In Case You Missed It: Updates from Recent Publications and Meetings

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Learning Objectives

After attending this presentation, learners will be able to:

- Describe the clinical presentation of mpox virus infection
- Outline new findings on complications of antiretroviral therapy
- Describe new data on management of co-infections and prevention of sexually transmitted infections
- Discuss key new findings on COVID-19 prevention in HIV

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Outline

1. Mpox Overview:
   a. Update on clinical presentation
   b. Vaccine Effectiveness
   c. Management Considerations in PWH
2. Non-AIDS Complications:
   a. Trends in 2022; Incidence in individuals with spontaneous control of HIV
   b. INSTIs, weight gain and cardiometabolic outcomes.
3. HIV Therapy and Cure agenda:
   a. DTG vs. Boosted PI in NNRTI Failure
   b. Disappointing results of VRC-01?
4. Coinfections:
   a. TDF vs. TAF in HBV/HIV Co-infected.
   b. PrEP and PEP: Disparities, STIs and Doxycycline PEP
5. COVID-19
   a. Outcomes in PWH.
   b. Impact of Omicron subvariants on treatment and preventive options.

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Mpox: Clinical Presentation Update

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Monkeypox Virus Infection in Humans

ac

tinents:
6% on ART, 95% with
nm3).
those with and without

Morbidity and Mortality Weekly Report

Epidemiologic and Clinical Characteristics of Monkeypox Cases — United States, May 17–July 22, 2022

- Concomitan

- Three people
- epiglottitis in
- person living

https://www.nejm.or

Clinical features and management of human monkeypox: a retrospective observational study in the UK

Hugh Adler, Susan Gould, Paul Hine, Luke B Snell, Waison Wong, Catherine F Houlihan, Jane C Osborne, Tommy Rampling, Mike BJ Beadsworth, Christopher JA Duncan, Jake Dunning, Tom E Fletcher, Ewan R Hunter, Michael Jacobs, Saye H Khoo, William Newsholme, David Porter, Robert J Porter, Libuse Ratcliffe, Matthias L Schmid, Malcolm G Semple, Anne J Tunbridge, Tom Wingfield*, Nicholas M Price* on behalf of the NHS England High Consequence Infectious Diseases (Airborne) Network†

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Mpox: How Common is Asymptomatic Infection?

- Sexual health clinic in Paris, France: PWH and on PrEP (June-July 2022)
- Anal swabs routinely collected for STI surveillance and negative for *Neisseria gonorrhea* and *Chlamydia trachomatis* were tested for MPX.

Table. Screening for Sexually Transmitted Infections and MPXV Infection in 706 MSM Visiting the Sexual Health Clinic Between 5 June and 11 July 2022

Variable	MSM With No Symptoms of MPXV Infection	MSM With Symptoms Suggesting MPXV Infection
Total number of MSM visiting between 5 June and 11 July 2022	323	383
C trachomatis infections detected on anal swab, *n/N (%)*	32/323 (9.9)	Not tested
N gonorrhoeae infections detected on anal swab, *n/N (%)*	24/323 (7.4)	Not tested
C trachomatis and *N gonorrhoeae* co-infection detected on anal swab, *n/N (%)*	8/323 (2.5)	Not tested
C trachomatis infections detected on first-void urine sample or urethral swab, *n/N (%)*	6/323 (1.9)	Not tested
N gonorrhoeae infections detected on first-void urine sample or urethral swab, *n/N (%)*	3/323 (0.9)	Not tested
C trachomatis and *N gonorrhoeae* co-infection detected on first-void urine sample or urethral swab, *n/N (%)*	1/323 (0.3)	Not tested
MPXV-positive test result, *n/N (%)*	13/200* (6.5)	271/383 (71)

C trachomatis = *Chlamydia trachomatis*; MPXV = monkeypox virus; MSM = men who have sex with men; *N gonorrhoeae* = *Neisseria gonorrhoeae*.
* All 200 of the asymptomatic participants who were tested for MPXV were negative for both *C trachomatis* and *N gonorrhoeae* on anal swab.

- 2 of these 13 patients later presented with symptoms c/w MPX infection.

Slide 6 Ferré VM et al. Ann Intern Med 2022 Aug 16

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Mpox: Clinical Presentation Update

- During the current global outbreak:
  - Lesions often occur in the genital and anorectal areas or mouth.
  - Rash is not always disseminated across many sites on the body.
  - Rash may be confined to only a few lesions or a single lesion.
  - Rash does not always appear on palms and soles.
- Rectal symptoms (e.g., purulent or bloody stools, rectal pain, or rectal bleeding) have been frequently reported in current outbreak.
- Lesions are often described as painful until the healing phase when they become itchy (crusts).
- Fever and other prodromal symptoms (e.g., chills, lymphadenopathy, malaise, myalgias, or headache) can occur before rash but may occur after rash or not be present at all.
- Respiratory symptoms (e.g. sore throat, nasal congestion, or cough) can occur.

Slide 7 Clinical Recognition | Monkeypox | Poxvirus | CDC

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Management Considerations in PWH

- People with advanced HIV or who are not virologically suppressed with antiretroviral therapy can be at increased risk of severe disease with mpox (CDC Health Alert Network September 29, 2022)
- Post-exposure prophylaxis and antiviral treatments are available for people exposed to mpox or with mpox virus infection.
- Tecovirimat may result in a reduction in levels of NNRTIs doravirine and rilpivirine, and the CCR5 antagonist maraviroc.
  - No evidence that dose adjustment is necessary
  - Avoid initiating CAB/RPV during TPOXX therapy
- Vaccination with JYNNEOS is considered safe for people with HIV.
- ACAM2000 should not be given to people with HIV

Slide 8

Https://www.cdc.gov/poxvirus/monkeypox/clinicians/people-with-HIV.html
Liverpool HIV Interactions (hiv-druginteractions.org)

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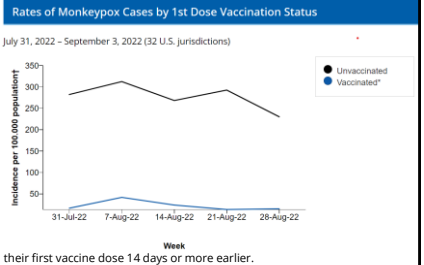
Mpox Vaccine Effectiveness

- **Unvaccinated people had 14** times the risk of monkeypox disease compared to people who were vaccinated*



*Those who had received their first vaccine dose 14 days or more earlier.

. https://www.cdc.gov/poxvirus/monkeypox/cases-data/mpx-vaccine-effectiveness.html

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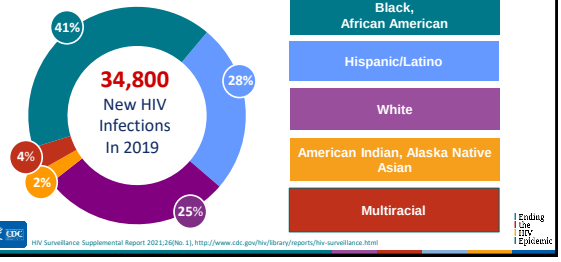
Black/African American and Hispanic/Latino Account for Majority of New HIV Infections



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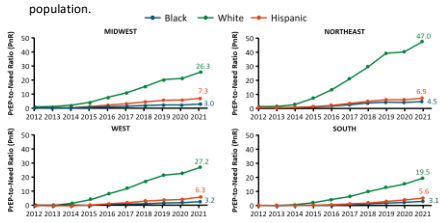
Unmet Needs in PrEP and PEP: Inequity…

The PrEP-to-Need Ratio (PnR) is the number of PrEP users divided by the number of new diagnoses in a given year. PnR serves as measurement of how PrEP use compares to the need for PrEP in a population.



PnR gap increased over time in all regions, but was highest for White and lowest for Black people

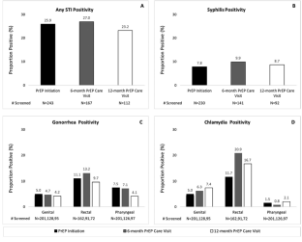
So, racial gap continues to widen…

Slide 11 Sullivan. AIDS 2022. Abstr OALBX0106

11

Unmet Needs in PrEP and PEP: What about STIs?:

- High incidence of STIs in PrEP recipients. Effectiveness of screening has been limited. IMPACT Partner Collaborative.
- Among 290 MSM initiating PrEP, 43.1% (n = 125) were screened per guidelines at PrEP initiation
- 25% with at least one STI



Schumacher. Clin Infect Dis. 2020 Dec 17;71(10):2637-2644.

Slide 12

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Unmet Needs in PrEP and PEP: What about STIs?:

- MSM/TGW with HIV or on PrEP. Had STI in past year.
- Randomized 2:1 to 200 mg doxycycline within 72 hours of condomless sex or no doxycycline with STI testing at enrollment, quarterly, and when symptomatic
- Quarterly STI incidence by HIV Status:

	HIV uninfected MSM/TGW on PrEP		MSM/TGW living with HIV	
	Doxy arm N=240	Control arm N=120	Doxy arm N=134	Control arm N=60
Follow up quarters	491	220	266	108
Participants with an incident STI (GC, CT or syphilis)	41	42	24	18
Primary STI endpoints	47 (9.6%)	65 (29.5%)	31 (11.7%)	30 (27.8%)
Gonorrhea	40 (8.1%)	45 (20.5%)	21 (7.9%)	20 (18.5%)
Chlamydia	7 (1.4%)	23 (10.5%)	12 (4.5%)	16 (14.8%)
Syphilis	1 (0.2%)	5 (2.3%)	3 (1.1%)	2 (1.9%)

Risk Reduction in STI Incidence per Quarter (95% CI)	Doxy PEP*
PrEP	0.34 (0.24-0.46)
PWH	0.38 (0.24-0.60)
Total	0.35 (0.27-0.46)

*All $P < .0001$

Risk Reduction per Quarter (95% CI)	PrEP	PWH
Gonorrhea	0.45 (0.32-0.65) $P < .0001$	0.43 (0.26-0.71) $P = .001$
Chlamydia	0.12 (0.05-0.25) $P < .0001$	0.26 (0.12-0.57) $P = .0007$
Syphilis	0.13 (0.03-0.59) $P = .0084$	0.23 (0.04-1.29) $P = .095$

Slide 13 Luetkemeyer A et al. AIDS 2022. Abstract OALBX0103

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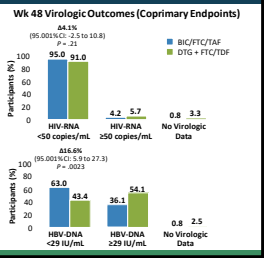
ALLIANCE: BIC/FTC/TAF vs. DTG + FTC/TDF in HIV/HBV

- Adults with HIV/HBV coinfection, Rx-naive for both, with HIV-1 RNA ≥500 copies/mL, HBV DNA ≥2000 IU/mL; HIV genotypic sensitivity to FTC and TFV; $eGFR_{CG}$ ≥50 mL/min (N = 243)
- Secondary endpoints at Week 48:

	BIC/FTC/TAF	DTG + FTC/TDF
ALT Normalization	73.3%	55.3%
HBsAg loss	12.6%	5.8%
HBeAg loss	25.6%	14.4%

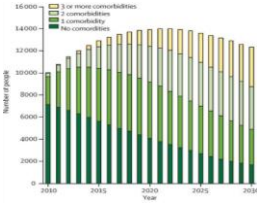


Slide 14 Avihingsanon. AIDS 2022. Abstr OALBX0105.

14

Unmet Needs?: Improving Survival in PWH on ART → Prevention of NCDs

- Predicted burden of non-communicable diseases (NCDs) in HIV patients modeled for 2010-2030
- Increasing proportion with more NCDs over time
- NCDs include
  - Cardiovascular disease (hypertension, hypercholesterolemia, myocardial infarction, stroke)
  - Diabetes
  - Chronic kidney disease
  - Osteoporosis
  - Non-AIDS malignancies

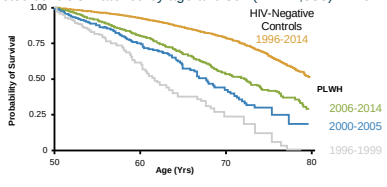


Slide 15 Smit Lancet ID 2015.

15

Decreased Life Expectancy in Older Adults with HIV in Modern ART Era

- Population-based cohort study of survival in HIV-infected pts (n = 2440) and uninfected controls matched by age and sex (n = 14,588) in Denmark



Slide 16 Legarth RA, et al. J Acquir Immune Defic Syndr. 2016;71:213-218.

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Pathogenesis of Chronic Complications of HIV Infection

#1: THE PATIENT
- **Individual and social factors**
- **Higher rate of traditional risk factors: smoking, dyslipidemia, HTN, diabetes, obesity**

Metabolic Complications:
Cardiovascular Disease
Renal Disease
Osteoporosis
Non-AIDS Cancers

#2: THE VIRUS(ES)
- **HIV infection itself**
- **Inflammation and immune activation**
- **Coinfections: HCV**

#3: THE TREATMENT
- **ART and toxicity**

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#2: THE VIRUS(ES)

Non-AIDS-events in individuals with spontaneous control of HIV-1

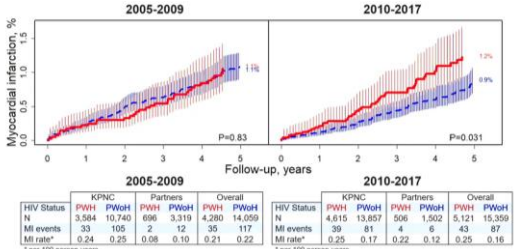
- Systematic Review: 12 studies were included: Five cohorts, two cross-sectional prevalence studies, four cross-sectional imaging studies and one case series.
- Four of five cohort studies showed that spontaneous controllers have a similar risk to develop nADEs compared with PLHIV on suppressive ART:
  - Specifically cardiovascular events, non-AIDS-malignancies, hepatic disease and bacterial pneumonia.
- Cross-sectional imaging studies showed a higher presence of subclinical cardiovascular disease in spontaneous controllers, like in PLHIV on ART, than in people without HIV.

Slide 18

Groenendijk AL. J Acquir Immune Defic Syndr. 2022 Aug 15.

18

Cumulative incidence of MI by HIV status:



2005-2009	KPNC		Partners		Overall	
HIV Status	PWH	PWoH	PWH	PWoH	PWH	PWoH
N	3,584	10,740	696	3,319	4,280	14,059
MI events	33	105	2	12	35	117
MI rate*	0.24	0.25	0.08	0.10	0.21	0.22

* per 100 person-years

2010-2017	KPNC		Partners		Overall	
HIV Status	PWH	PWoH	PWH	PWoH	PWH	PWoH
N	4,615	13,857	506	1,502	5,121	15,359
MI events	39	81	4	6	43	87
MI rate*	0.25	0.17	0.22	0.12	0.25	0.16

* per 100 person-years

Silverberg M. Trends In Myocardial Infarction Risk By HIV Status In Two Us Healthcare Systems. CROI 2022; Abstract 39)
Slide 19

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#2: THE VIRUS(ES)
CVD Risk with HIV/HCV Co-Infection

- Data from NA-ACCORD: January 1, 2000, to December 31, 2017, PWH (aged 40–79years) who had initiated antiretroviral therapy.
- The primary outcome was an adjudicated T1MI event.
- Among 23361 PWH, 4677 (20%) had HCV.
- No association b/w HCV coinfection with increased T1MI risk
- However, greater increase in T1MI with age in co-infected. Adjusted hazard ratio per 10-year increase in age :
  - Without HCV co-infection: 1.30 (95% CI, 1.13–1.50
  - With HCV Co-infection: 1.85 (95% CI, 1.38–2.48)
  - P<0.001, test of interaction

Slide 20

Lang. J Am Heart Assoc. 2022;11:e026473

20

CVD Risk with HIV/HCV Co-Infection

Table 2. Crude and Adjusted Hazard Ratios of Risk Factors Associated With Myocardial Infarction Among People With HIV in NA-ACCORD (N=23 361)

	cHR		aHR with no interaction term		aHR with interaction term b/w age and HCV	
Characteristic	cHR	95% CI	*aHR	95% CI	†aHR	95% CI
Age (per 10-y increase)	1.71	1.52–1.92	1.38	1.21–1.57	…	…
Per 10-y increase in age among HCV negative	…	…	…	…	1.30	1.13–1.50
Per 10-y increase in age among HCV positive	…	…	…	…	1.85	1.38–2.48
Hepatitis C infection	1.09	0.86–1.38	0.98	0.74–1.30	…	…

Slide 21

Lang. J Am Heart Assoc. 2022;11:e026473

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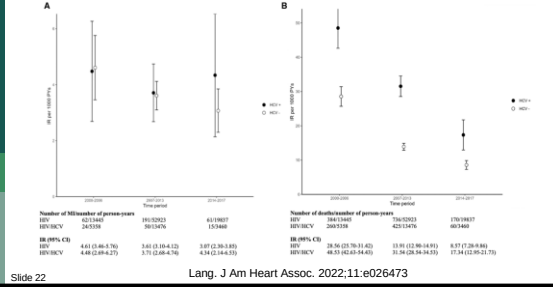
CVD Risk with HIV/HCV Co-Infection



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Lang. J Am Heart Assoc. 2022;11:e026473

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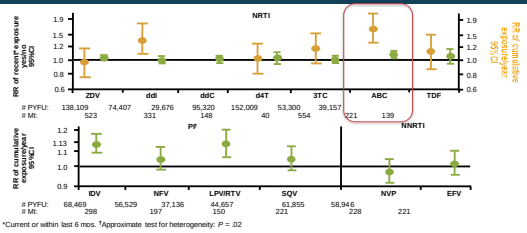
D:A:D: Recent and/or Cumulative ARV Exposure and Risk of MI



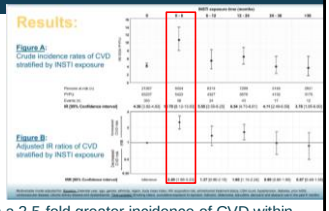
*Current or within last 6 mos. †Approximate test for heterogeneity: $P = .02$

Slide 23 Lundgren JD, et al. CROI 2009. Abstract 44LB.

23

RESPOND: INSTIs and CVD Risk

- International collaboration of 17 cohorts
- Composite endpoint of MI, stroke and invasive cardiovascular procedure; adjudicated events
- N=21267 (46% exposed to INSTI)
- 517 CVD events, 4.9/1000 PY
- Could not specifically examine ART-naive



- INSTI exposure associated with a 2.5-fold greater incidence of CVD within first 6 months of exposure compared to no exposure in adjusted analyses

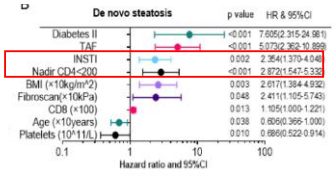
Slide 24 Neesgaard et al. vCROI 2021, abstract 488; *Lancet HIV* 2022 Jun 7; [e-pub].

24

De-Novo Hepatic Steatosis with Weight Gain After ART Initiation

- Exposure to TAF and INSTIs associated with de novo steatosis.

- Prospective cohort of 319 HIV mono-infected on ART;
  - 155 (52%) with no b/l steatosis → 69 (45%) developed steatosis on f/u
- BMI of >23 kg/m^2 for males is significantly associated with development of de-novo steatosis (68% risk vs. 25% for females)
- TDF associated with lower risk of de-novo steatosis.



Bischoff. EClinicalMedicine 2021 Sept 5;40:101116

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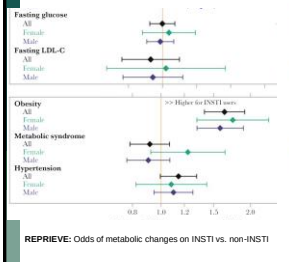
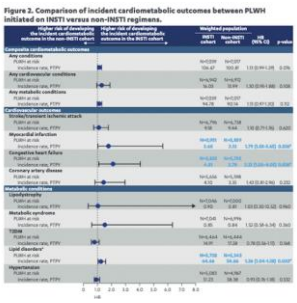
Metabolic Risks of INSTI?



REPRIEVE: Odds of metabolic changes on INSTI vs. non-INSTI



Slide 26

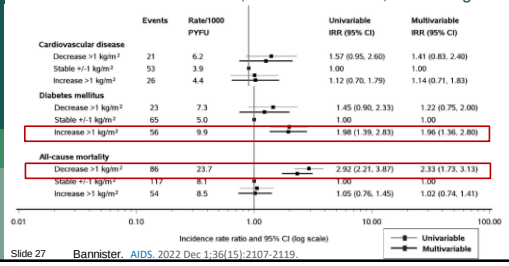
Kileel. OFID; 2021 Nov 20;8(12):ofab537

Rebeiro. AIDS 2022, Abstract EPB108.

26

Change in BMI and Clinical Outcomes - EuroSIDA

- 6721 PWH were included; 72.3% were male, median age 48 years



Slide 27

Bannister. AIDS. 2022 Dec 1;36(15):2107-2119.

27

DTG vs. Boosted PI in NNRTI-Experienced

- Meta-analysis of 4 RCTs of second-line Rx of NNRTI experienced

2662 participants:
- VISEND (n=783),
- DAWNING (n=624),
- NADIA (n=464),
- 2SD (n=791)

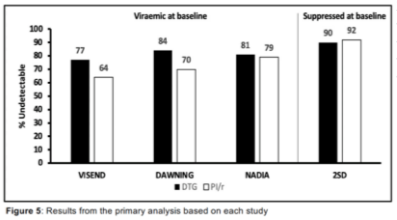


Figure 5: Results from the primary analysis based on each study

Slide 28

Mirchandani. HIV Drug Therapy Glasgow, October 23-26, 2022. Abstract P062.

28

IMPAACT 2008: Safety and Efficacy of VRC01

- Infants with HIV aged 72 hr to ≤84 days who started ART ≤14 days prior to study entry (n=61).
- Randomized to VRC01 + ART vs. ART alone
  - VRC01 dosed 40 mg/kg SC at Wk 0, 2, 6, and 10
- VRC01 was well tolerated, but had no apparent effect on HIV-1 RNA or HIV-1 DNA levels at Wk 14
- Pretreatment VRC01 resistance was common
- VRC01 plasma levels were lower and more variable than predicted by previous studies of HIV-exposed uninfected infants
- Post-hoc analysis: higher VRC01 concentrations correlated with larger reductions in HIV-1 DNA from Wk 0-14 (Spearman correlation -0.42)

HIV-1 DNA Level	VRC01 + ART	ART Only	*P* Value
Median change at Wk 14 vs Wk 0, log_{10} copies/million PBMCs (IQR)	-0.41 (-0.94 to -0.30)	-0.53 (-0.70 to -0.33)	.42

Slide 29 Khaitan. AIDS 2022. Abstr OALBB0102.

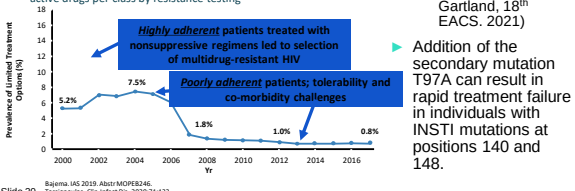
29

Heavily Treatment–Experienced Patients With Multiclass Resistance/Limited Treatment Options

- Caution about partial sensitivity to DTG at baseline; e.g. prior exposure to RAL
  - (BRIGHTE. Gartland, 18th EACS. 2021)
- Addition of the secondary mutation T97A can result in rapid treatment failure in individuals with INSTI mutations at positions 140 and 148.

•CNICS cohort of > 26,000 ART-experienced people with HIV receiving care in the US

•Limited treatment options defined as ≤ 2 available classes with ≤ 2 active drugs per class by resistance testing

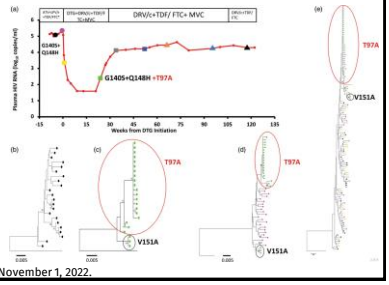


Slide 30 Bajema. IAS 2019. Abstr MOPE8246. Tasiopoulos. Clin Infect Dis. 2020;71:133.

30

Emergence of High Level DTG Resistance

- Case report of emergence of T97A-containing HIV from a large replicating population.
- T97A-containing variants spread by replication and recombination, and persisted for months after discontinuing DTG



Slide 31 AIDS. 36(13):1835-1840, November 1, 2022.

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Management of Heavily Treatment Experienced Patients

- Use of new drugs with a novel mechanism of action and no cross-resistance[1]
  - Ibalizumab
  - Fostemsavir
- Use of drugs in existing drug classes predicted to be fully active[1]
  - INSTI: dolutegravir BID (history of INSTI mutations)*
- Use of drugs in existing drug classes that may have residual activity[1]
  - PI: various drugs (dependent on phenotypic susceptibility)
  - Consider NRTIs

*Limited data in settings with high-level resistance but no Q148H mutation.[2]

Slide 32 1. DHHS ART Guidelines. June 2021. 2. Castagna. J Infect Dis. 2014;210:354.

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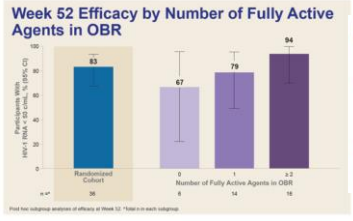
Lenacapavir in Heavily Treatment Experienced: CAPELLA Week 52



Conclusions

- In PWH who were HTE with limited treatment options due to MDR, LEN in combination with an OBR led to high rates of virologic suppression
- No clinically relevant differences were seen in efficacy among subgroups who were considered more difficult to treat (eg, those with high HIV-1 RNA, low CD4 count, INSTI resistance, no fully active agents in the OBR, or no DTG or DRV in the OBR)
- LEN has the potential to become an important agent for PWH who are HTE with MDR
- These data support the ongoing evaluation of LEN for treatment and prevention of HIV

Slide 33 Castagna. HIV Glasgow 2022, 23-26 Oct, Glasgow, UK

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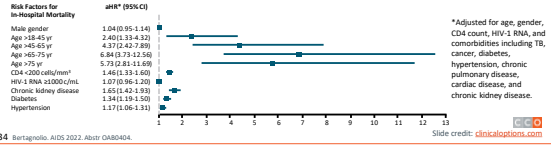
In-Hospital Mortality From COVID-19 Among PWH: Study Population, Methods, and Risk Factors

- WHO online platform for HCP-submitted electronic reports of hospitalized COVID-19 cases
  - 362,941 patient reports from 42 countries (96.8% in Africa); 8.2% (29,530) PWH
- Multivariable regression to determine risk of 21-day in-hospital mortality from COVID-19
- 59% PWH had ≥1 underlying condition vs 45% without HIV (P <.0001)
  - Among PWH: 52% had 1-2 underlying conditions; 7.1% had ≥3 underlying conditions



*Adjusted for age, gender, CD4 count, HIV-1 RNA, and comorbidities including TB, cancer, diabetes, hypertension, chronic pulmonary disease, cardiac disease, and chronic kidney disease.

Slide credit: clinicaloptions.com

Slide 34 Bertagnollo. AIDS 2022. Abstr OA80404.

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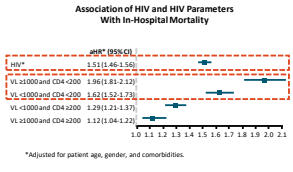
Risk of In-Hospital Mortality by HIV Factors and Differential Impact of COVID-19 Variant on Mortality



Mortality	Delta (Aug 2 - Oct 3, 2021)	Omicron (Nov 15, 2021 - May 26, 2022)	Absolute Difference With Delta vs Omicron, % (95% CI)	*P* Value
Without HIV	19.4%	8.1%	13.0 (12.5-13.6)	<.0001
With HIV	21.8%	17.6%	4.8 (3.1-6.5)	<.0001
Adjusted HR With vs Without HIV (95% CI)	1.55 (1.43-1.674)	2.47 (2.27-2.68)		

- Analysis did not account for COVID-19 vaccination status, prior COVID-19, BMI, or patient-level variant data

Slide 35 Bertagnolio. AIDS 2022. Abstr OAB0404.

Slide credit: clinicaloptions.com

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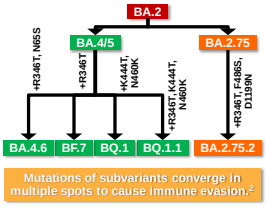
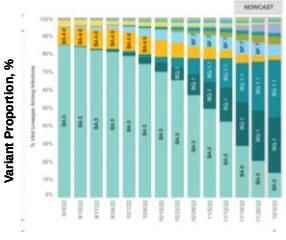
The Rise of Novel Omicron Subvariants

Lineage of Emerging Subvariants[1]



Novel Omicron Subvariants in the US[3]



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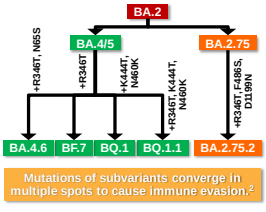
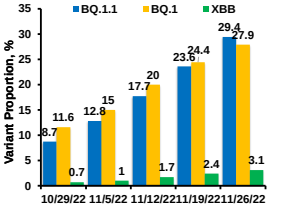
The Rise of Novel Omicron Subvariants

Lineage of Emerging Subvariants[1]



Novel Omicron Subvariants in the US[3]



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Transmissibility and Neutralization Escape of Novel Omicron Subvariants

- Increased transmissibility of BQ.1, BQ.1.1, and BA.2.75.2 due to mutations and high degree of neutralization resistance[1]
- BN.1 is being monitored by the CDC and is a descendent from BA.2[2]
  - High potential to be immune evasive
- XBB, BQ.1, and BQ.1.1 show strongest resistance to current anti-SARS-CoV-2 mAbs[3]
- Unclear whether symptoms will be more severe[3]

Improvement in mRNA Bivalent Vaccine Neutralization for Wild Type and Omicron Subvariants[4]

Subvariant	Rise in Vaccine Neutralizing Titer
WT	5.8-fold
BA.4/5	13-fold
BA.4.6	11.1-fold
BA.2.75.2	6.7-fold
BQ.1.1	8.7-fold
XBB	4.8-fold

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Effectiveness of Bivalent mRNA Vaccines in Preventing Symptomatic SARS-CoV-2 Infection

- Protection against symptomatic SARS-CoV-2 infection during circulation of BA.4/BA.5 and their sublineages
- Restoration of waning protection after monovalent vaccine. Caveat: . Most tests (81%) in this study were conducted during a period of BA.4/BA.5 predominance.

Age group, yrs	Absolute VE (95% CI), by no. of monovalent doses received before the bivalent vaccine dose			
	2 doses	3 doses	4 doses*	≥2 doses
18–49	41 (31–49)	43 (39–46)	NA	43 (39–46)
50–64	50 (35–61)	25 (17–33)	28 (20–34)	28 (22–33)
≥65	32 (9–49)	19 (8–29)	23 (15–30)	22 (15–29)

Age group, yrs/mos since receipt of most recent monovalent dose	Relative VE (95% CI), by no. of monovalent doses received†			
	2 doses	3 doses	4 doses§	≥2 doses
≥65				
2–3	—	—	32 (23–40)	28 (19–35)
4–5	—	21 (1–36)	36 (29–42)	33 (27–39)
6–7	—	14 (–6–30)	40 (33–46)	36 (29–41)
≥8	45 (27–58)	42 (35–48)	NA	43 (39–46)

Slide 39 Link-Gelles. MMWR / December 2, 2022 / Vol. 71 / No. 48

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TIX + CIL Susceptibility to Omicron Subvariants

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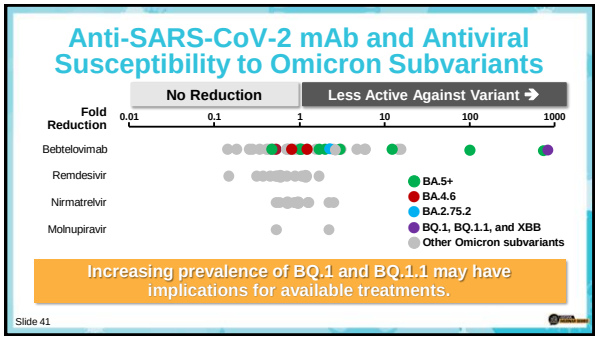
Anti-SARS-CoV-2 mAb and Antiviral Susceptibility to Omicron Subvariants
No Reduction
Less Active Against Variant
Fold Reduction
0.01
0.1
1
10
100
1000
Bebtelovimab
Remdesivir
Nirmatrelvir
Molnupiravir
BA.5+
BA.4.6
BA.2.75.2
BQ.1, BQ.1.1, and XBB
Other Omicron subvariants
Increasing prevalence of BQ.1 and BQ.1.1 may have implications for available treatments.
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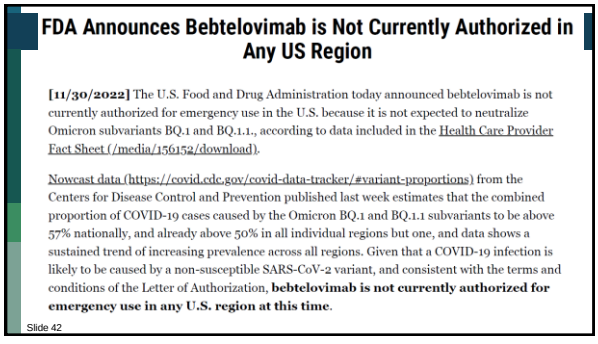
FDA Announces Bebtelovimab is Not Currently Authorized in Any US Region
[11/30/2022] The U.S. Food and Drug Administration today announced bebtelovimab is not currently authorized for emergency use in the U.S. because it is not expected to neutralize Omicron subvariants BQ.1 and BQ.1.1., according to data included in the Health Care Provider Fact Sheet (/media/156152/download).
Nowcast data (https://covid.cdc.gov/covid-data-tracker/#variant-proportions) from the Centers for Disease Control and Prevention published last week estimates that the combined proportion of COVID-19 cases caused by the Omicron BQ.1 and BQ.1.1 subvariants to be above 57% nationally, and already above 50% in all individual regions but one, and data shows a sustained trend of increasing prevalence across all regions. Given that a COVID-19 infection is likely to be caused by a non-susceptible SARS-CoV-2 variant, and consistent with the terms and conditions of the Letter of Authorization, bebtelovimab is not currently authorized for emergency use in any U.S. region at this time.
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Question-and-Answer Session

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