REACHING OUT, TESTING E LINKAGE TO CARE IN HIV:
ESPERIENZE, CONSIGLI PRATICI, COSA NON FARE

Reaching out popolazioni speciali
Focus donne in età fertile e non solo

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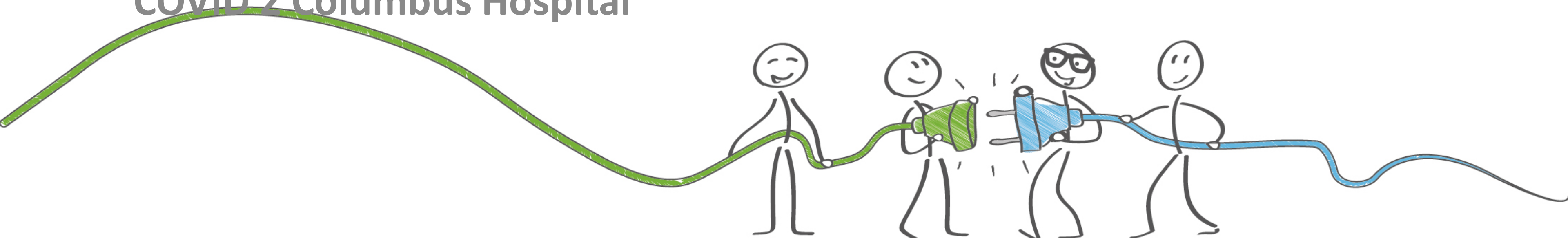
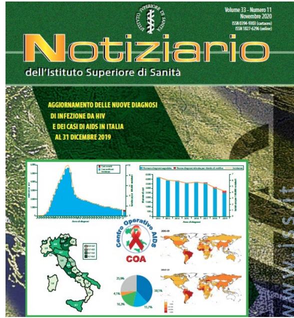


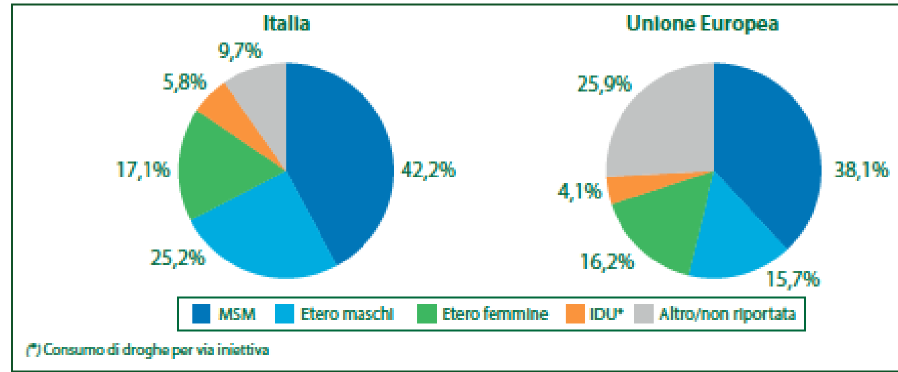
HIV in Women: 2018 Data

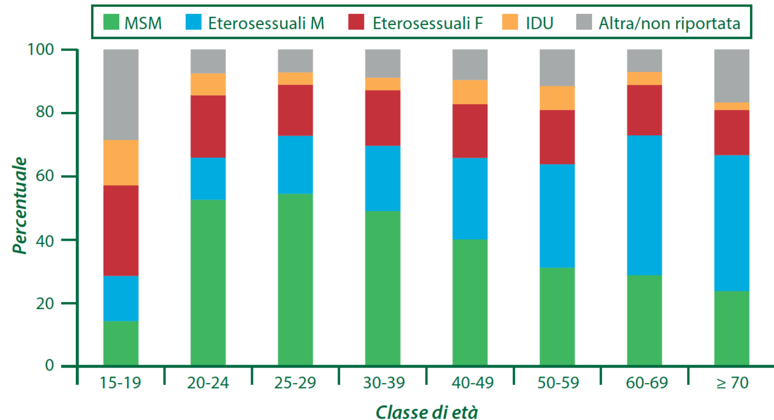
- ~ 18.8 million women 15 yrs of age or older living with HIV (52% of adults with HIV)
- > 46% of ~ 1.6 million new HIV infections in adults globally were among women
- **HIV among teens/young adults aged 15-24 yrs**
  - Females twice as likely to be living with HIV vs males
  - New infection rate 55% higher for females vs males
  - 6200 females in this age group infected with HIV every wk, most in sub-Saharan Africa
  - In sub-Saharan Africa, 80% of new infections among this age group are in females
- 82% of pregnant women living with HIV received ARVs to prevent mother-to-child HIV transmission

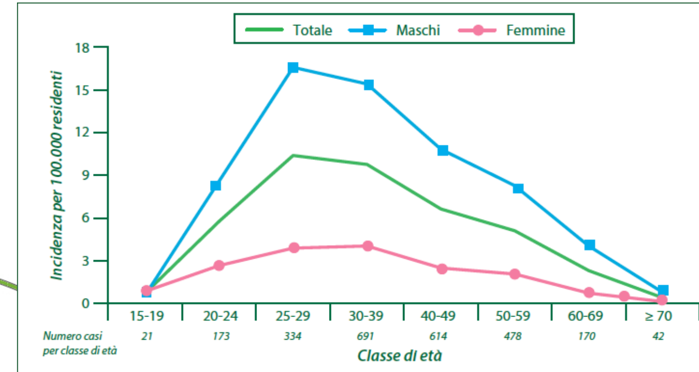
amfAR. https://www.amfar.org/about-hiv-and-aids/facts-and-stats/statistics--women-and-hiv-aids/.

Prevalence of HIV in women in Italy and impact of age

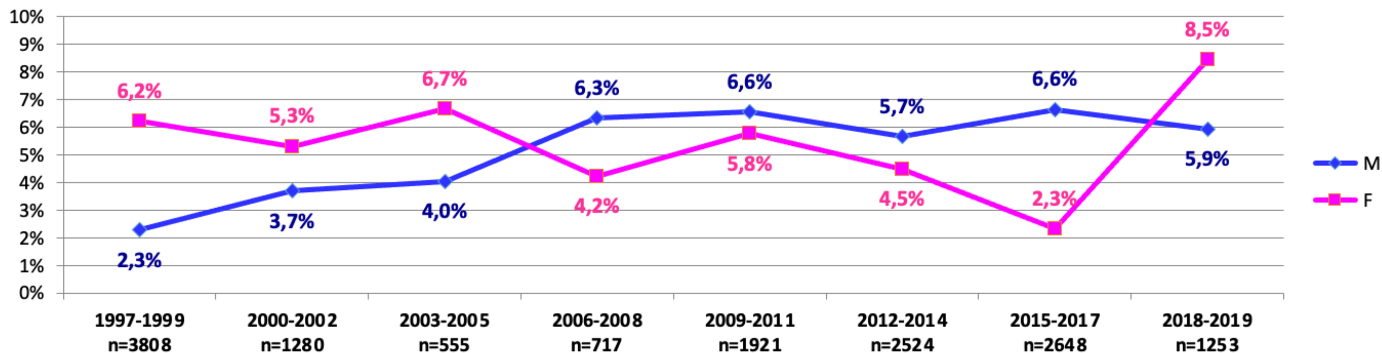




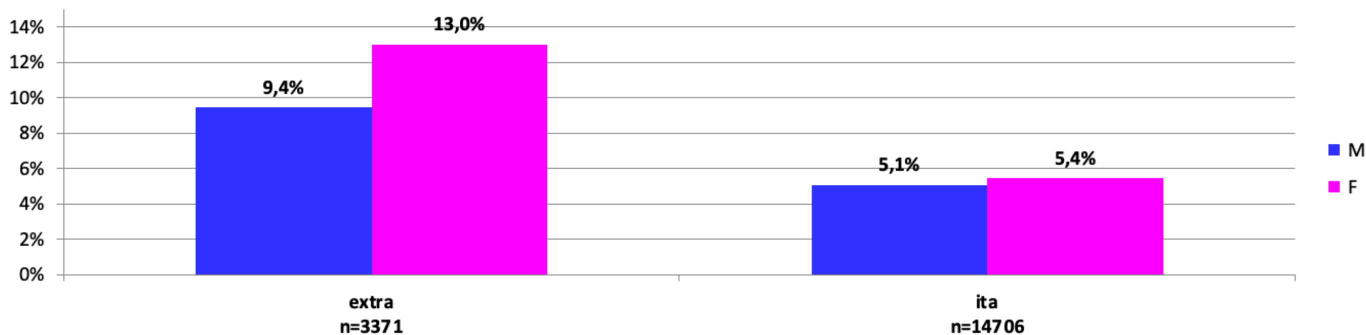




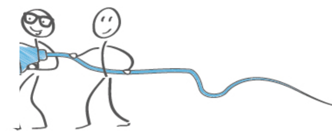
Proportion of italian patients aged 25 or less according to gender and to period of enrolment



Proportion patients aged 25 or less according to gender and to nationality



Jan 2019 Report



Key Gaps in Reaching Specific Populations: Children, Young Men 15-34 Yrs, and Young Women 15-24 Yrs

Key Gaps (children, young men 15-34 and young women 15-24) in Reaching Specific Populations *Community Viral Load Suppression By Age and Gender*

Males

Females

100
90
80
70
60
50
40
30
20
10
0

Percent (%)

73% VLS

0-14
15-24
25-34
35-44
45-59
0-14
15-24
25-34
35-44
45-59

Virally Suppressed
73% VLS
100% VLS

Pooled data from Lesotho, Malawi, Namibia, Swaziland, Tanzania, Uganda, Zambia, and Zimbabwe from PHIA projects.

ECHO Trial: High HIV Incidence, Low Pregnancy Rate Among Young Women on LA Hormonal Contraception

- Randomized trial among HIV-negative women aged 16-35 yrs comparing[1]:
  - DMPA-IM (n = 2609), LNG implant (n = 2613), copper IUD (n = 2607)
- **Overall HIV incidence/100 woman-yrs: 3.81 (95% CI: 3.45-4.21)[2]**
  - DMPA-IM: 4.19 (95% CI: 3.54-4.94)
  - Copper IUD: 3.94 (95% CI: 3.31-4.66)
  - LNG implant: 3.31 (95% CI: 2.74-3.98)
  - Rates statistically similar across arms in modified ITT analysis

- 255 pregnancies: 181 after contraception discontinuation[2]
- Pregnancy incidence/100 woman-yrs in continuous use analysis[2]
  - Copper IUD: 1.11 (95% CI: 0.77-1.55)
  - LNG implant: 0.63 (95% CI: 0.39-0.96)
    - P = .042 vs copper IUD
  - DMPA-IM: 0.61 (95% CI: 0.36-0.96)
    - P = .027 vs copper IUD

1. Panalee-Phillips. IAS 2019. Abstr LBPEC23. 2. ECHO Trial Consortium. Lancet. 2019;394:303.

High Rates of STIs Among Young Women and Girls in South Africa

- > 70% asymptomatic

Study	Population	*Chlamydia trachomatis*, %	*Neisseria gonorrhea*, %	*Trichomonas vaginalis*, %
Women's Initiative in Sexual Health (WISH)[1]	Females age 16-22 yrs in Cape Town and Soweto (n = 298)	18-42	5-11	4-9
Meta-analysis of 18 HIV prevention studies[2]	Females age 15-24 yrs in South Africa	8-21	1-9	3-20

1. Barnabas. Int J STD AIDS. 2018;29:531. 2. Torrone. PLoS Med. 2018;15:e1002511.

STIs and HIV Transmission/Acquisition Risk

- Screening and comprehensive management of STIs and reproductive tract infections important for overall sexual health
  - Includes syphilis, chancroid, herpes, ulcer, bacterial vaginosis and trichomoniasis leading to vaginal infection, vaginal candidiasis, HPV, cervical cancer, gonorrhea, chlamydia, pelvic inflammatory disease
- STIs are associated with increased risk of HIV transmission or acquisition
  - Highest increase in risk is for infections causing genital ulcers (eg, syphilis, chancroid, HSV-2)
  - Non-ulcerative STIs (eg, gonorrhea, chlamydia, trichomoniasis) also increase transmission through genital HIV shedding

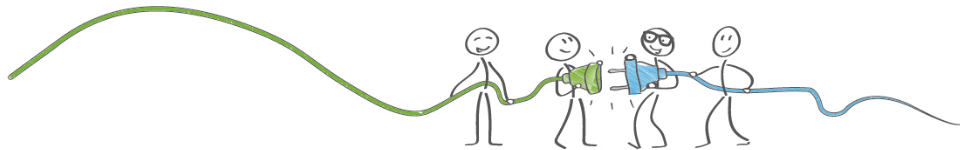
WHO. Consolidated guideline on sexual and reproductive health and rights of women living with HIV. 2017. https://apps.who.int/iris/bitstream/handle/10665/254885/9789241549998-eng.pdf?sequence=1

Women are less likely to be tested for HIV or offered PREP at the time of STI diagnosis

An electronic sexual health dashboard was used to identify patient encounters with a positive gonorrhea, chlamydia, and/or rapid plasma reagin test result between January 1, 2019, and August 23, 2019, at a large urban academic medical center.
A retrospective chart review was performed to assess HIV testing, completeness of STI screening, and HIV prevention discussion; inadequate screening was defined as no HIV test in 12 months before STI diagnosis.

Results: A total of 815 patients included. female (64.4%); median age was 24 years (range, 18-85 years).
Women were more likely to be inadequately screened for HIV (15.1% vs. 25.8%).
Documentation of PrEP discussion was rare (4.7% of patient encounters) compared with safe sex (44.6%) and condoms (49.8%).
Preexposure prophylaxis was discussed almost exclusively with men compared with women (17% vs. 1.1%).

Caitlin, Sex Transm Dis 2021



Cervical Cancer Prevention

- WHO: HPV vaccine recommended for girls age 9-13 yrs
  - **Individuals with HIV** (or other immunocompromise) **should receive vaccine on 3-dose schedule (0, 1-2, and 6 mos)**

WHO. Consolidated guideline on sexual and reproductive health and rights of women living with HIV. 2017.
https://apps.who.int/iris/bitstream/handle/10665/254885/9789241549998-eng.pdf?sequence=1

Cervical Cancer Screening

- HIV associated with increased risk for HPV-associated cancers[1-3]
  - Possibly due to increased HPV persistence,[4] replication[5,6]
- Invasive cervical cancer and anal cancer rates high among those with HIV (even with ART) vs general population[7]
  - Regular screening and treatment for high grade intraepithelial lesions mitigates cervical cancer risk[8]
- Recent systemic review showed lower prevalence of high-risk HPV and cervical intraepithelial lesions (CIN2+) with early ART initiation and adherence vs no ART[9]
- Because of increased risk, **cervical cancer screening should be annual* for women with HIV**[10]

*If by cytology or visual inspection with acetic acid or acetic acid and Lugol's iodine.

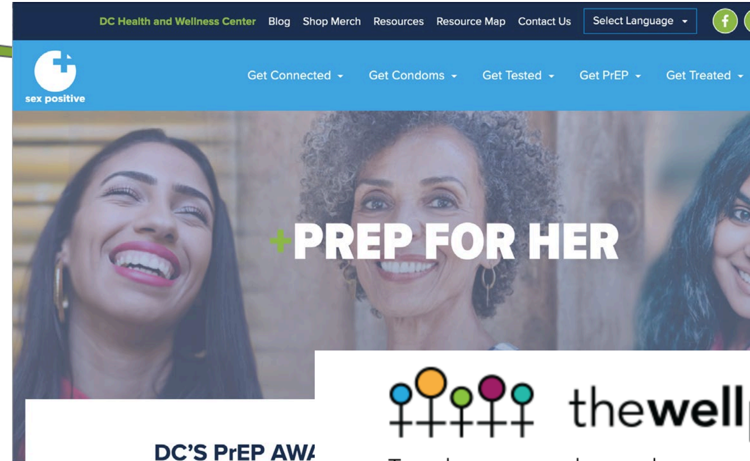
1. De Vuyst. Br J Cancer. 2012;107:1624. 2. Grulich. Lancet. 2007;370:59. 3. Ellerbrock. JAMA. 2000;283:1031. 4. Rowhani Rahbar. J Infect Dis. 2007;196:887. 5. Massad. AIDS. 2014;28:2601. 6. Denny. Vaccine. 2012;30(Suppl 5):F168. 7. Kojic. Sex Transm Dis. 2011;38:253. 8. Massad. Cancer. 2009;115:524. 9. Kelly. Lancet HIV. 2018;5:e45. 10. Kenya Ministry of Health. November 2018. http://www.health.go.ke/wp-content/uploads/2019/02/National-Cancer-Screening-Guidelines-2018.pdf.

Sexual and Reproductive Health for Women With HIV: Key Services to Provide Holistic Care

- Sexual health counselling and support services
- Violence against women services
- Family planning and infertility services
- Antenatal care and maternal health services
- Safe abortion services
- STI and cervical cancer services

WHO. Consolidated guideline on sexual and reproductive health and rights of women living with HIV. 2017.
https://apps.who.int/iris/bitstream/handle/10665/254885/9789241549998-eng.pdf?sequence=1

PREP as tool for comprehensive prevention strategy in women



thewellproject

Together, we can change the course of the epidemic...one woman at a time.

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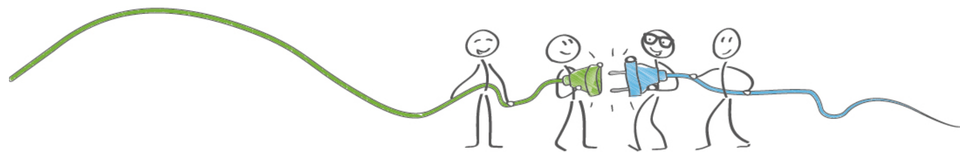
Home > HIV Information > Women, Children & Family > PrEP for Women

PrEP for Women

Submitted on May 23, 2019

PrEP for Women



Which strategies to reaching at-risk women for PrEP delivery?

These recommendations can be used to inform implementation strategies that are community-specific and reach women in a variety of settings, including those who have not traditionally been reached with HIV prevention interventions.

Stankevitz et al, Plos One 2019

Strategy	Description	Numbe mentione (
Community engagement		
Engagement meetings with gatekeepers	Before recruiting in the community, study teams visited gatekeepers-people who had influence within the community-to provide them information about the study and seek support.	
Community advisory boards (CABs)	Study teams worked with advisory boards consisting of members of the community to provide information about the study, get information about the community, and ensure the research was community owned.	
Information dissemination		
Community events	Recruitment staff attended local community events, such as health education events or World AIDS Day, and gave educational presentations, handed out study information sheets, and answered questions.	
Posters and flyers	Recruitment staff hung posters and handed out flyers in public spaces and health facilities to educate the public about PrEP and promote the trial.	
Media	Principal investigators and research staff were interviewed on local or national radio stations and studies ran television commercials to raise awareness about PrEP and promote the trial.	
Targeted recruitment		
Presentations in waiting rooms	Recruitment staff were stationed in waiting rooms of clinics thought to serve at-risk populations to provide information and answer questions.	
Word-of-mouth	Recruitment staff encouraged existing trial participants to promote participation among friends via word-of-mouth.	
Venue-based recruitment	Recruitment staff provided information about the trial in areas where women congregate, such as: bars, brothels, shopping malls, communal taps, markets, or places on the street where people socialize.	
Door-to-door	Recruitment staff provided door-to-door education about PrEP and the trial and discussed the details one-on-one with those who were interested.	
Clinician referral		
Clinician referrals	Clinicians in family planning, STI, or HIV testing and counseling clinics were trained on PrEP and the trial by study staff and asked to educate and refer their clients.	

Undetectable = Untransmittable

- A person living with HIV who has an undetectable viral load does not transmit the virus:
  - To their sexual partners[1-5]
  - During pregnancy (PMCTC)[6]
  - When Breastfeeding[7]
  - Potentially when sharing needles, in injecting drug populations[8]

1. Quinn. NEJM. 2000;342:921. 2. Rodger. Lancet. 2019;393:2428. 3. Cohen. NEJM. 2016;375:830. 4. Vernazza. Lancet. 2008;372:1806. 5. Bavinton. Lancet HIV. 2018;5:e4387. 6. Mandelbrot. Clin Infect Dis. 2015;61:1715. 7. Davis. J Acquir Immune Defic Syndr. 2016;73:572. 8. Solomon. Lancet HIV. 2016;3:e183.

DHHS Recommendations Before Initiating an INSTI in Person of Childbearing Potential

- A pregnancy test should be performed
- *"To enable individuals of childbearing potential to make informed decisions, providers should discuss the benefits and risks of using DTG around the time of conception, including the low risk of NTDs and the relative lack of information on the safety of using other commonly prescribed ARV drugs, including other INSTIs, around the time of conception"*

Persons of Childbearing Potential Initiating ART*

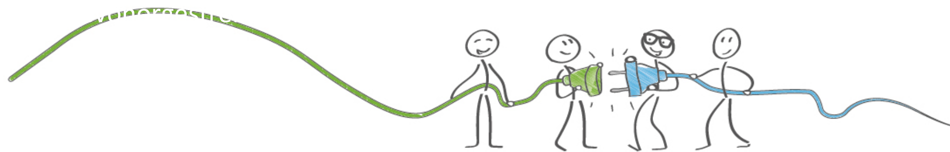
- Using effective contraception: DTG is a recommended option
- Sexually active, not planning to conceive, not using contraception: DTG is an alternative option

*Consider similar approach for BIC.

Drug–Drug Interactions Between Hormonal Contraceptives and ARVs: DHHS Guidelines

- Purple: No dose adjustment needed
- Green: Use alternative
- Yellow: Dose adjustments, additional monitoring, or alternative needed
- Dark blue: No data/recommendation

Hormonal Contraceptive	NRTI	PI				NNRTI					INSTI			
	Any*	ATV†	LPV	DRV	RTV	EFV	NVP	ETR	RPV	DOR	BIC	DTG	RAL	EVG/c
Combined oral contraceptives	No dose adjustment needed	Dose adjustments, additional monitoring, or alternative needed	Use alternative	Use alternative	Dose adjustments, additional monitoring, or alternative needed	Use alternative	No dose adjustment needed	No dose adjustment needed	No dose adjustment needed	No dose adjustment needed	No dose adjustment needed	No dose adjustment needed	No dose adjustment needed	Dose adjustments, additional monitoring, or alternative needed
Subdermal implant etonogestrel	No dose adjustment needed	No data/recommendation	No dose adjustment needed	No data/recommendation	No dose adjustment needed	Use alternative	No dose adjustment needed	No data/recommendation	No dose adjustment needed	No dose adjustment needed	No data/recommendation	No data/recommendation	No data/recommendation	No data/recommendation
Transdermal ethinyl estradiol/ norelgestromin	No dose adjustment needed	No data/recommendation	No dose adjustment needed	No data/recommendation	No dose adjustment needed	No data/recommendation	No data/recommendation	No data/recommendation	No data/recommendation	No data/recommendation	No data/recommendation	No data/recommendation	No data/recommendation	No data/recommendation
Vaginal ring segesterone/ethinyl estradiol	No dose adjustment needed	Use alternative	Use alternative	Use alternative	Use alternative	Use alternative	Use alternative	Use alternative	No dose adjustment needed	No dose adjustment needed	No data/recommendation	No data/recommendation	No data/recommendation	No data/recommendation
Vaginal ring etonogestrel/ethinyl estradiol	No dose adjustment needed	No dose adjustment needed	No data/recommendation	No data/recommendation	No data/recommendation	Use alternative	No data/recommendation	No data/recommendation	No dose adjustment needed	No dose adjustment needed	No data/recommendation	No data/recommendation	No data/recommendation	No data/recommendation
DMPA injectable	No dose adjustment needed	No dose adjustment needed	No dose adjustment needed	No dose adjustment needed	No dose adjustment needed	No dose adjustment needed	No dose adjustment needed	No dose adjustment needed	No dose adjustment needed	No dose adjustment needed	No data/recommendation	No data/recommendation	No data/recommendation	No data/recommendation



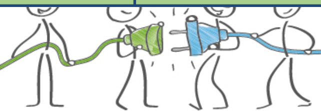
US DHHS ART Guidelines. 2019.

Drug – Drug Interactions Between Nonoral Hormonal Contraceptives and ARVs

No interaction expected (green) | Potential weak interaction (yellow) | Potential interaction (orange)

Contraceptive	BIC/FTC/TAF	DTG	EVG/COBI/ FTC/TAF	RAL
Etonogestrel (implant)	No interaction expected	No interaction expected	Potential weak interaction	No interaction expected
Etonogestrel (vaginal ring)	No interaction expected	No interaction expected	Potential interaction	No interaction expected
Levonorgestrel (implant)	No interaction expected	No interaction expected	Potential weak interaction	No interaction expected
Levonorgestrel (IUD)	No interaction expected	No interaction expected	No interaction expected	No interaction expected
Medroxyprogesterone (depot injection)	No interaction expected	No interaction expected	No interaction expected	No interaction expected
Norelgestromin (patch)	No interaction expected	No interaction expected	Potential weak interaction	No interaction expected
Norethisterone [norethindrone] (IM depot injection)	No interaction expected	No interaction expected	No interaction expected	No interaction expected

University of Liverpool. HIV drug interactions. https://www.hiv-druginteractions.org



DHHS Recommendations Before Initiating an INSTI in Person of Childbearing Potential

- *"To enable individuals of childbearing potential to make informed decisions, providers should discuss the benefits and risks of using DTG around the time of conception, including the low risk of NTDs and the relative lack of information on the safety of using other commonly prescribed ARV drugs, including other INSTIs, around the time of conception"*

Persons of Childbearing Potential Who Are Trying to Conceive

- Initiate a regimen preferred during pregnancy: RAL, ATV/RTV, or DRV/RTV + TDF/FTC, TDF/3TC, or ABC/3TC
- DTG would be an Alternative, rather than a Preferred, option
- EVG/COBI should not be used during pregnancy because of inadequate drug concentrations in the second and third trimesters
- Insufficient data on TAF in pregnancy

DHHS Guidelines. December 2019.

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NEWS RELEASES

Media Advisory Thursday, December 19, 2019

Many pregnant women with HIV prescribed treatment that does not meet federal guidelines

What

More than 20% of pregnant women beginning ar
federal guidelines for use during pregnancy, acc
Kathleen M. Powis, M.D., of Massachusetts Gener

The researchers analyzed data on women enrolle
Children Born to HIV Infected Women (SMARTT) s
HIV during pregnancy or at delivery. They compa
Prevention's treatment guidelines pdf, which cla
concerns in pregnancy), insufficient data for use

Of 1,867 women who began anti-HIV treatment b
or alternative. Another 492 (26.4%) were prescrib
recommended for use during pregnancy. Of 452
therapies with insufficient data or that were not r
why prescribing practices for pregnant women living

Institute/Center

Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)

Contact

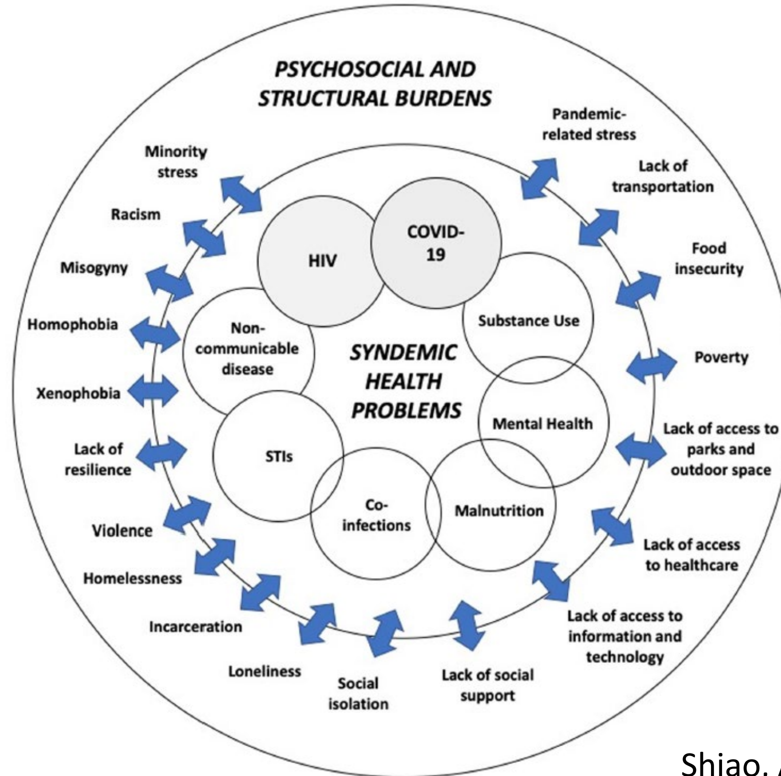
SMARTT Study 2008-2017 (18 US research hospitals)

- Only 49.5% of 1867 pregnancies among 1582 women receiving ART during pregnancy were associated with prescribed regimens listed as preferred or alternative by guidelines
- 26.4% involved regimens with insufficient data
- 7.3% involved regimens not recommended for use during pregnancy
- 20.1% of 452 women who began treatment during pregnancy were prescribed therapies with insufficient data or not recommended

Powis. JAMA Netw Open. 2019;2:e1917669.

Syndemic conceptualization of HIV and COVD-19 coinfection

A syndemic is defined as two or more epidemics interacting synergically to produce an increased burden of disease in a population



Shiao, AIDS &Behaviour 2019

Social responses to COVID-19 adversely impacted the health care of people living with HIV

Health Resources	Less COVID-19 Protective Actions (N = 65) N	%	Greater COVID-19 Protective Actions (N = 97) N	%	χ^2
Unstable housing	38	58	49	51	2.3
Unable to get food due to COVID-19	20	31	45	46	3.9†
Not food insecure at baseline	0		5	22	
Food insecure at baseline	20	36	40	54	
Did not attend a scheduled HIV care appointment.	14	21	17	17	0.4
Medical provider closed or canceled appointment because of the coronavirus.	25	39	48	49	1.5
Service provider closed or canceled appointment because of the coronavirus.	16	25	49	50	10.5‡
Unable to get to a pharmacy because of the new coronavirus	4	6	21	22	7.0‡
Unable to get to medicine you need because of the coronavirus.	2	3	21	21	10.8‡

Health Resources	M	SD	M	SD	t
Concerned about contracting coronavirus*	33.6	34.1	64.3	36.5	5.3‡
Number of COVID-19 severity risks	2.0	1.2	2.2	1.2	1.1
ART adherence the previous month	53.6	11.2	52.3	13.2	0.6
ART adherence during COVID-19 response	76.3	24.4	78.5	22.3	0.5

*100-point rating scale, 0 = not at all concerned and 100 = extremely concerned.
†$P < 0.05$.
‡$P < 0.01$.

Kalichman , J Acquir Immune Defic Syndr 2020

Protective behaviours against COVID-19 are different according to gender

Protective Behaviors	Men (N =118) N	Men %	Women (N = 44) N	Women %	χ^2
Staying indoors way from public places.	98	83	42	96	4.2†
Canceled plans that involve other people.	77	65	33	75	1.4
Canceled a clinic or doctor's appointment to avoid being around others.	14	12	15	34	10.7‡
Asked others to stay away to avoid getting the coronavirus.	63	53	27	61	0.8
Avoided the public transportation because of the coronavirus.	60	55	23	53	0.1
COVID-19 protective behaviors practiced					
0	9	8	2	5	15.4‡
1	19	16	5	11	
2	19	16	8	18	
3	33	28	4	9	
4	26	22	12	27	
5	12	10	13	30	

Protective Behaviors	Men M	Men SD	Women M	Women SD	*t*
Aggregate number of COVID-19 protective behaviors	2.7	1.5	3.5	1.8	2.6‡
Concern about contracting coronavirus*	52.3	38.3	53.9	39.7	0.2

*100-point rating scale, 0 = not at all concerned and 100 = extremely concerned.
†$P < 0.05$.
‡$P < 0.01$.

Kalichman , J Acquir Immune Defic Syndr 2020

Comprehensive Care is Essential for HIV continuum of care in Women of Childbearing Age

- Integration of sexual and reproductive health services into HIV care provides a more holistic approach
- ART is essential for women's health and public health (U = U)
- ART selection recommendations are straightforward, but patient counseling needed on latest data and risk-benefit considerations
- Contraception of various modalities (including long-acting reversible) highly effective and safe in women with HIV
- PREP as tool for comprehensive prevention approach