"ADAPTIVE" Immunity Vaccines to SPIKE Protein Could NOT be Safe or Effective Due to Spike Antibody "Selection of Variants" & "ADE"

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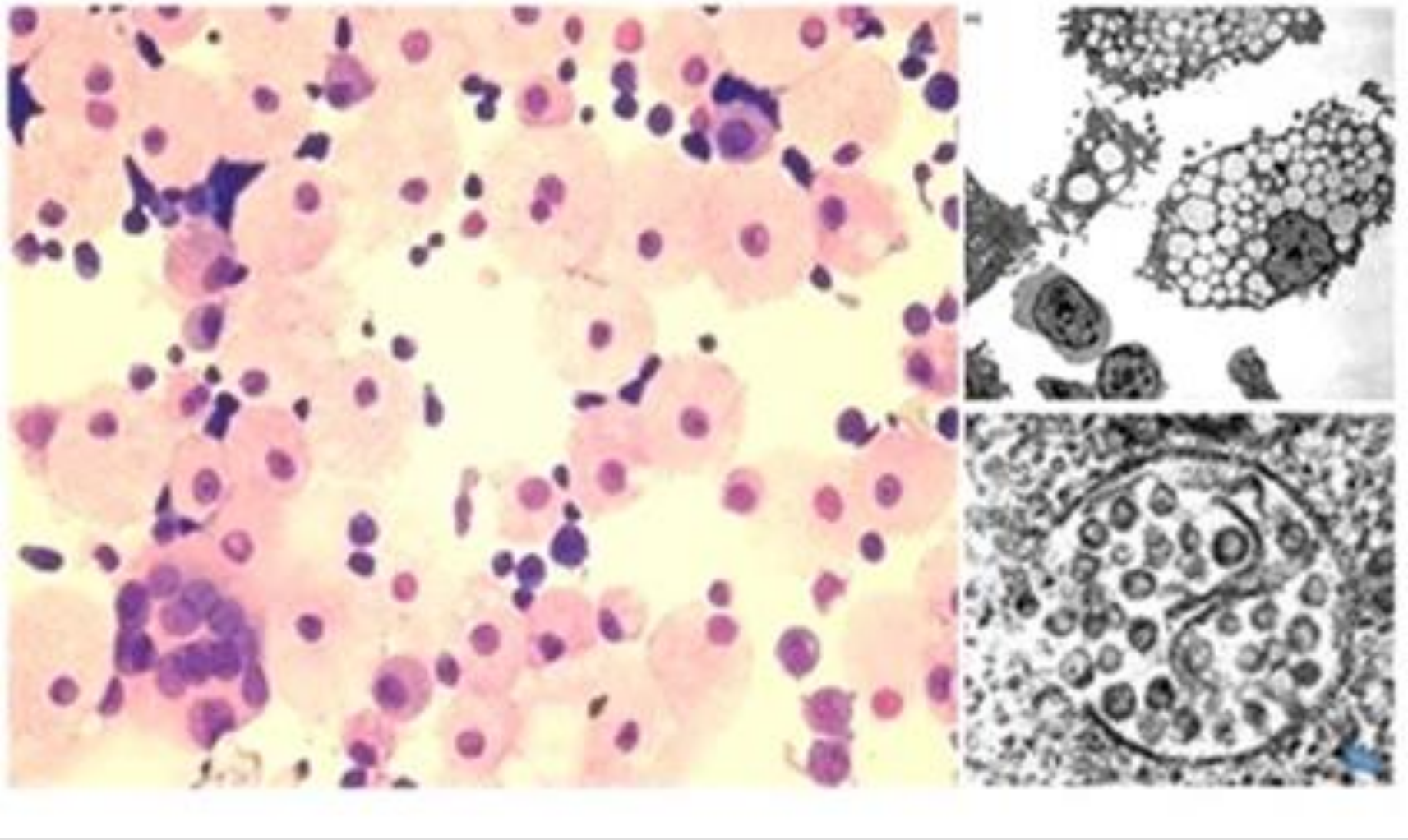
NATIONAL CITIZENS INQUIRY TESTIMONY:

EXPERT WITNESS & OPINION IN: EMERGING PATHOGENS/PANDEMICS/ZOONOTICS; IMMUNOLOGY/VACCINOLOGY/TRAINED (INNATE) IMMUNITY; THE HERV-K102 PROTECTOR SYSTEM/IMMUNOSENESCENCE; POST-MARKET EVALUATION OF PRODUCT SAFETY/REGULATION OF BIOLOGICAL PRODUCTS; SELECTION OF SARS-COV-2 IMMUNE ESCAPE VARIANTS/ 2 TYPES OF ADE FOR SARS-COV-2 (URT VS LRT).

COVID-19 Vaccines and Immunization Effects by Doses

COVID-19 Dose	One Dose	Two Doses
Classification	INNATE immunity	ADAPTIVE immunity
Antigen Recognition	Not specific to virus (heterologous)	Spike (virus specific)
Timing	As part of the interferon response, the first line of defense against pathogens (within hours)	Takes 2-3 weeks for optimal production (within weeks)
Memory	Trained Immunity (transient usually about 6 months)	Permanent (usually years or decades)
Provides Neutralizing Capacity	YES, uses antibodies to HERV-K102 envelope on budding virions	YES, uses antibodies to spike
Mediates "ADE"	NO	YES
Mediates "selection of immune escape variants"	NO	YES
Provides Sterilizing Immunity	YES (in healthy individuals)	NO (too late, ADE or selects for variants)
Primary Mechanisms	The interferon response, non-specific cytotoxicity by NK and innate T cells, innate B cells, and the HERV-K102 Protection System (virus anti-virus)	TcRs and BcRs undergo genetic modification (permanent)
Constitutive Activation in Mucosa?	YES for HERV-K102 Protection System (virus anti-virus) in sebocytes	NO
Critical for Responding to Emerging Pathogens/pandemic RNA viruses?	YES	Dangerous due to ADE & selection of immune escape variants

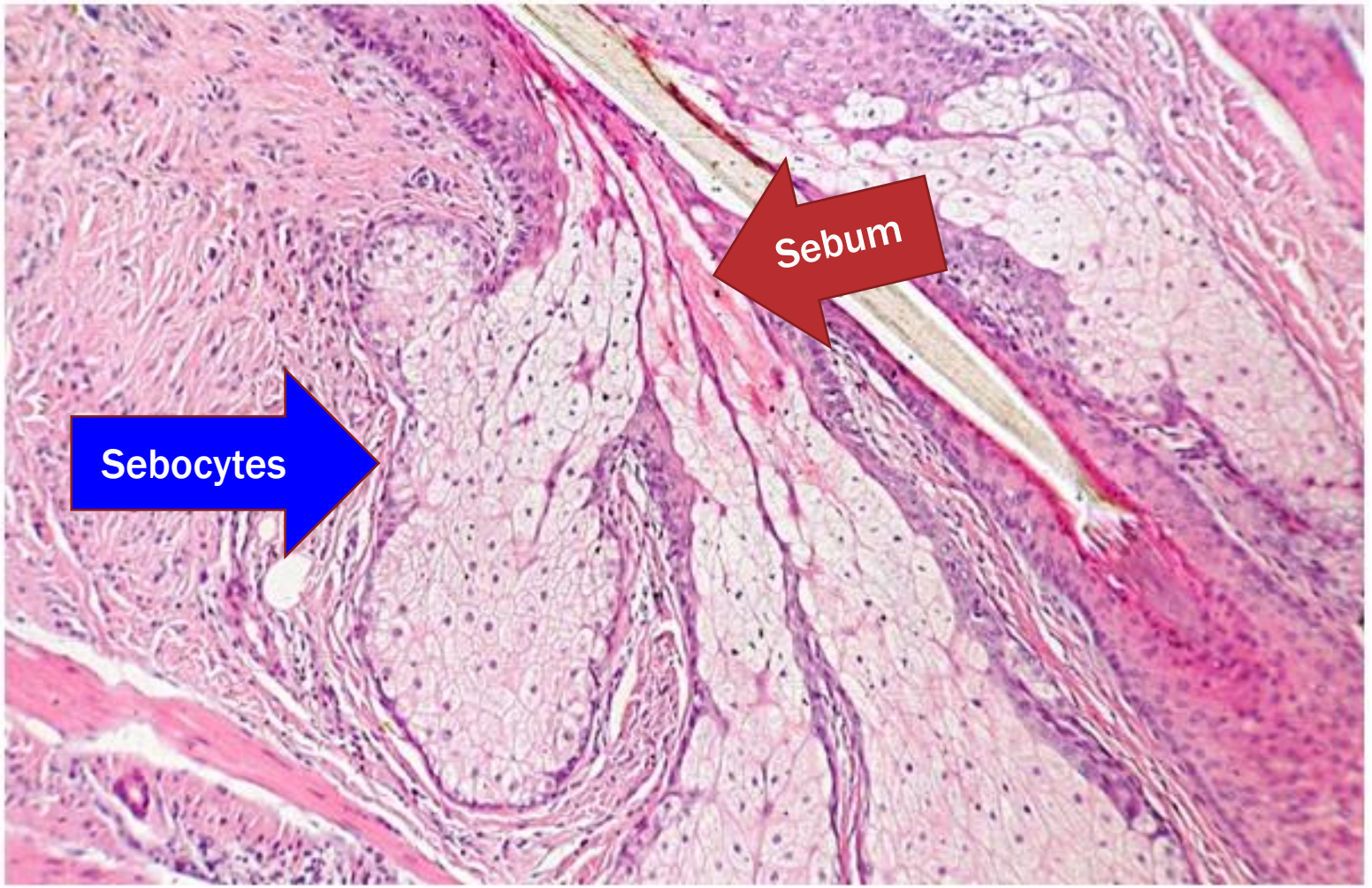


TRAINED Immunity involves the production of foamy macrophages and also involves epigenetic modifications. First described by Netea MG *et al.*, 2011 and for a recent review see Nica V *et al.*, 2022.

Trained (innate) immunity involves lipid body negative foamy macrophages (LB-FMs) producing the protector foamy virus: HERV-K102. HERV-K102 protects against emerging/pandemic RNA viruses such as HIV-1 [Laderoute MP *et al.*, 2007; 2015; Laderoute MP, 2018] and SARS-CoV-2 [Laderoute MP, submitted]

SEBOCYTES are specialized lipid body negative foamy macrophages (LB-FMs) releasing HERV-K102 particles [Laderoute MP, submitted] by lysis (novel Lysosomal DNAse2 **apoptosis mechanism [Fischer H *et al.*, 2017]) producing SEBUM that coats the mucosa**

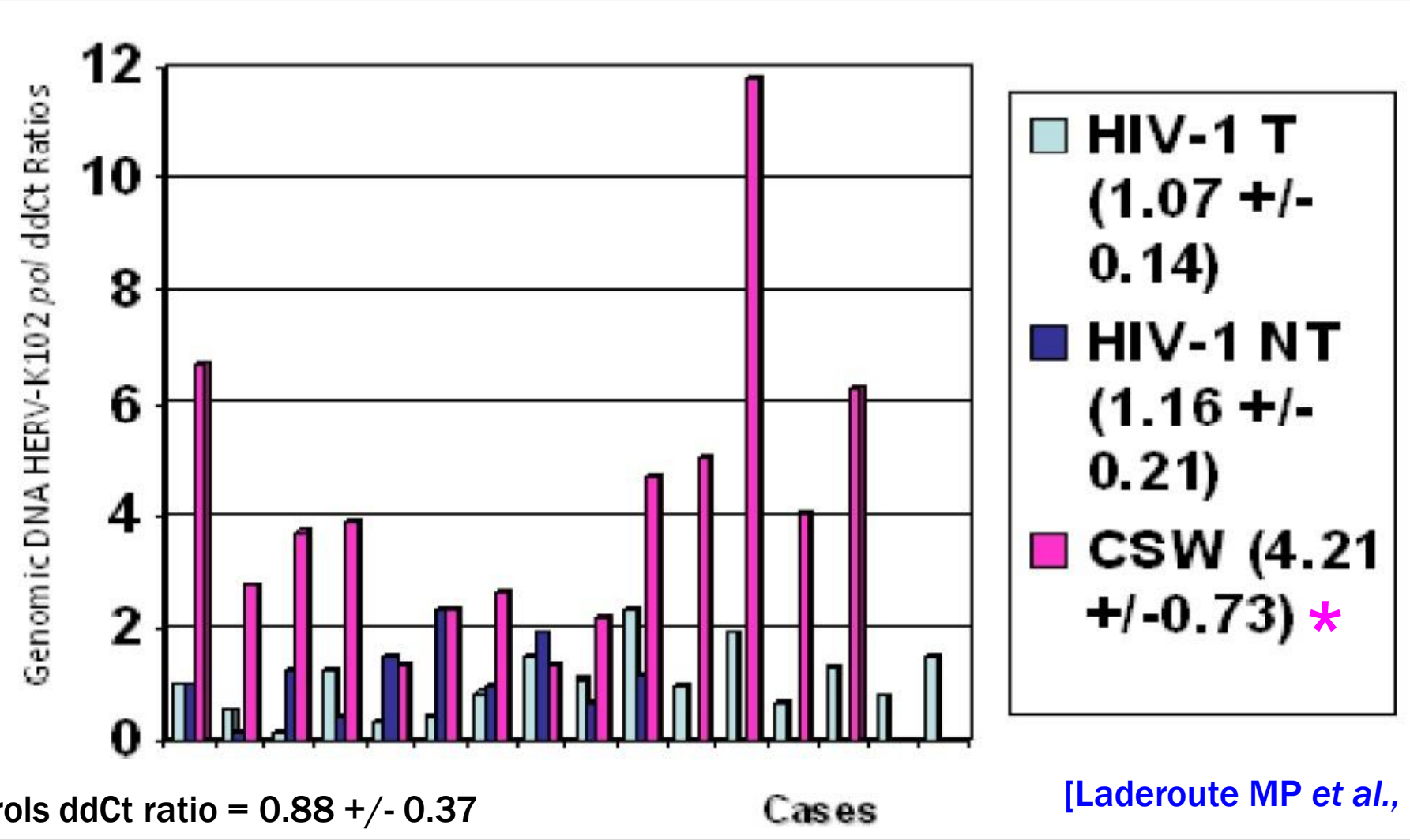
Constitutive Production of the Protector HERV-K102 Particles in SEBOCYTES [Nelson AM *et al.*, 2008; 2009]



https://commons.wikimedia.org/wiki/File:Insertion_of_sebaceous_glands_into_hair_shaft_x10.jpg

Sebocytes can become activated like LB-FMs [Torocsik D *et al.*, 2018] and once activated can be infected by SARS-CoV-2 through **classical ADE** involving FCGR2A [Ziegler CGK *et al.*, 2021].

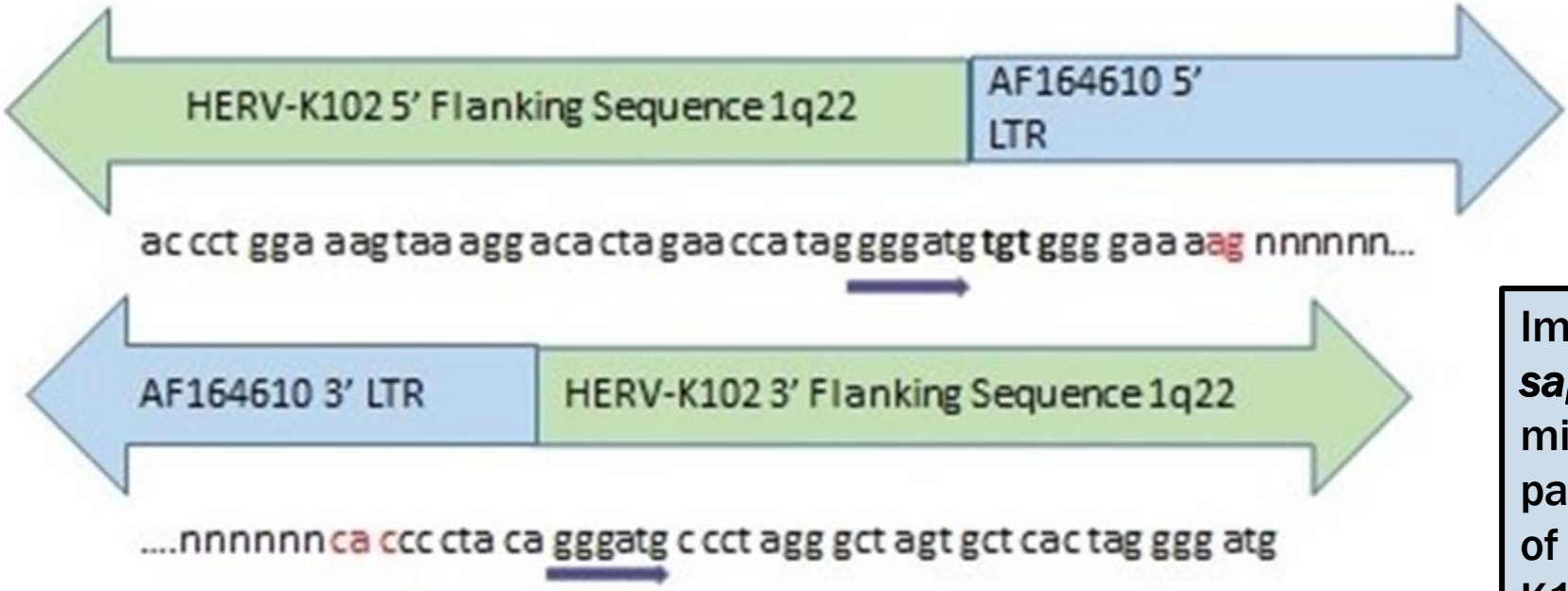
Integration into host genomic DNA is an obligatory requirement of all RETROVIRUSES to enable THEIR REPLICATION including HERV-K102. Here it is shown that HERV-K102 replication (5-fold increased provirus copy number in genomic DNA using 18S RNA to control for genomic equivalents over healthy controls) was associated with resistance to HIV-1 acquisition in the commercial sex trade worker (CSW) "HIV-1 exposed seronegative (HESN)" cohort (of the late Dr. Frank Plummer). This data suggests HERV-K102 replication may be associated with sterile immunity and which corresponds to LACK of IgG antibodies to HIV-1 envelope (cell entry molecule).



30 healthy controls ddCt ratio = 0.88 +/- 0.37

[Laderoute MP *et al.*, 2015]

Extinct Hominins Lost HERV-K102 at Orthologous Positions at 1q22



Evidence for Past Integration and Excision of HERV-K102 at Orthologous Positions (1q22) in the Neanderthal and Denisovan Genomes.

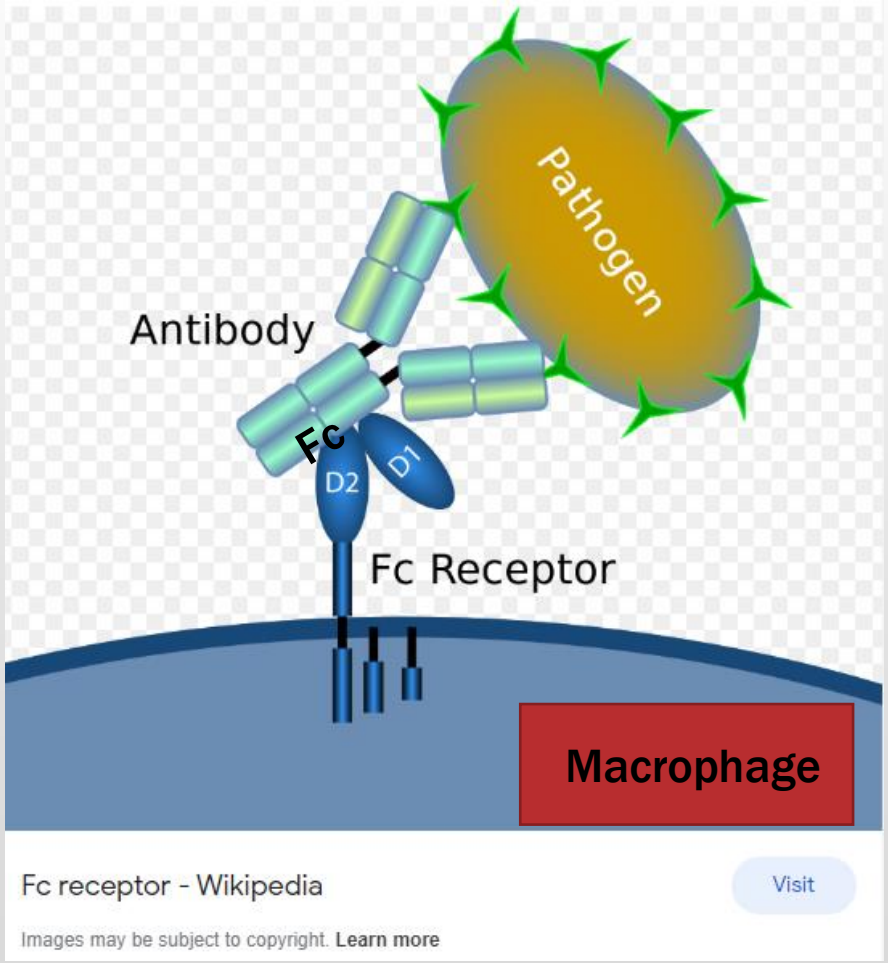
Direct repeats (gggatg) flank the orthologous HERV-K102 sequence in the human and extinct hominin genomes. The nucleotides marked in red were missing from the Denisovan orthologous position but present in the Neanderthal genome. Most of the HERV-K102 provirus was missing in both extinct hominins with only a few nucleotides corresponding to the ends of the LTRs remaining intact. "n" stands for missing nucleotides. Inquiry was made of the Altai Neanderthal or Denisovan genome at http://bioinf.eva.mpg.de/fetchseq/ on chromosome 1 strand at 155,596,423 to 155,605,644. AF164610 GenBank LTR flanking sequences used: 5' LTR sequence = AF095801 and 3' LTR sequence = AF095802.

Implies ***Homo sapiens***' survival might be explained in part by the retention of the powerful HERV-K102 virus-anti-virus INNATE protector system given the evidence for RNA virus selection pressure in the last few million years.

[Laderoute MP. *Submitted*].

Mechanism of ADE
Antibody Dependent Enhancement of Infection into Macrophages

Myeloid phagocytic cells (monocytes, neutrophils and macrophages) do not express ACE2; the primary receptor for SARS-CoV-2 entry into cells.



When activated, the macrophages express various Fc (fragment crystallization) receptors, that are typically used to clear pathogens, debris, toxins, etc. from the blood and tissues by phagocytosis.

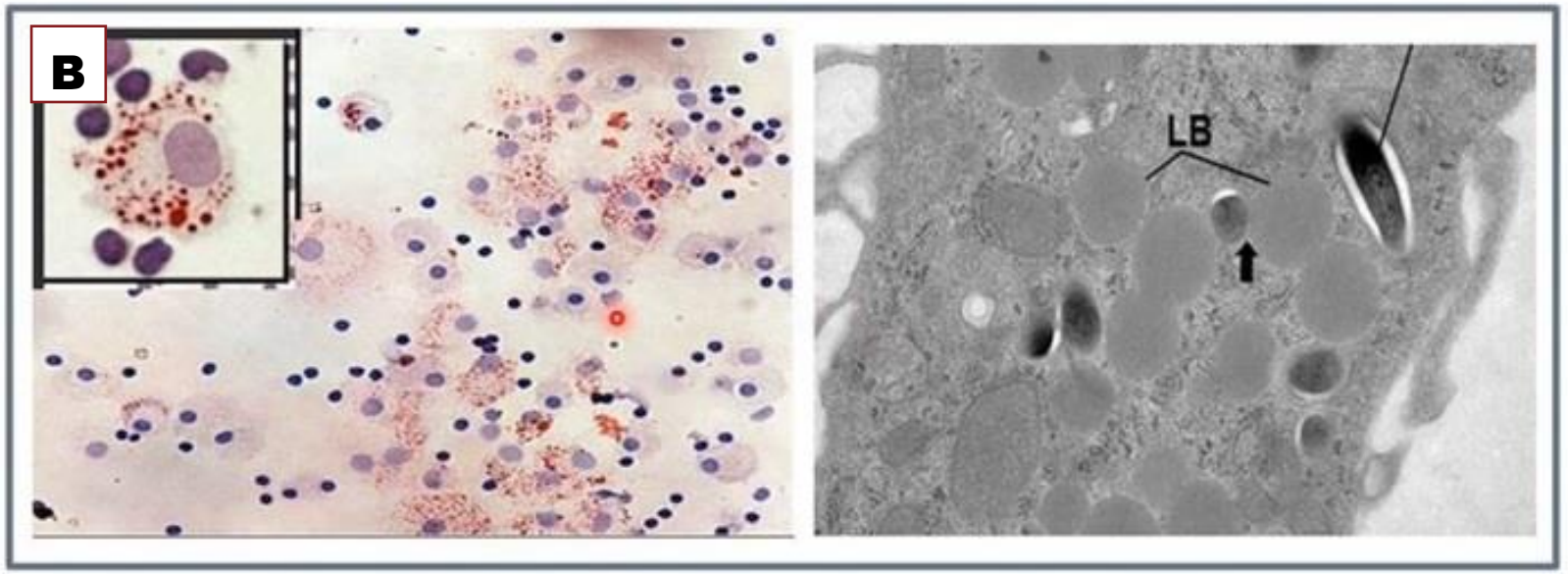
However, instead of ending up in the lysosome that digests the pathogen, the pathogen (SARS-CoV-2) escapes into the cytoplasm, to cause an infection such as in the lipid body negative foamy macrophages (LB-FMs).

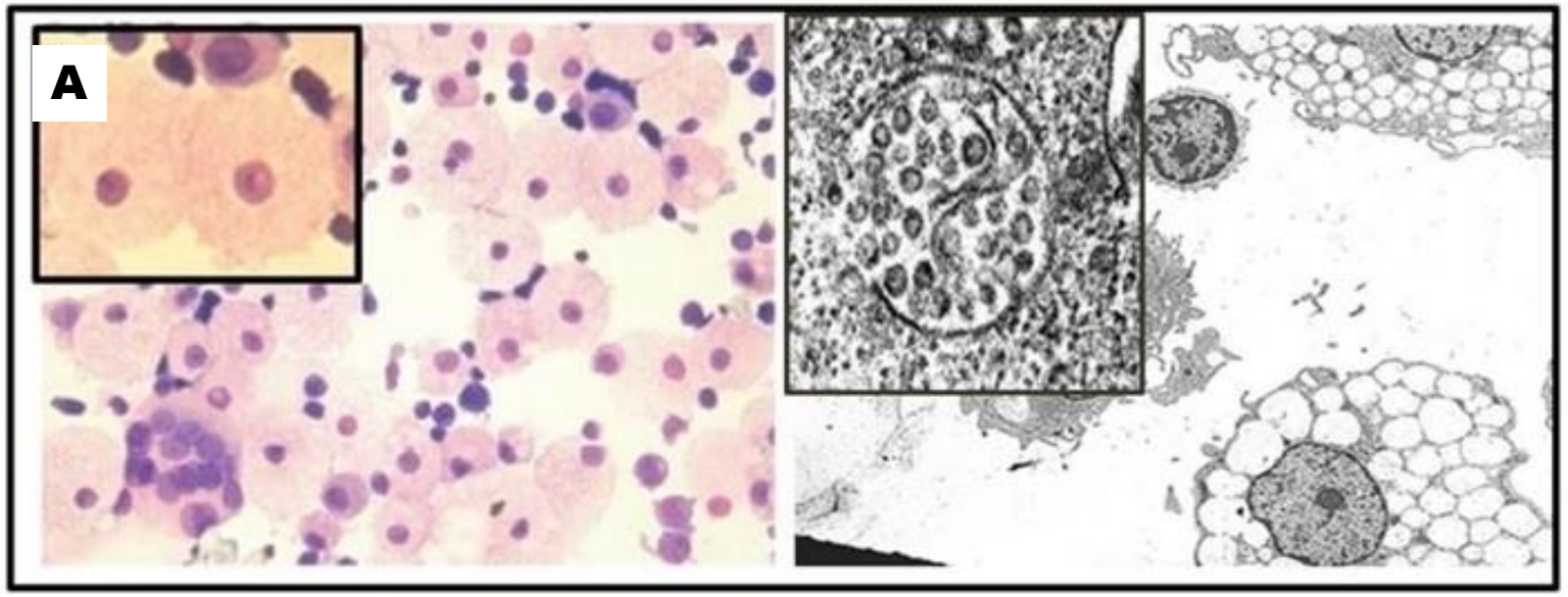
What the heck is ADE? Why does it matter?

- ADE = antibody dependent enhancement of SARS-CoV-2 infection into macrophages
- Macrophages mediate CRITICAL "trained (innate) immunity" against emerging pathogens/pandemic RNA viruses involving human endogenous retrovirus K102 (HERV-K102) particle production

- Macrophages lack the ACE2 receptor for SARS-CoV-2 entry, but express FC receptors capable of binding to IgG antibodies bound to SARS-CoV-2 virions which then mediates their entry into the protector macrophages
- The IgG antibodies produced in response to the second and subsequent doses of mRNA COVID-19 vaccine, cause the selection and transmission of immune escape variants from the upper respiratory tract (URT) prolonging the pandemic at the population level and at the individual level cause progression of disease such as acute respiratory distress syndrome (ARDS) in the lower respiratory tract (LRT).
- In fact, during natural infection it is uncommon to have IgG1/IgG3 to spike protein in the URT (only in severe or critical cases), but the SARS-CoV-2 spike protein vaccines strongly induce spike specific IgG in the URT with the second and subsequent doses commonly in most recipients. [Guerrieri M, Francavilla B, Fiorelli D, Nuccetelli M, Passali FM, Coppeta L, et al. Nasal and salivary mucosal humoral immune response elicited by mRNA BNT162b2 COVID-19 vaccine compared to SARS-CoV-2 natural infection. Vaccines (Basel). 2021 Dec 18;9(12):1499. doi: 10.3390/vaccines9121499.]

Two Types of Foamy Macrophages in HUMANS





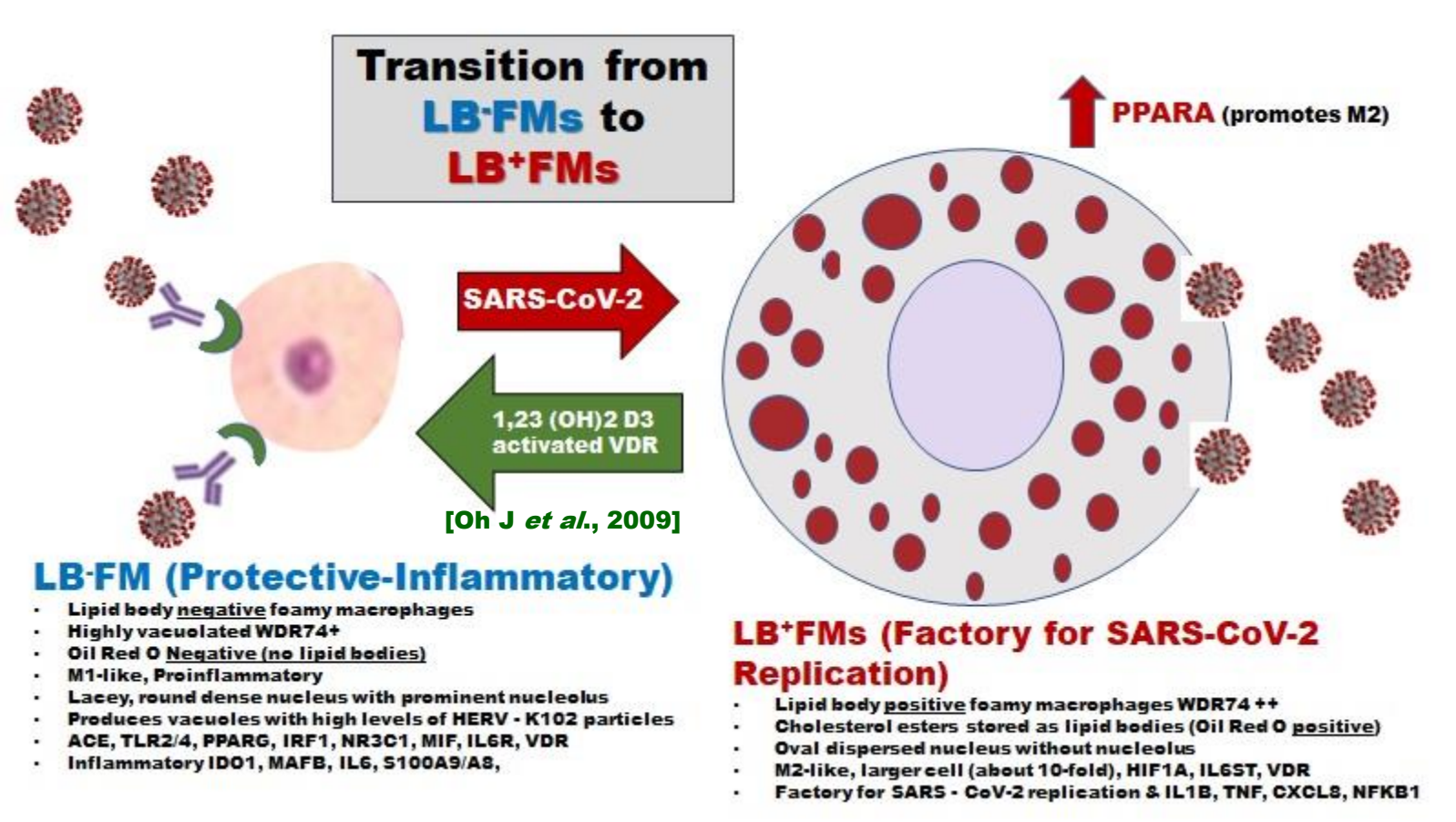
Both the A (M1-like) and B types (M2-like) are induced by *Mycobacteria tuberculosis* ***in vitro*** in PBMC [Peyron P *et al.*, 2008]. With time ***due to infection***, the A types are converted to the B types.

Only the A types produce the protector HERV-K102 foamy retrovirus particles [Laderoute MP et al., 2007; 2015].

Intracellular pathogens including SARS-CoV-2 favor the conversation of LB-FMs (A types) to LB+FMs (B types) because it provides a safe haven for their replication [Dias SSG *et al.*, 2020].

How does ADE cause progression of COVID-19 disease?

(ie., what happens upon entry of SARS-CoV-2 into the protector foamy macrophages?)



1. It blocks HERV-K102 particle production, & prevents the lytic release of the protector HERV-K102 particles, ie., abrogates critical Trained (innate) Immunity
2. Leads to immunosenescence of the foamy macrophages: i) state of being both proinflammatory & immunosuppressed, so renders macrophages dysfunctional, ii) causes chronic disease like hypertension, insulin resistance and even glucocorticoid resistance (e.g. CIRCI) which can lead to cytokine storm/hypercoagulable state
3. By converting the M1-like lipid body negative foamy macrophages (LB-FMs) to the M2-like lipid body positive foamy macrophages (LB+FMs), provides an immunologically privileged site for SARS-CoV-2 virion production and release by budding through the plasma membrane [Dias SSG et al., 2020].

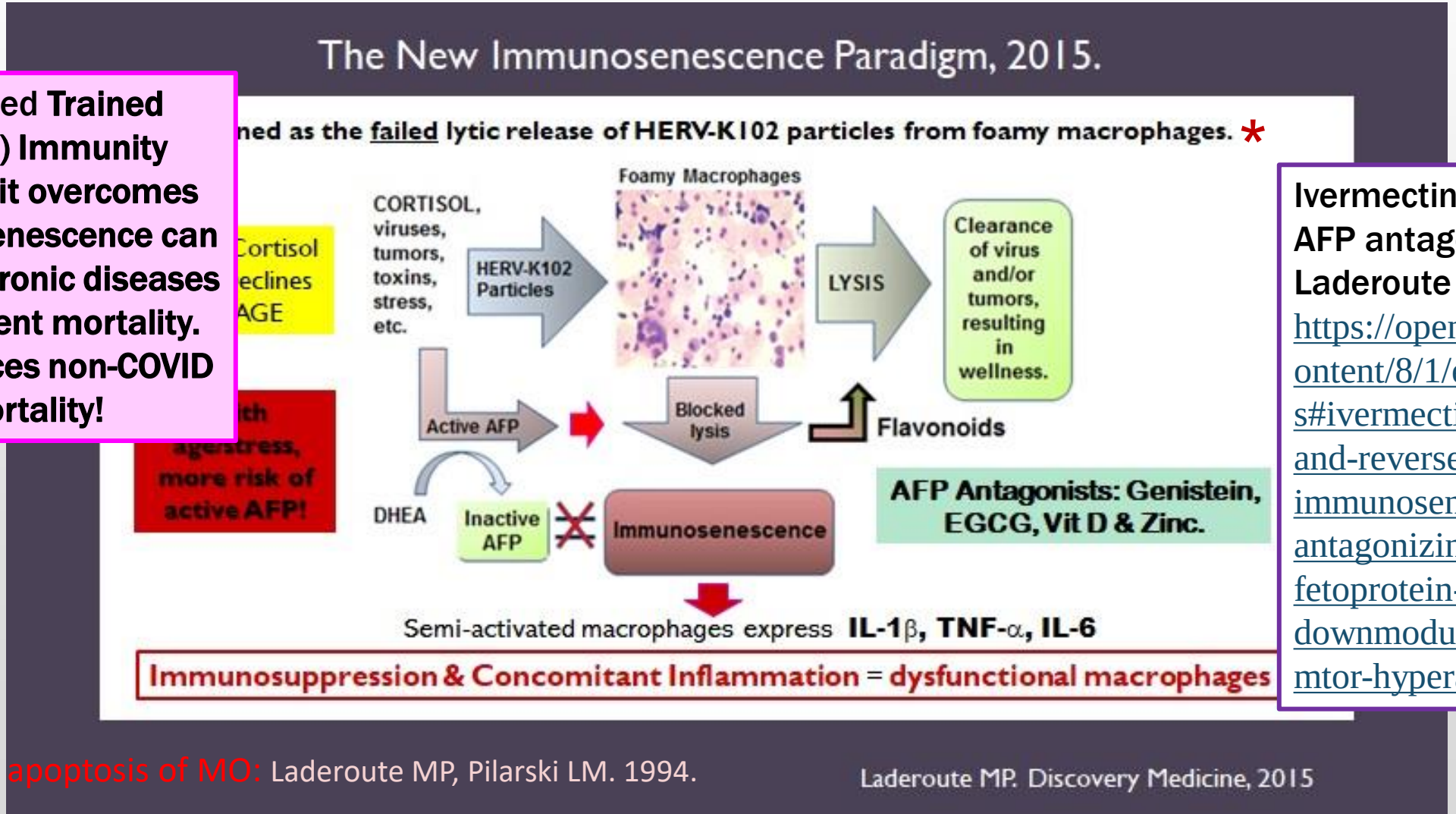
NB: It has been suggested that keeping vitamin D3 levels above 50 ng/ml provides more protection against COVID-19 mortality than any other singular approach including COVID-19 vaccines.

[**Borsche L**, Glauner B, von Mendel J. COVID-19 mortality risk correlates inversely with vitamin D3 status, and a mortality rate close to zero could theoretically be achieved at 50 ng/ml 25(OH)D3: results of a systematic review and meta-analysis. Nutrients. **2021** Oct 14;13(10):3596. doi: 10.3390/nu13103596.]

Systematic review and meta-analysis of Vitamin D3 levels in COVID-19 patients have proven the benefits are broad including prevention of symptomatic infections, hospitalizations, ICU admissions, as well as deaths. [Marik PE *et al.*, 2020; Chiodini I *et al.*, 2021; Jolliffe DA *et al.*, 2022; Nicoll R & Henein MY, 2022; Speeckaert MM & Delanghe JR, 2022.]

The new immunosenescence paradigm (2015) of macrophages

Activated Trained (innate) Immunity because it overcomes immunosenescence can reverse chronic diseases and prevent mortality. This reduces non-COVID mortality!

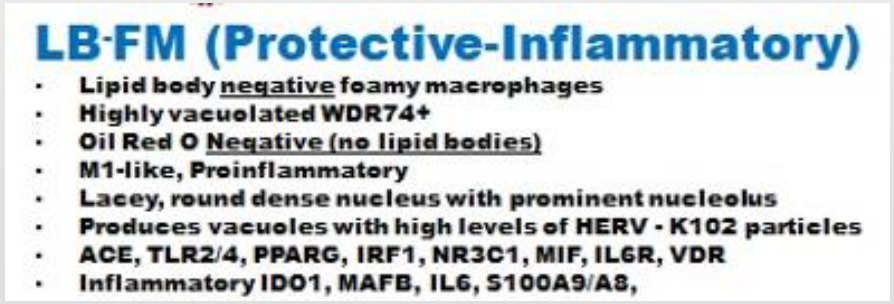


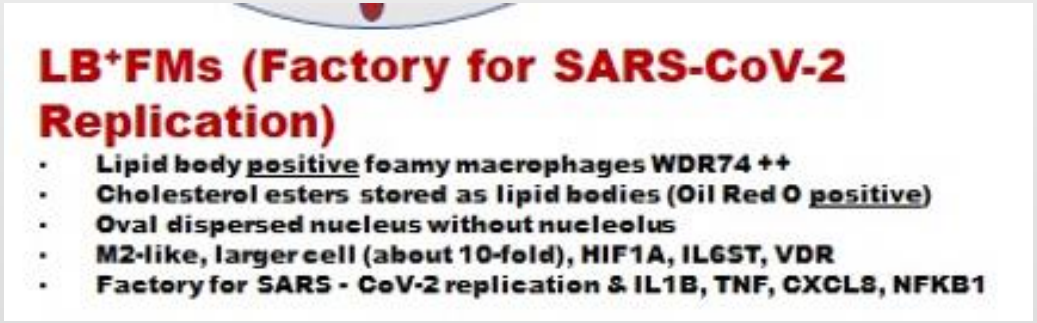
Ivermectin may also be an AFP antagonist [see Laderoute MP, 2021 https://openheart.bmj.com/content/8/1/e001655.responses#ivermectin-may-prevent-and-reverse-immunosenescence-by-antagonizing-alpha-fetoprotein-and-downmodulating-pi3k-akt-mtor-hyperactivity].

* AFP blocks apoptosis of MO: Laderoute MP, Pilarski LM. 1994.

Prior to Emergence of Omicron Variants in December 2021, the LRT pathology leading to death pertained to Acute Respiratory Distress Syndrome (ARDS) which involved an uncontrolled cytokine storm (driven by NFKB1) associated with CIRCI

- CIRCI= critical illness-related corticosteroid insufficiency (typical of sepsis/ARDS) *CIRCI can be treated early with corticosteroids to prevent cytokine storm/hypercoagulation state. Surprisingly, it does NOT impede the ability of the immune system to clear SARS-CoV-2 {as it may favor HERV-K102 M1 pro-inflammatory activation (related to MIF activation?) while inhibiting adaptive immunity which is a good thing!}*





For a fascinating discussion on CIRCI which involves mitochondrial dysfunction, downregulation of GRα, high levels of oxidative stress, pro-inflammatory cytokines regulated by NFKB1, depletion of vitamins B1, C and D3 etc. please see Meduri GU & Chrousos GP. Frontiers in Endocrinology, April 2020.

NB: Both Vit D3 / VDR and Cortisol / NR3C1 favor innate immunity and down-regulate adaptive immunity.

Both may prevent Critical Illness Related Corticosteroid Insufficiency (CIRCI), Acute Respiratory Distress (ARDS) and/or cytokine storm.

Being outside with skin exposed to produce Vitamin D from UV radiation and loading up the mitochondria with the anti-oxidant "melatonin" by exposures to "near infrared radiation" (penetrates through clothing), goes a long way to prevent CIRCI, ARDS, and/or cytokine storm [Zimmerman S & Reiter R, 2019; Twohig-Bennett C & Jones A, 2018; see also on YouTube, Dr. Roger Seheult. Sunlight: Optimize Health and Immunity. https://www.youtube.com/watch?v=5YV_iKnzDRg&t=2234s].

Recent evidence suggests near infrared radiation can **block TLR4 induction of inflammation** (NKFB1 and AP1) in foamy macrophages by both LPS (endotoxin) and **SARS-CoV-2 spike protein** [Aguida B et al., 2021]. Therefore, being outside is likely beneficial for those suffering long COVID and/or who are COVID-19 vaccine-injured. Being outdoors as therapy may have ALSO quenched symptoms in COVID-19 patients.

Long before EUAs for COVID-19 vaccines were awarded, a consensus emerged that during natural infection, IgG antibodies to spike protein did not protect or promote recovery but caused progression to more severe disease (same with SARS-CoV-1).

1. Zohar T, Alter G. Dissecting antibody-mediated protection against SARS-CoV-2. Nat Rev Immunol. 2020 Jul;20(7):392-394. doi: 10.1038/s41577-020-0359-5.
2. Chen W, Zhang J, Qin X, et al. SARS-CoV-2 neutralizing antibody levels are correlated with severity of COVID-19 pneumonia. Biomed Pharmacother. 2020 Oct;130:110629. doi: 10.1016/j.biopha.2020.110629.
3. Chen X, Pan Z, Yue S, *et al.* Disease severity dictates SARS-CoV-2-specific neutralizing antibody responses in COVID-19. *Sig Transduct Target Ther* **5**, 180 (2020). https://doi.org/10.1038/s41392-020-00301-9.
4. Hashem AM, Algaissi A, Almahboub SA, et al. Early humoral response correlates with disease severity and outcomes in COVID-19 patients. Viruses. 2020 Dec 4;12(12):1390. doi: 10.3390/v12121390.
5. Zhao J, Yuan Q, Wang H, et al. Antibody responses to SARS-CoV-2 in patients with novel coronavirus disease 2019. Clin Infect Dis. 2020 Nov 19;71(16):2027-2034. doi: 10.1093/cid/ciaa344.
6. Shrock E, Fujimura E, Kula T, et al. Viral epitope profiling of COVID-19 patients reveals cross-reactivity and correlates of severity. Science. 2020 Nov 27;370(6520):eabd4250. doi: 10.1126/science.abd4250.
7. Choteau M, Scohy A, Messe S, et al. Development of SARS-CoV2 humoral response including neutralizing antibodies is not sufficient to protect patients against fatal infection. Sci Rep. 2022 Feb 8;12(1):2077. doi: 10.1038/s41598-022-06038-5.
8. Legros V, Denolly S, Vogrig M, et al. A longitudinal study of SARS-CoV-2-infected patients reveals a high correlation between neutralizing antibodies and COVID-19 severity. Cell Mol Immunol. 2021 Feb;18(2):318-327. doi: 10.1038/s41423-020-00588-2.
9. Ren L, Fan G, Wu W, et al. Antibody responses and clinical outcomes in adults hospitalized with severe coronavirus disease 2019 (COVID-19): a post hoc analysis of LOTUS China trial. Clin Infect Dis. 2021 May 18;72(10):e545-e551. doi: 10.1093/cid/ciaa1247.
10. Wang K, Long QX, Deng HJ, et al. Longitudinal dynamics of the neutralizing antibody response to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection. Clin Infect Dis. 2021 Aug 2;73(3):e531-e539. doi: 10.1093/cid/ciaa1143.
11. Xu X, Nie S, Wang Y, et al. Dynamics of neutralizing antibody responses to SARS-CoV-2 in patients with COVID-19: an observational study. Signal Transduct Target Ther. 2021 May 18;6(1):197. doi: 10.1038/s41392-021-00611-6.
12. Gao L, Zhou J, Yang S, et al. The dichotomous and incomplete adaptive immunity in COVID-19 patients with different disease severity. *Sig Transduct Target Ther* **6**, 113 (2021). https://doi.org/10.1038/s41392-021-00525-3.
13. Huang AT, Garcia-Carreras B, Hitchings MDT, et al. A systematic review of antibody mediated immunity to coronaviruses: kinetics, correlates of protection, and association with severity. Nat Commun. 2020 Sep 17;11(1):4704. doi: 10.1038/s41467-020-18450-4.
14. Nair S, Chen X. Biology of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and the humoral immunoresponse: a systematic review of evidence to support global policy-level actions and research. Glob Health J. 2022 Mar;6(1):38-43. doi: 10.1016/j.glohj.2021.11.005.

IN FACT, protection against COVID-19 severity correlated with the absence of IgG antibodies to SARS-CoV-2 spike protein (analogous to the HESN cohorts resistant to HIV-1 acquisition). [Wu F, Liu M, Wang A, et al. Evaluating the association of clinical characteristics with neutralizing antibody levels in patients who have recovered from mild COVID-19 in Shanghai, China. JAMA Intern Med. 2020 Oct 1;180(10):1356-1362. doi: 10.1001/jamainternmed.2020.4616.]

Indeed, during natural infection with SARS-CoV-2, it was the **more rapid and enhanced development of IgG antibodies to spike protein** in higher risk older individuals [16-23] which was associated with progression to severe COVID-19 and not protection.

16. Zohar T, Loos C, Fischinger S, Atyeo C, Wang C, Slein MD, et al. Compromised humoral functional evolution tracks with SARS-CoV-2 mortality. Cell. 2020 Dec 10;183(6):1508-1519.e12. doi: 10.1016/j.cell.2020.10.052.
17. Tetro JA. Is COVID-19 receiving ADE from other coronaviruses? Microbes Infect. 2020 Mar;22(2):72-73. doi: 10.1016/j.micinf.2020.02.006.
18. Ricke DO. Two different antibody-dependent enhancement (ADE) risks for SARS-CoV-2 antibodies. Front Immunol. 2021 Feb 24;12:640093. doi: 10.3389/fimmu.2021.640093.
19. Moorlag SJCFM, Taks E, Ten Doesschate T, et al. Efficacy of Bacillus Calmette-Guérin vaccination against respiratory tract infections in the elderly during the Covid-19 pandemic. Clin Infect Dis. 2022 Mar 5:ciac182. doi: 10.1093/cid/ciac182.
20. Bigay J, Le Grand R, Martinon F, Maisonnasse P. Vaccine-associated enhanced disease in humans and animal models: lessons and challenges for vaccine development. Front Microbiol. 2022 Aug 10;13:932408. doi: 10.3389/fmicb.2022.932408.
21. Munitz A, Edry-Botzer L, Itan M, et al. Rapid seroconversion and persistent functional IgG antibodies in severe COVID-19 patients correlates with an IL-12p70 and IL-33 signature. Sci Rep. 2021 Feb 10;11(1):3461. doi: 10.1038/s41598-021-83019-0.
22. Ho M.S., Chen W.J., Chen H.Y., Lin S.F., Wang W.C., Di J. Neutralizing antibody response and SARS severity. *Emerg Infect Dis.* 2005;11:1730–1737.
23. Liu L, Wei Q, Lin Q, et al. Anti-spike IgG causes severe acute lung injury by skewing macrophage responses during acute SARS-CoV infection. JCI Insight. 2019 Feb 21;4(4):e123158. doi: 10.1172/jci.insight.123158.

During natural infection, the name of the game was that innate immunity had to clear/inactivate SARS-CoV-2 virions BEFORE the adaptive immune system produced high levels of IgG anti-spike antibodies [Laderoute MP, submitted].

No matter what context of the clinical use of IgG antibodies to spike protein, all systemic reviews revealed **failure to establish a benefit on all-cause mortality**.

Graña C, Ghosn L, Evrenoglou T, et al. Efficacy and safety of COVID-19 vaccines. Cochrane Database Syst Rev. 2022 Dec 7;12(12):CD015477. doi: 10.1002/14651858.CD015477.

Failed test for all-cause mortality benefit of all COVID-19 vaccines.

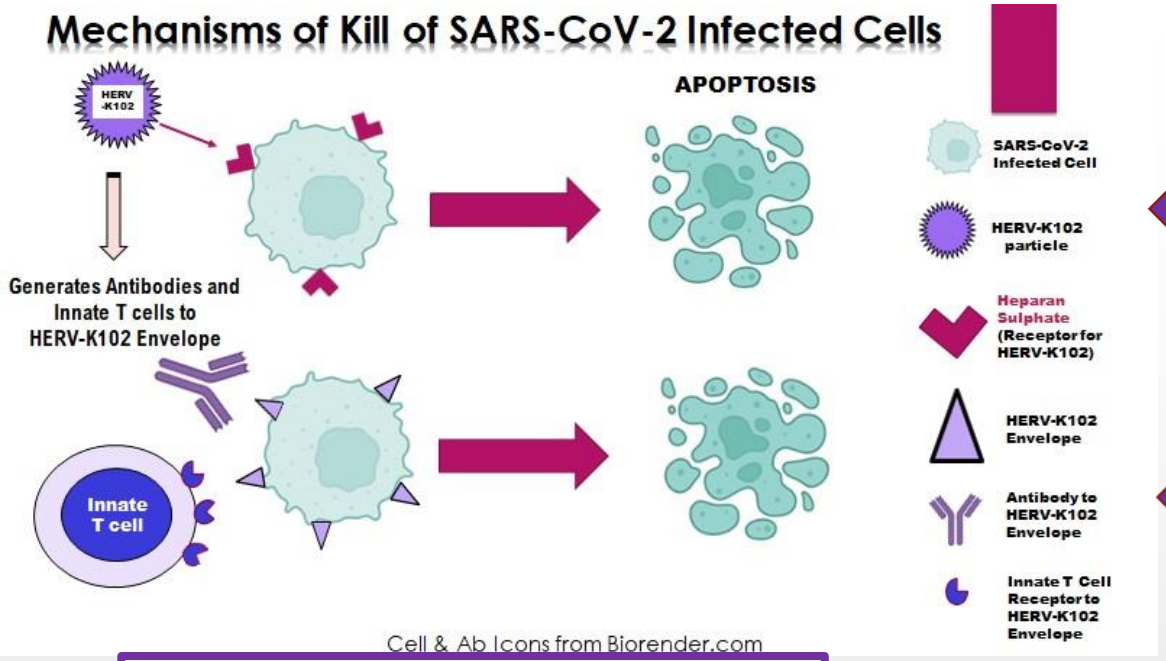
Hirsch C, Park YS, Piechotta V, et al. SARS-CoV-2-neutralising monoclonal antibodies to prevent COVID-19. Cochrane Database Syst Rev. 2022 Jun 17;6(6):CD014945. doi: 10.1002/14651858.CD014945.pub2.

Monoclonal neutralizing antibodies to spike protein did not show any benefit for all-cause mortality whether administered for pre-exposure or for post-exposure prophylaxis in a Cochrane Database systematic review.

Lee HJ, Lee JH, Cho Y, Ngoc LTN, Lee YC. Efficacy and safety of COVID-19 treatment using convalescent plasma transfusion: updated systematic review and meta-analysis of randomized controlled trials. Int J Environ Res Public Health. 2022 Aug 25;19(17):10622. doi: 10.3390/ijerph191710622.

Based on 11,767 participants for all-cause mortality from 34 studies suggested convalescent plasma (CP) often titrated for high levels of IgG or neutralizing antibodies to spike protein, had no benefit over risk as a therapy for severe COVID-19 disease.

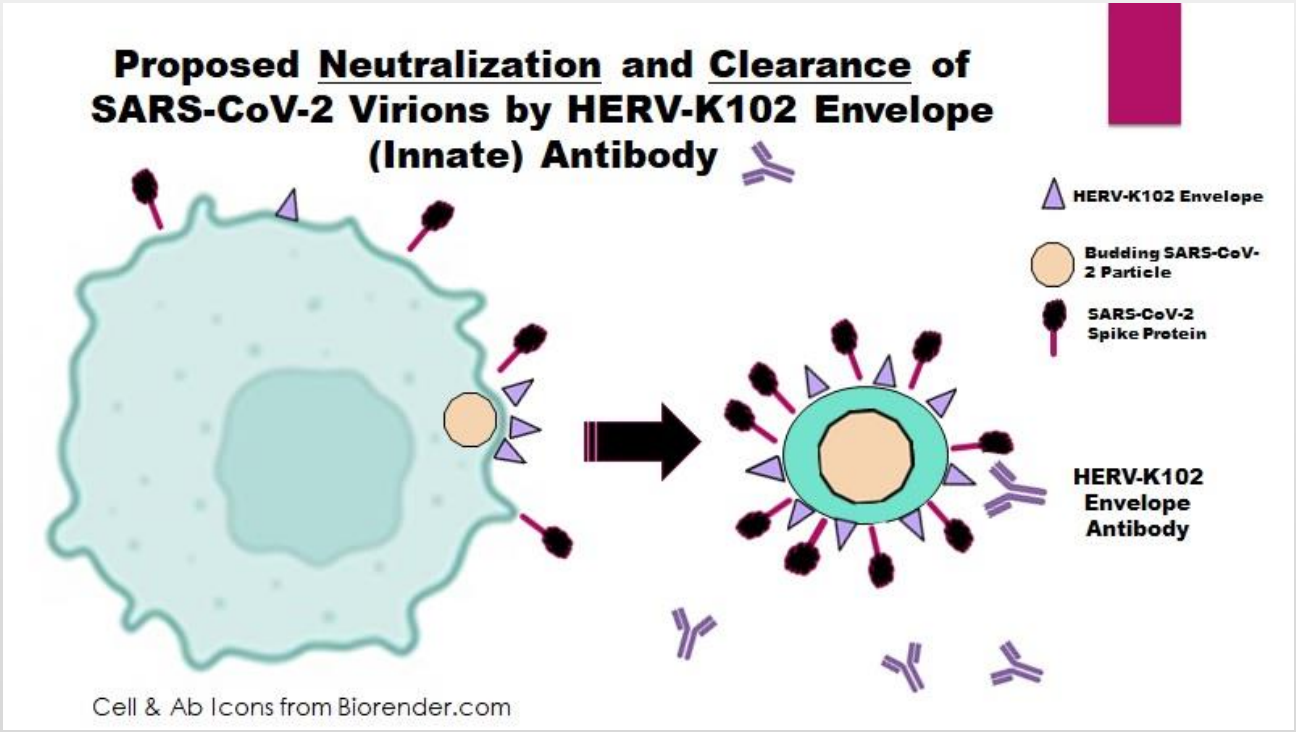
Also no correlate of protection established for adaptive immunity. On the other hand, Vitamin D levels and the type 1 interferon responses (both innate immunity) were established as correlates of protection against SARS-CoV-2 [reviewed in Laderoute MP, submitted]. All-cause mortality rate is mainly due to deaths from CVD, T2DM, respiratory disease, AD and other dementias, autoimmune diseases, and cancer, all of whose mortality rates are inversely correlated with serum 25(OH)D concentrations [Grant WB et al., 2022].



The HERV-K102 virus anti-virus system involves:

- 1) HERV-K102 particles (undergoes lytic infections in virus infected cells and spreads the interferon type 1 response upon release of cDNA into cytoplasm and with detection by GAS/STING) and,
- 2) innate T cells and antibody to HERV-K102 envelope

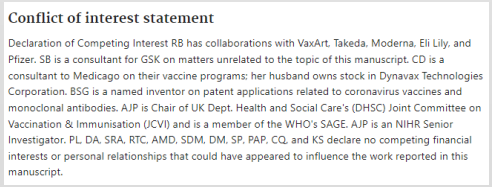
INNATE Immunity can neutralize, inactivate and clear SARS-CoV-2 virions with antibodies to HERV-K102 envelope. **HERV-K102 Envelope** becomes expressed on virally infected cells but not normal cells. It becomes incorporated into SARS-CoV-2 virions when it buds from the cell surface.



Evidence that the WHO, NIH, Pfizer, Moderna, CDC and other officials or their representatives (including Ralph Baric*) knew well about the ADE risks of an adaptive COVID-19 vaccine against SARS-CoV-2 spike protein.

On March 11, 2020 the World Health Organization declared SARS-CoV-2 a pandemic and the very next day the Coalition for Epidemic Preparedness Innovations (CEPI) and the Brighton Collaboration Safety Platform for Emergency vACcines (SPEAC) convened a two-day meeting to assess the risk of disease enhancement with COVID-19 *adaptive immunity* vaccines (ie., ADE) [1,2].

Lambert PH, Ambrosino DM, Andersen SR, Baric RS, Black SB, Chen RT, Dekker CL, Didierlaurent AM, Graham BS, Martin SD, Molrine DC, Perlman S, Picard-Fraser PA, Pollard AJ, Qin C, Subbarao K, Cramer JP. Consensus summary report for CEPI/BC March 12-13, 2020 meeting: Assessment of risk of disease enhancement with COVID-19 vaccines. Vaccine. 2020 Jun 26;38(31):4783-4791. doi: 10.1016/j.vaccine.2020.05.064.



Conflict of interest statement

Declaration of Competing Interest RB has collaborations with VaxArt, Takeda, Moderna, Eli Lily, and Pfizer. SB is a consultant for GSK on matters unrelated to the topic of this manuscript. CD is a consultant to Medicago on their vaccine programs; her husband owns stock in Dynavax Technologies Corporation. BSG is a named inventor on patent applications related to coronavirus vaccines and monoclonal antibodies. AJP is Chair of UK Dept. Health and Social Care's (DHSC) Joint Committee on Vaccination & Immunisation (JCVI) and is a member of the WHO's SAGE. AJP is an NIHR Senior Investigator. PL, DA, SRA, RTC, AMD, SDM, DM, SP, PAP, CQ, and KS declare no competing financial interests or personal relationships that could have appeared to influence the work reported in this manuscript.

Reveals many participants were employed or contracted to Big Pharma.

* **Dr. Ralph Baric a coronavirus expert of the University of North Carolina, allegedly contributed to the creation of SARS-CoV-2 at the Wuhan Institute of Virology which presumably started the pandemic via a lab-leak.**

There was much discussion in publications of medical journals prior to January 1, 2021 that a safe and effective COVID-19 vaccine was regarded as near impossible due to ADE. The lack of time to conduct proper safety evaluation was also a major concern. Finally the use of gene therapy for vaccines was a risky venture and lacked safety history.

1. Hotez PJ, Corry DB, Bottazzi ME. COVID-19 vaccine design: the Janus face of immune enhancement. Nat Rev Immunol. 2020 Jun;20(6):347-348. doi: 10.1038/s41577-020-0323-4.

25. Arvin AM, Fink K, Schmid MA, et al. A perspective on potential antibody-dependent enhancement of SARS-CoV-2. Nature. 2020 Aug;584(7821):353-363. doi: 10.1038/s41586-020-2538-8.
26. Bournazos S, Gupta A, Ravetch JV. The role of IgG Fc receptors in antibody-dependent enhancement. Nat Rev Immunol. 2020 Oct;20(10):633-643. doi: 10.1038/s41577-020-00410-0.
27. Morris KV. The improbability of the rapid development of a vaccine for SARS-CoV-2. Mol Ther. 2020 Jul 8;28(7):1548-1549. doi: 10.1016/j.ymthe.2020.06.005.
28. Graham BS. Rapid COVID-19 vaccine development. Science. 2020 May 29;368(6494):945-946. doi: 10.1126/science.abb8923.
29. Sariol A, Perlman S. Lessons for COVID-19 immunity from other coronavirus infections. Immunity. 2020 Aug 18;53(2):248-263. doi: 10.1016/j.immuni.2020.07.005.

Some, tried to use flimsy arguments that *in vitro* it was uncommon to show ADE ie., SARS-CoV-2 infection of monocytes or macrophages by antibodies. However, in ***all in vivo examinations* such as post-mortems, BALF, PBMCs etc, in patients with severe disease (but not mild disease) monocytes/macrophages were definitely infected with *replicating* SARS-CoV-2 despite not expressing ACE2 [Laderoute MP, submitted].**

Even for monoclonal neutralizing IgG antibodies to spike, their usefulness was often short lived and more often than not led to more critical disease (via ADE) since they selected for immune escape variants. It only took 10 days on average until the selected immune escape variant became established as a viremia (ie., high levels circulating in the blood). *

Jensen B, Luebke N, Feldt T, et al. Emergence of the E484K mutation in SARS-COV-2-infected immunocompromised patients treated with bamlanivimab in Germany. Lancet Reg Health Eur. 2021 Sep;8:100164. doi: 10.1016/j.lanepe.2021.100164.

* Many of the deteriorating patients were rescued with convalescent plasma (CP), but not all. As CP would contain not only antibodies to SARS-CoV-2 various antigens including the dangerous ones to spike protein, but also the protector HERV-K102 particles, and likely the antibodies to HERV-K102 envelope which neutralize and clear SARS-CoV-2 virions; unless one screened for low levels of spike specific IgG and high levels of HERV-K102 particles and preferably used donors with high levels of HERV-K102 envelope antibodies (see methods in Laderoute MP et al., AIDS, 2007), it is not surprising that the results with CP were unpredictable.

It was well established that for COVID-19 vaccines, that the first dose induced 'trained INNATE immunity' (and offered non-specific protection against non-COVID-19 mortality *) while the second dose induced the high levels of IgG and neutralizing antibodies to spike protein [e.g., for mRNA vaccines: Walsh EE et al., 2020; Chu L et al., 2021]. .

*Xu S, Huang R, Sy LS, et al. COVID-19 vaccination and non–COVID-19 mortality risk — seven integrated health care organizations, United States, December 14, 2020–July 31, 2021. MMWR Morb Mortal Wkly Rep 2021;70:1520–1524. doi: http://dx.doi.org/10.15585/mmwr.mm7043e2.

Walsh EE, Frenck RW Jr, Falsey AR, et al. Safety and immunogenicity of two RNA-based Covid-19 vaccine candidates. N Engl J Med. 2020 Dec 17;383(25):2439-2450. doi: 10.1056/NEJMoa2027906.

Chu L, McPhee R, Huang W, et al. A preliminary report of a randomized controlled phase 2 trial of the safety and immunogenicity of mRNA-1273 SARS-CoV-2 vaccine. Vaccine. 2021 May 12;39(20):2791-2799. doi: 10.1016/j.vaccine.2021.02.007.

In the 50 + age group in the UK and ONS data covering the period of January 1, 2021 to May 31, 2022, there were 1,455 lives saved from COVID-19 (by one dose but not two doses) and 414,430 excess non-COVID-19 deaths associated with vaccination (mostly mRNA gene therapies). # UK Office for National Statistics (ONS) data source provided in slide 26.

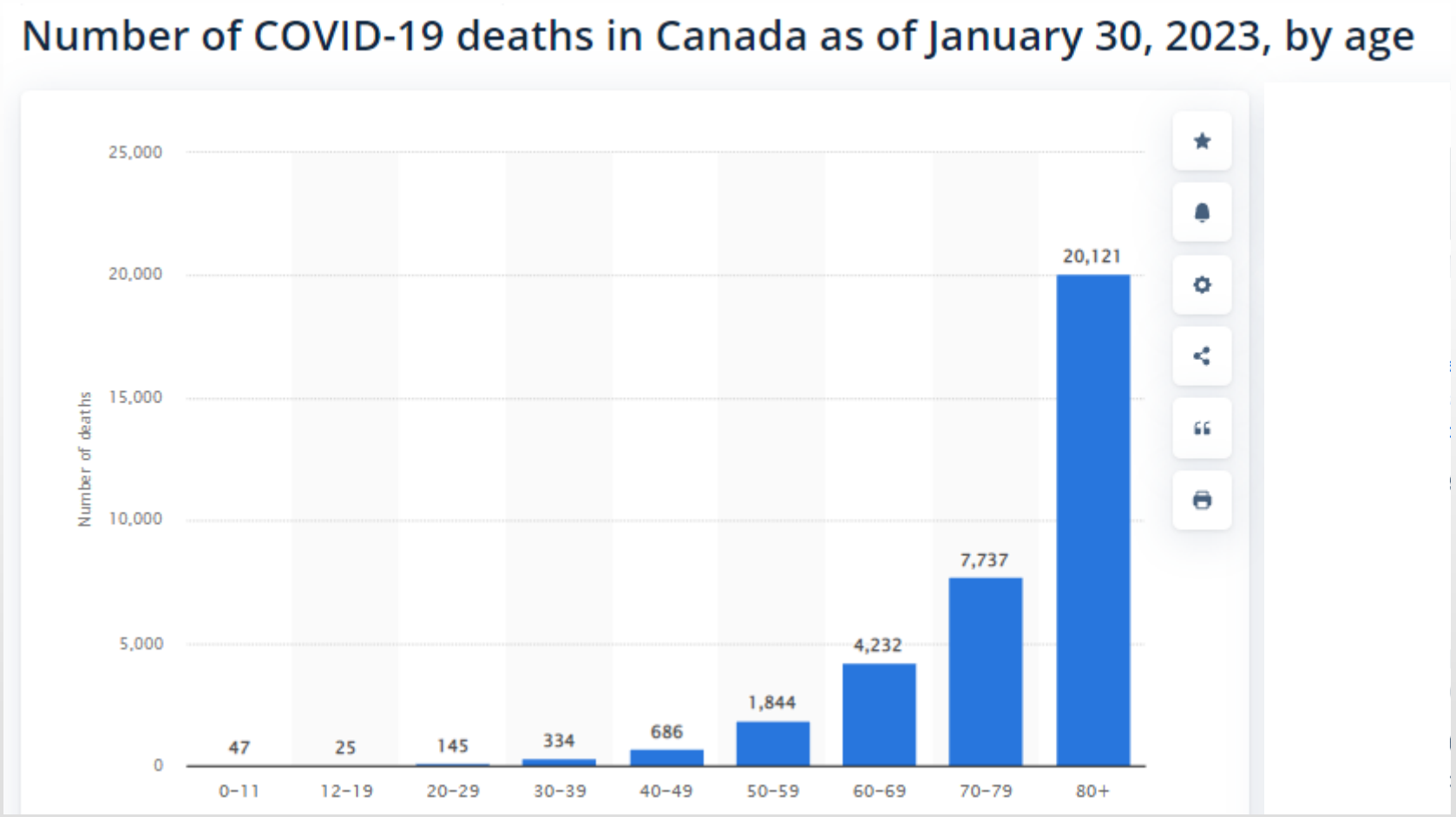
Table 1

RAW COUNTs of Deaths from Jan 1 2021 to May 31, 2022

	COVID-19 Deaths			Non-COVID-19 Deaths			All-Cause Deaths		
AGE GROUP	UNvax	VAXED	RATIO	UNvax	VAXED	RATIO	UNvax	VAXED	RATIO
90+	7191	9336	1.298	11829	116270	9.829	19020	125606	6.604
85-89	6437	7870	1.223	9707	94963	9.783	16144	102833	6.370
80-84	5841	6620	1.133	8887	84170	9.471	14728	90790	6.164
75-79	5044	4712	0.934	8515	67288	7.902	13559	72000	5.310
70-74	4194	3031	0.723	8090	49631	6.135	12284	52662	4.287
65-69	3051	1776	0.582	6303	29422	4.668	9354	31198	3.335
60-64	2425	917	0.378	5135	15876	3.092	7560	16793	2.221
55-59	1626	754	0.464	4084	13903	3.404	5710	14657	2.567
50-54	1069	407	0.381	3014	8471	2.811	4083	8878	2.174
SUBTOTAL	36878	35423	0.791	65564	479994	6.344	102442	515417	4.337

In the 50+ at risk group, **excess deaths occurred** in 1/51 ever- vaccinated individuals.

For each life saved from COVID-19 by vaccination (one dose), there were 285 excess deaths associated with ever being vaccinated. (**6.7 fold** excess Non-C19/C19 deaths in 50 +)



https://www.statista.com/statistics/1228632/number-covid-deaths-canada-by-age/

In Canada by 2023-01-30, the number of COVID-19 deaths in the 50+ was 33,934. Times 6.7 fold for the 50+; at least **227,358** excess non-COVID deaths associated with ever COVID-19 vaccinated, could be estimated.

Estimated Canadian EXCESS Fatalities in the 50 +

Associated with COVID-19 Vaccination

(based on ONS UK data of 1) non-C19 deaths 1/51 for the ever vaccinated in the 50+ or
2) 6.7 times the number of COVID-19 deaths in the 50 +)

"minimally 227,358 to 278,913 excess non-C19 deaths related to being ever COVID-19 vaccinated"

https://health-infobase.canada.ca/covid-19/#a9

Latest COVID-19 numbers (Last data update April 17, 2023, 11 am ET)

Weekly change in cases	Total cases	Weekly change in deaths	COVID-19 Total deaths
5,805	4,647,673	57	51,763

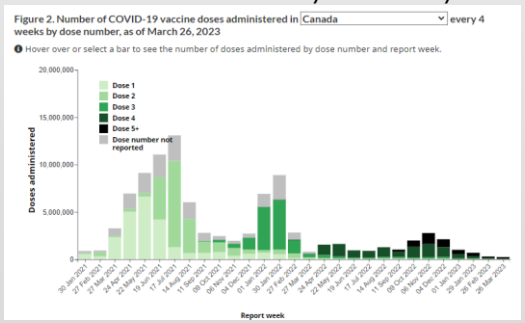
Weekly tests reported	Weekly percent positivity
37,325	10.4%

https://health-infobase.canada.ca/covid-19/vaccine-administration/

Table 1. Cumulative number of COVID-19 vaccine doses administered in Canada by vaccine product and dose number, as of March 26, 2023

Vaccine product	Total doses	Dose 1	Dose 2	Dose 3	Dose 4	Dose 5+
All vaccines	97,522,757	32,510,168	31,169,073	19,814,225	10,085,856	3,943,435

https://health-infobase.canada.ca/covid-19/vaccine-administration/



If we use 6.7 fold (UK) non-C19/C19 deaths for 50+, then up to **227,358 excess non-C19 deaths in the 50+ age group** related to ever being vaccinated.

https://health-infobase.canada.ca/covid-19/vaccination-coverage/

Table 2. Cumulative number and percent of people in Canada who have received a COVID-19 vaccine by age group and vaccination status, March 26, 2023

Age group (years)	At least 1 dose	Primary series completed	In the last 6 months, primary series completed or booster dose received
0 to 4	9.6% (180,263)	5.6% (105,119)	5.2% (97,415)
5 to 11	51.6% (1,498,166)	40.3% (1,170,776)	6.8% (198,595)
12 to 17	83.7% (2,116,197)	79.3% (2,004,643)	8.8% (222,434)
18 to 29	85.1% (5,194,715)	82.9% (4,053,289)	7.3% (447,340)
30 to 39	87.0% (4,786,989)	85.1% (3,709,140)	11.5% (634,010)
40 to 49	89.5% (4,457,423)	88.1% (3,376,803)	15.0% (746,637)
50 to 59	90.2% (4,561,461)	89.3% (3,504,566)	21.2% (1,069,310)
60 to 69	94.5% (4,677,425)	93.4% (3,508,116)	34.2% (1,691,703)
70 to 79	97.6% (3,184,776)	96.6% (2,367,753)	45.0% (1,466,261)
80 and older	≥99% (1,800,891)	≥99% (1,342,434)	45.5% (801,394)

50+ at least one dose = 14,224,553 **(1/51 = 278,913 excess deaths)**

ESTIMATE there have been at least 278,913 excess deaths in the 50+ age group related to having at least one dose of COVID-19 vaccine.

Mortality rates per 100,000 person-years.

Table 2.

		All-Cause Mortality			COVID-19 Mortality			Non-C19 Mortality		
		RATE Unvax	Actual RATE Ever Vax	Ratio of Vax/ Unvax Rates	RATE Unvax	Actual RATE Ever Vax	Ratio of Vax/ Unvax Rates	RATE Unvax	Actual RATE Ever Vax	Ratio of Vax/ Unvax Rates
2021	Jan	2507.6	3483.5	1.39	1187	1526	1.29	1320	1958	1.48
	Feb	5261.5	3205.4	0.61	2174	456.8	0.21	3087	2689	0.87
	Mar	3307.8	4192.7	1.27	5919	283.9	0.05	2716	3909	1.44
	April	2298.4	5039.7	2.19	145.8	184	1.26	2153	4855	2.25
	May	1718.8	8582.6	4.99	45.5	84.5	1.86	1673	8426	5.04
	June	1589.7	10060	6.33	55.6	87.7	1.58	1534	9916	6.46
	July	1610.7	10307.1	6.40	218.2	224.9	1.03	1392	9960	7.16
	Aug	1711.6	10340.7	6.04	404.2	402.9	1.00	1307	9266	7.09
	Sept	1664.5	8639	5.19	367.8	520.2	1.41	1297	7884	6.08
	Oct	1623.7	12456.3	7.67	322.3	568.6	1.76	1302	11845	9.10
	Nov	1708	15546.6	9.10	421.3	721	1.71	1287	14155	11.00
	Dec	1878.5	16974.3	9.04	520.5	1121.9	2.16	1358	15501	11.41
2022	Jan	1812	19997.9	11.04	584.6	2310.9	3.95	1227	16417	13.38
	Feb	1384.5	12474.4	9.01	258.7	1128.4	4.36	1126	11346	10.08
	Mar	1231.7	10257.2	8.33	183.5	763.6	4.16	1048	9445	9.01
	April	1204.6	12423.2	10.31	204.7	800.8	3.91	1000	11622.4	11.62
	May	872.9	8246	9.45	77.6	261.8	3.37	795	7914	9.95

UK ONS data (once *properly* compiled) is very clear:

1. The vaccination program should have been halted by the first week in February 2021, as the mortality rate ratios showed **all-cause mortality** was worse in the ever vaccinated in January 2021. [Dr. Peter McCullough concurs based on this data.]

2. The only month with a favorable all-cause mortality rate ratio was **February 2021**, at a time when about 96 % of the aged population had received one dose, but not the second dose (no IgG antibodies to spike protein in about 96% of the inoculated because they only had the first dose).

Office for National Statistics (UK). Deaths involving COVID-19 by vaccination status, England: Deaths occurring between 1 January 2021 and 31 May 2022. Age-standardised mortality rates and raw death numbers for deaths involving COVID-19 by vaccination status, broken down by age and /or sex group. https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/deaths/bulletins/deathsinvolvingcovid19byvaccinationstatusengland/deathsoccurringbetween1january2021and31may2022. Data released July 6, 2022.

Evidence for one dose only during February 2021 providing a favorable all-cause mortality rate ratio.

TABLE 3 Provisional cumulative COVID-19 vaccine uptake by age in England

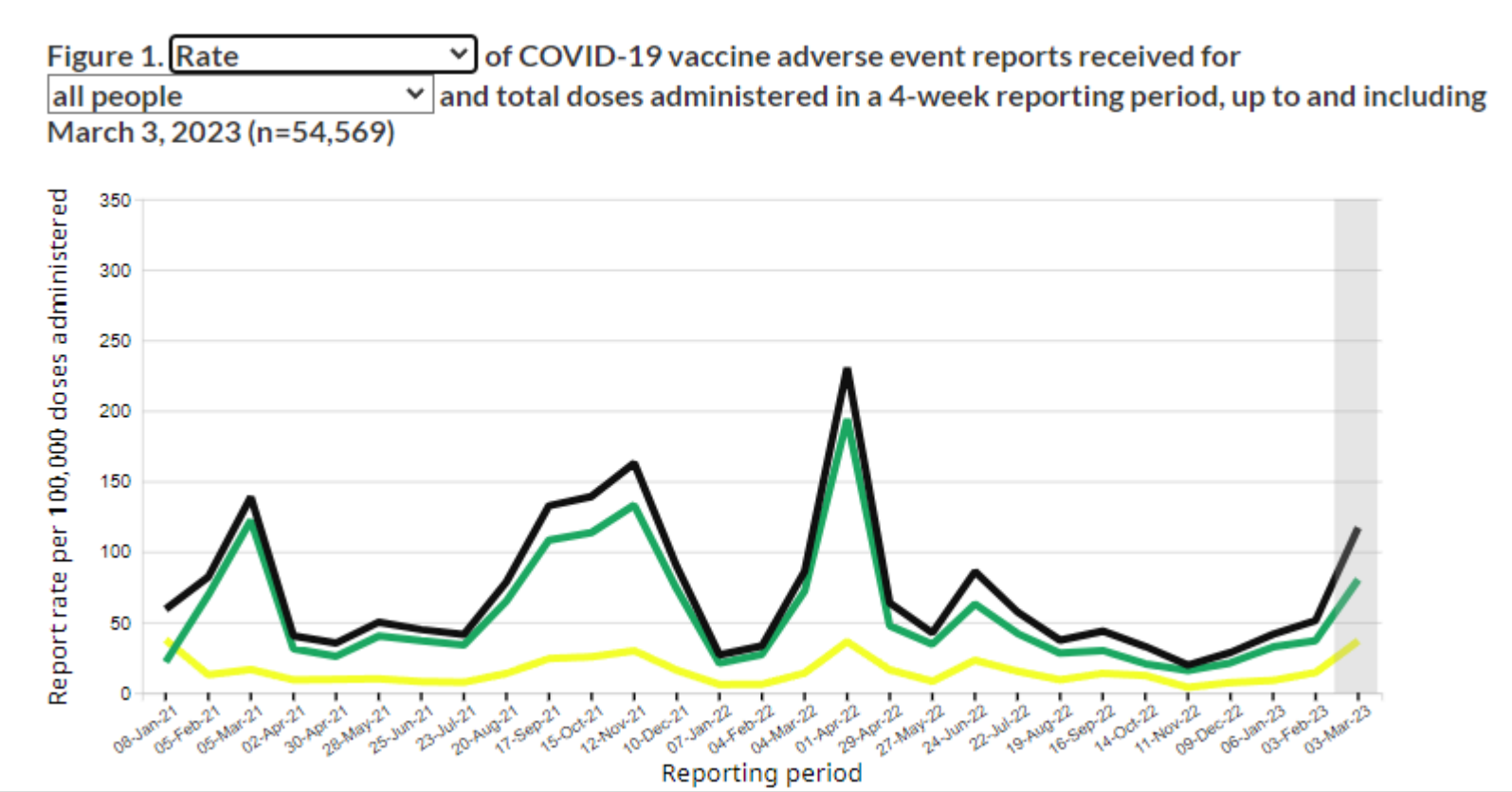
Age group	Vaccinated with at least 1 dose			Vaccinated with 2 doses		
	People in NIMS cohort	Number vaccinated	% vaccine uptake	People in NIMS cohort	Number vaccinated	% vaccine uptake
80 years and over	2,878,703	2,689,926	93.4	2,878,703	445,614	15.5
75 to under 80 years	2,095,762	1,965,161	93.8	2,095,762	18,521	0.9
70 to under 75 years	2,882,646	2,666,290	92.5	2,882,646	14,014	0.5
65 to under 70 years	2,890,187	2,494,520	86.3	2,890,187	17,368	0.6
60 to under 65 years	3,438,737	2,160,399	62.8	3,438,737	36,008	1.0
55 to under 60 years	4,053,137	1,541,559	38.0	4,053,137	48,073	1.2
50 to under 55 years	4,189,832	1,282,538	30.6	4,189,832	46,268	1.1
Under 50 years	38,842,004	4,161,989	10.7	38,842,004	170,696	0.4
Total	61,271,008	18,962,627	30.9	61,271,008	796,574	1.3

For those at the highest risk of dying (ie., >60 years of age), by March 7, 2021, the percentage of the ever vaccinated who received 2 doses only (ie., 4.4%) had received the second dose (ie., 95.6 % of vaccinated had only one dose). Data from ONS July 6, 2022.

As expected, only the one dose which provided trained innate immunity against an emerging pathogen/pandemic RNA virus was able to protect against C19; non-C19; and all-cause mortality (February 2021).

No convincing evidence of protection by or associated with spike IgG antibodies has ever been documented. Some have claimed neutralizing antibodies to spike protect but due to poor methodology they conflated innate antibody neutralization with spike specific {e.g., spike pseudotyped viruses produced in human cell lines used for neutralization assays}.

Serious Adverse Events (AEs) to CAEFIS of COVID-19 Vaccines Up to March 3, 2023



10,685 SERIOUS AEs (peaks of serious AEs appear to correspond to about 1-2 weeks after mass inoculation peaks implying they are related)

Yellow line = serious adverse events

https://health-infobase.canada.ca/covid-19/vaccine-safety/

5,913 of 10,685 SAEs were classified as Adverse Events of Special Interest (AESIs)

Table 1. Count of reported adverse events of special interest by vaccine type (Total) up to and including March 3, 2023 (n=5,913).

AESI Category	AESI	Total number of events
Auto-immune diseases	Guillain-Barré Syndrome[1]	27
	Thrombocytopenia (low blood platelets)[1]	196
	Subtotal	223
Cardiovascular system	Cardiac arrest	55
	Cardiac failure	73
	Myocardial infarction (heart attack)	145
	Myocarditis/Pericarditis[1] (inflammation of the heart muscle and lining around the heart)	1,153
	Subtotal	1,426
Circulatory system	Cerebral venous (sinus) thrombosis	30
	Cerebral thrombosis	17
	Cutaneous vasculitis	46
	Deep vein thrombosis	376
	Embolism	22
	Haemorrhage (bleeding)	78
	Pulmonary embolism	524
	Thrombosis (blood clot)	324
	Thrombosis with thrombocytopenia syndrome (blood clot with low platelets)[1]	87
	Subtotal	1,504
Hepato-gastrointestinal and renal system	Acute kidney injury	78
	Glomerulonephritis (kidney inflammation) and nephrotic syndrome (kidney disorder)	37
	Liver injury	37
	Subtotal	152
Nerves and central nervous system	Bell's Palsy[1]/facial paralysis	187
	Cerebrovascular accident (stroke – includes ischemic and hemorrhagic strokes)	281
	Transverse myelitis (inflammation of spinal cord)[1]	16
	Subtotal	484
Other system	Anaphylaxis[1]	776
	COVID-19[2]	1,132
	Multisystem inflammatory syndrome[1]	24
	Subtotal	1,932
Pregnancy outcomes[3]	Fetal growth restriction	5
	Spontaneous abortion	87
	Subtotal	92
Respiratory system	Acute respiratory distress syndrome	8
	Subtotal	8
Skin and mucous membrane, bone and joints system	Chilblains	29
	Erythema multiforme (immune skin reaction)	63
	Subtotal	92
All AESI categories	**Total**	**5,913**

Myocarditis/ Pericarditis #2

Clotting #1

Failed Vaccine #3

Pregnancy signal!

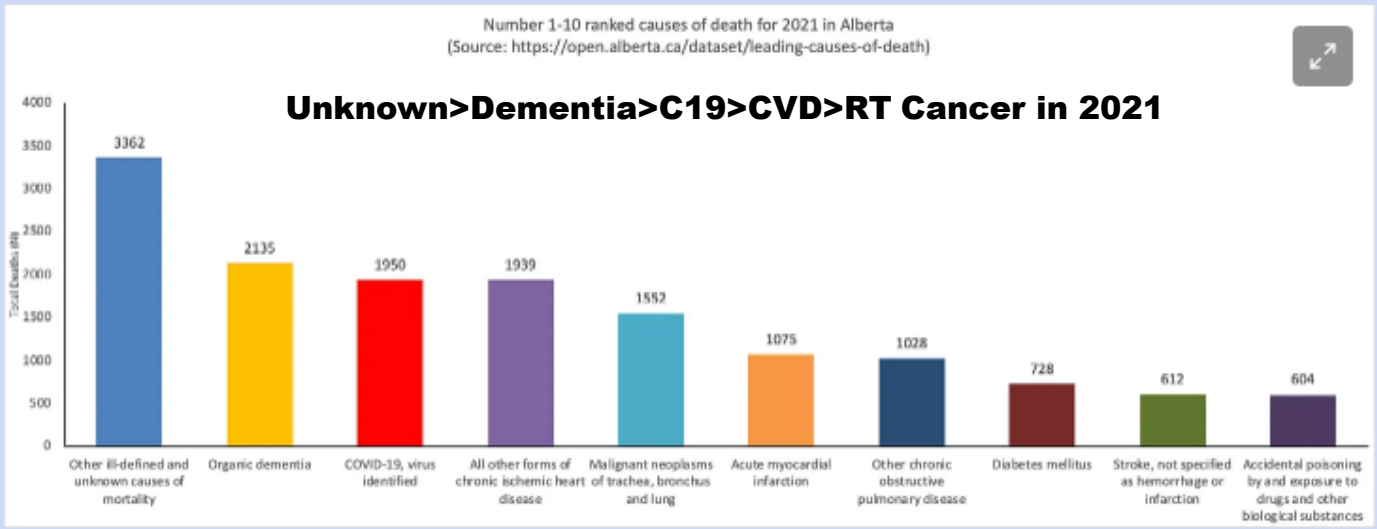


Figure 4: Number 1-10 ranked leading causes of death in Alberta for 2021. https://open.alberta.ca/dataset/leading-causes-of-death/resource/1a10c821-7399-4d0f-95fb-f96728d01fae

There were 1898 excess unknown causes of death in 2021 in ALBERTA over 2020.

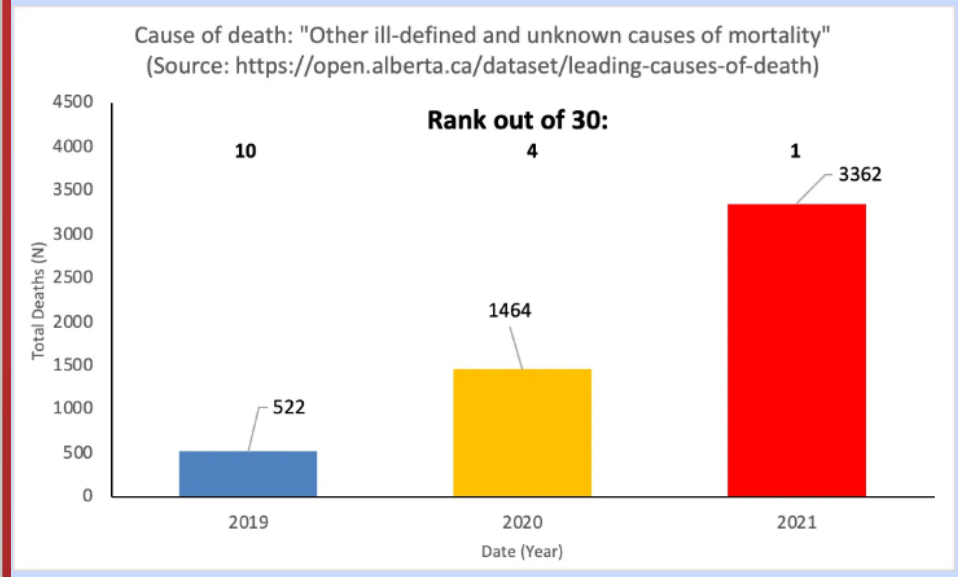


Figure 1: Leading cause of death in Alberta for 2019, 2020 and 2021. https://open.alberta.ca/dataset/leading-causes-of-death/resource/1a10c821-7399-4d0f-95fb-f96728d01fae

UNKNOWN Cause of Death Alberta

https://jessicar.substack.com/p/whats-the-leading-cause-of-death

427 Deaths Reported to (CAEFISS) re COVID-19 Vaccines Up to March 3, 2023

- ONLY 4 deaths of 427 reported deaths were considered causally related to vaccination as reviewed by ACCA
- All 4 deaths were related to clotting (thrombosis)
- Many sudden deaths reported in the news (thought to be related mostly to myocarditis/ pericarditis); Alberta had 1898 excess unknown causes of death in 2021 over 2020.

However, the estimates based on transparent reporting in UK suggest likely ***at least*** 250,000 non-COVID-19 ***excess*** deaths related to vaccination by February 2023. Thus, *underreporting is about a factor of* **585** and causality assessment a further *100-fold underestimation.*

1. **ONLY Doctors / Health care professionals (D/HCP) can report (excludes medical scientists).**

2. **D/HCP are not paid to report; do not have the time and are incentivized to <u>not report</u> for fear of loosing license (by admitting vax is not safe or effective).**

3. **At each level (local, provincial, federal, ACCA), causality is assessed and many reports dismissed; also at local levels reports are rejected if the reporting individual is NOT D/HCP.**

For deaths, autopsies are not performed so can't easily determine causality.

The structure for reporting deaths and other Serious Adverse Events for <u>COVID-19 vaccines</u> in Canada is ***<u>SERIOUSLY</u>*** compromised.

[I had to report directly to Pfizer and Moderna on life-threatening side effects for two individuals after gathering all the documents/follow-ups.]

Product Monographs (PMs) for COVID-19 mRNA Vaccines as of April 28, 2023 are SHAMS

- Periodic Safety Update Reports (PSURs) are reviewed by the Marketed Health Products Directorate at HC & are constantly submitted by the market authorization holder and report on the adverse events including Serious and deaths for Canada and internationally; reports are evaluated for signals and changes to PMs warnings & precaution, contraindications, and results of post-market surveillance are updated; in extreme cases, products can be taken off the market due to higher risk of serious adverse events over potential benefits.

- These PMs are not being updated https://covid-vaccine.canada.ca/info/pdf/pfizer-biontech-covid-19-vaccine-pm1-en.pdf latest is March 21, 2023; https://covid-vaccine.canada.ca/info/pdf/covid-19-vaccine-moderna-pm-en.pdf latest is January 12, 2023; they claim safety & efficacy without data to support; ie., **NO all-cause mortality analysis** {Grana C *et al*., 2022, showed or can be interpreted that no COVID-19 vaccine was safe or effective based on RCT data alone!}

- They do not itemize the number or causes of deaths or serious adverse events particularly for post-market surveillance; no contraindications or warnings to NOT use during pregnancy or breast-feeding despite mentioning, it (gene therapy) has NOT been studied; The 11 serious adverse events of special interest (Nasreen S *et al*., 2022) are not even discussed.

Dr. Marian Laderoute,

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PUBLICATIONS OF INTEREST

Laderoute MP, Controversies Concerning the Immunology of the COVID-19 **Adaptive Immunity** Vaccines, **INVITED** Book Chapter (**submitted**).

Laderoute MP. Trained immunity involving HERV-K102 activation may promote recovery from COVID-19 providing **a new innate immunity vaccination paradigm** against pandemic RNA viruses. **INVITED** review (**submitted**).

Laderoute M. **Ivermectin may prevent and reverse immunosenescence** by antagonizing alpha-fetoprotein and downmodulating PI3K/Akt/mTOR hyperactivity. Open Heart, April 29, 2021.

Laderoute MP. **Clues to finding correlates of risk/protection for HIV-1 vaccines** [version 2; peer review: 2 approved with reservations] F1000 Research 2018, 6:868. https://doi.org/10.12688/f1000research.11818.2.

Laderoute MP, Larocque LJ, Giulivi A, Diaz-Mitoma F. **Further evidence that human endogenous retrovirus K102 is a replication competent foamy virus that may antagonize HIV-1 replication.** Open AIDS J. 2015 Dec 7;9:112-22. doi: 10.2174/1874613601509010112.

Laderoute MP. **A new paradigm about HERV-K102 particle production and blocked release** to explain cortisol mediated immunosenescence and age-associated risk of chronic disease. Discov Med. 2015 Dec;20(112):379-91.

Laderoute MP, Giulivi A, Larocque L, Bellfoy D, Hou Y, Wu HX, Fowke K, Wu J, Diaz-Mitoma F. **The replicative activity of human endogenous retrovirus K102 (HERV-K102) with HIV viremia.** AIDS. 2007 Nov 30;21(18):2417-24. doi: 10.1097/QAD.0b013e3282f14d64.

SUMMARY

It is virtually **impossible** for IgG1/IgG3 antibodies to spike protein to protect against the emerging pathogen SARS-CoV-2 due to **ADE**. (However, this does not exclude a role of adaptive T cell immunity in some protection against severe disease.)

All parties knew in advance of the EUA of the COVID-19 vaccines that **ADE** was a major issue which would prevent the creation of safe and effective vaccines against the pandemic RNA virus, SARS-CoV-2.

Their attendance (or their representatives) at the CEPI meeting on March 12 & 13 2020 proves "*the authorities*" all knew and believed **ADE** to be a major concern. While they agreed to enhanced early surveillance and regulatory action, it is clear from the ONS UK data, they did not comply with their own rules. Moreover, they did not stop the carnage of the vaccines which in hindsight should have been stopped by the first week in February 2021 *at the latest*.

NCI TESTIMONY by Dr. Marian P. Laderoute:

1. The travesty here is that while there were **51,763 COVID-19 deaths in Canada**, there were likely an excess of 278,913 or more, non-COVID-19 deaths in the 50+ age group allegedly related to the extreme toxicity of the mRNA vaccines. This is an underestimation as the UK derived algorithm only covered up to 3 doses and deaths that occurred until the end of May 2022, while in Canada almost 4 million had 5 shots by March 26, 2023 (see data in slide 25). The number of Canadians disabled by the mRNA and other COVID-19 vaccines remains to be determined, but the prevalence might be at least 10 times higher than the non-COVID-19 excess deaths.
2. Public health officials in Canada and elsewhere were falsely claiming the safety and effectiveness of two doses of the ADAPTIVE COVID-19 vaccines TO SPIKE PROTEIN. The truth was and remains that 2 doses of the COVID-19 vaccines could not and did not save a single person from a COVID-19 death.
3. All authorities knew that the likelihood of a safe and effective COVID-19 ADAPTIVE IMMUNITY vaccine was near impossible due to ADE. No sufficient all-cause mortality data was presented to any regulatory authority worldwide that would have properly substantiated the granting of an EUA. Indeed, all data on the IgG antibodies to spike protein during natural infection clearly indicated they DID not protect and did not mediate recovery. Instead, these IgG to spike caused progression putatively via ADE as known and as anticipated.
4. There is no published unequivocal data that showed the IgG antibodies to spike protein were protective or correlates of protection. Claims to the contrary are fraught with poor methodology (usually involving pseudotyped surrogate viruses produced in human cells where virions likely expressed HERV-K102 envelope) where the protective innate antibodies to HERV-K102 envelope were conflated with the IgG antibodies to spike protein. Meta-analysis shows the IgG antibodies to spike protein under any clinical context (vaccine efficacy, neutralizing monoclonal antibodies, and/or convalescent plasma) did not provide evidence of any benefits on all-cause mortality.

5. It was a risky, highly dangerous and reprehensible choice by the CIA/DARPA/Homeland Security/NIH/HHS of the United States to push for gene therapy vaccines given also the allegation that Dr. Ralph Baric's research funded by the NIH appears to have significantly contributed to the genesis of SARS-CoV-2 and the ensuing putative "lab-leak" pandemic. This may or may not have been a panicked guilty response to cover-up the source of the pandemic in an effort to 'make good'. However, all claims that the COVID-19 mRNA vaccines were safe and effective were not substantiated and in fact as mentioned, all data showed the IgG antibodies to spike protein caused progression and not protection. Thus, despite knowing and understanding ADE the governments around the world tried to gaslight citizens, unfortunately also here in Canada. Part of the gaslighting effort involved censorship particularly the true injuries and deaths associated with the COVID-19 vaccines. I was ostracized from LinkedIn in late October 2021 for reporting compiled and assimilated data from Public Health England that implied during the delta wave that the first dose of vaccine provided the best protection against hospitalization and death in the 50+ (better than the not vaccinated), while the second dose increased death rates in the 50+ around 1% over the first dose and which seemed to increase over time. This information is consistent with the ONS data in Table 2. In terms of censorship, Robert F. Kennedy Jr and the Children's Health Defense filed a class action lawsuit against dozens of federal officials including Dr. Anthony Fauci on March 27, 2023 alleging the social media censorship (which limited the access to true stories or legitimate data for example, about the injuries and deaths following vaccination) was sponsored and supported by the federal government which was in collusion with Big Tech. These acts are considered evidence of being guilty of violating the 1st Amendment of the USA. Worst of all was the global mandating of complete series of COVID-19 vaccines for international and domestic travel also in Canada. This mandating came about when reports of injury and death started to surface. No country seems to have been diligent to provide the data in Tables 1-3 in a timely manner that would have stopped the COVID-19 mass vaccinations shortly after roll-out by the first week in February 2021.

Questions needing REAL answers

1. Where are the data equivalent to the ONS data for the UK shown here in Tables 1-3, for Canada? Did Canada also experience enhanced mortality by vaccination? How many Canadians became disabled after receiving the COVID-19 vaccines? How many Canadians suffered serious adverse events following COVID-19 vaccination? Why wasn't there mandatory reporting of all serious adverse events in a timely manner to the manufacturer, and DIRECTLY to Public Health Agency of Canada (PHAC), and where the patient or representative could report?

2. Why weren't all "unknown causes of death" subject to an autopsy with staining for spike protein in the heart if the death followed a recent COVID-19 vaccine injection?

3. Why weren't these data compiled properly and released in real time in the UK, at least by the first week of February 2021 when the vaccination campaign could have been stopped globally to prevent the ensuing mRNA gene therapy toxicity carnage (death and disability)? WHO is to blame?

4. Why did Stats Canada, PHAC, National Advisory Committee on Immunization (NACI), Health Canada (Post-Marketing Surveillance) not provide these critical data of the types in Tables 1-3 accurately, openly and in a timely manner?

5. What did the Periodic Safety Update Reports on the gene therapy COVID-19 vaccines (Post-Marketing Surveillance) reveal and when at Health Canada… why wasn't this communicated to the public and updated in the product monograph in a timely manner to provide proper informed consent for an **experimental intervention that in fact was mandated despite NOT KNOWING THE RISKS**?

6. How could Health Canada authorize an EUA for the various COVID-19 vaccines which were supposed to save lives, in trials **not designed** to provide statistically significant mortality data particularly the "all-cause mortality rates over time." How can NACI recommend an intervention meant to prevent death without any meaningful mortality rate data? How can PHAC and other public health officials recommend or mandate an intervention said to save lives but without meaningful mortality data??? How can Health Canada authorize an EUA for a product (to be injected into healthy people) but which was strongly believed or suspected of not being safe and effective against mortality, and where no data were provided to counteract this likelihood??

Due to #1 serious adverse event in CAEFIS for COVID-19 Vaccines being CLOTTING...

Why do the regulations for vaccines NOT state that any injectable vaccine (or health care product) must be safe to inject intravenously in order to get market authorization?

Recommendations for new federal laws

1. **No vaccines or any health products can be mandated for travel, for work, for entering public spaces, for attending schools OR ANY OTHER REASON SUCH AS CANCER IN CHILDREN. (This includes the barbaric notion that all kids with cancer must receive chemo and radiation even when the parents or guardians disagree.)**

2. No hospital administration or advisory group can decide the course of medical intervention for any patient. This is left to the patient and the physician. The patient or guardian always makes the final decision with a signed consent form detailing the risks and benefits specific to the intervention.

3. The Federal Government **must provide some means of support to those families harmed by the COVID-19 vaccines**. There should be a payout to families for loss of life, and payout to patients to cover the cost of tests and therapies and loss of income due to injury and disability. Also M.D.s need to be re-hired and reimbursed for loss of income along with return of their licenses for speaking the truth about the safety and effectiveness of the COVID-19 vaccines. **Autopsies must be performed on all unexplained deaths**.

4. In adults 50 years of age and up, the federal government should provide free annual testing for vitamin D, cortisol, and dehydroepiandrosterone (DHEA not DHEAS) (testing done in winter months) for those who would like to optimize their health. An annual report should be made public on these findings by province and overall.

5. No product intended to save lives can be authorized for market (EUA or otherwise) unless there is at least sufficient data to prove all-cause mortality benefit exceeds the risks. This must be made retroactive (which may take many questionable drugs off the market and save Canadian tax payers dollars).

6. No Advisory Committee member advising on health matters can have a conflict of interest.

Recommendations for new federal laws

7. PHAC and Marketed Health Products Directorate. PHAC must develop a more direct and rapid reporting system of all serious adverse events of vaccines to a central Canadian federal entity which ALSO allows the patient or guardian to report directly. The current system actually prevented the reporting of serious adverse events and/or in a timely manner! One was better off to report directly to the manufacturer as it is shared internationally and captured in the Periodic Safety Update Reports (PSURs) which guide updates to product monographs (to inform the consumer and health practitioner).

8. Big Pharma cannot contribute to cost of review of health products as it creates a conflict of interest. Canadians must pay for the cost of review and safety surveillance through taxation as was the case for many years.

9. No injectable vaccine/health care product can be approved for market if it is not safe to inject intra-venously.

10. The lack of liability of Big Pharma for injuries and deaths caused by vaccines should be outlawed. This indemnification simply creates bad vaccines like **the mRNA gene therapy horrific attempts at inoculation.**

11. It should be illegal for Big Pharma to request total indemnification in its contracts regarding emergency access authorization health care products.

Recommendations for new federal laws

12. Regarding health care interventions or pandemic policies, there cannot be censoring of opinion, discussion or true information on social media and/or regular media (freedom of speech laws need to be strengthened).

13. The true risks versus benefits of childhood vaccines needs to be revisited. Also, it may not be as safe as once thought to have more than one vaccine injected on the same day. The hepatitis B vaccine given at birth **should be immediately halted** pending an outcome of reevaluation of longer term safety such as risk of autism, ADHD, asthma, gender confusion etc. Babies born to Hepatitis B negative mothers do not require this dangerous vaccine. Most mothers are NOT hepatitis B positive.

14. No advertising of vaccines or other health products should be allowed in medical journals, magazines TV, radio, social media etc. In Canada recently, Big Pharma has resorted to advertisements where the viewers are recommended to ask their Doctors about drugs (for unknown purposes). This MUST STOP! **No social media or media should be able to accept funding for advertising from Big Pharma.**

15. Any incentives to physicians to recommend certain product usage such as by Big Pharma or governments must be outlawed or at the very least, details posted on-line and in the office, to permit transparency to the consumer. This goes for the statin drugs and others. Failure to comply would result in loss of license. Patients have the right to ask doctors about their conflicts of interest!

3 KEY Recommendations for RESEARCH

In preparation for pandemics, researching the HERV-K102 protector system should be made a number one priority at the Canadian Institutes of Health Research in collaboration with Biological (Laboratory) Safety Levels: BSL-3 and BSL-4 LABORATORIES at the National Microbiology Laboratory (significant additional direct funding should include the creation of the HERV-K102 Translational Division within NML-PHAC).

1. **A major priority would be to develop humanized Monoclonal Antibodies (MAbs)to the ML4 peptide sequence {**KRASTEMVTPVTWMDN (GenBank accession # AF164610)**} and to the ML5 peptide sequence** LETRDCKPFYTIDLNSS [Laderoute MP et al., 2007] **and testing of efficacy in humanized mice** [Wahl A et al. Precision mouse models with expanded tropism for human pathogens. Nat Biotechnol. 2019 Oct;37(10):1163-1173. doi: 10.1038/s41587-019-0225-9.] **against SARS-CoV-2/1, HIV-1. and other emerging or pandemic pathogens, prior to initiating randomized clinical trials in humans. These sequences are thought to be cryptic on HERV-K102 particles but accessible on the surface of virus infected cells and on budding viruses produced in human cells. Therefore, these MAbs would NOT eliminate the protector HERV-K102 particles, just the viruses and the virus infected cells.**
2. **As well, mechanisms by which HERV-K102 activation can be achieved safely (by therapies and/or novel vaccines) is also needed to prepare for future and current pandemics. How ivermectin, Vitamin D3, glucocorticosteroids, near infrared radiation, melatonin, UV radiation, statins (and other commonly used drugs), various anti-retrovirals used for HIV-1 patients, etc. affect HERV-K102 particle production needs also to be investigated. PHAC needs to screen approved drugs for efficacy in promoting or enhancing the HERV-K102 PROTECTOR SYSTEM (repurposed drugs program).**
3. **Since the activation of "trained innate immunity" reverses immunosenescence (slide 12) and associated chronic disease which reduces mortality** [Xu S, Huang R, Sy LS, et al. COVID-19 vaccination and non–COVID-19 mortality risk — seven integrated health care organizations, United States, December 14, 2020–July 31, 2021. MMWR Morb Mortal Wkly Rep 2021;70:1520–1524. doi: http://dx.doi.org/10.15585/mmwr.mm7043e2.] **additional funding needs to cover translational research such as with ivermectin, to develop a strategy/protocol to reverse and/or prevent common chronic disease. For example, once a year such as during the winter months, a 10-day course of ivermectin may prevent or reverse chronic disease which may save the Canadian taxpayer on health care costs.**

Thank you for your attention on the important issue that adaptive COVID-19 vaccines could not be safe and effective against the enveloped SARS-CoV-2 emerging/pandemic RNA virus.