

Strategie di eradicazione HIV e SARS-CoV-2 a confronto

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Scienze della Salute – Università degli Studi di
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Variola virus, Orthopoxvirus



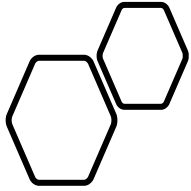
The smallpox vaccine, created by Edward Jenner in 1796, was the first successful vaccine to be developed. He observed that milkmaids who previously had caught cowpox did not catch smallpox and showed that a similar inoculation could be used to prevent smallpox in other people.

Smallpox eradication strategy

- Before 1967 **mass vaccination**. Ineffective in densely populated regions

<https://www.who.int/>





Prevention activities (case identification and treatment) and **surveillance programs** (data reporting, morbidity and mortality to study natural history and duration of immunity)

<https://www.who.int/>







**World Health
Organization**

Eradicated 1980 **a global achievement**

For at least 3000 years smallpox had
devastated humanity.



LIFE

July 1985

**A Race To Save
America's Great Movies**

**Koko (the Gorilla) Is
Captivated by Kittens**

**That Fabulous Night:
Teen Proms '85**

NOW NO ONE IS SAFE FROM AIDS



HIV: a 40-year old pandemic

Pneumocystis Pneumonia --- Los Angeles

05/08/2006 01:38 PM



Epidemiologic Notes and Reports

Pneumocystis Pneumonia --- Los Angeles

In the period October 1980-May 1981, 5 young men, all active homosexuals, were treated for biopsy-confirmed *Pneumocystis carinii* pneumonia at 3 different hospitals in Los Angeles, California. Two of the patients died. All 5 patients had laboratory-confirmed previous or current cytomegalovirus (CMV) infection and candidal mucosal infection. Case reports of these patients follow.

Patient 1: A previously healthy 33-year-old man developed *P. carinii* pneumonia and oral mucosal candidiasis in March 1981 after a 2-month history of fever associated with elevated liver enzymes, leukopenia, and CMV viremia. The serum complement-fixation CMV titer in October 1980 was 256; in May 1981 it was 32.* The patient's condition deteriorated despite courses of treatment with trimethoprim-sulfamethoxazole (TMP/SMX), pentamidine, and acyclovir. He died May 3, and postmortem examination showed residual *P. carinii* and CMV pneumonia, but no evidence of neoplasia.

Patient 2: A previously healthy 30-year-old man developed *p. carinii* pneumonia in April 1981 after a 5-month history of fever each day and of elevated liver-function tests, CMV viremia, and documented seroconversion to CMV, i.e., an acute-phase titer of 16 and a convalescent-phase titer of 28* in anticomplement immunofluorescence tests. Other features of his illness included leukopenia and mucosal candidiasis. His pneumonia responded to a course of intravenous TMP/SMX, but, as of the latest reports, he continues to have a fever each day.

Patient 3: A 30-year-old man was well until January 1981 when he developed esophageal and oral candidiasis that responded to Amphotericin B treatment. He was hospitalized in February 1981 for *P. carinii* pneumonia that responded to TMP/SMX. His esophageal candidiasis recurred after the pneumonia was diagnosed, and he was again given Amphotericin B. The CMV complement-fixation titer in March 1981 was 8. Material from an esophageal biopsy was positive for CMV.

Patient 4: A 29-year-old man developed *P. carinii* pneumonia in February 1981. He had had Hodgkins disease 3 years earlier, but had been successfully treated with radiation therapy alone. He did not improve after being given intravenous TMP/SMX and corticosteroids and died in March. Postmortem examination showed no evidence of Hodgkins disease, but *P. carinii* and CMV were found in lung tissue.

Patient 5: A previously healthy 36-year-old man with clinically diagnosed CMV infection in September 1980 was seen in April 1981 because of a 4-month history of fever, dyspnea, and cough.

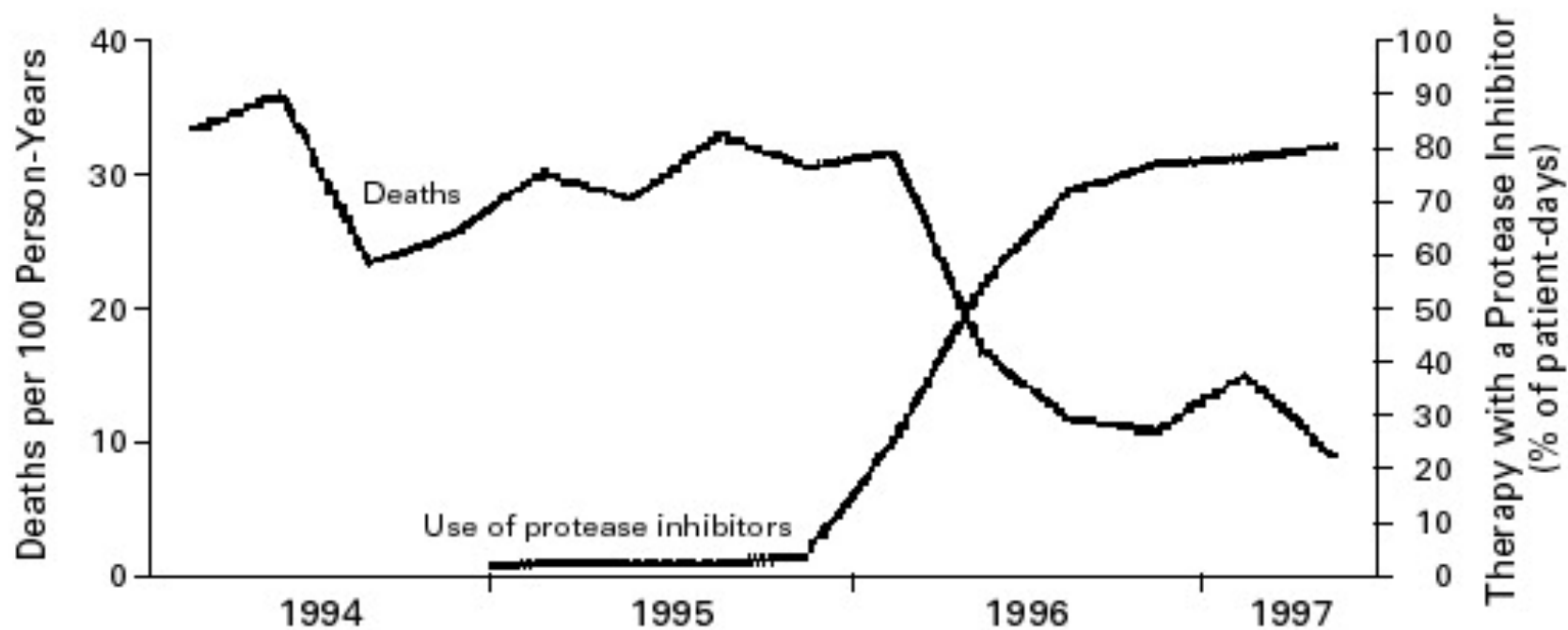
A graphic for the 40th anniversary of the HIV epidemic. It features a large "40" in black, with a red ribbon forming the "0". To the right of the "40" is the word "YEARS" in large, bold, black capital letters, and below it, "OF PROGRESS" in smaller, bold, black capital letters. The background is a light gray with a faint world map.

40 YEARS
OF PROGRESS

It's Time to End the HIV Epidemic

June 5, 2021 marks 40 years since the first official reporting, in CDC's *Morbidity and Mortality Weekly Report (MMWR)*, of five cases describing what later became known as Acquired Immune Deficiency Syndrome (AIDS) and what is now HIV Stage III. On this 40th anniversary, we remember the more than 32 million people who have died from HIV worldwide since the start of the global epidemic, and the 38 million people currently living with HIV. Along with the global community, we are redoubling our efforts to ensure equitable access to services and prevention strategies, especially for those disproportionately affected by HIV, so that we may end the HIV epidemic in the U.S. and around the world. The CDC Museum invites you to view this collection of representative materials.

<https://www.cdc.gov/>



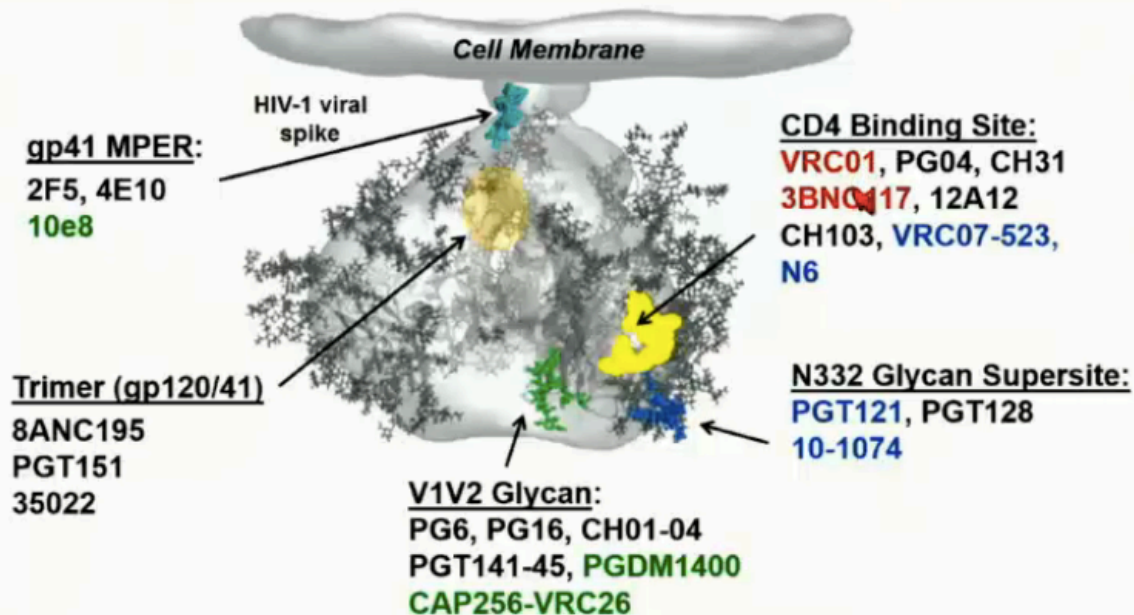
HIV: an unabated pandemic with 38 million people currently living with HIV, more than 32 million people who have died, 1.5 million new infections/year, 150,000 in infants

Which obstacles to HIV pandemic eradication?

A long unsuccessful run
for a vaccination

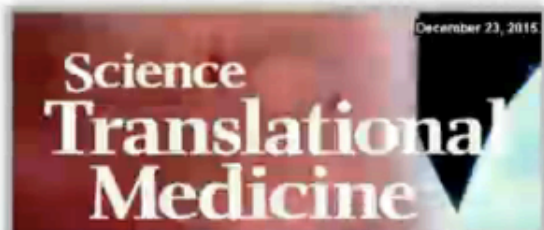
The last mile of the
unsuccessful run for a
vaccination: antibody
mediated prevention

Neutralizing Monoclonal Antibodies plans for clinical trials



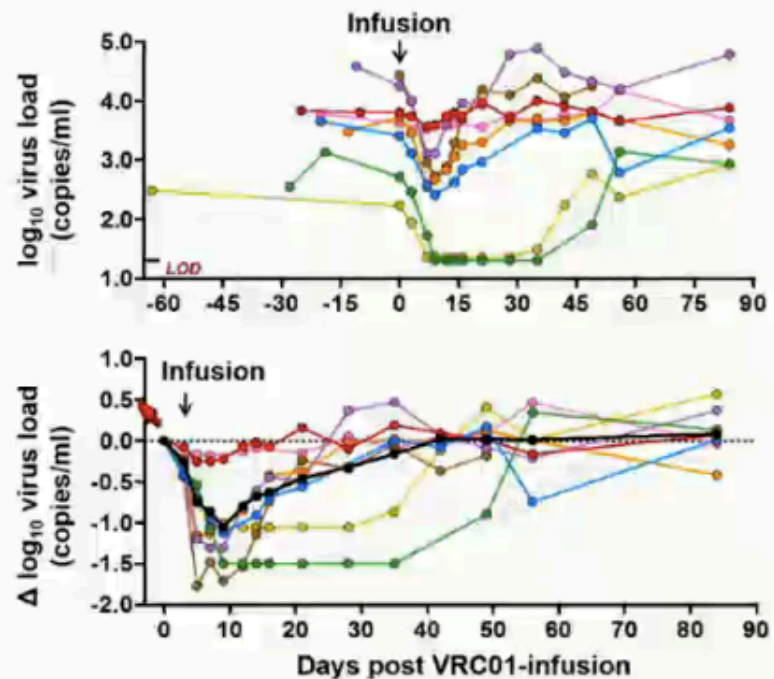
Cryo-EM of viral spike by Subramaniam group. Fit with atomic level structures from Kwong and Wilson groups

VRC01 Phase I Trial 8 HIV-1 infected subjects

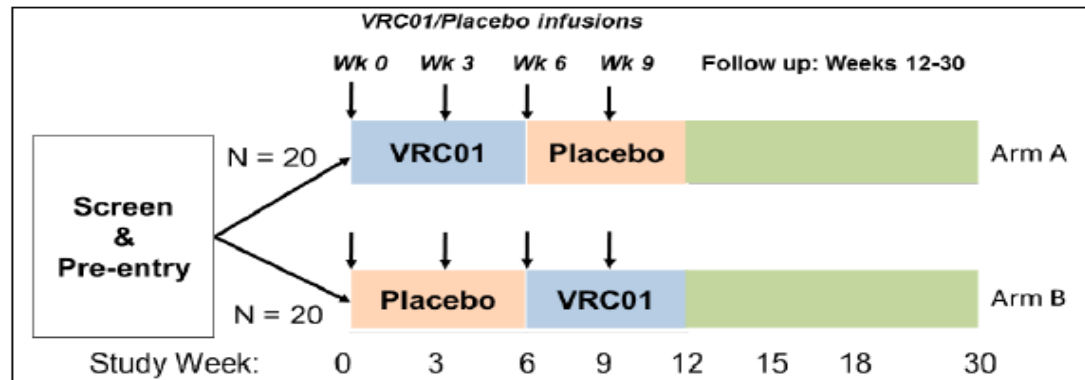


Virologic Effects of Broadly Neutralizing Antibody VRC01 Administration During Chronic HIV-1 Infection.

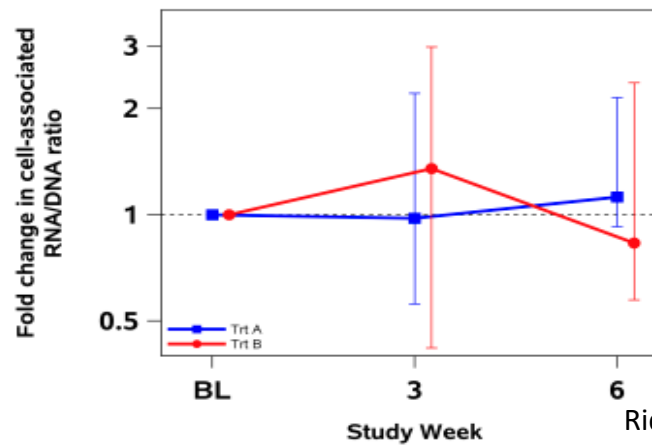
Lynch RM, Boritz E, Coates EE, DeZure A, Madden P, Costner P, Enama ME, Plummer S, Holman L, Hendel CS, Gordon I, Casazza J, Conan-Cibotti M, Migueles SA, Tressler R, Bailor RT, McDermott A, Narpala S, O'Dell S, Wolf G, Lifson JD, Freemire BA, Gorelick RJ, Pandey JP, Mohan S, Chomont N, Fromentin R, Chun TW, Fauci AS, Schwartz RM, Koup RA, Douek DC, Hu Z, Capparelli E, Graham BS, Mascola JR, Ledgerwood JE: VRC 601 Study Team.



VRC01: no effect on viral persistence on virally-suppressed patients



40 HIV+ on
virally-
suppressive
cART



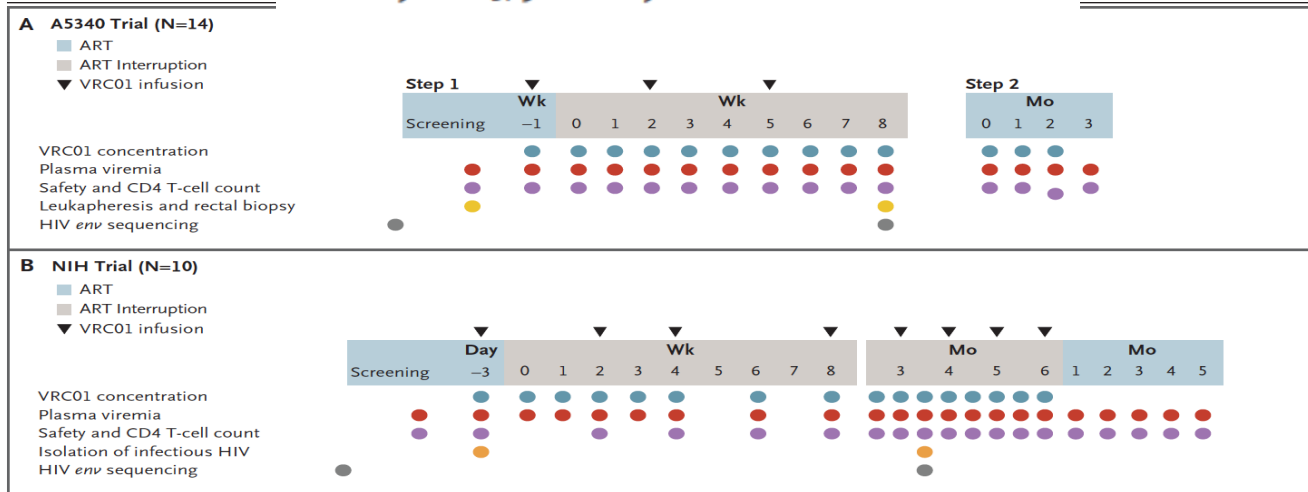
Riddler S LB 330 CROI 2017

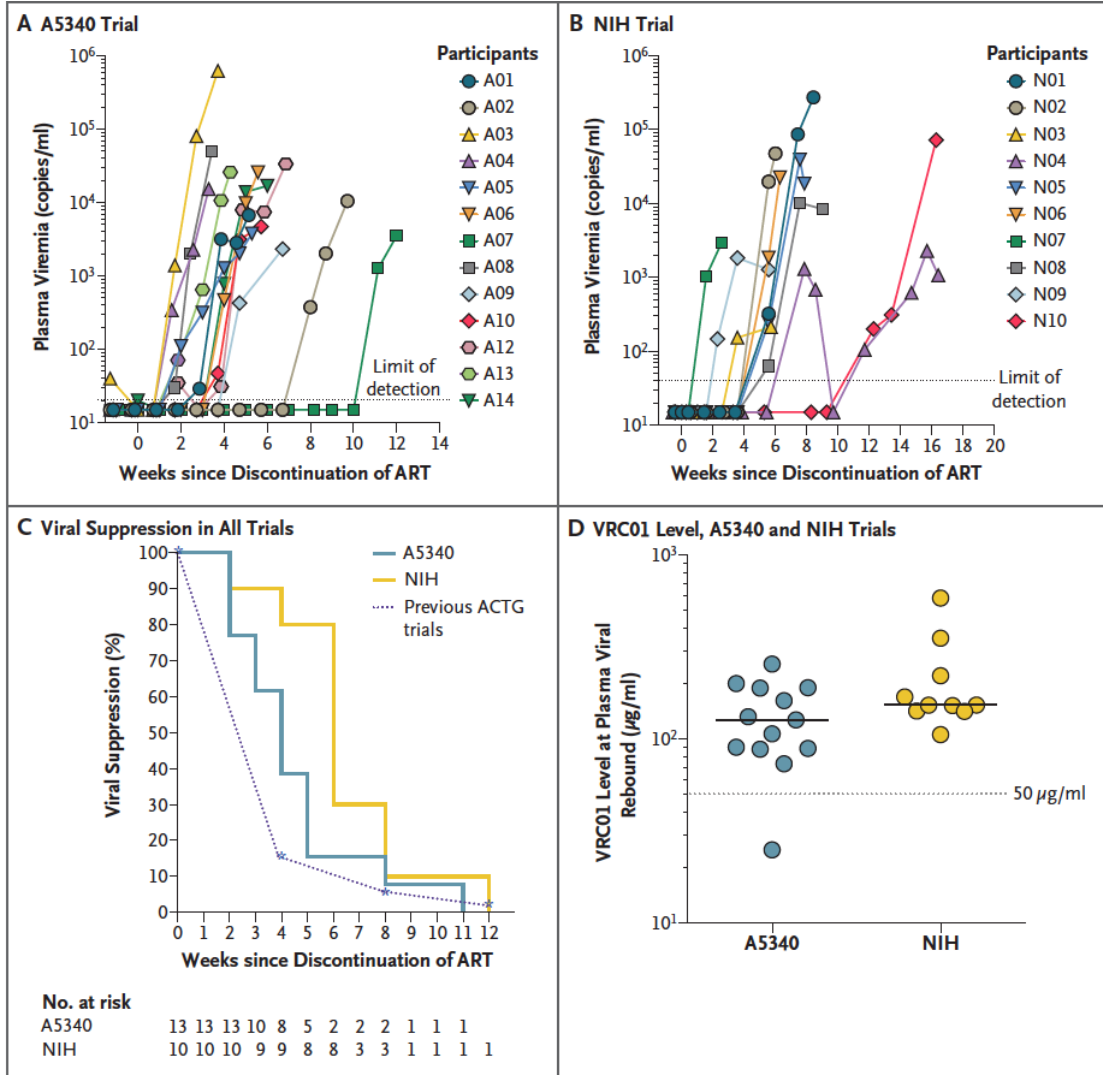
ORIGINAL ARTICLE

Effect of HIV Antibody VRC01 on Viral Rebound after Treatment Interruption

K.J. Bar, M.C. Sneller, L.J. Harrison, J.S. Justement, E.T. Overton, M.E. Petrone, D.B. Salantes, C.A. Seamon, B. Scheinfeld, R.W. Kwan, G.H. Learn, M.A. Proschan, E.F. Kreider, J. Blazkova, M. Bardsley, E.W. Refsland, M. Messer, K.E. Clarridge, N.B. Tustin, P.J. Madden, K.S. Oden, S.J. O'Dell, B. Jarocki, A.R. Shiakolas, R.L. Tressler, N.A. Doria-Rose, R.T. Bailer, J.E. Ledgerwood, E.V. Capparelli, R.M. Lynch, B.S. Graham, S. Moir, R.A. Koup, J.R. Mascola, J.A. Hoxie, A.S. Fauci, P. Tebas, and T.-W. Chun

N ENGL J MED 375;21 NEJM.ORG NOVEMBER 24, 2016





ORIGINAL ARTICLE

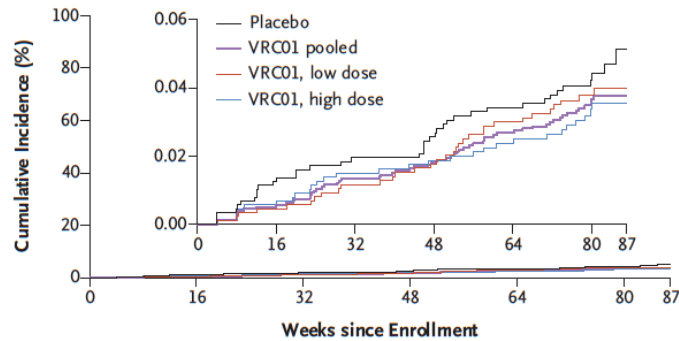
Two Randomized Trials of Neutralizing Antibodies to Prevent HIV-1 Acquisition

L. Corey, P.B. Gilbert, M. Juraska, D.C. Montefiori, L. Morris, S.T. Karuna, S. Edupuganti, N.M. Mgodhi, A.C. deCamp, E. Rudnicki, Y. Huang, P. Gonzales, R. Cabello, C. Orrell, J.R. Lama, F. Laher, E.M. Lazarus, J. Sanchez, I. Frank, J. Hinojosa, M.E. Sobieszczyk, K.E. Marshall, P.G. Mukwekwerere, J. Makhema, L.R. Baden, J.I. Mullins, C. Williamson, J. Hural, M.J. McElrath, C. Bentley, S. Takuva, M.M. Gomez Lorenzo, D.N. Burns, N. Espy, A.K. Randhawa, N. Kochar, E. Piwowar-Manning, D.J. Donnell, N. Sista, P. Andrew, J.G. Kublin, G. Gray, J.E. Ledgerwood, J.R. Mascola, and M.S. Cohen, for the HVTN 704/HPTN 085 and HVTN 703/HPTN 081 Study Teams*

VRC01, every 8 weeks for 20 mnths- 4623 participants

At-risk cg-men/tg persons (US, Switzerland, South America)

A Incidence of HIV-1 infection in HVTN 704/HPTN 085



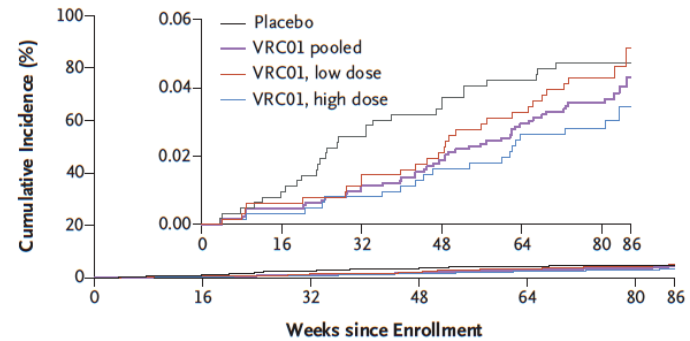
No. at Risk

Placebo	898	852	825	797	773	546	150
VRC01 pooled	1789	1711	1647	1600	1549	1072	340
VRC01, low dose	895	855	826	802	778	533	186
VRC01, high dose	894	856	821	798	771	539	154

Cumulative No. of HIV-1 Infections

Placebo	0	12	17	22	29	35	38
VRC01 pooled	0	10	23	31	45	59	60
VRC01, low dose	0	4	10	15	25	31	32
VRC01, high dose	0	6	13	16	20	28	28

B Incidence of HIV-1 infection in HVTN 703/HPTN 081



No. at Risk

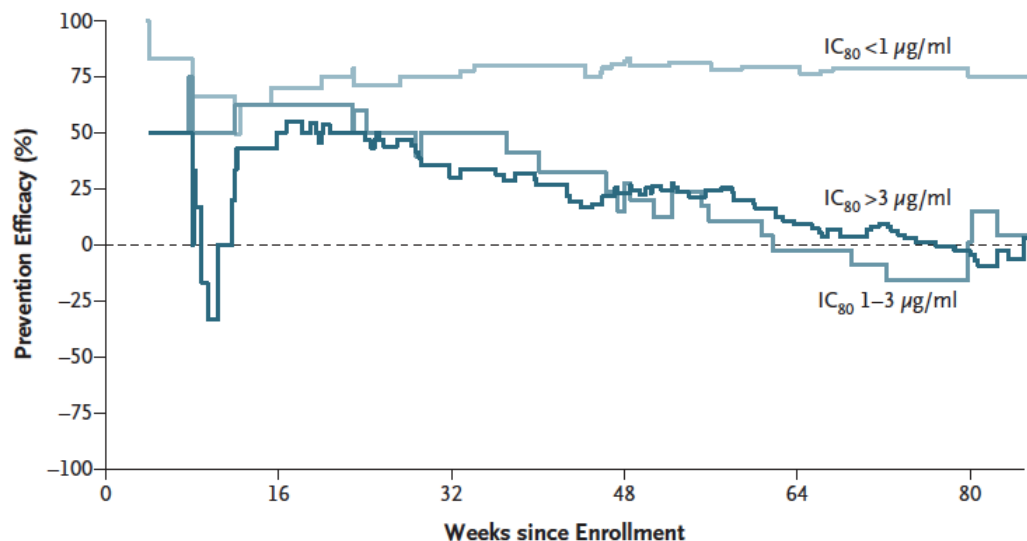
Placebo	637	617	600	582	572	454	157
VRC01 pooled	1287	1241	1211	1176	1146	938	312
VRC01, low dose	642	620	602	587	572	463	154
VRC01, high dose	645	621	609	589	574	475	158

Cumulative No. of HIV-1 Infections

Placebo	0	6	16	23	26	29	29
VRC01 pooled	0	6	14	23	36	43	47
VRC01, low dose	0	4	9	13	20	26	28
VRC01, high dose	0	2	5	10	16	17	19

C Annualized Incidence and Prevention Efficacy

Trial and Treatment Group	No. of HIV Infections	No. of Person-Yr	Rate per Person-Yr	Prevention Efficacy (95% CI)	P Value
HVTN 704/HPTN 085					
Placebo	38	1275	2.98		
VRC01 pooled	60	2555	2.35	26.6 (-11.7 to 51.8)	0.15
VRC01, low dose	32	1281	2.50	22.4 (-25.5 to 52.0)	
VRC01, high dose	28	1274	2.20	30.9 (-13.9 to 58.0)	
HVTN 703/HPTN 081					
Placebo	29	935	3.10		
VRC01 pooled	47	1889	2.49	8.8 (-45.1 to 42.6)	0.70
VRC01, low dose	28	941	2.98	-9.3 (-85.3 to 35.5)	
VRC01, high dose	19	948	2.00	27.0 (-30.7 to 59.3)	
Pooled trials					
Placebo	67	2207	3.04		
VRC01 pooled	107	4436	2.41	18.1 (-12.2 to 40.2)	0.21
VRC01, low dose	60	2217	2.71	7.2 (-33.3 to 35.3)	
VRC01, high dose	47	2219	2.12	29.0 (-4.0 to 51.6)	



75% efficacy for strains with $IC_{80} < 1 \mu g/ml$ (<30% of circulating viral strains)

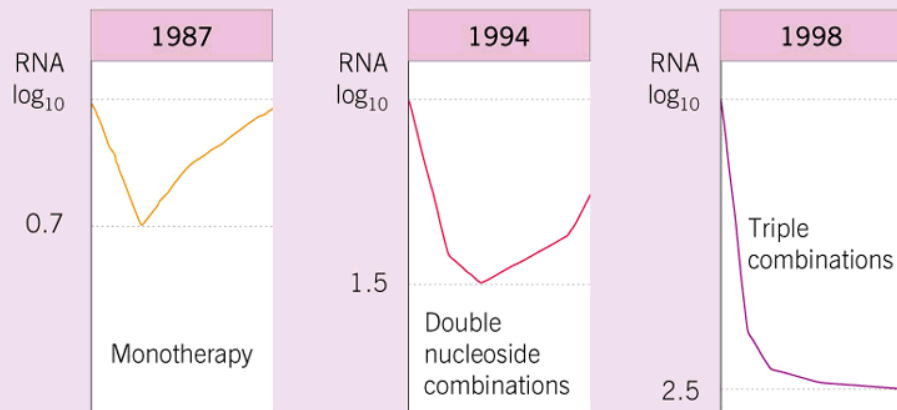
HIV isolates from VRC01 recipients were resistant to VRC01 than placebo

Prespecified IC_{80} Category and Treatment Group	No. of HIV-1 Infections	No. of Person-Yr	Rate per 100 Person-Yr	Prevention Efficacy (95% CI)
$< 1 \mu g/ml$				
Placebo	19	2203	0.86	
VRC01 pooled	9	4427	0.20	75.4 (45.5 to 88.9)
$1-3 \mu g/ml$				
Placebo	10	2203	0.45	
VRC01 pooled	19	4427	0.43	4.2 (-108.7 to 56.0)
$> 3 \mu g/ml$				
Placebo	35	2203	1.59	
VRC01 pooled	70	4427	1.58	3.3 (-48.0 to 36.8)

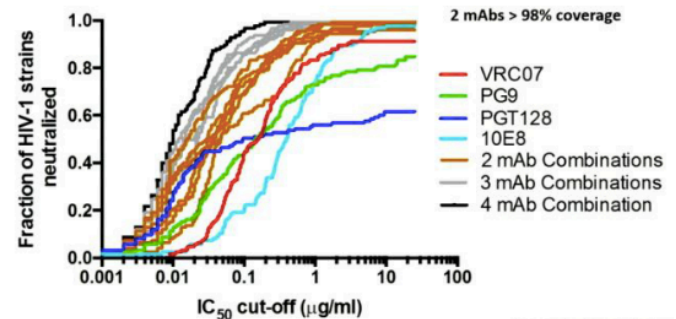
Obstacles to bNAb therapy:

- high circulation of isolates with innate resistance;
- selection of resistant strains

EVOLUTION OF CHANGES IN HIV-RNA PLASMA LEVELS OBTAINED WITH THE USE OF DIFFERENT ANTIRETROVIRAL REGIMENS



Combined Antibodies: Improved Potency and Breadth



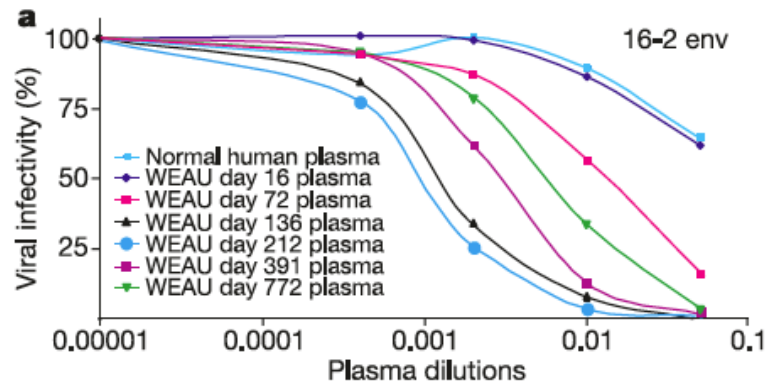
Kong, Montefiori, Korber et al.
J. Virol (2015)

HIV

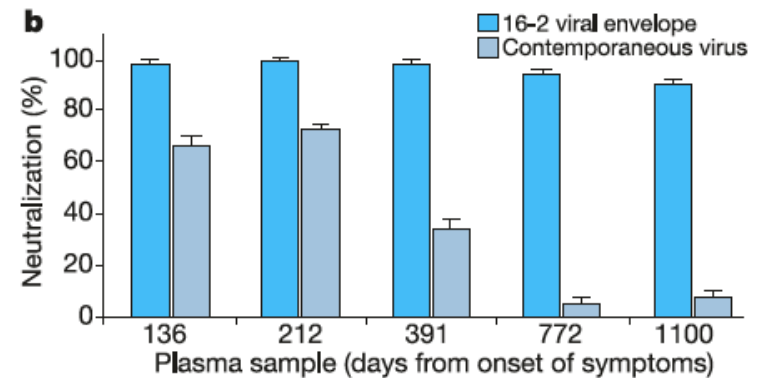
Which (biological) reasons behind the failure of vaccination, antibody-mediated prevention?

Nab viral escape

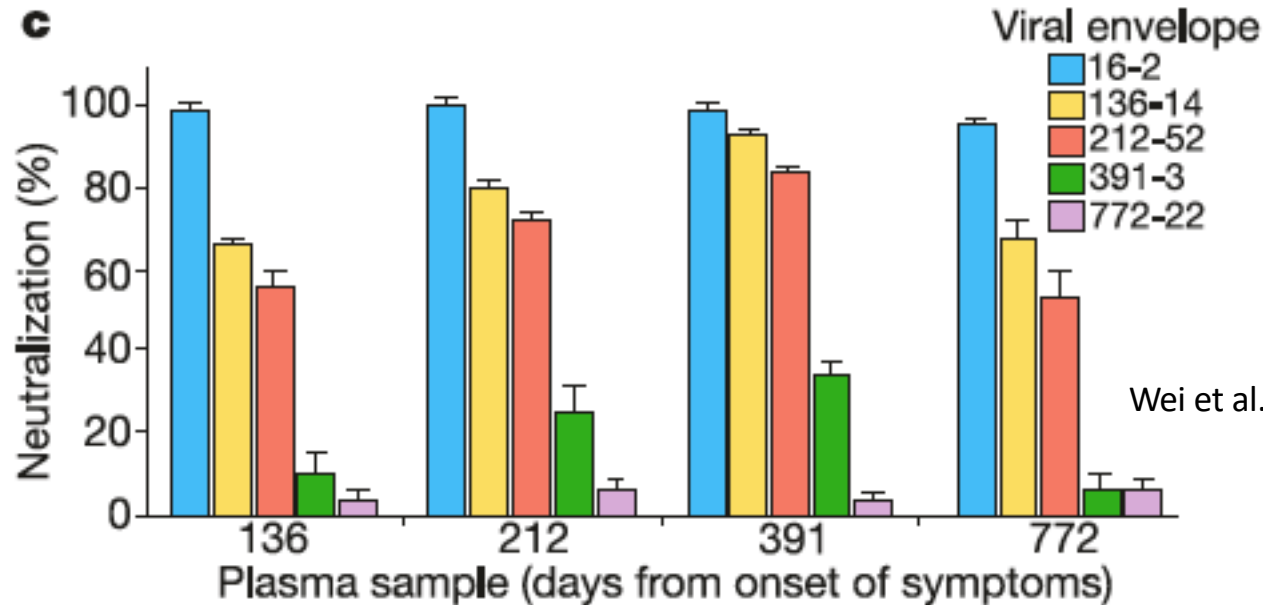
Early Nab production: Inhibition of HIV-1 entry by sequential autologous plasma from WEAU patient since acute infection.



Contemporaneous viruses less susceptible to neutralization than early day-16 virus, suggesting changes in viral envelope



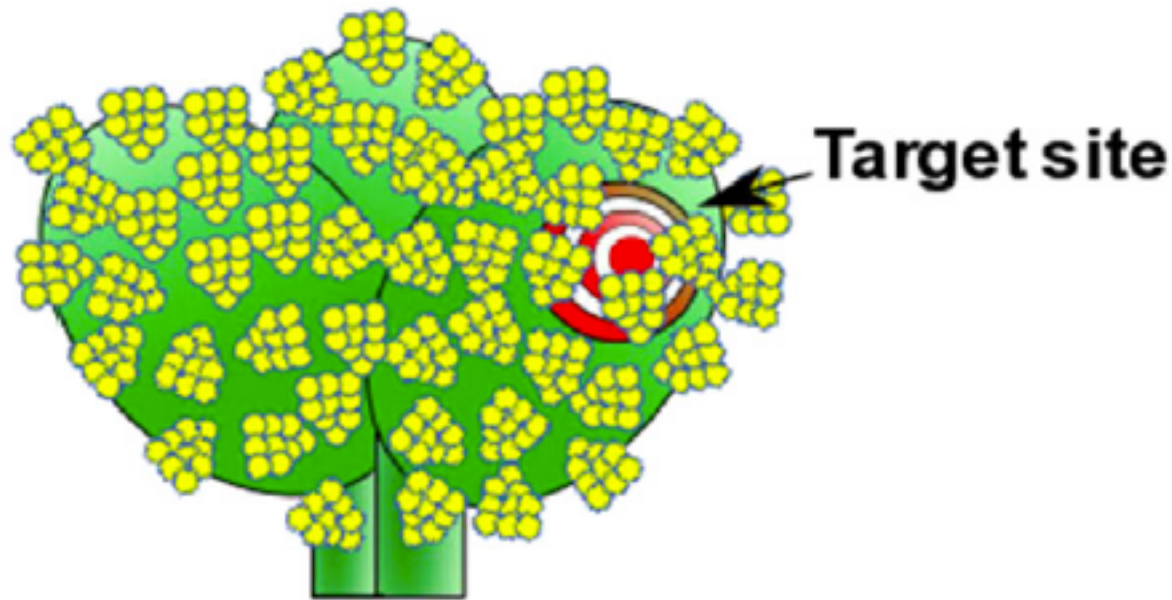
In the first 391 days Nab activity retained against subsequent viruses, then wanes



Wei et al. Nature 2003

HIV Glycan Shield as mechanism to hamper Nab activity

Escape viruses contain sparse mutation in the env gene involving changes in N-glycosylation, leading to «glycan shield», in turn preventing Jab binding but not receptor binding

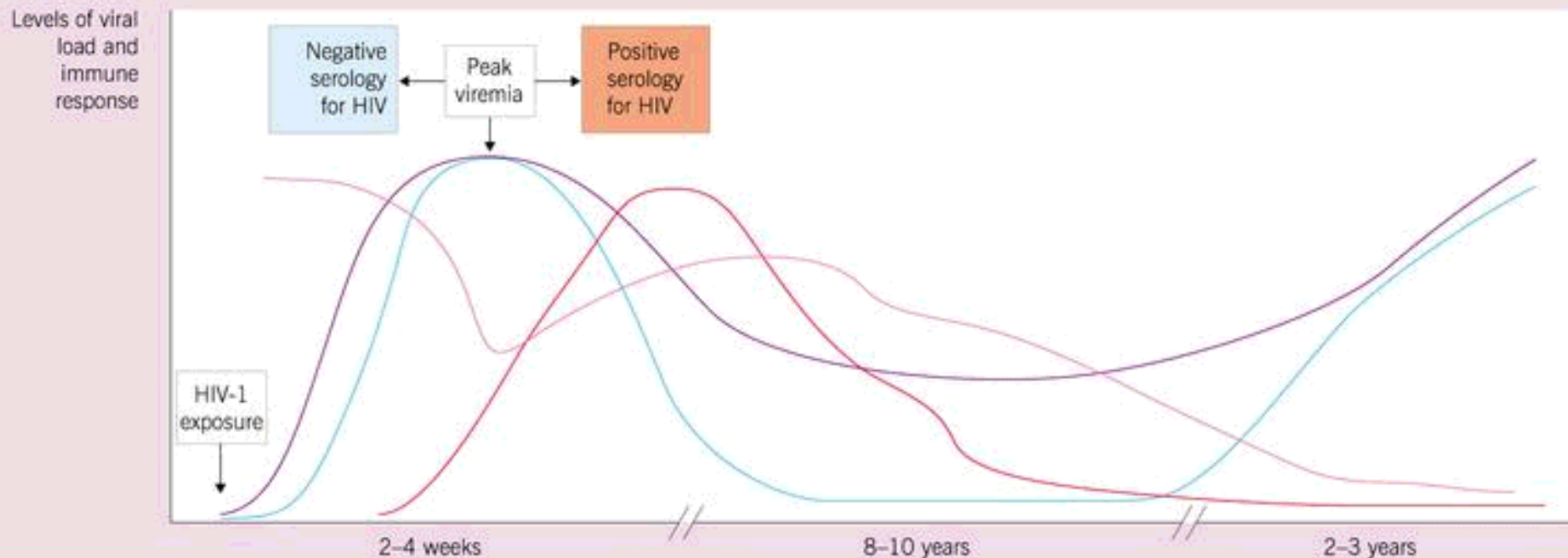


**HIV-1 native-like trimer
with intact glycan shield**

Which (biological) reasons
behind the failure of vaccination,
antibody-mediated prevention

Same reason for the failure to
naturally control HIV infection

KINETICS OF VIRAL LOAD AND IMMUNE RESPONSE DURING THE PHASES OF HIV-1 INFECTION



Acute clinical syndrome	
Symptoms	% of patients
Fever	80-90
Fatigue	70-90
Rash	40-80
Headache	32-70
Lymphadenopathy	40-70
Pharyngitis	50-70
Arthralgia	5-70
Myalgia	50-70
Night sweats	50
Gastrointestinal symptoms	30-60
Aseptic meningitis	24
Oral or genital ulcers	5-20

Phase of clinical latency
Late appearance of constitutional symptoms

Overt AIDS
Severe constitutional symptoms
Opportunistic infections
Neoplasms

— Plasma viremia	— Viral load in lymphoid tissue
— Immune response (HIV-1-specific cytotoxic lymphocytes)	— CD4 ⁺ T lymphocyte count

COVID-19: a new pandemic



Global Situation

172,630,637

confirmed cases



3,718,683

deaths



Source: World Health Organization

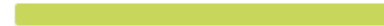
Situation by WHO Region

Americas



68,369,827
confirmed

Europe



54,625,827
confirmed

South-East Asia



32,654,915
confirmed

Eastern Mediterranean



10,276,459
confirmed

Africa



3,563,815
confirmed

Western Pacific



3,139,030
confirmed

Source: World Health Organization

A short and successful run
for vaccination and antibody
mediated prevention

COVID-19 Vaccine developer/manufacturer	Vaccine platform	Type of candidate vaccine	Number of doses	Timing of doses	Route of Administration	Clinical Stage			
						Phase 1	Phase 1/2	Phase 2	Phase 3
Moderna/NIAID	RNA	LNP-encapsulated mRNA	2	0,28 days	IM	NCT04283461 Interim Report Final Report		NCT04405076	NCT04470427
BioNTech/Fosun Pharma/Pfizer	RNA	3 LNP-mRNAs	2	0,28 days	IM	NCT04368728 Study Report	2020-001038-36 ChiCTR2000034825 NCT04537949 NCT04588480 Study Report1 Study Report2		NCT04368728

Phase I, RNA vaccine, mRNA-1273 encoding SARs-Cov2 spike protein; 2 doses 28 day apart (25 microg and 100 microg)

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine

L.R. Baden, H.M. El Sahly, B. Essink, K. Kotloff, S. Frey, R. Novak, D. Diemert, S.A. Spector, N. Rouphael, C.B. Creech, J. McGettigan, S. Khetan, N. Segall, J. Solis, A. Brosz, C. Fierro, H. Schwartz, K. Neuzil, L. Corey, P. Gilbert, H. Janes, D. Follmann, M. Marovich, J. Mascola, L. Polakowski, J. Ledgerwood, B.S. Graham, H. Bennett, R. Pajon, C. Knightly, B. Leav, W. Deng, H. Zhou, S. Han, M. Ivarsson, J. Miller, and T. Zaks, for the COVE Study Group*

ORIGINAL ARTICLE

An mRNA Vaccine against SARS-CoV-2 — Preliminary Report

L.A. Jackson, E.J. Anderson, N.G. Rouphael, P.C. Roberts, M. Makhene, R.N. Coler, M.P. McCullough, J.D. Chappell, M.R. Denison, L.J. Stevens, A.J. Pruijssers, A. McDermott, B. Flach, N.A. Doria-Rose, K.S. Corbett, K.M. Morabito, S. O'Dell, S.D. Schmidt, P.A. Swanson II, M. Padilla, J.R. Mascola, K.M. Neuzil, H. Bennett, W. Sun, E. Peters, M. Makowski, I. Albert, K. Cross.

The NEW ENGLAND JOURNAL of MEDICINE

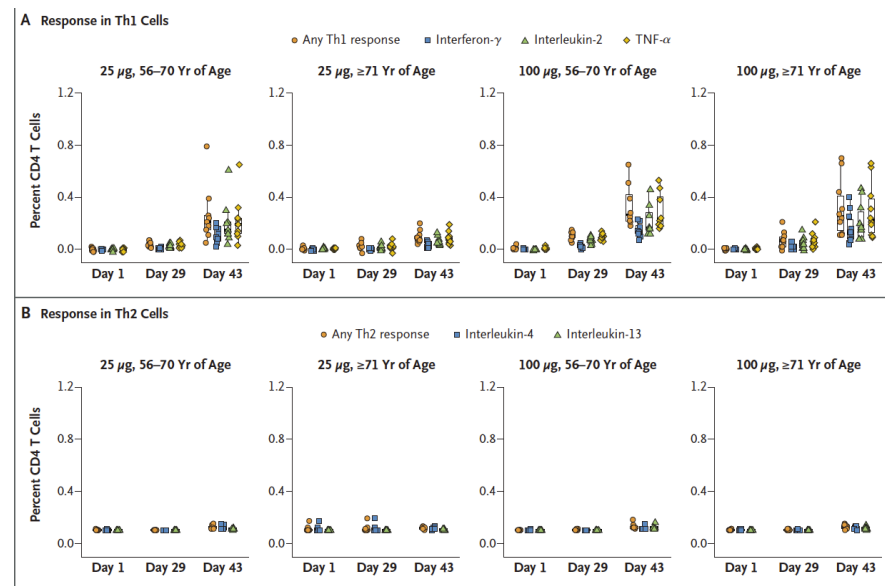
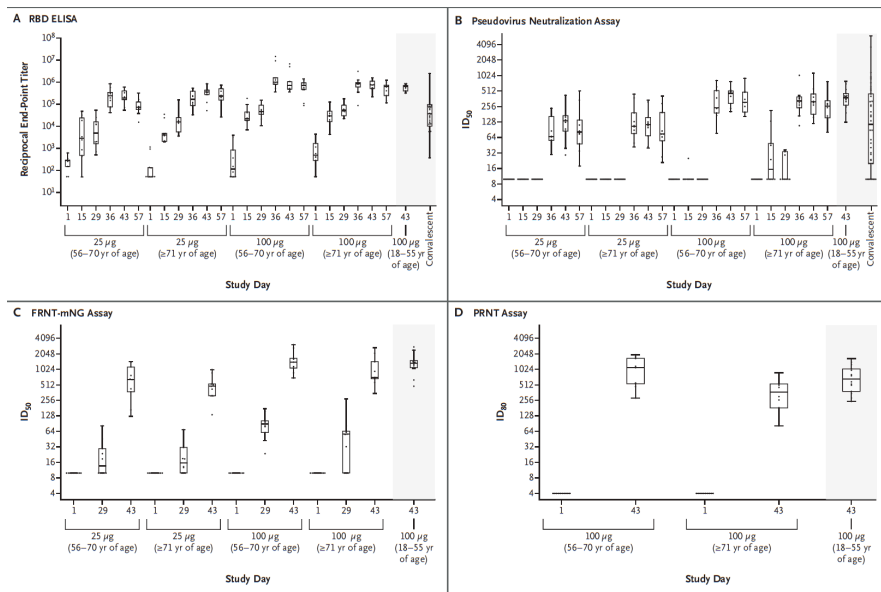
ORIGINAL ARTICLE

Safety and Immunogenicity of SARS-CoV-2 mRNA-1273 Vaccine in Older Adults

E.J. Anderson, N.G. Rouphael, A.T. Widge, L.A. Jackson, P.C. Roberts, M. Makhene, J.D. Chappell, M.R. Denison, L.J. Stevens, A.J. Pruijssers, A.B. McDermott, B. Flach, B.C. Lin, N.A. Doria-Rose, S. O'Dell, S.D. Schmidt, K.S. Corbett, P.A. Swanson II, M. Padilla, K.M. Neuzil, H. Bennett, B. Leav, M. Makowski, J. Albert, K. Cross, V.V. Edara, K. Floyd, M.S. Suthar, D.R. Martinez, R. Baric, W. Buchanan, C.J. Luke, V.K. Phadke, C.A. Rostad, J.E. Ledgerwood, B.S. Graham, and J.H. Beigel, for the mRNA-1273 Study Group*

This article was published on December 30, 2020, at NEJM.org.

DOI: 10.1056/NEJMoa2035389



COVID-19 is an emerging, rapidly evolving situation.

• Get the latest public health information from CDC • Get the latest research information from NIH • NIH staff guidance on coronavirus (NIH Only) •

Home » News & Events » News Releases

NEWS RELEASES

Monday, November 16, 2020

Institute/Center

20

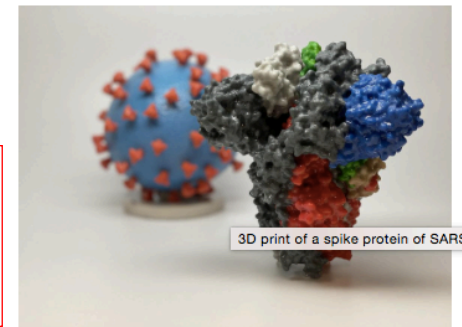
- 30,000 participants at 100 clinical research sites in the United States
- launched on July 27, 2020
- 94.5% efficacy
 - 90 cases in placebo
 - 5 cases in vaccinated group
- 11/95 were severe cases
 - all in placebo

Promising Interim Results from Clinical Trial of NIH-Moderna COVID-19 Vaccine



An independent data and safety monitoring board (DSMB) overseeing the Phase 3 trial of the investigational COVID-19 vaccine known as mRNA-1273 reviewed trial data and shared its interim analysis with the trial oversight group on Nov. 15, 2020. This interim review of the data suggests that the vaccine is safe and effective at preventing symptomatic COVID-19 in adults. The interim analysis comprised 95 cases of symptomatic COVID-19 among volunteers. The DSMB reported that the candidate was safe and well-tolerated and noted a vaccine efficacy rate of 94.5%. The findings are statistically significant, meaning they are likely not due to chance. 90 of the cases occurred in the placebo group and 5 occurred in the vaccinated group. There were 11 cases of severe COVID-19 out of the 95 total, all of which occurred in the placebo group.

The mRNA-1273 vaccine candidate was co-developed by the Cambridge, Massachusetts-based biotechnology company Moderna, Inc., and the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health. It combines Moderna's mRNA (messenger RNA) delivery platform with the [stabilized SARS-CoV-2 spike immunogen \(S-2P\)](#) developed by NIAID scientists.



3D print of a spike protein of SARS-CoV-2

3D print of a spike protein of SARS-CoV-2, the virus that causes COVID-19, in front of a 3D print of a SARS-CoV-2 virus particle. The spike protein (foreground) enables the virus to enter and infect human cells. On the virus model, the virus surface (blue) is covered with spike proteins (red) that enable the virus to enter and infect human cells. *NIH*

COVID-19 Vaccine developer/manufacturer	Vaccine platform	Type of candidate vaccine	Number of doses	Timing of doses	Route of Administration	Clinical Stage			
						Phase 1	Phase 1/2	Phase 2	Phase 3
Moderna/NIAID	RNA	LNP-encapsulated mRNA	2	0,28 days	IM	NCT04283461 Interim Report Final Report		NCT04405076	NCT04470427
BioNTech/Fosun Pharma/Pfizer	RNA	3 LNP-mRNAs	2	0,28 days	IM	NCT04368728 Study Report	2020-001038-36 ChiCTR2000034825 NCT04537949 NCT04588480 Study Report1 Study Report2		NCT04368728

INTERIM REPORT

Article

Phase I/II study of COVID-19 RNA vaccine BNT162b1 in adults

<https://doi.org/10.1038/s41586-020-2639-4>
Received: 29 June 2020
Accepted: 4 August 2020
Published online: 12 August 2020

Check for updates

Mark J. Mulligan^{1,2,12}, Kirsten E. Lyke^{3,12}, Nicholas Kitchin^{4,12}, Judith Absalon^{5,12}, Alejandra Gurtman⁵, Stephen Lockhart⁴, Kathleen Neuzil³, Vanessa Raabe^{1,2}, Ruth Bailey⁴, Kena A. Swanson⁵, Ping Li⁶, Kenneth Koury⁵, Warren Kalina⁵, David Cooper⁵, Camila Fontes-Garfias⁷, Pei-Yong Shi⁷, Özlem Türeci⁸, Kristin R. Tompkins⁵, Edward E. Walsh^{9,10}, Robert Frenck¹¹, Ann R. Falsey^{9,10}, Philip R. Dormitzer⁵, William C. Gruber⁵, Uğur Şahin⁸ & Kathrin U. Jansen⁵

This article was published on October 14, 2020, at NEJM.org.

The NEW ENGLAND JOURNAL of MEDICINE DOI: 10.1056/NEJMoa2027906

Phase I, RNA vaccine, RNA 2 doses 21 day apart (10, 30, 100 microg)

ORIGINAL ARTICLE

Safety and Immunogenicity of Two RNA-Based Covid-19 Vaccine Candidates

FINAL REPORT

Edward E. Walsh, M.D., Robert W. Frenck, Jr., M.D., Ann R. Falsey, M.D., Nicholas Kitchin, M.D., Judith Absalon, M.D., Alejandra Gurtman, M.D., Stephen Lockhart, D.M., Kathleen Neuzil, M.D., Mark J. Mulligan, M.D., Ruth Bailey, B.Sc., Kena A. Swanson, Ph.D., Ping Li, Ph.D., Kenneth Koury, Ph.D., Warren Kalina, Ph.D., David Cooper, Ph.D., Camila Fontes-Garfias, B.Sc., Pei-Yong Shi, Ph.D., Özlem Türeci, M.D., Kristin R. Tompkins, B.Sc., Kirsten E. Lyke, M.D., Vanessa Raabe, M.D., Philip R. Dormitzer, M.D., Kathrin U. Jansen, Ph.D., Uğur Şahin, M.D., and William C. Gruber, M.D.

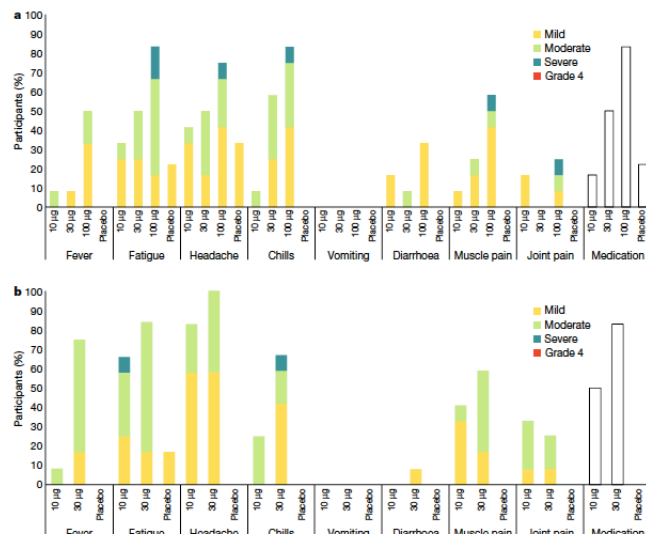
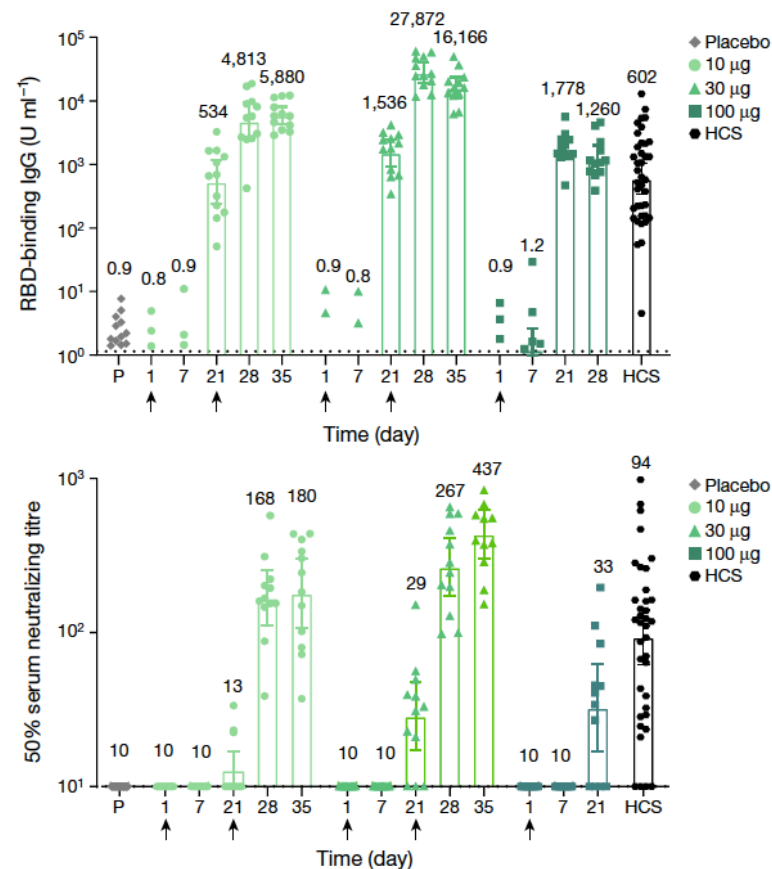


Fig. 3 | Systemic events and medication use reported within 7 days after vaccination. **a**, Systemic events and medication use reported within 7 days after vaccination 1 for all dose levels. **b**, Systemic events and medication use reported within 7 days after vaccination 2 for the 10-µg and 30-µg dose levels. Solicited systemic events were: fatigue, headache, chills, new or worsened muscle pain, new or worsened joint pain (mild, does not interfere with activity; moderate, some interference with activity; severe, prevents daily activity), vomiting (mild, 1–2 times in 24 h; moderate, >2 times in 24 h; severe, requires

Intravenous hydration), diarrhoea (mild, 2–3 loose stools in 24 h; moderate, 4–5 loose stools in 24 h; severe: 6 or more loose stools in 24 h); grade 4 for all events: emergency room visit or hospitalization; and fever (mild, 38.0–38.4 °C; moderate, 38.5–38.9 °C; severe, 39.0–40.0 °C; grade 4, >40.0 °C). Medication indicates the proportion of participants who reported the use of antipyretic or pain medication. Data were collected with the use of electronic diaries for 7 days after each vaccination.



- 43000 enrolled
- 95% efficacy
- 162 cases in placebo
- 8 cases in vaccinated
- 10/170 were severe:
9 in placebo, 1 in vaccinated group

NEWS / Pfizer and BioNTech Conclude Phase 3 Study of COVID-19 Vaccine Candidate, Meeting All Primary Efficacy Endpoints

PFIZER AND BIONTECH CONCLUDE PHASE 3 STUDY OF COVID-19 VACCINE CANDIDATE, MEETING ALL PRIMARY EFFICACY ENDPOINTS

Wednesday, November 18, 2020 - 06:59am

- Primary efficacy analysis demonstrates BNT162b2 to be 95% effective against COVID-19 beginning 28 days after the first dose; 170 confirmed cases of COVID-19 were evaluated, with 162 observed in the placebo group versus 8 in the vaccine group
- Efficacy was consistent across age, gender, race and ethnicity demographics; observed efficacy in adults over 65 years of age was over 94%
- Safety data milestone required by U.S. Food and Drug Administration (FDA) for Emergency Use Authorization (EUA) has been achieved
- Data demonstrate vaccine was well tolerated across all populations with over 43,000 participants enrolled; no serious safety concerns observed; the only Grade 3 adverse event greater than 2% in frequency was fatigue at 3.8% and headache at 2.0%
- Companies plan to submit within days to the FDA for EUA and share data with other regulatory agencies around the globe
- The companies expect to produce globally up to 50 million vaccine doses in 2020 and up to 1.3 billion doses by the end of 2021
- Pfizer is confident in its vast experience, expertise and existing cold-chain infrastructure to distribute the vaccine around the world

NEW YORK & MAINZ, Germany--(BUSINESS WIRE)-- [Pfizer Inc.](#) (NYSE: PFE) and [BioNTech SE](#) (Nasdaq: BNTX) today announced that, after conducting the final efficacy analysis in their ongoing Phase 3 study, their mRNA-based COVID-19 vaccine candidate, BNT162b2, met all of the study's primary efficacy endpoints. Analysis of the data indicates a vaccine efficacy rate of 95% ($p < 0.0001$) in participants without prior SARS-CoV-2 infection (first primary objective) and also in participants with and without prior SARS-CoV-2 infection (second primary objective), in each case measured from 7 days after the second dose. The first primary objective analysis is based on 170 cases of COVID-19, as specified in the study protocol, of which 162 cases of COVID-19 were observed in the placebo group versus 8 cases in the BNT162b2 group. Efficacy was consistent across age, gender, race and ethnicity demographics. The observed efficacy in adults over 65 years of age was over 94%.

This press release features multimedia. View the full release here: <https://www.businesswire.com/news/home/20201118005595/en>

There were 10 severe cases of COVID-19 observed in the trial, with nine of the cases occurring in the placebo group and one in the BNT162b2 vaccinated group.

News Release

Regulatory News Service



This announcement contains inside information

23 November 2020 07:00 GMT

AZD1222 vaccine met primary efficacy endpoint in preventing COVID-19

Two different dosing regimens demonstrated efficacy with one showing a better profile

No hospitalisations or severe cases of COVID-19 in participants treated with AZD1222

Safety and immunogenicity of the ChAdOx1 nCoV-19 vaccine against SARS-CoV-2: a preliminary report of a phase 1/2, single-blind, randomised controlled trial

Pedro M Folegatti*, Katie J Ewer*, Parvinder K Aley, Brian Angus, Stephan Becker, Sandra Belji-Rammerstorfer, Duncan Bellamy, Sagida Bibi, Mustapha Bittaye, Elizabeth A Clutterbuck, Christina Dold, Saul N Faust, Adam Finn, Amy L Flaxman, Bassam Hallis, Paul Heath, Daniel Jenkin, Rajeka Lazarus, Rebecca Makinson, Angela M Minassian, Katrina M Pollock, Maheshi Ramasamy, Hannah Robinson, Matthew Snape, Richard Tarrant, Merryn Voysey, Catherine Green*, Alexander D Douglas*, Adrian V S Hill*, Teresa Lambe*, Sarah C Gilbert*, Andrew J Pollard*, on behalf of the Oxford COVID Vaccine Trial Group†



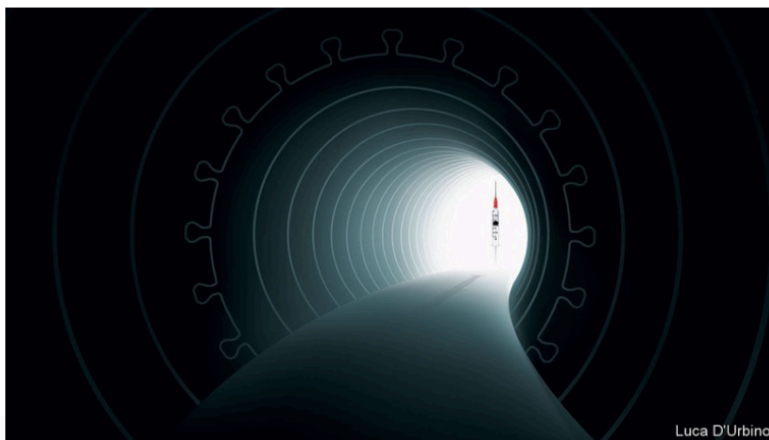
Leaders

Nov 14th 2020 edition >

Suddenly, hope

The promise of the new covid-19 vaccine is immense

But don't underestimate the challenge of getting people vaccinated



Emergency Use Authorization of Covid Vaccines — Safety and Efficacy Follow-up Considerations

Philip R. Krause, M.D., and Marion F. Gruber, Ph.D.

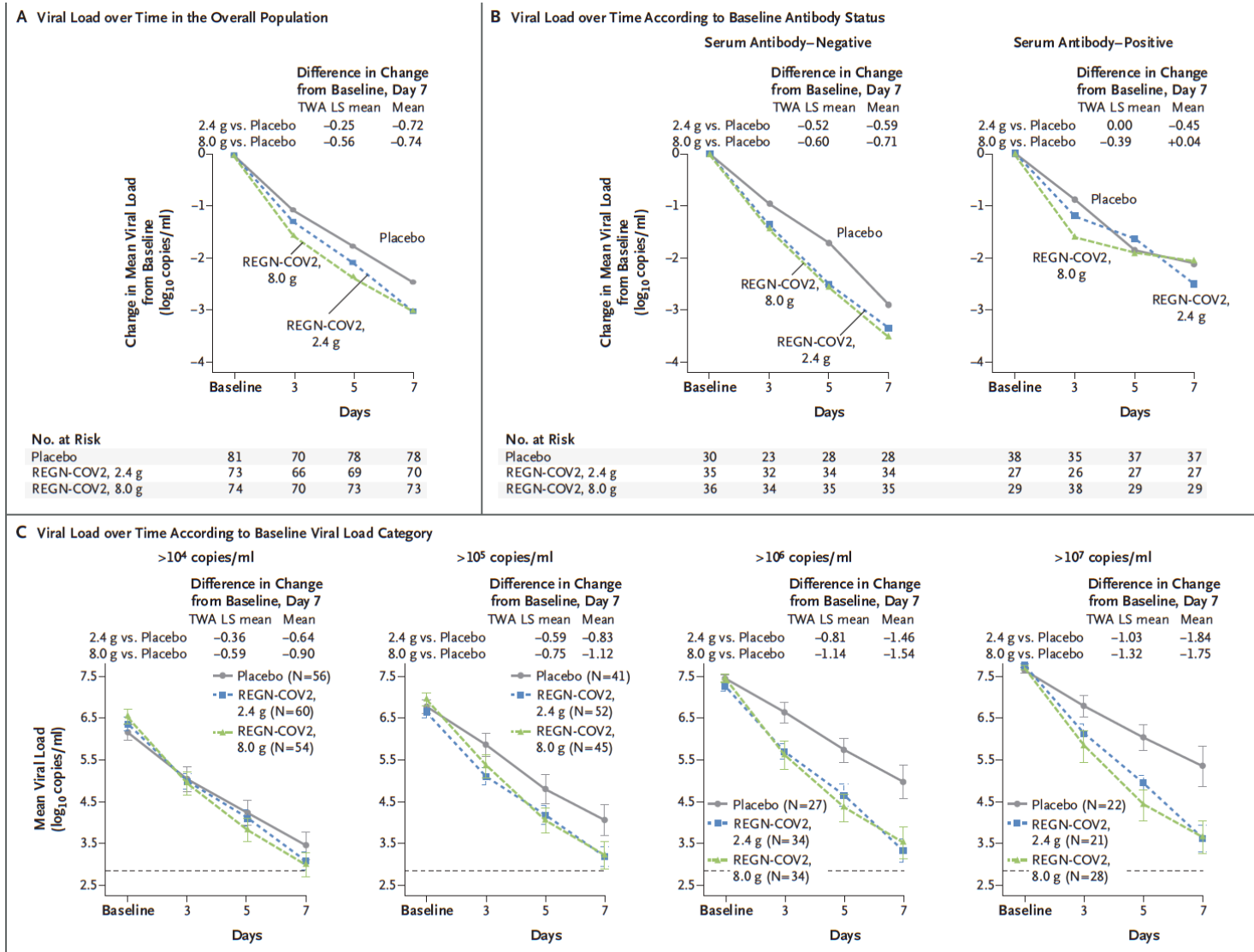
Time for regulatory approval

- **Emergency Use Authorization:** median follow-up duration of at least 2 months (FDA)/3 months (WHO) after completion of the full vaccination regimen
- **safety:** identification of potential adverse events that were not apparent in the immediate postvaccination period and will also provide greater confidence in their absence
- **efficacy:** data on whether protection mediated by early responses (IgM and IgG peak at or before 2 to 4 weeks after vaccination) has started to wane

“...we believe that a median 2-month follow-up after completion of the vaccine regimen will provide the necessary safety and effectiveness data to support distribution of an investigational vaccine under an EUA. Curtailment of this minimum follow-up could destroy the scientific credibility of the decision to authorize any vaccine for use under an EUA in the United States”.

REGN-COV2

275 SARS-COV2+ outpatients, 7 days within symptoms onset, 72 hrs within positive swab



LyCOV555

452 SARS-COV2+ outpatients, 4 days within symptoms onset

B Viral Load on Day 7 in Each Trial Group

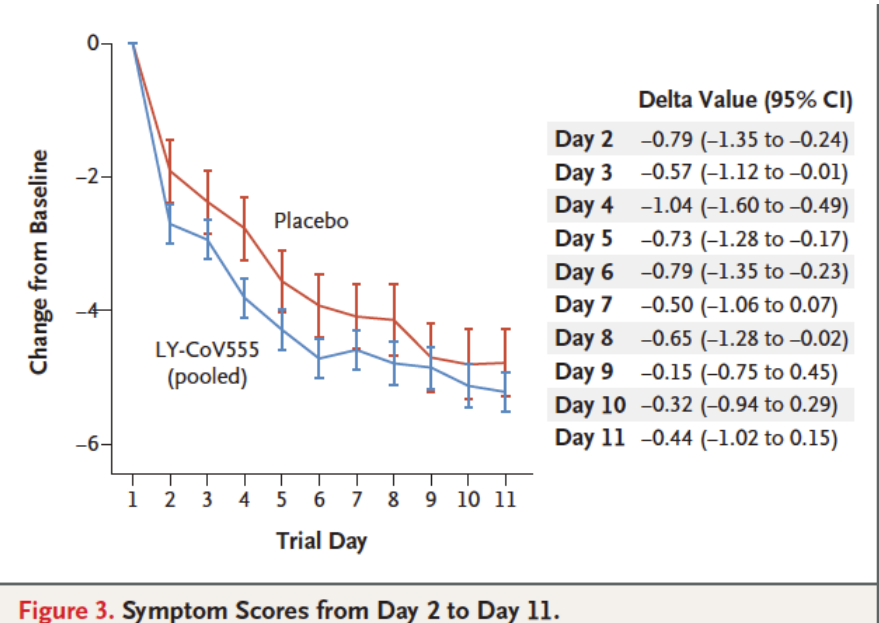
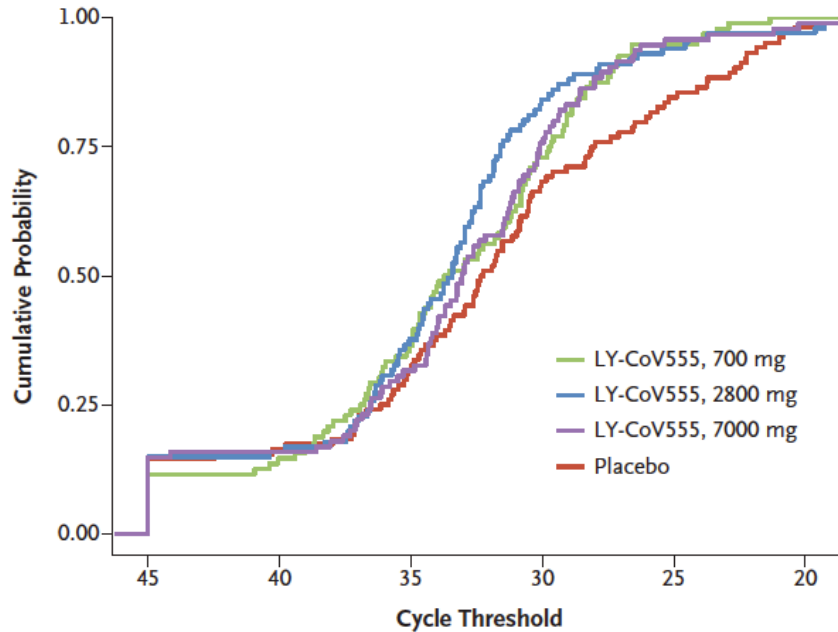


Figure 3. Symptom Scores from Day 2 to Day 11.

SARS-COV-2

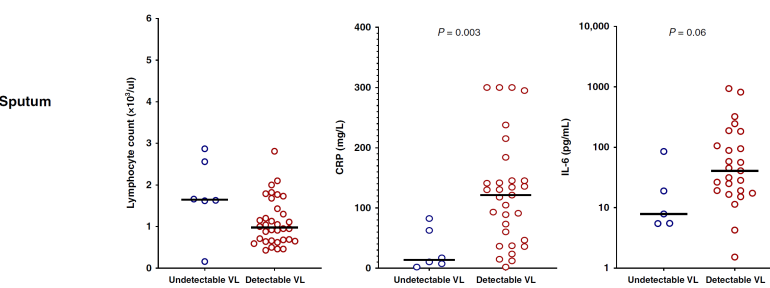
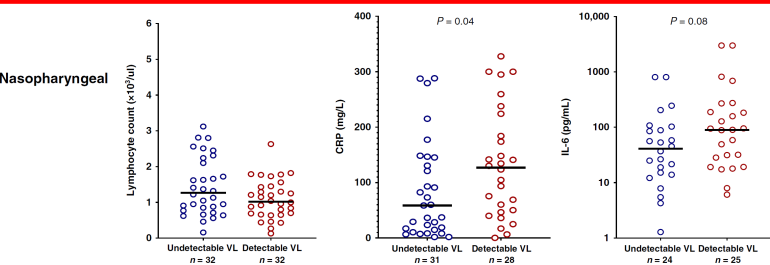
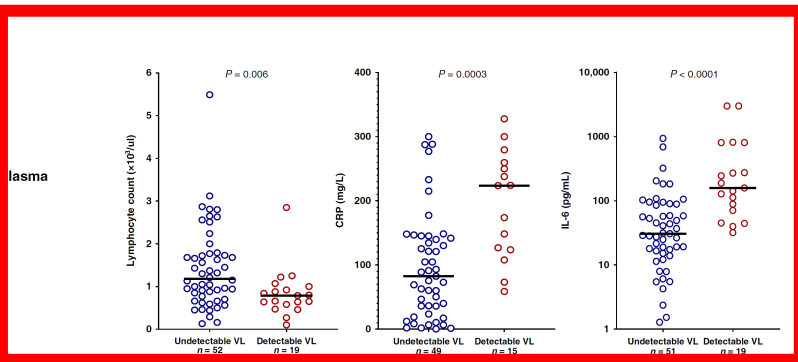
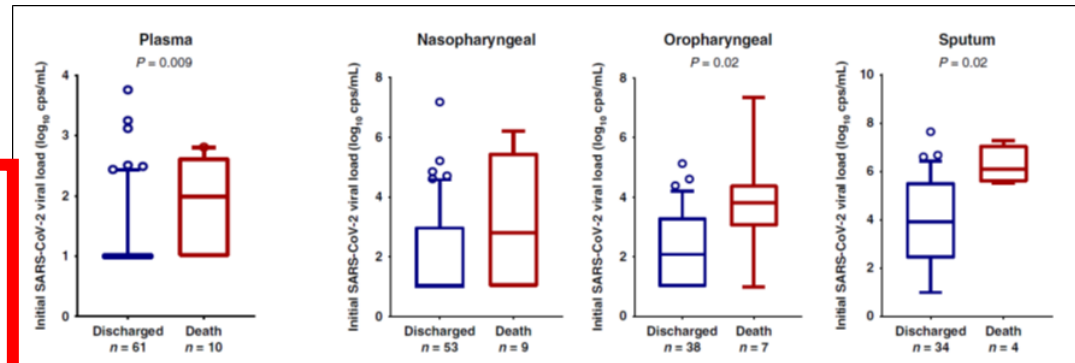
Which (biological) reasons behind the efficacy of antibody-mediated therapy/prevention and vaccine?

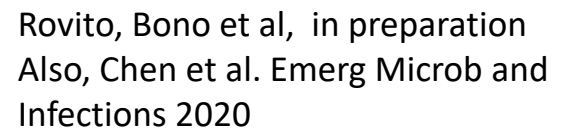
SARS-COV-2

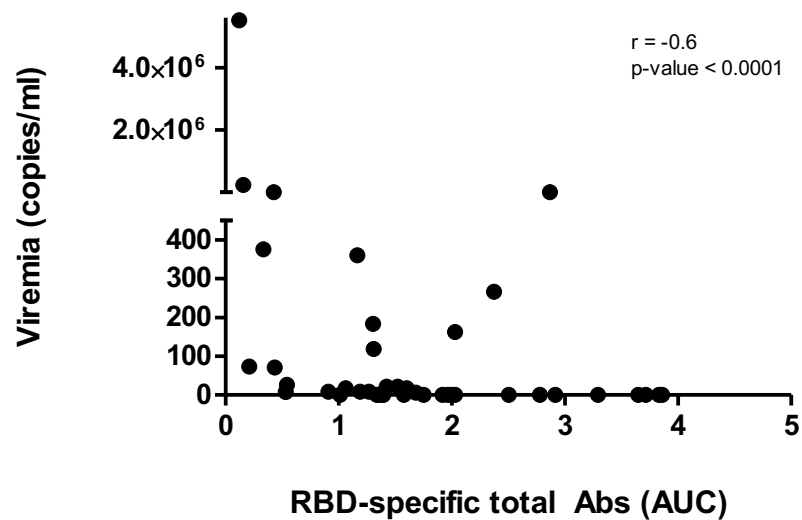
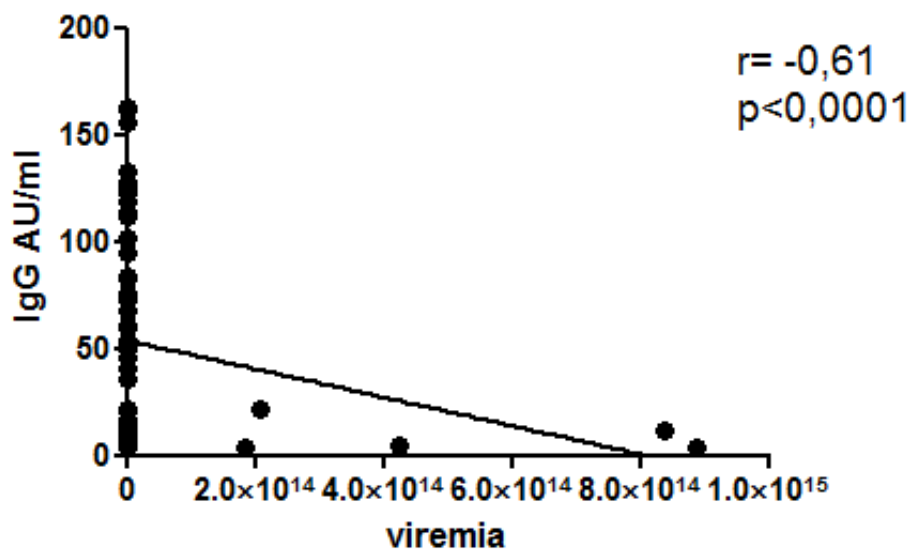
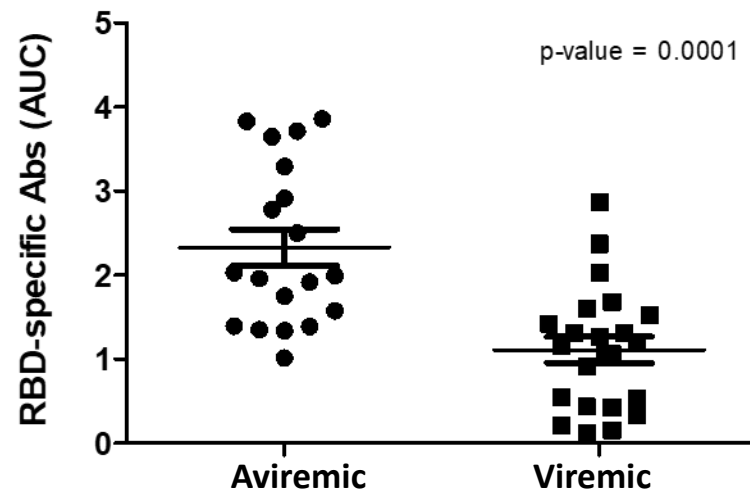
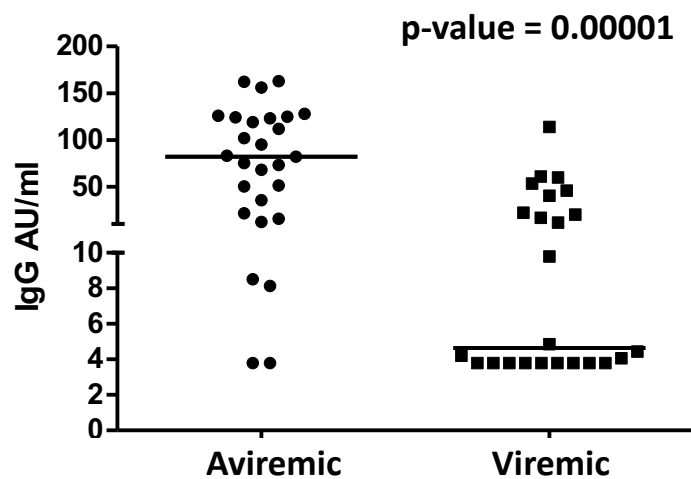
Which (biological) reasons behind the efficacy of antibody-mediated therapy/prevention and vaccine?

Potent effect of Mab in
reducing SARS-COV-2 viral load

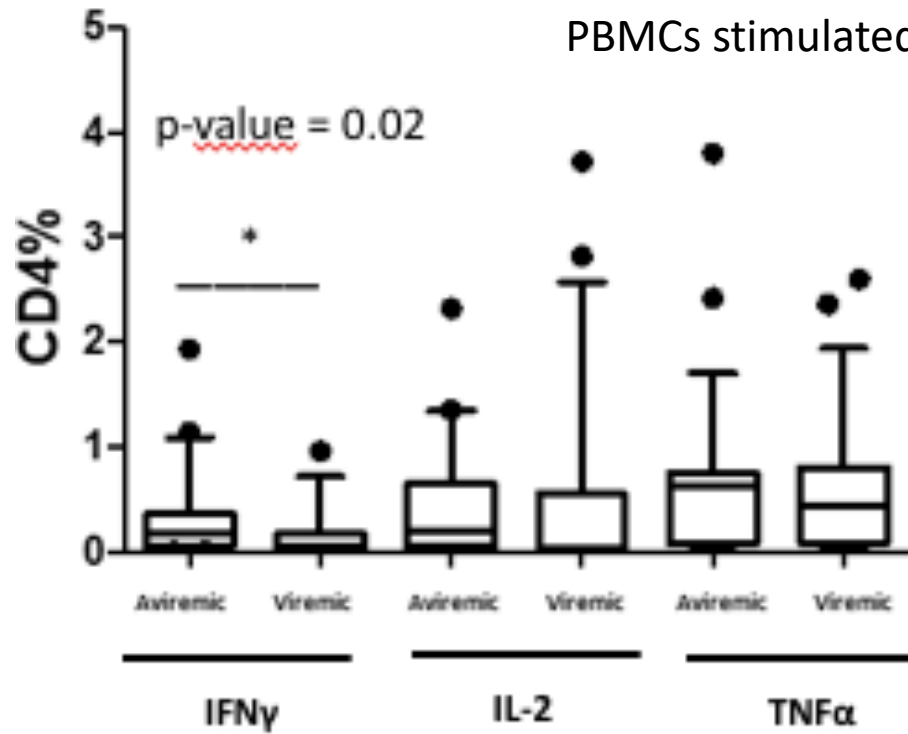
SARS-CoV-2 viral load strongly associated to disease severity



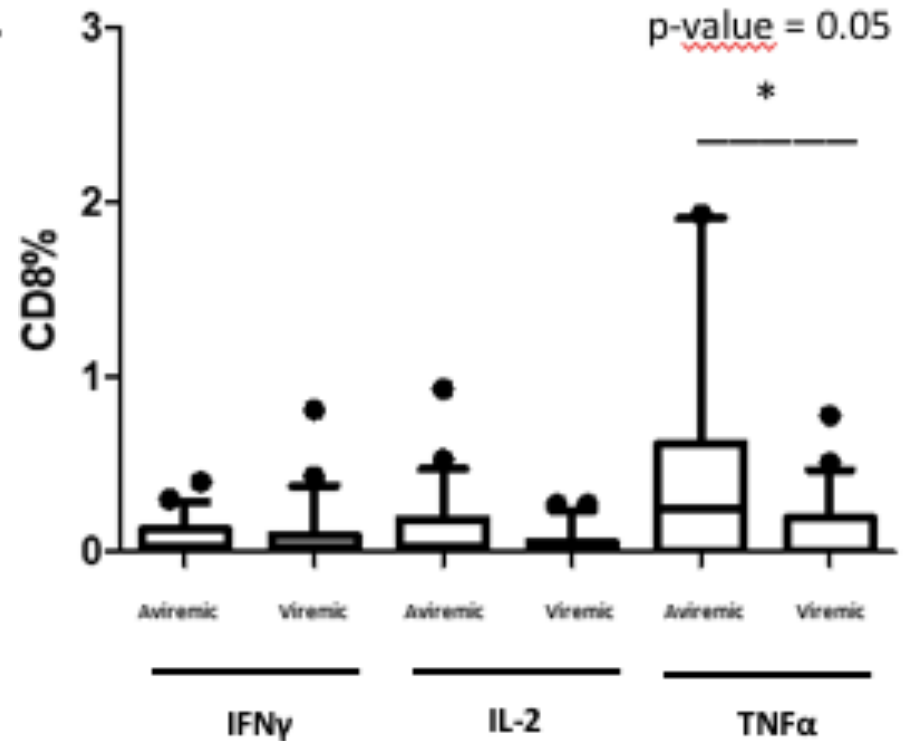




PBMCs stimulated with SARS-CoV-2 peptide pool (S, N and M)

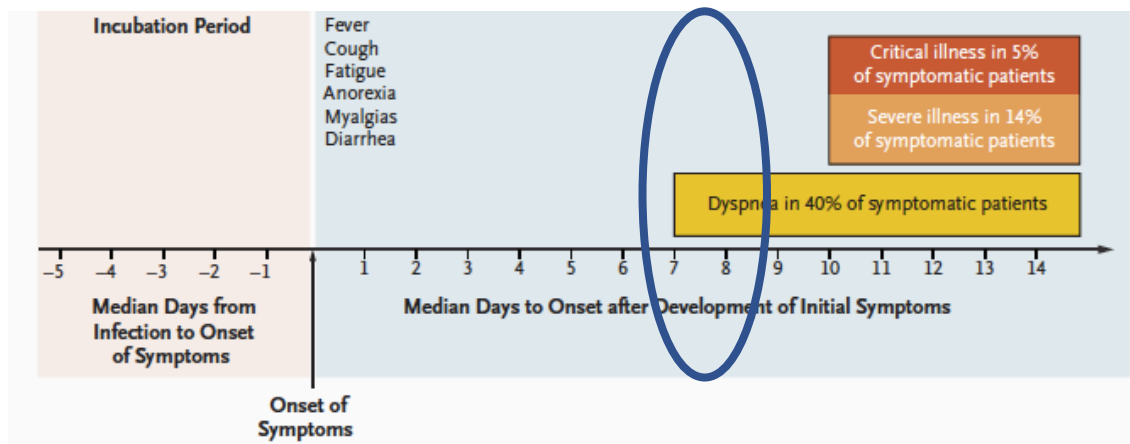


Negative interaction between SARS-COV2 viremia and SARS-COV-2-specific adaptive immunity

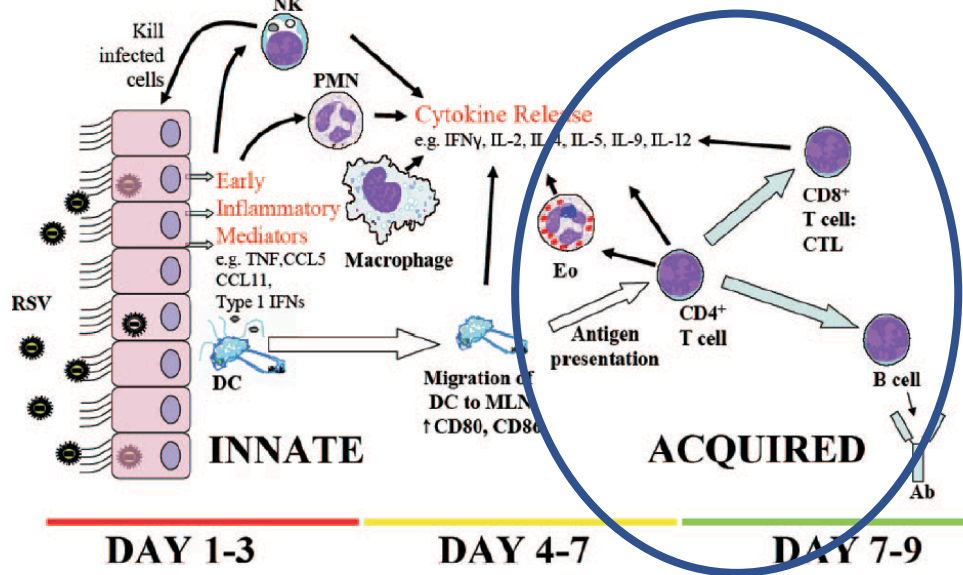


Research question

By accelerating SARS-COV-2 viral load reduction in the earliest phases of COVID-19, mAb will boost SARS-COV-2-specific adaptive immunity?

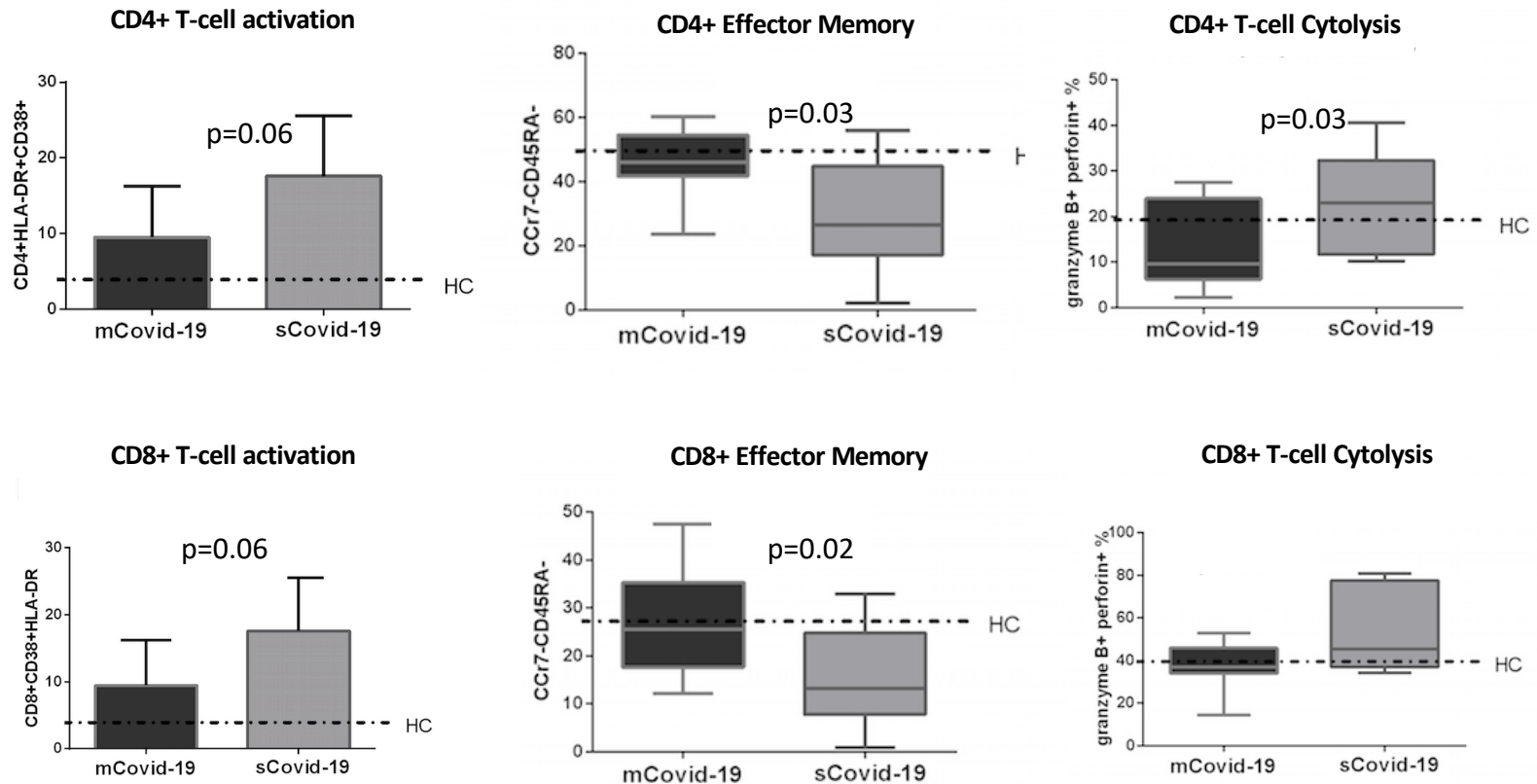


Berlin NEJM 2020



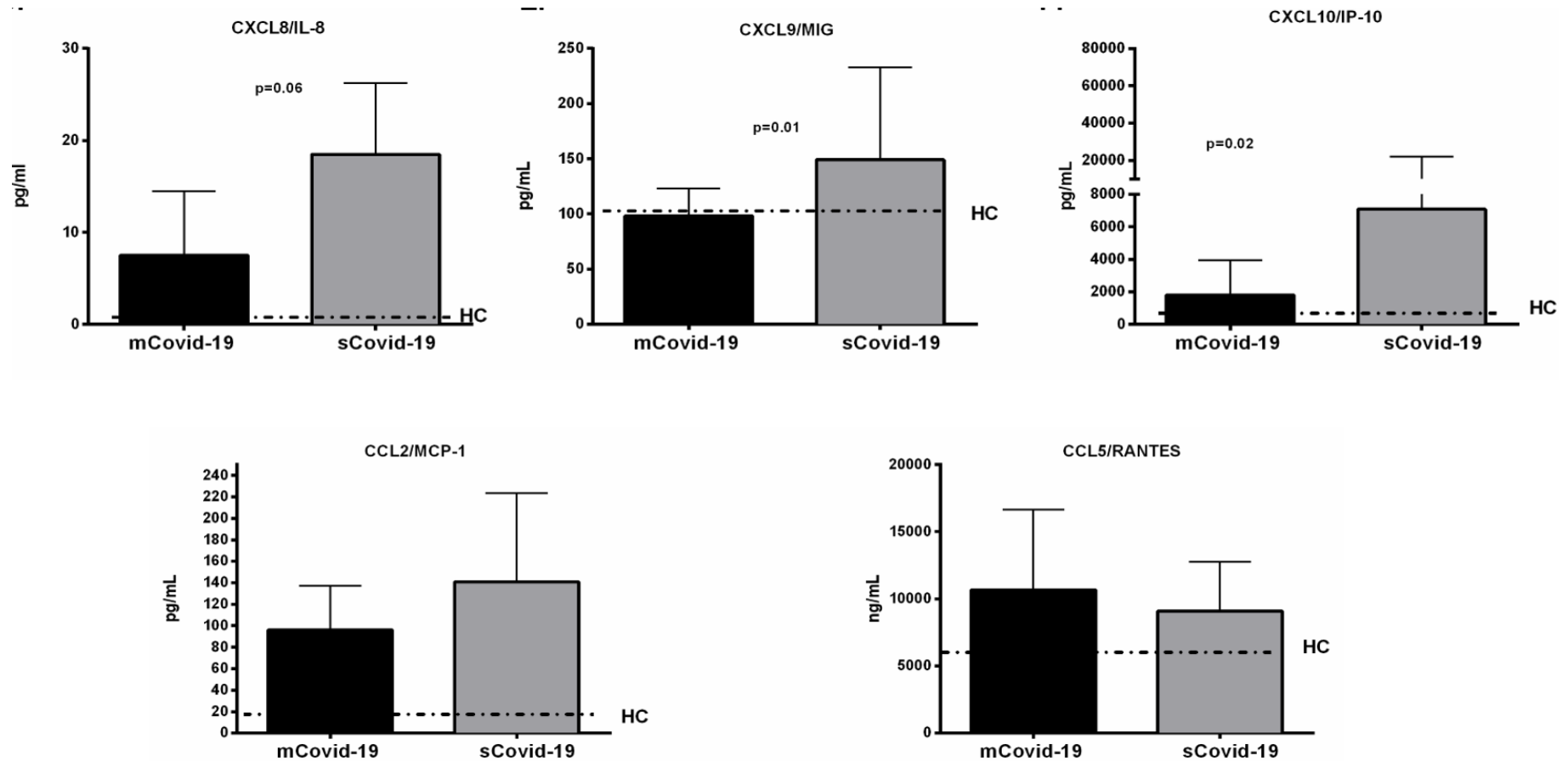
Openshaw et al. Clinical Microbiology Reviews 2005

Adult patients with severe Covid-19 show heightened activated, senescent pro-cytolytic T-cells

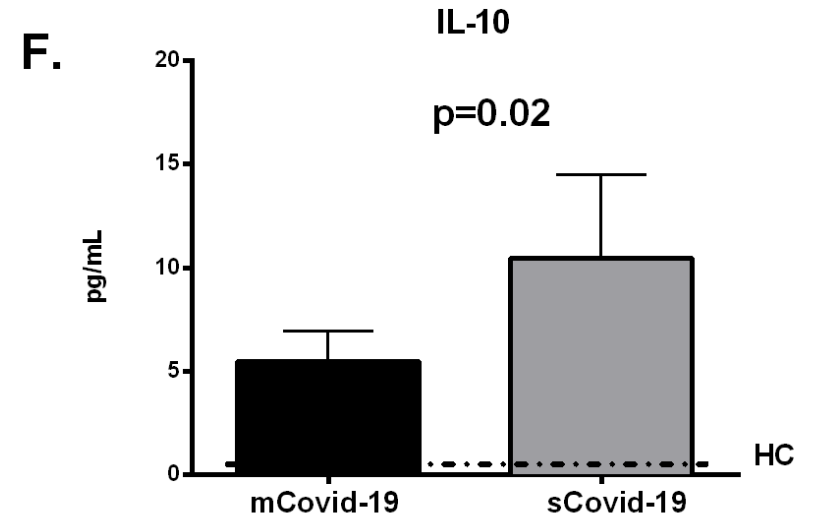
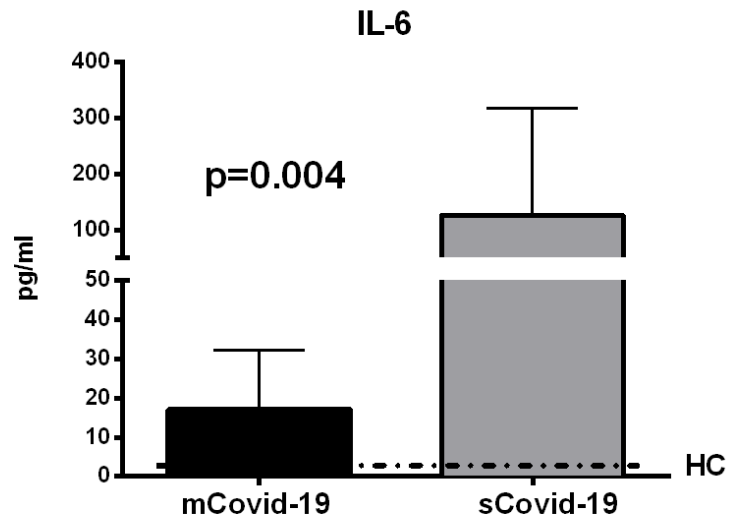


No differences between groups: B-cells/B-cell activation; IgM/IgG; Treg, Tfh, Th17

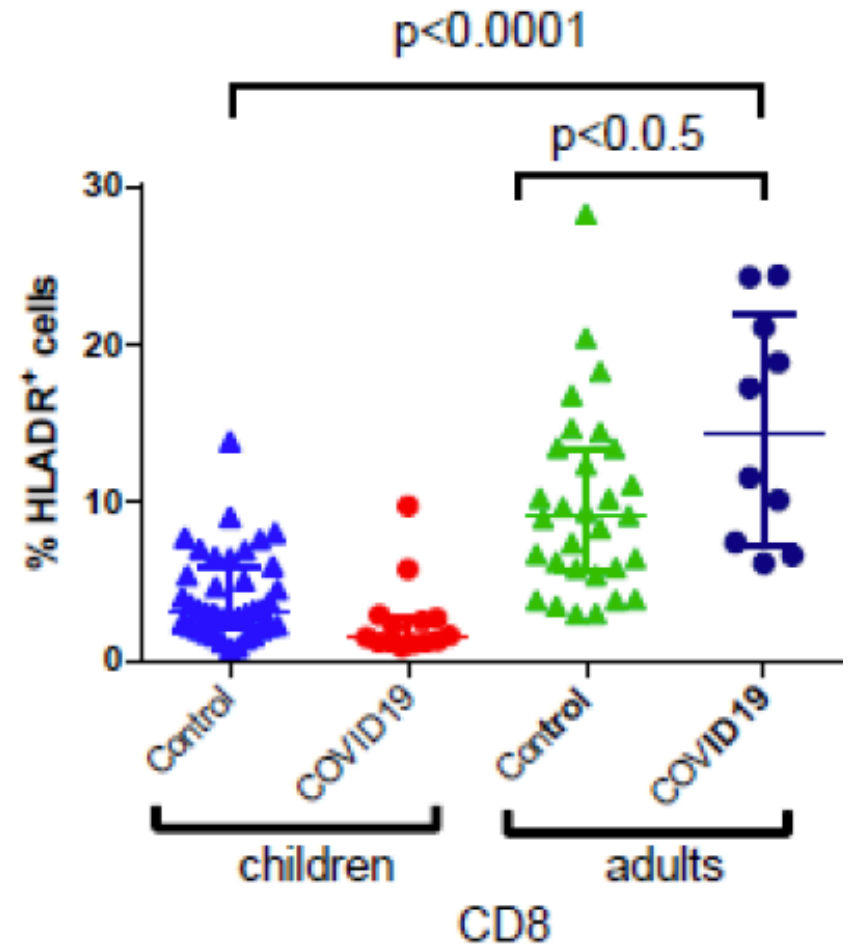
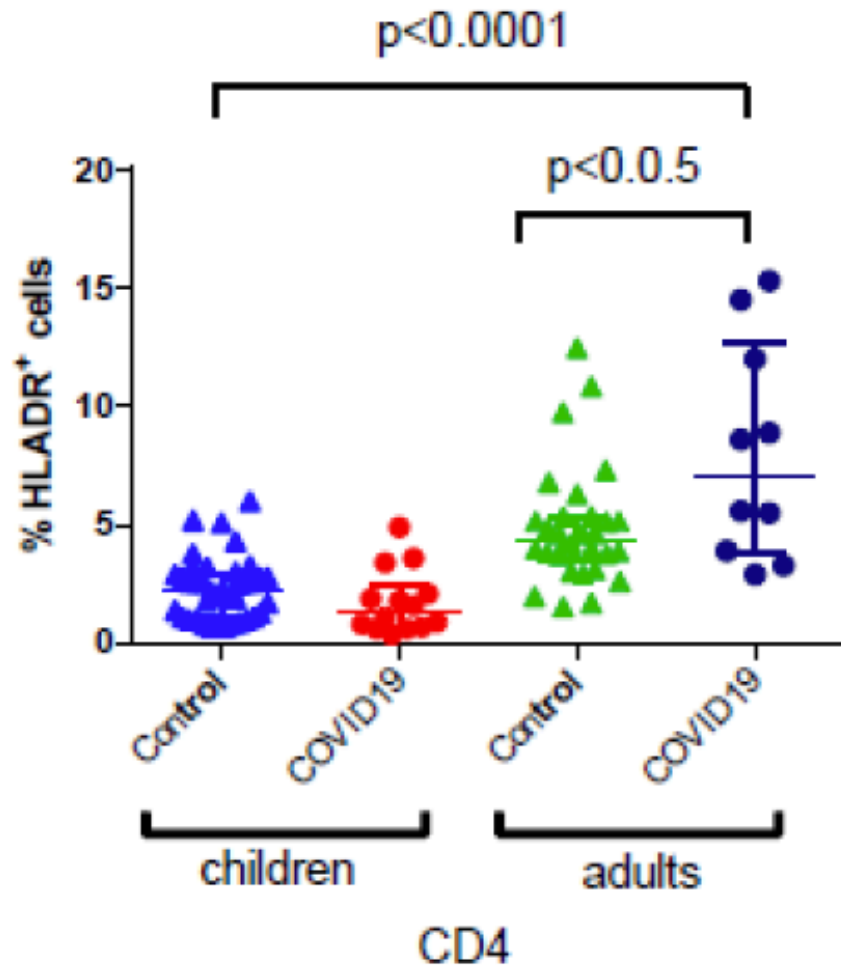
Patients with severe Covid-19 feature higher plasma chemokines

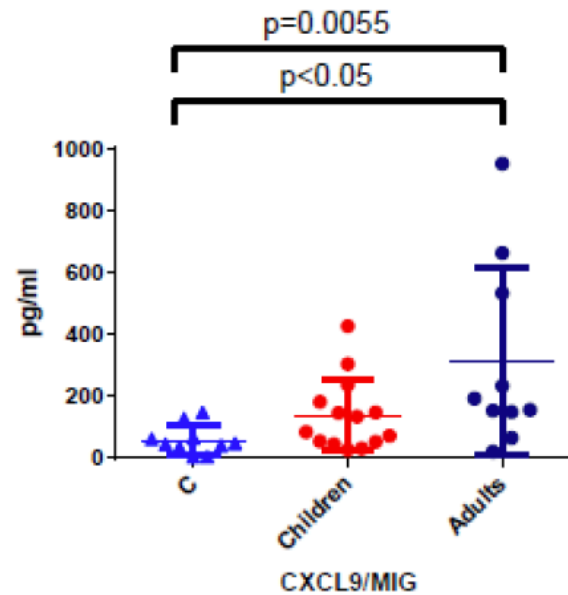
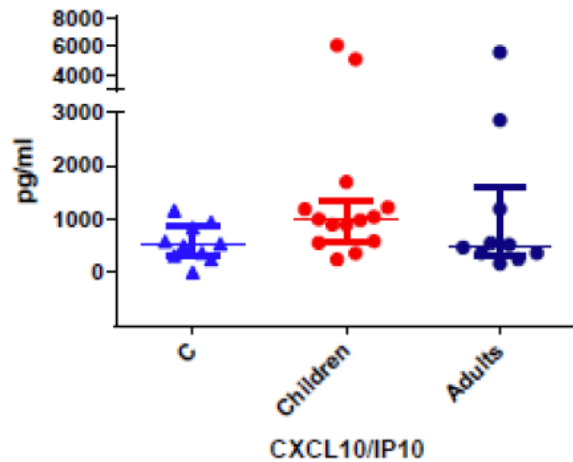


Patients with severe Covid-19 feature higher plasma cytokines

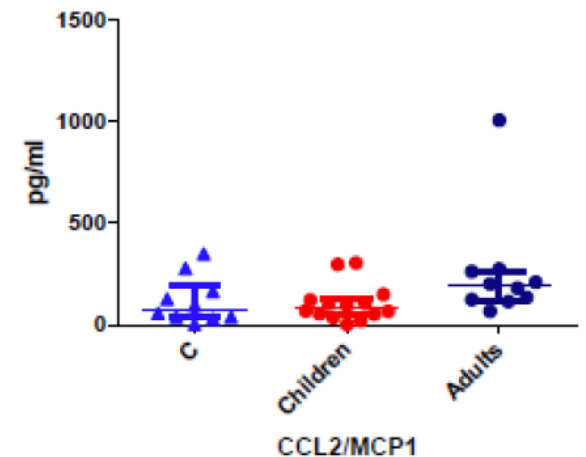
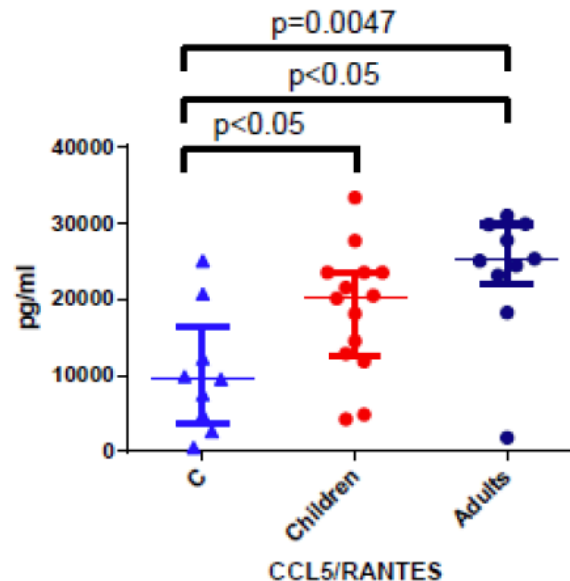


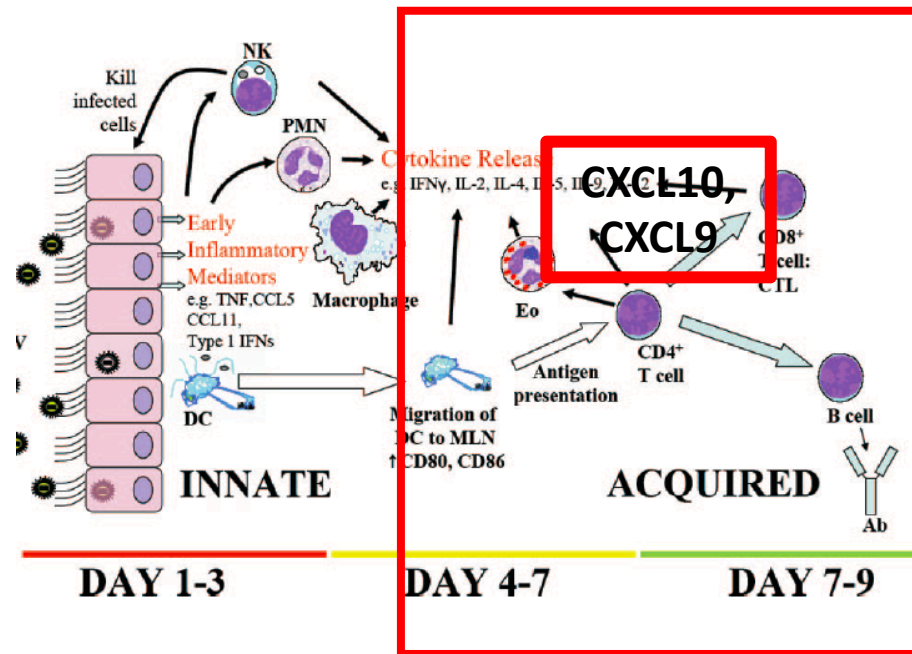
Higher T-cell activation in Covid-19 adults



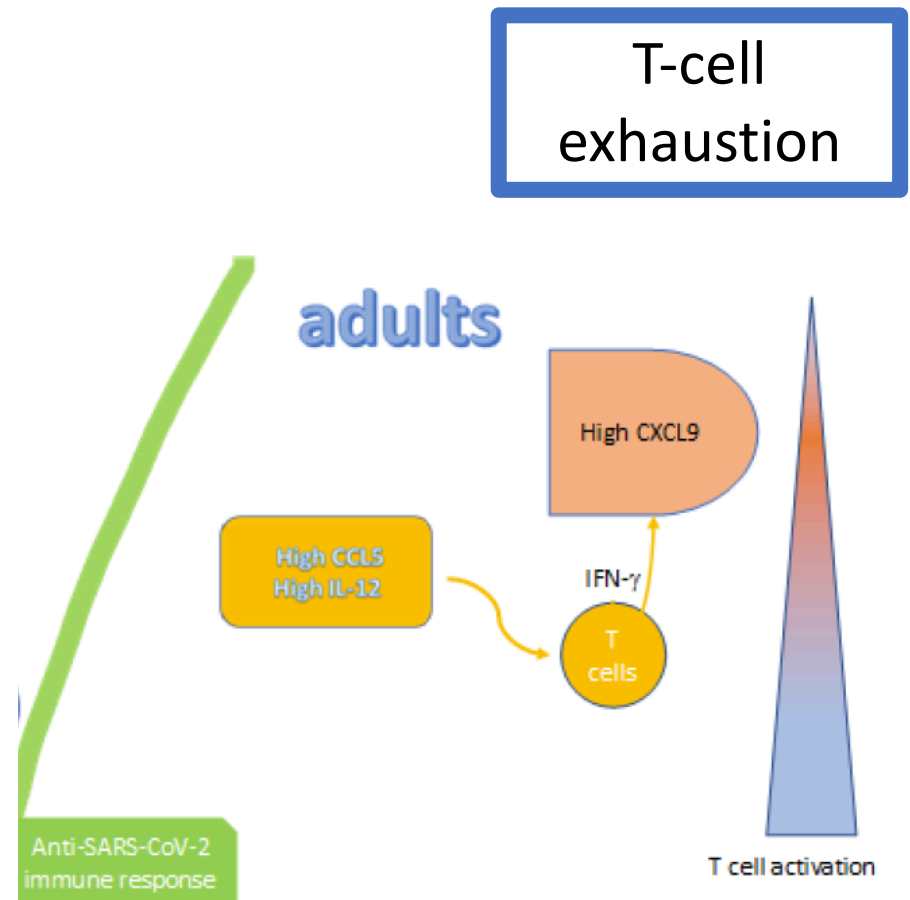


Higher pro-inflammatory chemokines in adults



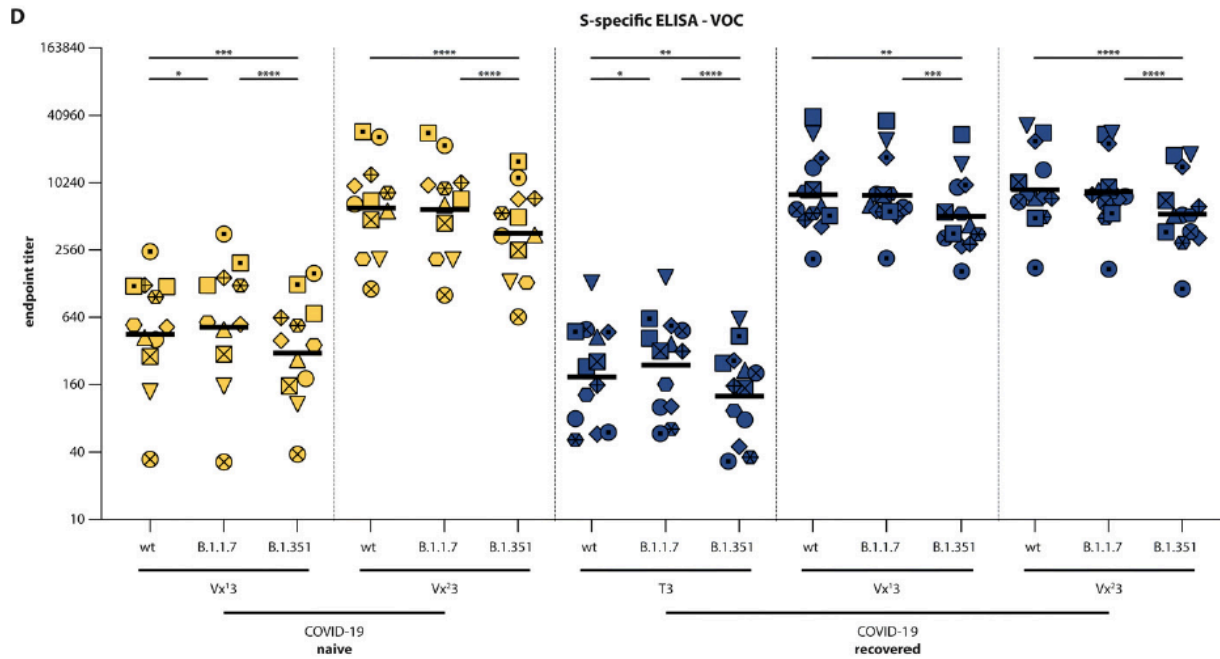


Modified from Openshaw et al. Clin Microbiol Rev 2005

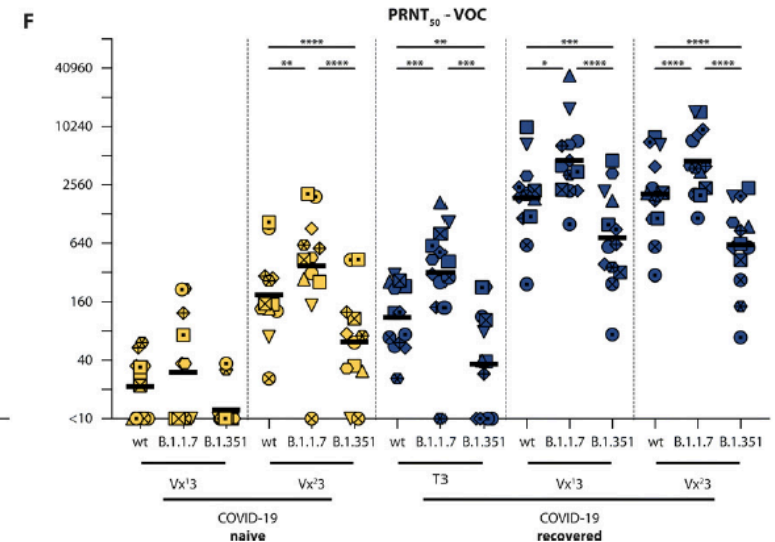
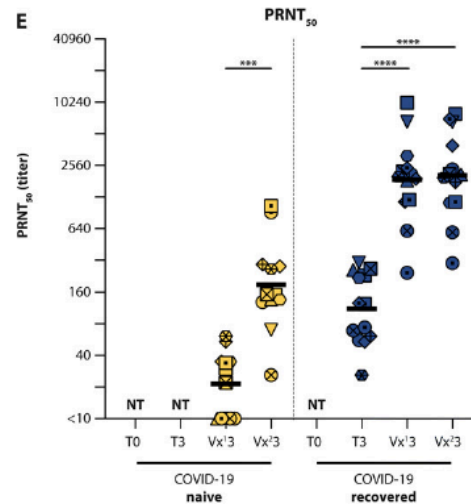


SARS-COV-2

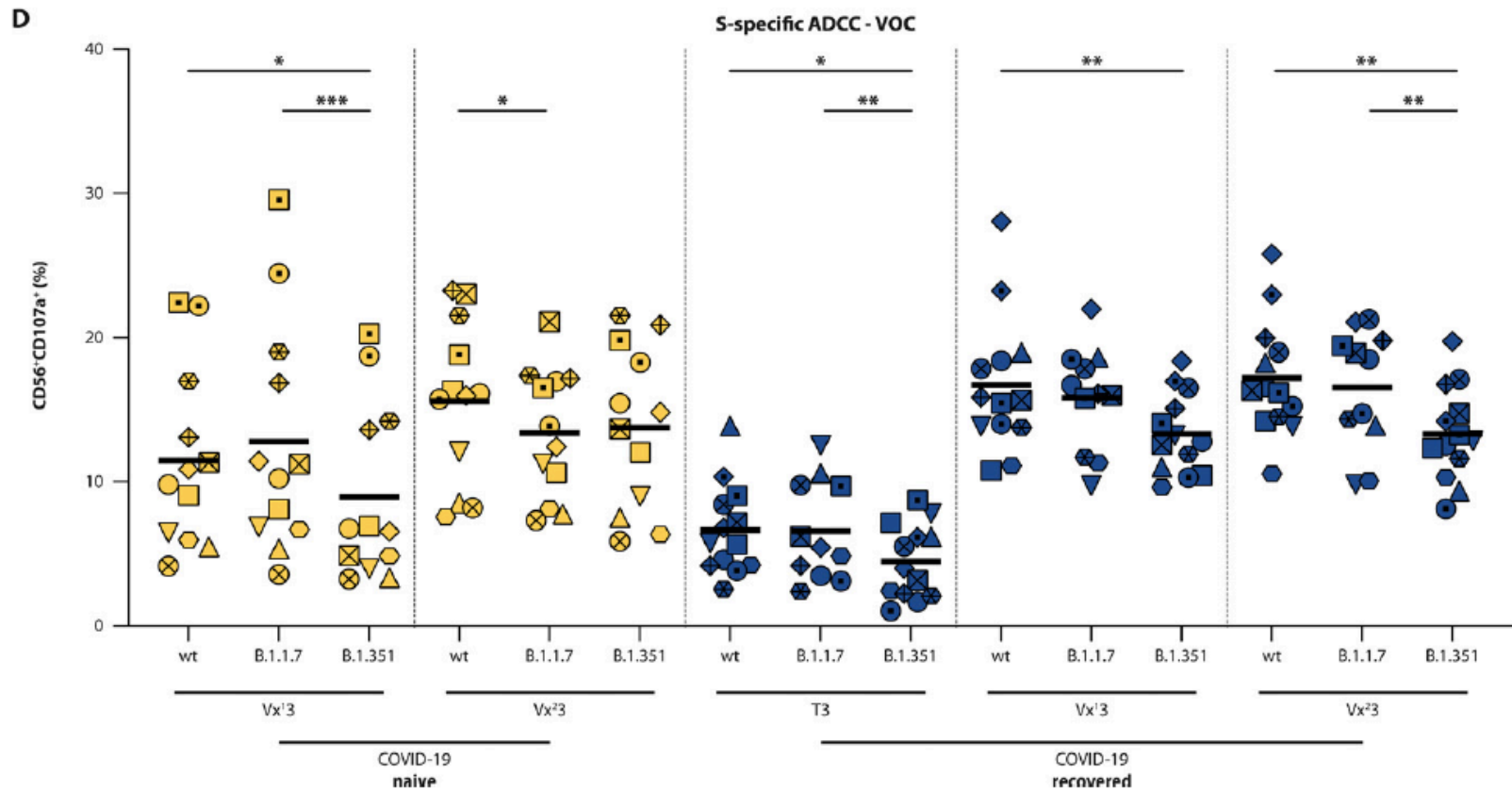
Which (biological) reasons behind the efficacy of antibody-mediated therapy/prevention and vaccine?



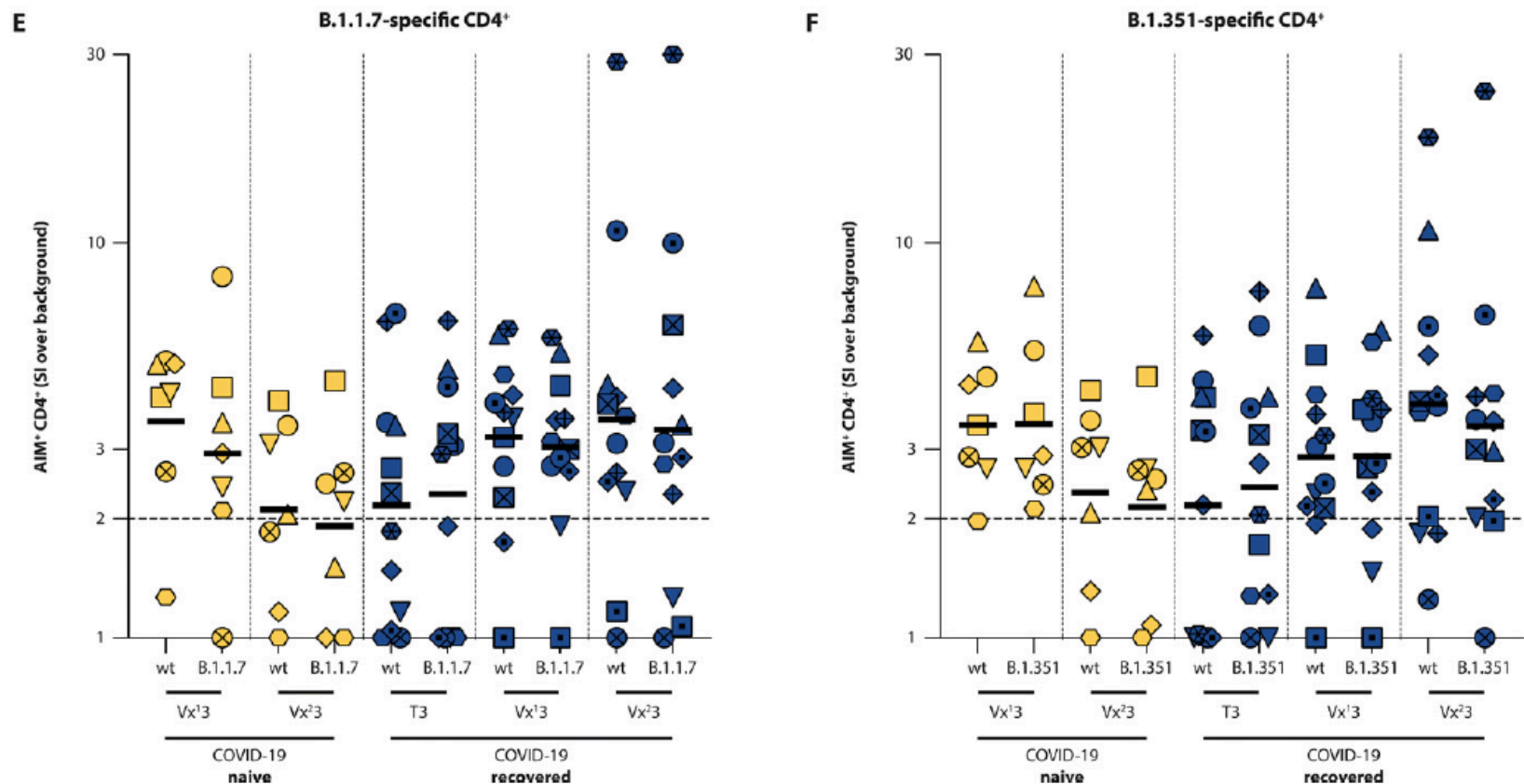
Reduced
neutralizing
capacity by
B.1.351 (South
Africa) variant



Reduced ADCC by B.1.351 (South Africa) variant



B.1.1.7 (UK) and B.1.351S (South Africa) variants do not escape T-cell mediated immunity elicited by WT





After You're Fully Vaccinated

If you are fully vaccinated, you can resume activities that you did prior to the pandemic.



**l'Italia rinasce
con un fiore
vaccinazione
anti-Covid 19**

HIV

How should we define success today?

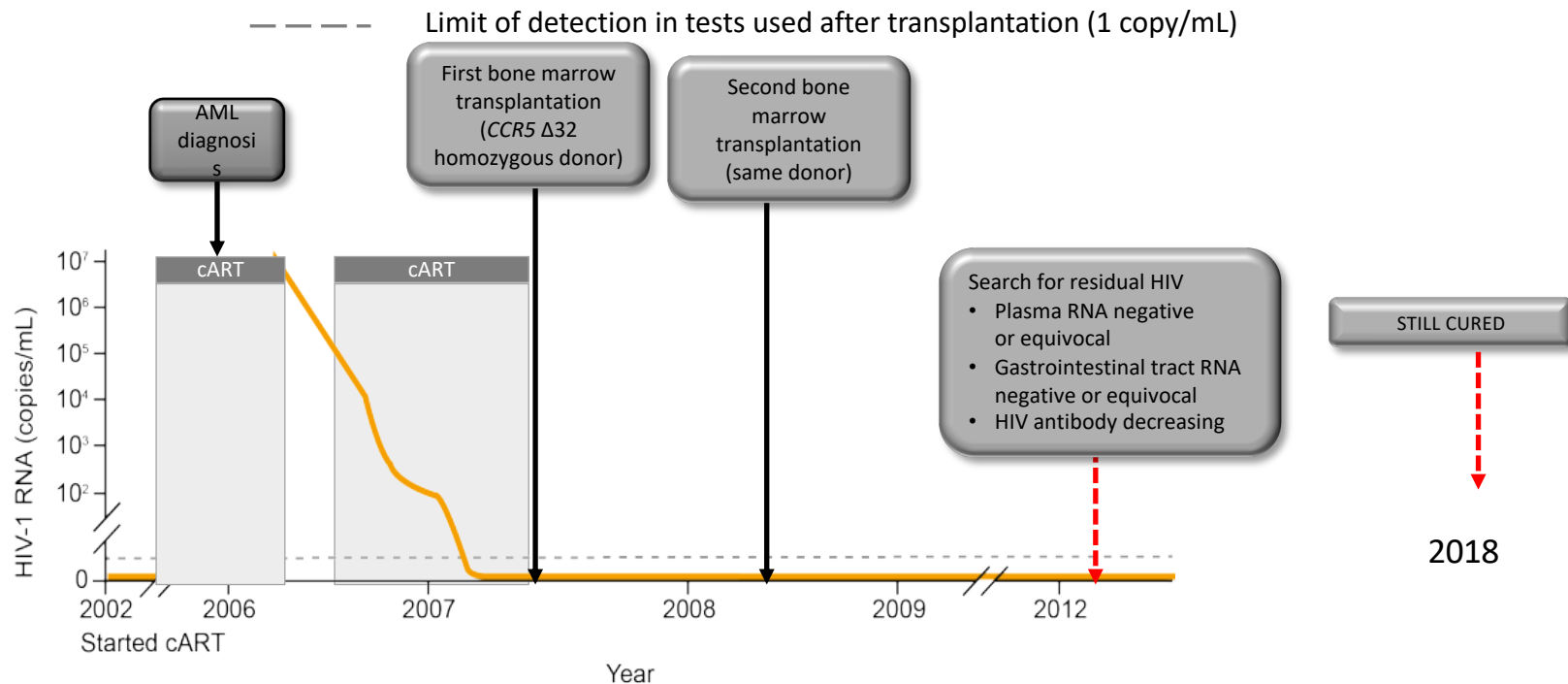
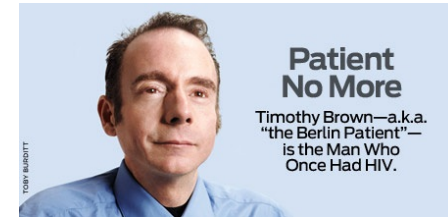
Defining success

cure versus remission

- Cure: complete removal of all replication-competent HIV cells
 - May have happened to Berlin (and London) patient, but impossible to prove

HIV cure is possible

Timeline for the Berlin patient: the first and longest duration clinical cure case



AML, acute myeloid leukaemia; cART, combination antiretroviral therapy; CCR5, chemokine (C-C motif) receptor 5.
Kent SJ, et al. Lancet Infect Dis 2013;13:614–21.

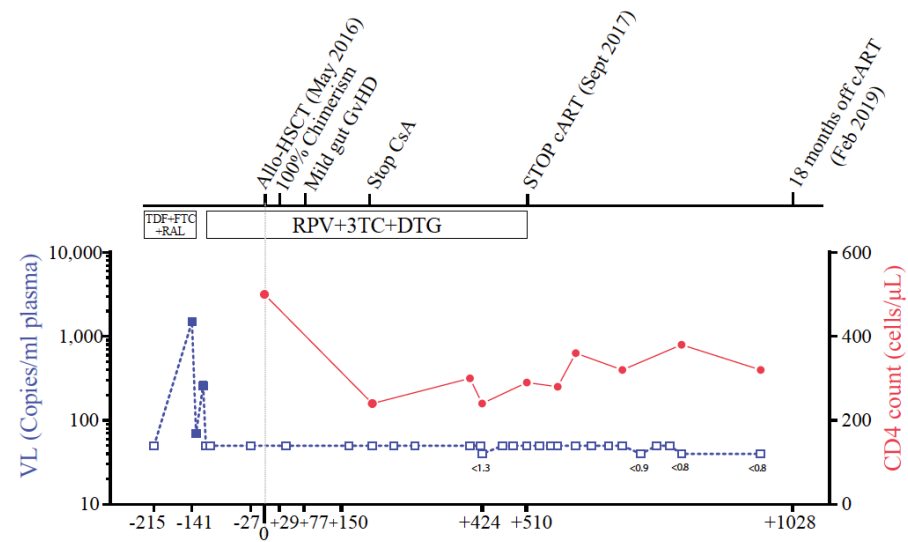
Accelerated Article Preview Published online 5 March 2019.

LETTER

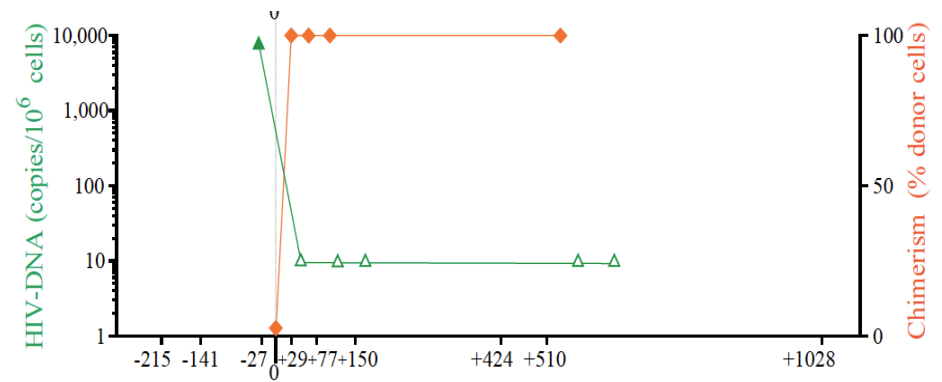
doi:10.1038/s41586-019-1027-4

HIV-1 remission following CCR5 Δ 32/ Δ 32 haematopoietic stem-cell transplantation

Ravindra K Gupta, Sultan Abdul-jawad, Laura E McCoy, Hoi Ping Mok, Dimitra Peppas, Maria Salgado, Javier Martinez-Picado, Monique Nijhuis, Annemarie M.J. Wensing, Helen Lee, Paul Grant, Eleni Nastouli, Jonathan Lambert, Matthew Pace, Fanny Salasc, Christopher Monit, Andrew Innes, Luke Muir, Laura Waters, John Frater, Andrew ML Lever, SG Edwards, Ian H Gabriel & Eduardo Olavarria

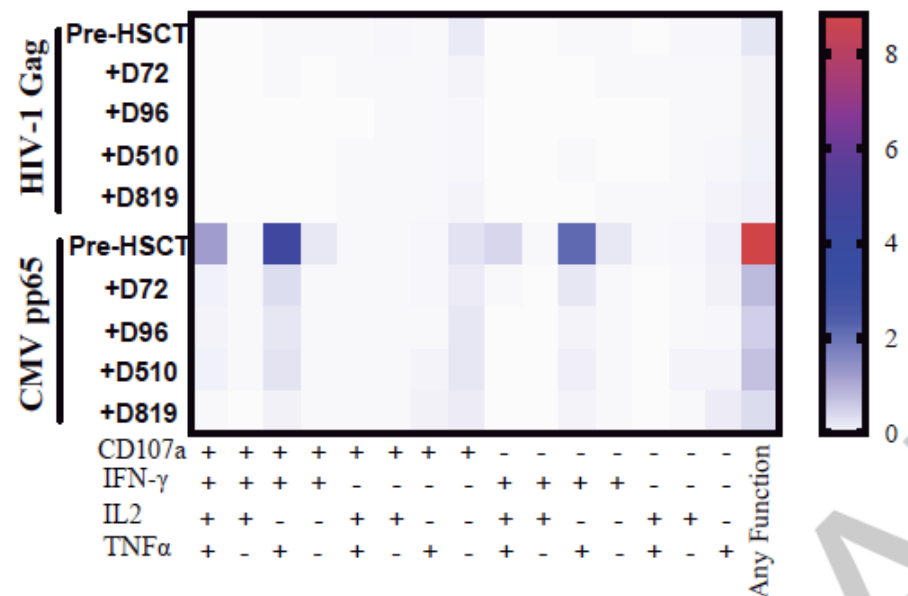
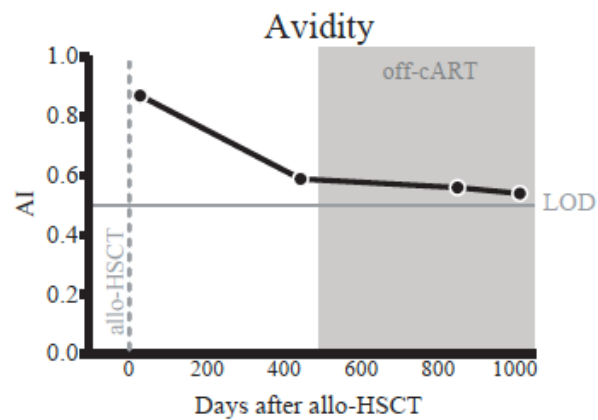
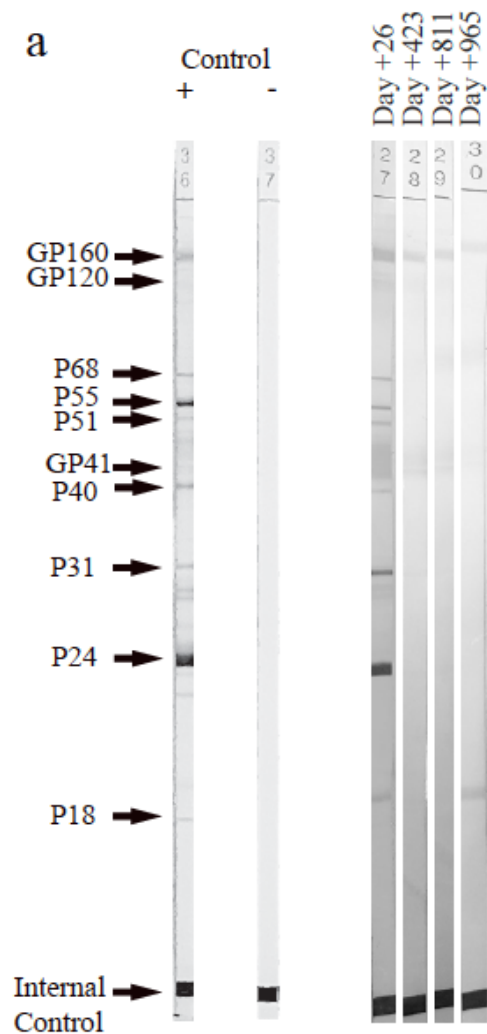


Stage IV non-Hodgkin
lymphoma, homozygous CCR5
WT
CCR5 Δ 32/ Δ 32 allo-HSCT
transplant
Mild GVH



Hematological treatment: LACE, α CD52, MIX, CsA

Time after allo-HSCT (Days)



THE LONDON PATIENT AND A PLAN TO END THE H.I.V. EPIDEMIC IN THE UNITED STATES

Caveat to and lessons from the Berlin, London, Dusseldorf ...patients:

- Extremely difficult to achieve
- Gene therapy approaches (from generation of HIV resistant CD4 + to the eradication of HIV infected cells by immune cell engineering)

Defining success

cure versus remission (functional cure)

- Remission: sustained virus (HIV) control or disease-free period in the absence of treatment
- Replication-competent virus persists at levels that does not cause harm or that is not transmitted

Functional cure – the question(s)

Can we generate HIV-specific immune responses capable to fully contain viral replication even in tissue (sanctuaries) once cART is stopped?

Functional cure – the assumption(s)

- LTNPs* and ECs**: high CD4 counts and/or HIV RNA control without therapy
- PTCs***: long-term virological remission following the interruption of cART started during early(est) infection

LTNPs, long-term non progressors; **ECs, elite controllers; *PTCs, post-treatment controllers*

Grabar et al. AIDS 2009; Saag & Deeks CID 2010; Saez-Cirion Plos Path 2013

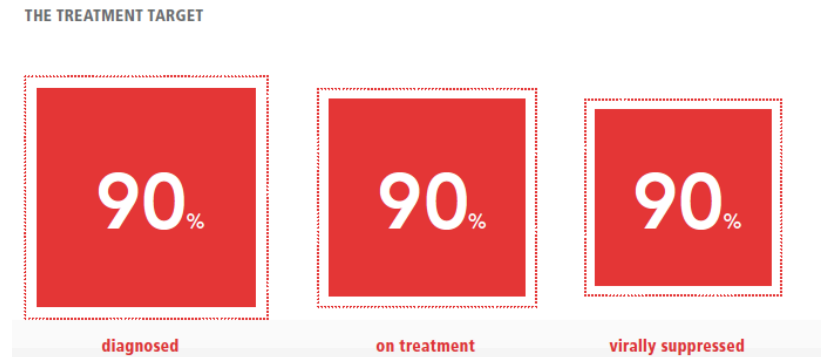
Functional cure – the strategy

First “debulk” the disease (cART)
also reaching tissues, then
eradicate or control the infection
by enhancing immune function
(immunotherapy)

Functional cure – what do we need? (and why have we failed?)

- **Low viral burden**
- **Low inflammation**
- **Sustained host responses, that are primed, reside in tissues, target susceptible epitopes**

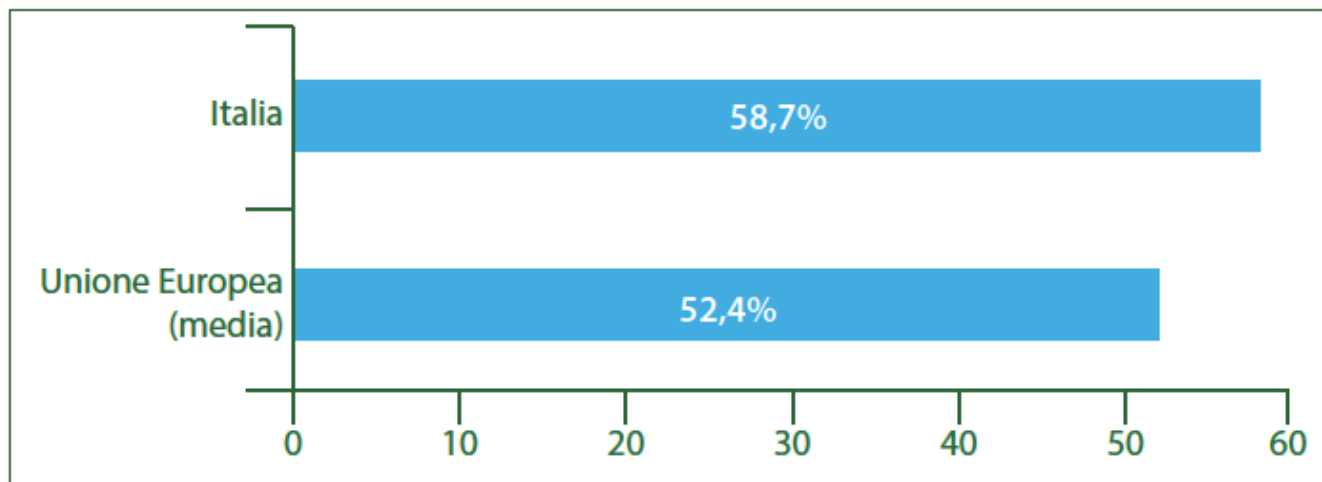
- By 2020, 90% of all people living with HIV will know their HIV status.
- By 2020, 90% of all people with diagnosed HIV infection will receive sustained antiretroviral therapy.
- By 2020, 90% of all people receiving antiretroviral therapy will have viral suppression.



Quarto 90: 90% persone HIV abbiano buona qualità vita

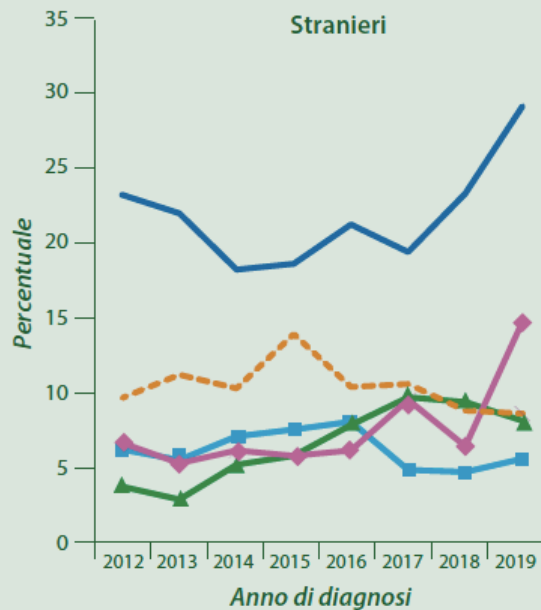
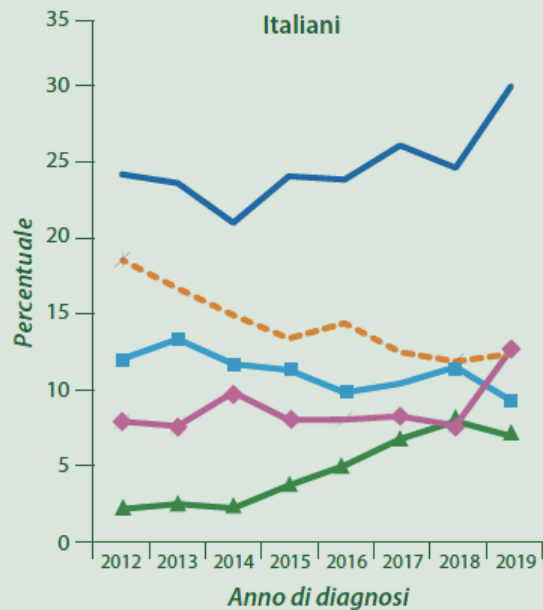
<https://aidstargets2025.unaids.org/>

Late presenters 2019*



(*) *Late presenters*: nuove diagnosi di infezione da HIV con numero di linfociti CD4 < 350 cell/ μ l

Fonti: Sistema di Sorveglianza HIV nazionale, ECDC/WHO 2020 HIV/AIDS surveillance in Europe 2020-2019 data (1)



Necessità di implementazione programmi/campagne di screening (anche) sul territorio

Figura 2 - Percentuale di nuove diagnosi HIV per motivo di effettuazione del test in italiani e stranieri, 2012-2019

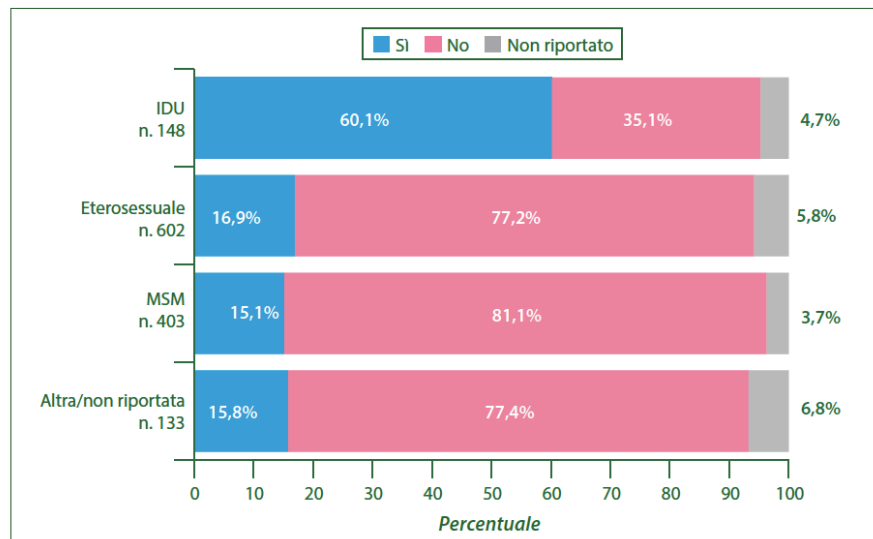


Figura 18 - Uso di terapie antiretrovirali pre-AIDS, per modalità di trasmissione (2018-2019)

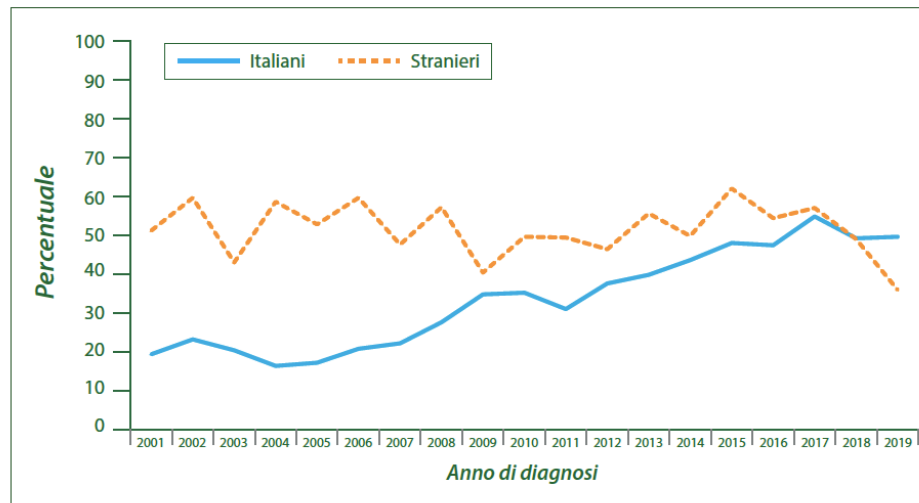


Figura 17 - Proporzione di pazienti che non hanno effettuato terapie antiretrovirali pre-AIDS per nazionalità (2001-2019)





General Assembly

Distr.: General
22 June 2016

Seventieth session
Agenda item 11

Resolution adopted by the General Assembly on 8 June 2016

[*without reference to a Main Committee (A/70/L.52)*]

70/266. Political Declaration on HIV and AIDS: On the Fast Track to Accelerating the Fight against HIV and to Ending the AIDS Epidemic by 2030

The General Assembly

Adopts the political declaration on HIV and AIDS annexed to the present resolution.

*97th plenary meeting
8 June 2016*

Risk reduction measures



Pre-exposure prophylaxis (PrEP)



Effectiveness and Safety of Tenofovir Gel, an Antiretroviral Microbicide, for the Prevention of HIV Infection in Women

Quarraisha Abdool Karim *et al.*

Science **329**, 1168 (2010);

DOI: 10.1126/science.1193748

Abstract

The Centre for the AIDS Program of Research in South Africa (CAPRISA) 004 trial assessed the effectiveness and safety of a 1% vaginal gel formulation of tenofovir, a nucleotide reverse transcriptase inhibitor, for the prevention of HIV acquisition in women. A double-blind, randomized controlled trial was conducted comparing tenofovir gel (n = 445 women) with placebo gel (n = 444 women) in sexually active, HIV-uninfected 18- to 40-year-old women in urban and rural KwaZulu-Natal, South Africa. HIV serostatus, safety, sexual behavior, and gel and condom use were assessed at monthly follow-up visits for 30 months. HIV incidence in the tenofovir gel arm was 5.6 per 100 women-years (person time of study observation) (38 out of 680.6 women-years) compared with 9.1 per 100 women-years (60 out of 660.7 women-years) in the placebo gel arm (incidence rate ratio = 0.61; P = 0.017). In high adherers (gel adherence > 80%), HIV incidence was 54% lower (P = 0.025) in the tenofovir gel arm. In intermediate adherers (gel adherence 50 to 80%) and low adherers (gel adherence < 50%), the HIV incidence reduction was 38 and 28%, respectively. Tenofovir gel reduced HIV acquisition by an estimated 39% overall, and by 54% in women with high gel adherence. No increase in the overall adverse event rates was observed. There were no changes in viral load and no tenofovir resistance in HIV seroconverters. Tenofovir gel could potentially fill an important HIV prevention gap, especially for women unable to successfully negotiate mutual monogamy or condom use.

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Pre-exposure prophylaxis (PrEP)

The NEW ENGLAND JOURNAL *of* MEDICINE

ESTABLISHED IN 1812

DECEMBER 30, 2010

VOL. 363 NO. 27

Preexposure Chemoprophylaxis for HIV Prevention in Men Who Have Sex with Men

Abstract

BACKGROUND: Antiretroviral chemoprophylaxis before exposure is a promising approach for the prevention of human immunodeficiency virus (HIV) acquisition.

METHODS: We randomly assigned 2499 HIV-seronegative men or transgender women who have sex with men to receive a combination of two oral antiretroviral drugs, emtricitabine and tenofovir disoproxil fumarate (FTC-TDF), or placebo once daily. All subjects received HIV testing, risk-reduction counseling, condoms, and management of sexually transmitted infections.

RESULTS: The study subjects were followed for 3324 person-years (median, 1.2 years; maximum, 2.8 years). Of these subjects, 10 were found to have been infected with HIV at enrollment, and 100 became infected during follow-up (36 in the FTC-TDF group and 64 in the placebo group), indicating a 44% reduction in the incidence of HIV (95% confidence interval, 15 to 63; $P=0.005$). In the FTC-TDF group, the study drug was detected in 22 of 43 of seronegative subjects (51%) and in 3 of 34 HIV-infected subjects (9%) ($P<0.001$). Nausea was reported more frequently during the first 4 weeks in the FTC-TDF group than in the placebo group ($P<0.001$). The two groups had similar rates of serious adverse events ($P=0.57$).

CONCLUSIONS: Oral FTC-TDF provided protection against the acquisition of HIV infection among the subjects. Detectable blood levels strongly correlated with the prophylactic effect. (Funded by the National Institutes of Health and the Bill and Melinda Gates Foundation; ClinicalTrials.gov number, NCT00458393.).

Treatment as prevention

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812

AUGUST 11, 2011

VOL. 365 NO. 6

Prevention of HIV-1 Infection with Early Antiretroviral Therapy



BACKGROUND

Antiretroviral therapy that reduces viral replication could limit the transmission of human immunodeficiency virus type 1 (HIV-1) in serodiscordant couples.

METHODS

In nine countries, we enrolled 1763 couples in which one partner was HIV-1-positive and the other was HIV-1-negative; 54% of the subjects were from Africa, and 50% of infected partners were men. HIV-1-infected subjects with CD4 counts between 350 and 550 cells per cubic millimeter were randomly assigned in a 1:1 ratio to receive antiretroviral therapy either immediately (early therapy) or after a decline in the CD4 count or the onset of HIV-1-related symptoms (delayed therapy). The primary prevention end point was linked HIV-1 transmission in HIV-1-negative partners. The primary clinical end point was the earliest occurrence of pulmonary tuberculosis, severe bacterial infection, a World Health Organization stage 4 event, or death.

RESULTS

As of February 21, 2011, a total of 39 HIV-1 transmissions were observed (incidence rate, 1.2 per 100 person-years; 95% confidence interval [CI], 0.9 to 1.7); of these, 28 were virologically linked to the infected partner (incidence rate, 0.9 per 100 person-years, 95% CI, 0.6 to 1.3). Of the 28 linked transmissions, only 1 occurred in the early-therapy group (hazard ratio, 0.04; 95% CI, 0.01 to 0.27; $P < 0.001$). Subjects receiving early therapy had fewer treatment end points (hazard ratio, 0.59; 95% CI, 0.40 to 0.88; $P = 0.01$).

CONCLUSIONS

The early initiation of antiretroviral therapy reduced rates of sexual transmission of HIV-1 and clinical events, indicating both personal and public health benefits from such therapy. (Funded by the National Institute of Allergy and Infectious Diseases and others; HPTN 052 ClinicalTrials.gov number, NCT00074581.)

The Partner Study

Research

JAMA. 2016;316(2):171-181. doi:10.1001/jama.2016.5148

Last corrected on November 13, 2016.

Original Investigation

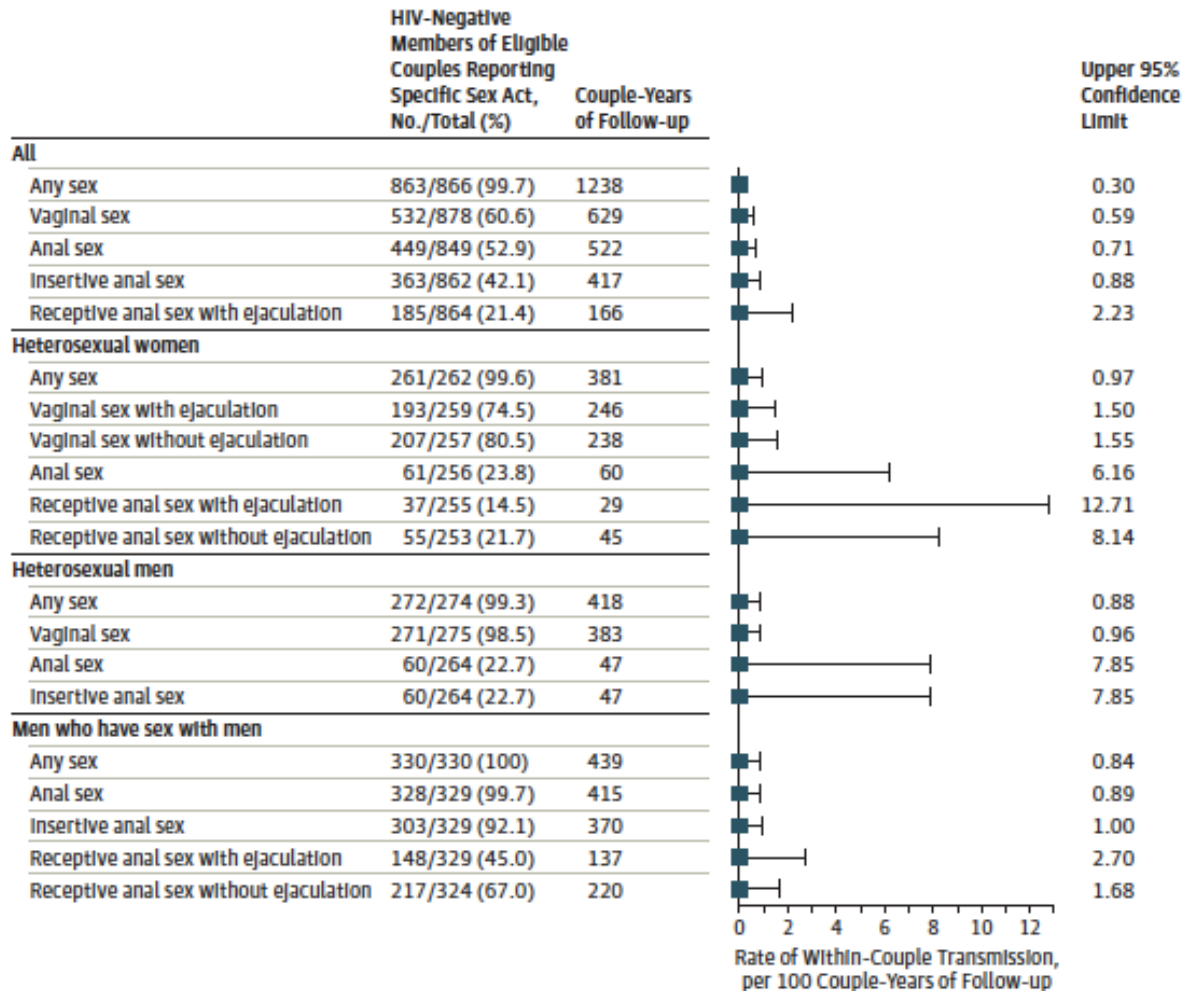
Sexual Activity Without Condoms and Risk of HIV Transmission in Serodifferent Couples When the HIV-Positive Partner Is Using Suppressive Antiretroviral Therapy

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Background: A key factor in assessing the effectiveness and cost-effectiveness of cART as a prevention strategy is **the absolute risk of HIV transmission** through condomless sex with suppressed HIV-1 RNA viral load for both anal and vaginal sex

Objective: To evaluate the rate of within-couple HIV transmission (heterosexual and MSM) during periods of **sex without condoms and when the HIV-positive partner had HIV-1 RNA <200 copies/mL**

Figure 1. Rate of HIV Transmission According to Sexual Behavior Reported by the HIV-Negative Partner



A total of **11** (10 MSM, 1 HS) of the originally HIV-negative partners were observed to acquire HIV during eligible follow-up, but there were **no phylogenetically linked transmissions**

Denominators are the group-specific number of HIV-negative participants who contributed eligible couple-years of follow-up. The upper limit of the 95% confidence interval was estimated using the exact Poisson method.

The study's reported transmission risk estimates and their corresponding 95% confidence intervals as:

- For any sex among heterosexual and male-male couples: 0.00 (0.00 – 0.30) per 100 couple-years
- For anal sex among male-male couples: 0.00 (0.00 – 0.89) per 100 couple-years

The Opposites Attract Study



THE LANCET
HIV

ARTICLES | VOLUME 5, ISSUE 8, PE438-E447, AUGUST 01, 2018

Viral suppression and HIV transmission in serodiscordant male couples: an international, prospective, observational, cohort study

Benjamin R Bavinton, PhD • Angie N Pinto, MBBS • Nittaya Phanuphak, PhD • Beatriz Grinsztejn, PhD • Garrett P Prestage, PhD • Iryna B Zablotska-Manos, PhD • et al. [Show all authors](#) • [Show footnotes](#)

Published: July 16, 2018 • DOI: [https://doi.org/10.1016/S2352-3018\(18\)30132-2](https://doi.org/10.1016/S2352-3018(18)30132-2) • [Check for updates](#)

- 358 couples were enrolled
- 258 (75%) of 343 HIV-positive partners had viral loads consistently <200 copies/mL and 115 (34%) of 343 HIV-negative partners used daily PrEP during follow-up.
- 253 (74%) of 343 couples reported within-couple CLAI during follow-up, with a total of **16 800 CLAI acts**.
- Three new HIV infections occurred but none were phylogenetically linked

Transmission risk estimates and 95% confidence interval:
0.00 (0.00 – 1.59) per 100 couple-years

The Partner2 Study



Lancet 2019; 393: 2428–38



Risk of HIV transmission through condomless sex in serodifferent gay couples with the HIV-positive partner taking suppressive antiretroviral therapy (PARTNER): final results of a multicentre, prospective, observational study



*Alison J Rodger, Valentina Cambiano, Tina Bruun, Pietro Vernazza, Simon Collins, Olaf Degen, Giulio Maria Corbelli, Vicente Estrada, Anna Maria Geretti, Apostolos Beloukas, Darthe Raben, Pep Coll, Andrea Antinori, Nneka Nwokolo, Armin Rieger, Jan M Prins, Anders Blaxhult, Rainer Weber, Arne Van Eeden, Norbert H Brockmeyer, Amanda Clarke, Jorge del Romero Guerrero, Francois Raffi, Johannes R Bogner, Gilles Wandeler, Jan Gerstoft, Felix Gutiérrez, Kees Brinkman, Maria Kitchen, Lars Ostergaard, Agathe Leon, Matti Ristola, Heiko Jessen, Hans-Jürgen Stellbrink, Andrew N Phillips, Jens Lundgren, for the PARTNER Study Group**

The aim of the second phase of the PARTNER2 was to provide precise estimates of **transmission risk in gay serodifferent partnerships**

972 gay couples were enrolled

During eligible couple-years of follow-up, **couples reported condomless anal sex a total of 76 088 times**

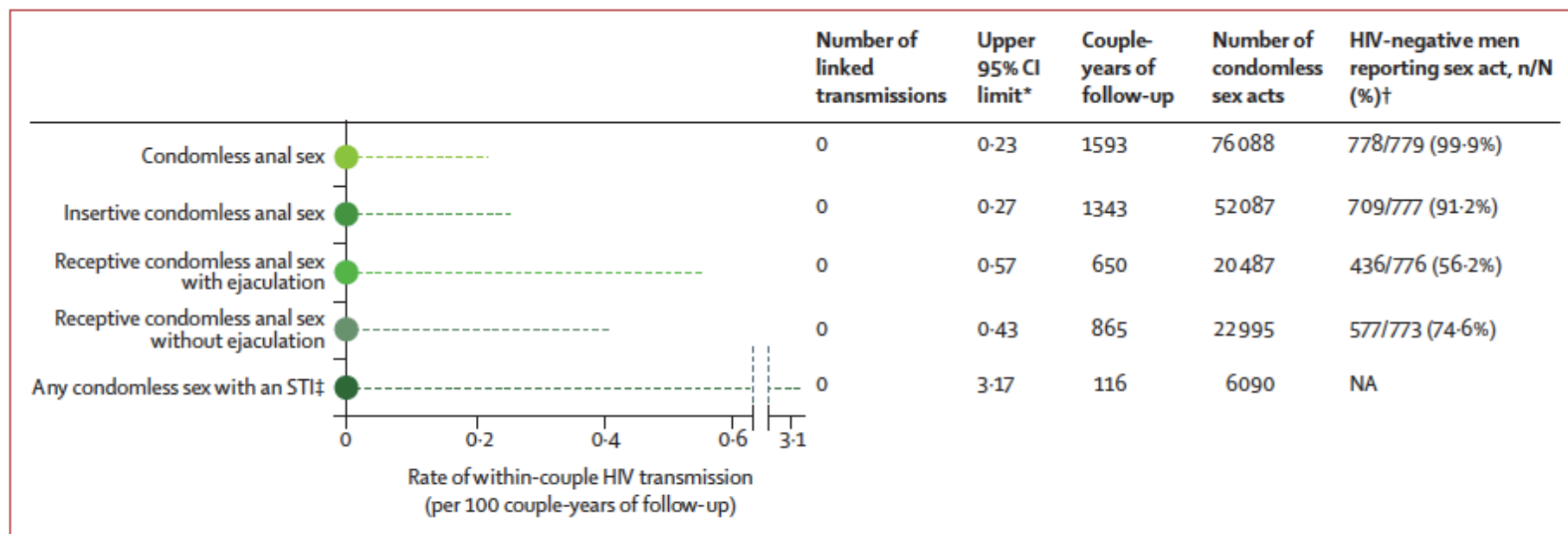


Figure 1: Rate of within-couple HIV transmission through condomless sex according to sexual behaviour reported by the HIV-negative partner
 STI=sexually transmitted infection. NA=not applicable. *Estimated using the exact Poisson method. †Numerator is the number of HIV-negative men within the eligible couples ever reporting that specific sexual act and denominator is the group-specific number of HIV-negative participants who contributed eligible couple-years of follow-up. ‡Refers to STIs (excluding HIV) self-reported by the HIV-negative partner.

Study transmission risk estimates and 95% confidence interval for anal sex among male-male couples:

PARTNER2: **0.00** (0.00 – 0.23) per 100 couple-years

PARTNER+ PARTNER2: **0.00** (0.00 – 0.24) per 100 couple-years

Interpretation Our results provide a similar level of evidence on viral suppression and HIV transmission risk for gay men to that previously generated for heterosexual couples and suggest that the risk of HIV transmission in gay couples through condomless sex when HIV viral load is suppressed is effectively zero. Our findings support the message of the U=U (undetectable equals untransmittable) campaign, and the benefits of early testing and treatment for HIV.

U=U

UNDETECTABLE = UNTRANSMITTABLE

A PERSON LIVING WITH HIV WHO HAS AN UNDETECTABLE VIRAL LOAD DOES NOT TRANSMIT THE VIRUS TO THEIR PARTNERS.



SPEAK THE WORD

The International AIDS Society is proud to endorse the U=U consensus statement of the Prevention Access Campaign.

thewellproject



The Well Project is proud to endorse the Consensus Statement by the Prevention Access Campaign that U=U, and believes the campaign has the potential to dismantle HIV stigma.



Undetectable = Untransmittable #UequalsU

www.hivsmart.org/undetectable-untransmittable

**HIV
smart+**



U=U

Undetectable = Untransmittable

It's a fact...

"A person living with HIV who has an undetectable viral load will not pass HIV to their sexual partners."

The Saving Lives charity is proud to support the Prevention Access Campaign's U=U consensus statement

SAVING
LIVES
UK.COM

Webinar #2 in our 2017 series

Undetectable=Untransmittable: Building Hope and Ending HIV Stigma

Thursday, July 13, 2017 | 12:00 PM - 1:30 PM ET

SPEAKERS: Ben Young, MD, PhD
International Association of Providers of AIDS Care
Grace Richman
Prevention Access Campaign &
Undetectable=Untransmittable (U=U)

Gina Brown, MSW
The Well Project
Mario Mejia
The Well Project

Please visit:
www.thewellproject.org
for a link to register

#UequalsU

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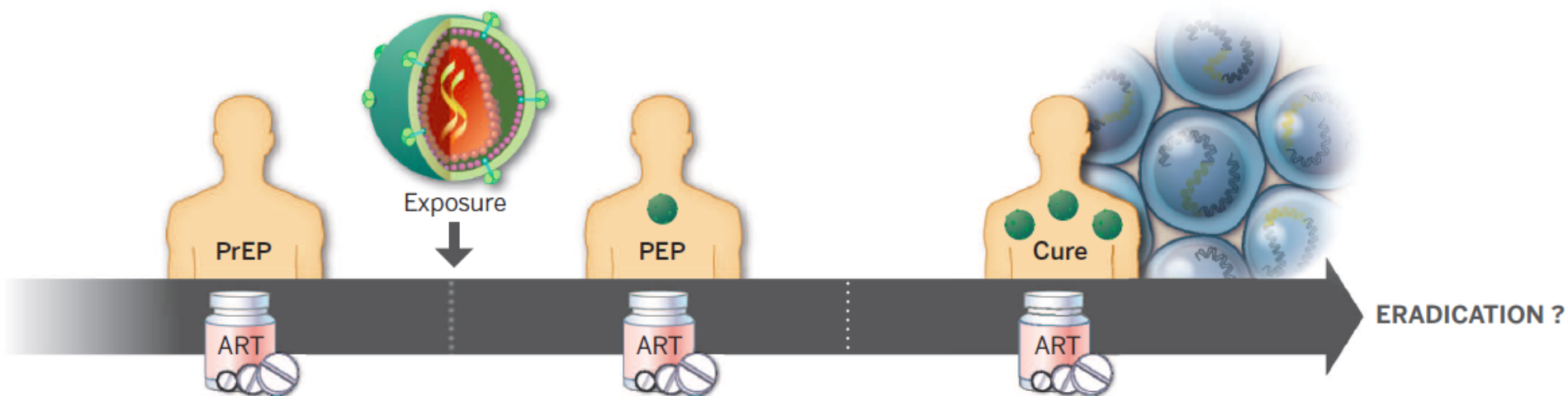
PREVENTION ACCESS CAMPAIGN



UNDETECTABLE = UNTRANSMITTABLE



The paradigm of PrEP/PEP/cure continuum



VIEWPOINT

Fortieth anniversary reflections on the early days of HIV and the current era

Kenneth H Mayer^{1,2,3,5} 

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the Treatment Action Campaign. In an era of U = U and PrEP, the inevitability of powerful and successful tools may seem obvious, but decades of suffering, advocacy and careful clinical investigation led to these outcomes. And despite these advances, we remain without a safe and effective vaccine or cure, so the AIDS pandemic is far from over.

the ability to jumpstart responses to future health crisis. Tools and templates created to address HIV have been leveraged to respond to SARS-CoV-2 [5]. For example NAAT screening is a

national authorities to share data. Now is the time for the mobilization of resources to ensure that everyone has access to SARS-CoV-2 vaccines and state-of-the-art treatment, as a basic human right. Addressing these immediate issues is an essential first step, but if we are to avoid endless pandemic cycles, we also need to attend to the more entrenched structural inequities, since poverty, crowding, poor nutrition and insufficient access to healthcare will potentiate the reach of any new pathogen. We need to recognize that we live in a glo-

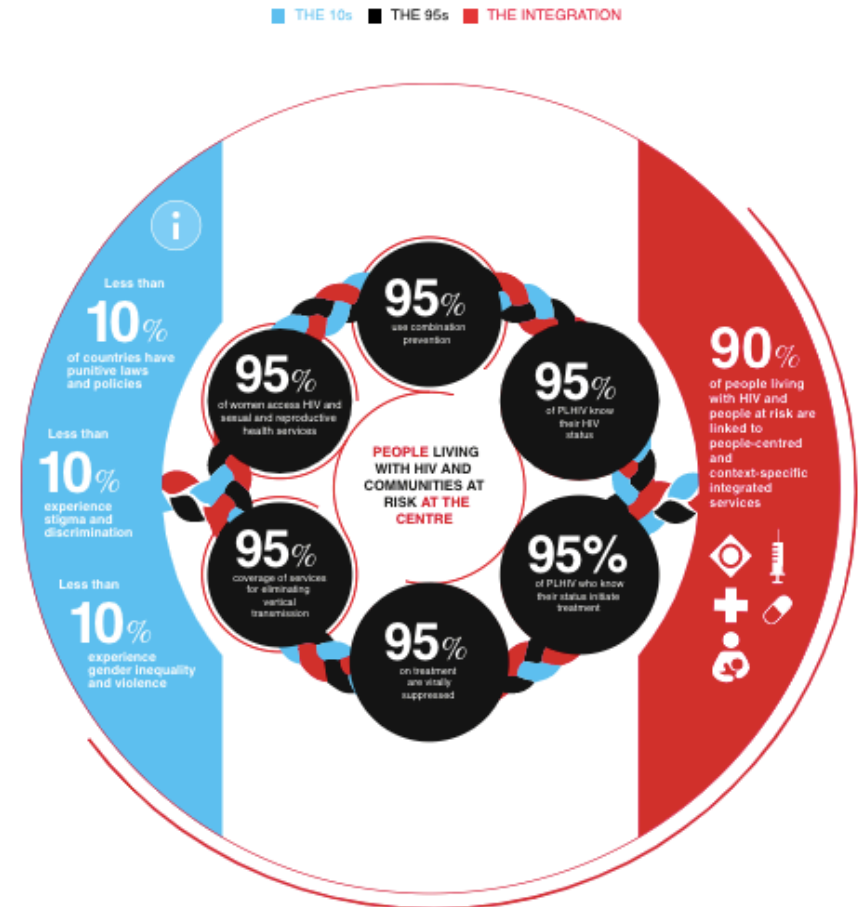
2025 AIDS TARGETS

PUTTING PEOPLE LIVING WITH HIV AND COMMUNITIES AT RISK AT THE CENTRE

“

These targets address the inequalities on which HIV, COVID-19 and other pandemics thrive and put people at the centre, especially the people most at risk and the marginalized.

WINNIE BYANYIMA
UNAIDS Executive Director



<https://aidstargets2025.unaids.org/>

PROGRAMME AREAS

2025 AIDS targets

AIDS and SDGs

Children

Community mobilization

Data

Fast-Track cities

Gender

H6 partnership

HIV prevention

HIV treatment

Human rights

Key populations

Private sector and the AIDS
response

Resources and financing

Security and humanitarian
affairs

Social protection

TB/HIV

Universal health coverage

Young people



<https://aidstargets2025.unaids.org/>

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San Paolo and San Carlo Hospitals - "Covid-19" wards- Milan, Italy

- All Staff
- Patients and their families

Funding

Fondazione Cariplo/Fondazione Umberto Veronesi/Regione Lombardia