 3TC is still the preferred backbone, protease inhibitors are frequently used as third drug and a few patients initiate integrase inhibitors. Standardization of first line regimens is guaranteed in Latin America.

Background

- WHO Consolidated Guidelines recommend ART initiation in all adults living with HIV regardless of clinical stage and at any CD4 count

- The preferred 1st line regimen is TDF - 3TC (FTC) + EFV with NVP, EFV 400 mgs and DTG as alternative regimens as well as AZT - 3TC in place of TDF - xTC.
- Latin-American countries follow local guidelines, each one recommending different approaches for time and ART combinations for ART initiation.

First-line ART	Preferred first-line regimen
Adults	TDF + 3TC (or FTC) + EFV

Alternative first-line regimens[1,2]

AZT + 3TC + EFV (or NVP)
TDF + 3TC (or FTC) + DTG[2,3]
TDF + 3TC (or FTC) + EFV_{400}[4,5]
TDF + 3TC (or FTC) + NVP

Recommendation

- ART should be initiated among all adults with HIV regardless of WHO clinical stage and at any CD4 cell count *(strong recommendation, moderate-quality evidence)*.
  - As a priority, ART should be initiated among all adults with severe or advanced HIV clinical disease (WHO clinical stage 3 or 4) and adults with CD4 count ≤350 cells/mm³ *(strong recommendation, moderate-quality evidence)*.

Methods

- Data were provided by participant centres.
- No individual information from patients was collected. Data analysed came from sheets containing aggregated information.

Figure 1. Image of the sheet used for solicit data of ART-backbone

- For every single analysis different sheets were provided, explaining some slight differences in totals.
- Analysis were performed by centre, by country and for the whole sample. Variance within-centres and among centres was considered for estimations. Heterogeneity among centres was expressed using I^2 index.

Participant centers

	Country	n centers	n patients	Linked to care	New cases
1	Argentina	4	8.649	8.021	609
2	Chile	10	12.726	9.952	1.506
3	Colombia	10	17.988	16.930	2.935
4	Costa Rica	2	2.883	1.746	444
5	Ecuador	5	13.035	8.942	393
6	México	1	3.090	1.740	210
7	Panamá	1	2.468	2.468	0
8	Paraguay	1	844	719	0
9	Perú	2	9.698	5.987	1.616
10	R. Dominicana	1	358	348	19
11	Venezuela	1	1.692	1.156	0
	Total	38	73.431	58.009	7.732

Results

Results: ART initiation during 1st year follow - up

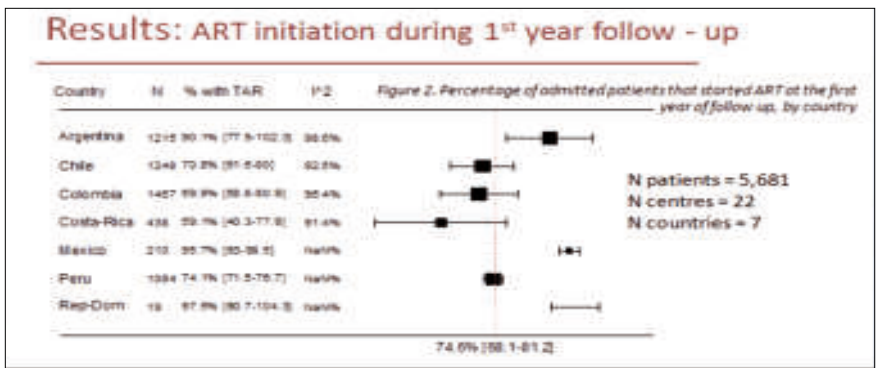
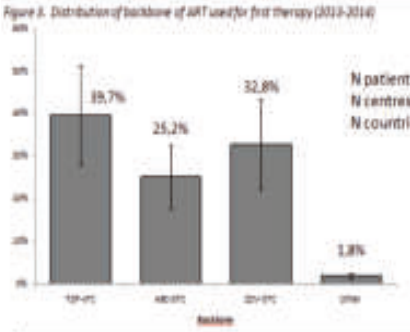


Figure 2. Percentage of admitted patients that started ART at the first year of follow up, by country

- **74.6 %** of 5,681 patients admitted to care during 2013-2014 started ART during the 1st year.
- Significant heterogeneity within countries was observed.
- Argentina, México and Dominican Rep. showed the highest rates of ART initiation (over 90%) while the other countries had ART initiation rates ranging between 60 and 75%.

Results: Backbone distribution

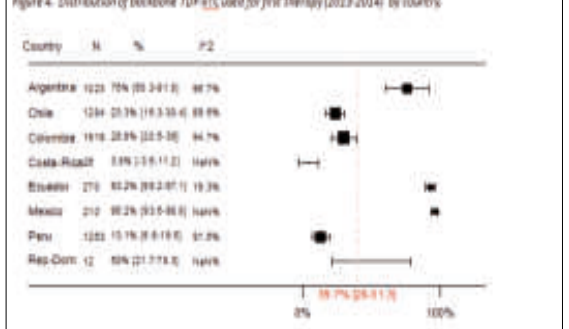
Figure 3. Distribution of backbone of ART used for first therapy (2013-2014)



- Similar preferences for TDF and ZDV first line containing regimens.
- 32,8% of patients initiating first ART with Zidovudine containing regimens increases to 52.2% on considering patients initiating ART before 2013.

Results: Backbone distribution by country

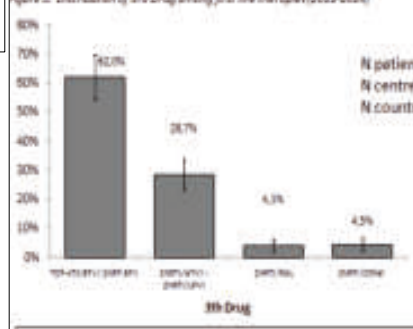
Figure 4. Distribution of backbone TDF+FTC used for first therapy (2013-2014) by country.



- Significant heterogeneity in TDF use in first line regimens ranging from less 25% in Costa Rica and Perú, to more than 90% in Argentina, México and Ecuador.

Results: Third drug distribution

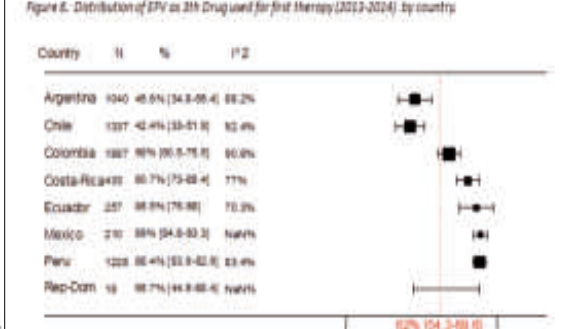
Figure 5. Distribution of 3rd Drug among first line therapies (2013-2014)



- EFV is the preferred 3rd drug followed by PI/r.
- Very low rates of Raltegravir use as first line ARV in Latin America.

Results: Third drug distribution by country

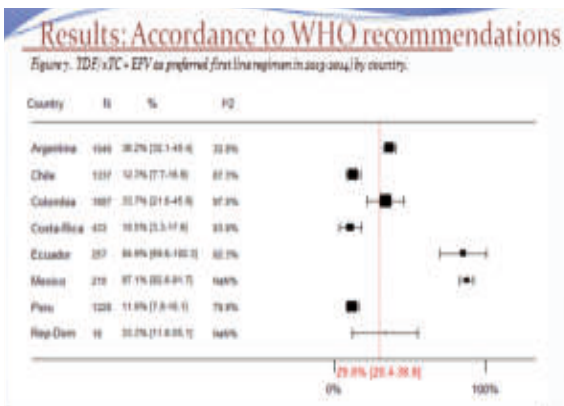
Figure 6. Distribution of EFV as 3th Drug used for first therapy (2013-2014) by country



- Differences in EFV use observed among countries (40 to 90%).

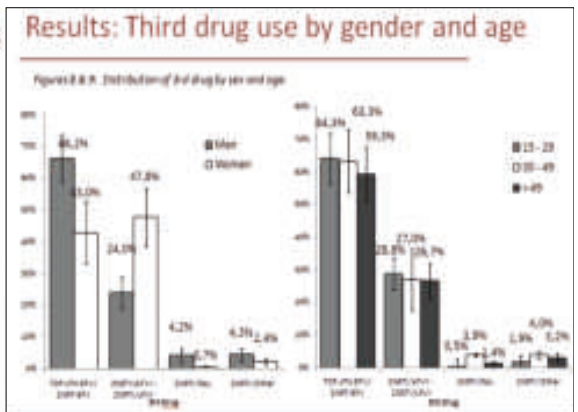
Results: Accordance to WHO recommendations

Figure 7. TDF/xTC + EFV as preferred first line regimen in 2013-2014 by country.



- Large differences between countries in adherence to WHO recommendations
- TDF/xTC + EFV as first regimen ranges from 10% to more than 80% in Mexico and Ecuador

Results: Third drug use by gender and age



- Significant differences between EFV vs bPI use in men as compared to women.
- No differences in frequency of third drug use by age

Conclusions

- A modest reduction in new HIV infections has been reported in Latin America.
- Young people especially men between 15 and 24 years old show an important increase in new HIV cases in 2013 -- 2014 in most countries in spite of some differences between centers.
- In the context of the 90 -- 90 -- 90 goals specific policies should be implemented targeting this key population.

Argentina; La Plata. Centro de estudio y tratamiento infectológico (CETI) María M. Greco; Jorge Contarelli - Argentina; Buenos Aires. HELIOS SALUD. Isabel Cassetti, Edgardo Bottaro; Paula Rodríguez - Chile; Arica. CENTRO ATENCION VIH ADULTO ARICA Carlos Gallo; Roxana Galvez; Ana Miles - Chile. Iquique Hospital Ernesto Torres Galdames Olga Lopez; Natalia Esquivel - Chile; Temuco. HOSPITAL DR. HERNÁN HENRÍQUEZ ARAVENA, Carolina Chahin; Claudia Molina - Chile; Santiago. HOSPITAL BARROS LUCO TRUDEAU Angelo Gonzalez; Carlos Beltrán; Pedro Zitko - Chile; Santiago. HOSPITAL SAN JOSE Beatriz Marincovich; María T. Silva; Alcia Scharaffia - Chile; Santiago. Hospital San Juan de Dios, Fernando Bernal; Patricia Vásquez; Leonardo Chanqueo - Chile; Santiago. COMPLEJO ASISTENCIAL DR.SOTERO DEL RIO, Martin Lasso; Ana María Fernández - Chile; Santiago. Hospital de Enfermedades Infecciosas Dr. Lucio Córdova, Nell Pico; Laura Baamondes - Chile; Santiago. Hospital Clínico Universidad de Chile, Alejandro Afani; Carla Bastías - Colombia; Bogotá. IPS Centro de Expertos para Atención Integral CEPAIN. Mónica Mantilla, Leonardo Arévalo -Colombia, Bogotá. VIHONCO IPS, Eric Delgado - Colombia; Bogotá. Infecto clínicos Otto Sussmann; Carol Páez - Colombia; Bogotá. Asistencia Científica Otto Sussmann; Carol Páez - Colombia; Medellín - Cali. SIES, María P. Posada; Ernesto Martínez-B.; Claudia González - Colombia; Cali. IPS ESIMED, José A. Pardo - Colombia; Cali. COMFANDI SOS, William Lenis - Colombia Cali G OCHO IPS- COMFENALCO VALE, Jenny Santamaría - Colombia; Cali. RECUPERAR IPS, William Lenis; Pedro Martínez - Costa Rica; San José, Hospital Rafael Ángel Calderón Guardia, Jorge Chaverri: Antonio Solano - Costa Rica; San José. Hospital San Juan de Dios;Carmen Vargas; Manuel Villalobos - Ecuador; Quito. HOSPITAL EUGENIO ESPEJO, Alberto Castillo; Grace Loza - Ecuador; Quito. HOSPITAL ENRIQUE GARCÉS, Rosa Terán; Nelson Cevallos - Ecuador; Quito. Hospital de Especialidades de las Fuerzas Armadas;Ana P. Celi; Andrea Araujo - México C. México. I. Nacional de Cs. Médicas y Nutrición "Salvador Zubirán", Juan Sierra Madero; Francisco Belaunzarán - Perú; Lima. Hospital Nacional Arzobispo Loayza, Aldo Lucchetti; Julio Maquera - Perú; Lima. Hospital Nacional Cayetano Heredia; Fernando Mejía - R. Dominicana; Sto Domingo. HOSPITAL SALVADOR B GAUTIER, Monica Thorman; Marlene Cosme.

Use of Social Networking Applications and Meeting Sites in patients with acute HIV infection in a specialized clinic Mexico City

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Background: The acute infection of HIV is a crucial moment. After infection, during the first 3 weeks there is an exponential replication growth of the virus and the person is most infectious, knowing the risks involved [1,2]. We observed a significant impact of applications among men who have sex with men (MSM) and meeting places in sexual health, use of these leads to a greater likelihood of having unprotected sex and spread of disease sexual transmission [3]

Methodology: Semistructured interview about risky sexual behavior and substance use self-report in the three months prior to HIV diagnosis is applied. In categorical variable frequencies and percentages for the means and standard deviations continuous variables were performed.

Results:

Table 1. Sociodemographic data	
Variable	**N (%)**
Men	**103**
Single	72 (70.8)
Occupation	
• Employees	46 (44.6)
• Student	23 (22.3)
• Unemployed	20 (19.4)
Variable	**(X±DE)**
Age	27.6 ±7.7
Years of study (X±DE)	13.62 ±2.96

Table 2. Biological data	
Variables	**X±DE**
Viral load	3 386 079 ±3 601 811
CD4	364 ±183

Table 3. Sexual Orientation / Position	
Sexual orientation	**N (%)**
• Homosexual	94 (91.3)
• Heterosexual	3 (2.9)
• Bisexual	6 (5.8)
Sexual position	
• Top	16 (15.5)
• Bottom	12 (11.6)
• Versatile	22 (21.3)
• +Top	34 (33)
• +Bottom	19 (18.4)

Table 4. Sexual characteristics	
Variables	**N (%)**
Circumcision	16(15.5)
	(X±DE)
• Age of sexual life onset	17.9 ±14.8
• Sexual partners throughout life	113.9 ±156.8
• Sexual partners in last 3 mo.	7.8 ±18.99
• Condomless sexual partners in last 3 mo.	5 ±13

Table 5. Networking Applications & Meeting sites	
Variable	**N (%)**
Use of networking Applications	41 (39)
One application	5 (12.2)
Two applications	25 (60.8)
> Two applications	11 (27)
Contact success via applications	35 (85.3)
Variable	**(X±DE)**
Sexual partners via application	12± 25
Application type	**N (%)**
Grindr	30 (73)
Manhunt	3 (7.3)
Hornet	3 (7.3)
Facebook	3 (7.3)
Others	2 (5.1)
Attend sexual meeting places	**41(39)**
One meeting place	14 (34.1)
Two meeting places	20 (48.7)
> Two meeting places	7 (17.2)
Type of sexual meeting places	
Bath houses	17 (41.4)
Orgias	12 (29.3)
Public transportation	5 (12.2)
Others	7 (17.1)

Conclusions: As we know this is the first study that describes the use of networking applications for sexual contacts in newly diagnosed patients with HIV in Mexico City. Knowing risk sites could allow preventive policies and procedures to prevent risk behaviors.

References:
1.-Nicola Z, Pilcher C. Diagnosis in managment of acute HIV infection. Infect Dis Clin N Am 21(2007)19-48
2.- Van Kesteren N, Hospers H, Kok G. Sexual Risk Behavior among HIV positive men who have sex with men: A literature review. Patient education and counseling. 65, 2007 5-20
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Sexual Risk Behaviors Among MSM with HIV in Acute Infection in a Specialized Clinic in Mexico City

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Introduction

The phase of acute or recent HIV infection is a crucial moment of infection to the spread of the virus. Week 2-3 after infection exponential growth of the decrease in viral load and CD4 occurs. This reported in the literature that sexual risk behaviors as traumatic sex, receptive anal intercourse, active ulcerative disease, sex work, drug use and regulate multiple sexual partners. In men, the risk factors have been associated with who are not circumcised.

Methodology

Semistructured interview about risky sexual behavior and substance use self-report in the three months prior to HIV diagnosis is applied. In categorical variable frequencies and percentages for the means and standard deviations continuous variables were performed.

Results

Table 1. Sociodemographic data

Variables	N%
Men	103(100)
Age (X±DE)	27.6±7.7
Single	72(70.8)
Years of study (X±DE)	13.62±2.96
Emploiment • Employees • Student • Unemployed	 46(44.6) 23(22.3) 20(19.4)

Table 2. Viral load and CD4

Variables	X±DE
Viral load	3386079.33±3601811.13
CD4	364.11±183.22

Table 3. Sexual characteristics

Variables	N%
Sexual position • Active • Passive • Active/passive • +Active/Passive • Active/passive +	 16(15.5) 12(11.6) 22(21.3) 34(33) 19(18.4)
Circumcision	16(15.5)
Sexual Orientation • Homosexual • Heterosexual • Bisexual	 94(91.3) 3(2.9) 6(5.8)

Table 4. Sexual Risk behavior

Variables	N%
Age of first sexual intercourse (X±DE)	17.9±14.8
Number of sexual partners along life (X±DE)	113.9±156.8
Number of sexual partners 3m (X±DE)	7.8±18.99
STI's	41(39.8)
Anal bleeding	17(16.5)
Sustance in coitus	36(34.9)
Type of substances • Alcohol • Cannabis • Poppers	 24(66.6) 12(33.3) 12(33.3)

Conclusions

It is the first time a report in Mexico of sexual behaviors in persons with acute infection is. Knowing the sexual behaviors that are having acute patients will allow us to make strategies to prevent the spread of HIV

References:

1. Nicola z, Pilcher C. Diagnosis in managment of ascute HIV infection. Infect Dis Clin N Am. 21, 2007; 19-48
2. Van Kesteren N, Hospers H, Kok G. Sexual risk Behavior among HIV positive men who have sex with men: A literatura review. Patient education and counseling 65, 2007; 5-20
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P03

Poster P003

Passcode: P003

A Randomized, Double-Blind Comparison of Tenofovir Alafenamide (TAF) vs Tenofovir Disoproxil Fumarate (TDF), Each Coformulated with Elvitegravir, Cobicistat, and Emtricitabine (E/C/F) for Initial HIV-1 Treatment: Week 96 Results

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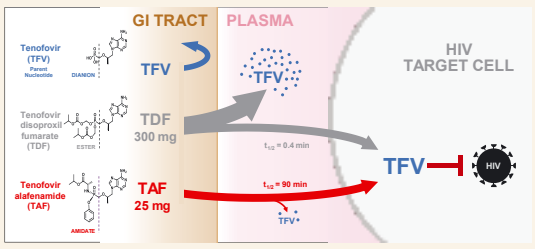
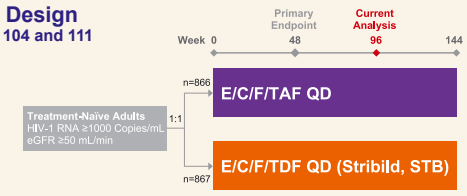
Introduction

Mechanism of Action: TAF vs TDF[1-6]



- TAF, a novel oral prodrug of TFV, is more stable in plasma than TDF, allowing for a 10-fold lowering of dose, which results in a substantial reduction (90%) in circulating TFV, while achieving a 4-fold increase in intracellular levels of TFV diphosphate (TFV-DP) and comparably high efficacy[4]

Study Design
Studies 104 and 111



E/C/F, elvitegravir/cobicistat/emtricitabine; eGFR, estimated glomerular filtration rate

- Two phase 3 international, randomized, double-blind, double-dummy studies
  - Study 104 (North America, EU, Asia; ClinicalTrials.gov NCT01780506), Study 111 (North America, EU, Latin America; NCT01797445): TAF vs TDF, each coformulated with E/C/F
  - Stratified by HIV-1 RNA, CD4 cell count, geographic region
- Primary endpoint met: E/C/F/TAF efficacy noninferior to STB at Week 48[6]
  - HIV-1 RNA <50 copies/mL by FDA snapshot analysis at 12% margin
- Secondary endpoints: hip and spine BMD, change in serum creatinine, safety and tolerability through Week 48
- At Week 48, both arms achieved high rates of virologic suppression (>90%)[6]
  - At Week 48, patients randomized to E/C/F/TAF had significantly reduced bone demineralization in lumbar spine and hip, significantly smaller mean serum creatinine change, and significantly lower rates of total proteinuria, albuminuria, and proximal tubular proteinuria vs those assigned TDF

Objective

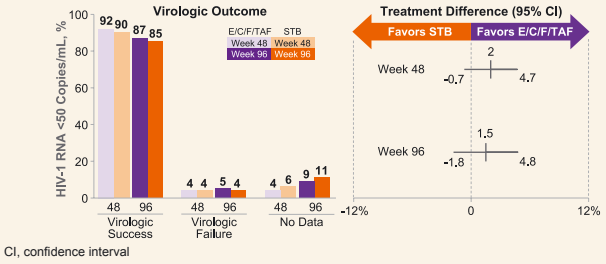
- To compare longer term (96 week) efficacy, safety, and tolerability of treatment with E/C/F/TAF vs STB in treatment-naïve patients with HIV-1 from Studies 104 and 111

Results

Baseline Demographics, HIV Risk Factors, and Medical History

	E/C/F/TAF n=866	STB n=867
Median age, y (range)	33 (18-74)	35 (18-76)
Female, %	15	15
Race and ethnicity, %		
Black or African heritage	26	25
Asian	11	10
Hispanic or Lantino	19	19
Median CD4 count, cells/μL	404	406
CD4 <50 cells/μL, %	3	3
HIV-1 RNA >100,000 c/mL, %	23	22
Medical history, %		
Diabetes mellitus	3	5
Hypertension	14	17
Cardiovascular disease	1	2
Hyperlipidemia	11	12
Median eGFR, mL/min (Cockcroft-Gault)	117	114

Week 48 and 96 Virologic Outcomes[7]



CI, confidence interval

- By 96 weeks, virologic failure with resistance occurred in 18 patients
  - 10/866 TAF patients (1.2%): 2 with M184V, 6 with M184V/I+integrase strand transfer inhibitor-resistance (INSTI-R), 1 with K65R+M184V+INSTI-R, 1 with K65N+INSTI-R
  - 8/867 TDF patients (0.9%): 3 with M184V, 1 with M184V+INSTI-R, 2 with K65R+M184V+INSTI-R, 1 with K65N+INSTI-R, 1 with INSTI-R
    - M184V/I: 9 TAF, 6 TDF; K65R/N: 2 TAF, 3 TDF; primary INSTI resistance: 8 TAF, 5 TDF (all genotypically susceptible to dolutegravir)
- 3 patients in each arm had antiretroviral resistance that was newly detected between Weeks 48 and 96

Results (Cont'd)

Safety Summary

Patients, %	E/C/F/TAF n=866	STB n=867
Any AE	93	95
Any drug-related AE	42	46
Grade 3 or 4 AE	12	12
Drug-related Grade 3 or 4 AE	2	1
Serious AE	11	10
Drug-related serious AE	0.6	0.2
AE-related discontinuation	1	2
Renal AE discontinuation, n	0	6*
Death	0.2†	0.3‡

*p=0.03; †Stroke (n=1), alcohol intoxication n=(1); ‡Alcohol and drug intoxication (n=1), myocardial infarction (n=2); AE, adverse event

Common Adverse Events: All Grades

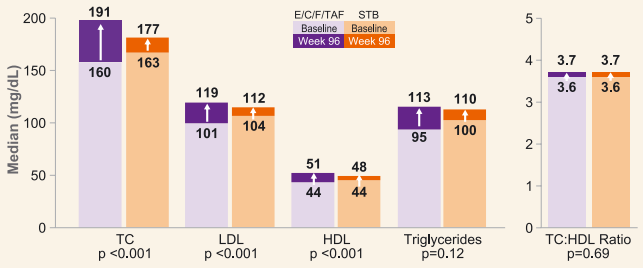
AEs in ≥10 % of Patients, %	E/C/F/TAF n=866	STB n=867
Diarrhea	20	23
Headache	17	15
Upper respiratory tract infection	17	17
Nausea	16	19
Nasopharyngitis	12	12
Cough	11	10
Fatigue	11	10

Grade 3 or 4 Laboratory Abnormalities

Patients, %	E/C/F/TAF n=866	STB n=867
Any Grade 3 or 4 lab abnormalities*	28	25
Creatine kinase elevation	9	7
LDL elevation (fasting)	8	4
Lipase	5	9
Hypercholesterolemia (fasting)	3	2
Hematuria (quanititative)	3	3
AST	2	2
Amylase	2	4
ALT	2	2
Neutrophils	2	3
Urine glucose	2	2
GGT	1	3
Hyperglycemia (nonfasting)	1	1
Triglycerides (fasting)	1	<1

*≥1% on E/C/F/TAF arm. ALT, alanine aminotransferase; AST, aspartate aminotransferase; GGT, γ-glutamyltransferase; LDL, low-density lipoprotein

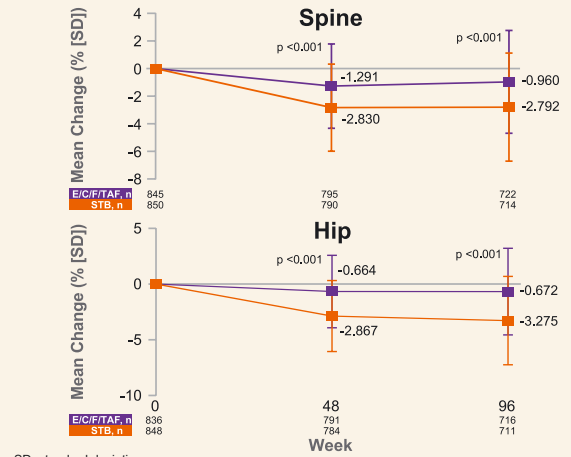
Fasting Lipids



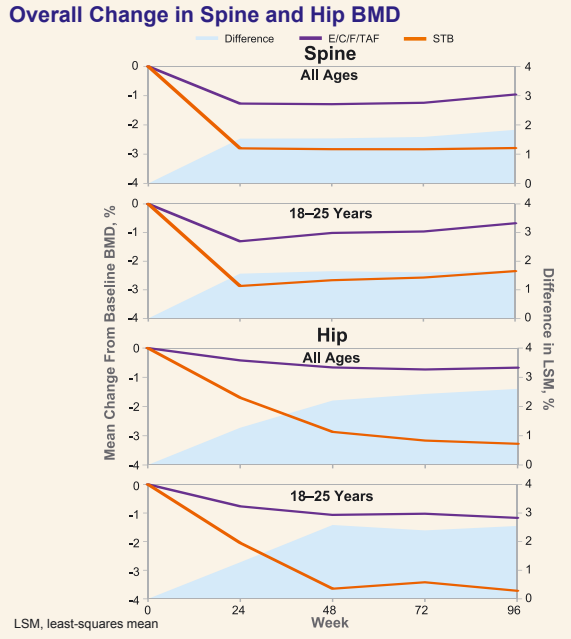
HDL, high-density lipoprotein; TC, total cholesterol

- No difference (TAF vs TDF) in:
  - Cardiovascular AEs: 21 (2.4%) vs 27 (3.1%), p=0.46
  - Serious cardiovascular AEs: 5 (0.6%) vs 4 (0.5%), p= 0.75
  - Rate of initiation of lipid-modifying agents: 33 (3.8%) vs 38 (4.4%), p=0.63

Overall Change in Spine and Hip BMD



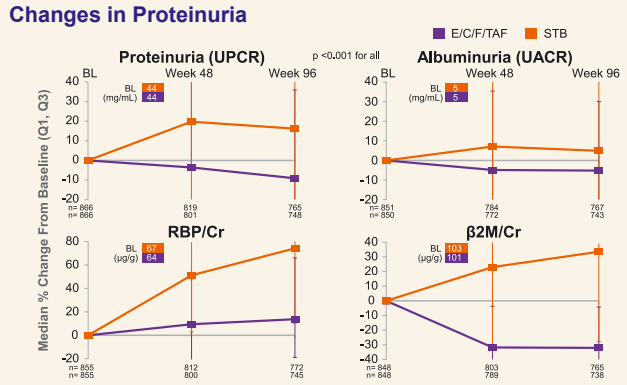
SD, standard deviation



LSM, least-squares mean

- Rate of initiation of BMD medications (mostly calcium and vitamin D): 15% with TAF vs 18% with TDF; p=0.06

Changes in Proteinuria



BL, baseline; β2M, β2-microglobulin; CR, creatinine; Q, quartile; RBP, retinol-binding protein; UACR, urinary albumin–CR ratio; UPCR, urinary protein–Cr ratio.

- No cases of proximal tubulopathy with E/C/F/TAF vs 2 with STB

Conclusions

- After 2 years, TAF combined with E/C/F produced a high rate of virologic suppression (87%) and remained noninferior to STB in treatment-naïve patients
- Emergent antiretroviral resistance was rare (1%; 18/1733)
- E/C/F/TAF continued to have a statistically superior bone and renal safety profile compared with STB
  - Differences between BMD widened from Weeks 48 to 96, with spine BMD with E/C/F/TAF improving towards baseline, but remaining decreased with STB
  - Quantitative proteinuria and renal tubular proteinuria markers continued to favor E/C/F/TAF
  - No E/C/F/TAF patients developed proximal tubulopathy vs 2 TDF patients (1 led to discontinuation)
- There were increases in the TAF arm in TC, HDL, and LDL cholesterol, but no difference in TC:HDL ratio compared with the TDF group, consistent with the known off-target lipid effect of TDF[8,9]
- These longer term safety data support the hypothesis that higher circulating TFV levels cause TDF bone and renal toxicity, and the lower levels delivered by TAF reduce exposure, and are protective against bone and renal effects
- E/C/F/TAF is a safe, well-tolerated, and durable regimen for initial and ongoing HIV-1 treatment

References & Acknowledgment

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We extend our thanks to the patients, their partners and families, and all participating study investigators. This study was funded by Gilead Sciences, Inc.

Poster P004

Passcode: P004

Influence of Age on Outcomes in HIV-Infected Adults Initiating Tenofovir Alafenamide Fumarate (TAF) vs Tenofovir Disoproxil Fumarate (TDF) with Elvitegravir, Cobicistat, and Emtricitabine (E/C/F/TAF vs E/C/F/TDF)

J Andrade[1], ES Daar[2], B Trottier[3], A Clarke[4], D Parks[5], C Brinson[6], H Martin[7], S Guo[8], S Friborg[9], M Laurido[10], M Fordyce[11]

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Introduction

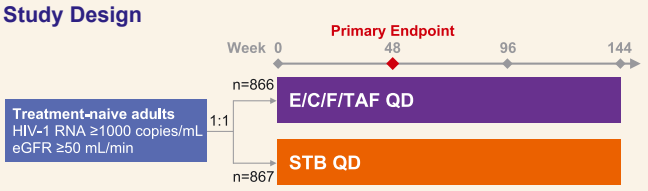
- As the HIV-infected population ages, and morbidity and mortality are increasingly driven by non-AIDS-defining conditions, the demonstration of efficacy and safety in older patients is critical
- In the overall study population of two phase 3 trials of treatment-naive patients with HIV, elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide (E/C/F/TAF) demonstrated high and similar efficacy, and improved renal and bone safety compared with E/C/F/tenofovir disoproxil fumarate (TDF; Stribild® [STB], Gilead)[1]

Objective

- To examine the efficacy and safety of E/C/F/TAF vs STB in patients aged ≥50 years

Methods

Study Design



eGFR, estimated glomerular filtration rate

- Two phase 3, randomized, double-blind, double-dummy, active-controlled studies[1]
  - Study 104 (NCT01780506; North America, EU, Asia); Study 111 (NCT01797445; North America, EU, Latin America)
  - Stratified by HIV-1 RNA, CD4 cell count, geographic region
- Primary endpoint: proportion of patients with HIV-1 RNA <50 copies/mL (COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test v2.0, Roche Molecular Diagnostics, Pleasanton, CA)
  - Noninferiority (12% margin) based on Week 48 FDA snapshot analysis
  - Combined efficacy analysis prespecified
- Secondary endpoints: efficacy, safety, and tolerability at Weeks 96 and 144
  - Prespecified Week 48 safety: serum creatinine, proteinuria, hip and spine bone mineral density (BMD)
- Prespecified, pooled, Week 48 analysis of patients aged ≥50 years is presented

Results

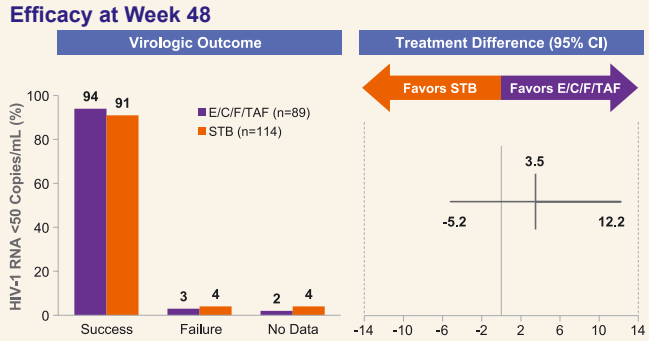
Baseline Characteristics

	E/C/F/TAF n=866	STB n=867
Median age, year	33	35
≥50 years, n (%)	89 (10)	114 (13)
Sex, %		
Male	85	85
Female	15	15
Race/ethnicity, %		
Black/African descent	26	25
Hispanic/Latino ethnicity	19	19
Median HIV-1 RNA, log_{10} copies/mL	4.58	4.58
>100,000 copies/mL, %	23	23
Median CD4 count, cells/µL	404	406
≤200 cells/µL, %	13	14
Median eGFR, mL/min*	117	114
Dipstick proteinuria (any grade), %	10	10

*Cockcroft-Gault

Results (Cont'd)

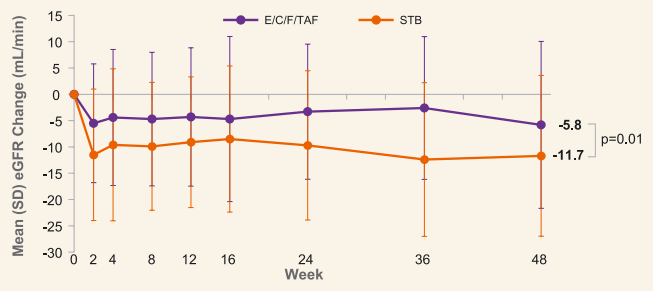
Efficacy at Week 48



CI, confidence interval

- Median change from baseline CD4 count: 174 vs 183 cells/uL (p=0.57)

Change in eGFR



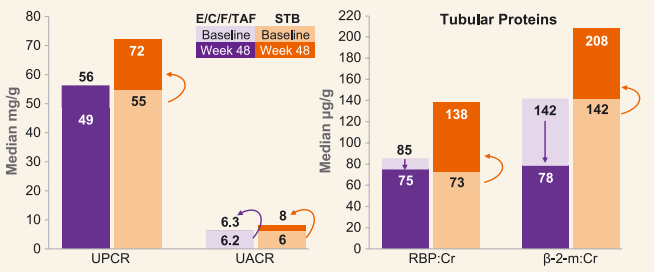
SD, standard deviation

Overall Safety

	E/C/F/TAF n=89, %	STB n=114, %
Any AE	89	93
Drug-related AE	42	38
Grade 3/4 AE	8	5
Drug related	2	1
Serious AE	8	10
Drug related	1	0
AE-related discontinuation	1	4
Death	0	0

AE, adverse event

Proteinuria: Change From Baseline to Week 48

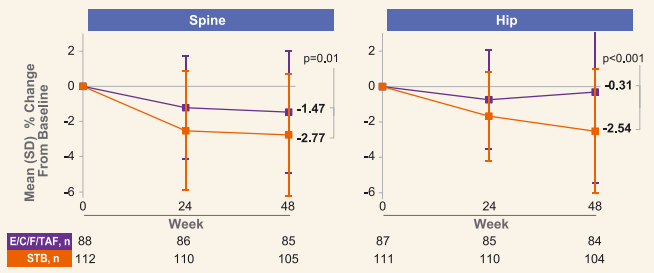


β-2-m, β2-microglobulin; Cr, creatinine; RBP, retinol-binding protein; UACR, urine albumin/Cr ratio; UPCR, urine protein/Cr ratio

Adverse Events Leading to Discontinuation

	E/C/F/TAF, n=89	STB, n=114
AE, n (%)	1 (1)	4 (4)
Type	♦ Eye irritation, pain, pruritus	♦ Decreased eGFR ♦ Renal failure ♦ Vomiting, bladder spasm, pyrexia, headache, myalgia, maculopapular rash ♦ Arthropod bite, dermatitis

Changes in Spine and Hip BMD Through Week 48



Common AEs (All Grades): ≥10% of Patients

AE, %	E/C/F/TAF n=89	STB n=114
Diarrhea	17	18
Headache	12	10
Rash	12	6
Fatigue	11	8
Arthralgia	11	8
Nausea	10	15
Upper respiratory tract infection	10	10
Back pain	9	12

Grade 3/4 Laboratory Abnormalities

	E/C/F/TAF n=89	STB n=114
Any grade 3/4 abnormality, %*	22	18
LDL elevation (fasting)	13	4
Hypercholesterolemia (fasting)	6	2
Hematuria (quantitative)	2	1
Hyperglycemia (fasting)	2	1
Serum amylase elevation	2	3
AST elevation	1	1
Triglycerides (fasting)	1	0
Hypokalemia	1	0
GGT elevation	1	1
Neutropenia (<1000 cells/µL)	1	2
ALT elevation	1	1

*≥1% in E/C/F/TAF arm. ALT, alanine aminotransferase; AST, aspartate aminotransferase; GGT, -glutamyl transferase; LDL, low-density lipoprotein

Conclusions

- Among patients aged ≥50 years, those receiving 48 weeks of E/C/F/TAF had high and comparable efficacy, and improved renal and bone safety compared with those on STB, as previously demonstrated in the overall study population[1]
- These findings demonstrate an important safety improvement of TAF relative to TDF in patients aged ≥50 years, which is of particular importance as the population living with HIV ages and experiences more non-AIDS-related conditions

References & Acknowledgment

1. Sax PE, et al. Lancet 2015;385:2606-15.

We extend our thanks to the patients, investigators, and staff who participated in these studies.
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Co-Morbidities in a Sample of HIV-Positive Adults in Puerto Rico

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INTRODUCTION

By 2010 in the United States (U.S.), the estimated rate of adults and adolescents with a diagnosed HIV infection was 583 per 100,000[1]. Currently, it is estimated that nearly 26,872 are diagnosed with HIV or AIDS in Puerto Rico (PR). The number of HIV/AIDS cases and the number of deaths has reduced substantially throughout the years, lowering the case fatality rate from 82% in 1986 to 2% in 2015[2]. People diagnosed with HIV infection may have an increased risk of developing co-morbidities compared to the general population due to HIV disease itself and the use of long-term antiretroviral therapy. As HIV survival has increased and persons living with HIV enjoy life expectancies similar to those of the general population, they are likely to share the same comorbidities [3,4].

OBJECTIVE

Estimate the prevalence of common co-morbidities among people with HIV who attend HIV treatment clinics in PR.

METHODS

Data were collected from an exploratory, retrospective, cross-sectional study conducted between January and April 2015 at five clinics that provide services to people with HIV in different areas of PR. Both public and private-owned clinics were included for data collection. A random sample of medical records was reviewed.

Eligibility criteria included having an HIV diagnosis, at least 21 years of age at the time of the beginning of the study and being engaged in care in the clinic during the last 6 months. Patients with an AIDS diagnosis and pregnant women were excluded from the study due to additional medical conditions associated with their health status. Similarly, individuals enrolled in clinical trials at the time of data collection or during the last six months prior to their medical chart revision were excluded from the sample.

Following an extensive literature review and clinician's recommendations, an in-depth data collection instrument was created, allowing for the recollection of HIV clinical information, as well as patient history of a numerous comorbidities, lipids, glucose and creatinine data, and comorbidities treatment history.

Patient's demographic information was also collected. Data entry was completed using a paper and pen survey-like instrument and then data was transferred to an electronic version using the Questionnaire Development System (QDS).

Descriptive statistics were used to summarize patient demographics, morbidity, and clinical characteristics. Multivariate analyses were conducted to explore differences by age and sex. SPSS v.20 was used to conduct all statistical procedures. All study procedures were approved by the Human Research Subjects Protection Office (IRB) of the University of Puerto Rico-Medical Sciences Campus.

RESULTS

As included in Table 1, a total of 250 medical records were reviewed. Of these, 179 were of men (71.6%) and 71 (28.4%) of women. The mean age of the subjects was 47.9 years and, on average, they had been living with HIV for 9.3 years.

Table 1. General characteristics of a sample of HIV-positive people in Puerto Rico

	Mean	SD
Mean Age [Range: 21 – 82]	47.9	12.6
Age at HIV diagnosis	38.0	11.6
Age at HIV treatment initiation1	39.6	12.5
Years living with HIV [Range: 0.9 – 25.7]	9.3	8.1
Years in HIV Treatment1 [Range: 0.1 – 20.7]	3.4	3.6
Mean CD4 [Range: 218 – 2,620]	723.8	363.2
Days since last CD4 test [Range: 10 – 687]	80.2	75.7
Mean Viral Load2 [Range: ND– 110,089]	3,341,1	14,342.9
Days since last viral load test [Range: 10 – 492]	81.4	84.6

[1]n=103 (Men=74, Women=29). [2]n=137 (Men=97, Women=40)

Considering the role that body max index (BMI) may have with certain co-morbidities, bivariate analyses were conducted to assess the BMI by sex and by age. More than a third (33.6%) of the study sample was overweight. Among men, 36.9% had normal BMI, while 35.2% of women were obese. These differences were statistically significant by sex.

The vast majority (97.6%) of the subjects had been diagnosed with one or more co-morbidities during the 6 month period that preceded data collection. Among the most common co-morbidities for both men and women were dyslipidemia (total: 60.8%; men: 60.8%; women: 69.0%), alcohol abuse (total: 48.8%; men: 48.8%; women: 25.4%), and hypertension (total; 39.6%; men: 39.6%; women: 46.5%). Table 2 includes all the co-morbidities found in the study sample. In general, the mean amount of co-morbidities reported in the sample was 3.7 (SD=1.9). Men reported significantly less co-morbidities (Mean=3.5, SD=1.9), than women (Mean=4.1, SD=1.9; p=0.035).

Men were more likely to have been diagnosed with alcohol abuse (p<0.001) while women were more likely to have been diagnosed with obesity (p=0.001), HPV infection (p=0.002), hypothyroidism (p=0.006) and osteoporosis (p=0.003).

Table 2. Co-morbidity prevalence in a sample of HIV-positive people in Puerto Rico

	Total (N = 250)		Men (N = 179)		Women (N = 71)	
Co-morbidity	n	%	N	%	n	%
Prevalence of comorbidities	244	97.6	174	97.2	70	98.6
Dyslipidemia	152	60.8	103	57.5	49	69.0
Alcohol abuse	122	48.8	104	58.1	18	25.4
Hypertension	99	39.6	66	36.9	33	46.5
Cigarette smoking	89	35.6	67	37.4	22	31.0
Overweight	67	26.8	46	25.7	21	29.6
Diabetes mellitus	49	19.6	32	17.9	17	23.9
Obesity	48	19.2	25	14.0	23	32.4
Depression	48	19.2	29	16.2	19	26.8
Drug abuse	42	16.8	33	18.4	9	12.7
HPV infection	42	16.8	22	12.3	20	28.2
Chronic Hepatitis C infection	33	13.2	24	13.4	9	12.7
Vitamin D Deficiency	24	9.6	15	8.4	9	12.7
Hypothyroidism	20	8.0	9	5.0	11	15.5
Chronic Hepatitis B infection	12	4.8	7	3.9	5	7.0
Chronic Kidney Disease	10	4.0	5	2.8	5	7.0
Lipodystrophy	9	3.6	8	4.5	1	1.4
Osteoporosis	9	3.6	2	1.1	7	9.9
Benign Prostatic Hyperplasia	7	2.8	7	3.9	--	--
Revascularization Procedure	6	2.4	4	2.2	2	2.8
Peripheral vascular disease	6	2.4	5	2.8	1	1.4
Acute Coronary Syndrome (ACS)	5	2.0	5	2.8	0	--
Pre-Diabetes	5	2.0	3	1.7	2	2.8
Angina Pectoris	4	1.6	3	1.7	1	1.4
Previous Stroke /TIA	2	0.8	0	--	2	2.8
Congestive heart failure	1	0.4	1	0.6	0	--

The group aged <50 years were more likely to have an alcohol abuse diagnosis (p=0.006) while the older individuals were more likely to have been diagnosed with dyslipidemia (*p*<0.001), hypertension (*p*<0.001) and diabetes mellitus (*p*<0.001). Participants who had been diagnosed with dyslipidemia and hypertension had been living with HIV for a longer period of time than those who had not been diagnosed with these (*p*<0.001 and *p*=0.046; respectively).

The most common treatments reported in the sample were multivitamins (71.5%), lipid lowering therapy (57.6%) and antihypertensive agents (37.6%). These were also the most common treatments when stratified by sex. The mean amount of treatment in the study sample was of 2.1 (SD=16). Men were using less medications (Mean=2.5, SD=1.5) than women (Mean=3.5, SD=1.6, *p*<0.001).

A multivariate analysis using sex and age as covariates was conducted. As included in Table 3, findings suggest that women were more likely to have been diagnosed with obesity and depression.

On the other hand, they were less likely to have been diagnosed with alcohol abuse, HPV infection, and hypothyroidism. Co-morbidities associated with the 50+ age group were dyslipidemia, hypertension, HPV infection, diabetes mellitus, and lipodystrophy.

Table 3. Multivariate analysis of the prevalence of co-morbidities by age and sex in a sample of HIV-positive people in Puerto Rico

	Sex		Age	
	Men	Women	<50 yrs	50+ yrs
Co-morbidity	Ref.	OR (95% CI)	Ref.	OR (95% CI)
Prevalence of comorbidities	1	1.258 (0.133 – 11.891)	1	3.313 (0.354 – 31.040)
Alcohol abuse	1	**0.266 (0.143 – 0.496)**	1	0.595 (0.349 – 1.013)
Dyslipidemia	1	1.288 (0.697 – 2.379)	1	**3.075 (1.769 – 5.346)**
Cigarette smoking	1	0.821 (0.450 – 1.498)	1	0.641 (0.374 – 1.098)
Hypertension	1	1.181 (0.658 – 2.119)	1	**2.852 (1.670 – 4.871)**
Overweight	1	1.162 (0.623 – 2.168)	1	1.177 (0.663 – 2.088)
HPV	1	**0.282 (0.136 – 0.584)**	1	**2.547 (1.205 – 5.385)**
Drug abuse	1	0.703 (0.312 – 1.581)	1	0.644 (0.320 – 1.298)
Obesity	1	**3.197 (1.625 – 6.290)**	1	0.700 (0.357 – 1.372)
Depression	1	**1.986 (1.008 – 3.914)**	1	0.785 (0.407 – 1.514)
Diabetes mellitus	1	1.118 (0.558 – 2.240)	1	**3.331 (1.684 – 6.589)**
Chronic Hepatitis C	1	0.790 (0.340 – 1.836)	1	2.085 (0.971 – 4.474)
Vitamin D Deficiency	1	0.706 (0.288 – 1.733)	1	0.611 (0.255 – 1.462)
Hypothyroidism	1	**0.300 (0.116 – 0.779)**	1	0.859 (0.331 – 2.230)
Chronic Hepatitis B	1	1.990 (0.591 – 6.707)	1	0.727 (0.217 – 2.439)
Angina Pectoris	1	1.020 (0.100 – 10.432)	1	0.388 (0.038 – 3.941)
Chronic Kidney Disease	1	2.175 (0.592 – 7.992)	1	2.461 (0.603 – 10.047)
Revascularization Procedure	1	1.046 (0.181 – 6.054)	1	2.398 (0.418 – 13.768)
Pre-Diabetes	1	1.513 (0.237 – 9.656)	1	1.655 (0.261 – 10.516)
Lipodystrophy	1	0.217 (0.026 – 1.808)	1	**5.348 (1.073 – 26.656)**
Osteoporosis	1	**7.831 (1.548 – 39.622)**	1	2.929 (0.573 – 14.986)
Peripheral vascular disease	1	0.345 (0.039 – 3.075)	1	7.202 (0.816 – 63.535)

*Acute coronary syndrome, congestive heart failure, tuberculosis, previous stroke/TIA and fat accumulation were excluded from this analysis due to lack of reported cases in certain subgroups. Benign prostatic hyperplasia was also excluded from the analysis.

CONCLUSIONS

Based on a comprehensive narrative analysis of the scientific literature, and to the best of our knowledge, this is the first observational study that assessed comorbidities among people with HIV in PR, and one of the few among Latino/Hispanic populations in the U.S. Despite these limitations and consistent with other studies, cardiovascular diseases – specifically dyslipidemia and hypertension - were found to be common among people with HIV in PR. Certain characteristics such as age, sex, and use of medication may play a role in the co-morbidities among people with HIV. Findings support the need for creating awareness of the co-morbidities of people living with HIV, particularly when implementing prevention strategies and prescribing drug therapy. Further, this information should be available to physicians and other healthcare providers to improve differentiated and comprehensive approaches to address the needs of people with HIV in PR.

ACKNOWLEDGEMENTS

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Establishment of a prospective cohort of adult HIV positive patients in Latin America (LATINA Prospective Cohort)

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BACKGROUND

Though HIV epidemics is not decreasing in most Latin American countries, there is little information about the baseline demographics, clinical status at diagnosis and therapeutic course of patients initiating follow up. LATINA Cohort has already provided information about these issues in its retrospective component. We present here the first analysis of its prospective component based upon sites from three countries.

MATERIAL AND METHODS

The Cohort is built by a multinational Executive Committee and National Coordinating Centers in charge of local logistics, identification and inclusion of contributing sites. From initial involvement of sites who participated in the Retrospective Cohort we moved forward to include new sites specialized in HIV and continuing to ensure data quality. The Prospective Cohort started gathering data in September 2013 from 6 sites and progressed to the current 12 distributed in: Argentina (9 sites), Mexico (2 sites) and Perú (1 site). Data presented here correspond to the first 18 months of follow up (up to March 2015). Inclusion criteria were recent HIV diagnosis (within 1 year) and at least 2 prior visits to the site in order to ensure commitment. Data collection was performed through a web site (www.latina.cical.org) presenting the following sections: A - Patient identification and Demographics, B - HIV history, C - Co-morbidities and D - visits.

Diagnosis for AIDS defining diseases was based on CDC criteria and standardized criteria were developed by the Executive Committee for serious non aids events. Database was periodically checked for incompleteness and consistency. All data was consolidated in an Access database and analyzed using Statistics V17.

RESULTS

972 patients had been included, of those 748 (81%) had data included in all of the sections of baseline visit. 578 (77%) were from Mexican sites, 158 (21%) from Argentinian and 12 (2%) from Peruvian site. Characteristics of our cohort were as follows:

Table 1: ***Demographic Characteristics (N=972)***

Characteristic	Value	Range
Age (yrs)	34	27-42
Education (Yrs)	11.1	8-15
Male at birth (%)	86	84-89
White Race	41	37-44

Table 2: ***Anthropometric characteristics (N=972)***

	Mean	SD
Weight (kg)	67.4	14.84
Height (cm)	168.72	21
SBP (mmHg)	111.31	13.51
DBP (mmHg)	70.46	9.9

Age was significantly lower in Mexican population (34.71 vs 38.27, mean difference 3.57 (95%CI 1.66-5.46) as well as SBP and DBP (108.32 vs 120.58 p value 0.04 and 68.87 vs 75.43 p value 0.01).

Table 3: ***Mode of transmission (N= 752)***

	N	%	95% IC
MSM/ Bisexual	456	60.6	57.11-64.09
Heterosexual	254	33.8	30.42-37.18
Missing data	29	3.9	2.5-5.28
Parenteral	5	0.7	0.1-1.3
Vertical	1	0.1	0-0.33
Unknown	7	0.9	0.23-1.57

Only 2.5% of patients had missing data as to diagnosis symptoms. The most common symptoms at diagnosis are presented in Table 4.

Table 4: ***Symptoms at diagnosis (N= 276)***

	N	%	95% IC
Weight Loss	110	14.6	10.43-18.77
Fever > 2 weeks	63	8.4	5.13-11.67
Chronic diarrhoea	49	6.5	3.59-9.41
Lymphadenopaties	22	2.9	0.92-4.88
Herpes	20	2.7	0.79-4.16
Oral Candidiasis	11	1.5	0.07-2.93
Oral Leucoplakia	1	0.1	0-0.47

CD4 counts and viral load values are presented in Table 5.

Table 5: ***CD4 (cells/ml) and Viral Load (VL, copies/ml) values***

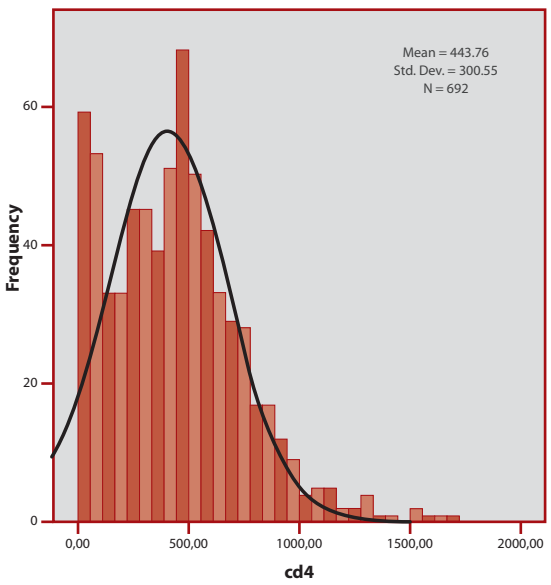
	Median	IQR
CD4	443	218-614
VL	32509	2590-138000

There were no significant differences among countries concerning these laboratory values.

Table 6: ***Patients showing Progression of Disease at baseline (POD) (N=752)***

	N	%	95%CI
POD Yes	179	23.8	20.76-26.84
POD NO	573	76.2	73.16-79.24

Figure 1:
CD4 Distribution



Alcohol consumption was reported in 28.3% (21.99-33-61), drug use in 8.6% (5.29-11.91) and 45% (39.13-50.87) of patients were current smokers Health Coverage was provided in 88.1% (95% CI: 85.8-90-4) of cases by Public Sector, 6.8 % (95% CI: 5.0-8.6) by Private Sector and 5% (3.5-6.7) of cases by Social Security.
The co-morbidity most frequently found was STD 5.9% of patients (3.12-8.68). Chronic conditions were found in 18.1% (15.35-20.85) being hypertension the most frequent finding in 4.4% of patients (1.98-6.82). HBV and HCV co-infection was found in 1.9% (0.29-3.51) and 1.5% (0.07-2.93) of patients respectively.

CONCLUSIONS

Data reflects the situation of the HIV epidemics in Latin America even in the era of broad access to antiretroviral therapy, with mostly young males, predominantly MSMs and with significant proportion of late presenters and self-reported users of alcohol and tobacco.

Major limitation of this cohort is selection bias due to convenience sampling. Patients entering during the analyzed period were maintained in care at the sites and loss to follow up was less than 3%. Missing data was markedly improved during the last months when the database interface was improved. Overall, the data quality is acceptable among all participating sites and constitutes a quite diverse and interesting data set for both continue to follow up and expand its regional representativity.

P08

Poster Number
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Ledipasvir/Sofosbuvir is Safe and Effective for the Treatment of Patients with Genotype 1 Chronic HCV Infection in Both HCV Mono- and HIV/HCV Coinfected Patients

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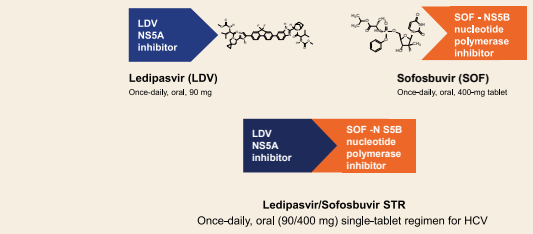
Introduction



STR: single-tablet regimen; HCV: hepatitis C

- HIV coinfection has been historically considered a negative predictor of HCV response to treatment with interferon/ribavirin (IFN/RBV).
- HIV/HCV coinfected patients have also faced historical barriers to HCV treatment that include low response rates, comorbidities, drug-drug interactions, and poor tolerability of available regimens.
- Ledipasvir/sofosbuvir (LDV/SOF) is FDA approved for HIV/HCV coinfection and dosage recommendations are the same as in HCV monoinfection.
- With the introduction of Direct Acting Antivirals (DAAs) the recently updated AASLD/IDSA/IAS-USA Guidance state "HIV/HCV coinfected persons should be treated and retreated the same as persons without HIV infection, after recognizing and managing interactions with antiretroviral medications".

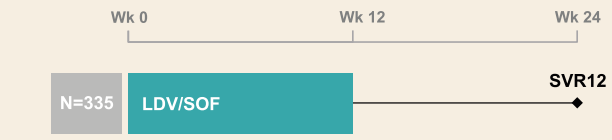
Objective

- This analysis retrospectively compared the efficacy and safety of 12 weeks with LDV/SOF in HCV GT 1 HIV/HCV coinfected patients in the Phase 3 ION-4 study with GT 1 HCV mono-infected patients in the Phase 3 ION 1-3 studies*.
- SVR12 rates, rates of virologic failure including relapse rates and the impact of baseline NS5A substitutions were evaluated between groups.
- Negative predictors of response were evaluated including race, GT 1 subtype, treatment history, and cirrhosis status.

*Only RBV-free, 12 week arms will be used from ION 1-3

HIV/HCV Coinfection

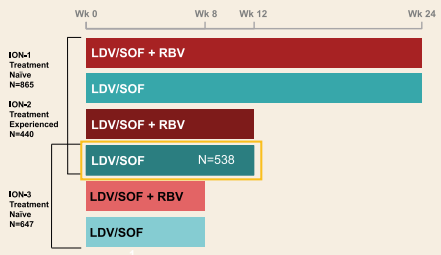
Study Design: (ION-4)



- Phase 3, multicenter, open-label study (NCT02073656)
- HIV/HCV GT 1 or 4 patients in US, Canada, Puerto Rico, and New Zealand
- ART regimens:
  - Efavirenz + FTC + TDF
  - Raltegravir + FTC + TDF
  - Rilpivirine + FTC + TDF

HCV Monoinfection

Study Design: ION-1, ION-2, ION-3



ION Phase 3 Studies Inclusion and Exclusion Criteria

Inclusion Criteria

- Age ≥ 18 years
- HCV RNA > 10,000 IU/mL at screening
- Cirrhosis determination using a liver biopsy, Fibroscan, FibroTest and/or APRI results
- Screening laboratory values within defined thresholds
- Use of two effective contraception methods if female of childbearing potential or sexually active male
- GFR ≥ 60 ml/min

Exclusion Criteria

- Pregnant or nursing female or male with pregnant female partner
- Current or prior history of clinical hepatic decompensation
- HCC or other malignancy (with exception of certain resolved skin cancers)
- History of clinically significant illness or any other medical disorder that may interfere with subject treatment, assessment or compliance with study

Endpoints

- The primary efficacy endpoint for each study was sustained virologic response and virologic failure including relapse rates with 12 weeks LDV/SOF in both HCV mono- and HIV/HCV coinfected patients.
  - SVR12 was defined as an HCV RNA level of less than 25 IU/mL at 12 weeks after the end of treatment
  - HCV RNA analyzed by COBAS® TaqMan® HCV Test v2.0 HPS, with LLOQ of 25 IU/mL.
- Safety
  - Adverse events and discontinuations

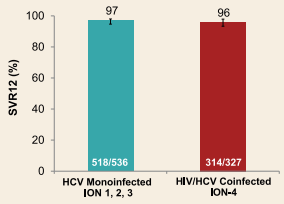
Table 1. Demographics: ION Phase 3 Studies

Characteristic	LDV/SOF 12 weeks ION-1 n = 214*	LDV/SOF 12 weeks ION-2 n = 109	LDV/SOF 12 weeks ION-3 n = 216	LDV/SOF 12 weeks ION 1-3 n = 539*	LDV/SOF 12 weeks ION-4 n = 327
Mean age, years (range)	52 (18-75)	56 (24-67)	53 (20-71)	54 (18-71)	52 (26-72)
Mean BMI, kg/m² (range)	27 (18-41)	29 (19-47)	28 (19-45)	28 (18-47)	27 (18-66)
Male, n (%)	127 (59)	74 (68)	128 (59)	329 (61)	272 (83)
Race, n (%)					
Black	24 (11)	24 (22)	42 (19)	90 (17)	114 (35)
Hispanic	26 (12)	7 (6)	14 (7)	47 (9)	55 (17)
Cirrhosis	34 (16)	22 (20)		56 (10)	67 (20)
Mean HCV RNA, $\log_{10}$ IU/mL (SD)	6.4 (± 0.69)	6.5 (± 0.44)	6.4 (± 0.8)	6.4 (± 0.64)	6.7 (± 0.65)
HCV genotype 1a, n (%)	145 (68)	86 (79)	172 (80)	403 (75)	250 (76)
IL28B genotype Non-CC, n (%)	159 (74)	99 (91)	160 (74)	474 (88)	247 (76)
Baseline ALT > 1.5 x ULN	119 (56)	53 (49)	99 (46)	271 (50)	135 (41)
Treatment experienced		109 (100)		109 (20)	181 (55)

*Includes 1 GT4 patient and 2 patients with missing genotype

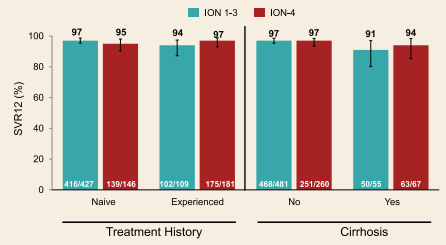
Results

Figure 1. Overall SVR12 in HCV Monoinfected and HIV/HCV Coinfected GT1 Patients Treated with LDV/SOF x 12 Weeks



Similar response rates in HIV/HCV coinfected patients compared to HCV monoinfected patients

Figure 2. SVR12 by Prior Treatment Experience and Cirrhosis Status



Comparable efficacy between monoinfected and HIV/HCV coinfected

Figure 3. SVR12 for Combined Treatment History and Cirrhosis Status

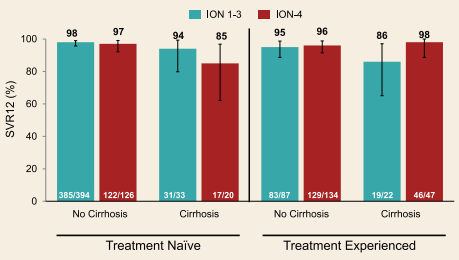


Figure 4. SVR12 by Genotype 1 Subtype

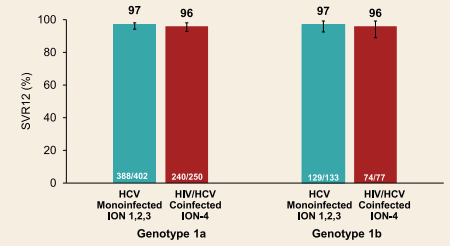
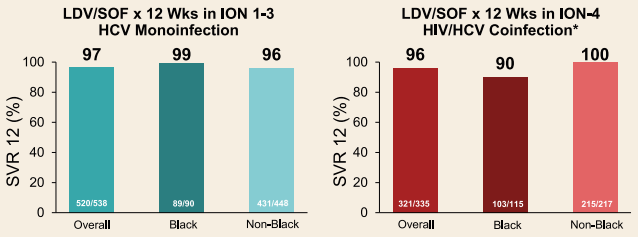


Figure 5. SVR12 in Black and Non-Black Patients



* All patients who reported their race were included in the analysis.

- No difference in SVR in HCV monoinfected ION program (12 weeks) for black (89/90, 99%) versus non-black (431/448, 96%) treated with 12 weeks of LDV/SOF
- Overall in ION-4, 10 patients had virologic relapse. All ten were black, seven had the TT allele of the IL28B gene, and eight received efavirenz.
  - In the multivariate analysis, black race was identified as the only independent, statistically significant predictor of relapse.
  - A comprehensive genome-wide association study (GWAS) of LDV/SOF treatment relapsers in ION-4 revealed no significant genomic associations with HCV relapse.

Table 2. Race Did Not Impact PK Parameters of LDV, SOF, and GS-331007 ION-4: LDV/SOF x 12 weeks in HIV/HCV Coinfection

	Mean Parameter (%CV)*	Black n=115	Non-Black n=217	%GMR (90% CI)
LDV	AUC_t, ng•h/mL	6160 (53.4)	5830 (54.4)	107 (96.9, 118)
	C_{max}, ng/mL	278 (48.6)	263 (48.3)	106 (97.2, 116)
	C_t, ng/mL	183 (56.5)	167 (56.4)	111 (99.5, 123)
SOF	AUC_t, ng•h/mL	1310 (23.1)	1330 (24.2)	98.3 (94.1, 103)
	C_{max}, ng/mL	716 (25.0)	685 (27.7)	106 (99.8, 112)
GS-331007	AUC_t, ng•h/mL	12,900 (32.3)	13,600 (24.9)	93.2 (88.5, 98.1)
	C_{max}, ng/mL	814 (30.4)	845 (27.2)	95.2 (90.3, 100)

*PK parameters presented to 3 significant digits; 3 patients with undisclosed race information were excluded from analyses.

- Pharmacokinetic analyses in ION-4 did not reveal clinically relevant differences in the concentrations of ledipasvir, sofosbuvir or GS-331007 based on race
- 90% CIs of %GMRs were within PK lack-of-alteration boundaries of 70–143%
- Results are consistent with population PK findings from Phase 2/3 LDV/SOF program

Table 3. Reasons for Not Achieving SVR: ION Phase 3 Studies

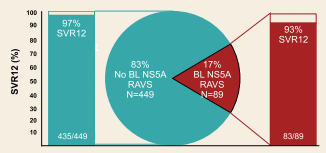
Patients, n (%)	LDV/SOF 12 weeks ION-1 n = 214*	LDV/SOF 12 weeks ION-2 n = 109	LDV/SOF 12 weeks ION-3 n = 216	LDV/SOF 12 weeks ION 1-3 n = 539*	LDV/SOF 12 weeks ION-4 n = 327
SVR12	210 (99)	102 (94)	206 (95)	518 (96)	313 (96)
	0	0	0	0	2 (<1)
Relapse	1 (<1)	7 (6)	3 (1)	11 (2)	10 (3)
Lost to Follow-Up	2 (<1)	0	7 (3)	9 (<2)	1 (<1)*
Withdrew Consent	0	0	0	0	0
Deaths	0	0	0	0	1 (<1)*

* One patient with confirmed IV drug use developed Staphylococcus aureus sepsis, endocarditis with associated embolic brain abscesses, and multi-organ system failure.

Table 4. Baseline Characteristics of Virologic Relapsers ION Phase 3 Studies (GT 1, LDV/SOF x 12 weeks)

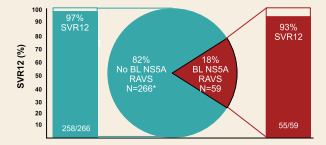
Study	Age (years)	Sex	Race	Prior HCV Treatment	HCV Genotype	IL28B	NS5A RAVs at Baseline	NS5A RAVs Post-treatment
ION 1	56	M	White	N/A	1a	TT	L31M	L31M
ION 2	64	M	White	PI+Peg-IFN+RBV	1b	CT	None	L31M, Y93H
ION 2	62	M	White	Peg-IFN+RBV	1b	CT	None	L31V
ION 2	64	M	White	PI+Peg-IFN+RBV	1a	CT	None	Q30H, Y93H
ION 2	61	M	White	Peg-IFN+RBV	1b	CT	Y93H	Y93H
ION 2	58	F	White	PI+Peg-IFN+RBV	1a	CT	Q30R, Y93N	Y93N
ION 2	57	F	White	PI+Peg-IFN+RBV	1a	CT	M28T, Q30R, L31M	Q30R, L31M
ION 2	54	M	White	Peg-IFN+RBV	1a	CT	Q30H, Y93H	Q30H, Y93H
ION 3	56	M	Black	N/A	1b	TT	None	L31I, Y93H
ION 3	44	M	Black	N/A	1a	CT	Y93F, Y93N	Y93N
ION 3	51	M	Other	N/A	1a	CT	None	None
ION 4	35	M	Black	N/A	1a	CT	None	None
ION 4	58	M	Black	Peg-IFN+RBV	1a	TT	Y93F, Y93N	Y93N
ION 4	61	M	Black	N/A	1a	TT	L31M, Y93N	L31M, Y93N
ION 4	61	F	Black	Peg-IFN+RBV	1a	CT	None	L31M
ION 4	51	M	Black	NS5a+Peg-IFN+RBV	1a	TT	L31M, H58D	L31M, H58D
ION 4	65	F	Black	N/A	1b	TT	None	L31V
ION 4	60	M	Black	N/A	1a	CT	None	None
ION 4	63	M	Black	Peg-IFN+RBV	1a	TT	None	Y93N
ION 4	55	M	Black	Peg-IFN+RBV	1a	TT	None	Q30R, L31M, Y93H
ION 4	58	M	Black	Peg-IFN+RBV	1b	TT	Y93H	L31I, Y93H

Figure 6. SVR12 by Baseline NS5A Substitutions ION 1-3: All Oral LDV/SOF STR x 12 weeks in HCV monoinfection (Phase 3)



- NS5A RAVs were observed in 10 of the 11 patients at time of virologic failure
- No NS5B S282T was observed in any patient at baseline or at time of virologic failure

Figure 7. SVR12 by Baseline NS5A Substitutions ION-4: All-Oral LDV/SOF STR x 12 weeks in HIV/HCV Coinfection (Phase 3)



* Analysis done for all available samples and includes 8 GT4 patients.

- NS5A RAVs were observed in 10 of the 12 patients at time of virologic failure (8 of 10 at time of relapse, 2 of 2 at time of viral breakthrough)
- No NS5B S282T was observed in any patient at baseline or at time of virologic failure

Table 5. LDV/SOF x 12 Weeks Safety in HCV Monoinfected and HIV/HCV Coinfected

Patients, n (%)	LDV/SOF 12 weeks ION-1 n = 214*	LDV/SOF 12 weeks ION-2 n = 109	LDV/SOF 12 weeks ION-3 n = 216	LDV/SOF 12 weeks ION 1-3 n = 539*	LDV/SOF 12 weeks ION-4 n = 335
AEs	169 (79)	73 (67)	149 (69)	391 (73)	257 (77)
Grade 3–4 AEs	4 (2)	2 (2)	7 (3)	13 (2)	14 (4)
Serious AEs	1 (<1)	0	5 (2)	6 (1)	8 (2)
Treatment D/C due to AEs	0	0	2 (1)	2 (<1)	0
Death	0	0	0	0	1 (<1)
Grade 3–4 laboratory abnormality	10 (5)	5 (5)	16 (7)	31 (6)	36 (11)
Hemoglobin <10 g/dL	0	0	1 (<1)	1 (<1)	1 (<1)
Hemoglobin <8.5 g/dL	0	0	0	0	0

*Safety analysis done for all patients enrolled.

Table 6. Common Adverse Events: ION Phase 3 Studies*

Patients, n (%)	LDV/SOF 12 weeks ION-1 n = 214*	LDV/SOF 12 weeks ION-2 n = 109	LDV/SOF 12 weeks ION-3 n = 216	LDV/SOF 12 weeks ION 1-3 n = 539*	LDV/SOF 12 weeks ION-4 n = 327
Headache	53 (25)	28 (26)	33 (15)	114 (21)	83 (25)
Fatigue	44 (21)	23 (21)	49 (23)	116 (22)	71 (21)
Diarrhea	24 (11)	7 (6)	9 (4)	40 (7)	36 (11)
Nausea	24 (11)	13 (12)	24 (11)	61 (11)	33 (10)
Insomnia	17 (8)	10 (9)	15 (7)	42 (8)	0
Arthralgia	0	7 (6)	16 (7)	23 (4)	22 (7)

*Safety analysis done for all patients enrolled in studies.

Table 7. Discontinuations Due to Adverse Events Were 1% or Less: ION Phase 3 Studies

LDV/SOF ION-1 N=214*	LDV/SOF ION-1 N=109	LDV/SOF ION-1 N=216	LDV/SOF ION-1 N=539*	LDV/SOF ION-1 N=327
0%	0%	<1%	<1%	0%

*Includes one GT4 patient.

- Most common adverse events (>10% reported in any arm) were fatigue, headache, diarrhea, and nausea in both monoinfected and HIV/HCV coinfected patients treated with LDV/SOF.

Conclusions & References

- Efficacy rates with 12 weeks LDV/SOF in HIV/HCV coinfected patients (SVR12 = 96%) were similar to those seen in HCV monoinfected patients (SVR12 = 97%).
  - Prior HCV treatment status or the presence or absence of cirrhosis did not impact outcome
  - LDV, SOF, and GS-331007 exposures were comparable in black and non black subjects
- Safety profile of 12 weeks LDV/SOF in HIV/HCV coinfected patients was similar to HCV monoinfected patients.
  - Most common adverse events (>10% reported in any arm) were fatigue, headache, nausea and diarrhea
  - No adverse impact on HIV disease or its treatment
- LDV/SOF represents a highly effective treatment option for patients with HIV/HCV coinfection and HCV monoinfection.

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Poster P010

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Improved Safety and Efficacy of TAF vs TDF Single-Tablet Regimen in HIV-1 Treatment-Naïve Women through Week 48

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Introduction

- Women represent half of all HIV-infected individuals globally, but current treatment practices are based largely on data from male populations[1-3]
- Elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide (E/C/F/TAF) achieved noninferior efficacy, and improved renal and bone safety profiles compared with E/C/F/tenofovir disoproxil fumarate (TDF; Stribild, Gilead; STB) at 48 weeks in 2 randomized phase 3 trials of treatment-naïve patients[4]

Mechanism of Action: TAF vs TDF[4-9]

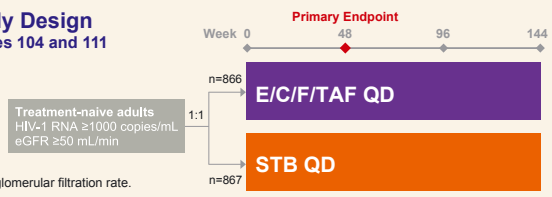
GI, gastrointestinal; TFV, tenofovir.

Objective

- To compare the 48 week efficacy and safety of TAF and TDF in treatment-naïve women with HIV from 2 randomized phase 3 trials

Methods

Study Design
Studies 104 and 111



eGFR, glomerular filtration rate.

- Two Phase 3 randomized, double-blind, double-dummy, active-controlled studies
  - Study 104 (North America, EU, Asia; ClinicalTrials.gov NCT01780506); Study 111 (North America, EU, Latin America; NCT01797445)
  - Stratified by HIV-1 RNA, CD4 cell count, and geographic region
- A prespecified analysis of efficacy and a post-hoc analysis of safety of TAF vs TDF at 48 weeks by gender were conducted
- Key endpoints
  - Efficacy
    - % with virologic success (HIV-1 RNA <50 copies/mL) at 48 weeks by FDA snapshot analysis
    - Change in CD4 cell count from baseline
  - Safety
    - Treatment-emergent adverse events (AE) leading to study drug discontinuation
    - Grade 3 or 4 AEs
  - Renal parameters
    - Changes in eGFR, and urine protein/creatinine (UPCR), urine albumin creatinine (UACR), urine retinol binding protein/creatinine (RBP:Cr) and urine β2-microglobulin/creatinine (β2-m:Cr) ratios
  - Bone mineral density (BMD)
    - – Changes in spine and hip BMD over 48 weeks

Results

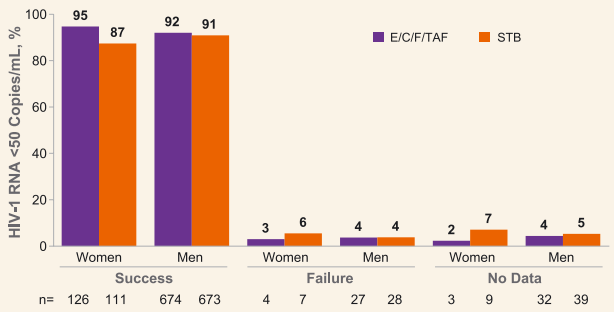
Baseline Demographics and Disease Characteristics

	Women		Men	
	E/C/F/TAF n=133	STB n=127	E/C/F/TAF n=733	STB n=740
Median age, y	37	40	32	34
Race, n (%)				
American Indian or Alaska Native	2 (2)	0	3 (<1)	8 (1)
Asian	41 (31)	32 (25)	50 (7)	57 (8)
Black	51 (38)	41 (32)	172 (23)	172 (23)
Native Hawaiian or Pacific Islander	0	0	5 (1)	4 (<1)
White	24 (18)	33 (26)	461 (63)	465 (63)
Hispanic/Latino	32 (24)	34 (27)	135 (18)	133 (18)
Other	15 (11)	21 (17)	42 (6)	34 (5)
US region, n (%)	51 (38)	53 (42)	481 (66)	479 (65)
Median HIV-1 RNA, log_{10} copies/mL	4.5	4.5	4.6	4.6
≤100,000 copies/mL, n (%)	106 (80)	103 (81)	564 (77)	569 (77)
>100,000–≤400,000 copies/mL, n (%)	20 (15)	19 (15)	127 (17)	135 (18)
>400,000 copies/mL, n (%)	7 (5)	5 (4)	42 (6)	36 (5)
Median CD4 cell count, /μL	358	367	414	417
<50/μL, n (%)	4 (3)	6 (5)	20 (3)	21 (3)
≥50–<200/μL, n (%)	16 (12)	11 (9)	72 (10)	79 (11)
Mode of infection: IV drug use, n (%)	2 (2)	0	3 (<1)	6 (1)
Median eGFR, mL/min*	116	104	117	115
Proteinuria, n (%)				
Grade 1	18 (14)	10 (8)	62 (8)	57 (8)
Grade 2	2 (2)	3 (2)	6 (1)	15 (2)
Grade 3	0	0	0	1 (<1)
Diabetes mellitus, n (%)	8 (6)	13 (10)	17 (2)	27 (4)
Hypertension, n (%)	23 (17)	23 (18)	95 (13)	123 (17)
Median 10-y hip fracture probability (FRAX), %	0.04	0.04	0.1	0.12

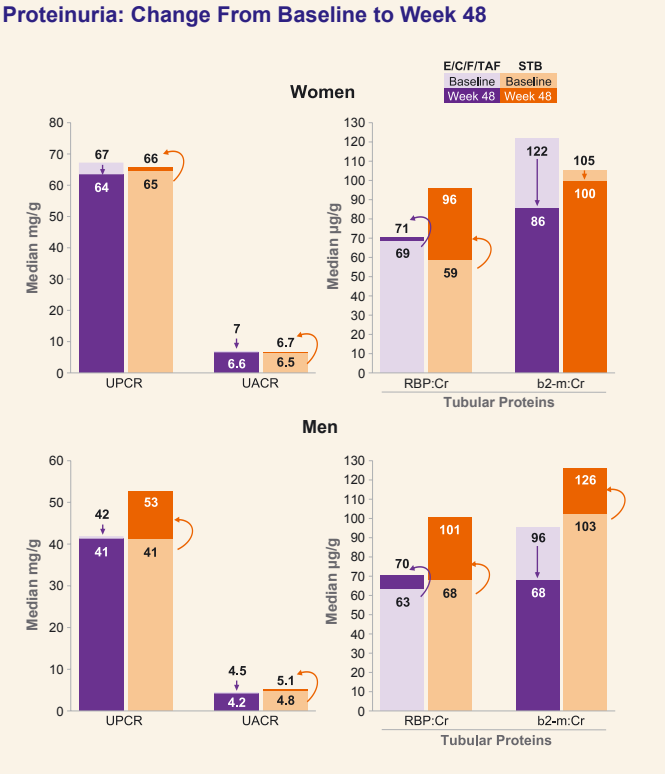
*Cockcroft-Gault; FRAX, Fracture Risk Assessment Tool

Results (Cont'd)

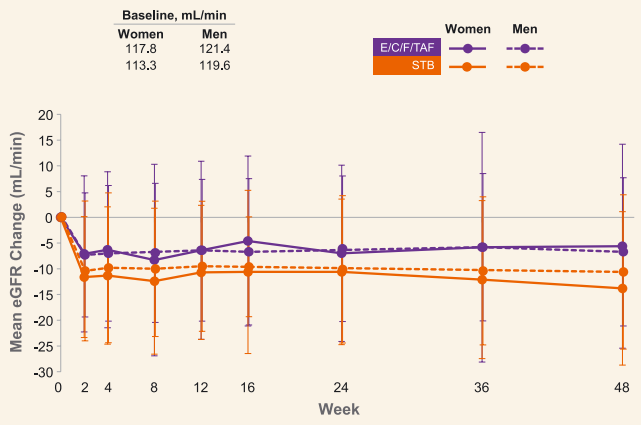
Virologic Success by Snapshot Analysis at Week 48



Proteinuria: Change From Baseline to Week 48

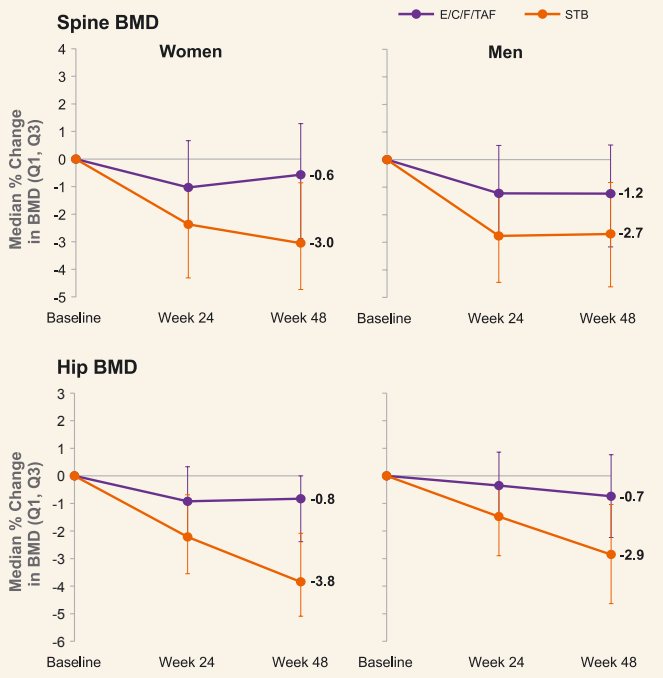


eGFR*: Change From Baseline to Week 48

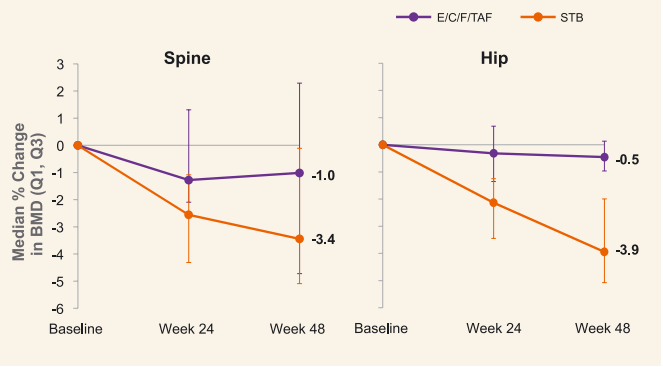


Proteinuria: Change From Baseline to Week 48

Proteinuria: Change From Baseline to Week 48



Change in BMD in Women Aged ≥50 Years



Conclusions

- Use of E/C/F/TAF (n=133 women) vs STB (n=127 women) at Week 48:
  - E/C/F/TAF demonstrated high and noninferior rates of virologic success in women (95% vs 87%; p=0.02)
  - Both regimens were well tolerated and proximal renal tubulopathy was not observed
  - Among women, decline in eGFR was significantly less and median decrease in proteinuria numerically greater with E/C/F/TAF
  - Women and men had similar BMD declines, while those on E/C/F/TAF had less spine and hip BMD loss vs those on STB (including women aged >50 years)
- These results support the use of E/C/F/TAF for the initial treatment of HIV in women

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Pregnancies in adolescents infected with HIV in the state of Sao Paulo, Brazil: Challenges to avoid mother-to-child transmission of HIV and keep these adolescents alive

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Background: Adolescence is the transition between childhood and adulthood. Primary care health units concentrate visits in antenatal care (AN), child health and chronic diseases, which may prevent adolescents from using these services. Adolescents may only access services when pregnant or with symptoms of a disease, including, sexually transmitted diseases (STDs). This study describes AN, time of HIV diagnosis and pregnancy outcome in HIV-positive adolescents in the state of Sao Paulo (SSP), 1999-2015

Materials and methods: Descriptive study of 12-19 year-old HIV positive pregnant teenagers, living in SSP, diagnosed with HIV between 01/01/1999 and 06/30/2015. Data source: cases reported to the Disease Information System (Sinan).

Results: 1,793 pregnancies were reported in HIV-infected adolescents, about 8% (1,793/21,662) of total of the SSP. Pregnancies occurred in 1,591 adolescents: 88.3% (1,405/1,591) had one pregnancy, 10.7% (171/1,591) two, and 0.9% (15/1,591) three or more.

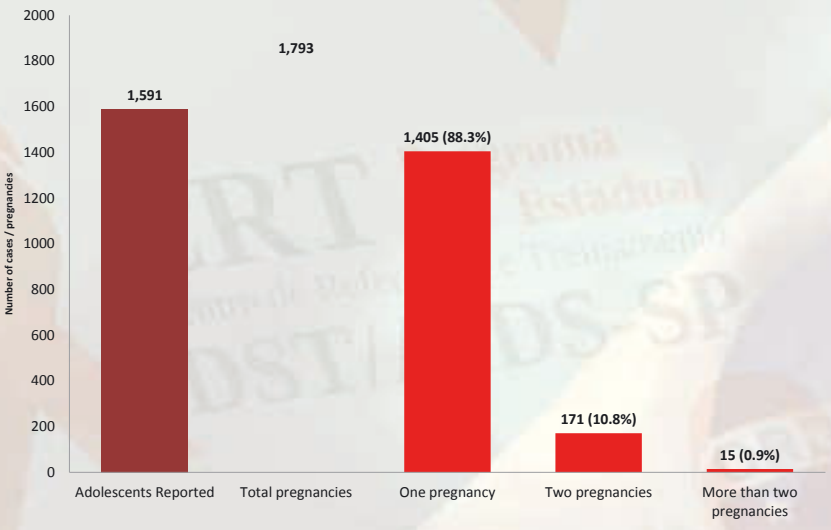

Figure 1. Number of pregnancies in adolescents with HIV, according to the time of HIV infection. State of São Paulo - 1999-2015.
Source: Sinan – VE-PEDST/Aids – SP

In 43.9% (788/1,793) of pregnancies HIV diagnosis was before AN, 44.3% (795/1,793) during AN, and 9.0% (162/1,793) during or after childbirth; AN occurred in 91.2% (1,636/1,793) of pregnancies, with 56.8% (929/1,636) starting in the 2nd or 3rd trimester; in 74.5% (1,335/1,793) antiretrovirals were used during AN, in 7.3% (131/1,793) not used, and in 18.2% (327/1,793) not specified; 56.0% (1,004/1,793) evolved to cesarean delivery and 26.9% (482/1,793) to vaginal delivery; miscarriages and stillbirths accounted for 2.3% (41/1,793). Excluding miscarriages, stillbirths and ongoing pregnancies, in 73.3% (1,263/1,722) intravenous zidovudine was used during childbirth, in 9.9% (171/1,722) not used, and in 16.7% (288/1,722) not specified.

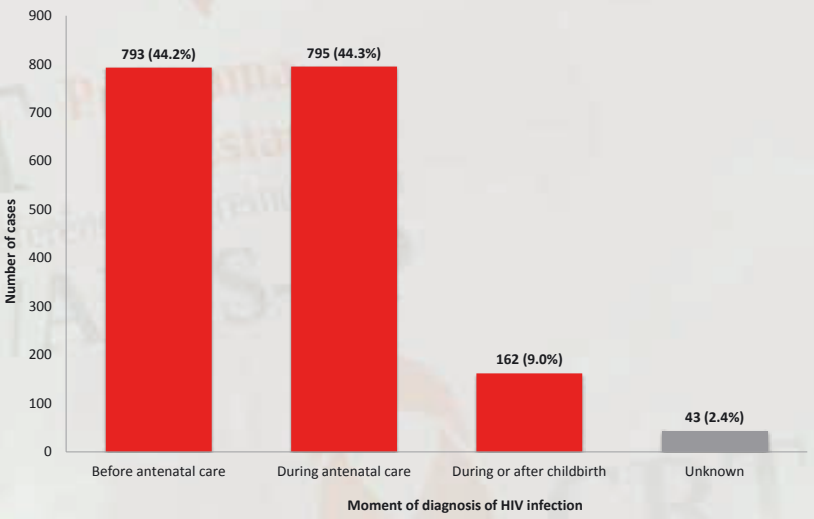

Figure 2. Number of Pregnancies in Adolescents with HIV, reported in the State of São Paulo - 1999-2015 *
Source: Sinan – VE-PEDST/Aids – SP

Conclusions: In this population, the high proportion of pregnancies diagnosed with HIV before AN suggests adolescents infected by perinatal transmission or with unprotected early sexual activity. The care network must discuss specific strategies of access to services for adolescents, prevention inputs, sexual and reproductive health care, including access to long-acting contraceptives. It is important to link and retain this population in HIV services, to improve coverage and adherence to antiretrovirals, reduce viral load and maintain virologic suppression, prevent mother-to-child transmission of HIV and keep these adolescents alive.

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Case investigation protocol and committee as strategies to reduce and eliminate mother-to-child transmission of HIV: Experience of the state of Sao Paulo, Brazil

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Background: Although intervention measures to prevent mother-to-child transmission of HIV (MTCT) are available in health care services for pregnant women, postpartum women and children, several social, political, economic and individual factors may hinder access of this population to these measures, contributing to the occurrence of cases. In 2014, the National STD/AIDS department recommended the implementation of state and municipal committees to investigate, discuss and propose measures to reduce and eliminate MTCT of HIV, using a pre-established protocol to identify determinants of the disease. The committees are intra-institutional, inter-institutional, multidisciplinary bodies with confidential technical performance and educational function, essential for monitoring and evaluating health care policies. The state of Sao Paulo (SSP) proposed using Mother and Child Mortality Committees, given they have already been established and are operating regularly. MTCT has declined in SSP – 538 cases in 1996 and 21 in 2013, by year of birth (Figure1). In 2013, the state of São Paulo had 0.03 case of MTCT of HIV per 1,000 live births; 2.7% MTCT of HIV rate; 98% coverage of antenatal care; and 86.5% coverage of antiretroviral in pregnant women. This study describes MTCT research results in children under 5 years of age, born in the SSP between 2007 and 2013.

Materials and methods: Descriptive study using research protocol with 67 questions in 3 groups: antenatal, delivery and postpartum / child monitoring (Available: http://www.aids.gov.br/sites/default/files/anexos/publicacao/2014/56592/tv_2_pdf_18693.pdf). At the conclusion of the Protocol, determinants are classified into types of vulnerability: individual-social maternal and program (service or management) for decision making.

Results: The 90 protocols studied - 53 cases (58.9%) by individual-social maternal vulnerability, 8 (8.9%) program-service, 17(18.9%) in both areas, 9 (10%) under investigation, and 3 (3.3%) despite infection, followed prophylactic measures correctly. Main categories of individual and social vulnerability: 20 cases of drug use ("crack", alcohol and others), 7 living in the streets and drug use, 17 with low-income and 10 immigrants; for program-service: gaps in prevention measures, search for absences, and improving adherence to antiretroviral drugs. Median maternal age of 30 years, 37.8% were single and 41% housewives. In 44 cases (48.9%) the mothers had the HIV diagnosis before or during antenatal care, 15 (16.7%) at birth, and 21 (23.3%) after birth, and in these cases 23.8% (5/21) of the mothers were HIV negative during antenatal care and at birth.

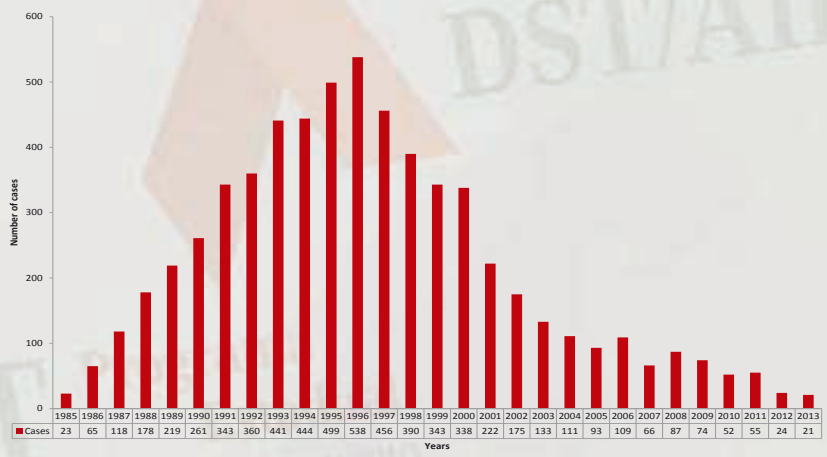

Figure 1. AIDS cases of mother-to-child transmission of HIV, per year of birth. State of São Paulo, 1985-2013.
Source: SINAN – VE-PEDST/Aids- SES-SP

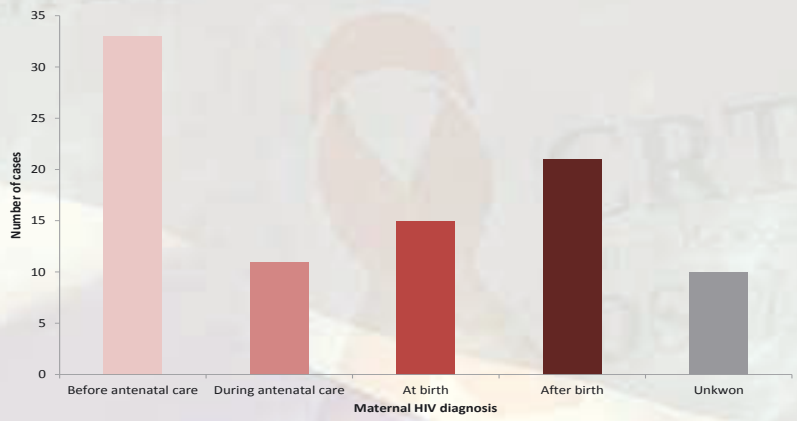

Figure 2. Maternal HIV diagnosis according to the time of diagnosis. State of São Paulo, 2007 – 2013.

Conclusions: The success of the national HIV/AIDS policy has reduced MTCT of HIV. Currently, determinants of this disease are mainly related to individual and social components of this population and their accessibility to services. Action strategies for pregnant users of crack and other drugs are being developed with other Departments, including: expanding diagnosis and treatment, access to long-acting contraceptives, prevention supplies, sexual and reproductive health care, among others. Expanding access and improving AN, early diagnosis and timely treatment are important actions to eliminate MTCT of HIV. Committees can contribute to improve health care activities and quality of public policies to overcome these barriers.

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Reference number 3353360

P13

Long-term follow-up of HIV-infected mothers from Perinatal and LILAC studies in Buenos Aires, Argentina

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ABSTRACT

Introduction: HIV treatment guidelines updates following the results of the Strategic Timing of AntiRetroviral Treatment (START) study and WHO B guidelines have changed antiretroviral (ARV) treatment practices for HIV-infected post-partum women. Factors significant to predicting treatment abandonment (ABND) among these patients differ globally. Our study aim was to evaluate the factors that are associated with ABND in this cohort.

Methods: Retrospective review of charts from all women that participated in either or both the BA perinatal study (2002 - 2007) and BA LILAC: The longitudinal study in Latin American countries (2008 - 2012) were included. Data collected included patient status at the study completion visit through 31 July 2015, medical indication for ARV treatment, ABND, alcohol (ETOH), smoking or substance use, CD4 nadir and most recent count, hospitalizations, hepatitis co-infection (B/C), opportunistic infections (OIs), change in CDC status, sex industry employment and year last seen in clinic. Associations with the defined outcome were estimated using chi-square analysis.

Results: Of the 150 women (178 pregnancies), charts were available on 108 women. Only 72 out of 150 were still in care through 2015. Of the 51 women recommended to continue ARV post-perinatal/LILAC; age 32, (range 26.2- 43.7 years, SD 3.75), 27% had Hep B/C, 6% were sex workers, 27% were drug abusers, 13% ETOH, 33% smoked cigarettes and 29% were AIDS defined (41% CDC A). Thirty-seven (72%) abandoned ARV treatment at some point with 40% of those women developing an OI while off-treatment; 65 women did not have an end of study indication for ARVs. On average, they were 27.6 years of age (range 18.49 - 37.38, SD 4.96); 12% had Hep B/C and 5% were sex workers; 27% were drug abusers, 11% ETOH and 36% smoked cigarettes. At the time of completion of their prior study, 94% were CDC A. Forty-one were later recommended to start therapy, of which 71% abandoned therapy. 46% of those recommended to start therapy (post-perinatal/LILAC) but who ABND, developed an OI. Maternal ARV ABND was not predicted by smoking status, ETOH/substance use, Hep B/C status, HIV status of infant, or prior parity. Being a sex worker (p 0.03) and CDC C (pB0.001) were associated with predicting ARV ABND.

Conclusions: In this long-term follow-up study, many women continued in intermittent care despite not taking ARVs; 71-72% of these women stopped ARV treatment at least once during the follow-up period despite having an indication to continue treatment. Barriers to retention in care required further evaluation.

OBJECTIVE

Objective: To assess factors significant to LTFU among HIV+ pregnant mothers in Buenos Aires, Argentina.

METHODS

Study Population and Procedures: Perinatal (2002-2007) and LILAC (2008-2011) comprised a prospective observational study of HIV-infected pregnant women and HIV-exposed uninfected infants at clinical sites in Latin America and the Caribbean. For this analysis, we included entry visit data for 130 participants w/ available patient paper charts.

Eligibility Criteria: Pregnant women from the Perinatal (2002-2007) and LILAC (2008-2011) cohorts followed in Buenos Aires, Argentina who were diagnosed with HIV infection either prior to or during pregnancy or within 1 month postpartum, and whose paper charts were available for review and analysis at Hospital Jose Ramos Mejia during June-August 2015.

Study Outcomes and predictors:

- Abandonment of HAART treatment at any point between the end of Perinatal/LILAC and July 2015
- Progression of CDC status
- Smoking and drug use status
- Participation in the adult entertainment industry

Statistical Methods: All data analysis done in Excel and with Chi squared tests.

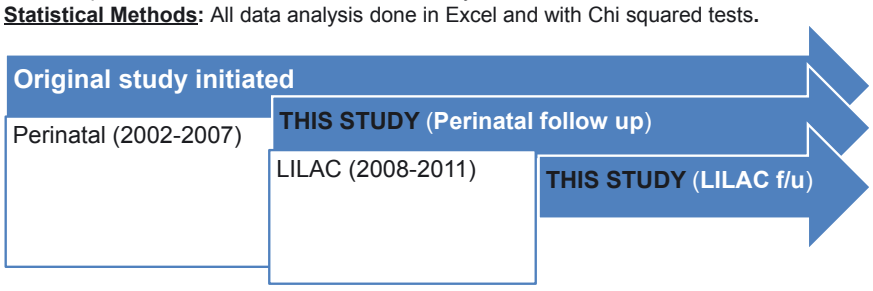


Table 2. ARV abandonment and OIs

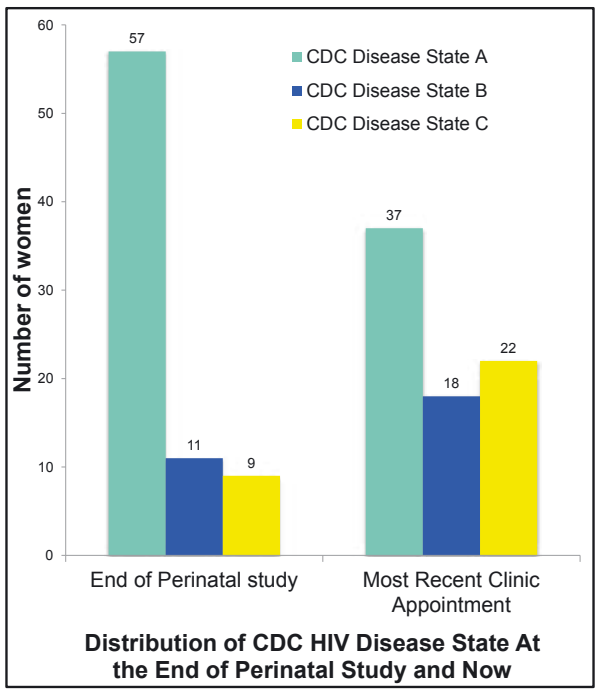
Characteristics		N (%)
No ARV at end of study (n=65)	ARV abandonment at any point	27 (42)
	Total number of OIs	16 (25)
	Mean most recent CD4	513
With ARV at end of study (n=51)	ARV abandonment at any point	37 (72)
	Total number of OIs	15 (29)
	Mean most recent CD4	380
Women with appointment in 2014-15 (n=77)	ARV abandonment at any point	34 (44)
	Total number of OIs	17 (22)
	Hep B/C coinfection	17 (22)
	Significant drug use (current or past)	18 (23)
	Significant alcohol consumption	8 (10)
	Mean most recent CD4	472

Table 3. Baseline characteristics as compared to ARV treatment abandonment

Characteristic		Abandon ARV (n=66) N (%)	Never abandon ARV (n=50) N (%)	P-value
CDC status at last Perinatal/LILAC visit	C	13 (20)	3 (6)	*.03
Most Recent CDC Status per patient chart	C	32 (48)	4 (8)	*0.001
Significant consumption	Alcohol use	5 (10)	9 (14)	.55
	Drug use	19 (29)	12 (24)	.76
	Tobacco	29 (44)	14 (28)	.08
Other risk factors	Sex worker	6 (.09)	0	*0.03
	Hep B/C coinfection	16 (24.2)	7 (14)	.17

Note: * P value < 0.05; Study group differences tested with Pearson's Chi-Square test.

Figure 2. Progression of CDC State Among Patients Last Seen in Clinic During 2014-15



Distribution of CDC HIV Disease State At the End of Perinatal Study and Now

Figure 3. Retention in Care of HIV+ Perinatal Study Mothers

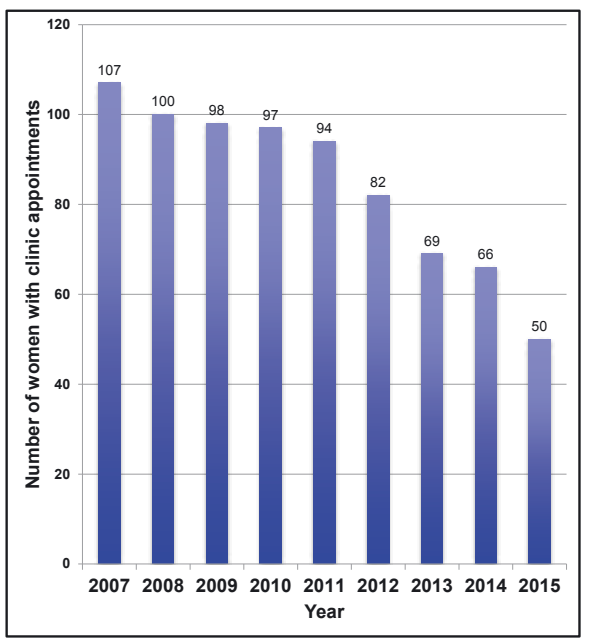
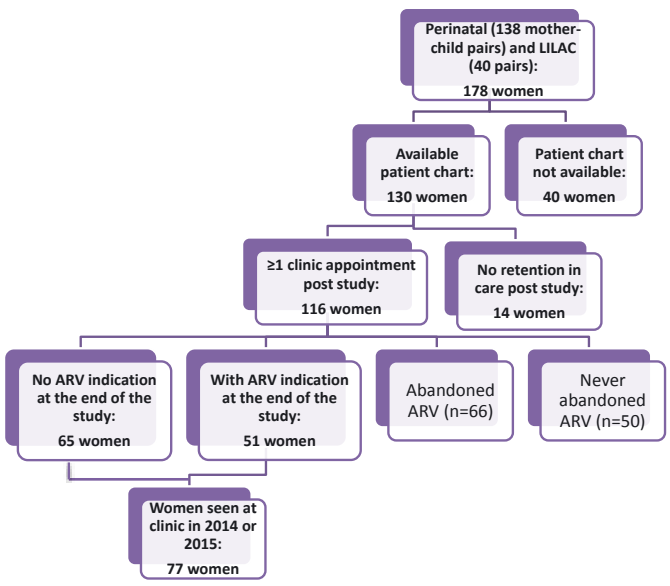


Figure 1. Methodology to define sample study



We would like the entire Perinatal and LILAC research teams as well as the families and care providers who participated in this study.

Table 1. Baseline Characteristics), Perinatal (n=140) + LILAC (n=38)

Characteristic		No ARV indication (n=65) N (%)	With ARV indication (N=51) N (%)
Age	Mean, yrs	27.6	32
	Range (SD)	18.49 - 37.38 (4.96)	26.2 - 43.7 (3.75)
CDC status at Perinatal/LILAC completion	A	61 (94)	21 (41)
	B	4 (6)	15 (29)
	C	0	15 (29)
Significant consumption	Alcohol use	7 (11)	7 (13)
	Drug use	17 (26.5)	14 (27)
	Tobacco	23 (36)	17 (33)
Other risk factors	Sex worker	4 (6)	3 (5)
	Hep B/C coinfection	8 (12.5)	14 (27)

INTERPRETATION AND FUTURE QUESTIONS

- Although both current and previous guidelines dictate ARV treatment for all expectant HIV-infected mothers, previous guidelines allowed asymptomatic post-partum mothers to discontinue ARV use directly or soon after birth per MD, leading to significant LTFU soon after the birth of their children with continued LTFU of cohort mothers with passage of time (Figure 3)
- In Buenos Aires Argentina, where many patients live far from the hospital, and numerous administrative hurdles exist in the otherwise public healthcare system, many patients reinitiate treatment only in the context of a fall in CD4 count or an opportunistic infection, leading to continued progression of CDC disease state (Figure 2)
- Maternal ARV ABND was not predicted by smoking status, ETOH/substance use, Hep B/C status, HIV status of infant, or prior parity. Being a sex worker (p=0.03) and CDC C (p=0.001) were associated with predicting ARV ABND (Table 3)
- Further research should be done in order to ascertain the importance of factors that are significant for predicting LTFU and abandonment of antiretroviral treatment, in the hopes of decreasing rates of both in the future.

Implementation gaps for interventions to prevent mother to child transmission of HIV in Mexico during 2014

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Introduction

Since the commitment to eliminate the mother to child transmission (MTCT), of HIV by 2018, the Mexican Health Ministry has generated evidence that contributes to the design of strategies for HIV testing promotion in pregnant women and their linkage to HIV health services. Using the continuum of care cascade as a monitoring framework is possible to identify the biggest implementation gaps for the interventions to prevent mother to child transmission of HIV.

Methods

Descriptive study based on health sector information in 2014 and 2015. The estimated number of pregnant women with HIV in 2014 was obtained through the UNAIDS *Spectrum* model. The screening coverage was used to estimate the detection gap; the access to antiretroviral therapy (TARV) for prevention of MTCT (PMTCT) of HIV was estimated from the reports of the HIV Sector Information Group. The perinatal cases were classified according to the year of birth and the diagnosis age. Finally an estimate of the expected number of cases was performed.

Objective

To describe the gap between the detection and the antiretroviral therapy access to prevent the MTCT by using the continuum of care cascade.

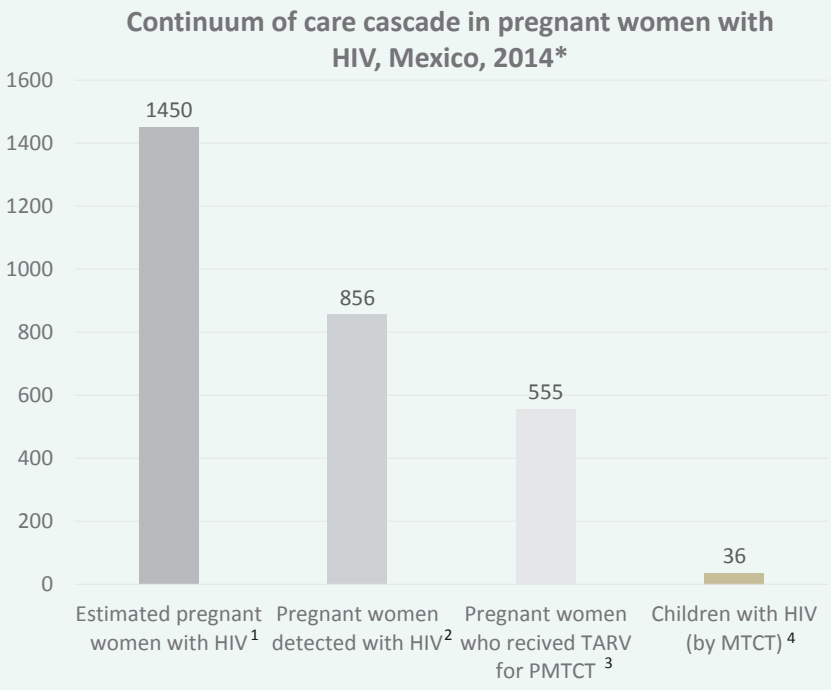
Results

Continuum of care cascade in pregnant women with HIV

- 1,450 pregnant women with HIV were estimated to be addressed throughout the Mexican health system in 2014. According to the detection coverage, 59% (n=856) women were diagnosed, however, only 38% (n=555) women received antiretroviral treatment to prevent mother to child transmission of HIV.

- Based on the data from the National Register Cases of AIDS, in 2014 were diagnosed 90 children with HIV by MTCT and 71 were diagnosed in 2015. From these children, only 36 were born in 2014, therefore, they were the result of the gap between detection, diagnosis and access to antiretroviral therapy.

Graphic 1.

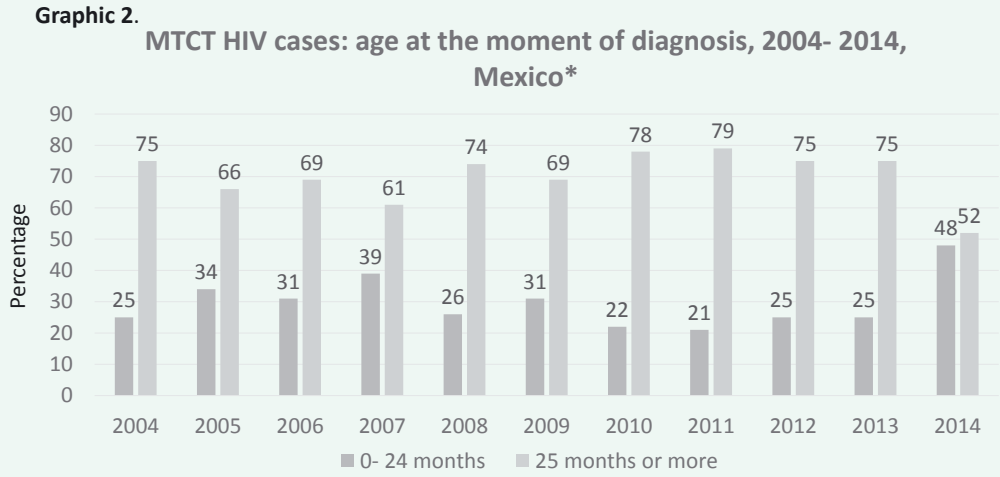


- Information from all Mexican health sector.
1. *Spectrum* model
2. Pregnant women detected with HIV
3. Pregnant women who recieved TARV por PMTCT (new diagnosis)
4. Children with HIV (adjusted by year of birth)

MTCT HIV cases

- The mother to child transmission cases of HIV were reviewed from 2004 to 2014. The diagnosed cases between 0 and 24 months were classified like “timely diagnosed”. The records shows that on average, 32% of these cases were timely diagnosed. The trend was similar in the 10 years (between 21% to 39%), except in 2014, where there was an increase compared to 2013 (48% vs 25%) (Graphic 2).

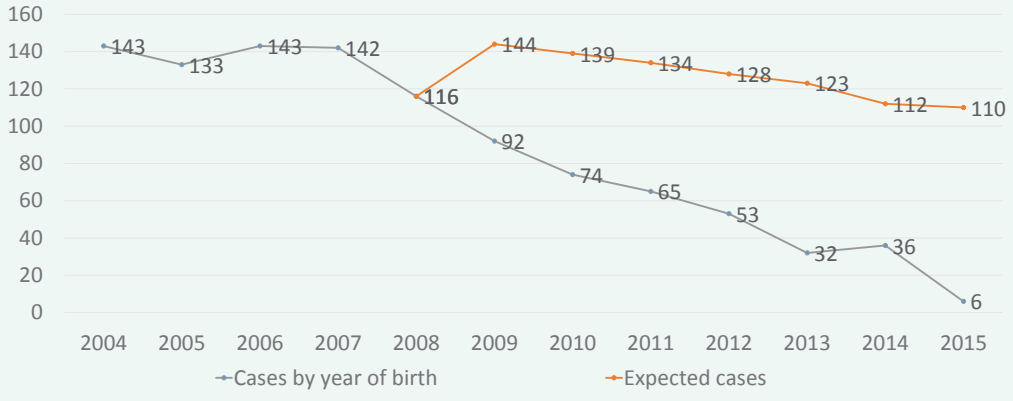
Graphic 2.



*National Register Cases of AIDS, Mexico 2004- 2014

The cases analysis according to the year of birth, showed that the observed decrease based on the number of diagnostics reported annually, is a reflection of the delay diagnoses, but not a reduction in transmission, because according to the estimation, 113 cases are finally expected in 2014 (Graphic 3).

Graphic 3.



*National Register Cases of AIDS, Mexico 2004- 2014

Conclusions

- Early diagnosis of HIV infection during pregnancy is essential to prevent TMI . In Mexico, the low coverage of detection and low connection to the continuum of care result in a low proportion of pregnant women having access to antiretrovirals.
- The Pan American Health Organization recommended surveillance based on case reports to facilitate longitudinal tracking of infected people, however the gaps make the surveillance partially retrospective, limiting, for now, the possibility of preventing the transmission.
- Achieve the goal of MTCT elimination of HIV in Mexico is still far, because in a divided health system, a sectoral effort is required to ensure detection from the first prenatal visit, the continuum of care and monitoring cases.

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HIV TESTING, PRENATAL CARE AND DIAGNOSIS IN PREGNANT WOMEN HOSPITALIZED IN A PUBLIC HOSPITAL IN BUENOS AIRES

HIV/ HEP AMERICAS 2016 – Mexico City April 28 – 30, 2016

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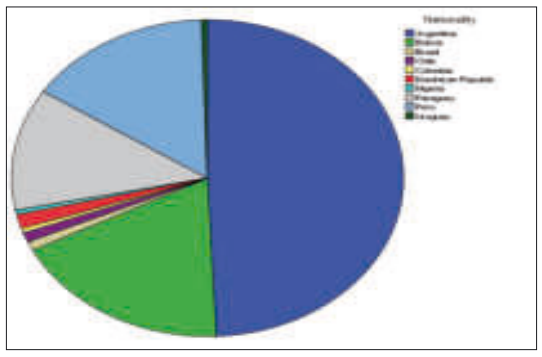
BACKGROUND: HIV mother-to-child-transmission (MTCT) it is by far the most common way that children become HIV infected. Without treatment, transmission rates range from 15 to 45%, but this can be reduced to less than 2% with timely intervention. Thus, for the prevention of MTCT (PMTCT) it is key that pregnant women have knowledge of their HIV status. Hospital J.M. Ramos Mejía is a public institution where most of the well-known strategies for PMTCT are available. Nonetheless, in the period of 2003-2009 there were nine cases of HIV vertically infected children, resulting in the highest rate of MTCT among 12 hospitals evaluated in Buenos Aires city (MoH, 2011). In a study performed in the period Sep-Dec 2007 two issues were identified potentially contributing to this high infection rate: the lack of Prenatal Care (PC) and the late diagnosis of maternal HIV status (Bulló, 2009). Another concerning outcome of the study was the high percentage (38%) of women that did not receive counselling either before or after testing. 6 more cases of MTCT were reported between 2010 and 2015. The present study aims to re-evaluate PC and provision of HIV testing as reported by women hospitalised in the maternity ward of this institution. Outcomes of interest were the proportion of women: 1) with term pregnancies (TP) that have not done an HIV test or do not have test results available; 2) with TP that did not receive PC; 3) with TP that received adequate PC (≥5 visits); 4) that know their partner's HIV status; and 5) that received pre- and post-test counselling. In addition, the nº of prenatal visits, and the results of HIV, VDRL and hepatitis B testing as reported by the women were compared with the information available in their clinical charts. Also the results of this study were compared with the results from that performed in 2007.

METHODOLOGY: description of results of two cross sectional studies. During an 8 week period between April and June 2015, all women hospitalised in the maternity ward were invited to participate in a structured interview (15'). The questionnaire covered four main aspects: I) Social demographic data: neighbourhood, distance to hospital, patient's knowledge of her partner's HIV status. Women were considered to be negative when they stated to have done an HIV test in the last year. Women were considered to know their partners HIV status if they reported that their partner had at least one test done in the last year. II) Obstetrical information: reason for hospitalisation, nº of pregnancies, types of deliveries, abortions, and gestational age. III) Prenatal care; location and nº of visits; VDRL and HVB serology. IV) HIV testing: if it was requested during PC, by whom and when, pre- and post-test counselling, perceived difficulties making appointments or obtain test results. Answers were noted on a report form and compared against information available in the clinical charts. The study received ethical approval from the IRB. Written informed consent was obtained from all participants. *Statistical analysis*: Frequency values (absolute and relative) were computed for qualitative variables. For quantitative variables a mean (SD) or median (25th and 75th percentile) were calculated as appropriate. IBM SPSS Statistics 20 was used to perform statistical analyses.

Figure 2



Results: 255 women hospitalized between April 2015 and 10 June 2015 (*figure 1 -flow chart*). Age ranged:15-45 years, mean of 26.8 (SD: 6.7). Nationality: 103 (49.3%) Argentina, 38 (18.2%) Bolivia, 32 (15.3%) Peru, 26 (12.4%) Paraguay and 10 (4.8%) from other countries (*figure 2*). Almost half had finished secondary education or attained higher education levels (*figure 3*). 120 women (57%) live in the city, with a median travelling time of 20' (10-30') and 89 women (43%) in the suburban area, with 60 min (60-90'). 146 (69.9%) were TP , 25 (12.0%) interrupted pregnancies and 38 (18.0%) other obstetric related conditions. 51 of the 209 women (24.4%) reported not to know their HIV status.19.0% with TP did not know their HIV status. 158 (75.6%) knew their HIV status, 155 reported to be negative and 3 (1.4%) positive (*table 1a*). Country of origin seems to be associated with not knowing one's HIV status. 17.5% of the Argentineans, versus 31.1% of women from other countries did not to know their serostatus (*table 1b)*. 103 (49.3%) of the patients responded to know their partner's status (all negative). 106 women (50.7%) did not know their partners serostatus, or responded not to know if their partner had a test done in the last year. All TP women but one, testified to have attended prenatal visits. 26 of the 27 women reporting not to have received PC were in the first trimester. 50% reported to start PC in the first trimester, and 6% in the third trimester. 50% did not know whether or not VDRL was requested, 15.9% reported that VDRL was not requested. Participants reported that HIV testing was not requested (3.8%) or did not know if HIV testing was requested during PC. Moreover, of the women saying that HIV testing was asked for, only 4 out of 5 of women knew their test result (*table 2*). Only 34.0% (48 of 141) and 20.6% (29 out of 140) of the women who did an HIV test and had their test results available reported to have received pre- and post-test counselling respectively. 83 women (59.6%) said not to have received either pre- or post-test counselling. HIV test results are available for just 106 out of 5 out of 182 (58.2%) of the women *(figure 4)*. *Table 3* shows a comparison between results of questionnaires held in 2007 and 2015.

Figure 1: Flow Chart

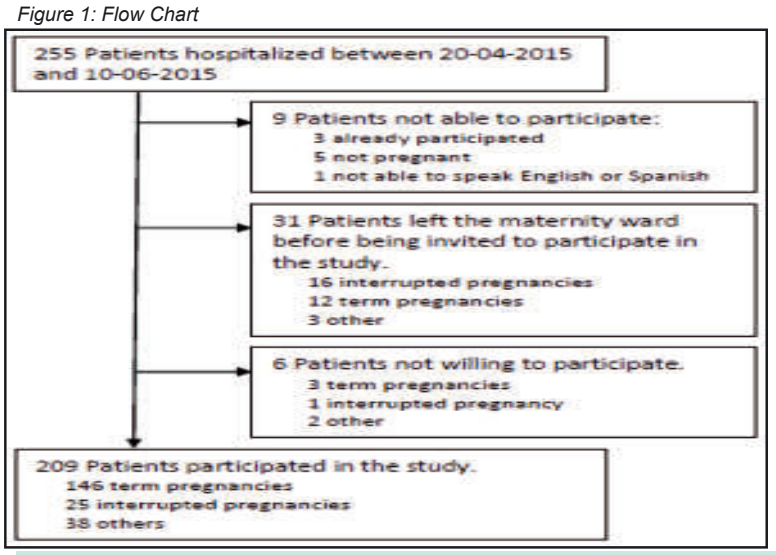


Table 1(a/b)

a	Status	Non-term pregnancies	Term pregnancies	Total
	Positive	2 (3.2%)	1 (0.7%)	3 (1.4%)
	Negative	38 (60.3%)	117 (80.1%)	155 (74.2%)
	Does not know	23 (36.5%)	28 (19.2%)	51 (24.4%)
	Total	*63*	*146*	*209*

b	Status	Argentina	Other	Total
	Positive	2 (1.9%)	1 (0.9%)	3 (1.4%)
	Negative	83 (80.6%)	72 (67.9%)	155 (74.2%)
	Does not know	18 (17.5%)	33 (31.1%)	51 (24.4%)
	Total	*103*	*106*	*209*

Figure 3

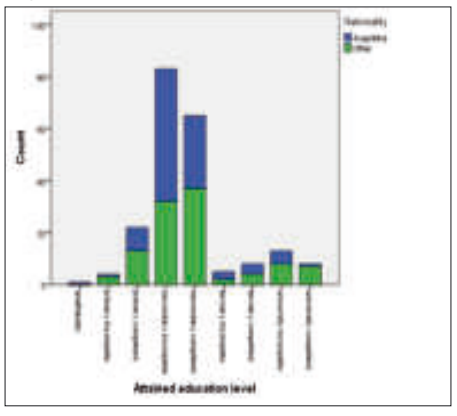


Table 2

	HIV testing for all women with PC		HIV testing for TP	
	% of total	% of test requested	% of total	% of test requested
Test not requested	7 (3.8%)		4 (2.8%)	
Does not know if test was requested	8 (4.4%)		8 (5.5%)	
Test requested	166 (91.7%)		133 (91.7%)	
Positive		1 (0.6%)		0
Negative		132 (79.5%)		112 (84.2%)
Does not know test result		8 (4.8%)		7 (5.3%)
Result not yet available		2 (1.2%)		1 (0.8%)
Did not do analysis		7 (4.2%)		1 (0.8%)
Problems withdrawing results		16 (9.6%)		12 (9.0%)
Total	*181*		*145*	

Figure 4

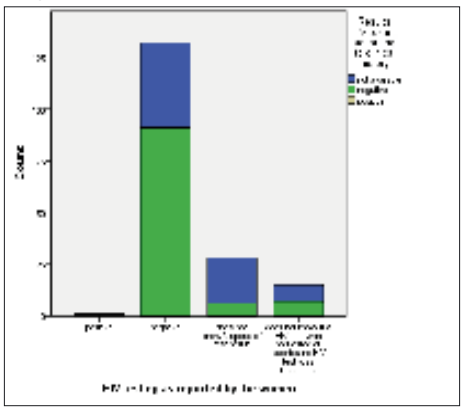


Table 3	Women with PC		Women with TP	
	study 2007 (n=256)	study 2015 (n=182)	study 2007 (n=218)	study 2015 (n=146)
Lives in Buenos Aires city	50.2% (128 of 255)	54.9%	55.0%	52.7%
Secondary completed	37.4% (74 of 198)	46.7%	28.9%	46.6%
Knows own HIV status	84.4%	79.7%	84.4%	80.8%
Knows partner's HIV status	62.5%	49.5%	60.1%	50.0%
No PC	-	-	3.3%	0.0%
≥5 prenatal visits	82.4%	73.6%	83.9%	82.9%
Primiparous	35.0% (82 of 234)	27.5%	39.6%	28.1%
HIV test requested	93.8%	91.2%	92.7%	91.7%
Knows HIV test result	76.7% (184 of 240)	80.1% (133 of 166)	79.2% (160 of 202)	84.2% (112 of 133)
Received pre-test counselling	45.2% (108 of 239)	30.7% (51 of 165)	44.5% (89 of 200)	33.1% (44 of 133)
Received post-test counselling	32.4% (68 of 210)	20.6% (29 of 141)	31.9% (58 of 182)	20.2% (24 of 119)
Received neither pre- nor post-test counselling	44.8% (94 of 2010)	59.6% (84 of 141)	44.5% (81 of 182)	58.8% (70 of 119)

Conclusions: It is concerning that a quarter of interviewed women reported not to know their HIV status and 50% had no knowledge about their partner's HIV status. The rate of MTCT continues to be far above what is potentially achievable. Comparing the findings of this study with that from 2007, there has been no improvement in the provision of PC, HIV testing and counselling in our institution. Our results highlight the need to explore better understand the causes of this performance and the opportunities to improve these outcomes in order to achieve better results in reducing HIV-MTCT.

HIV/STI testing among MARPs in Mexico City: a key first step to improve the cascade of care

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Background

Mexico City has had the highest burden of HIV in the country since the first case was detected in 1983. It has an estimated HIV prevalence of 0.78%, whereas the rest of the country has a prevalence of 0.2% according to the 2015 UNAIDS report. The HIV epidemic in Mexico City is characterized by being predominantly concentrated in males (8 males for each female), located in the heavily populated boroughs of the city, affecting the communities of the Most at Risk Population (MARPs) groups, such as men who have sex with men (MSM) and Transgender Women.

Methodology

Condesa Specialized Clinic has a lab specializing in the latest technologies for HIV and STI diagnosis. The testing algorithm has as its goal Viral Load Supression (**Fig. 1**). This has helped view HIV testing as part of the treatment process becoming an integral part of the treatment cascade and the "Test and Treat" strategy. The lab algorithm not only includes HIV testing, but also Syphilis, HBV, and HCV testing (**Fig. 2**). Patients diagnosed as having HIV receive rapid CD4 count testing and viral load testing. For patients that are HIV negative are also tested for STIs and are tested for the p24 antigen. This has allowed the detection of acute HIV cases with very high VL count. Those who are negative but with high risk of infection are considered for Pre-Exposure Prophylaxis (PrEP).The HIV/aids Program partners with NGOs in the communities to access MARPs and enroll them into treatment.

Results

During 2015, 3,480 persons were diagnosed as having an HIV infection at Condesa Specialized Clinic in Mexico City (**Fig. 3**). Of these 91.4% were men and 7.6% were women. This includes **59** patients diagnosed during the acute stage of the infection , with a negative Western Blot result but a positive p24 antigen result with an average VL >500,000 copies/ml of blood. The people detected were MARPs with significantly higher prevalences than the national prevalence of 0.23% (**Table 1**). Of all the persons diagnosed with HIV at our facility, 409 had a prior HIV diagnosis and were receiving treatment. This was identified through undetectable VL. Of the remaining 3,071 patients, 60.2% were enrolled into HAART, 18.7% were referred to other providers and 21% were lost to follow-up (**Fig. 4**). Of the cases detected 34.8% had a late diagnosis with CD4 count less than 200 (**Fig. 5**). Nevertheless, once in treatment patients responded well with 64.6% having a VL<40copies/ml of blood after 6 months in treatment (**Fig. 6**). Of the patients with at least 6 months of HAART, 95% has a VL<1,000 copies/ ml of blood, meaning that their ability to pass on the infection to another person is greatly diminished. Half of the detected HIV cases in Mexico City are concentrated in 3 of the city´s boroughs, Iztapalapa, Cuauhtemoc and Gustavo A. Madero. These three boroughs are located in the northern and eastern parts of the city, where the higher number of HIV cases are located (**Fig. 7**).

Figure 1.

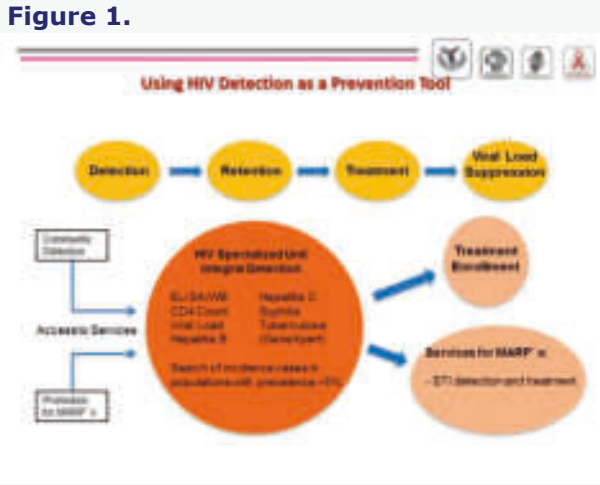


Figure 2.

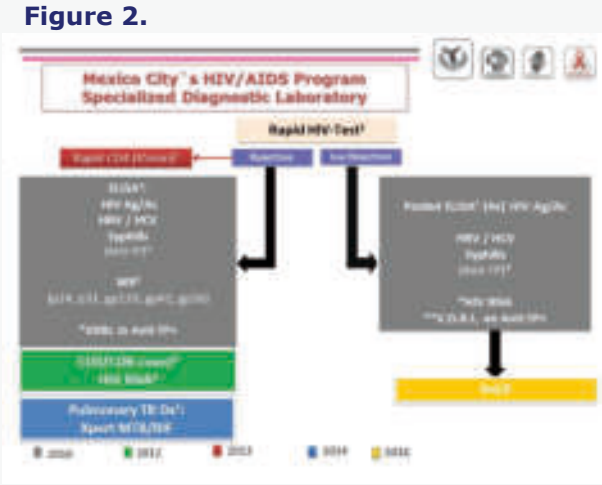


Figure 3.

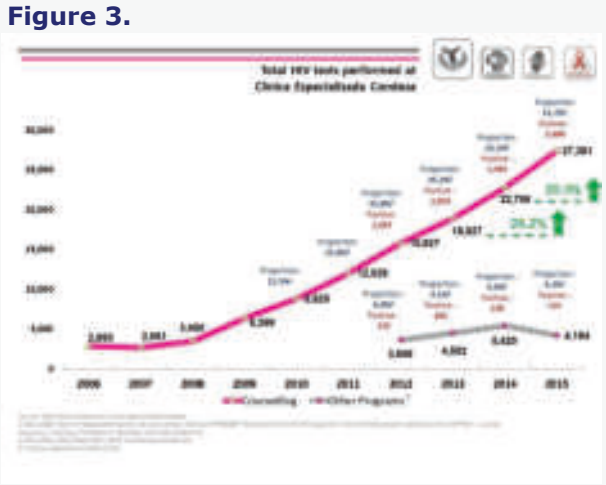
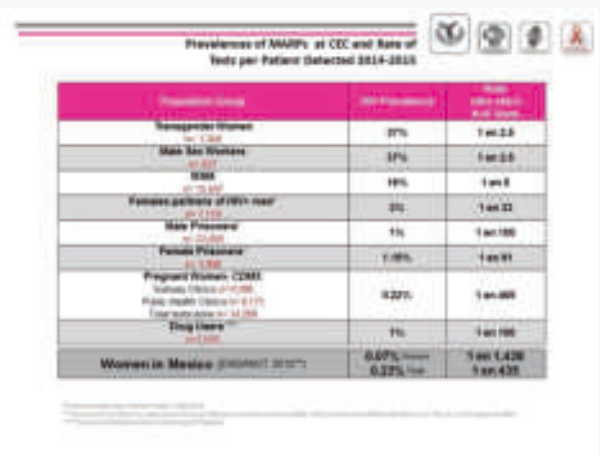


Table 1.



Transgender Women	31%	1 en 3.3
Male Sex Workers	14%	1 en 7.1
MSM	14%	1 en 7
Females partners of HIV+ men	3%	1 en 33
Male Prisoners	1%	1 en 100
Female Prisoners	1.08%	1 en 91
Pregnant Women (CDMX)	0.22%	1 en 455
Drug Users	1%	1 en 100
Women in Mexico	0.07% 0.23%	1 en 1,428 1 en 435

Figure 4.

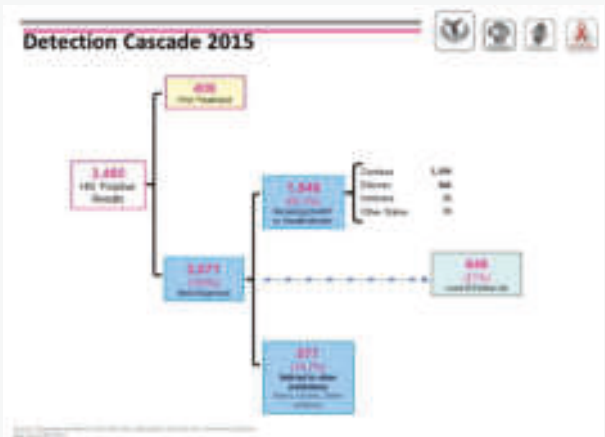


Figure 5.

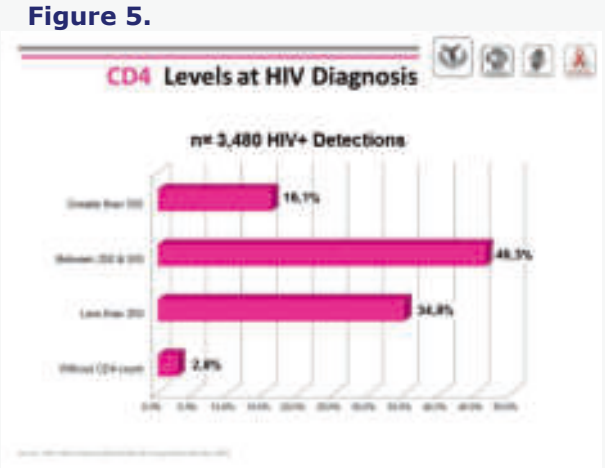


Figure 6.

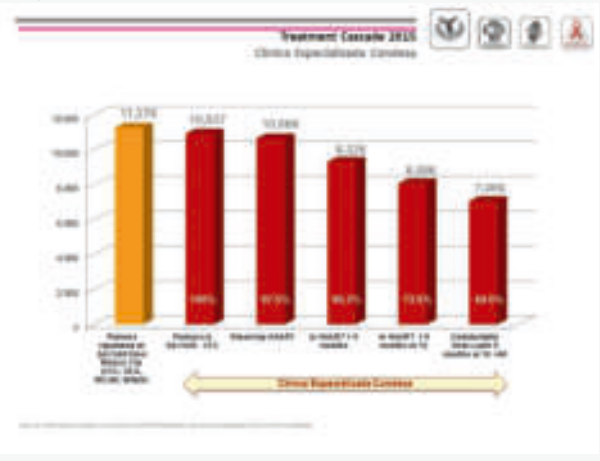


Figure 7.

Discussion

Targeted HIV testing can be a powerful tool in locating HIV cases in concentrated epidemics if focused on MARPs with the assistance of community groups such as NGOs. Getting people to test early is key as it reduces mortality and morbidity and there is a better response to achieve VL suppression. Using the p24 Antigen testing has allowed us to detect people during the acute stages of infection, when VL are higher and are more likely to pass on the infection to other people. Treating this group to achieve VL suppression quickly is key to preventing passing the infection to their sexual partners. Patients diagnosed at later stages of the infection (<200 CD4) may present clinical issues that are more difficult to treat, which require more resources and the outcome may not be as good.

Conclusions

HIV testing is the door to enter the Treatment Cascade. Test and Treat is a sound strategy to achieve the 90-90-90 goal. Knowing your epidemic is key to best target limited resources in the most affected communities, both geographically and socially. Coordinating the detection efforts with community groups that are knowledgeable and part of the MARPs is key to winning over their trust and building friendly and accessible testing services. Investment in the latest detection technology and strategies is worthwhile only if you have adequate access to HAART.

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CONDESA

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Implementation of New Strategies for Timely HIV Diagnosis in Mexico City´s Prison System and Its Impact on the Continuum of Care.

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Background

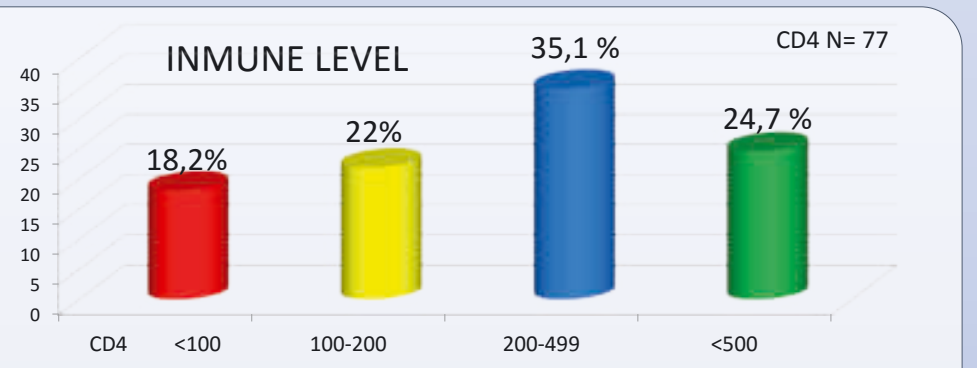
In Mexico City about 35,000 men are in prison distributed throughout 8 centers with an HIV prevalence of 1.0% (1). Prison inmates that are diagnosed with HIV are then transferred to the Santa Martha Acatitla (SMA) Prison, where they are offered HAART and specialized medical care. During the beginning of 2015 there were 192 patients at SMA, 54.9% of the total of estimated cases (N=350). During 2014 4,559 HIV tests were performed in all detention centers in Mexico City.

Material and Methodology

During 2015 several innovative strategies were implemented aimed at prison inmates: in the two largest centers, voluntary HIV testing was offered to inmates by correctional facility medical staff when they entered the prison. In one center (the second largest) all the prison population was HIV screened (only those who voluntarily accepted were tested) while in another there was a health fair where HIV testing was offered to inmates as well as their family members. All prison centers received periodic visits by the HIV Mobile Diagnosis Team. The data was collected until October 31st, 2015 in order to analyze the impact in the continuum of care of all new diagnosis.

Results

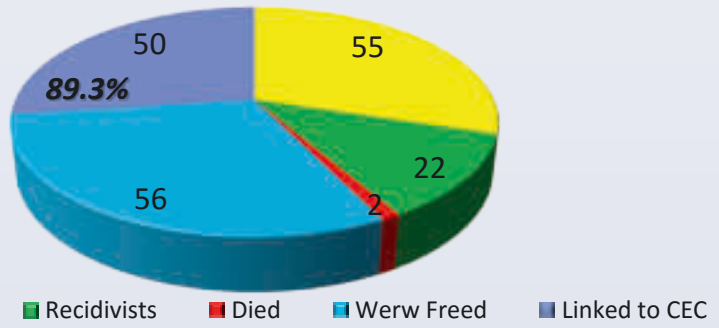
20,535 HIV tests were performed from January 1st, 2015 through October 31st 2015 in all the prison centers in Mexico City (4.5 times of all tests performed in 2014). 55 new cases were diagnosed, along with 22 previously diagnosed cases, with an average CD4 count of 327 cel/ml (SD=258) graph 2. During this time 56 patients were freed and two died. By October 31st, 216 inmates with HIV were aware of their HIV positive status (61.7% of the total estimated cases), 211 (60.3%) were incorporated to care, 210 (60.0%) retained in care, 204 (58.3%) received HAART. 190 (54.3%) had a viral load <200 copies/ml and 175 (50.0%) had a VL<40 copies/ml. 96.7% of the newly diagnosed patients are receiving HAAART and 90% of patients on HAART have a VL<40 copies/ml (83% with VL<200 copies/ml) graph 1.



Graph 2. Inmune level at HIV diagnosis. 59.8% with CD4 >200. with an average CD4 count of 327 cel/ml (SD=258)

Conclusions

- The HIV care program in prisons has achieved two of the goals set by the WHO 90-90-90 initiative.
- The implementation of new diagnosis strategies has been translated into a significant increase in the number of HIV detections in prisons.
- The widespread implementation of these strategies in all the prison system of Mexico City might allow us to diagnose 90% of HIV cases among prison inmates.



Graph 3. October 31st 2015. 56 patients were freed, 89.3% were linked to health care in Condesa Clinic.

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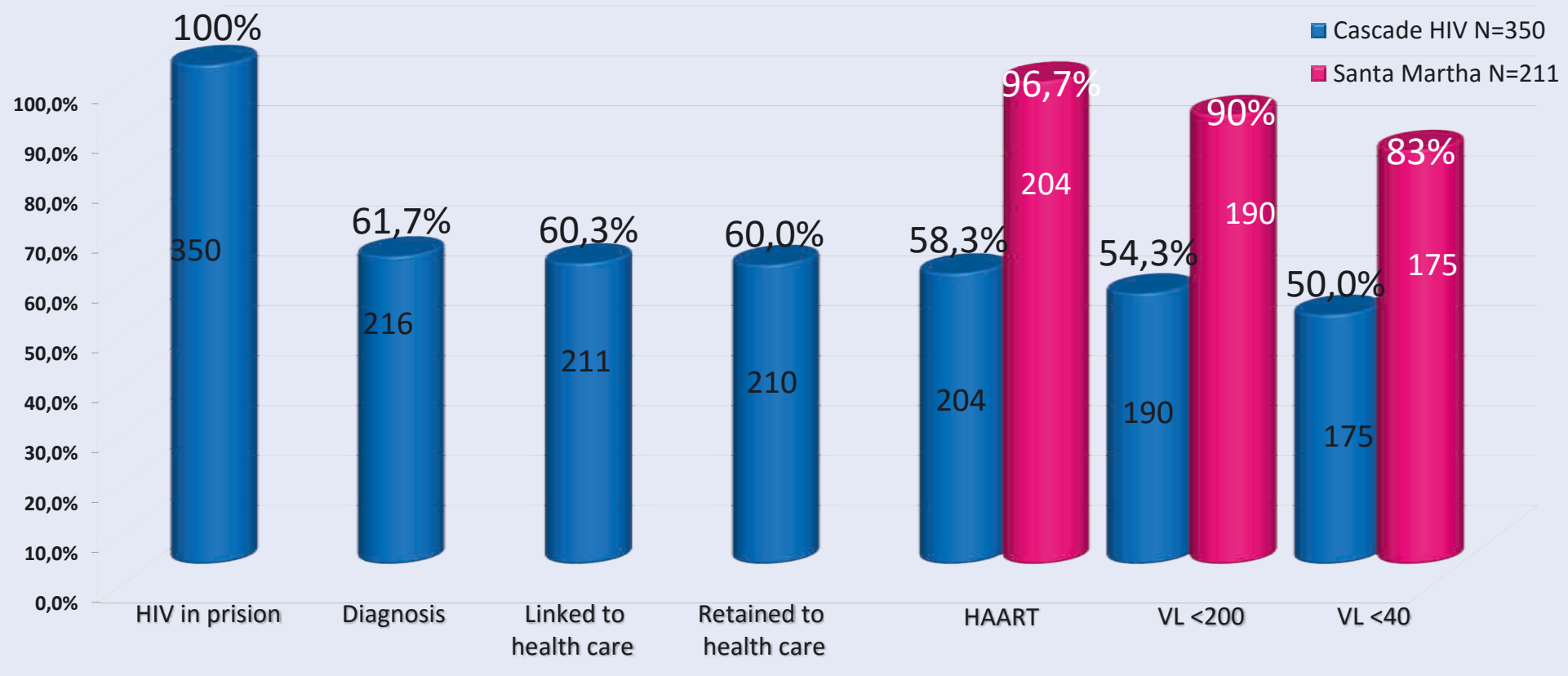
- Graphics: Data from the national System for Logistics Administration and Surveillance of ARV in Mexico (SALVAR) 31 of October, 2015. Database of the CIENI/CENSIDA, 2015. Database of the HIV Prison Programme in Mexico City 2015.



Graph 1~. Shows the number and percentage of incarcerated people with HIV in different stages of care at the Santa Martha Acatitla Penitentiary in Mexico City during January – October 2015 with 50 % in virology control (VL <40).

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Incidence and Time-Varying Predictors of HIV and Sexually Transmitted Infections (STIs) Among Male Sex Workers in Mexico City

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Background

Mexico City has a high HIV prevalence of 18.2% among male sex workers (MSWs) compared to 0.3% among the adult population.[1] Studies have shown that despite a decline in HIV in recent years among the general adult population, HIV prevalence among MSWs has actually risen.[2] The elevated transmission rate among MSWs is due to a greater number of sexual partners and more risky sexual behaviors.[1] Therefore it seems likely that MSWs in Mexico City would have increased prevalence of all STIs not just HIV.

An estimation of HIV and STI incidence rates among MSWs in Mexico City would offer a better understanding of HIV/STI prevalence within this particularly vulnerable population. In addition, time-varying predictors of STI acquisition need to be identified in order to inform targeted interventions.

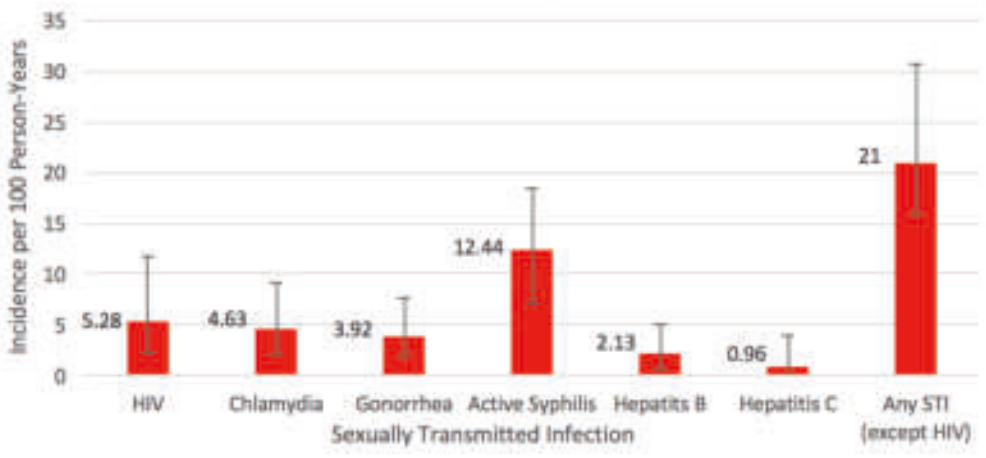
Methods I: Sample and Variables

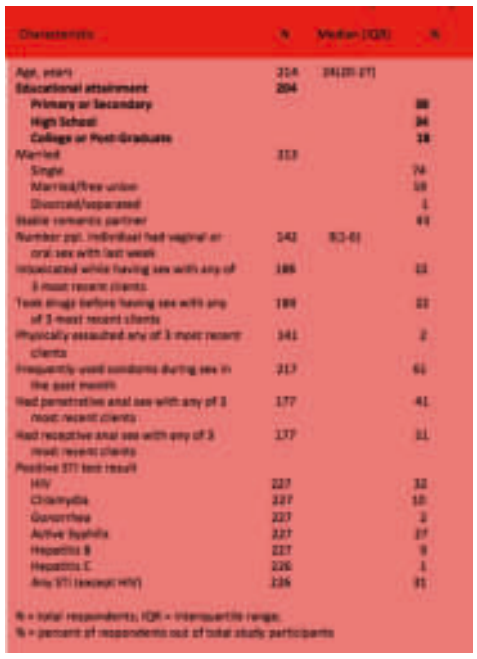
MSWs recruited from Clínica Condesa HIV Testing Clinic and community sites in Mexico City were tested and treated for STIs (chlamydia, gonorrhea, syphilis, and HIV) and only tested for viral hepatitis (hepatitis B and C) at a baseline, 6-month follow-up, and 12-month follow-up clinic visits. The initial sample consisted of 227 males who self-identified as MSWs and MSM who had anal sex with at least 10 male partners over the last six months in exchange for money. Participants completed surveys at all visits to document sociodemographic characteristics and health behaviors.

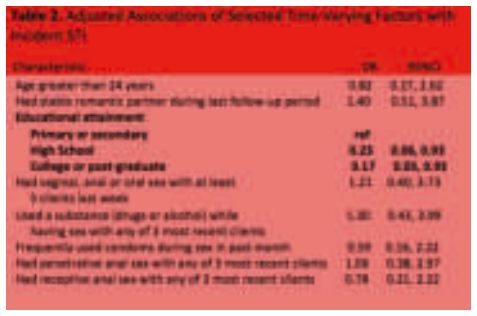
Methods II: Statistical Analyses

We estimated incidence rates and calculated 95% confidence limits using a bias-corrected and accelerated bootstrap method with 1,000 replicates. We used mixed effects logistic regression with individual fixed effects and a random intercept for each person to examine unadjusted and multivariable adjusted time-varying predictors of incident STIs (excluding HIV in order to retain participants with prevalent HIV infection). Time-varying predictors included in the models were age, education, marital status, number of sexual partners, substance use, assault, condom use, and types of sexual activity.

Figure 1. Incidence of HIV and STIs in a Cohort of Male Sex Workers, Mexico City







Results

The highest incidence rates among the 227 participants were active syphilis (12.44 per 100 PY; 95% 8.17, 18.51) and HIV (5.28 per 100 PY; 95% 2.25, 11.75).

In the adjusted mixed effects models, risk of incident STIs did not vary by age, marriage, engagement in a stable romantic relationship, offering services to five or more clients, alcohol use, polysubstance use, sexual assault perpetration, condom use, provision of penetrative sex, or provision of receptive sex (Table). **However, risk of STIs did differ by educational attainment and was lower among those who completed high school (odds ratio (OR) = 0.23, 95% 0.06, 0.93) or college/post-grade education (OR=0.17, 95% 0.03, 0.93) compared to those who only had completed primary or secondary schooling. The association between risk of STI infection and completion of high school (unadjusted OR [UOR]=0.28; 95% 0.09, 0.85) or college/post-graduate education (UOR=0.13; 95% 0.03, 0.53) persisted in the multivariable adjusted model.**

Discussion and Conclusion

These findings suggest that HIV/STI incidence is high among MSW in Mexico City, and should be a priority population for treatment and prevention interventions. It suggests this population could benefit from pre-exposure prophylaxis (PrEP) methods to reduce risks of HIV infection. Education appears to be a key potential predictor of HIV/STI infections and may be an important component of economic and structural interventions to prevent infections.

References

1. Galarraga, O. (2014). The disproportionate burden of HIV and STIs among male sex workers in Mexico City and the rationale for economic incentives to reduce risk. *Journal of the International Aids Society*, *17*(19218).
2. Baral, S. D. (2014). Male sex workers: practices, contexts, and vulnerabilities for HIV acquisition and transmission. *The Lancet*.

Acknowledgements

Clínica Condesa: Andrea González, Florentino Badial, Nathalie Gras, Octavio Parra, and Jehovani Tena. INSP: Biani Saavedra, María Olamendi, Santa García. Database construction by CEO: Edgar Díaz. Project management and administration by CISIDAT (Consortium for HIV/AIDS and TB Research). We especially thank the participants for agreeing to become part of Punto Seguro. Funding: US National Institutes of Health (R21HD065525; "Conditional economic incentives to reduce HIV risk: A pilot in Mexico"; PI "Galárraga O."). Agency for Healthcare Research and Quality, 5K12HS022998-02.

Poster P020

Passcode: P020

Changes in Renal Laboratory Parameters and Bone Mineral Density in Treatment-Naïve HIV-1-Infected Adolescents Initiating Therapy with INSTI-Based Single-Tablet Regimens Containing Tenofovir Alafenamide (TAF) or Tenofovir Disoproxil Fumarate (TDF)

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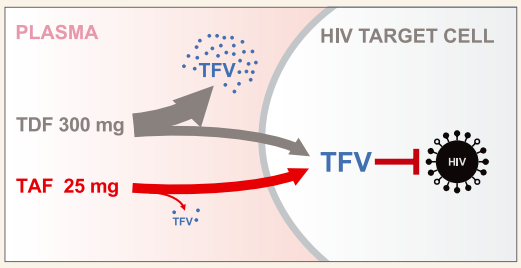
Fax (650) 578-9264

Introduction

Tenofovir Alafenamide (TAF, GS-7340) Novel Prodrug of Tenofovir[1-6]



- 90% lower TFV levels minimizes renal and bone effects while maintaining high potency for suppressing HIV

Background

E/C/F/TAF and E/C/F/TDF

- E/C/F/TDF (commercially available as Stribild) and E/C/F/TAF (may not be commercially available in some countries) are single pill formulations that both contain elvitegravir (EVG) 150 mg, cobicistat (COBI) 150 mg, and emtricitabine (FTC) 200 mg
  - E/C/F/TAF contains TAF 10 mg
  - E/C/F/TDF (Stribild) contains TDF 300 mg
- Two phase 3 double blind adult studies[6] comparing E/C/F/TAF to E/C/F/TDF demonstrated
  - Noninferior efficacy of E/C/F/TAF
  - Significantly reduced renal and effects with E/C/F/TAF
- Two single-arm open-label studies[7,8] of E/C/F/TAF and E/C/F/TDF conducted in treatment-naïve adolescents have shown
  - These STRs are well tolerated
  - Plasma levels of all components are similar to those in adults

Methods

- Cross-study comparison of 2 ongoing open-label, single-arm studies in treatment-naïve adolescents
  - Study 292-0106: E/C/F/TAF administered for 48 weeks (N=50)
  - Study 236-0112: E/C/F/TDF administered for 48 weeks (N=50)
- Primary endpoint: safety
- Secondary endpoint: viral suppression
- For both studies key inclusion/exclusion criteria:
  - Age ≥12 to <18 years
  - Weight >35 kg
  - HIV-1 RNA >1000 copies/mL
  - No prior ARV therapy
  - CD4 count >100 cells/mm^3

Study Assessments and Analysis Methods

- Safety assessments
  - Adverse events and laboratory assessments: hematology, chemistry, renal tubular protein biomarkers
  - Dual X-ray absorptiometry (DXA) of spine and total body less head (TBLH) at baseline and every 24 weeks
- Efficacy assessments
  - HIV-1 RNA (TaqMan 2.0) and CD4 count at every visit
  - Resistance testing in cases of confirmed virologic failure (HIV-1 RNA >400 copies/mL)
- Statistical methods
  - Cross-calibration between DXA scanner types (Hologic and Lunar)
  - Calculation of standard and height-adjusted Z-scores and predicted BMD change
  - Snapshot algorithm for HIV-1 RNA <50 copies/mL at Week 24

Results

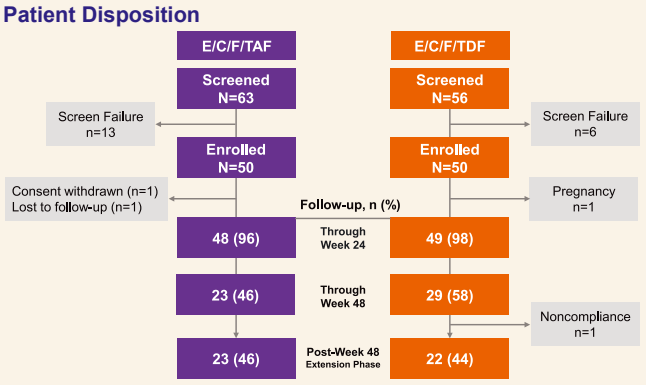
Demographics and Baseline Characteristics

		E/C/F/TAF n=50	E/C/F/TDF n=50	p-value
Age	Years, median (range)	15 (12-17)	16 (12-17)	0.040
Sex	Male, n (%)	22 (44)	35 (70)	0.009
Country of Origin	Uganda, n (%)	30 (60)	0	
	South Africa	3 (6)	22 (44)	
	Thailand	6 (12)	14 (28)	
	United States	11 (22)	14 (28)	
eGFR (Schwartz)	mL/min/1.73 m^2, median	156.0	139.5	0.082
Spine BMD	g/cm2, median	0.78	0.93	0.027
	Standard Z-score	-1.30	-0.72	0.20
	Height-adjusted Z-score	-0.54	+0.09	0.015

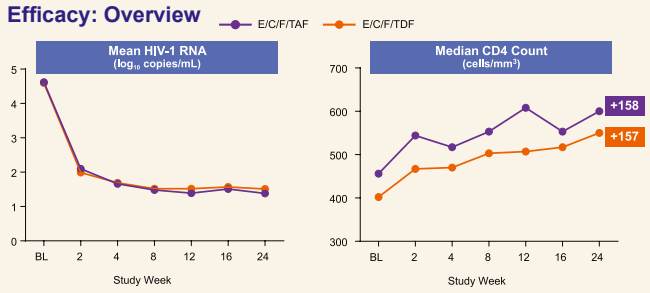
Baseline Disease Characteristics

		E/C/F/TAF n=50	E/C/F/TDF n=50	p-value
HIV-1 RNA	Log_{10} copies/mL, mean (SD)	4.62 (0.59)	4.60 (0.55)	0.98
	>100,000 copies/mL, n (%)	11 (22)	10 (20)	0.81
CD4 Count	Cells/μL, median (Q1, Q3)	456	0	0.060
	(332, 574)	402	22 (44)	
	(298, 486)	0.060	14 (28)	
	<200 cells/μL, n (%)	4 (8)	2 (4)	
Mode of Infection	Vertical transmission, n (%)	32 (64)	17 (34)	
	Heterosexual sex	12 (24)	12 (24)	
	Homosexual sex	8 (16)	19 (38)	

Patient Disposition



Efficacy: Overview



- All subjects achieved HIV-1 RNA <50 copies/mL by Week 12
- Proportion with HIV-1 RNA <50 copies/mL at Week 24: E/C/F/TAF 90% (45/50), E/C/F/TDF 88% (44/50)
- Most failures were associated with decreased adherence
- No emergent resistance

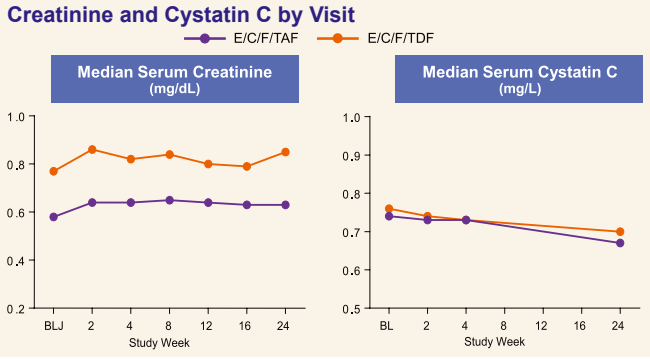
Safety Overview

E/C/F/TAF: 5 SAEs in 4 patients	E/C/F/TDF: 5 SAEs in 4 subjects
Urinary retention, neuropathic pain, constipation	1) Suicide gesture 2) Shigella dysentery, acute renal injury
Conduct disorder, polysubstance abuse, bipolar disorder	Pre-term labor
Intermediate uveitis, visual disorder*	Immune reconstitution inflammatory syndrome
1) Substance abuse 2) Suicidal ideation, suicide attempt	Acute asthma exacerbation

*Only treatment-related SAE and resolved without E/C/F/TAF interruption.

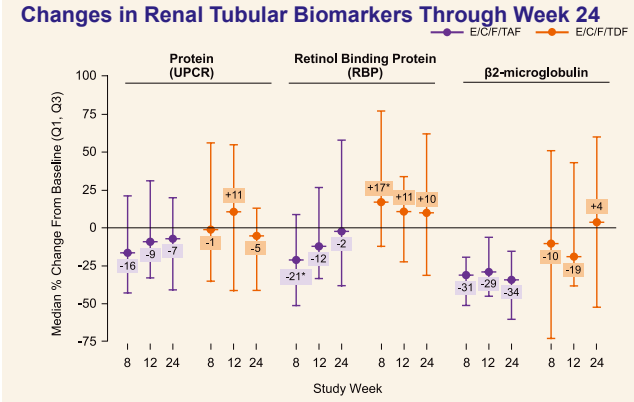
- No deaths or adverse events (AEs) leading to treatment discontinuation
- Most AEs mild or moderate and unrelated to study treatment
- No cases of proximal renal tubulopathy or Fanconi syndrome
- Serious adverse events:

Creatinine and Cystatin C by Visit



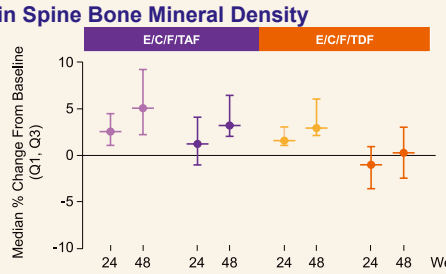
- Median change in Cr (mg/dL) at Week 24: E/C/F/TAF **+0.08**, E/C/F/TDF **+0.08**
- Median change in eGFR (mL/min/1.73 m^2) at Week 24: E/C/F/TAF **-15.0**, E/C/F/TDF **-14.0**
- Slight decrease in Cystatin C (not affected by COBI) in both groups

Changes in Renal Tubular Biomarkers Through Week 24



Expressed as ratio of urine marker to urine creatinine. *p<0.05 in favor of E/C/F/TAF.

Changes in Spine Bone Mineral Density



		E/C/F/TAF Predicted	E/C/F/TAF Actual	E/C/F/TDF Predicted	E/C/F/TDF Actual	p-value
Median (Q1, Q3) % Change	Week 24 (n=47)	+2.55 (+1.11, +4.54)	+1.25 (-0.96, +4.11)	+1.55 (+1.11, +3.07)	-0.985 (-3.57, +0.95)	0.009
	Week 48 (n=23)	+5.09 (+2.23, +9.23)	+3.25 (+2.07, +6.47)	+2.95 (+2.20, +6.08)	+0.299 (-2.45, +3.04)	0.12

- At Week 24, compared to spine BMD at baseline a decrease of ≥4% was seen in:
  - 3/47 participants (6.7%) in the E/C/F/TAF cohort
  - 10/47 participants (21%) in the E/C/F/TDF cohort (p=0.070)

Conclusions

- While being cognizant that this was a cross-study comparison and there were differences (age, gender, geography, mode of transmission) at baseline, we note
  - Both groups exhibited rapid virologic response and high rates of virologic success at Week 24, with no emergent resistance
  - E/C/F/TAF and E/C/F/TDF generally well tolerated
  - Small observed increases in serum Cr, consistent with known effect of cobicistat in adults
  - E/C/F/TAF decreased renal biomarkers, similar to that observed in adult E/C/F/TAF phase 3 studies
  - E/C/F/TAF group had increased median spine BMD at Week 24 (+1.3%) compared with a decrease (-1.0%) in E/C/F/TDF group
  - These data support use of both regimens in treatment-naïve adolescents and suggest potential renal and bone safety advantages of TAF

Acknowledgments

Principal Investigators: H Kizito, A Gaur, W Prasitsuebsai, N Rakhmanina, M Rassool, R Chakraborty, C Orrell, P Kosalaraksa, W Luesomboon, J Batra , J Fourie, A Violari, R Kaplan, R Strehlau, G Cotton, G Latiff, K Chokephaibulkit, T Bunupuradah, J Ananworanich, J Burack, W Borkowsky, J Chen, D Futterman, C Rodriguez, J Schneider; **The Gilead team:** D Podesta, M Hottman, S Goudar, M Myers, Y-P Liu, Y Shao, K Hasegawa, S Fong-Cohen, E Doyle, D Porter, A Coluci, S Bennett, M Fordyce, E Quirk, A Cheng; **Our patients and their families**

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Prevalence of HIV infection among imprisoned women in Brazil: a cross-sectional survey in the State Prison System of Sao Paulo

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Background: The increase of 78.3% of the female prison population in Brazil in the period 2005-2013, has brought great challenges, especially those related to the vulnerability to sexually transmitted infections[1]. Gender inequality, stigma, and discrimination increase imprisoned women's vulnerability to HIV infection[1,2]. The state of Sao Paulo (SSP) accounts for 30% of this Brazilian population, and has sought to develop actions within the National Policy for Integral Women's Health[3]. The aim of this study was to estimate the prevalence of HIV infection in women deprived of freedom in SSP, to establish parameters for monitoring and evaluation.

Materials and methods: Cross-sectional seroepidemiological survey for HIV infection conducted in 19 female prisons of SSP. This study was coordinated by the State Program of STD/AIDS in Sao Paulo and conducted from August 2012 to December 2013. The estimated population basis was 11,530 women in all prisons units. The stages of the study include: counseling, information about the intervention, guidance on the sexual transmitted diseases, free and informed consent to data collection and the offer of testing for HIV and syphilis. For the definition of HIV infection status we used rapid diagnostic tests. Data analysis was based on the estimated prevalence with calculation of confidence intervals.

Results: Of the total of 8,821 (76.5%) addressed women, 8,740 (99.1%) underwent rapid diagnosis for HIV testing. The estimated prevalence of HIV infection from this evaluation was 2.84% (95% confidence interval [CI]: 2.46%-3.16%), 248 infected women. HIV infection by prison unit in Sao Paulo varied from 0 (CRF and CRF Araraquara Rio Claro) to 10.20% (PF Capital - 95% CI: 7.64%-12.76%). The integrated analysis identified coinfection (HIV and Treponema pallidum) in 36 women, estimated prevalence of 0.47% (95% CI: 0.33%-0.61%).

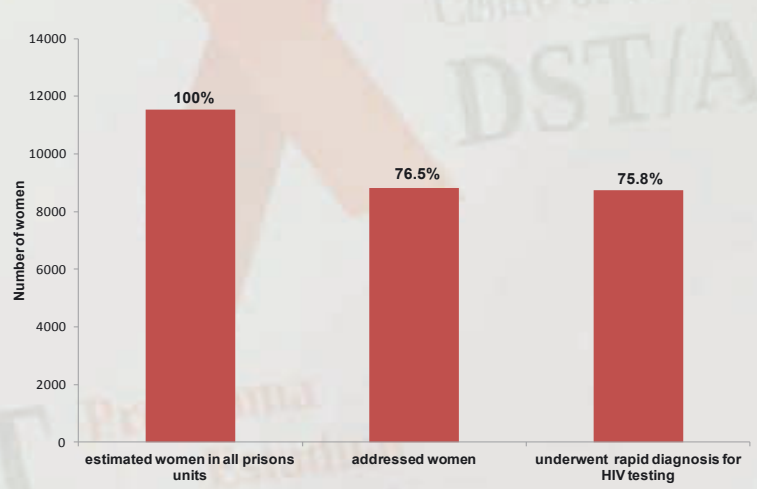

Figure 1. Number of estimated women in all prisons units, women invited to participate the study, and women that underwent for HIV testing. State of Sao Paulo, August 2012 to December 2013.

Conclusions: This is the first study-based action in this extension in SSP. This population-based survey reinforces the status of great vulnerability to HIV infection for women in the State penal system, both in urban and rural realities. This study brings as possibilities to be assigned: establishment of flowcharts and indicators for monitoring and evaluation of preventive and therapeutic strategies to this population; establishment of appropriate flowcharts to the State Epidemiological Surveillance System; definition of elements for interventions in the prison system addressing public health policies, and scientific knowledge production from this and other nested publications to the project[3,4]. These initiative could ultimately contribute to improving the quality of life of women with a neglected and vulnerable condition[2,3,4].

Acknowledgments

We are grateful to Luiza H Matida (in memoriam) for her important collaboration in the area of vertical HIV transmission and congenital syphilis. Dr. Matida was the mentor of this study.

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P024

HIV Cascade of Care and Viral Load Suppression in Trans-Women and Men who have sex with Men populations in the Dominican Republic

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Introduction

Overall rate of new HIV infections appears to be in decline worldwide; however, among key populations, Men who have sex with Men (MSM), and Trans-women new HIV infections continue growing. Since the introduction of highly acute antiretroviral therapy (HAART), people living with HIV live longer than ever before. The HIV Cascade of Care is a comprehensive monitoring tool to evaluate the HIV continuum of care, and to evaluate "leakage points" along the points of attention. The objective of this study was to evaluate the HIV cascade along the services in Men who have sex with men (MSM), and trans-woman (TGW) and compare this with the general HIV population in an outpatient clinic in Santo Domingo, Dominican Republic.

Methods

We developed a retrospective database of one outpatient clinic for HIV patients to assess our population-based cascade. A paper-based data was collected from clinical files. Characterization of target populations was assessed through the implementation of Fichas de Caracterización, which collected past clinical history, sexual identification, gender orientation, and self-identification as exclusively MSM or transgender woman. We classified all patients attending the clinic within the last year. Treatment access and administration of HIV drugs was based according with the Dominican Republic MoH criteria (<350 cell/uL), and viral suppression below 20 copies/mL. We compared the data with the rest of the population attending the services.

Results

We identified 405 HIV diagnosed individuals during the study period; 60% were male. Of these, 25.18% (n=102) were MSM and TGW. Overall, 64.44% in the +WUR was retained in care vs 65.68% in MSM/TGW (**Figure 1**). HAART access in +WUR was 56.04%, while in MSM/TGW 38.29%. Viral suppression in +WUR was 43.70%, and in MSM/TGW 24.50%.
(**Figure 2**).

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FIGURE 1. HIV CASCADE OF CARE KEY POPULATIONS

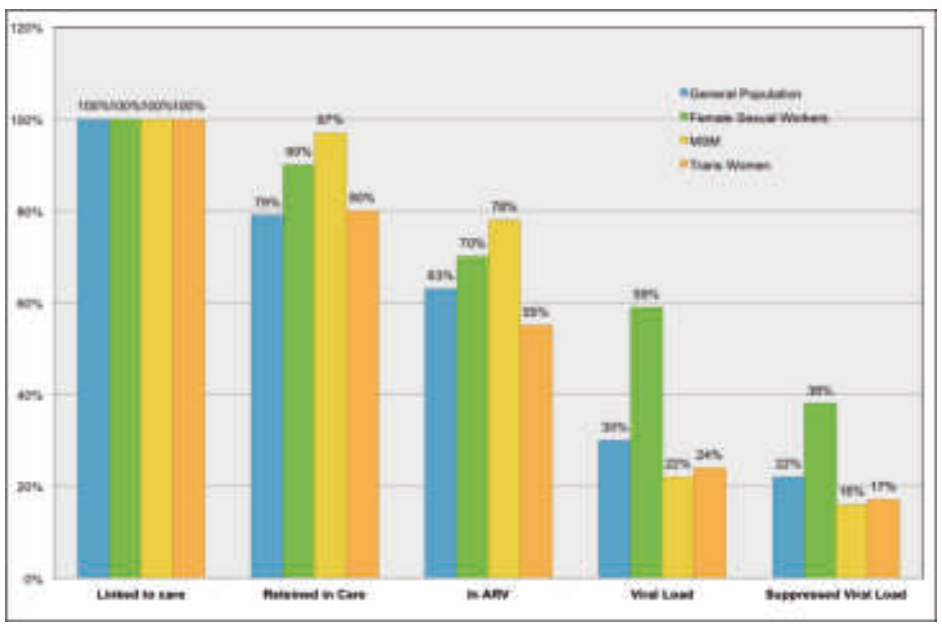
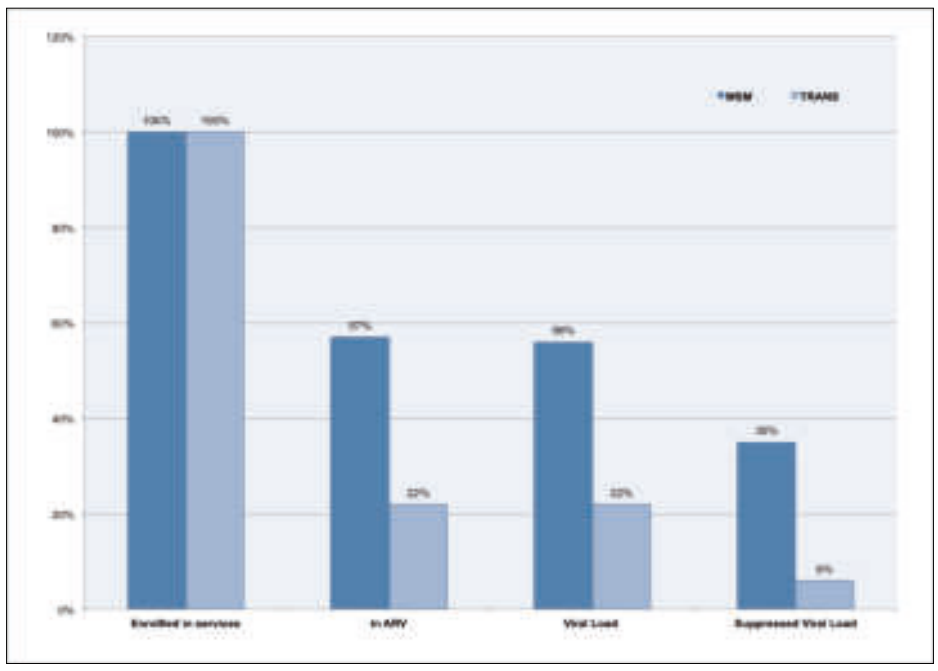


FIGURE 2. HIV CASCADE OF CARE TRANS WOMEN AND MSM



Conclusions

We found a significant difference between access to HAART and viral suppression in both groups. Is necessary to note that higher viral loads among these groups will be of significant influence for HIV persistence in social and sexual networks. Drops in the proportion to be achieved in each step may be a reflection of challenges specific to MSM/TGW access to care. It is necessary to evaluate the potential role of antiretroviral and hormone replacement therapy interactions.

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Prevalence of Depression Symptoms and Key Associated Factors Among Female Sex Workers and Women Living with HIV/AIDS in the Dominican Republic

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SUMMARY:

This research was carried out in San Felipe de Puerto Plata, Dominican Republic (DR). Participants were female sex workers (FSW), women living with HIV/AIDS (WLWHA), and a comparison group of low-income, HIV-negative women who were not FSW. This project estimated the prevalence of depression and identified key correlates of this outcome in the three groups. Depression was prevalent for FSW (70.2%), WLWHA (79.8%), and comparison (52.2%) groups. Internalized stigma was strongly associated with depression for FSW (OR=2.73) and WLWHA (OR=3.06). Interventions to address depression could benefit all women, regardless on HIV risk/ status but should focus on internalized stigma for FSW and WLWHA.

BACKGROUND:

- Little is known about the mental health of FSW and WLWHA in the Dominican Republic (DR).
- Cross-cultural studies show that the prevalence of depression in FSW ranges from 50-80% and from 25.8-81.0% in WLWHA.
- The Dominican Republic is home to a generalized HIV epidemic (0.8-1.5%) and a concentrated HIV epidemic for FSW (3.3%-8.4%).

Purpose and significance:

This project estimated the prevalence of depression and identified key correlates of this outcome in FSW, WLWHA, and the comparison group. Findings will help public health workers to design more effective HIV prevention, testing and treatment programs both generally and regionally.

METHODS:

Research setting and participants:

- This study took place in San Felipe de Puerto Plata, Dominican Republic and its municipalities (April - December 2014).
- Participants were Spanish-speaking, not pregnant, at least 18 years old, and were: sex workers (FSW group), HIV-positive (WLWHA group), or low-income HIV-negative women who were not FSW (comparison).
- Since this study was a secondary analysis of a larger project looking at motherhood, stigma and HIV, respondents had at least one child under the age of 16.

Sampling and approach:

- WLWHA and comparison group women were recruited from clinics; FSW were recruited from diverse sex work sites (e.g., bars, cabarets).
- Investigators verbally administered questionnaires in Spanish assessing demographics and depression to FSW (N=349), WLWHA (N=233), and comparison group women (N=314).
- All FSW and WLWHA completed items ascertaining HIV or sex work-related internalized stigma.

Measures:

- Depression was measured using the CES-D 10 (range: 0-3) and internalized stigma was measured using a modified version of the Internalized AIDS-Related Stigma Scale (IA-RSS; range: 1-4). The IA-RSS was adapted to measure internalized sex work-related stigma.
- Income was measured using the WHO's permanent income index for low/middle income countries. PCA reduced scale to relevant items only.

Analysis:

- Descriptive statistics summarized demographic characteristics; chi-square (categorical) and t-tests (continuous) detected significant differences between the comparison group and FSW or WLWHA.
- Unadjusted and adjusted logistic regressions identified significant relationships between covariates and depression.

RESULTS:

Table 1: Demographic, stigma, and depression characteristics of FSW, WLWHA, and the comparison group (2014)

	FSW (N=349)	WLWHA (N=213)	Comparison (N=314)
	Mean±SD	Mean±SD	Mean±SD
Age	27.5 ± 6.7	32.4 ± 7.6*	28.0 ± 7.2
Years of education	8.4 ± 3.0*	6.9 ± 6.9*	9.5 ± 2.7
# living biological or adopted children	2.2 ± 1.3	2.8 ± 1.4*	2.1 ± 1.2
Permanent income score	0.4± 0.1*	0.3 ± 0.2*	0.4 ± 0.1
Internalized stigma	2.8 ± 0.8	3.1 ± 0.8	N/A
	N(%)	N(%)	N(%)
Nationality (Dominican)	254 (73.0%)*	145 (68.4%)*	278 (88.5%)
Partnered (Yes)	112 (32.4%)*	133 (62.4%)	207 (65.9%)
Children live with respondent (Yes)	176 (50.6%)*	151 (70.9%)*	273 (87.5%)
Depression (Yes)	245 (70.2%)*	170 (79.8%)*	164 (52.2%)

* = significant difference between case (FSW or WLWHA) and comparison group; $p<0.05$

Table 2: Adjusted logistic regressions between covariates and depression for FSW, WLWHA, and comparison group women

	FSW (N=342)	WLWHA (N=203)	Comparison (N=311)
Age	1.03 [0.98, 1.08]	1.00 [0.94, 1.05]	1.06* [1.01, 1.10]
Years of education	0.97 [0.88, 1.06]	1.04 [0.92, 1.16]	0.89* [0.80, 0.99]
# living biological or adopted children	0.95 [0.75, 1.21]	1.18 [0.83, 1.66]	1.04 [0.80, 1.34]
Permanent income score	0.08* [0.01, 0.80]	1.26 [0.07, 22.04]	0.04* [0.00, 0.45]
Internalized stigma	2.73* [1.95, 3.84]	3.06* [1.86, 5.05]	N/A[b]
Nationality (Dominican)	1.05 [0.56, 1.96]	0.76 [0.24, 2.46]	2.07 [0.88, 4.84]
Partnered (Yes)	1.10 [0.64, 1.90]	0.45 [0.19, 1.04]	1.07 [0.65, 1.77]
Children live with respondent (yes)	0.83 [0.50, 1.37]	1.11 [0.47, 2.60]	0.87 [0.39, 1.97]

* = significant difference between case (FSW or WLWHA) and comparison group; $p<0.05$

CONCLUSIONS:

- Women in the DR are facing a serious depression epidemic, since depression prevalence was alarmingly high across all participant groups, regardless of HIV risk or status.
- Interventions to address depression in women are urgently needed in the DR; special attention should be paid to internalized stigma for FSW/WLWHA.
- Future depression-related interventions should address poverty, since this appears to play an important role in mental health.

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Trends of the HIV / AIDS epidemic in men who have sex with men in the state of Sao Paulo, Brazil

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Background: Trends study allows perform future projections and anticipate results on the HIV/AIDS epidemic trends. The objectives was describe and analyze the AIDS and the HIV-positive cases trends in the state of Sao Paulo, in teenagers and adults, during the period of 2004 to 2013, according to age groups and MSM.

Methods: trends study performed with AIDS and HIV positive notification data compared by age group and exposure categories. It was considered as a dependent variable (Y) the annual number of HIV positive patients and the number of AIDS cases, in each of the studied categories, and the independent variable (X) was the time, represented by the calendar years, concerning the study period. The goodness of fit via R^2 and $p<0.05$ were used to determine which models and data were most appropriate.

Results: Among the MSM were analyzed 15,810 cases of AIDS and 16,138 cases of HIV infected patients. The obtained modeling was of first order to all age groups. The trends of the HIV infected patients were growing in all age groups during the period of 2004 to 2013. The trends were linearly growing in the age groups of 13 to 19 years ($Y=5+16X$, $R^2=0.78$, $p=0.032$); 20 to 29 years ($Y=13+63X$, $R^2=0.89$, $p=0.001$); 30 to 39 years ($177+49X$, $R^2=0.86$, $p=0.002$); 40 to 49 years ($Y=60+22X$, $R^2=0.92$, $p<0.001$) and 50 years and more ($Y=17+8X$, $R^2=0.82$, $p<0.001$). However, to the AIDS cases it was observed a growing trends only in the age groups of 13 to 19 years ($Y=13+3X$, $R^2=0.52$, $p=0.050$) and in the 20 to 29 years group ($Y=63+22X$, $R^2=0.93$, $p<0.001$). In the age groups of 30 to 39 years, 40 to 49 years and, 50 years and more, the trend analysis of the AIDS cases revealed stability along the historical series.

Table 1. Regression models and trends for new male AIDS and the HIV-positive cases by age in the state of Sao Paulo

Age	Status	Year	Model	R^2	*p*
13 to 19 years	HIV (+)	2004 - 2013	Y = 5 + 16 X	0.78	0.032
	AIDS		Y = 13 + 3 X	0.52	0.050
20 to 29 years	HIV (+)	2004 - 2013	Y = 13 + 63 X	0.89	0.001
	AIDS		Y = 63 + 22 X	0.93	< 0.001
30 to 39 years	HIV (+)	2004 - 2013	Y = 177 + 49X	0.86	0.002
	AIDS		Y = 525 + 6 X	0.14	0.263
40 to 49 years	HIV (+)	2004 - 2013	Y = 60 + 22 X	0.92	< 0.001
	AIDS		Y = 356 - 5 X	0.22	0.143
50 years and more	HIV (+)	2004 - 2013	Y = 17 + 8 X	0.89	< 0.001
	AIDS		Y = 111 + 2 X	0.14	0.396

Y = cases number

X = year of diagnosis; r ² = determination coefficient

Figure 1. Trends for the HIV-infected (without AIDS) new cases among MSM, by age group, in the state of Sao Paulo, 2004 to 2013

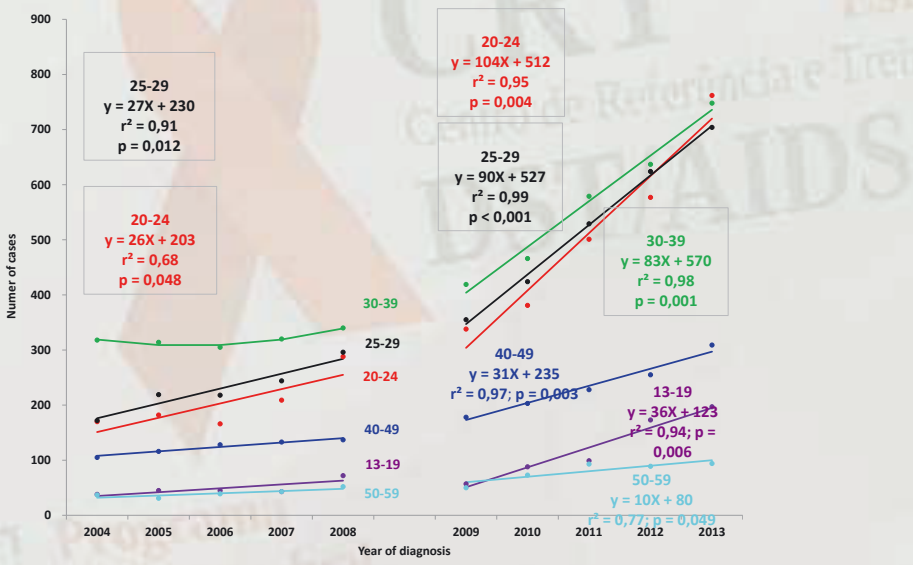
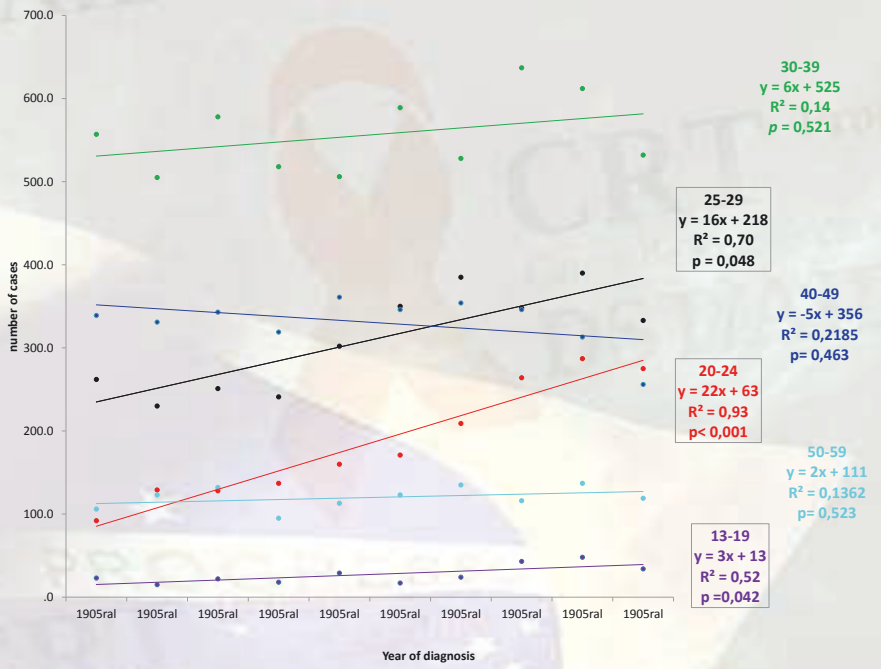


Figure 2. Trends for the AIDS new cases among MSM, by age group, in the state of Sao Paulo, 2004 to 2013



Conclusions: During the period of 2004 and 2013 it was observed among the HIV infected patients that the higher growth rate occurred among the MSM in age group of 20 to 29 years, followed by the age group of 30 to 39 years. Among the AIDS cases it was observed that the MSM in the age group of 20 to 29 years also presented the highest growth rate. This analysis points to the importance of this most vulnerable group that are the young MSM and the need to prioritize to them, planning actions of the epidemic control programs.

P029

Poster #: P029

Assessing mental health among recently diagnosed HIV patients at *Condesa* Clinic in Mexico City

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BACKGROUND.

Several factors, such as psychosocial and uncontrolled HIV infection in the central nervous system contribute to the onset of a mental disorder. Common mental disorders are more prevalent in people with HIV (i.e., depressive disorders, cognitive impairment and substance use disorders)[1]. *Condesa* Clinic (CsC) is the free healthcare center for people with HIV in Mexico City (n≈11,000). The Mental Health Programme (MHP) from CsC is a part of the HIV treatment cascade and it was created in 2012. As a part of the initial protocol, the MHP makes assessment to each patient to detect any mental disorder that could interfere with HAART therapy or adherence.

OBJETIVE.

The aim of this study is to describe the mental healthcare process and preliminary results of patients recently diagnosed with HIV assessed by the MHP at the CsC.

METHODS.

We describe the model of care of the MHP incorporated to the HIV treatment cascade at the CsC for patients recently diagnosed with HIV. We used univariate analysis for preliminary data.

RESULTS.

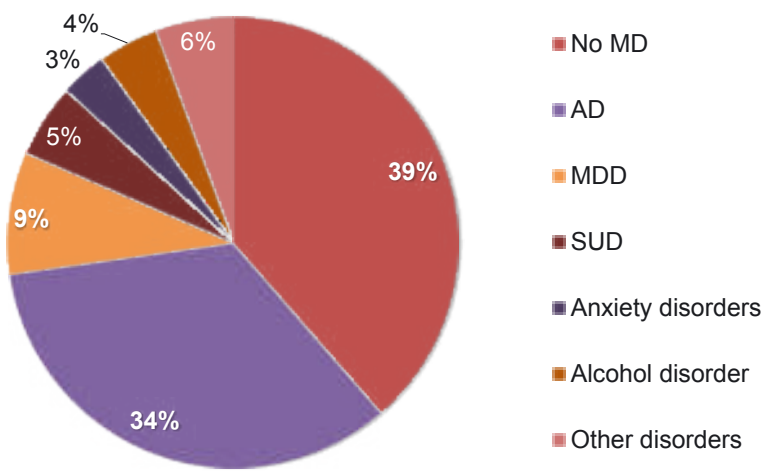
Based on the international evidence[2] and the needs of the CsC's patients, the MHP developed a process to early detect and treat mental disorders in recently patients diagnosed with HIV. Within the first two weeks after the confirmed diagnosis, the mental health assessment is performed. A clinical psychologist through a clinical interview based on DSM-5 / ICD-10 criteria and valid psychometric instruments[3] makes diagnosis of any mental disorder. Depending on the mental disorder, the patient could have a different treatment outcome (Figure 1). The MHP has evaluated 2,752 patients recently diagnosed with HIV, whose principal characteristics are shown on Table 1 and morbidity of mental disorders are on Figure 2. We also found high prevalence of risk factors related to mental health, such as history of violence, suicidal attempts, life stressors, etc. (Table 2).

DISCUSSION.

We found that sociodemographic characteristics in this sample were similar to other HIV concentrated epidemic in other American countries. Most of the patients were men and were well educated compared to general Mexican population. This is probably because CsC is in a urban area. We also found that women and transgender women had more history of violence (any type), suicidal attempts, and life stressors during the last year previous to HIV diagnosis. In the other hand, men were more likely to hide their HIV status and had more history of mental health treatments (i.e., psychotherapy). All these risk factors related to mental health are 2-5 times higher than in general Mexican population.

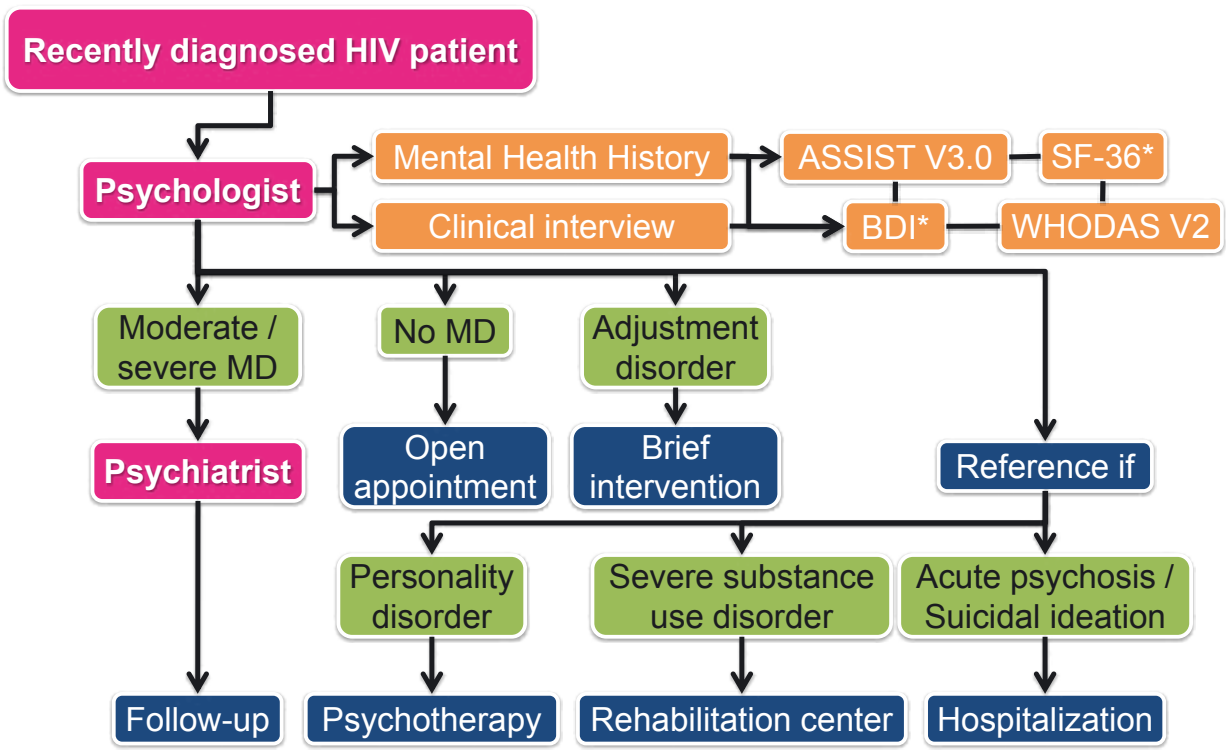
CONCLUSION.

Incorporation of mental healthcare services to the HIV treatment cascade at first level facilities could be feasible and probably effective in order to help retention, adherence to HAART and to get undetectable viral loads in patients. Further analysis to detect mental health factors related to unfavorable outcomes in HIV patients should be performed.



***MD:** Mental disorder; **AD:** Adjustment disorder; **MDD:** Major depressive disorder; **SUD:** Substance use disorder*

***Figure 2.** Morbidity of Mental Disorders of patients from MPH-CsC, 2012-15*



MD: Mental disorder; ASSIST: Alcohol, Smoking and Substance Involvement Screening Test; SF-36: 36-Item Short Form Health Survey; BDI: Beck Depression Inventory; WHODAS: WHO Disability Assessment Schedule ** These instruments are adapted short versions, previously validated and adapted*

***Figure 1.** Healthcare flowchart of Condesa Clinic's Mental Health Programme*

TABLE 1. Sociodemographic & HIV related characteristics of patients from MHP-CSC, 2012-15 (n= 2,752)

VARIABLE	*%*	*n*
Sex		
Male	89.2	2,454
Female	8.9	247
Transgender woman	1.9	51
Occupation		
Employee	34.4	925
Unemployed	21.9	589
Student	12.2	329
Merchandiser	8.2	221
Freelancer	6.9	187
Other	16.4	451
Transmission of HIV		
Sexual	99.8	2,749
Injecting drug user	0.2	3
Under HAART (< 4 wk.)	39.1	1,077

	MEAN	SD	RANGE
Age (y.o.)	31.0	9.2	14 – 77
Education (y.o.)	11.9	3.9	0 – 20
Viral load (copies/mL)	339,264	917,962	1004 – 9,998,996
CD4 count (cells/µL)	284	214	10 – 1,598

TABLE 2. Risk factors related to Mental Health of patients from MHP-CSC, 2012-15

RISK FACTOR	MALE (*n*= 2,454)	FEMALE (*n*= 247)	TRANSGENDER WOMAN (*n*= 51)
Violence history % (n)			
Sexual	13.3 (327)	19.4 (48)	15.6 (8)
Physical	14.6 (358)	37.7 (93)	21.6 (11)
Psychological	17.2 (423)	37.7 (93)	23.5 (12)
Previous psychotherapy % (n)	17.3 (424)	15.8 (39)	9.8 (5)
Psychiatric drugs previously prescribed % (n)	13.1 (322)	11.7 (29)	9.8 (5)
Suicidal attempt % (n)	9.5 (234)	17.4 (43)	19.6 (10)
Mean age at 1st attempt	19.3 (±6.7)	18.9 (±8.3)	22.8 (±8.6)
HIV disclosure to family % (n)	55.7 (1,367)	79.8 (197)	70.6 (36)
Presence of life stressors, last year % (n)	45.6 (1,120)	53.0 (110)	60.8 (31)

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#P030

High Rate of Linkage to Care and Antiretroviral Therapy Initiation in Haiti, and Improvements over Time

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BACKGROUND

High attrition during the period from HIV testing to antiretroviral therapy (ART) initiation is widely reported worldwide. Though treatment guidelines have changed to broaden ART eligibility and services have been widely expanded over the past decade, data on the temporal trends in ART initiation rates are limited.

METHODS

We evaluated temporal trends and predictors of retention for each step from HIV testing to ART initiation over the past decade at the GHESKIO (Haitian Group for the Study of Kaposi's Sarcoma and Opportunistic Infections) Centers in Port-au-Prince, Haiti. GHESKIO is the largest provider of HIV services in the Caribbean. Most patients live in extreme poverty on <$US 1 per day.

The 22,638 patients >17 years of age who received a positive HIV test at GHESKIO from March 1, 2005 to February 28, 2015 were included. Patients were followed to determine if they received all steps for ART staging, and initiated ART within 6 months after HIV testing.

RESULTS

22,638 patients (60% female, median age 35 years) were included. A total of 15,756 patients (70%) had blood drawn for CD4 count – this increased from 31% in 2005 to 82% in 2014 ($p<0.0001$). The time from HIV test to blood draw for CD4 count decreased over time, from a median of 79 days (IQR: 30 to 182) in 2005 to 0 days (IQR: 0 to 14) in 2014 ($p<0.0001$). A total of 14,482 patients (92%) returned for CD4 count results; this increased from 93% in 2005 to 96% in 2014 ($p=0.61$). The time from blood draw to return for CD4 count result decrease over time, from a median of 8 days (IQR: 3 to 15) in 2005 to 6 days (IQR: 2 to 14) in 2014 ($p=0.04$). A total of 7,760 patients were eligible for ART at presentation, according to the criteria in place at the time. Of these, 5,885 patients (76%) initiated treatment within 6 months; this increased from 24% in 2005 to 95% in 2014 ($p<0.001$). The median time from return for CD4 count result to ART initiation decreased from 3 days (IQR: 0 to 19) in 2005 to 0 days (IQR: 0 to 0) in 2014 ($p<0.001$). See Figure 1 for a bar chart of retention at different time points. Predictors of ART initiation included later year of HIV testing, older age, higher educational status, and referral from a provider for HIV testing, compared with self-referral.

CONCLUSIONS

The proportion of patients newly diagnosed with HIV who initiate ART has increased over the last decade in Haiti. Over the same time period, services have been delivered more rapidly. ART is now provided to most patients on the day that CD4 count results are provided, with very high rates of treatment initiation.

Figure 1. HIV Positive Patients Who Received CD4 Counts (%)

Figure 2. Patients Returning For CD4 Count Results (%)

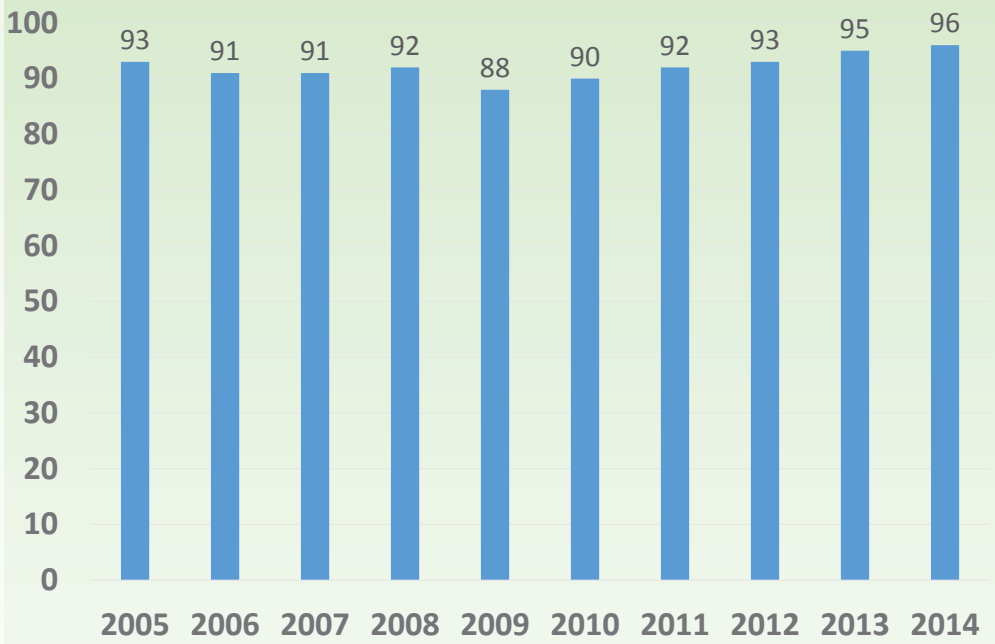
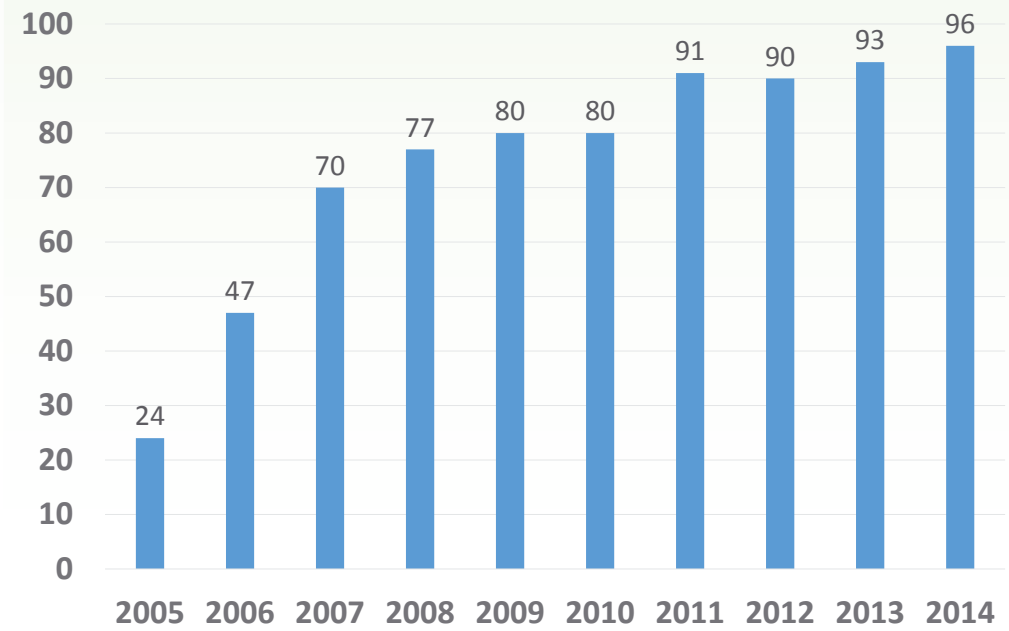


Figure 3. Treatment-Eligible Patients Initiating Timely ART (%)



CENSIDA
Centro Nacional para la Prevención y el Control del VIH y el sida

Median CD4 count increase at ART initiation in MoH of Mexico between 2010 & 2015

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Background

The global scale-up of antiretroviral therapy (ART) over the past decade represents one of the great public health and human rights achievements of recent times. The Standardization and simplifying both prescribing practices has been critical to ART scale-up.

Actually, an antiretroviral regimen for a treatment-naive patient generally consists of two nucleoside reverse transcriptase inhibitors in combination with a third active antiretroviral drug. These guidelines are supported by studies of effectiveness and durability and optimal tolerance and comfort.

Material and methods

The objective of this study was to assess trends in the median CD4 count, number of people living with HIV initiating ART and the proportion of people in each regimens according to the third ARV, between 2010 and 2015 in Mexico Ministry of Health (MoH).

We examined transversal data from 63,970 adults (aged ≥15 years) who initiated HIV treatment programs at 138 HIV care clinics in Mexico between 2010 and 2015. The clinics included are part of Mexico MoH. Patient information is routinely collected in the "Antiretroviral Management, Logistic and Surveillance System" (SALVAR in Spanish). We defined CD4 count "at ART initiation" as any measurement 3 months before or 1 month after ART initiation. Statistical analyses were carried out using STATA, version 11.1.

Results

Between 2010 and 2015 the median ART initiation age was 33 years old. The median CD4 count at ART initiation increased from 183 to 242 cells/µL, k-sample test on the equality of medians was performed, p<0.0001, and an increase of 9.8 cell/year was observed, and sex disparities were reduced from a male-female difference of 52 cells in 2010 to 13 cells in 2015.

The number of persons initiating ART each month has increased from 720 in 2010 to 1,174 in 2015, year with the highest annual change observed in the last five years. In 2010, 52.9% of ART initiation schemes had Efavirenz, in 2015 was the 80.1%.

Figure 1

Median CD4 count at ART initiation
Mexico, 2015

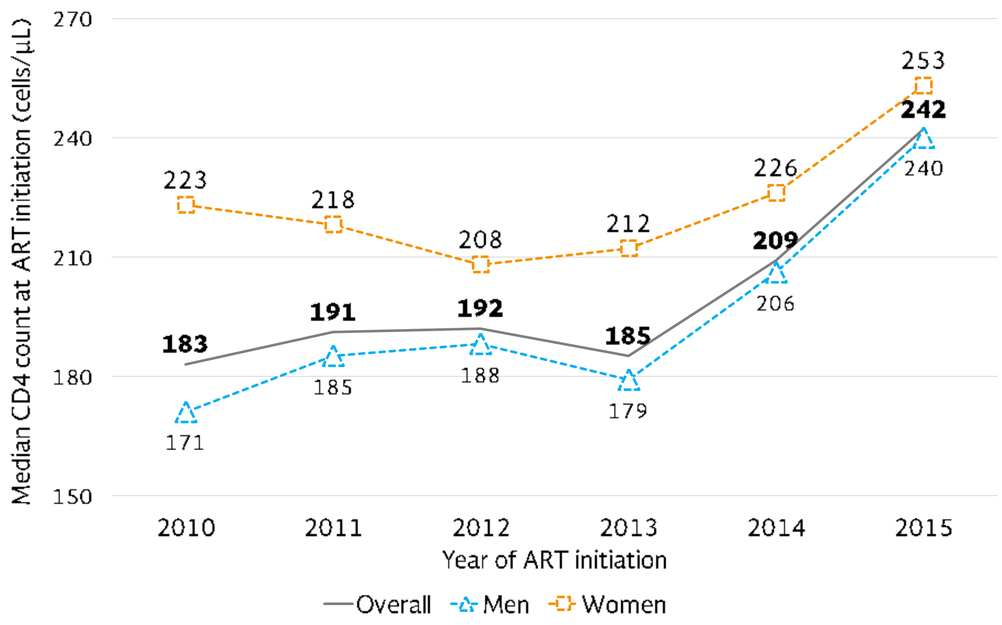


Table 1

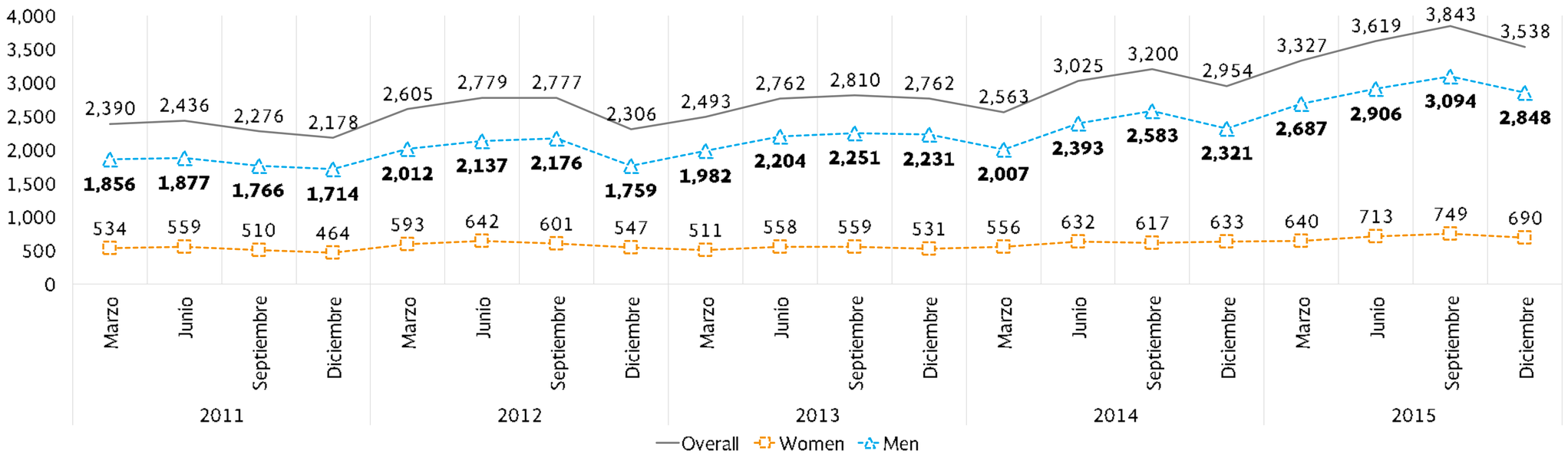
ART initiation of people living with HIV
Mexico, 2015

Year of ART initiation	N	Average monthly ART initiation	Annual change
2010	8,645	720	
2011	9,002	750	4.13%
2012	10,181	848	13.10%
2013	10,593	883	4.05%
2014	11,457	955	8.16%
2015	14,092	1,174	23.00%

Year of ART initiation	EFV	ATV	DRV	LPV	NVP	RAL	Other
2010	52.98%	11.46%	0.13%	16.01%	8.47%	0.27%	10.69%
2011	56.58%	10.31%	0.14%	16.13%	10.81%	0.26%	5.78%
2012	69.38%	8.79%	0.15%	12.65%	6.19%	0.21%	2.63%
2013	78.09%	6.70%	0.08%	9.57%	3.75%	0.41%	1.41%
2014	76.48%	10.22%	0.12%	8.97%	2.69%	0.72%	0.80%
2015	80.06%	10.20%	0.53%	6.24%	0.79%	1.83%	0.34%
Total	70.43%	9.59%	0.21%	11.01%	4.93%	0.70%	3.13%

Figure 2

ART initiation of adult patients by trimester
Mexico, 2015



Conclusion

- Guidelines in Mexico have been in change, especially in the last couple of years, and the impact of this changes it's observed in the increase of CD4 at ART initiation.
- In accordance with national guidelines, Efavirenz has been the preferred third ARV, and the increased in the use of this ARV shows also a prescription more standardized. Still intensified efforts are needed to initiate ART more opportunely.

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P033

CARE MODEL FOR HIV PREGNANT WOMEN.
CONDESA SPECIALIZED CLINIC, MEXICO CITY PUBLIC HEALTH SERVICES

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BACKGROUND: Condesa Specialized Clinic`s (CEC) OB/GYN area offers free diagnosis and treatment for women with HIV/aids. In Mexico HIV prevalence in pregnant women is 0.06% [1] and in CEC is 0.22%. The objective of this study is to describe a cohort of pregnant patients that received healthcare at CEC.

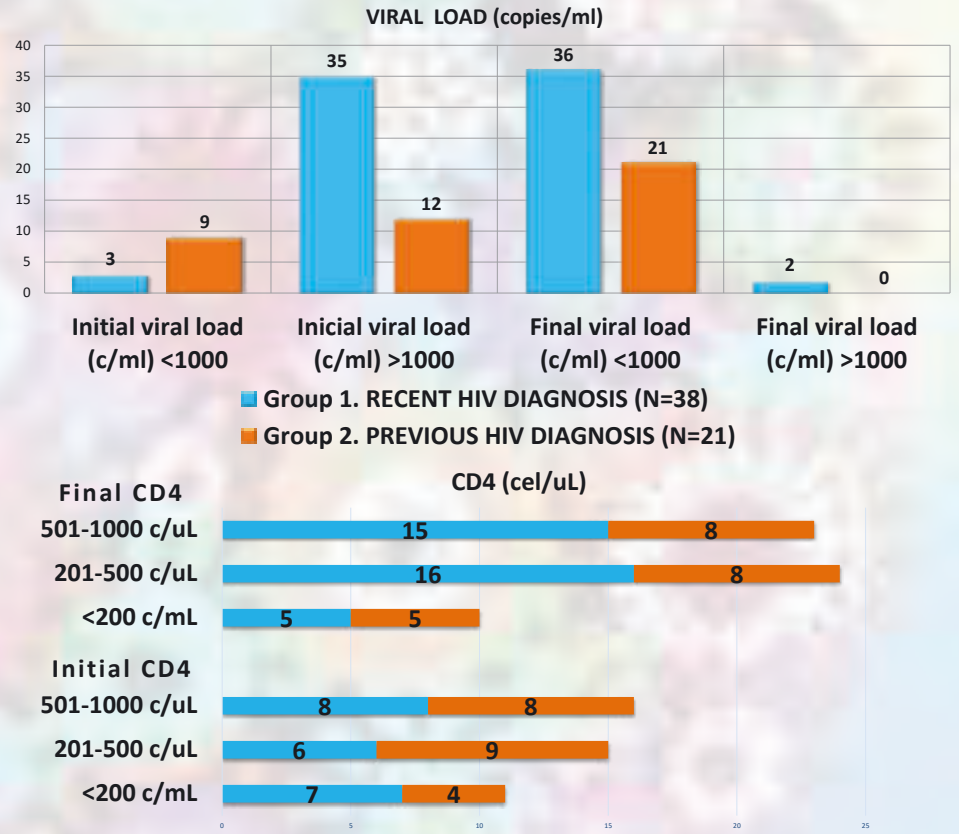
MATERIAL AND METHODS: Cross-sectional, descriptive study with a cohort of pregnant women with HIV/aids at CEC, from August 2013 through October 2015. Patients were referred from outpatients clinics and detection clinics located in the subway with a reactive rapid HIV test. At CEC other diagnostic tests for HIV confirmation, HBV, HCV, Syphilis, viral load (VL) and CD4 count were performed. Patients with reactive tests are immediately evaluated by OB/GYN, internal medicine and mental health to initiate HAART. VL were performed weekly until patients reach undetectable VL (<40 copies/ml) and then follow-up were every month. At the 37th week they are referred to a hospital for determination of birthing technique.

RESULTS: We had 69 pregnant women, 85.5% gave birth to a live baby. Of these 64.4% were diagnosed with HIV during pregnancy (group 1) and 35.5% already had an HIV+ diagnosis prior pregnancy (group 2).

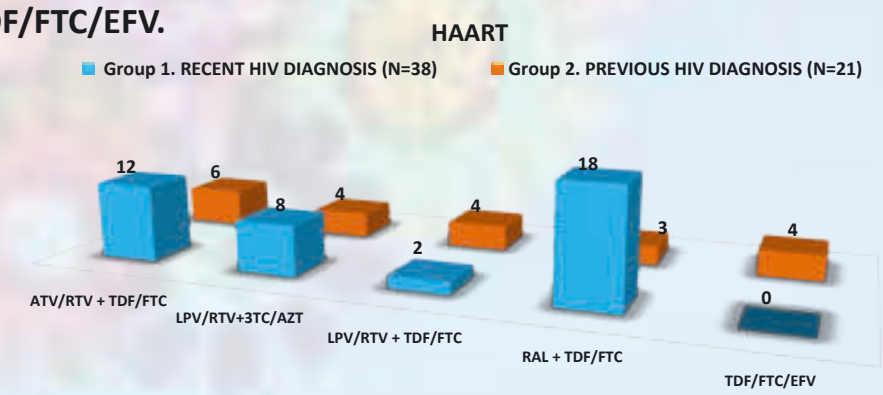
	Group 1. RECENT HIV DIAGNOSIS (N=38)	Group 2. PREVIOUS HIV DIAGNOSIS (N=21)
SOCIODEMOGRAPHIC CHARACTERISTICS		
Age (mean), y.o.	24.1	24.2
Education		
Iliteracy	13.1 %	0 %
Primary	31.5 %	14.2 %
Secondary	38.8 %	42.8 %
High school	10.5 %	33.3 %
University	7.8 %	9.5 %
Ocupation		
Unpaid employment	68.4 %	66.6 %
Employed	23.6 %	19%
Student	2.6 %	4.7 %
Other	5.2 %	9.5 %
Marital status		
Common-law union	76.3 %	52.3 %
Single	21%	33.3 %
Married	2.6 %	14.2 %
Drug use (during pregnancy)		
Legal (OH, tobacco)	5.2 %	0 %
Ilegal	5.2 %	4.7 %
Partner HIV status		
Negative	31.5%	57.1 %
Positive	55.2 %	9.5 %
Unknow	13.1 %	33.3 %

In group 1 HIV diagnosis was established at week 25.7 (SD=8) of pregnancy. In group 2 pregnancy was detected at week 17.4 (SD=9.4). First pregnancy in group 1 was 34.2% vs. 67% in group 2.

In group 2, 42.8% had a VL<40 when received notification of pregnancy. 73.6% and 100% of group 1 and group 2 had a VL<40 at the end of the pregnancy, respectively. 94.7% of group 2 had a VL CV<1,000 copies; in two patients virologic control was not achieved due to a late HIV diagnosis during pregnancy.



42.1% of group 1 received RAL+TDF/FTC, 31.5% received ATV/r + TDF/FTC.
58.6 % of group 2 received ATV/r+ or LPV/r, and 23.5% received TDF/FTC/EFV.



97.3% of group 1 had a C-section birth; vs 80.9% in group 2. The rest were natural births. 79% of patients had birth control method, in group 1 definitive family planning method 66% vs 62% in group 2, temporary method 21% and 24% respectively.
18.4 % of group 1 and 23.8% of group 2, were lost to follow-up after birth. In those who continued treatment there have not been any cases of vertical transmission of HIV reported.

CONCLUSIONS: **HIV diagnosis in women in group occurs at advanced stages of pregnancy increasing the risk of vertical transmission. In Mexico coverage HIV testing during pregnancy is about 58% [2]. Better strategies must be implemented to increase coverage of HIV testing in pregnant women.**

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[2] Eliminación de la transmisión maternoinfantil del VIH y la sífilis en las Américas. Actualización 2015. Washington, DC: OPS, 2015: 19.

CONDESA
CDMX
CIUDAD DE MÉXICO

Are we doing enough preventive primary care for older HIV positive patients? A survey in a third level hospital in Mexico City

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Background:

Life expectancy of people living with HIV has increased as it has become a chronic manegeable condition. Primary care preventive services play a crucial role in older patients with HIV infection given the higher incidence of comorbidities when compared to non-HIV population and their impact on overall survival. We aimed to assess the frequency of screening tests for malignant and non-communicable diseases in HIV+ patients >50 years, seen by infectious diseases fellows and specialists at INCMNSZ in Mexico City before and after an intervention designed to improve awareness among physicians.

Methods:

All HIV+ patients >50 years old were included **(Fig.1)** The application of internationally recommended primary care screening tests[1] was reviewed in clinical charts and compared to HIV related care tests and interventions (Tuberculin skin test, VDRL and vaccination). We evaluated the frequency of tests prescribed at least once since patients became 50 years old and, for annually applicable tests, the frequency of tests prescribed in the last year of follow-up. Factors associated with better screening practices (defined as more than 75% of screening performed as recommended) were analyzed. A checklist of appropriate screening tests for non-communicable disease was added to patients files, as a reminder tool for physicians in each visit during a follow up period of one year. Frequency of tests before and after this intervention were compared and the percentage of improvement was calculated.

Table 1. Screening tests done during follow-up, before "checklist" intervention. N=384

	Ever since patient became 50 years old %			During the last year of attention %		
Non-communicable diseases screening:	Men n=325	Women=59	p	Men n=325	Women n=59	p
Blood pressure	99.7	100		100	98.3	
Lipid profile	99	100		99	98.3	
Glucose/A1c(%)	99.7	100		99.4	98.3	
Densitometry	16.9	61	<0.005	8	33.9	<0.005
Colorrectal cancer screening	28.6	20.3		8.7	6.8	
Mastography		88.1			47.5	
Cervical citology		89.8			50.8	
Anal citology MSM (N=245)	64			19.15		
Cardiovascular risk (Framingham)	12.3	10.2		8.9	5.1	
HIV related care:						
Vaccination	96.3	96.6		96.3	96.6	
VDRL	97.2	94.9		97.2	94.9	
PPD	92.9	91.5		92.3	91.5	

Figure 2.1. Proportion of patients stratified by groups of screening tests reported at least once during the period of care

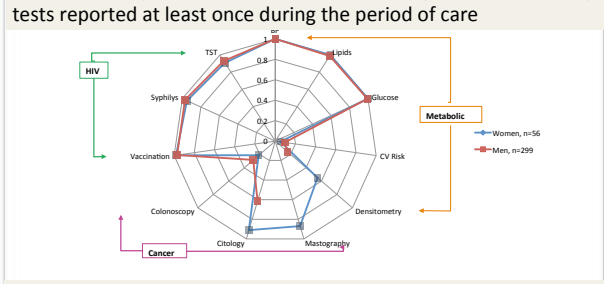


Figure 2.2. Proportion of patients, stratified by groups of screening tests done in the last year of care

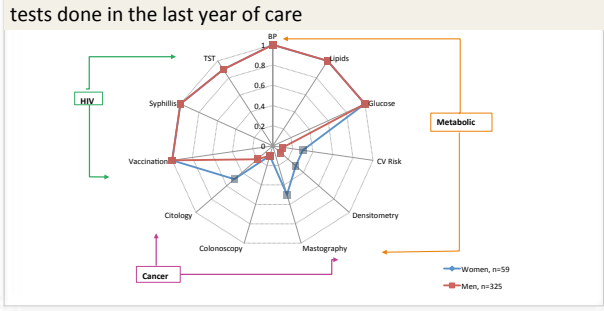


Fig. 1. Study Design

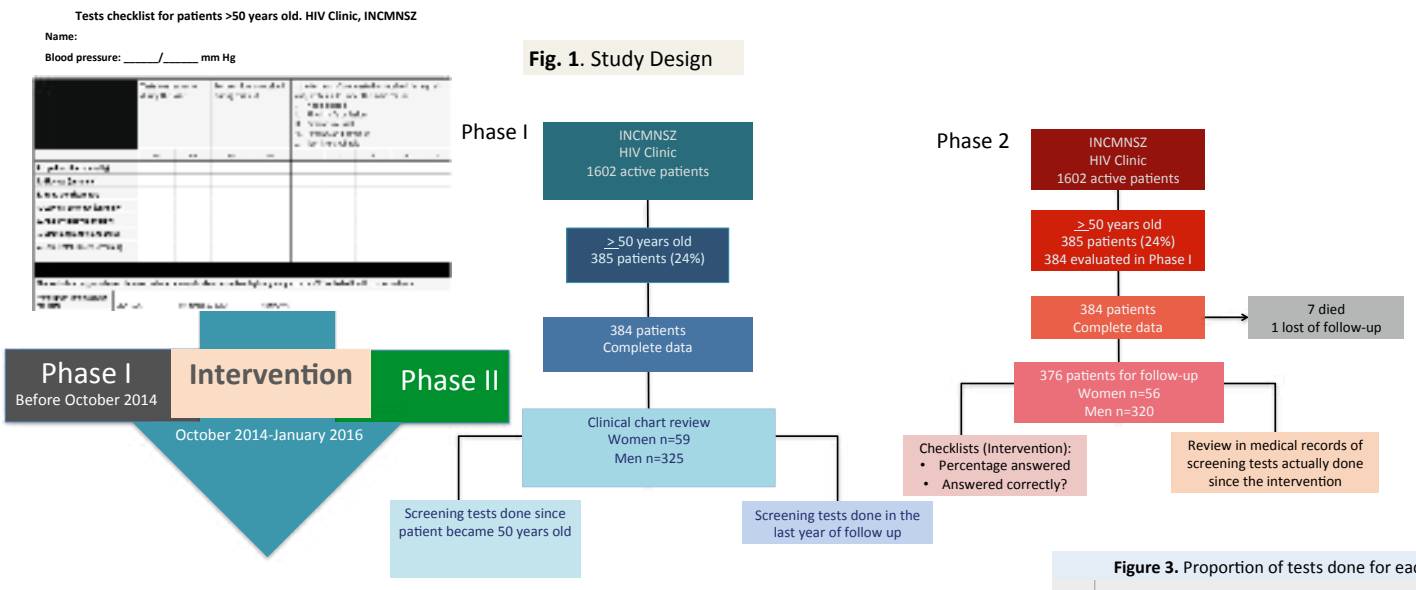


Figure 3. Proportion of tests done for each study period

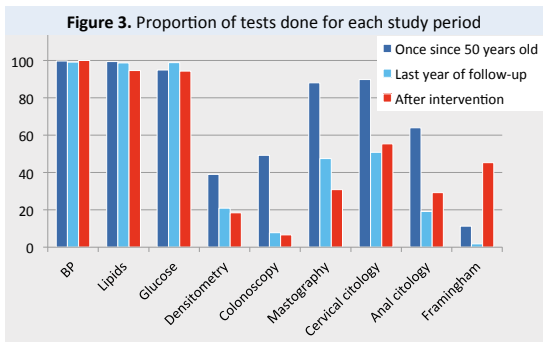
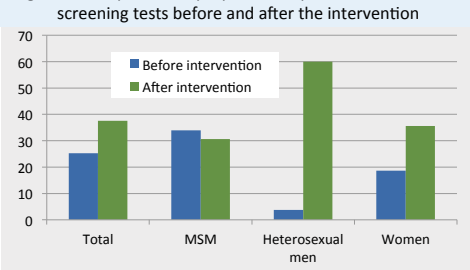


Figure 4. Comparison of proportion of patients with >75% of screening tests before and after the intervention



Results:

385 patients (24%) were ≥50 years old, 84% were men with a mean age at HIV diagnosis of 45 years and a median time in care of 10.2 years (SD 5.94). After reaching 50 years during care, 88% of women had at least one mammogram and 90% cervical cancer screening; 64% of MSM had anal cancer screening; colorectal cancer screening was done in 24.6%; cardiovascular risk was calculated in <13%. Frequency of densitometries was higher in women (61% vs 17%; p<0.001) **(Table 1).** In the last year of care, only vaccination, TST, VDRL, dyslipidemia, hypertension and diabetes screening were achieved in >90% **(Fig.2)**. Only 25% of patients had >75% of non communicable diseases related tests compared to 89% of complete HIV-care related tests (Syphilis, vaccination, PPD) before our intervention **(Table 2)**. Women were more likely to have better screening (p=0.003). Neither smoking nor family history of cancer or cardiovascular risk were statistically associated with better performance of screening (p=0.2, p=0.3 respectively). After the intervention, screening remained low for malignancies (55% and 26% for cervical and anal cancer, 31% for mammographies, 19% for colorectal cancer) and densitometries (19%) **(Fig.3)**. Cardiovascular risk assessment improved in 45% **(Table 3)**. After the intervention 37.5% of patients had >75% of screening tests for non-communicable diseases; improvement was evident only in women and heterosexual men **(Fig.4)**. Only 36% of checklists were answered correctly by physicians. The main cause of missing tests, according to checklists, was physician's omission **(Table 4).**

Table 3. Proportion of improvement for each test after intervention

Test	% vs since since 50 years old	% vs last year of care
Blood pressure	100	100
Lipid profile	95.8	95.8
Glucose	95.5	95.5
Densitometry	38.7	38.9
Colorectal cancer screening	32.8	38.9
Cardiovascular risk	44.8	44.8
Anal citology	25.7	25.7
Cervical citology	5.7	27.7
Mastography	80.5	80.5

Table 2. Comparison of the proportion of patients with adequate screening practices (more than 75% of screening performed as recommended) for non-communicable diseases and HIV related care

	Ever since 50 years old	In the last year of attention	After intervention
Non communicable diseases	40.9%	25.3%	37.5%
HIV related care	88.5%	88.5%	

Table 4. Information from checklists

	%
Checklists answered by physicians	54.52
Checklists answered correctly	36.09
Checklists with cardiovascular risk registered	83.90
Main reason of missing tests:	Physician's omission

Conclusions:

1. HIV+ patients over 50 years old: **vulnerable population**
2. ID doctors and fellows: **suboptimal primary care**
3. In contrast, **HIV-related care is done appropriately** in 90%
4. Reminder tool (checklist) did not improve non-communicable diseases screening practices in this study
5. Main reason for missing tests**: Physician's omission**
6. **Area of opportunity** for improvement of patient's care

[1] Aberg JA, Gallant JE, Ghanem KG, Emmanuel P, Zingman BS, Horberg MA**. Primary Care Guidelines for the Management of Persons Infected With HIV: 2013 Update by the HIV Medicine Association of the Infectious Diseases Society of America.** IDSA. Nov, 2013

P35

P-035-Frantchez V
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Human Papilloma Virus and Anal Associated Lesions in Men who Have Sex with Men HIV and non HIV-Infected. First Cross-Sectional Study in Uruguay. Preliminary Report.

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Background:

Gay and bisexual men, among other men who have sex with men (MSM), especially HIV-infected, have an increased risk of anal intraepithelial neoplasia, anal human papilloma virus (HPV) infection, and anal cancer associated to HPV infection. Screening program includes anal cytology (Pap test), and high-resolution anoscopy and biopsy in patients with abnormal cytology findings. The estimate prevalence in Uruguay for HIV infection in MSM is 9,7%. Anal cytology screening is yet to be implemented as a routine in Uruguay and there is no previous data of anal HPV infection prevalence in MSM.

Objective:

To determine, HPV genotypes, and abnormal cytology prevalence in anal samples from HIV-infected and non-infected MSM.

Material and method:

During the implementation of the first screening program for anal cancer in HIV positive MSM, a cross-sectional study has been conducted since June 2015 until December 2015 in Montevideo, Uruguay.
Sample: gay and bisexual men, trans women, and other MSM over 18 years. Exclusion criteria: vaccinated against HPV and HPV-associated anal squamous intraepithelial and invasive lesions previously diagnosed. Informed consent was obtained from all study participants, and the study was approved by the Ethical Committee of the Facultad de Medicina, Universidad de la República.
Data was collected through anal examination, demographics characteristics, medical background, ano rectal symptoms and sexual behavior. A rapid HIV diagnostic test was performed to those patients whose last HIV serology was 120 days before entering the program.
Anal visual inspection is performed and 2 samples were taken from the anal canal for Pap cytology technique (Bethesda Classification 2001), molecular diagnosis and genotyping of HPV (SerpaA).
Patients with abnormal inspection or anal cytology are referred for anoscopy and eventual biopsy (Graphic 1).
For the bivariate analysis, the x^2 test was applied. The significance level α was 0,05. Data analyses were performed using SPSS statistical software system for Windows

Definitions:
MSM: Epidemiological term used to define cis gender males and Trans females who have sex with men, regardless of how they identify themselves in terms of sexual identity. Abnormal Cytology: atypical squamous cells of undetermined significance (ASC-US), atypical squamous cells that cannot exclude high-grade anal squamous intraepithelial lesions (ASC-H), low-grade squamous intraepithelial lesions (L-SIL), high-grade squamous intraepithelial lesions (H-SIL), or carcinoma.

Results:

During the first 6 months of implementation: 38 patients were included. Median age: 34 years. Median age of first anal sexual intercourse: 18 years. Average number of sexual partners in the last six months: 14.5 (Table 1). 29 (76.3%) were HIV-positive, all on antiretroviral therapy, with median CD4+ 620 cells/μL and 23 (79.3%) with suppressed viral load (Table 2). Anal inspection was abnormal in 14 (36.8%) patients. 27 patients had a pathological cytology: 14 (36.8%) ASC-US, 12 (31.6%) L-SIL, 1 (2.6%) H-SIL, 9 (23.7%) had normal cytology. 2 samples were unrepresentative (Table 3). The molecular diagnosis of HPV was positive in 23 (65.8%) patients, negative in 6 (17.1%) and unrepresentative in 6 (17.1%) (Table 4). Up until this moment, genotyping has only been possible in 14 of the 23 HPV positive patients. The genotypes found were: 6, 11, 16, 18 and 54 (Table 5). Anoscopy was performed in 15 (55.5%) of 27 patients with indication for it: 9 without macroscopic alteration and 6 pathological (condillomatosis). HPV detection was positive in 18 (78.35) HIV-infected patients, and 5 (21.7%) HIV non-infected patients (p 0.555). Cytology was abnormal in 23 (85.2%) HIV-positive patients (14.8%) and 4 HIV-negative (p 0.064) (Table 6).

Discussion:

This is the first transversal cut of a prospective study, and the preliminary report after 6 months, and the sample is still small. However, the results agree with those obtained in international studies in terms of the high prevalence of HPV infection and abnormal cytology in this population, especially in HIV positive patients.
The genotypes found in most of the samples have a low oncogenic grade (6, 11, 54), and in 50% of this patients the anal inspection presented warts, anal or genital condilloma, which could explain this findings. 1 of every 3 patients included presented an abnormal anal inspection, which can be associated with a selection bias, given many of the patients were referred to the program because they communicated signs and symptoms of anal pathology. Another limitation for our study is that we only have access to conventional anoscopy for the follow up of our patients, which may determine an underestimation of the anal lesions.
The results of our study will help to develop national strategies of prevention through the implementation of anal cancer screening.

Graphic 1. Diagnostic algorithm.

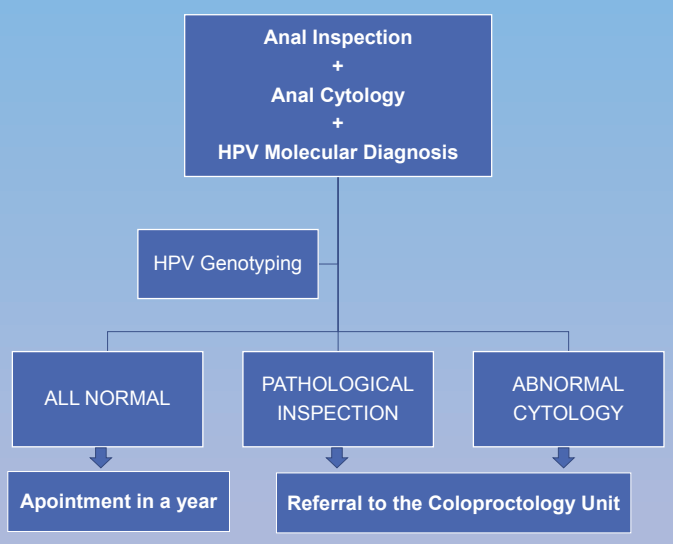

Table 1. Demographics and personal background.

Characteristics	n: 38 (%)
Median age, years (range)	34 (18-53)
Male	33 (86,8)
Female	5 (13,2)
Medical background:	
HIV positive	29 (76,3)
Current cigarette smoker	18 (47,4)
Sexually Transmitted Diseases	19 (50)
Anal pathology related to VPH	11 (28,9)
Anal pathology not related to VPH	11 (28,9)
Sexual history:	
Age of first anal intercourse, median (range)	18 (8-40)
N° of sex partners in past 6 months (range)	14,5 (1-200)
Only had receptive anal intercourse	9 (26,5)
Had receptive and insertive anal intercourse	27 (79,4)
Anal inspection:	
Normal	24 (63,2)
Abnormal	14 (36,8)

Table 2. Clinical Characteristics of HIV positive patients.

Characteristics, HIV positive	n: 29 (%)
HAART	29 (100)
Median CD4+ cell count, cells/uL	620
Baseline CD4+ cell count, cells/uL	4 (13,8)
50-200	25 (86,2)
≥200	
Viral load of <20 copies/mL	23 (79,3)
Diagnosis ≤ 1 year	14 (48,3)

Table 3. Cytologycal diagnosis

Diagnosis	n: 38 (%)
Negative	9 (23,7)
ASC-US	14 (36,8)
L-SIL	12 (31,6)
H-SIL	1 (2,6)
ASC-H	0
Not representative sample	2 (5,3)

Table 4. HPV Molecular diagnosis

Diagnosis	n: 35 (%)
Negative	6 (17,1)
Positive	23 (65,8)
Not representative sample	6 (17,1)

Table 5. Bivariate Analysis. HPV infection and pathological cytology according HIV status.

Characteristics	HIV negative	HIV positive	p
HPV infection	5 (21,7%)	18 (78,3%)	0,555
Pathological cytology	4 (14,8%)	23 (85,2%)	0,064

Table 6. Characteristics of the patients with HPV diagnosis according to de genotype.

Genotype	Cytology	Anal inspection	HIV serology	Age, years
18, other	L-SIL	Warts	Positive	47
6	L-SIL	Warts	Positive	29
6	ASC-US	Warts	Positive	34
11	ASC-US	Warts	Positive	21
6	L-SIL	Warts	Positive	36
6,11,54	L-SIL	Warts	Positive	35
6,11	ASC-US	Normal	Positive	34
11	Negative	Warts	Negative	18
11	Negative	Normal	Positive	32
6	ASC-US	Normal	Positive	42
18, other	ASC-US	Normal	Positive	35
Multiple	ASC-US	Normal	Positive	53
6	L-SIL	Normal	Negative	30
11	Negative	Normal	Positive	33

Conclusions:

A high prevalence of HPV infection and pathological anal cytology was found in the population studied, especially in HIV infected patients.

References: Conley LJ, Bush TJ, Darragh TM et al. Incidence and Predictors of Abnormal Anal Cytology Findings Among HIV-Infected Adults Receiving Contemporary Antiretroviral Therapy. *J Infect Dis* 2016;213:351–60.
Machalek D, Poynten M, Jin F et al. Anal human papillomavirus infection and associated neoplastic lesions in men who have sex with men: a systematic review and meta-analysis. *Lancet Oncol* 2012;13:477-500.
Solomon D, Davey D, Kurman R et al., Forum Group Members; Bethesda 2001 Workshop. The 2001 Bethesda system. Terminology for reporting results of cervical citology. *JAMA* 2002;287:2114-9.

P036

Analysis of HIV/AIDS mortality in Mexico by State and Municipal level from 2003 to 2013

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Keywords: Mortality, HIV, AIDS, Mexico

Introduction

Since 2003, Mexico has a policy of free and universal access to treatment for HIV/AIDS. At the end of 2013, 89,000 persons were receiving HAART. However, from 2003 to 2013, 54,140 persons have died from AIDS. The death rate for HIV/AIDS has not decreased as expected, reducing only from 4.4 deaths per 100,000 inhabitants in 2003 to 4.2 in 2013. The aim of the present study was to analyze the distribution of AIDS mortality according to state and municipal levels, with the purpose of identifying the sites where resources should be targeted to reduce HIV/AIDS mortality in Mexico.

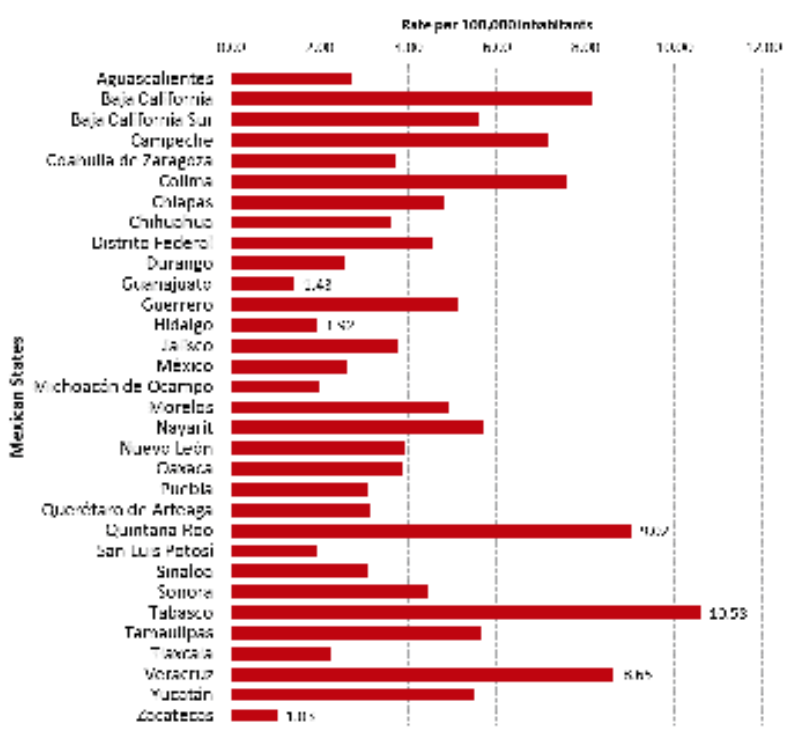
Materials and methods

We estimate the increase/decrease in the death rate from HIV/AIDS by state from 2003 to 2013, and the average annual HIV/AIDS mortality rate among 2437 municipalities in Mexico from 2009 to 2013. Considering only the municipalities with 20,000 or more inhabitants, we selected the 25 municipalities with the highest mortality rates. The information for these calculations was obtained from INEGI and CONAPO, institutions providing official figures of population and mortality, respectively.

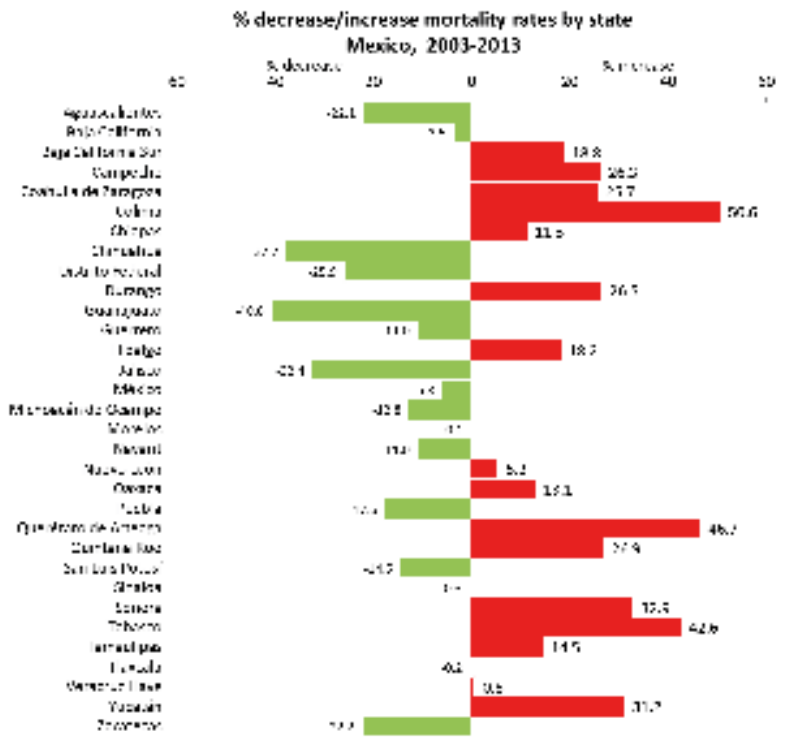
Results

In 2013, the states with the highest AIDS mortality rates were Tabasco (10.58 per 100 000 inhabitants), Quintana Roo (9.02), and Veracruz (8.65). In contrast, Zacatecas (1.03), Guanajuato (1.43) and Hidalgo (1.92) recorded the lowest rates. The difference between the states with the highest and lowest rate (Tabasco and Zacatecas) is more than seven times.

AIDS mortality by State. Mexico, 2013

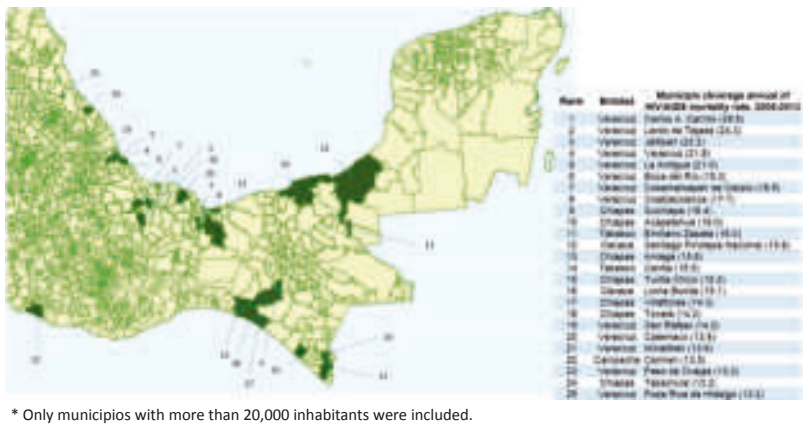


It is important to emphasize that, from 2003 to 2013, in 50% of Mexican states (16/32) the AIDS mortality rate increased, rather than decreased.



The 25 municipios with the highest death rate from AIDS are located in five states, all of them in the Southeast (Veracruz, Chiapas, Tabasco, Campeche and Oaxaca). The municipio of Carlos A. Carrillo, Veracruz, ranked number one with a rate of 39.6 HIV/AIDS deaths per 100,000 inhabitants (nine times higher than the national rate), and Poza Rica, Veracruz, being number 25 with a rate of 13.4 (three times higher than the national rate).

25 municipios with the highest AIDS mortality rates from 2009 to 2013*



* Only municipios with more than 20,000 inhabitants were included.

Conclusions

Data highlight the need for enhanced HIV detection and treatment for 25 municipios with the highest AIDS mortality rates, as well as the states most affected. Findings can help to apply interventions to link and retain in care persons until they are virologically suppressed. It is urgent to reduce AIDS mortality in Mexico.

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Significant increase in new HIV infections among young adults in Latin America

Gallo, Carlos ; López, Olga ; Chahin, Carolina ; Marincovich, Beatriz ; Zitko, Pedro ; Beltrán, Carlos

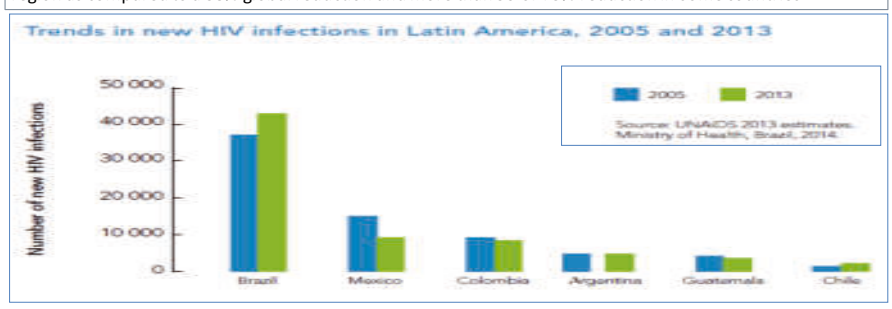
on behalf of the Latinamerican Workshop Study Group

Abstract Text

Background: The UNAIDS -- WHO 2,0 initiative and its 90-90-90 goal aims to reduce new HIV infections by 90% through a significant increase in diagnosis, care and ART of HIV infected population around the world. Most Latin-American countries launched expanded access to ART long time ago but show low rates of diagnosis of HIV infected people explaining at least in part the modest 3% reduction in new infections in the region as compared to a 38% global reduction and more than 50 or 75% reduction in some countries. **Materials and methods**: The Latin-American Workshop Study Group is an expanding network of 38 HIV Care Centers form 11 countries of South America, Central America, the Caribbean and Mexico with clinical data from 73,431 patients up to September 2015, 7,732 of them being new 2013-2014 HIV cases. Age and gender distribution was analyzed globally and by participating centers and countries. Statistical analysis by chi square test **Results**: Among new HIV infections 33.8% were 15 to 29 years old being the largest age group in all countries except Argentina with wide differences between centers in each country. 79.4% of new cases were men with 34.5% of them 15 -- 29 y/o and 20,6% in women with 31.0% 15 -- 29 y/o ($p<0.01$). On the contrary 14.1% of new HIV infections occurred in men older than 50 y/o as compared to 18.1% of new cases in women older than 50 y/o. In a sub analysis in Chile the largest increase in new cases among people younger than 30 y/o was observed between 15 to 24 years old. **Conclusions**: A modest reduction in new HIV infections has been reported in Latin America. Young people especially men between 15 and 24 years old show an important increase in new HIV cases in 2013 -- 2014 in most countries in spite of some differences between centers. In the context of the 90 -- 90 -- 90 goals specific policies should be implemented targeting this key population.

Background

- The UNAIDS -- WHO 2,0 initiative and its 90-90-90 goal aims to reduce new HIV infections by 90% through a significant increase in diagnosis, care and ART of HIV infected population around the world.
- Most Latin-American countries launched expanded access to ART long time ago but show low rates of diagnosis of HIV infected people explaining at least in part the modest 3% reduction in new infections in the region as compared to a 38% global reduction and more than 50 or 75% reduction in some countries



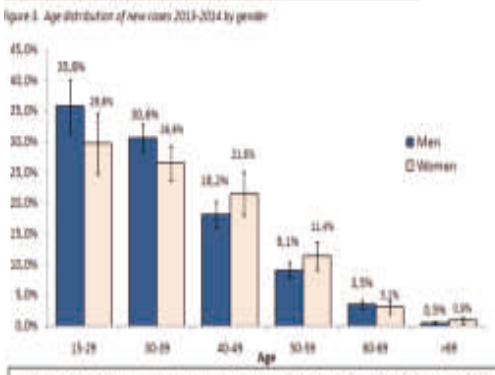
Methods

- The Latin-American Workshop Study Group is an expanding network of 38 HIV Care Centers form 11 countries of South America, Central America, the Caribbean and Mexico with clinical data from 73,431 patients up to September 2015, 7,732 of them being new 2013-2014 HIV cases.
- Age and gender distribution was analyzed globally and by participating centers and countries.
- Descriptive statistical analysis performed considering variance within and between centers (random effect). Heterogeneity expressed using I^2

Participant centers

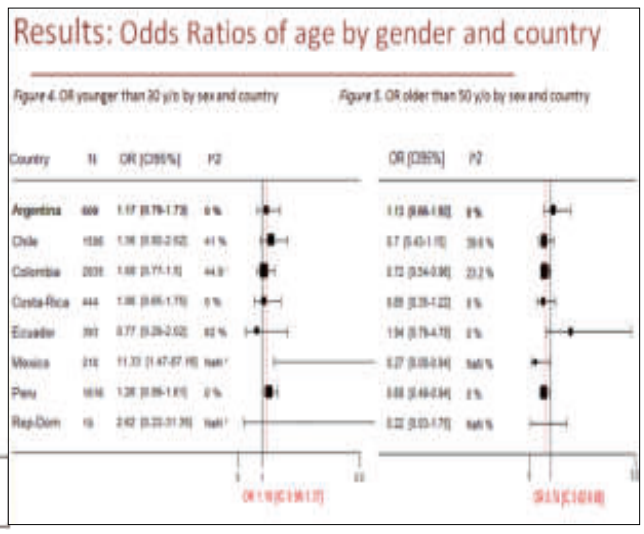
	Country	n centers	n patients	Linked to care	New cases
1	Argentina	4	8.649	8.021	609
2	Chile	10	12.726	9.952	1.506
3	Colombia	10	17.988	16.930	2.935
4	Costa Rica	2	2.883	1.746	444
5	Ecuador	5	13.035	8.942	393
6	México	1	3.090	1.740	210
7	Panamá	1	2.468	2.468	0
8	Paraguay	1	844	719	0
9	Perú	2	9.698	5.987	1.616
10	R. Dominicana	1	358	348	19
11	Venezuela	1	1.692	1.156	0
	Total	38	73.431	58.009	7.732

Results: Age distribution by gender



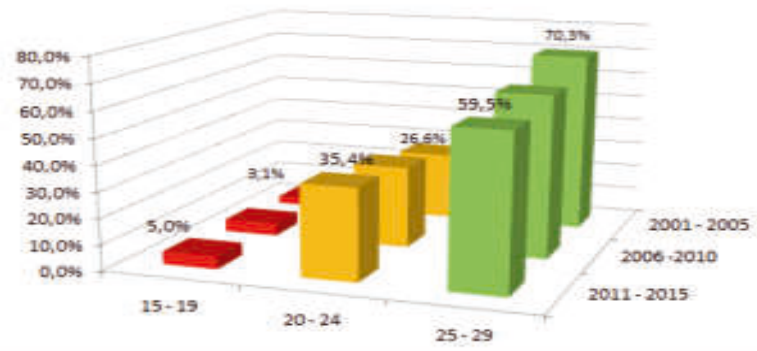
- 79,4% of new cases were men with 35.8% of them 15 – 29 y/o and 20,6% in women with 29.8% 15 – 29 y/o

Results: Odds Ratios of age by gender and country



Results: Subanalysis new cases < 30 y/o Chile

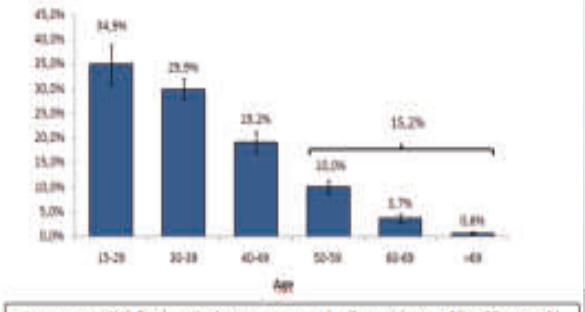
Figure 6. New cases in Chile 2001-2015 within the range 15 – 29 y/o



- Within the range 15 – 29 y/o most cases seen in the group 25 – 29
- Nevertheless largest relative increases seen in the very young (60% and 30%)

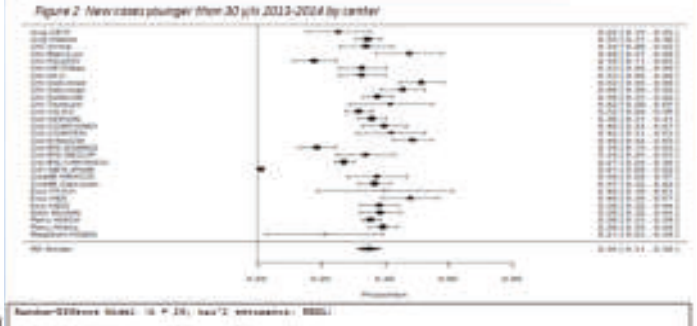
Results

Results: Age distribution of new cases



- Among new HIV infections the largest age group in all countries was 15 to 29 years old
- Wide differences between centers in each country with some of them with more than 50% of younger people
- A clear trend to more infections at younger ages is observed

Results: Distribution of < 30 y/o by center



Conclusions

- A modest reduction in new HIV infections has been reported in Latin America.
- Young people especially men between 15 and 24 years old show an important increase in new HIV cases in 2013 -- 2014 in most countries in spite of some differences between centers.
- In the context of the 90 -- 90 -- 90 goals specific policies should be implemented targeting this key population.

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P038

PRESENTATION TO CARE WITH ADVANCED HIV DISEASE IS STILL A PROBLEM IN LATIN AMERICA

Celi, Ana Paulina ; Greco, Maria ; Martinez, Ernesto ; Vargas, Carmen ; Belaunzaran, Francisco ; Mejia, Fernando
for the Latin American HIV Workshop Study Group

BACKGROUND

Presentation to care with advanced HIV disease, defined as first CD4 count below 200 cells/mm^3, has been reported previously between 38% and 45% by PAHO, CCASAnet and the Latin-American Workshop Group with significant differences among countries. The UNAIDS -- WHO 2.0 initiative beside 90-90-90 goal aims to reduce late presentation to ART to 10% of new cases by increasing strategies to promote testing in different key population and at a general level.

MATERIALS AND METHODS

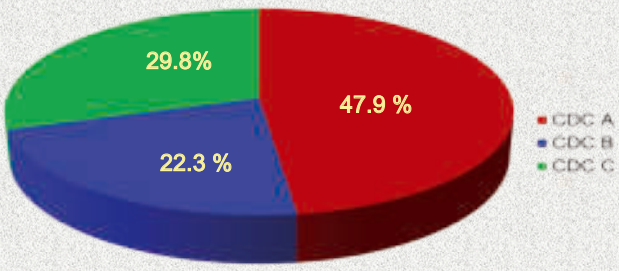
The Latin-American Workshop Study Group is an expanding network of 38 HIV Care Centers from 11 countries of South America, Central America, the Caribbean and Mexico with clinical data from 73,431 patients up to September 2015, 6,072 of them being new 2013-2014 HIV cases.
Late presentation to care was analyzed globally, by gender, age and by participating centers and countries according to the first CD4+ count and the clinical stage at the first visit. Statistical analysis by chi square test and Odds Ratios.

RESULTS

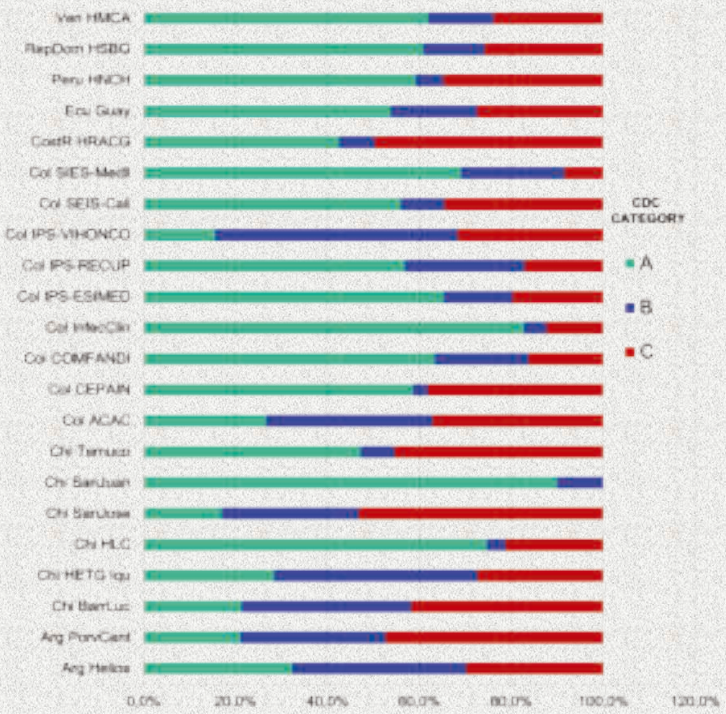
Among new HIV infections presented to care:

- 37.0% with a CD4+ < 200 cells/mm^3
- 23.1% with a CD4+ between 200 and 350 cells/mm^3.

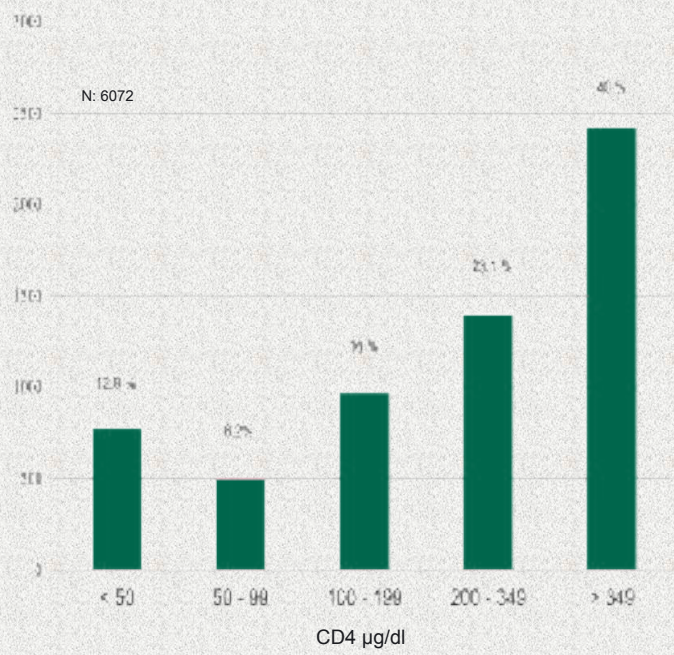
CDC STAGE AT DIAGNOSIS



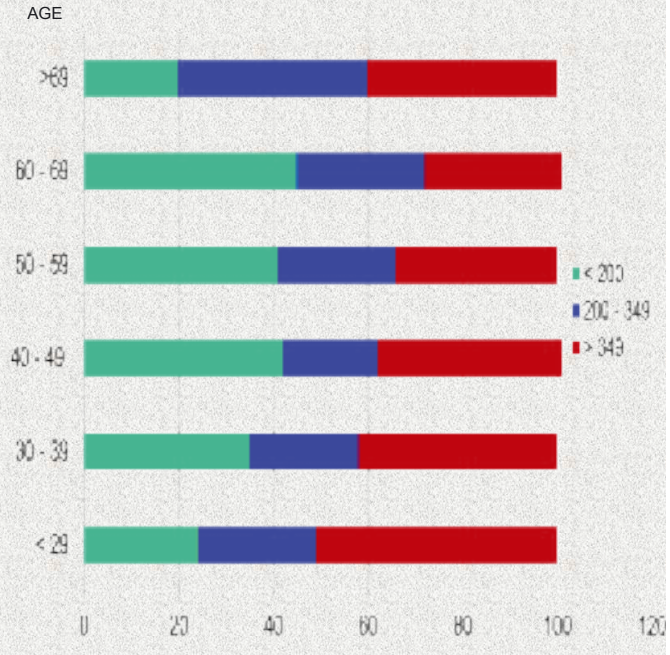
CLINICAL STAGE
PARTICIPATING CENTERS



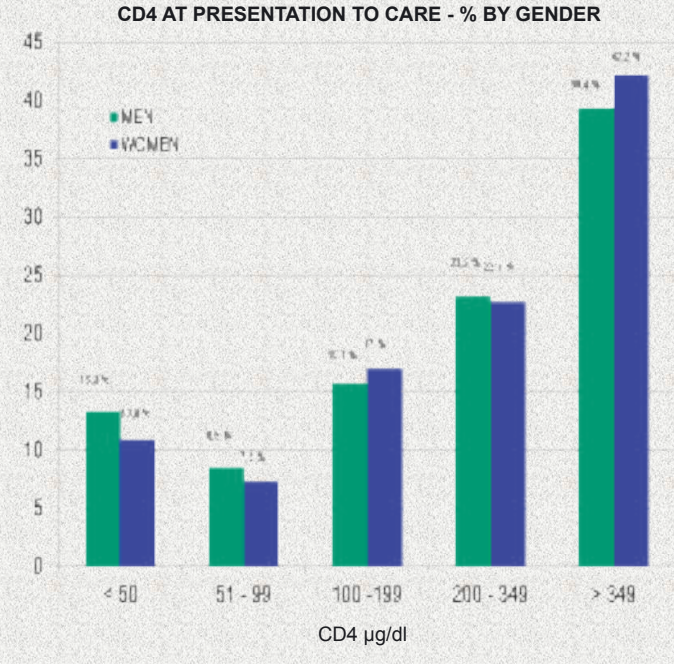
PATIENTS - CD4 AT PRESENTATION TO CARE



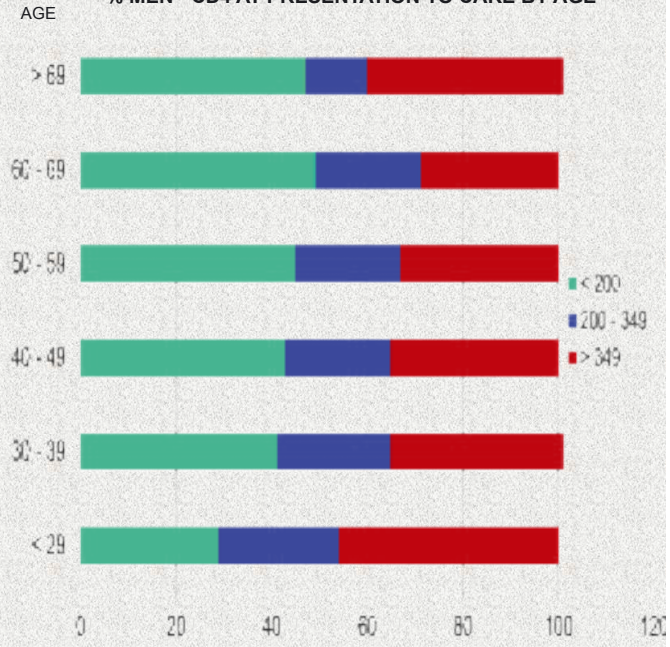
% WOMEN - CD4 AT PRESENTATION TO CARE BY AGE



CD4 AT PRESENTATION TO CARE - % BY GENDER



% MEN - CD4 AT PRESENTATION TO CARE BY AGE



CONCLUSIONS

Very late presentation to care is a direct consequence of insufficient testing in Latin America.
A very modest reduction in presentation to care with less than 200 cells/mm^3 has been observed in new HIV cases in 2013 -- 2014 in all countries in spite of some differences among centers.
Women and people younger than 30 years old have the lowest risk for presentation to care with advanced HIV disease. Strategies for increase in testing should address the higher prevalence in key populations but also promotion of testing in people at risk for late presentation.

P040 - Clinical monitoring system of people living with HIV/AIDS (SIMC): Brazilian strategy to reduce GAP treatment

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INTRODUCTION

Brazil published a National guidelines in 2013 implementing the "Treatment for All," first developing country to recommend ART for all people living with HIV/AIDS (PLWHA), regardless of CD4 count and HIV viral load.

MATERIALS AND METHODS:

To expand ART coverage, Brazilian Ministry of Health (BMoH) developed in 2013 a **clinical monitoring information system (SIMC)** combining data from both ARV dispensing and laboratory systems. SIMC comprises data on treatment GAP in service level.

Treatment GAP means people living with HIV/AIDS, who are being followed in public services, who are not on ART.

State and municipal coordinations and HIV/AIDS services have access to lists of PLWHA on treatment GAP patients in SIMC to **implement actions with the objective of location these patients and offer them treatment**

RESULTS

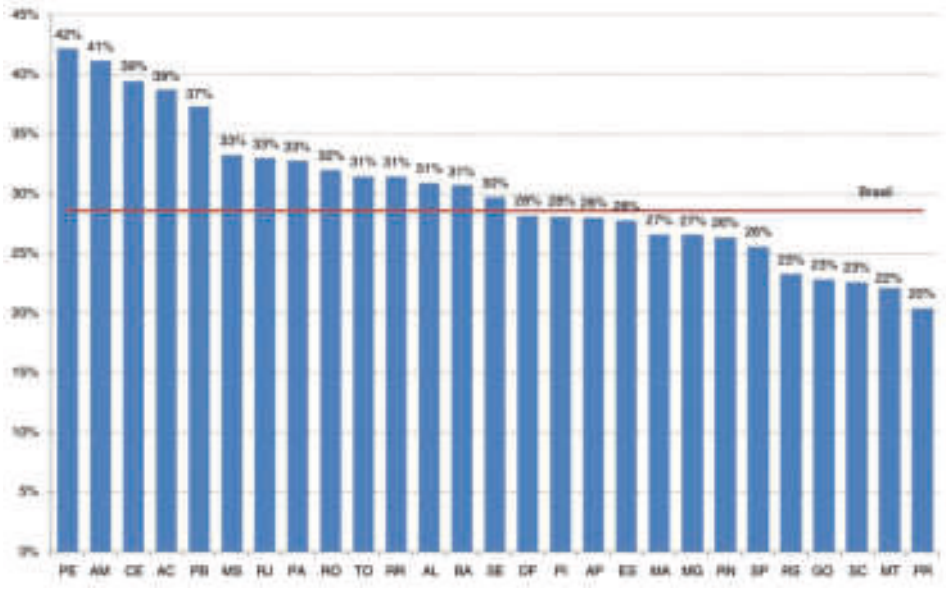
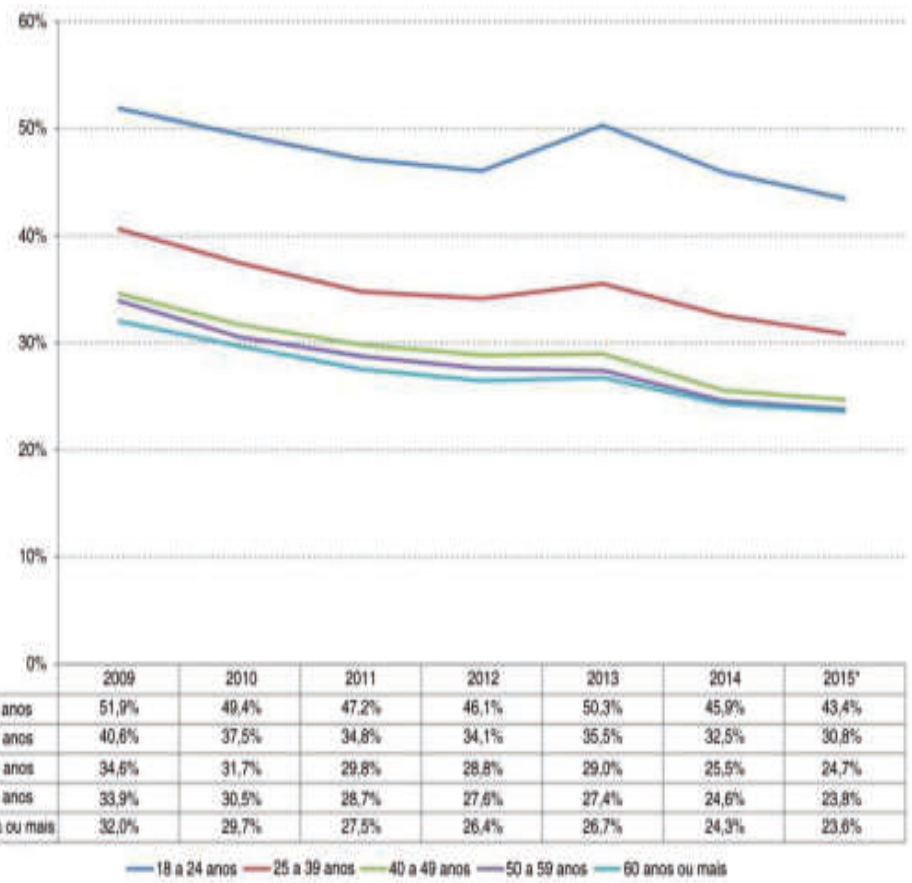


Figure 1. Treatment GAP of Brazilian states (N=27), aged 18 and over, 2015.



	2009	2010	2011	2012	2013	2014	2015*
18 a 24 anos	51,9%	49,4%	47,2%	46,1%	50,3%	45,9%	43,4%
25 a 39 anos	40,6%	37,5%	34,8%	34,1%	35,5%	32,5%	30,8%
40 a 49 anos	34,6%	31,7%	29,8%	28,8%	29,0%	25,5%	24,7%
50 a 59 anos	33,9%	30,5%	28,7%	27,6%	27,4%	24,6%	23,8%
60 anos ou mais	32,0%	29,7%	27,5%	26,4%	26,7%	24,3%	23,6%

18 a 24 anos — 25 a 39 anos — 40 a 49 anos — 50 a 59 anos — 60 anos ou mais

Figure 2. Proportion of PLWHA eligible for HAART who did not start treatment (GAP) by age group. Brazil, 2009 - 2015.

CONCLUSIONS

SIMC is an effective monitoring tool that allows services to identify PLWHA treatment GAP and to conduct active surveillance of patients for starting ART.

- Important disparities among states;
- GAP decreased from 32.5% to 29%;
- General reduction in all age groups;
- Substantial GAP (43%) observed in age group 18-24 years old.

This analysis showed that treatment GAP in Brazil presents substantial variations within different age groups and states. To tackle such inequities is key to effectively reduce the GAP and increase access to treatment

Low level viremia in people living with HIV at antiretroviral therapy

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Mexico's National Center for HIV and AIDS Prevention and Control (Censida)/DAI, Mexico

Background

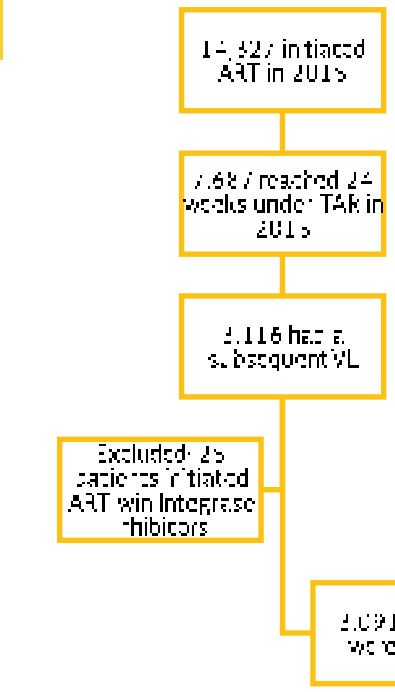
HIV viremia is recognized as a significant prognostic indicator of disease progression in HIV-infected patients, and HIV viral load (VL) is used as a marker for treatment response.

The goal of antiretroviral therapy (ART) is to reduce viral load to undetectable levels, below 50 copies/mL. However, these goals are not always achieved. Some patients experience persistent low level viremia, which may be considered as a significant prognostic indicator of virologic failure and promotes the selection of drug resistance mutations. Low level viremia is defined as VL between 50-200 copies/mL HIV-1 RNA.

Material and methods

The objective of this study was to estimate the prevalence of LLV in people with HIV that recently initiated antiretroviral therapy (ART) at the Ministry of Health of Mexico. A total of 3,791 patients were studied, of which 77.2% were women. They were under first-line therapy and reached 24 weeks under treatment on 2015 with a subsequent VL.

Viral loads results were related to clinical data retrospectively recording ART composition, and they were subdivided into NNRTIs (Efavirenz) and PIs (Atazanavir, Darunavir, Lopinavir). Patients were classified into four groups: less than 50 copies/mL, 50-200 copies/mL, 201-500 copies/mL and ≥501 copies/mL.



Results

Success of therapy was defined as <50 copies/mL and was observed in 407 (75.5%) women and 2,088 (81.6) men, the difference observed was statistically significant (p=0.0001). A bivariate analysis showed that men had a higher probability to achieve success than women (OR=1.35, CI95% 1.08 to 1.71, p=0.0068).

HIV VL (copies/mL)	Women		Men		Total	
	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)
<50	407	75.5 (72.67-80.04)	2,088	81.6 (80.04-83.06)	2,495	81.6 (79.27-82.20)
50 to 200	29	7.3 (5.25-9.69)	259	10.1 (8.98-11.36)	288	9.6 (8.62-10.74)
201 to 500	16	3 (1.75-4.84)	44	1.7 (1.25-2.30)	60	1.9 (1.49-2.49)
>501	70	13.2 (10.40-16.33)	168	6.6 (5.64-7.59)	238	7.7 (6.79-8.70)
Total	532		2,559		3,091	

The prevalence of LLV in women and men was 7.3% and 10.1% respectively, and 9.6% for each sex. The amount of patients with LLV differed significantly between NNRTI-based first-line regimens (9.7%) and PI-based regimens (7.62%) (p=0.0001). A bivariate analysis showed that patients on NNRTI-based regimen had a higher probability to achieve <50 copies/mL (OR=1.65, CI95% 1.34 to 2.06, p=0.0001). When data was subdivided into ART composition and sex the difference between genders were not statistically significant for NNRTI-based regimens (p=0.478), but they remain statistically significant for PI-based regimens (p=0.0001).

Table 1

Bivariate analysis
Mexico, 2015

	<50 copies/mL	OR	95%CI	p-value
Gender				
Women	75.5%	-	-	-
Men	81.6%	1.36	1.06-1.71	0.0068
First-line regimens				
PI-based	73.7%	-	-	-
NNRTI-based	82.4%	1.66	1.34-2.06	<0.0001

Figure 1

Low level viremia prevalence after 24 weeks on ART at MoH
Mexico, 2015

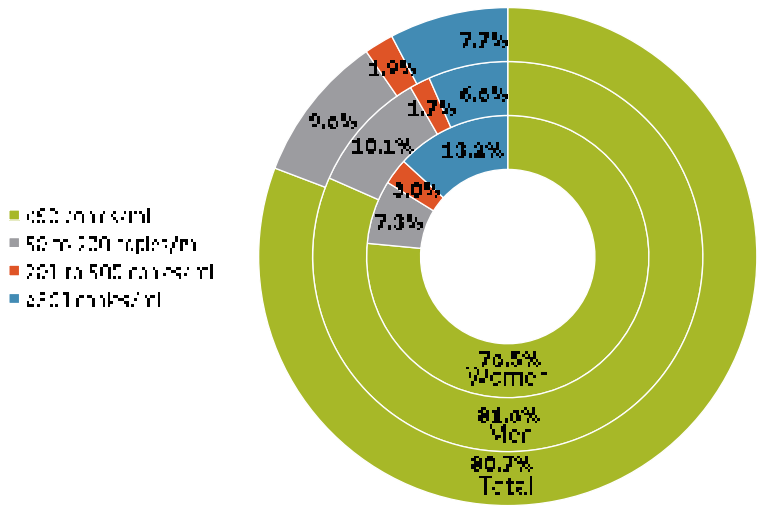
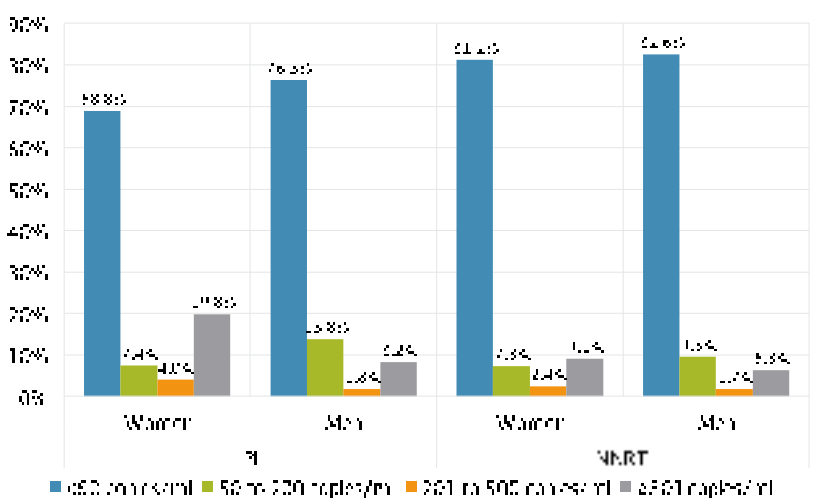


Figure 2

VL after 24 weeks on ART at MoH by sex and regimen
Mexico, 2015



Conclusion

- Containing regimens NNRTI plus two NRTIs have been shown to suppress VL to lower HIV-1 RNA copy numbers than those with two NRTIs plus PI, with significant gender differences that impact on women ART outcomes.

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1. Wensing AM, et al. Prevalence of drug-resistant HIV-1 variants in untreated individuals in the Americas and Europe. J Acquir Immune Defic Syndr. 2005 Nov 1;40(3):287-96.
2. Palella FJ Jr, et al. Human Immunodeficiency Virus Outpatient Study Investigators. Virologic response to highly active antiretroviral therapy--the role of adherence. J Infect Dis. 2003 Nov 15;188(10):1-7.

Persistency of First-Line ART in a Real-World Setting in a Cohort of HIV-Positive Patients from Santiago, Chile.

Chanqueo, Leonardo; Bernal, Fernando; Vásquez, Patricia; Gutiérrez, Catalina; Giadalah, Carolina; Serri, Michel
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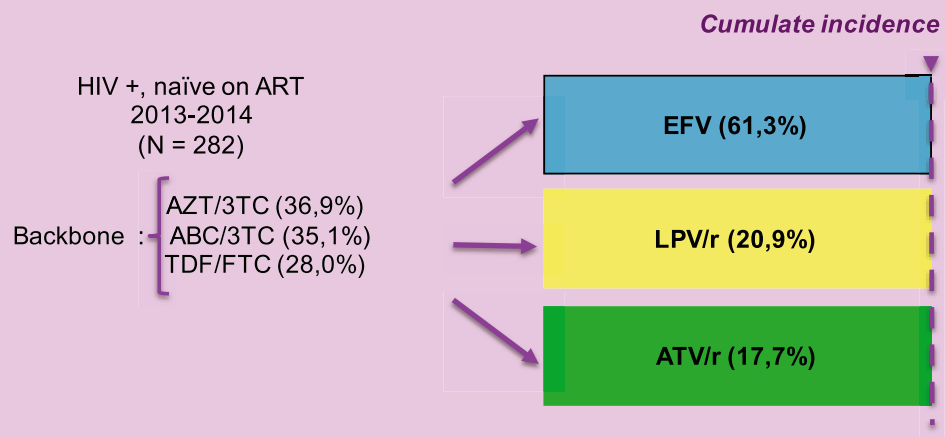
1 BACKGROUND

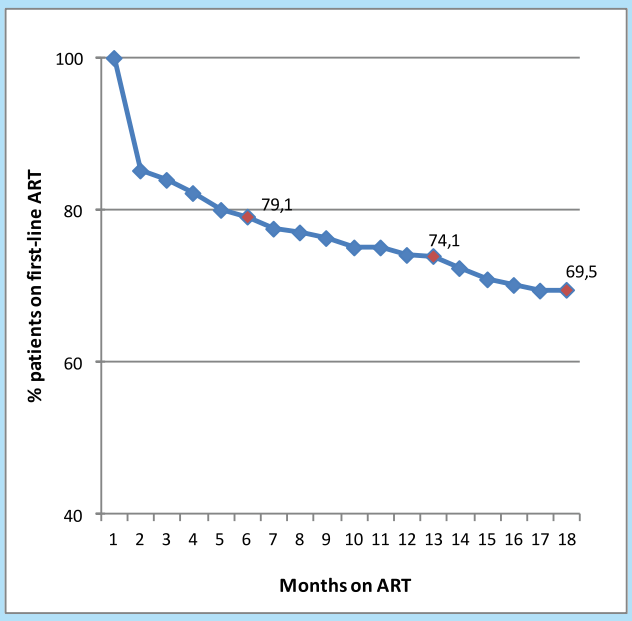
Prolonging ART regimen durability is a key to achieving long-term treatment success in the management of HIV-infected patients. However, risk factors such as frequency of dosage, complexity of regimens and medication side effects may result in the discontinuation of ART. The aim of this study was to estimate the persistence of the most commonly used first-line ART regimens used in HIV-infected adults in Chile and the most common causes of changed ART in our cohort.

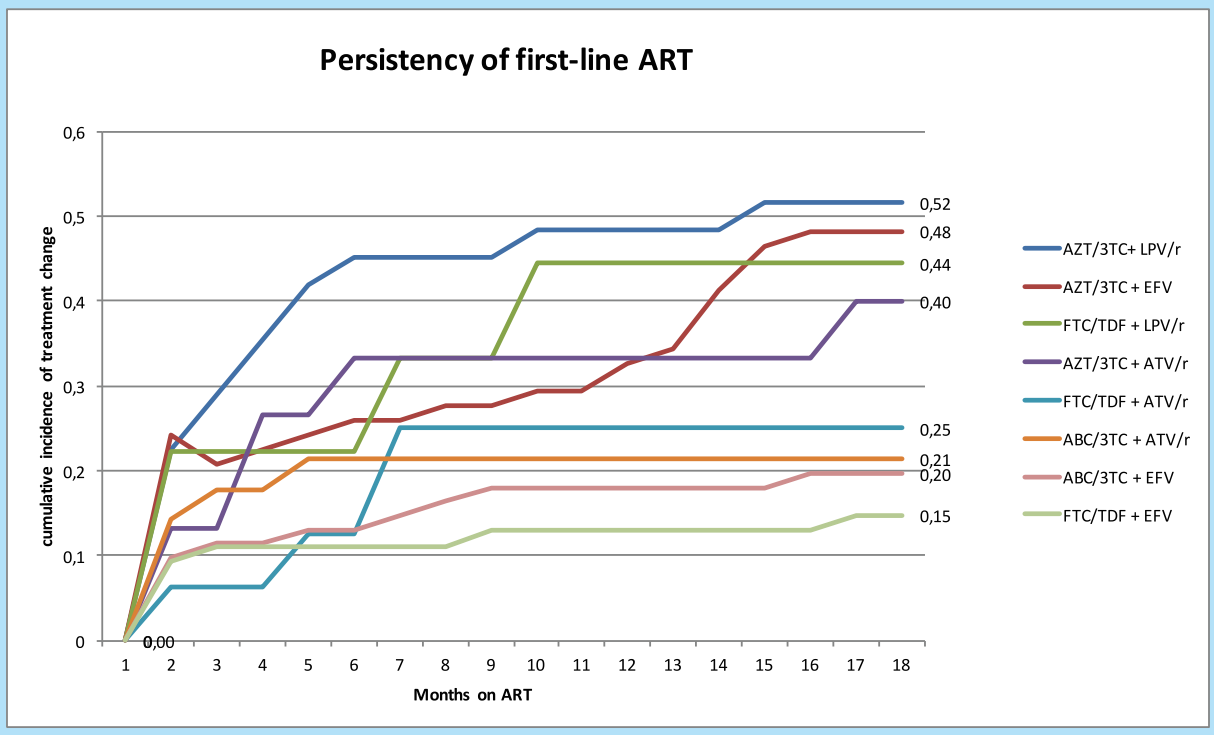
2 MATERIALS & METHODS

Using restrospective data from our cohort from Hospital San Juan de Dios de Santiago, Chile, we included naive HIV+ patients between 2013 and 2014 who initiated ART with one of the following regimens: fixed-dose backbone (ABC/3TC, TDF/FTC or ZDV/3TC) plus EFV, ATV/r or LPV/r . The cumulative incidence of treatment change was calculated at 18 months. In addition, the distribution of the reasons for changing was calculated in patients who changed their initial ART regimen.



3 RESULTS





A total of 282 ART-naive patients were included, 85% were male - 80% MSM- and 15% female. 104 (36,9%) started with ZDV/3TC, 99 (35,1%) with ABC/3TC and 79 (28%) with TDF/FTC as a backbone. The most commonly prescribed third drug was EFV (173, 61,3%) followed by ATV/r (59, 20,9%) and LPV/r (50, 17,7%). At 18 months of ART, 70% of patients maintained the same regimen. BID regimen was associated with a higher risk of treatment change compared with QD regimen, TDF/FTC plus (EFV or ATV/r) and ABC/3TC plus (EFV or ATV/r) regimen had a cumulative incidence of treatment change at 18 month of 0.148/0.197 and 0.214/0.250, respectively. However, BID regimens such as ZDV/3TC plus (EFV, ATV/r or LPV/r) had a cumulative incidence of treatment change of 0.483/0.400/0.516, respectively. The reasons for treatment change were toxicity/adverse event (n= 62, 66,1%) - hematologic toxicity (n=23, 25%), skin rash (n=13,14%) and CNS side effects (n=11, 12%) - followed by simplification (n=12, 14%) and treatment failure/resistance (n=5, 6.5%).

4 CONCLUSIONS

- HIV patients initiating first-line ART with QD regimen are more likely to be persistent with the same therapy than those beginning treatment with BID regimen.
- Toxicity remains as the main reason for discontinuation of ART.
- Discontinuation and switching of initial ARV regimens is still frequent, therefore the choice of an easy and non-toxic ARV regimen for initial therapy is the most important issue in the care of our HIV+ patients.

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P043

48 weeks CD4 cell recovery in HIV infected patients on effective antiretroviral treatment

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Background

The CD4+ cell counts recovery in HIV infected individuals receiving antiretroviral therapy (ART) shows high variability.

HIV-infected patients who initiate ART and fail to achieve an optimal CD4 recovery,are in increased risk of developing an AIDS-defining event or death compared with immunological responders.

We aimed to evaluate the factors associated with successful CD4 recovery in the first year of treatment in a cohort of patients on effective ART.

Methods

We reviewed medical records of all naive outpatients for whom ART was started between January 2008 and December 2014 in our unit. We excluded pregnant and patient enrolled in clinical trials.

CD4+ recovery was defined as an increment >100 cell/µL in the first year of therapy and effective treatment as the achievement of HIV-RNA <50 copies/ml.

Logistic regression models were performed to examine the factors associated with CD4+ cells recovery.

Results

463 patients started ART during the study period, of whom 418 (90%) achieved virologic suppression. Nine patients (1,9%) died during follow up. Data on CD4 recovery was available for 338 (82%) patients. Baseline characteristics of the patients are shown in Table 1. Median CD4+ gain at 48 weeks was 196 cells/µl (IQR: 102-301). The proportion of patients with a successful immune recovery was 75% (256/338). It was higher in males, whereas co-infection with HCV and use of intravenous drugs were associated to a reduced likelihood of attaining a CD4+ cell gain > 100 cells/µl. (Table 2).
Age, baseline CD4+ cell count, heterosexual (vs. homosexual) transmission, NNRTI (vs. PI) based regimens, and AIDS events were not associated with CD4+ recovery in this cohort.
In a multivariate model including sex, age, HCV coinfection and baseline CD4+ cell counts, only male sex and HCV coinfection remained as predictive determinants of immune recovery. Of note, IVDU was not included in this model given interaction with HCV coinfection.

Table 1. Baseline characteristics of the patients

	n:338
Male sex % (n)	67.1 (227)
Median age; years (IQR)	41 (35-48)
MSM transmission % (n)	35.8 (121)
IVDU % (n)	2.36 (8)
HCV positive % (n)	7.70 (26)
AIDS at ART initiation. % (n)	29.8 (101)
Baseline CD4+ count, median cells/µl (IQR)	183 (87-250)
NNRTI based regimen % (n)	89 (301)

Table 2. Factors associated with successful immune recovery

	Univariate Analysis		Multivariate Analysis	
	Exp (β) CI 95%	p	Exp (β) CI 95%	p
Male Sex*	1.80 (1.06 to 3.07)	**0.02**	1.84 (1.03 to 3.25)	**0.03**
Age (per year)*	1.00 (0.97 to 1.03)	0.75	1.01 (0.98 to 1.04)	0.35
MSM	1.54 (0.86 to 2.76)	0.14		
Intravenous drugs use (IVDU)	0.16 (0.05 to 0.53)	**0.02**		
HCV Coinfection*	0.13 (0.06 to 0.31)	**<0.001**	0.14 (0.06 to 0.32)	**<0.001**
AIDS at ART initiation	1.15 (0.65 to 2.04)	0.61		
CD4+ at baseline*	0.99 (0.97 to 1.01)	0.24	0.99 (0.99 to 1.01)	0.19
NNRTI regimen use (vs PI)	0.65 (0.13 to 3.03)	0.58		

* Included in multivariate analysis.

Conclusions

We found that a successful immune recovery is feasible in most of naive patients at 48 weeks of effective antiretroviral therapy, even in those who start ART with low CD4+ cell counts or AIDS events. HCV co-infection was deleterious for CD4+ reconstitution in our cohort. We did not found differences in CD4+ recovery with the use of PI or NNRTI based regimens.

Prevalence of HIV-1 Drug Resistance Associated Mutations in Patients Experiencing First-Line Antiretroviral Therapy Failure in a Cohort of HIV-Positive Patients from Santiago, Chile 2012 -2014

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1 BACKGROUND

Antiretroviral therapy (ART) has dramatically decreased morbidity and mortality among HIV-1 infected patients through the durable suppression of viral replication to undetectable levels. However, the efficiency of these treatments can be compromised by the presence of drug resistance associated mutations (DRMs), resulting in virological failure. Although international guidelines, such as those of the UK & US, recommend a basal genotypic HIV resistance testing, in Chile this standard-of-care management test is recomended only in patients who experienced virological failure on first-line ART. The aim of this study was to estimate the prevalence of HIV-1 DRMs in patients experiencing first-line ART therapy failure in a cohort of adult HIV-positive patients from Santiago, Chile.

2 MATERIALS & METHODS

Using restrospective data from our cohort from Hospital San Juan de Dios de Santiago, Chile, we included all the HIV genotypic testing request forms from adult HIV patients with ART therapy failure - defined as a plasma viral load > 1,000 RNA copies/ml- between 2012 and 2014 who initiated ART according to the Chilean HIV treatment guideline. The frequency of DRMs was analysed from the HIV genotypic test reports, which were done by ViroSeq HIV-1 Genotyping System at the Chilean HIV reference laboratory (Laboratorio de Biología Molecular - Hospital Lucio Córdova, Santiago).

3 RESULTS

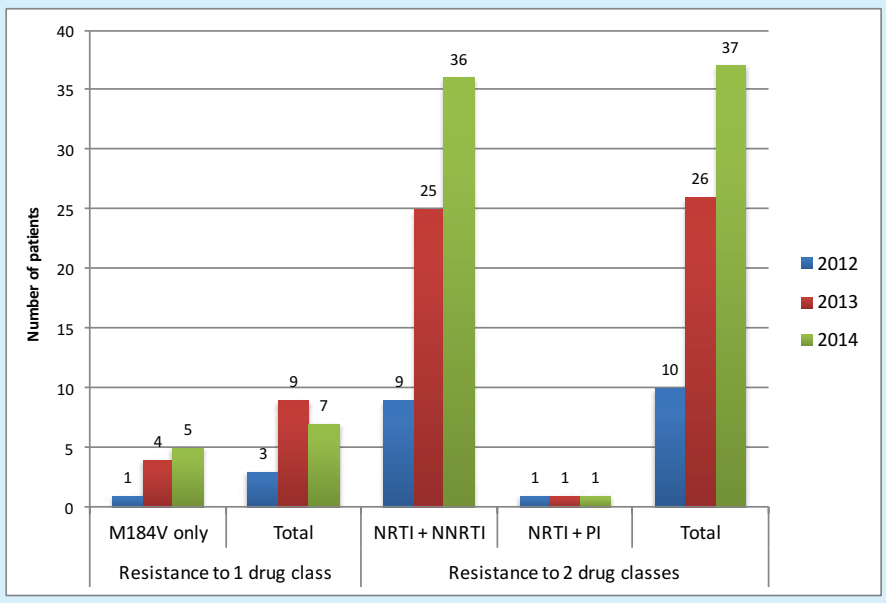
	NRTI						NNRTI										PI		II
	M184V	TAM 1	TAM 2	Others	L74	K65R	K103N	L100I	P225	Y188	G190S	Y181C/I	K101E	H221Y	E138A	M230L/I	Other (V179/108)	Major	Minor	R
2012	12	1	2	4	3	0	8	1	3	1	1	2	1	0	0	0	4	1	11	
2013	30	7	7	13	4	0	22	2	5	3	3	4	4	0	0	1	8	1	28	
2014	34	5	8	10	7	2	24	3	5	7	4	5	1	0	0	3	11	1	39	1

There were 20 requests for HIV genotypic resistance tests in 2012, 77 in 2013, and 79 in 2013.

A total of 168 HIV genotypic resistance tests were requested; 134 (80%) were analysed and 34 (20%) rejected because the viral load was lower than 1,000 RNA copies/ml.

We determined that 99/134 (74%) patients had viruses harbouring DRMs. Among them, 69 (70%) patients had two-class resistance (nucleoside reverse transcriptase inhibitors [NRTI] and non-nucleoside reverse transcriptase inhibitors [NNRTI])

The most common NRTI and NNRTI DRMs detected were the M184V and K103N; only in 3 patients was M230L detected. Major PI mutations were found only in 3.82% of patients (4/99)



4 CONCLUSIONS

Our findings emphasise the importance of using the genotypic test at the first treatment failure in order to guide the choice of an effective alternative regimen. In addition, our study gave insights into the distribution of DRMs in our population that are related to the initial ART regimen used.

Two-class resistance (NRTI plus NNRTI) was very frequently developed, but major PI-mutations were infrequently detected and no etravirine or rilpivirine DRMs were found in patients in our cohort who experienced virological failure on first-line ART.

Poster Number
3343222

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Ledipasvir/Sofosbuvir (LDV/SOF) for 8 Weeks in Genotype 1 Treatment-Naïve Non-Cirrhotic Patients with HCV Viral Load <6 million IU/ml: A Comparative Analysis of the Phase 3 ION-3 Efficacy Data to Real World Effectiveness

Jordan Feld,[1] Peter Buggisch,[2] Jorg Peterson,[2] Stefan Mauss,[3] Kris Kowdley,[4] Michael Curry,[5] Peter Ruane,[6] Dani Ain,[6] Naoky Tsai,[7] Yoori Lee,[8] Edward Eggleton,[9] Macky Natha,[9] Bruce Kreter,[9] Diana Brainard,[9] Monica Mora,[9] Nelson Cheinquer,[9] and Patrick Ingiliz[10]

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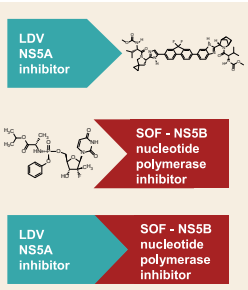
Introduction

- **Ledipasvir (LDV)**
  - Picomolar potency against multiple HCV genotypes
  - Effective against NS5B RAV S282T
  - Once-daily, oral, 90 mg
- **Sofosbuvir (SOF)**
  - Potent antiviral activity against HCV GT 1–6
  - Effective against NS5A RAVs
  - High barrier to resistance
  - Once-daily, oral, 400-mg tablet
- **Ledipasvir/Sofosbuvir STR**
  - Once-daily, oral fixed-dose (90/400 mg) combination tablet, RBV-free



Lawitz E, et al. EASL 2011, poster 1219; Cheng G, et al. EASL 2012, poster 1172; SOVALDI® [PI].

Gilead Sciences, Inc. Foster City, CA August 2015; HARVONI® [PI]. Gilead Sciences, Inc. Foster City, CA February 2016; Data on File. Gilead Sciences, Inc.

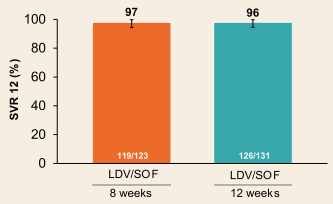
To date, >250,000 patients treated with LDV/SOF globally

Background

- ION-3 was a phase 3, randomized, open-label study comparing 8 vs.12 weeks of LDV/SOF in GT 1 treatment-naïve, non-cirrhotic patients
- SVR12 rates were non-inferior between the 8 and 12 week LDV/SOF arms (94% vs. 96%, respectively)
- Post-hoc analysis showed that the relapse rates in the 8 week arm were comparable to 12 weeks of LDV/SOF in patients with a baseline HCV RNA of <6M IU/ml
- The FDA, EMA and several treatment guidelines have endorsed the 8 week LDV/SOF regimen as a first line treatment option for treatment naïve (TN), non-cirrhotic (NC), GT1 patients with HCV RNA <6M IU/ml

HARVONI® [PI]. Gilead Sciences, Inc. Foster City, CA February 2016
Kowdley K, et al. N Engl J Med 2014;370:1879-1888.

Figure 1. ION-3: Efficacy and Relapse by Baseline HCV RNA <6 vs ≥6 Million IU/mL

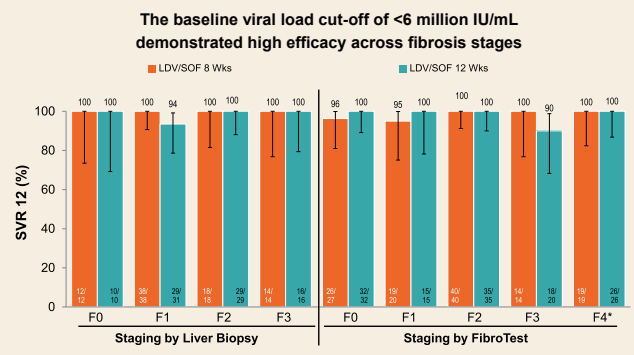


	LDV/SOF 8 weeks	LDV/SOF 12 weeks
Relapse Rates < 6M	1.6% (2/123)	1.5% (2/131)
Relapse Rates ≥ 6M	9.8% (9/92)	1.2% (1/85)

*2 patients were lost to follow-up after their baseline visit and never achieved HCV RNA < lower limit of quantitation on treatment.

Kowdley K, et al. N Engl J Med 2014;370:1879-1888.
Jacobson I, et al. AASLD, 2014, Poster #1945.
Gordon S, et al. ACG 2015, Poster 459

Figure 2. ION-3 - SVR12 by Fibrosis Scores in Patients with Baseline HCV RNA <6 Million IU/mL



* FibroTest is based on quantitative results of 5 serum biochemical markers (alpha-2-macroglobulin, haptoglobin, apolipoprotein A1, gamma glutamyl transpeptidase (GGT) and bilirubin) – can overestimate stage of fibrosis. If patients had discordant biochemical tests, a liver biopsy was used.

Objectives & Methods

Objectives
- Evaluate the effectiveness of LDV/SOF for 8 weeks in real world datasets
- Compare SVR data from ION-3 to several real world cohorts

Methods
- Three large, prospective, open-label, multicenter real world cohorts and two retrospective single center real world cohorts were reviewed
- Cohorts with missing or incomplete baseline demographic data or single center cohorts with less than 50 patients were excluded

Results

Studies Included

Study/Cohort Name	ION 3 N=123	TARGET N=154	TRIO N=263	GECCO N=148	IFI N=103	VA- Ohio N= 60

ION 3 Study* | HCV-TARGET | TRIO Cohort | GECCO | IFI/ Buggisch | VA-Ohio

Multicenter: US and Germany | Single center: Germany and US

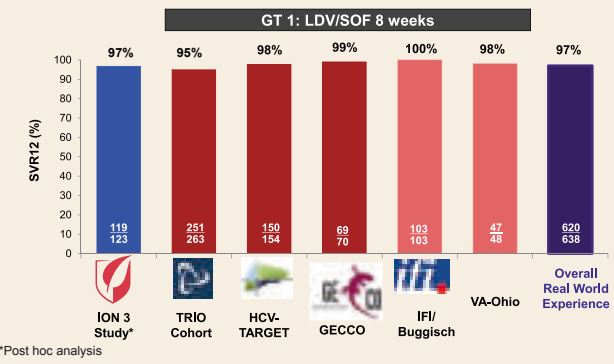
* Defined as >6 million with Roche TaqMan® v2.0, >2 million with the Abbott Real Time PCR **15% were cirrhotic on FibroTest but confirmed non-cirrhotic with biopsy, 2% had no data, ***FibroScan® >12.5 or APRI >2.0, n/a= not available, ^ mean age used, ^^ All patients had fibroscan <12.5 kPa

Table 1. Baseline Demographics

Characteristic	ION 3 N=123	TARGET N=154	TRIO N=263	GECCO N=148	IFI N=103	VA- Ohio N= 60
Median age, years (range)	52 (22-73) ^	58 (19-84)	57 (18-84) ^	52 (44-58)	50 (22-77)	61 (32-75) ^
Male, n (%)	67 (54)	70 (46)	121 (46)	79 (42)	43 (42)	56 (93)
Race, n (%)						
Non black	96 (78)	120 (78)	224 (85)	n/a	103 (100)	27 (46)
Black	27 (22)	34 (22)	39 (15)	n/a	0	33 (54)
HCV GT 4	0	0	0	3	2	0
HCV genotype 1a, n (%)	89 (72)	(66)	180 (68)	71 (48)	49 (46)	36 (59)
VL >6 M IU/ml	0	n/a	8	13*	2	0
Treatment Experienced	0	8	0	26	3	7
HIV/HCV	0	1	0	28	3	0
Fibrosis Score (liver biopsy), n (%)						
F0-F2	87 (71)	n/a	205 (78)	n/a	98(95)	n/a
F3	14 (12)	n/a	32 (12)	n/a	5 (5)	n/a
F4	0	n=6	0	n=5 ***	0	0
Unknown/other	22 (17) **	n/a	26 (10)	n/a	0	60^^

* Defined as >6 million with Roche TaqMan® v2.0, >2 million with the Abbott Real Time PCR **15% were cirrhotic on FibroTest but confirmed non-cirrhotic with biopsy, 2% had no data, ***FibroScan® >12.5 or APRI >2.0, n/a= not available, ^ mean age used, ^^ All patients had fibroscan <12.5 kPa

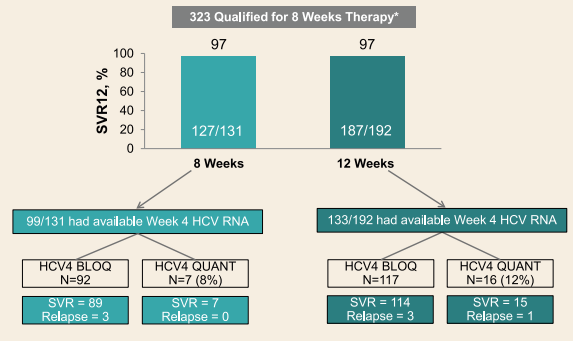
Figure 3. SVR12 in ION-3 Compared to Real-World Cohorts



*Post hoc analysis

Kowdley KV, et al. N Engl J Med 2014;370:1879-88; Curry M, et al AASLD 2015; Terrault N, et al AASLD 2015; Buggisch P, et al. AASLD 2015; Christensen, et al. AASLD 2015; Marshall et al. AASLD 2015

Figure 4. HCV TARGET- SVR12 Among Those Who Qualified for 8 Week Treatment

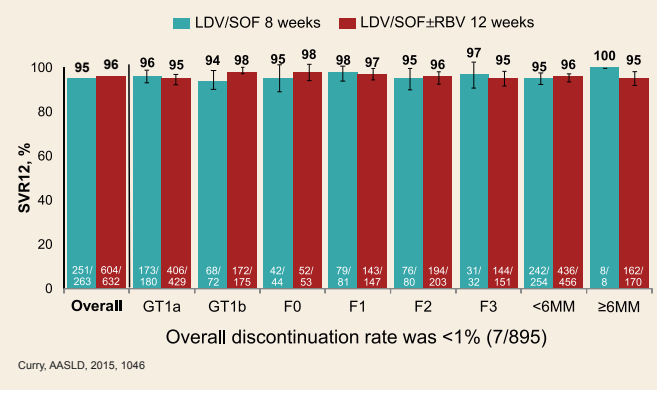


*Qualified = Treatment-naïve, no cirrhosis, HCV RNA ≤ 6 million IU/mL

Terrault, AASLD, 2015, 94

Figure 5. TRIO Cohort

TRIO Real-World Cohort: LDV/SOF ± RBV for 8 or 12 Weeks in Treatment-Naïve, Non-Cirrhotic GT 1 HCV, non randomized, observational cohort

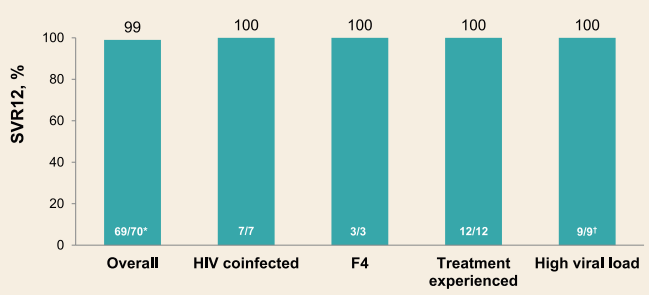


Overall discontinuation rate was <1% (7/895)

Curry, AASLD, 2015, 1046

Figure 6. GECCO Real-World Cohort

LDV/SOF for 8 Weeks in HCV-Monoinfected and HIV/HCV-Coinfected Patients: Interim Analysis



*1 patient relapsed
†High viral load defined as >6M IU/mL (Roche) or >2M IU/mL (Abbott) at baseline

Christensen, AASLD, 2015, 1081

Conclusions

- 8 weeks of LDV/SOF resulted in SVR rates of 97% in multiple, large, real-world cohorts
  - comparable to the SVR rates observed in the ION-3 post-hoc analysis
  - Real-world patients were more heterogeneous as many did not fit the standard criteria of TN, NC and VL < 6million
- Data from these cohorts suggest that the 8 week regimen is highly efficacious and underutilized in both community and academic centers
- Data confirm the use of the 8 week LDV/SOF regimen, and the validity of the post-hoc analysis that led to the dosing recommendation

Characterization of a large hepatitis C patients cohort in a reference center in Brazil: a descriptive cohort study.

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BACKGROUND

Chronic hepatitis C affects 1.5-3 million people in Brazil and it is probably one of the most important health problems to be faced by Brazilian medical authorities nowadays. Nevertheless, access to hepatitis C treatment may be difficult to the majority of Brazilian patients. Diagnostic tests are either not easily available or not requested by primary care physicians.

The majority of patients with indication of hepatitis C treatment are followed in secondary or tertiary medical services. Probably the most important barrier to treatment in Brazil is the lack of trained physicians and medical services. Cost is also another important concern.

In Brazil until December 2015 the majority of patients have been treated with interferon based therapy. The treatment of chronic hepatitis C (CHC) with direct acting agents (DAAs) has been recently introduced only for patients with severe liver disease due to the high cost of these medications.

Hospital das Clinicas, is probably the biggest public hospital in South America. Around 2,000 patients with chronic hepatitis C are presently followed up at this institution.

Patients with different levels of complexity are regularly attended at this unit at the present time.

We understand that it is important to distinguish more potentially difficult-to – treat-patients from potentially more easily treatable patients.

Difficult-to – treat patients may be best served by individualized regimen under the care of specialists. More easily treatable patients might be followed by secondary or primary care physicians. This type of medical management could be a more rational way to provide easier access to complex patients to terciary services. It could eventually provide access to medical care to a larger number of patients.

OBJECTIVES

Primary objective: To describe the demographic, epidemiological and clinical characteristics of a group of patients treated in a Hepatitis C tertiary medical care unit in Brazil

Secondary objectives:

- To estimate the number of patients with complex characteristics
- To estimate the number of patients with less complex features

MATERIAL AND METHODS

Methods

Study Design: We developed a retrospective and descriptive cohort study at Hospital das Clinicas which is a public hospital and a reference center to treat CHC in Sao Paulo, Brazil.

Study Population: The enrolled patients were selected from those registered at the Infectious Diseases Division.

Variables Analyzed

- Medical records from all patients with CHC were reviewed in order to analyze selected variables: age, gender, HIV co-infection, HCV genotype, stage of liver fibrosis (by using Metavir Score and/or evidence of portal hypertension), information regarding previous hepatitis C treatment.
- In this study, difficult -to treat patients were defined as follows: experienced genotype 3-infected or genotype 1-infected patients who failed to first generation protease inhibitors, cirrhotic or HIV co-infected patients.

Statistical Methods: Descriptive analysis of frequency distribution of selected variables.

RESULTS

Between April 2015 and December 2015, 1757 patients with CHC were identified and included in our data bank.

Among them 219 (12.4%) had HIV coinfection (fig. 1). 893 (50.8%) were women (fig. 2) and mean age was 41.95±14.5 years. Genotype 1 predominated with 972 (55.3 %) cases. Genotype 2, 3, 4 and 5 were 50 (2.85%), 513 (29.2%), 11 and 01 cases respectively. Among all patients 747 (42.5%) were F3 or F4 (fig. 3) and 293 (16.6%) had cirrhosis (fig. 4).

Chronic hepatitis Among all patients 1048 (59.6%) had received previous hepatitis C treatment, with interferon based therapy (n=901, 86%) or telaprevir/boceprevir based therapy (n=147,14%) (fig. 5).

Among 1048 previously treated patients only 480 (46%) obtained sustained virologic response at a previous treatment and 250 were genotype 3 patients.

Among all included patients 1277 (73%) were yet to be treated and only 660 (37.5%) were considered difficult-to treat patients.

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Fig 1. HIV coinfection

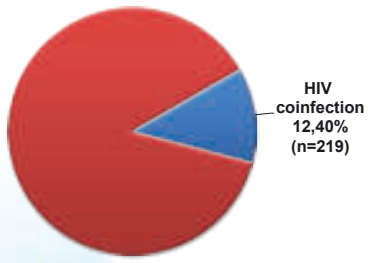


Fig 2. Gender

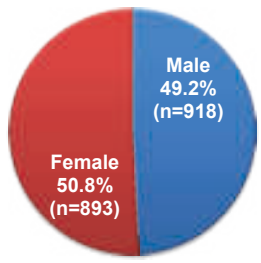


Fig 3. F3 or F4

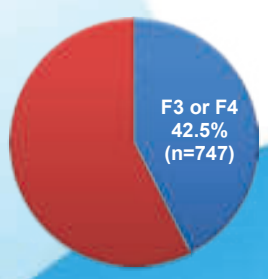


Fig 4. Cirrhosis

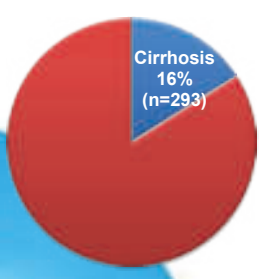
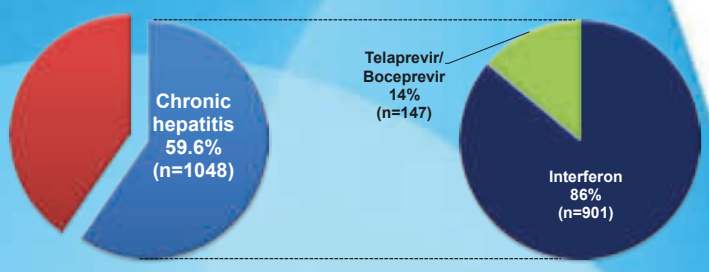


Fig 5. Chronic hepatitis and previous treatment



DISCUSSION

In general, our data revealed that the most difficult to treat patients represented the minority of patients been followed up at a tertiary medical center. According to our data, in our institution, an urban tertiary medical center,the majority of included patients, were considered easy-to–treat patients. Also according to our results the majority of patients were yet to be treated.

The recent introduction of directly acting antiviral agents has demonstrated the potential to transform outcomes for individuals infected with HCV. New treatment schedules have raised the possibility of eradicating HCV in populations where resources are not constrained. However, these improvements in the efficacy and tolerability of antiviral therapies have also brought into sharp focus the major challenges of accessing the HCV-infected population.

In order to realize the vision of eradication of HCV infection, it will be mandatory to engage infected individuals with adequate treatment pathways.

Many steps need to be accomplished to decrease the burden of CHC at an individual and public health level. Tertiary centers play a critical role in the final steps in the care cascade for patients with CHC, specifically as it is involved and responsible for the resolution of the more complex situations, such as decompensated patients and liver transplant procedures.

Also important to mention that primary and secondary services, in this era of highly effective and simple treatment regimens for CHC, have the potential to broaden access to treatment. The easy to treat patients, could eventually be treated and followed up in the primary/secondary care setting, after proper training of local physicians, to do so.

We believe our data reinforce the need of changes of local care pathways regarding hepatitis C cascade of care. It is important to mention though, that this study was performed at a specific tertiary center and may not reflect the reality of the other tertiary centers in our country.

We believe that the application of these interventions into our current care model will allow more patients to benefit from curative treatments and accelerate the decline in HCV disease burden in our country.

CONCLUSION

In this Brazilian cohort, the majority of included patients at an urban tertiary medical center, were considered easy-to–treat patients. Also according to our results the majority of patients were yet to be treated. Urgent interventions into our current care model are needed in order to allow more patients to benefit from curative treatments and accelerate the decline in HCV disease burden in our country.

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Integrated Analysis of Emergent Drug Resistance Through 96 and 144 Weeks From Clinical Studies of HIV-1 Treatment-Naive Subjects Receiving Dolutegravir-Based Regimens

P050

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Introduction

- The integrase inhibitor dolutegravir (DTG) plus 2 NRTIs has been evaluated in 3 Phase III studies in treatment-naive subjects. Dolutegravir-based regimens (DBRs) achieved non-inferiority in SPRING-2[1] vs raltegravir (RAL)-based regimens, while superiority was achieved in SINGLE[2] and FLAMINGO[3] vs Atripla® (ATR) and boosted darunavir (DRV/r)-based regimens, respectively
- Analyses of subjects experiencing protocol-defined virologic failure (PDVF) showed the absence of resistance on DBRs, whereas resistance to the third agent and/or 2 NRTIs was observed in the comparator arms of SPRING-2 and SINGLE
- This report integrates the resistance analyses in the treatment-naive studies, comparing plasma viral load (pVL) and emergent resistance at the time of PDVF for the DTG and respective comparator arms

Methods

- Genotypic and phenotypic resistance was analyzed on paired plasma from baseline and PDVF, regardless of pVL at PDVF
  - PhenoSense® GT from Monogram Biosciences was attempted on all PDVFs
  - The frequency of reportable results with respect to pVL at PDVF was assessed
  - The relationship of pVL with resistance was also evaluated
- PDVF was defined as confirmed plasma HIV-1 RNA >200 c/mL on or after Week 24 in FLAMINGO and >50 c/mL on or after Week 24 in SINGLE and SPRING-2

Results

- A total of 1,067 subjects received a DBR across the 3 studies
- The range of pVL at PDVF was similar between the DTG and comparator arms (Table 1)

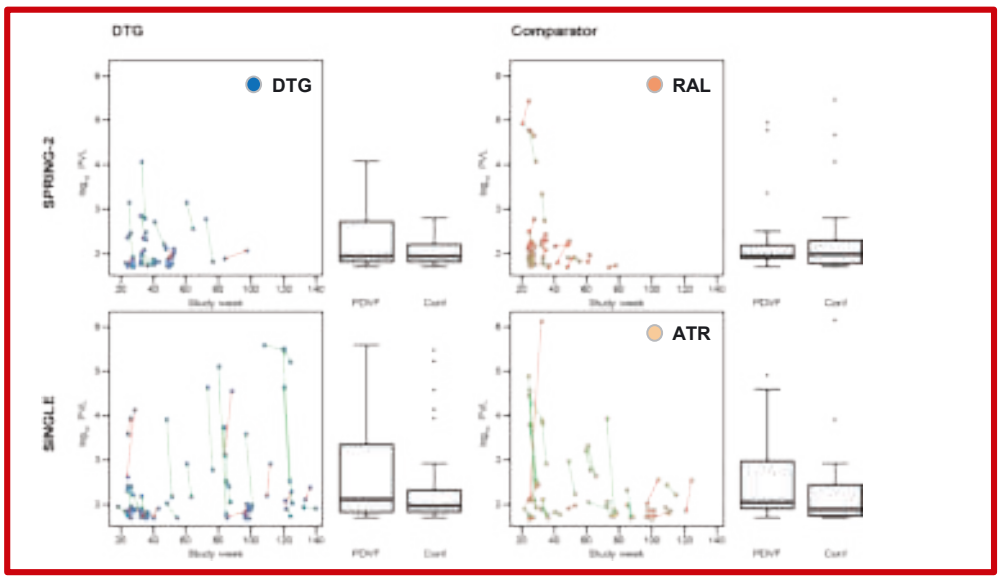
Table 1. Characteristics of PDVF*

	SINGLE (Week 144)		SPRING-2 (Week 96)		FLAMINGO (Week 96)	
	DTG	ATR	DTG	RAL	DTG	DRV/r
Treatment (N)	414	419	411	411	242	242
n (%)	39 (9%)	33 (8%)	22 (5%)	29 (7%)	2 (<1%)	4 (2%)
PDVF						
Log pVL	2.14 (1.72-5.61)	2.07 (1.70-4.91)	1.94 (1.71-4.09)	1.93 (1.70-4.95)	3.17 (2.82-3.36)	3.62 (2.34-4.79)
Confirmation of PDVF						
Log pVL	1.97 (1.71-5.49)	1.89 (1.71-6.16)	1.93 (1.70-2.80)	1.98 (1.70-5.45)	3.03 (2.72-3.21)	3.02 (2.98-4.92)
Time between PDVF and confirmation pVL						
Weeks	3.3 (1.3-12.4)	3.9 (2.0-17.7)	3.4 (1.1-13.1)	3.0 (1.0-8.1)	2.2 (2.0-2.4)	3.4 (3.0-5.0)

*Median (range) shown for log pVL and weeks.

- pVL generally decreased between PDVF and confirmation of PDVF (Figure 1)
- The time between these 2 visits ranged from a few to several weeks

Figure 1. Log HIV-1 RNA Levels at PDVF and Confirmatory Visits



Viral load decrease (green) or increase (red) from PDVF to confirmatory visit.

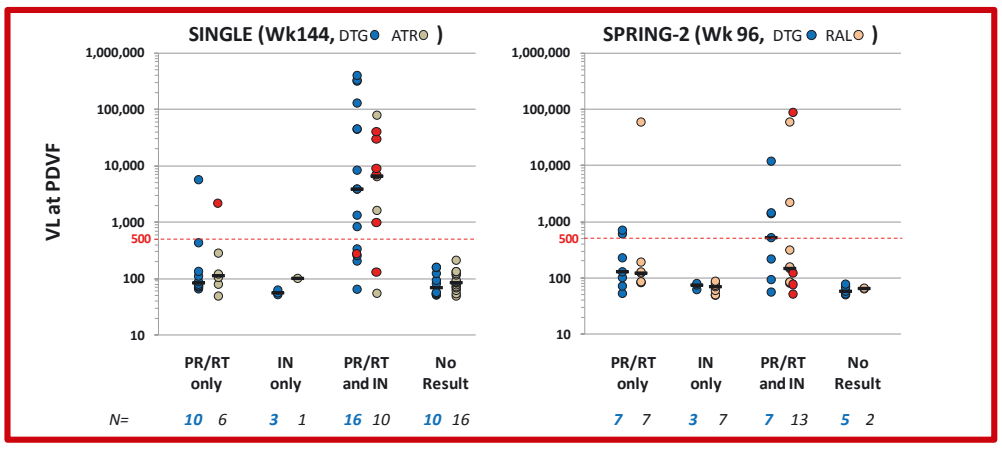
Reportable Resistance Results

- Reportable results were obtained on the majority of samples (73.2%) tested from SINGLE and SPRING-2 (Figure 1)
  - A non-reportable result was associated with, but not limited to, lower pVL
  - 37.4% of subjects had reportable results for both PR/RT and IN (Figure 2)
- In FLAMINGO, reportable results were obtained for all 6 PDVFs (2 DTG, 4 DRV/r)
  - No emergent resistance in PR, RT, or IN was detected in any of these subjects (Table 3)

Detection of Resistance-Associated Substitutions (SINGLE and SPRING-2)

- No resistance was detected in subjects on DBRs
- Third agent and/or NRTI resistance was detected in the comparator arms
- Using a pVL threshold of >500 c/mL (>2.7 log), resistance would have been detected 6/9 ATR and 1/4 RAL PDVF

Figure 2. Log HIV-1 RNA Levels at PDVF and Resistance Results*†



*Red circles indicate resistance-associated substitutions detected; black dash = median; red line = 500 c/mL HIV-1 RNA.

†The IN polymorphism E157Q/P detected in 1 DTG PDVF in SINGLE with no significant change in phenotypic susceptibility.

Table 2. Resistance-Associated Emergent Substitutions*

Arm	PDVF	pVL	NRTI	NNRTI	INI
SINGLE (Week 144)					
ATR	1 Week 24	131	**K65K/R**, D67D/G, Q197Q/R	**G190/G/E**	
	2 Week 24	29,777	L264L/S	V179V/D, **G190G/A**	
	3 Week 24	40,751	V35V/I	**K103N, G190G/A**	
	4 Week 32	6,882	I178I/M	**K103K/N**	
	5 Week 48	992	T286T/A	**K101E**	
	6 Week 60	2,183	A288A/T	**K103K/N**	
	7 Week 72	9,043	I135K	**K103N**	
SPRING-2 (Week 96)					
RAL+TDF/FTC	1 Week 24	52	**M184M/I**		
	2 Week 24	76	A62A/V		
	3 Week 24	88,126	A62A/V, **K65K/R, K70K/E, M184V**		**T97T/A, E138E/D**, V151V/I, **N155H**
RAL+ABC/3TC	4 Week 24	123	**M184M/V**		

*Primary resistance-associated mutations in **bold**. pVL = HIV-1 RNA c/mL.

Table 3. PDVF in FLAMINGO (Week 96)

Arm	#	PDVF	pVL (c/mL)	Resistance
DRV/r	1	Week 36	61,754	None
	2	Week 48	218	None
	3	Week 72	5,140	None
	4	Week 84	3,162	None
DTG	1	Week 24	668	None
	2	Week 24	2,270	None

Conclusions

- DBRs demonstrated durable virologic suppression across 3 trials in treatment-naive patients through 96 and 144 weeks of treatment[1-3]
- pVL at time of PDVF was comparable between arms, and reportable resistance results were obtained across a range of pVL, including pVL <500 c/mL (<2.7 log) at PDVF
- Analysis of the PDVF sample offers the best chance of identifying genotypic changes, as confirmatory pVL is lower in most samples and time between samples may vary substantially
- No resistance to DTG or NRTIs has been detected in clinical trials of treatment-naive patients receiving DBRs to date
- Use in clinical practice will further inform the virologic characteristics of failure on a DBR

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