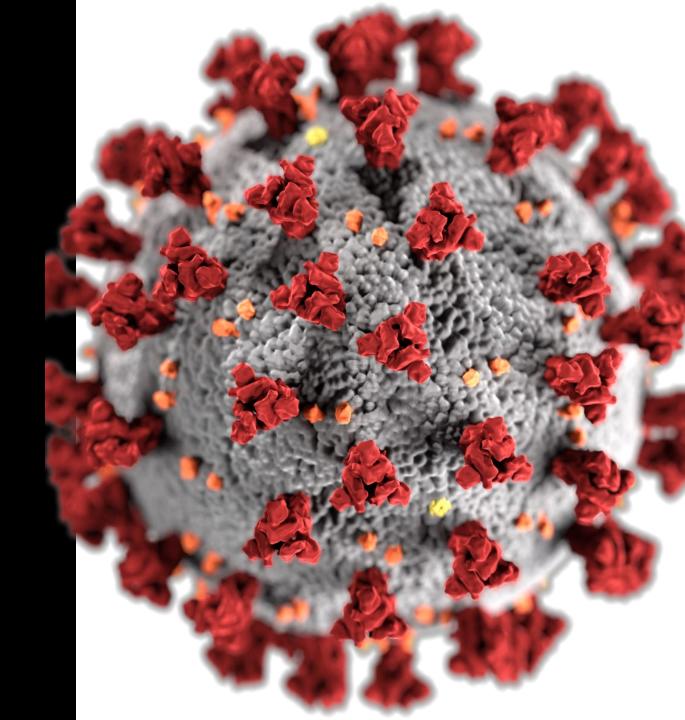
SARS-CoV-2, in Persons Living With HIV

Celestine N. Wanjalla, M.D. Ph.D. SE AETC
July 22nd, 2020



Disclosures

I have no disclosures



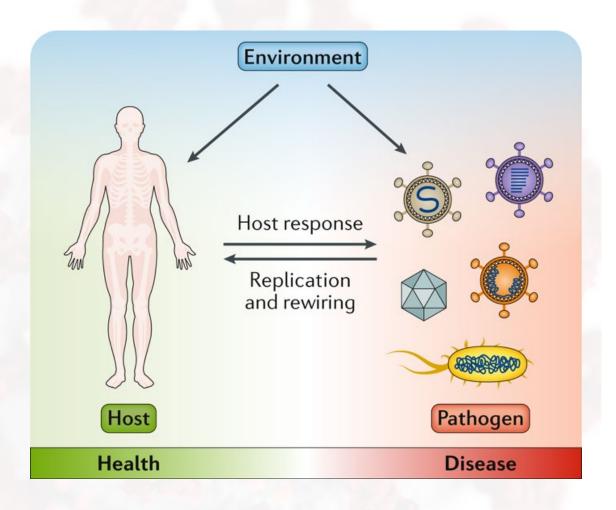
Key points

- Persons Living with HIV infected with SARS-CoV2 have similar symptoms as HIV-negative persons
- There is a fine balance between the host and pathogen response
- Severe COVID-19 is a manifestation immune imbalance
- Lymphopenia predicts severe disease even in persons living with HIV
- There has been no evidence to suggest that HIV-positive are at higher risk of mortality than HIV-negative individuals
- Remdesivir can be given along with ART therapies
- Possible role of ART in SARS-CoV2

Outline

- SARS-CoV2 and the immune system
- Sum of consecutive cases of COVID-19 in PLWH from different published case reports/series
 - Comorbidities
 - CD4 counts and viral load
 - Outcomes
 - Long-term sequelae
 - Mental health
 - ART: To switch or not to switch?
- ART and SARS-CoV2
 - What about patients on PrEP?
- Vaccines
 - Moderna
- Future studies

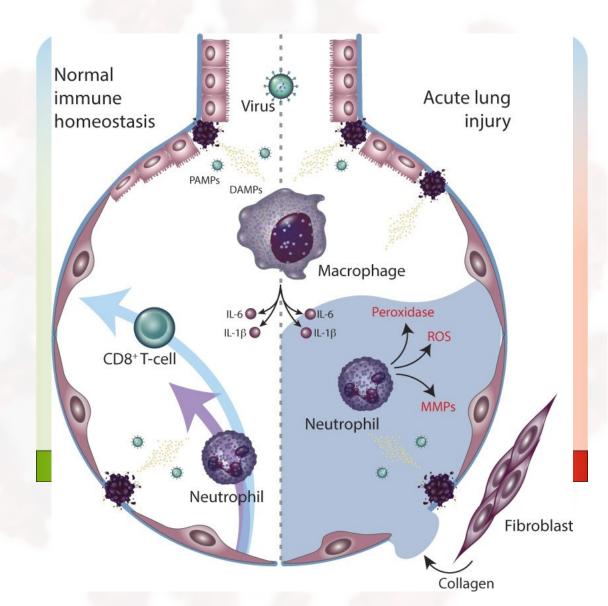
Intricate relationships between the host and pathogen dictate the outcome of infections

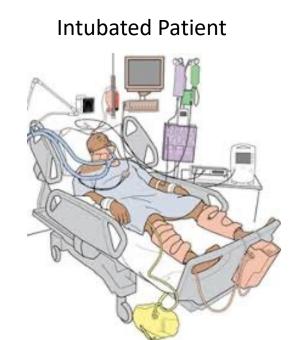




SARS-CoV-2 immune responses and clinical outcomes





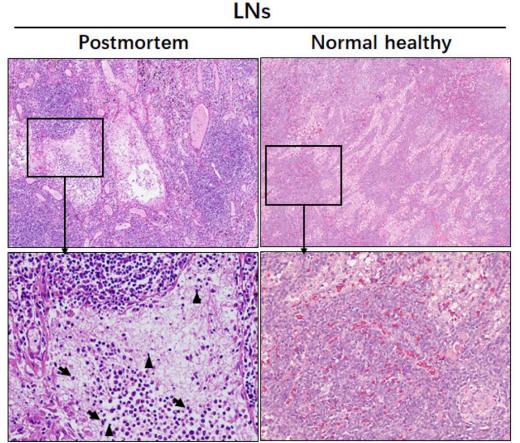


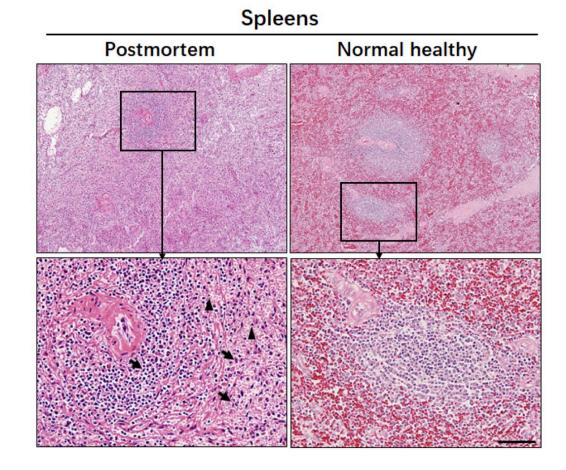


SARS-CoV-2 induces lymphocyte cell death



March 31^{sr}, 2020



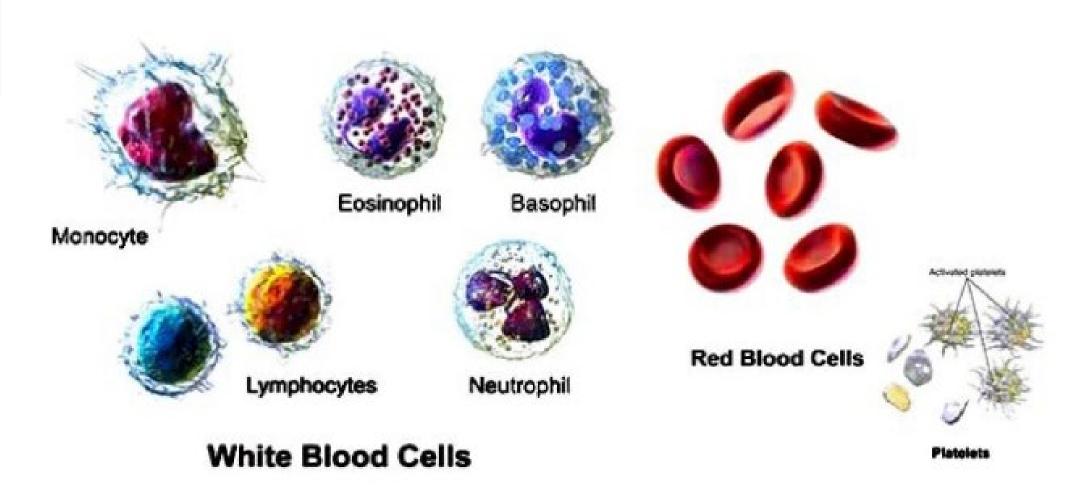




Lymphopenia in five-randomly selected individuals that died of COVID-19



March 28th, 2020



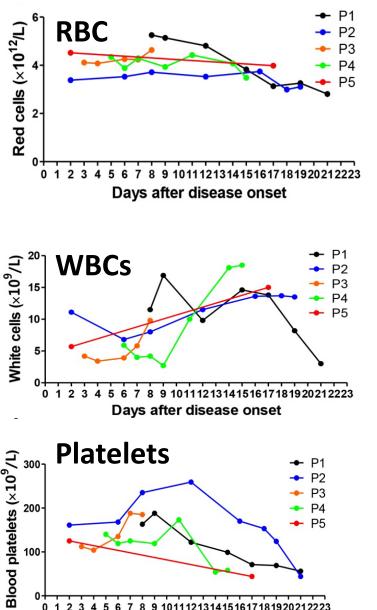
Tan, L., Wang, Q., Zhang, D. et al. Sig Transduct Target Ther **5**, 33 (2020) Slideshare.net

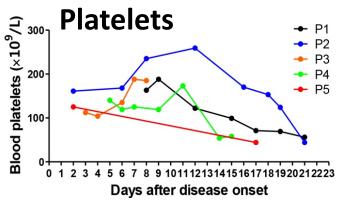


Lymphopenia in five-randomly selected individuals that died of COVID-19

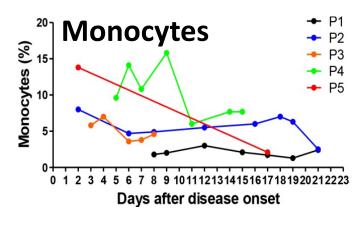


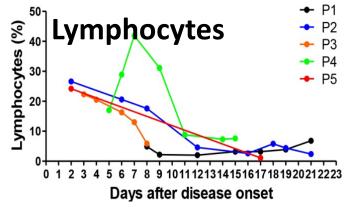
March 28th, 2020





Neutrophils Neutrophils (%) P3 P4 0 1 2 3 4 5 6 7 8 9 1011121314151617181920212223 Days after disease onset





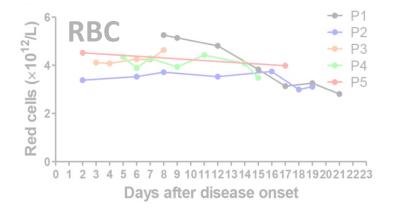
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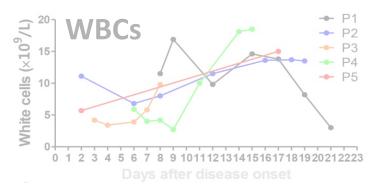


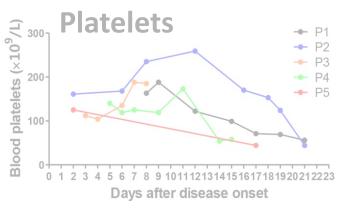
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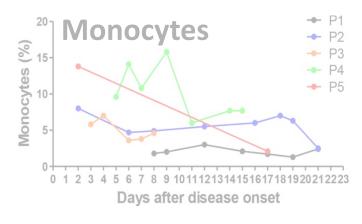


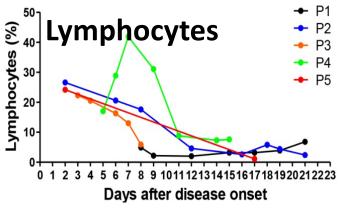




Neutrophils

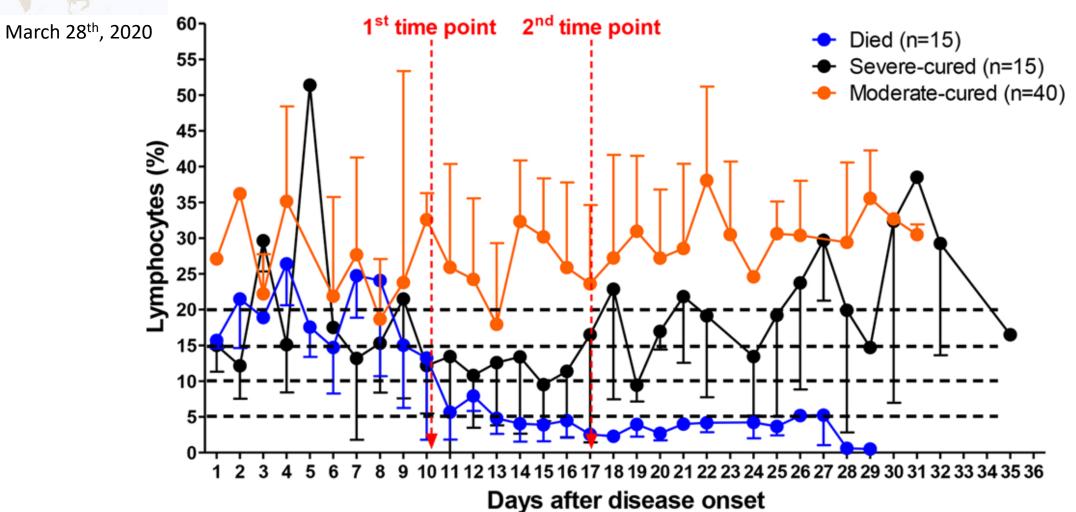
P1
P2
P3
P4
P4
P5
Days after disease onset





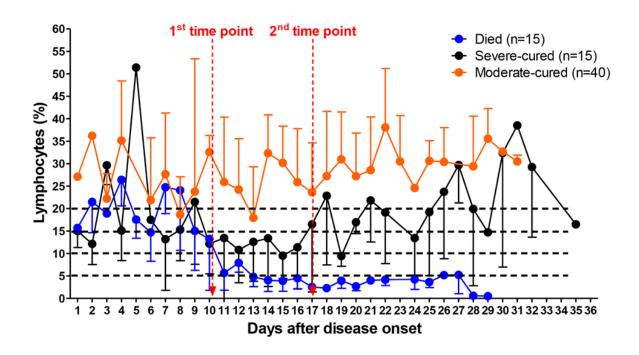
Tan, L., Wang, Q., Zhang, D. et al. Sig Transduct Target Ther **5**, 33 (2020) Slideshare.net







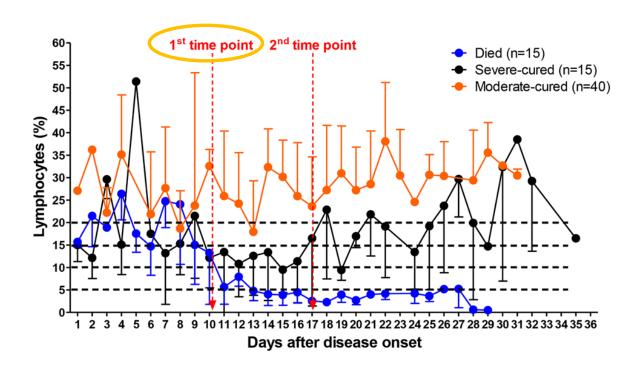
March 28th, 2020

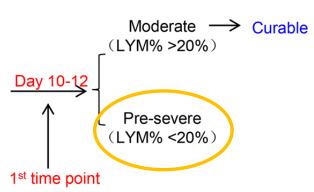


LYM%



March 28th, 2020

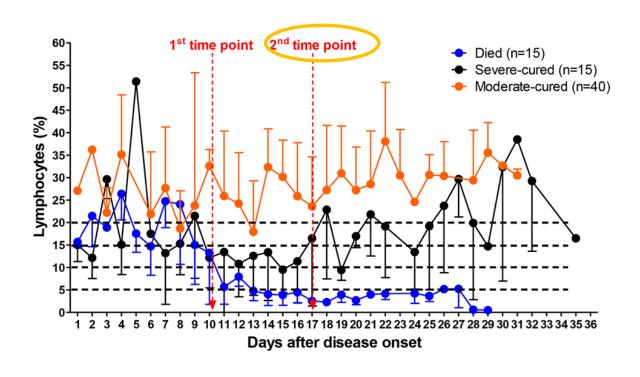


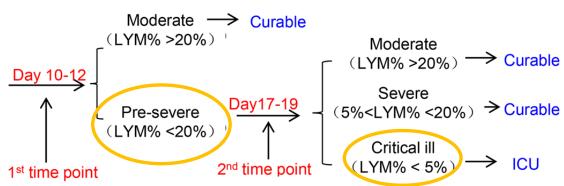


LYM%



March 28th, 2020





LYM%



COVID-19 patients have decreased NK cells, CD4 and CD8 T cells and increased myeloid cells in peripheral blood

Healthy Controls Early Recovery

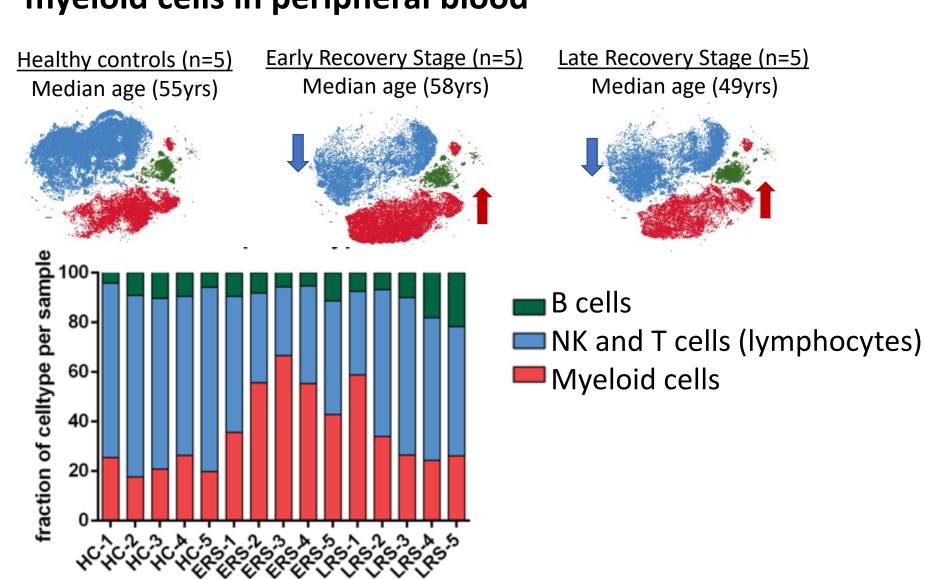


March 28th, 2020

Days since negative SARS-CoV-2 PCR testing

>> If < 7 days, Early Recovery (ERS)

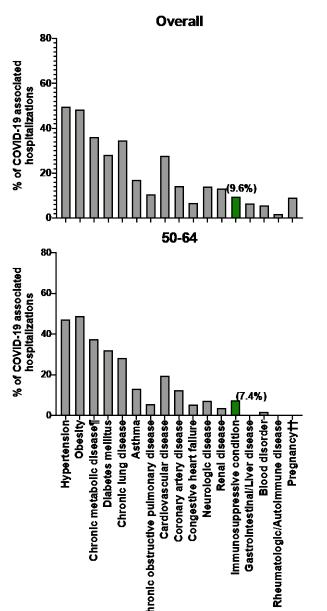
>> If > 14 days, Late Recovery (LRS)

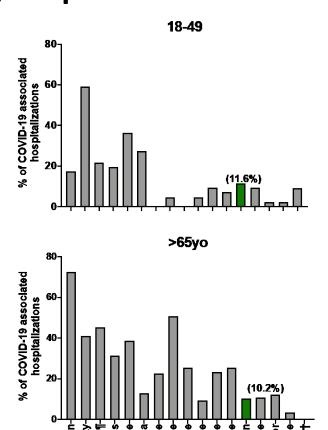




What proportion of COVID-19 patients requiring hospitalization are immune suppressed?







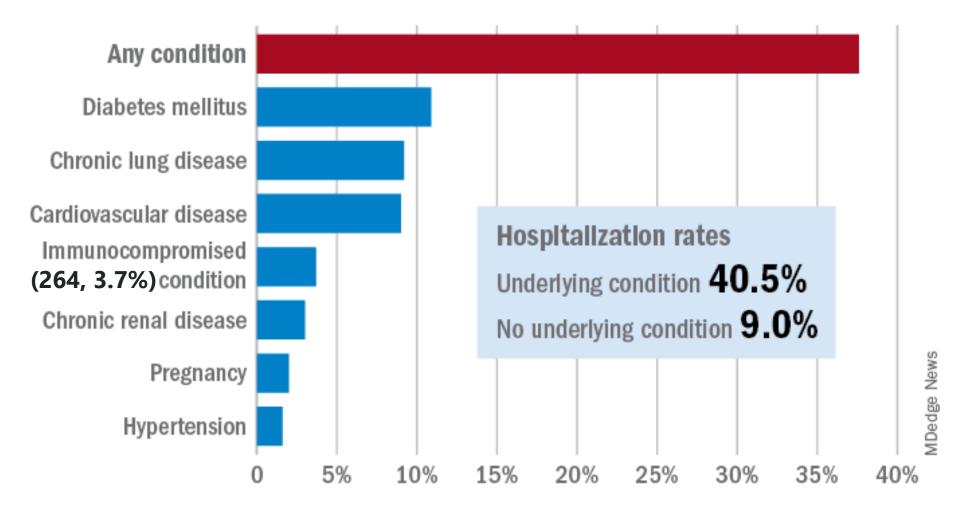






3.7% of hospitalized patients in the USA of COVID-19 patients had an immunocompromised condition



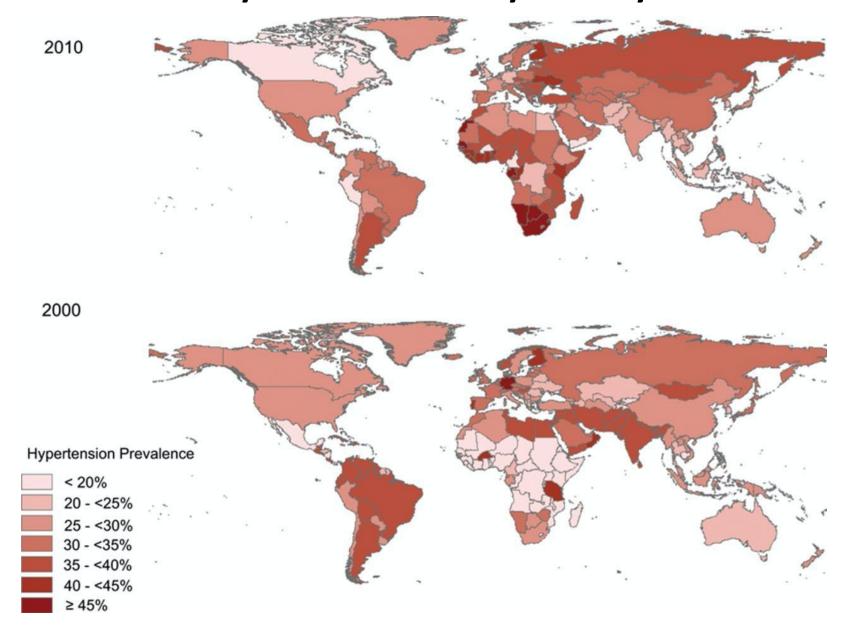


Note: Data on underlying health conditions/risk factors were available for 7,162 (5.8%) of the 122,653 COVID-19 cases reported to the CDC as of March 28.

Source: MMWR. 2020 Mar 31;69[early release]:1-5



Worldwide age- and sex-standardized prevalence of hypertension in adults 20 years and older by country.



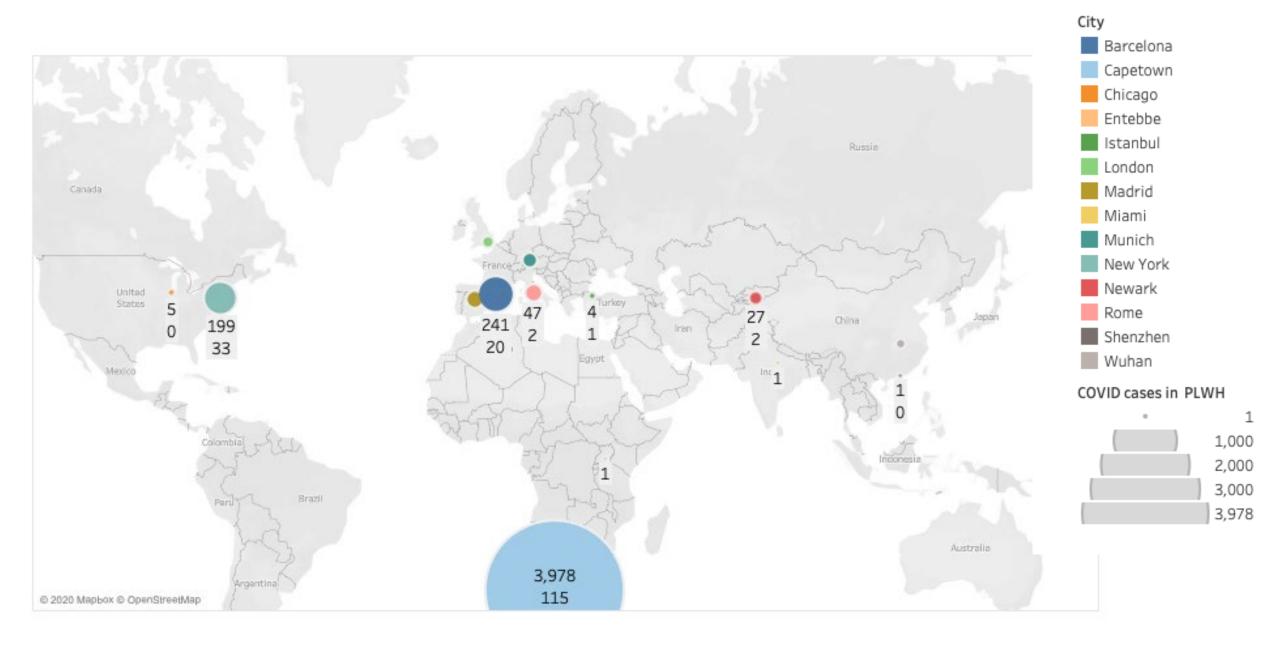
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What do we know about COVID-19 in Persons Living with HIV?



Published Case Reports of COVID-19 in Persons Living with HIV

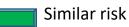


Published Case Reports of COVID-19 in Persons Living with HIV

Country	Author	Conclusion	COVID cases in PLWH	Deaths
China	Guo W et al. Lancet 2020	PWH have similar risk as the general population	8	1
	Wu, Q et al. J Med Virol 2020	New Diagnosis of HIV during Pandemic	2	0
	Zhu F et al. J Med Virol. 2020	PWH are vulnerable	1	0
	Zhao, J et al. CID 2020	Negative PCR tests in patients, suggest that PLWH exposed to the virus may be symptomatic but test negative	1	0
Germany	Haerter G etl al. MedRxiv 20	76% of PWH have mild disease	33	3
Italy	Gervasoni C et al. CID 2020	PWH not a greater risk	47	2
South Africa	Davies MA et al. MedRXIV 2	2-fold increased risk of death from COVID-19 in PLWH irrespective of viral suppression, similar increase in patients with TB. Persons on T	3,978	115
Spain	Amo JD Annals of Interni Me	Risk of COVID-19 diagnosis was lower in the HIV-positive population	236	20
	Vizcarra P et.al. Lancet 2020	Lower CD4 has higher risk of complication	51	2
	Blanco J et al. Lancet HIV 20	Recognize new diagnosis of HIV	5	0
Turkey	Aydin OA at al. J Med Virol 2	Measured SARS-CoV2 antibodies before discharge, present in 2/4 pts tested, patient with comorbidities had worse outcomes	4	1
Uganda	Baluku, J et al. J Med Virol 2	Importance of paying attention to COVID-19 mimics in low income areas	1	
United Kingdom	Child K. et al CID 2020	Hospitalized patients had low median CD4/ substancial morbidity	18	5
USA	Sigel K. et al. CID 2020	Risk of severe disease comparable to the general populaton	88	18
	Richardson, S et al. JAMA 20	0.8% of total patients in this series had HIV	43	
	Shalev N et al. CID 2020	7/8 deceased were receiving tenofovir prodrug at time of death 4> 65yo and 4 patients between age 50 and 65	31	8
	Okoh A et al. JAIDS 2020	Patients that died were elderly with multiple comorbidities	27	2
	Karmen-Tuoh, S et al. JAIDS	No difference in clinical presentation, course including thrombotic events and myocardial infarction	21	
	Suwanwongse K. et. al. J Me	Hospital in South Bronx, known for poverty. Patients with low CD4 had a higher mortality rate. HIV-related T cell suppression does not ap	9	7
	Ridgway JS et al. AIDS Patie	All survived, 1/5 presented with tachycardia, test positive 3 days later	5	0
	Patel RH et al. J Med Virol 2	Speculate on possible benefit on ART on COVID19, hence less severe disease	1	
	Argenziano MG et al. BMJ 20.	Age, BMI and HIV or renal disease associated with death		
	Goyal P et al NEJM 2020	None	7	







There is no evidence to suggest that persons Living with HIV are at higher risk of infection with COVID-19



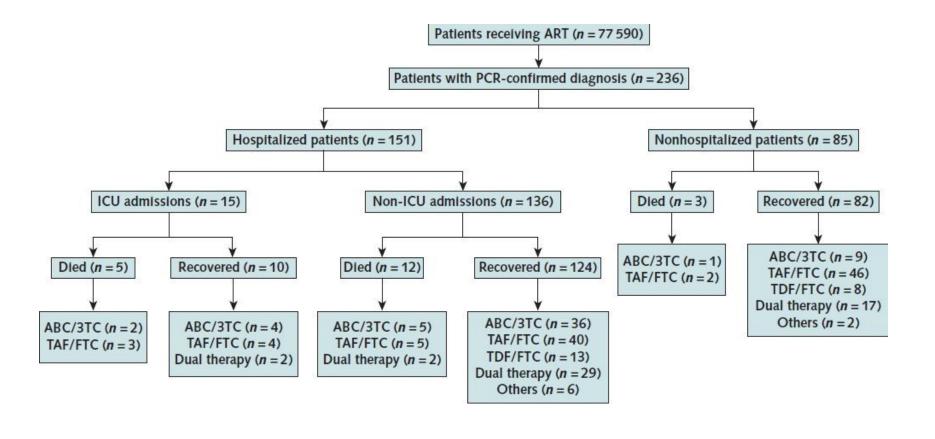
Thirty-three PLWH diagnosed with COVID-19. 30 male and 3 females, with 7 (21%) inpatient and 26 (79%) outpatient. PLWH did not have increased morbidity or mortality in this large group.

The risk for COVID-19 diagnosis was lower in the HIV-positive population (30.0 per 10 000)



SPAIN

June 26, 2020 February 1 – April 15th, 2020



The risk for COVID-19 diagnosis was lower in the HIV-positive population (30.0 per 10 000) than in the general population (41.7 per 10 000)



Table 1. Characteristics of PCR-Confirmed COVID-19 Diagnoses, Hospital Admissions, ICU Admissions, and Deaths Among 77 590 HIV-Positive Persons Receiving ART, 1 February to 15 April 2020, Spain

SPAIN

June 26, 2020 February 1 – April 15th, 2020

Characteristics	HIV-Positive Persons Receiving ART, n (%)*	COVID-19 Diagnoses, n (%)	COVID-19 Hospital Admissions, n (%)	COVID-19 ICU Admissions, n (%)	COVID-19 Deaths, n (%
Total	77 590	236	151	15	20
Sex					
M	58 120 (75)	204 (86)	136 (90)	12 (80)	16 (80)
Women	19 470 (25)	32 (14)	15 (10)	3 (20)	4 (20)
Age, y					
20-39	14 506 (19)	41 (18)	15 (10)	1 (7)	0
40-49	19 373 (25)	54 (23)	39 (26)	1 (7)	2 (10)
50-59	32 321 (42)	85 (36)	54 (36)	7 (47)	7 (35)
60-69	8762 (11)	34 (14)	24 (16)	4 (26)	4 (20)
70-79	2628 (3)	22 (9)	19 (12)	2 (13)	7 (35)
NRTI					
TDF/FTC	12 395 (16)	21 (9)	13 (9)	0	0
TAF/FTC	25 570 (33)	100 (42)	52 (34)	7 (46)	10 (50)
ABC/3TC	20 105 (26)	57 (24)	47 (31)	6 (40)	8 (40)
Other regimens	19 520 (25)	58 (25)	39 (26)	2 (14)	2 (10)
Third drug					
NNRTI	15 733 (21)	36 (15)	24 (16)	4 (27)	5 (25)
Protease inhibitor	14 267 (19)	34 (15)	27 (18)	3 (20)	5 (25)
Integrase inhibitor	37 622 (50)	143 (60)	86 (57)	7 (47)	9 (45)
Other	9968 (10)	23 (10)	14 (9)	1 (6)	1 (5)

³TC = lamivudine; ABC = abacavir; ART = antiretroviral therapy; COVID-19 = coronavirus disease 2019; FTC = emtricitabine; ICU = intensive care unit; NNRTI = nonnucleoside reverse transcriptase inhibitor; NRTI = nucleos(t)ide reverse transcriptase inhibitor; PCR = polymerase chain reaction; TAF = tenofovir alafenamide; TDF = tenofovir disoproxil fumarate.

^{*} Distribution derived from the 2019 National HIV Hospital Survey (13); counts are estimated from this distribution.

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HIV was associated with a doubling of COVID-19 mortality risk



	Public	Public sector patients with HIV			Public sector patients without HIV			
	No diagnosed COVID-19 n=536,574	COVID-19 not deceased n=3,863	COVID-19 deceased n=115	No diagnosed COVID-19 n=2,902,050	COVID-19 not deceased n=17,820	COVID-19 deceased n=510		
Sex								
female	356,356 (66%)	3,039 (79%)	62 (54%)	1,627,124 (56%)	11,877 (67%)	278 (55%)		
male	180,218 (34%)	824 (21%)	53 (46%)	1,274,926 (44%)	5,943 (34%)	232 (45%)		
Age								
20-39 years	310,551 (58%)	2,187 (57%)	17 (15%)	1,603,235 (55%)	9,453 (53%)	29 (6%)		
40-49 years	147,344 (27%)	1,136 (29%)	28 (24%)	457,632 (16%)	3,379 (19%)	35 (7%)		
50-59 years	59,345 (11%)	418 (11%)	40 (35%)	388,394 (13%)	2,809 (16%)	122 (24%)		
60-69 years	15,856 (3%)	98 (3%)	21 (18%)	260,226 (9%)	1,325 (7%)	157 (31%)		
≥70 years	3,473 (1%)	24 (1%)	9 (8%)	192,562 (7%)	854 (5%)	167 (33%)		
Diabetes								
none	517,609 (96%)	3,491 (90%)	57 (50%)	2,659,479 (92%)	15,090 (85%)	196 (38%)		
diabetes HbA1c <7%	3,493 (1%)	65 (2%)	8 (7%)	41,561 (1%)	426 (2%)	50 (10%)		
diabetes HbA1c 7 - 8.9%	2,998 (1%)	77 (2%)	16 (14%)	44,213 (2%)	505 (3%)	78 (15%)		
diabetes HbA1c ≥9%	4,562 (1%)	126 (3%)	25 (22%)	61,077 (2%)	960 (5%)	133 (26%)		
diabetes no HbA1c measurement	7,912 (1%)	104 (3%)	9 (8%)	95,720 (3%)	839 (5%)	53 (10%)		
Other non-communicable diseases								
hypertension	62,676 (12%)	692 (18%)	48 (42%)	501,232 (18%)	4,218 (24%)	314 (62%)		
chronic kidney disease	6,348 (1%)	82 (2%)	21 (18%)	55,319 (2%)	412 (2%)	90 (18%)		
chronic pulmonary disease / asthma	23,501 (4%)	218 (6%)	10 (9%)	169,086 (6%)	1,359 (8%)	74 (15%)		
Fuberculosis								
previous tuberculosis	129,259 (24%)	864 (22%)	42 (37%)	157,630 (5%)	834 (5%)	45 (9%)		
current tuberculosis	24,357 (5%)	172 (4%)	16 (14%)	29,895 (1%)	145 (1%)	10 (2%)		

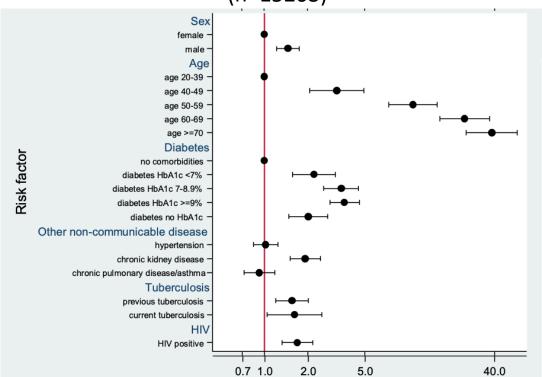
Note: Column percentages may add up to >100% due to rounding; HbA1c glycosylated haemoglobin

Death in COVID-19 cases and hospitalized patients was increased in men and older persons



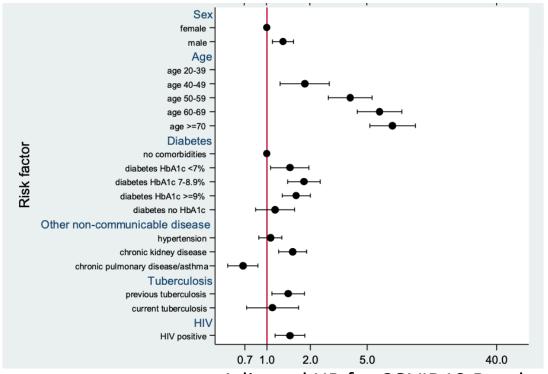
All COVID-10 cases older than 20yrs before 6/1/2020

(n=15203)



Adjusted HR for COVID19 Death

Hospitalized COVID-19 cases (n=2,978)

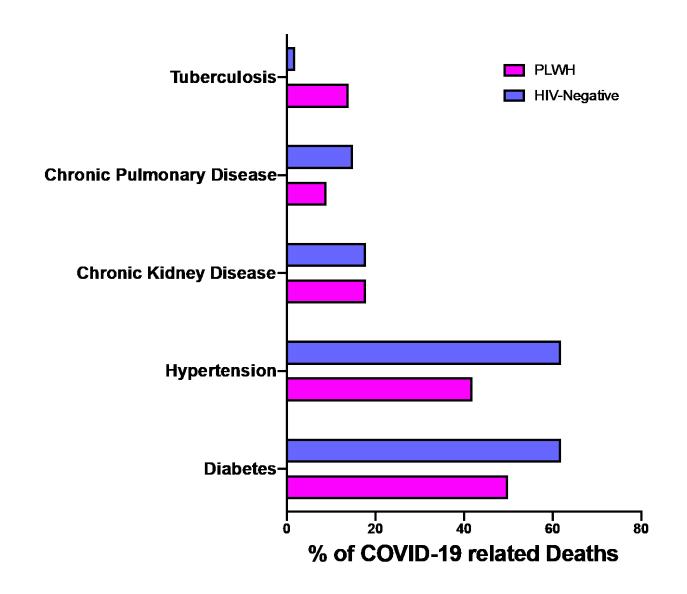


Adjusted HR for COVID19 Death



PLWH had an increased hazard of death compared to HIV-negative COVID-19 cases







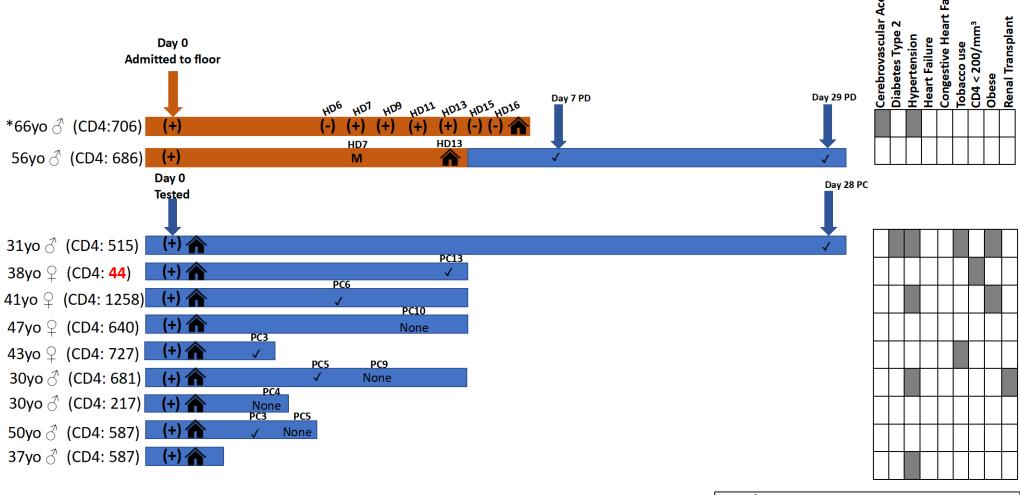
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Description of data used in analysis	Including all COVID-19 cases diagnosed until study closure (9 June 2020)				
Certainty of evidence for comorbidities		All certainty			
	Adjusted HR	95% CI	p-value		
Sex	-				
female	Ref				
male	1.47	1.25; 1.72	<0.001		
Age					
20-39 years					
40-49 years	2.70	1.83; 3.98	<0.001		
50-59 years	8.72	6.17; 12.31	<0.001		
60-69 years	19.05	13.37; 27.13	<0.001		
≥70 years	31.43	21.93; 45.05	<0.001		
Diabetes					
none					
diabetes HbA1c <7%	2.54	1.89; 3.43	<0.001		
diabetes HbA1c 7 - 8.9%	3.48	2.70; 4.48	<0.001		
diabetes HbA1c ≥9%	3.96	3.19; 4.91	<0.001		
diabetes no HbA1c measurement	2.07	1.55; 2.76	< 0.001		
Other non-communicable diseases					
hypertension	1.07	0.89; 1.27	0.488		
chronic kidney disease	1.81	1.45; 2.25	<0.001		
chronic pulmonary disease / asthma	0.83	0.66; 1.05	0.125		
Tuberculosis					
never tuberculosis					
previous tuberculosis	1.53	1.20; 1.95	0.001		
current tuberculosis	1.78	1.19; 2.66	0.005		
HIV					
negative					
positive	1.75	1.40; 2.19	<0.001		
VL <1000 copies/ml (last 15 mo) & ART script (last 6 mo) ^{\$}	1.75	1.34; 2.29	<0.001		
VL <1000 copies/ml (2yr to 15 mo prior)	4.50	•			
OR ART script (last 6 mo) & VL <1000 copies/ml >2yr prior	1.59	0.87; 2.92	0.135		
VL ≥ 1000 copies/ml (last 15 mo) or CD4 <200 cells/µl (last 18 mo)	3.80	2.07; 6.95	<0.001		
No VL (last 15 mo); CD4 ≥200 cells/µl or unknown (last 18 mo)	1.54	1.01; 2.33	0.042		
	1.57	1.01, 2.55	0.072		
ART in PLWH with script issued in last 12 months*	5.6				
abacavir or zidovudine	Ref	0.20. 0.00	0.0131		
tenofovir	0.49	0.28; 0.86	0.0121		
efavirenz	Ref	0.00 4.77	0.5374		
lopinavir	0.76	0.33; 1.77	0.5271		
atazanavir	0.76	0.23; 2.51	0.6540		
dolutegravir	0.73	0.25; 2.15	0.5732		



Sequalae of COVID-19 in PLWH



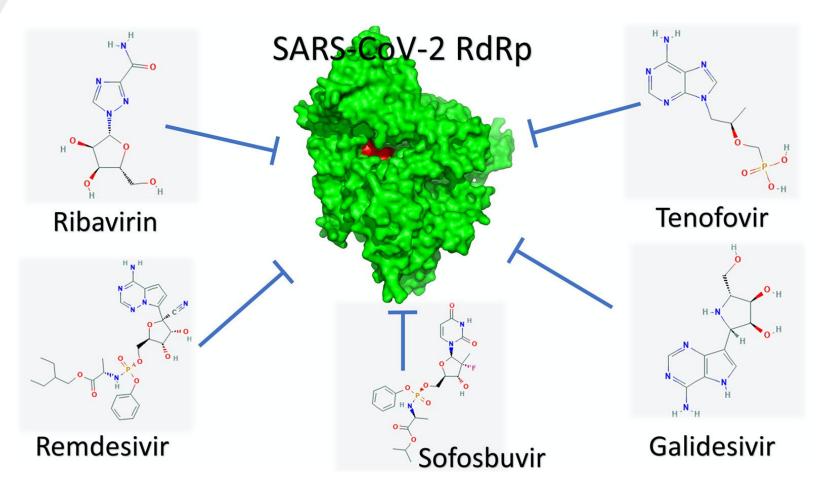


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- ART and SARS-CoV2
 - What about patients on PrEP?
 - DHHS guidelines
- HIV Screening and care during the pandemic
- IDSA guidelines, Key points and Future studies

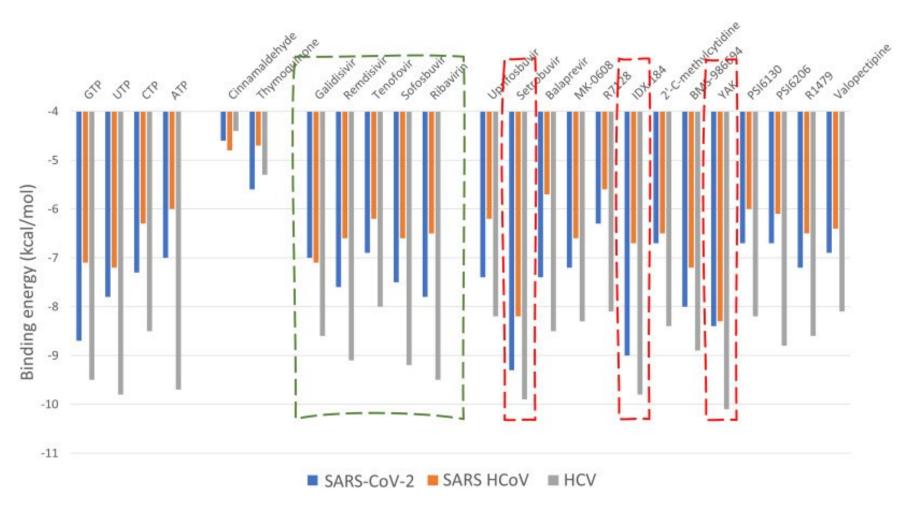


Ribavirin, Remdesivir, Sofosbuvir, Galidesivir, and Tenofovir against SARS-CoV-2 RNA dependent RNA polymerase: A molecular docking study





Ribavirin, Remdesivir, Sofosbuvir, Galidesivir, and Tenofovir against SARS-CoV-2 RNA dependent RNA polymerase: A molecular docking study

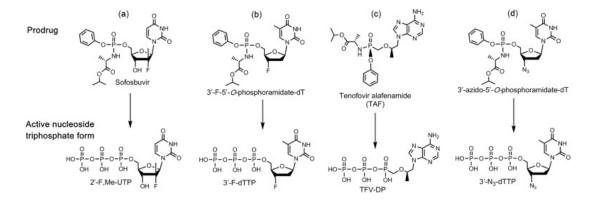


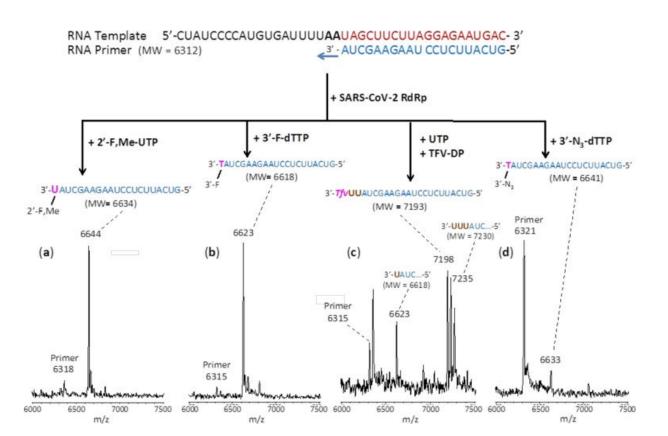


Nucleotide analogues 2'-F,Me-UTP, 3'-F-dTTP, 3'-N3-dTTP, and TFV-DP are permanent terminators for the SARS-CoV-2 RdRp



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DHHS Guidelines for PLWH

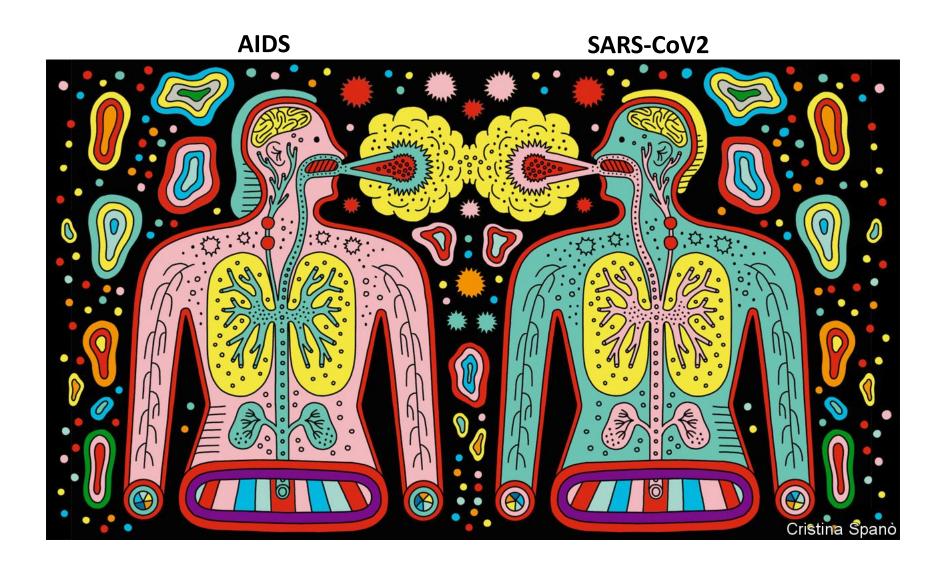


Individuals aged >60 years and those with diabetes, hypertension, cardiovascular disease, pulmonary disease, or obesity are at highest risk of life-threatening COVID-19, the illness caused by the virus known as SARS-CoV-2.
The limited data currently available do not indicate that the disease course of COVID-19 in persons with HIV differs from that in persons without HIV. Before the advent of effective combination antiretroviral therapy (ART), advanced HIV infection (i.e., CD4 cell count <200/mm³) was a risk factor for complications of other respiratory infections. Whether this is also true for COVID-19 is yet unknown.
Some people with HIV have other comorbidities (e.g., cardiovascular disease, lung disease) that increase the risk for a more severe course of COVID-19 illness. Chronic smokers are also at risk of more severe disease.
Thus, until more is known, additional caution for all persons with HIV, especially those with advanced HIV or poorly controlled HIV, is warranted.
Every effort should be made to help persons with HIV maintain an adequate supply of ART and all other concomitant medications.
Influenza and pneumococcal vaccinations should be kept up to date.

Outline

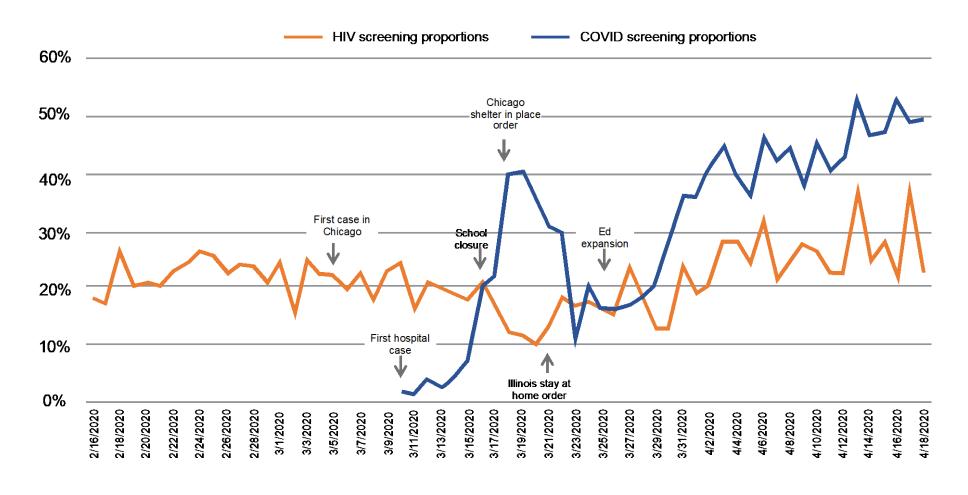
- SARS-CoV2 and the immune system
- Sum of consecutive cases of COVID-19 in PLWH from different published case reports/series
 - Comorbidities
 - CD4 counts and viral load
 - Long-term sequelae
 - Mental health
 - ART: To switch or not to switch?
- ART and SARS-CoV2
 - What about patients on PrEP?
 - DHHS guidelines
- HIV Screening and care during the pandemic
- IDSA guidelines, Key points and Future studies

HIV Screening and care during the pandemic





Routine Screening for HIV in an Urban Emergency Department During the COVID-19 Pandemic



Published Case Reports of COVID-19 in Persons Living with HIV

Country	Author	Conclusion	COVID cases in PLWH	Deaths
China	Guo W et al. Lancet 2020	PWH have similar risk as the general population	8	1
	Wu, Q et al. J Med Virol 2020	New Diagnosis of HIV during Pandemic	2	0
	Zhu F et al. J Med Virol. 2020	PWH are vulnerable	1	0
	Zhao, J et al. CID 2020	Negative PCR tests in patients, suggest that PLWH exposed to the virus may be symptomatic but test negative	1	0
Germany	Haerter G etl al. MedRxiv 20	76% of PWH have mild disease	33	3
Italy	Gervasoni C et al. CID 2020	PWH not a greater risk	47	2
South Africa	Davies MA et al. MedRXIV 2	2-fold increased risk of death from COVID-19 in PLWH irrespective of viral suppression, similar increase in patients with TB. Persons on T	3,978	115
Spain	Amo JD Annals of InternI Me	Risk of COVID-19 diagnosis was lower in the HIV-positive population	236	20
	Vizcarra P et.al. Lancet 2020	Lower CD4 has higher risk of complication	51	2
	Blanco J et al. Lancet HIV 20	Recognize new diagnosis of HIV	5	0
Turkey	Aydin OA at al. J Med Virol 2	Measured SARS-CoV2 antibodies before discharge, present in 2/4 pts tested, patient with comorbidities had worse outcomes	4	1
Uganda	Baluku, J et al. J Med Virol 2	Importance of paying attention to COVID-19 mimics in low income areas	1	
United Kingdom	Child K. et al CID 2020	Hospitalized patients had low median CD4/ substancial morbidity	18	5
USA	Sigel K. et al. CID 2020	Risk of severe disease comparable to the general populaton	88	18
	Richardson, S et al. JAMA 20	0.8% of total patients in this series had HIV	43	
	Shalev N et al. CID 2020	7/8 deceased were receiving tenofovir prodrug at time of death 4> 65yo and 4 patients between age 50 and 65	31	8
	Okoh A et al. JAIDS 2020	Patients that died were elderly with multiple comorbidities	27	2
	Karmen-Tuoh, S et al. JAIDS	No difference in clinical presentation, course including thrombotic events and myocardial infarction	21	
	Suwanwongse K. et. al. J Me	Hospital in South Bronx, known for poverty. Patients with low CD4 had a higher mortality rate. HIV-related T cell suppression does not ap	9	7
	Ridgway JS et al. AIDS Patie	All survived, 1/5 presented with tachycardia, test positive 3 days later	5	0
	Patel RH et al. J Med Virol 2	Speculate on possible benefit on ART on COVID19, hence less severe disease	1	
	Argenziano MG et al. BMJ 20	Age, BMI and HIV or renal disease associated with death		
	Goyal P et al NEJM 2020	None	7	

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Infectious Diseases Society of America (IDSA) guidelines



- Among patients with COVID-19, the IDSA guideline panel suggests against hydroxychloroquine/chloroquine plus azithromycin outside of the context of a clinical trial. (Conditional recommendation, very low certainty of evidence
- Among patients who have been admitted to the hospital with COVID-19, the IDSA guideline panel recommends the combination of lopinavir/ritonavir only in the context of a clinical trial. (Knowledge gap)

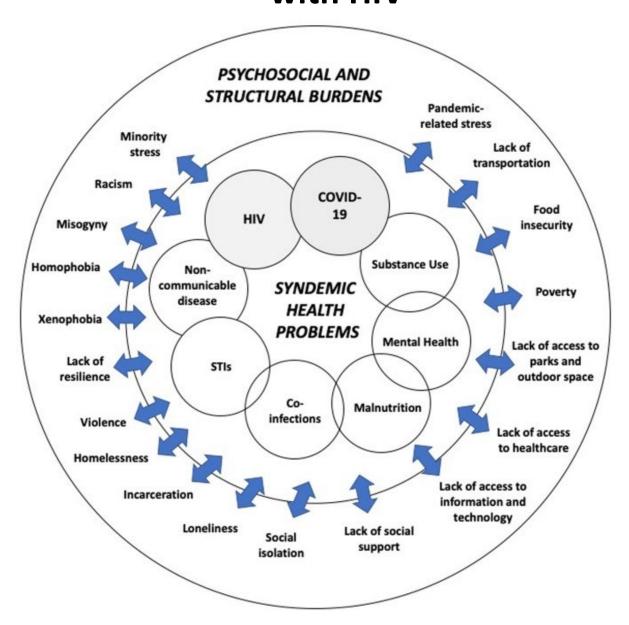
Steroids

- Among hospitalized patients with severe* COVID-19, the IDSA guideline panel suggests glucocorticoids rather than no glucocorticoids. (Conditional recommendation, Moderate certainty of evidence)
- Among hospitalized patients with COVID-19 without hypoxemia requiring supplemental oxygen, the IDSA guideline panel suggests against the use of glucocorticoids. (Conditional recommendation, Low certainty of evidence)
- Among hospitalized patients with severe* COVID-19, the IDSA panel suggests remdesivir over no antiviral treatment. (Conditional recommendation, Moderate certainty of evidence)
- Among patients with severe COVID-19 on supplemental oxygen but not on mechanical ventilation or ECMO, the IDSA panel suggests treatment with five days of remdesivir rather than 10 days of remdesivir. (Conditional recommendation, low certainty of evidence)

https://www.idsociety.org/COVID19guidelines *Published 6.25.2020*



A syndemic conceptualization of HIV & COVID-19 co-infection in people living with HIV





Key points

- Greater proportions of comorbidities in PLWH could account for differences in outcomes in different case reports
- Data points in PLWH with CD4 < 200 are sparse
- We not have enough evidence to justify switching ART due to COVID-19
- Severe COVID-19 is a manifestation immune imbalance, even in PLWH
- Lymphopenia predicts severe disease even in persons living with HIV
- Larger data points from well curated assays are needed to make conclusions about outcomes.
- Remdesivir can be given along with ART therapies, if patients have severe COVID-19
- Possible role of ART in SARS-CoV2 needs to be investigated. Consecutive cases or lack of reported in patients on PrEP might be helpful