

NARRATIVE REVIEW

Chimpanzee-Plasma-Derived Hepatitis-B Vaccines: A Historical Review and Call for Transparency

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Abstract

This paper investigates historical documents to establish a timeline for chimpanzee-plasma-derived Hepatitis-B vaccines. Obscure symposium proceedings, archived during the AIDS epidemic's emergence, uncover internal communications among health officials, providing a comparison to their public statements, similar to the 2023 Slack Message Leak on COVID-19 origins. A key focus is the 1982 WHO Symposium, held two months after AIDS recognition, where the use of chimpanzee plasma-derived vaccines on humans was discussed, and concerns linking it to AIDS were raised. Despite this, officials publicly claimed all vaccines were made from human plasma with no AIDS link. These vaccines were then banned in many developed countries but continued to be marketed in Africa without safety-testing lots. The symposium's details are available on archive.org.

This paper does not address vaccine safety, but rather calls on the CDC to clarify the reported 5:1 HIV rate ratio between vaccine and placebo recipients in one trial group. Avoiding speculation, it focuses on verifiable points regarding the use of chimpanzee-plasma-derived Hepatitis-B vaccines, and invites public comment and counterclaims, urging individuals to reconcile public and private statements. The study aims to establish a consensus on key facts acknowledged by all parties for inclusion in the final peer-reviewed paper. By documenting engagement or censorship instances, this paper also examines transparency and accountability in public health communications, especially given recent calls for legislation mandating pharmaceutical products and arbitrating truth through pandemic treaties, vaccine passports, and digital IDs.

Introduction

Many scientists central to the SARS-CoV-2 origins debate were similarly involved in the AIDS origins debate 40 years ago. Notably, two of Robert Garry's papers refuting a lab origin of COVID-19,^{1,2} parallel his 1990 paper³ that refuted a common concern over a plasma-derived Hepatitis-B vaccine:

Many fear that the AIDS agent could be included in the vaccine and be spread by it.⁴ (Published in the Lancet, 1983)

For SARS-CoV-2, the 2023 Slack Message Leaks revealed differences between scientists' public declarations and private beliefs, similar to how symposium proceedings from the 1970s-80s reveal private views on AIDS origins. To conduct a similar analysis for AIDS, a team of researchers searched university archives and bookstores across North America and Europe. These communications were often found in obscure, nearly 1,000-page proceedings from frequent symposiums, primarily circulated among attendees. The focus is the 1982 WHO Symposium on Viral Hepatitis in Greece, held two months after AIDS recognition, available on archive.org.⁵ This paper will present only information that can be corroborated with online documents and invite clarification.

This paper does not address vaccine safety and viral transmission. The trial documents indicate that transmission must be determined by comparing vaccine versus placebo rates. I am working to get the CDC to comply with my FOIA request for the withheld data. The scientific community can then assess if the CDC's partial results, shown below, were an anomaly. The paper's mention of the correlation between HIV and the vaccine aims to demonstrate that, even if the vaccines were harmless, manufacturers might have had an incentive to obscure their chimpanzee origin. Regardless of harm, informed consent is questioned if species-agnostic language misled customers. The goal is to establish a consensus on the obfuscation of the plasma origin.

Objective: Consensus on key elements

I established FactMission, a 501(c)(3) non-profit research foundation, in response to the debate surrounding COVID-19 origins. Researchers often engage in debating comprehensive theories, such as the theory that AIDS originated from chimpanzee blood entering a hunter's wound. However, it might be more productive to start by establishing consensus on the most basic, fundamental facts, or *elements*, upon which the theory is constructed. For instance, is there universal agreement that for 62 years before the discovery of HIV, scientists had been injecting humans with chimpanzee blood, often raw? (see Timeline) Isolating and demonstrating consensus on these elements could aid sincere research and expose work based on false assumptions or contradictions to universally agreed-upon *elements* without refuting or acknowledging them. This preprint uses distinct symbols to identify 12 elements for which consensus is sought, serving as a proof of concept:

question Qu	In lieu of speculation, this paper will only ask <i>questions</i> , with links to threads to reply with answers.
research R	When further information is needed it will be a request for <i>research</i> , with threads to reply with research protocols or data if it exists.
negative Ne	Assertions that evidence does not exist are a <i>negative</i> , with threads to verify or challenge.
claim C	<i>Claims</i> that are demonstrably true or false based on the citations, with threads to verify or challenge.

All posts on X related to this preprint will be marked with [#chimpvax](#), and a [publicly accessible spreadsheet](#) will link to all relevant threads, document all requests for comment and non-private communications, and note instances of censorship or blocking. All counter-arguments and claims will be added and incorporated in the final paper submitted for peer review, with the goal of establishing a public record of consensus on basic elements regarding chimpanzee-plasma-derived vaccines.

Chimpanzee-plasma-derived vaccines: the 12 elements

This paper asks for comment on the following elements. Detailed explanations and excerpts from cited works are provided in the Timeline section following the Conclusion. Each element links to an associated discussion thread on \mathbb{X} .

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In 1972, certain plasma-derived Hepatitis B vaccine(s) began incorporating antigens derived from the plasma of chimpanzees.⁶⁻⁸ Retroactive testing has identified these chimpanzees as the sole lab-confirmed HIV-positive creatures in the Western Hemisphere at that time.⁹ The enrollment of gay men in New York for vaccine testing began in 1974.¹⁰ (Timeline § 1972-1974)

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During the 1960s and 1970s, Dr. Alfred Prince of the New York Blood Center, a principal supplier of chimpanzee plasma, utilized chimpanzees in cross-circulation treatments.^{11,12} This involved connecting humans and chimpanzees of the same blood type via intravenous tubes, allowing the chimpanzees' organs to purify the mixed blood flowing between the species. Care manuals suggest that the same chimpanzees were frequently used with multiple human patients requiring repeated treatments.¹³ Could this practice have resulted in blood mixing between species, thereby facilitating the evolution of SIVcpz into a human-adapted variant like HIV-1B, akin to serial passaging in gain-of-function research?

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In 1976, WHO scientists initiated the collection of chimpanzee blood from the London Zoo¹⁴ to produce their own in-house chimpanzee-plasma-derived Hepatitis B vaccines.^{15,16} The following year, they commenced seroprevalence studies in the Caribbean,¹⁷ where Haiti exhibited the highest rates of infection among the general population in the Western Hemisphere.¹⁸ (Timeline § 1976)

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In 1978, Dr. Prince acknowledged that chimpanzee plasma contained "host components" that could not be removed without causing "morphological damage," but argued that the risk was no greater than that of a blood transfusion.¹⁹ He had been transfusing humans with raw chimpanzee blood for over a decade. (Timeline § 1966-1978) At a 1978 WHO Symposium, he proposed that NYBC's upcoming phase 3 trial "should include at least two or three of the major candidate HB vaccines". He suggested testing chimpanzee plasma formulations on male homosexuals.^{20(tbls50-10)} Merck presented Lot 559 made from the plasma of "four human donors",^{20(p525)} and Lot 751 made from the "plasma of chronic carriers"²¹. Lot 751 was given to gay men in the trial, while, in parallel, medical personnel got a different lot made from different antigens.²² (Timeline § 1978)

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During the clinical trials Merck and NYBC trademarked, licensed, and/or presented 3 brand names with different formulations (Fig. 1):

Merck Heptavax-B: FDA-approved, trademarked in the US, Spain, Canada, made from human plasma. (Fig 1a)

Merck H-B-Vax: trademarked in 31 overseas markets, made from "plasma of chronically infected, asymptomatic carriers"²³ (Fig 1c). Not to be confused with Merck "H-B-VAX II" which was not plasma-derived.

NYBC B-Vax: made from chimpanzee-plasma and "less purified... to be made inexpensively"^{24,25} (Fig 1b)

NYBC-B-Vax was not used in the phase 3 clinical trials in 1978. NYBC used a different inactivation method than Merck (Tween), and omitted what Dr. Prince called Merck's "harsh purification".²⁶ However, at another large World Health Organization Symposium, Dr. Prince expressly notified health leaders that the NYBC vaccine had been used in 2 clinical trials (Fig 2) and was made from chimpanzee plasma (Fig 3,4). It's unclear if this refers to phase 1 and 2 trials in New York between 1974 and 1978.

(a)

Merck Sharp & Dohme announces

NEW Heptavax·B[®]
(Hepatitis B Vaccine | MSD)

The only vaccine providing active immunity against hepatitis B

Unique Vaccine
HEPTAVAX-B is a *noninfectious*, formalin-inactivated subunit viral vaccine derived from hepatitis B surface antigen (HBsAg) which is harvested and purified from the plasma of human carriers of hepatitis B virus. Utilization of viral fragments (HBsAg) from plasma, rather than virus derived from tissue culture, to induce immunity makes HEPTAVAX-B unique among viral vaccines. HEPTAVAX-B will not prevent hepatitis caused by other agents, such as hepatitis A virus, non-A, non-B hepatitis viruses, or other viruses known to infect the liver.

(c)

Summary of worldwide clinical experience with H-B-Vax[®] (B, MSD)

A. A. McLean, M. R. Hilleman, W. J. McAleer and E. B. Buynak
Virus and Cell Biology Department, Merck Sharp & Dohme Research Laboratories, West Point, PA 19486, U.S.A.

Introduction

The vaccine produced in our laboratories, H-B-Vax, consists of hepatitis B surface antigen (HBsAg) which is purified from the plasma of chronically infected, asymptomatic carriers of the hepatitis B virus. The HBsAg is subjected to three inactivation treatments (pepsin, urea and formaldehyde) to ensure killing of hepatitis B virus and any other viral contaminant which may remain. Early studies showed aqueous vaccine to be poorly immunogenic for man, so the purified antigen is adsorbed on to aluminium hydroxide as an adjuvant. Thimerosal is added as preservative. A one ml dose of the vaccine contains 20 µg of purified HBsAg adsorbed on to 0.5 mg of aluminium hydroxide and suspended in saline. This is the usual adult dose and the usual regimen is two doses administered a month apart, followed by a third six months after the first. With the exception of persons with haemophilia or similar disorders, all injections are given intramuscularly. We have studied antibody responses to other dose levels and vaccination regimens and routes and in many other population groups and have studied protection following natural challenge via various modes of virus transmission; those findings are the subject of the present paper.

(b)

PAGE 95

Fig. 5. New York Blood Center. B-Vax properties of starting material for inactivation.

PAGE 97

7. Vnek, J., Ikram, H. and Prince, A.M. The heterogeneity of hepatitis B surface antigen isolated from chimpanzee plasma. *Infect. Immun.* 16, 335-343, 1976.

8. Prince, A.M., Vnek, J., Neurath, R.A. and Trepo, C. Vaccine for Active Immunization Containing Hepatitis B Surface Antigen and Associated Antigens. U.S. Patents No. 4,118,478 and No. 4,118,479, 1978.

INFECTION AND IMMUNITY, Apr. 1977, p. 335-343
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Heterogeneity of Hepatitis B Surface Antigen-Associated Particles Isolated from Chimpanzee Plasma
J. VNEK,* H. IKRAM, AND A. M. PRINCE
The Lindsley F. Kimball Research Institute of the New York Blood Center, New York, New York 10021
Received for publication 26 July 1976

Hepatitis B surface antigen (HBsAg) was purified from approximately 8 liters of pooled plasma from a carrier chimpanzee. Precipitation of HBsAg with

United States Patent [19] **4,118,479**
Prince et al. [45] **Oct. 3, 1978**

[54] **VACCINE FOR ACTIVE IMMUNIZATION CONTAINING HEPATITIS B SURFACE ANTIGEN AND ASSOCIATED ANTIGEN**
[75] Inventors: Alfred M. Prince, Stamford, Conn.; John Vnek, Bronx, Robert A. Neurath, New York, both of N.Y.; Christian Trepo, Bron, France
[73] Assignee: The New York Blood Center, Inc., New York, N.Y.
[21] Appl. No.: 631,961
[22] Filed: Nov. 17, 1975

OTHER PUBLICATIONS
Almeida-Lab-Lore, vol. 16, No. 6, Feb. 1975.
Primary Examiner—Sam Rosen
Attorney, Agent, or Firm—Burgess, Dinklage & Sprung

[57] **ABSTRACT**
A vaccine against viral hepatitis comprising:
A. Antigenic particles having a particle size in the range of 30 to 50 nanometers, said antigenic particles containing hepatitis B surface antigens;
B. Said antigen having less than 10 units of free antibody to hepatitis B surface antigens per 1,000 units

DETAILED DESCRIPTION OF INVENTION
Source Material
Plasma used as source material for the purification procedures detailed below is obtained by conventional plasmaphoresis procedures from chronic HB_sAg carriers. These may be humans or animal species such as chimpanzees in which the chronic HB carrier state can be induced. The chimpanzee offers the practical advantage that it can be infected with human hepatitis B strains of any desired immunologic sub-type, and can develop chronic carrier state infections which in our experience show particularly high titers of HB_sAg and are frequently associated with high concentrations of both Dane particles and e-antigen. Furthermore, these animals can be conveniently plasmaphoresed at frequent intervals without damage to their health or reduction in HB_sAg or e Ag content of their plasma.

EXAMPLE 1: PURIFICATION AND CHARACTERIZATION OF HB ASSOCIATED PARTICLES FROM 7.8 LITERS OF PLASMA FROM A SINGLE HB_sAg CARRIER CHIMPANZEE
Materials and Methods
Source of HBsAg
The antigen was purified from pooled plasma of a carrier chimpanzee previously inoculated with human HB_sAg-positive plasma of the adw subtype. The e-antigen was present on the surface of identifiable Dane particles in the plasma used.

Fig 1. (a) Merck Heptavax²⁷, (b) NYBC B-VAX^{24,28,29}, (c) Merck H-B-Vax²³

Second WHO/IABS Symposium on Viral Hepatitis: Standardization in Immunoprophylaxis of Infections by Hepatitis Viruses, Athens, Greece, 1982, Develop. Biol. Standard. vol. 54, pp. 13-22 (S. Karger, Basel, 1983)

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² Biotest Serum Institute, Frankfurt/Main, F.R. Germany

A NEW HEPATITIS B VACCINE CONTAINING HBeAg IN ADDITION TO HBsAg

A.M. Prince¹, J. Vnek¹ and W. Stephan²

ABSTRACT

A new vaccine is reported which contains HBeAg in addition to highly purified HBsAg. The rationale for this approach depends on the following data indicating that anti-HBe/anti-HBc may play an active role in prevention of HBV infection; (1) active immunization of chimpanzees with HBeAg(s) devoid of detectable HBsAg protected against subsequent challenge with HBV; (2) passive immunization of chimpanzees with an anti-HBe/anti-HBc intravenous immunoglobulin devoid of anti-HBs significantly delayed and appeared to attenuate HBV infection following subsequent challenge with HBV.

The purification procedure utilized for production of the NYBC vaccine was designed to accomplish a high degree of purification with minimal use of complex equipment. This may facilitate eventual utilization of the vaccine on a mass scale for prevention of the HBV carrier state in high prevalence regions of the world.

This procedure uses PEG precipitations and hydroxylapatite adsorption steps, followed by only a single isopycnic separation in a zonal rotor, to achieve a vaccine which is substantially free of serum proteins and detectable HBV DNA yet contains immunogenic quantities of HBsAg and HBeAg.

The vaccine is inactivated by Tween 80 and formalin. Four lots have passed chimpanzee safety tests; two of them have been tested in clinical trials.

INTRODUCTION

In 1978, we first reported development of a new hepatitis B virus vaccine specifically designed to contain HBeAg as well as HBsAg. (2) This was based on the hypothesis that anti-HBe, in addition to anti-HBs, was a protective antibody in this infection. Inclusion of HBeAg was made possible by the fact that all forms of HBsAg associated particles from HBeAg positive plasma can be shown to contain HBeAg where treated with detergents. (4)

In the present report, we present an update on the procedures used for preparation of this vaccine, and its properties. Furthermore, we will present additional data to support the hypothesis that anti-HBe is a protective antibody.

METHODS

Purification of HBsAg

Pooled HBeAg containing plasma is adjusted to pH 4.6 and clarified at 10,000 rpm in a Westphalia continuous flow centrifuge. The clarified supernatant is adjusted to 4% PEG 6000 at 4°C and stirred for 20 minutes. The precipitate is recovered by sedimentation for two hours

**Fig 2. Page 13 of the 1982 WHO Symposium Proceedings in Greece
NYBC confirms two lots were tested in clinical trials⁵**

without centrifugation and is solubilized in 1/5th volume of starting plasma with distilled water by adjusting the pH to 8.1. The pH is then adjusted to 5.0 and the resulting precipitate is recovered by centrifugation. The pH of the supernate is then adjusted to 4.6 and PEG is added to a final concentration of 3%. After sedimentation overnight at 4°C, the precipitate is redissolved and precipitated at pH 5.0 as before. The material is adjusted to pH 6.8 and 0.005 M phosphate buffer and further purified by 2-3 adsorptions with equal volumes of packed hydroxylapatite. The hydroxylapatite supernatants are pooled with 0.02 and 0.05 M phosphate buffer washes of the hydroxylapatite sediments, clarified by centrifugation and concentrated to about 0.3% of starting plasma volume with an Amicon hollow fiber cartridge. The concentrated HBsAg is then adjusted to a density of 1.25 Gm/ml with solid KBr and dynamically loaded under a linear 1.05 to 1.2 Gm/ml KBr gradient over a 1.3 Gm/ml cushion into a Beckman T₁-14 rotor. The gradient is centrifuged for 18 hours at 28,000 rpm and fractionated by pumping water into the center of the rotor. Fractions corresponding to densities between 1.17 and 1.22 Gm/ml are pooled.

Inactivation Procedure

The purified antigen is adjusted to a concentration of 1 mg/ml (based on $OD_{280} \cdot E_{1\text{cm}}^{0.1\%} = 3.73$) and diluted with an equal volume of 2% Tween 80. After 1 hour at room temperature, the solution is filtered through a 0.22µm Millipore filter and adjusted to 1 : 2000 formalin. The solution is incubated with slow magnetic stirring for 72 hours at 37°C, dialyzed against normal saline containing 1 : 10,000 Thimerosal, and finally sterile filtered.

Adjuvanting Procedure

To the desired concentration of antigen suspended in sterile saline, 1 : 10,000 Thimerosal, 1/10 volume of sterile filtered 0.2 M Al₂(SO₄)₃ · 12 H₂O is added. The pH is adjusted to 5.0 with sterile 1N NaOH and the suspension is stirred at room temperature for 3 hours. The alum precipitated antigen is recovered by centrifugation for 10 minutes at 2000 rpm, re-suspended in sterile normal saline containing 1 : 10,000 Thimerosal, and filled under sterile conditions.

Stability Testing

To determine the stability of HBsAg adsorbed to alum, the antigen was recovered by resolubilizing the alum in 3% sodium citrate followed by dialysis successively against 3% sodium citrate and 0.1 M NaCl 0.01 M phosphate buffer pH 7.2 (PBS). HBsAg was then determined by parallel line radioimmunoassay against dilutions of a purified HBsAg standard prepared by Dr John Gerin. The standard was held frozen at -70°C in the form of a 1 : 100 dilution made in PBS 50% newborn calf serum.

Preparation of HBeAg Free of HBsAg

Chimpanzee plasma containing HBeAg and HBsAg was clarified for 1 hour at 19,000 rpm and then adsorbed twice with 2% Aerosil® for 3-24 hours at room temperature to remove HBsAg. The supernate after adsorption was negative by Ausria II and contained HBeAg detectable by gel diffusion. This preparation was kindly provided by Dr A.R. Neurath. To inactivate any residual infectivity, the preparation was adjusted to 1 : 100,000 neutral red and exposed to 2 fluorescent lamps at a distance of 6 inches for 30 minutes.

Preparation of Anti-HBe + Anti-HBc Intravenous γ-Globulin

Five liters of plasma from chronic HBsAg carriers having an average anti-HBe titer of 1 : 8 by gel diffusion were successively adsorbed with 2% Aerosil® - 380 for 4 hours at 45°C until free of detectable HBsAg by Ausria II. The supernatant was treated with β-propiolactone 0.13 ml/100 ml, and then U.V. irradiated by passage in a thin film under 2 U.V. lamps at a rate of 10L/hr. γ-globulin was isolated by the Rivanol-ammonium sulfate technique, dialyzed against water and saline, concentrated, and further purified by adsorption and elution from Protein A-Sepharose. The resulting globulin solution (5% w/v) had an anti-HBe titer of 1 : 32 by gel diffusion, was strongly positive by Corab test, and was free of detectable HBsAg or anti-HBs.

Fig 3. Page 13 of the 1982 WHO Symposium Proceedings in Greece Starting material for the lots in Fig 2. was chimpanzee plasma⁵

IMMUNOGENICITY OF HBeAg IN THE NEW YORK BLOOD CENTER HEPATITIS B VACCINE

J. Vnek¹, N. Hashimoto² and A.M. Prince¹

ABSTRACT

A new hepatitis B vaccine has been developed which contains both HBsAg and HBeAg since evidence suggests that anti-HBe may have useful biologic activities. It was thus important to determine whether HBeAg is immunogenic in this type of a preparation.

We now report data indicating that highly purified HBsAg particles, derived from HBeAg containing plasma, release a proportion of their contained cryptic HBeAg following the detergent treatment used in the preparation of this vaccine. Both the soluble and the residual particle associated HBeAg are immunogenic in guinea pigs.

There was no detectable anti-HBe response in animals injected with similar HBsAg particles which had not been exposed to detergent.

INTRODUCTION

A vaccine has been developed which contains HBeAg in addition to HBsAg. This was accomplished by using HBeAg containing source plasma free of anti-HBe. As previously reported (1), all HBsAg particle types from such source plasma contain HBeAg in a cryptic form which can be revealed by treatment of the particles with detergents such as Tween 80. The rationale for inclusion of HBeAg in a hepatitis B vaccine has been supported by the finding that active immunization of chimpanzees with HBeAg devoid of detectable HBsAg, or passive immunization with anti-HBe, protected these animals against challenge with hepatitis B virus.

In the present report, we provide evidence that HBeAg in detergent treated HBsAg particles is immunogenic in experimental animals.

MATERIALS AND METHODS

Purification of HBsAg

HBsAg particles were purified from plasma of a chronic carrier chimpanzee by sequential precipitation with polyethylene glycol, adsorption with hydroxylapatite, and isopycnic centrifugation in CsCl gradients as previously described (2). Purified antigen was exposed to 1% v/v Tween 80 in 0.02 M sodium phosphate buffer, pH 7.2 for two hours at room temperature prior to further fractionation by zone convection isoelectric focussing (3), or similarly fractionated without detergent treatment. Protein concentration was determined by O.D.₂₈₀ using $E_{1\text{cm}}^{1\%} = 3.73$.

Fig 4. Page 217 of the 1982 WHO Symposium Proceedings in Greece Chimpanzee-plasma-derived Hepatitis-B vaccine⁵



Before the November 1982 WHO Symposium⁵, the FDA, WHO, and NYBC each prepared their own chimpanzee-plasma-derived Hepatitis B vaccines.²⁵ (Timeline § January 1982) At the symposium, NYBC presented:

A new Hepatitis B Vaccine... [from] Chimpanzee plasma containing HBeAg and HBsAg [Hepatitis B surface antigen, the active ingredient]... Four lots have passed chimpanzee safety tests; two of them have been tested in clinical trials (Figs 2,3).⁵

The proceedings noted of NYBC's clinical trials:

Throughout the entire two years of the trial in homosexual men he [the trial investigator] told us over and over again at monthly meetings, that the study was a disaster.⁵

The symposium proceedings stated:

Much controversy still exists regarding the safety against possible new or unknown syndromes... certain risks remain ; ... possible presence of other ... theoretical (e.g., Acquired Immune Deficiency Syndrome) viral agents... strongly suggest that the acquired immunodeficiency is caused by a virus of man that may be present in blood.⁵

In parallel the CDC assured the public that all “vaccine licensed in the United States is prepared from human plasma... However, lots used in early studies may have been produced before the occurrence of AIDS.”³⁰ Merck H-B-Vax and NYBC B-Vax were not licensed in the U.S.

The CDC earlier warned makers that AIDS “may be transmitted through blood products”³¹ In internal memos one maker wrote “there is strong evidence to suggest that AIDS is passed on to other people through . . . plasma products” and later that the FDA wanted it “quietly solved without alerting the Congress, the medical community and the public”³¹

However, one month later, the FDA claimed AIDS was “never documented to be transmitted by blood... the known risk of hepatitis B... far exceeds the risks of vaccine-induced infection... all persons at high risk for hepatitis B should receive hepatitis B vaccine”³²

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Excluding Robert Garry's sample, which was "inadvertently destroyed" before independent verification,³³ the earliest uncontested, lab-confirmed HIV-positive human blood samples collected in the Western Hemisphere came from the cohort of gay men in the vaccine study.³⁴

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Before the clinical trials Merck and NYBC had filed three patents describing chimpanzee plasma as having a 'practical advantage' for mass production.^{29,35,36} After, Merck and NYBC refused to change the language to "human plasma".³⁷ (Timeline § November 15, 1982) NYBC also updated the trial documents, now stating that medical personnel received the same Lot 751 as gay men,³⁸ rather than Lot 761 with different antigens as previously reported.²² The vaccine was added to the "prohibited" list in the European Pharmacopoeia.²⁶ According to a later BMJ article, "H-B-Vax; MSD and Ny-B-Vax; Biotest NYBC" were "widely used",³⁹ though there is no mention of their use outside of Africa after 1983. (Timeline § 1982-1984)

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Despite the frequent discussions about chimpanzee-plasma-derived Hepatitis B vaccines prior to the 1982 Symposium, this paper will be, to the best of my knowledge, the first to be indexed online that acknowledges their existence in the 42 years that followed.

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In 1984, NYBC/CDC were able to retroactively test trial participants' blood samples to compare HIV rates between vaccine and placebo recipients.⁴⁰ During the NYBC trial, HIV rates increased from ~0% to ~30% (Fig 5a),⁴⁰ and during the CDC trial they exceeded 40% (Fig 5b).⁴¹ However, among the 148 unvaccinated men who received only placebo and later contracted Hepatitis B, the HIV rate was 9% (Fig 5c).^{42(fig1)} The HIV rate in the unvaccinated placebo recipients who did not later contract Hepatitis B was not disclosed. Instead of testing viral transmission by comparing vaccine versus placebo as stipulated in the trial documents,²² the CDC argued that transmission did not occur because (by 1984) HIV rates in a "higher risk" group excluded from the trial due to a prior history of Hepatitis B infection had caught up with the average rate of vaccine and placebo trial participants (Fig 5d).^{43,44} (Timeline § 1984)

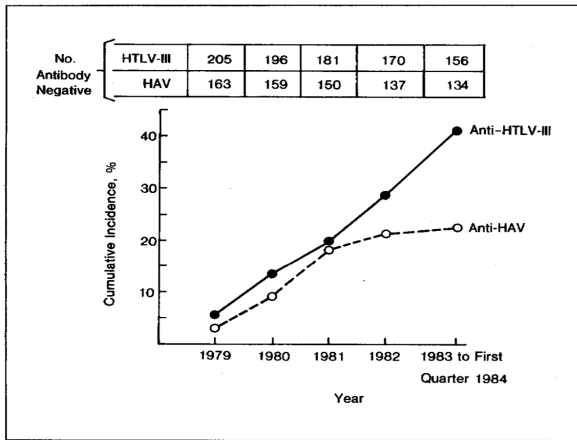


Fig 1.—Incidence of human T-cell lymphotropic virus type III (HTLV-III) and hepatitis A virus (HAV) antibody seroconversion among hepatitis B vaccine trial participants, by year. Note that length of period 1983 to early 1984 is increased proportionately in figure to include first quarter of 1984.

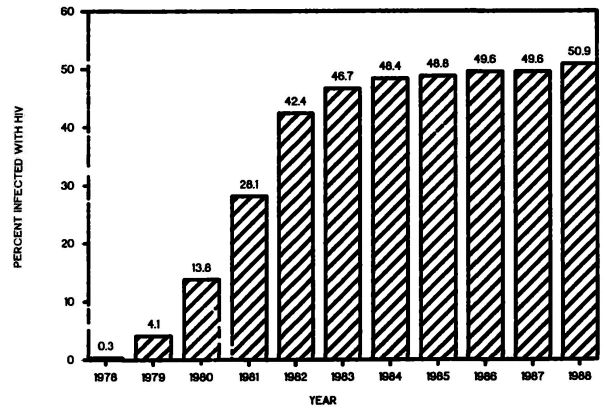


FIGURE 1. Annual cumulative prevalence of human immunodeficiency virus infection among 320 hepatitis B vaccine trial participants, San Francisco, 1978–1988.

Hepatitis B Infection in Homosexual Men

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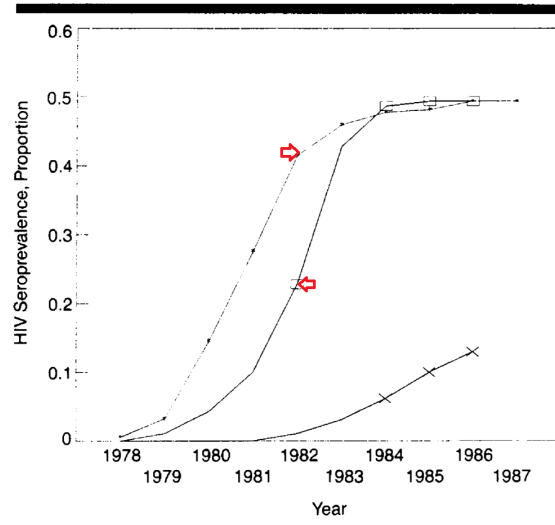
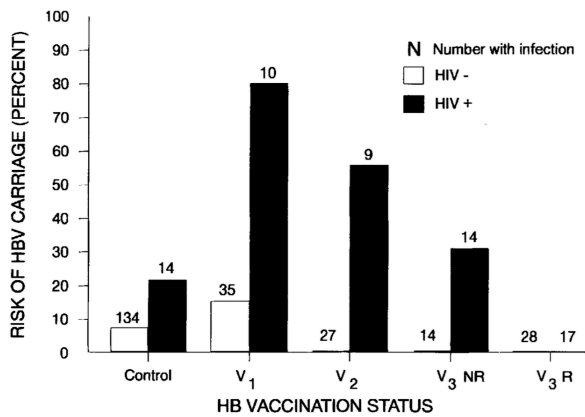


Fig 1.—Human immunodeficiency virus (HIV) seroprevalence among homosexual and bisexual men and heterosexual intravenous drug users in San Francisco, Calif, from 1978 to 1987. Data for homosexual and bisexual men are from the San Francisco City Clinic Cohort Study (asterisks) and the San Francisco Men's Health Study (squares). Data for heterosexual intravenous drug users are from cross-sectional surveys of drug users in treatment settings (X's). Extrapolated data points are represented by solid lines without markers.

Fig 5. (a) NYBC New York HIV rates⁴⁰, (b) CDC San Francisco HIV rates⁴¹, (c) CDC HIV rates by dose among men who later contracted Hepatitis-B⁴², (d) Comparison of trial participants (left line) versus men excluded for prior infection (middle line) with arrows added to indicate the rate when the trial ended⁴⁴

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In 1984, following the vaccine's prohibition in the European Pharmacopoeia, Dr. Prince proposed at a WHO Conference on Africa, held in France, that it could still be used in Africa.²⁶ He defended the "less purified preparations... [to] enable hepatitis B vaccines to be made inexpensively,"²⁵ emphasizing their advantage over the "harsh purification steps employed in preparing the Merck vaccine".²⁶ Dr. Prince argued that to achieve a low price point, safety-testing lots for infectious viruses "can probably be dispensed with," accepting the "theoretical, albeit so far unproven, dangers due to the inclusion of host antigenic components".²⁶ (Fig 6) (Timeline § 1984)

Table 2. Currently available HBV vaccines

Manufacturer	Source plasma	Purity	Inactivation steps	Dose (µg)	Efficacy	Approximate cost per dose
A. Licensed						
Merck, Sharp, & Dohme	HBeAg(+)	High	Purification pepsin-hydrochloride Urea Formalin	20	Good	\$30
Institut Pasteur	Anti-HBe(+)	High	Purification Formalin	5	Good	\$25
Korean Green Cross	HBeAg(+)	High	Purification Formalin	10	?	\$10
B. Undergoing clinical trials						
Netherlands Red Cross	Anti-HBe(+)	Low	Purification 102°C for 90 s 65°C for 10 h	3	Very good	?
New York Blood Center	Anti-HBe(+)	High	Purification Tween 80 102°C for 90 s 65°C for 10 h	?	?	?

26

Fig 6. New York Blood Center presentation at WHO Conference on Africa

FactMission seeks support to secure the following data, with the results published in raw form, without commentary, for independent analysis by the scientific community:



1. Acquire from the CDC and NYBC the previously withheld trial data for their 1978-1981 trials involving gay men, specifically focusing on HIV rates stratified by the number of vaccine doses administered.
2. For Merck H-B-Vax, NYBC B-Vax and the WHO chimpanzee-derived vaccine(s), obtain confirmation of the following details: lot numbers, lot sizes, administration locations, and the species used as the source of plasma.
3. Obtain from NYBC information on the two clinical trials they reported to WHO officials had been completed on B-Vax.⁵ If these are not the same trials, acquire data on any phase 1 and 2 trials conducted before 1978.

Conclusion

This paper employs an unconventional research method omitting speculation to focus on consensus over key "*Elements*" to avoid dismissal of an unpopular subject without establishing consensus on the basic facts. After 42 years, the conventional approach has failed to answer fundamental questions:

- Were America's gay men inoculated with plasma from humans or chimpanzees?
- What was the difference in HIV rates between vaccine and placebo recipients in the NYBC/CDC clinical trials?

Private communications indicate that HIV rates may have been combined for vaccine and placebo groups due to concerns that the public might not accept a discrepancy as evidence that vaccine recipients were healthy and on sex tourism holidays, while placebo recipients were ill at home with Hepatitis. Given some of the same officials and agencies are calling for legislation to mandate their products and arbitrate truth, such as with pandemic treaties, vaccine passports, and digital ID, questions arise regarding transparency and accountability:

- For taxpayer-funded trials, should such essential data not be made available for public discourse, especially considering that, following the decision to withhold the data, the vaccine continued to be marketed in Africa?
- Some African papers refer to the same vaccine lot as both Heptavax and HB-Vax.⁴⁵ Were vaccine recipients assured they were getting an FDA-approved product made from human plasma, like Heptavax-B, when in fact, it was an unapproved product that used species-agnostic language to conceal a chimpanzee-plasma origin?
- Should the WHO be able to mandate vaccine passports without disclosing basic information such as the species from which their own vaccine's active ingredient is derived, inoculation during their campaign in Haiti around 1978, and the species of plasma used in their African programs in the 1980s and 1990s?

- If this paper is the first since the November 1982 WHO Symposium to acknowledge the existence of chimpanzee-derived vaccines, has there been censorship of this topic for the past 42 years?
- Should immense power to censor require full transparency?
- We will document which preprints, journals, and media platforms engage with or censor this discussion. If media outlets claim they need to censor "misinformation" to protect themselves from liability, is there liability in censoring demonstrably accurate information if it results in harm?

In a spirit of transparency and good faith, I will be reaching out publicly to all relevant parties. All counterarguments, claims, and any communications, unless marked as private, as well as instances of "no comment" will be included in the [publicly accessible spreadsheet](#) and Supplementary Materials for the final version submitted for peer review and publication. The goal will be a balanced presentation of facts, aiding others who may wish to propose theories.

Mastodon is an open-source platform functioning similarly to X, but its open-source nature enables customization. A white paper on Qurnec.org details a tailored version for researchers that integrates academic paper tagging and citation. It also incorporates polling features to assess consensus on *Elements*, as demonstrated in this study, and utilizes AI to generate succinct summaries.

Supplementary Material:

Timeline of chimpanzee-plasma-derived vaccines

To support the key claims above, this chronological timeline provides background and excerpts.

1922

Scientists began injecting humans with chimpanzee plasma for disease management.⁴⁶

1959

A polio vaccine was administered in Kinshasa, Congo, claimed by some to have been made using chimpanzee kidneys.⁴⁷ The first HIV+ blood samples began to appear in Kinshasa the following year (ZR59, DRC60, DRC66), HIV-1 subtypes A, C, D.^{48,49} The closest chimpanzee ancestor is the *P. t. Troglodytes* subspecies.⁵⁰

1963

“Marilyn”, a chimpanzee of the *P. t. Troglodytes* subspecies, is caught and sent to the US where she was used for Hepatitis-B research.^{9,51} Her archived blood samples will test HIV+ the year a commercial test is available and, as she was presumed infected at birth, she will become the earliest uncontested, lab-confirmed, HIV+ creature in the Western Hemisphere.⁵²

1960's

Three lab-confirmed AIDS deaths predate the Hepatitis-B clinical trials. They presumably contracted the virus in the Western Africa in the 1960's and died 12 to 18 years later:⁵³

- Arvid Noe and family HIV-1 subtype O

- Grethe Rask HIV-1 subtype D
- "Dr. Bryceson's patient" HIV-2

1966

NYU/NYBC operated LEMSIP, provided chimpanzee organs for donation, and Dr. Prince cross-circulated raw human/chimp blood between the species:

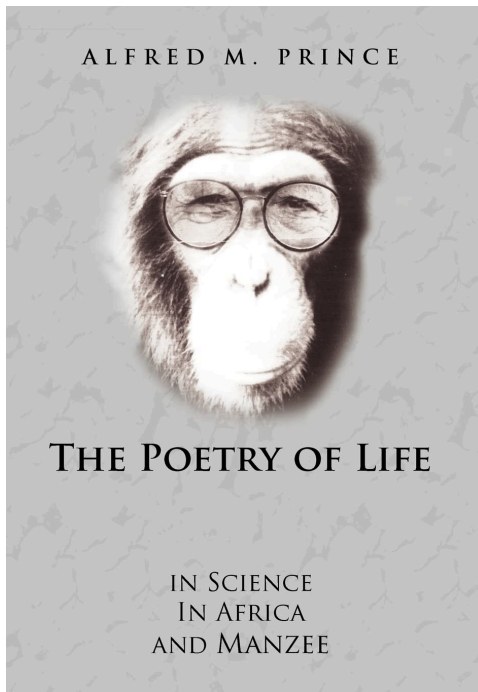
Since 1966, we and others have been investigating the efficiency of heterologous cross circulation between nonhuman primates and human patients in hepatic failure... Prince has demonstrated the presence of hepatitis specific antigen in chimpanzees and has described the carrier state in man and in subhuman primates. These observations are now being pursued with the goal of creating an antiserum against hepatitis without the need for experimentation on human subjects.^{11,12}

Dr. Prince wrote:

The previously accepted distinction between man as "human" and the chimpanzee as "animal" is becoming blurred... Chimpanzee chromosomes... are almost identical to those of man... Type A red blood cells survive normally when transfused into chimpanzees with type A blood. Chimpanzee kidneys have survived for 9 months in a human recipient. Clearly, the biochemical and immunologic data provide little basis for separation of these species.⁵⁴

He wrote an "almost entirely fictional" account of raising a "manzee" hybrid son (Fig 7):

My love for Mary was intense.... Finally the time came. After fondling Mary, I used a fine needle to inject Mary with a small amount of ketamine to induce a mild sleep. Slowly, I penetrated her, and began to move more vigorously. Soon I came, filling her with my human sperm.⁵⁵



Mary. Who would not fall in love?

Fig 7. Alfred Prince autobiography

1972

CDC and NIAID scientists wrote:

Experimental infection of chimpanzees with the virus of hepatitis B⁶

They cited it in:

Type B Hepatitis: A Review of Current Prospects for a Safe and Effective Vaccine

The results of these studies and the finding that the chimpanzee is susceptible to HBV infection prompted the development of a second generation of hepatitis B vaccines.⁷

Dr. Prince and NYBC filed the first patent application (Ser. No. 301,347, filed Oct. 27, 1972):

The present invention relates to the field of immunology generally, and more particularly to a large scale procedure for producing commercial quantities of highly purified type B hepatitis antigen (HB Ag) which may be used in the commercial production of a vaccine against type B hepatitis infections.

Hepatitis B antigen was purified from 8 liters of chimpanzee plasma (type ad), 5 liters of human plasma (type adx) and 2 liters of human plasma (type ayx).⁸

The WHO Noted:

Human HBV has been successfully transmitted to chimpanzees... antigenic markers of virus replication are antigenically indistinguishable from the homologous antigens and antibodies from man.⁵⁶

1974

NYBC began enrollment:

Participants were recruited from approximately 13,000 homosexual men from New York, who were screened for the presence of HBV markers during our baseline studies conducted between 1974 to 1978.¹⁰

There is indirect evidence of HIV infections in New York beginning this year.⁵⁷

1976

WHO scientists reported:

February, 1976... Persistent carriage of hepatitis B virus in extremely high titre was identified in 5 out of 9 chimpanzees kept at the London Zoo... Hepatitis B surface antigen or surface antibody and hepatitis A virus and antibody in captive chimpanzees are antigenically

indistinguishable from the homologous antigens and antibodies obtained from man.¹⁴

They cited those antigens:

Hepatitis B surface antigen.

The purification of HBs 20 to 25 nm particles from plasma obtained from a persistently infected chimpanzee has been previously described...

These studies provide a basis for an alternative method of preparing a subunit vaccine for the immunoprophylaxis of hepatitis B and demonstrate that purified HBsAg 20 to 25 nm particles contain significant quantities of serum albumin.¹⁵

Also cited in:

The development of hepatitis B vaccines and antiviral therapy⁵⁶

And presented at a WHO Symposium in France:

HEPATITIS B MICELLE VACCINES

MATERIALS AND METHODS

Hepatitis B surface antigen

The purification of the 22 nm surface antigen spherical particles from the 11 serum of a persistently infected chimpanzee has been previously described.⁵⁸

Also in 1976, the WHO reported seroprevalence surveys would begin in the Caribbean¹⁷. In Haiti nearly 14% had chronic Hepatitis-B, the highest in the hemisphere.¹⁸

March 1978

The Second Symposium on Viral Hepatitis, at UC San Francisco, was sponsored by the NIH, CDC, NIAID, FDA, and NCI. The hundred participants came from 13

countries and included representatives from these agencies, the WHO, the U.S. military, research institutions, and pharma. The proceedings note:

On the assumption that the most significant utilization of a Hepatitis-B vaccine will be in the prevention of chronic carrier state infection in high-prevalence regions of the world, most of which are in developing nations where vaccine cost is of paramount importance, we have chosen to attempt to develop a highly purified Hepatitis-B antigen vaccine by methods lending themselves to inexpensive, large scale processing by methods conventional in the manufacturer of blood derivatives. A candidate vaccine has been prepared utilizing high-titer e-antigen positive plasma from chronic HBsAg carriers as source material. This vaccine is purified by modifications of methods which have been described in detail (... Journal of Clinical Microbiology 3:626-631; Vnek, J., Ikram, H., Prince, A.M. (1977), Infection and Immunity 16:335-343).^{20(p712)}

The citation lists the starting material:

MATERIALS AND METHODS

Source of HBsAg. HBsAg of the adw subtype was purified from pooled plasma of a carrier chimpanzee previously inoculated with plasma from a chronic carrier chimpanzee.²⁸

NYBC cites the same chimpanzee antigens:

AN ALTERNATE CANDIDATE HB VACCINE: NYBC B-VAX

At the New York Blood Center we have been working for the past 8 years on the development of an HB vaccine.²⁰

Concerning the upcoming trials, NYBC writes:

Such trials should include at least two or three of the major candidate HB vaccines to permit their comparative evaluation under conditions of potential use. Indeed, it is conceivable that different candidate vaccines

may prove to be superior in one or another of the potential applications. For instance, a vaccine that is highly effective in prevention of carrier state infections may require the rapid production of anti-HBs and a higher relative immunogenicity due to the possible need to immunize infants at a very early age.

This section 50 exclusively details chimpanzee-plasma-derived vaccines, and includes the chart in Fig 7. This is the only section that mentions trials on “Male Homosexuals”.

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Table 50-10. Populations Available for HB Vaccine Trials

A) Prevention of Acute Hepatitis	
1. Renal Dialysis	A) Staff
	B) Patients
2. Male Homosexuals	(HB Seronegative)
3. Peace Corps	
4. Army	
B) Prevention of Carrier State	
1. Infants	A) Africa
	B) Asia

Fig 7. Proposed vaccine trial participants for NYBC B-Vax

Section 51 was written by Dr. Hilleman of Merck:

The most extensive animal and clinical testing has been confined to a single lot of vaccine, designated 559. This can be discussed as a prototype that has been prepared in different antigen strengths and in different formulations. Lot 559 vaccine was derived from plasma pools collected from four human donors.

Dr. Prince noted of NYBC B-Vax:

HBsAg/adw was purified from 2.6 liters of pooled plasma from a single chimpanzee carrier.

The normal plasma components associated with purified HBsAg [the vaccine's active ingredient] can only be removed after detergent treatment, which causes morphological damage.... The fact remains that conventional purification techniques, such as proposed for vaccine manufacture [Prince et al, 1978], will not provide particles free of traces of serum protein contaminants. As human blood derivatives have been administered to man for many years without evidence of induction of 'serum sickness,' we do not believe that this phenomenon has clinical significance.¹⁹

November 1978

The NYBC trial began:

We assessed the efficacy of an inactivated hepatitis B vaccine in a placebo-controlled, randomized, double-blind trial in 1083 homosexual men known to be at high risk for hepatitis B virus infection. The first participant was inoculated in November 1978.²¹

One lot (no. 751) of the Merck vaccine, consisting of HBsAg, subtype adw with alum adjuvant, has been extensively studied in human volunteers... Two lots of the Merck vaccine, both in alum formulation, are being used: one of sub-type adw (no. 751) in the homosexual trial, and another of subtype ayw (no. 761) in the dialysis trial.²²

Though NYBC B-Vax was reportedly used in 2 clinical trials (Fig 2,3),⁵ there is no mention of NYBC B-Vax being used in this phase three trial. Dr. Prince noted "The most controversial point appears to be whether HBeAg positive plasma, i.e., plasma that is Dane-particle-rich and highly infective, should be used as the starting material".²⁶ The phase three trial compared two different Merck vaccines. As noted earlier, during the clinical trials Merck and NYBC trademarked, licensed, and/or presented 3 brand names with different formulations (Fig. 1):

Merck Heptavax-B: FDA-approved, trademarked in the US, Spain, Canada, made from human plasma (Fig 1a)

Merck H-B-Vax: trademarked in 31 overseas markets, made from “plasma of chronically infected, asymptomatic carriers”²³ (Fig 1c)

NYBC B-Vax: made from chimpanzee-plasma and “less purified... to be made inexpensively”²⁵ (Fig 1b)

September 1979

In an interview, the NYBC principal trial investigator, Wolf Szmunes reported:

On the surface the flare-up of non-A non-B hepatitis appeared to be a vaccine-associated event... there were fourteen possible cases of non-A non-B hepatitis and of these eleven had occurred among vaccinated people, two among the placebos. I wanted to stop the trial at once because the basic principle of any clinical experiment is not to do harm to the participants. Their interests are always of the first importance. You should not -you don't have the right to - harm them. So my first inclination was to see what happened with the vaccine and through that find the cause of this non-A, non-B hepatitis outbreak. We weren't the only people to notice it. Government scientists who worked independently with another vaccine were seeing several cases; some were occurring among [Trappist⁵⁹] monks in Texas. So I felt only if we found a reasonable explanation could we then continue.

His colleagues, Aaron Kellner, Cladd Stevens, and Saul Krugman:

Reassured and teased him... if the problems were real they'd pay the lawyers, take care of Maya [his wife], bring him food and flowers in jail... They would, Kellner assured him, tap the best lawyers in the United States.⁶⁰

They never specified how they diagnosed the non-a, non-b flareup, but medical papers at the time described “eruptions in non-A, non-B hepatitis”

as “red bumps” appearing with negative blood tests for the known Hepatitis-A and B.⁶¹ New York Dermatologist Alvin Friedman-Kien reported unusual “red bumps” on gay men the following month.⁶²

The “red bumps” required simultaneous coinfection with both HIV and Kaposi Sarcoma Herpes Virus (KSHV).⁶³ “PtRV-1 is the closest relative of KSHV”,⁶⁴ and was also found in the chimpanzees. KSHV is an oral, not a sexual virus.⁶⁵ The dual infection was generally seen at trial sites⁶⁶ during the 1980’s.^{62,67}

March 1980

The CDC began trialing the same vaccine Lot 751 on 1,400 gay men mostly in California with 688 receiving placebo.^{59,68} The CDC broke down many data points by vaccine versus placebo (Table 41-2, 41-3), but for “Non-a,Non-B” (Table 41-4) only combined rates: San Francisco(12), Los Angeles(6), Denver(12), Chicago(9), St. Louis(9).⁵⁹

April 1981

After the NYBC trial, Dr. Szmunes noted “non-a,non-b” rates in vaccine went from 500% higher than placebo 10 months post inoculation (11:2) to 46% at the end (16:11):⁵⁹

One might speculate that the reason fewer cases of non-A,non-B hepatitis were diagnosed among placebo recipients than among vaccine recipients (11 vs. 16: difference not statistically significant) is that infection with a non-A,non-B agent in placebo recipients would often not be recognized due to a concomitant hepatitis B event. Since vaccine recipients were protected against HBV infections, those who were exposed to both agents would have non-A,non-B hepatitis which was not masked by an HBV infection.⁵⁹

November 1981

In 1981 Los Angeles Dermatologist and cancer researcher Alan Cantwell diagnosed “red bumps”:

The very recent ‘miniepidemic’ with a 50% mortality rate of Kaposi’s sarcoma in young and middle-aged male homosexuals in New York City and San Francisco suggests a possible infectious agent.^{69.69}

He claimed:

Through AIDS antibody blood testing of pre-1978 stored blood, the scientists proved that THE NEW AIDS VIRUS DID NOT EXIST IN AMERICA BEFORE 1978. There was complete agreement that the AIDS virus had been "introduced" into the United States through the male homosexual population in Manhattan sometime around the years 1978-1979... The origin of HIV and the KS virus came out of the experimental hepatitis B vaccine trials (1978-1981) in which thousands of healthy gay men were injected with an experimental Vaccine. In the United States, the earliest positive HIV blood tests were discovered in samples of blood donated by male homosexuals in New York City, as part of this experiment. There was no "incubation period" for HIV in the United States, the earliest HIV+ blood specimens were from 1978 - the same year the first gay hepatitis B experiments took place in Manhattan, at the New York Blood Center.... In January 1979, two months after the hepatitis B experiment began, purple skin lesions began to appear on the bodies of young white gay men in New York City....⁷⁰

The incubation period in someone who received a heavy infection dose of virus would be shorter than the incubation period of the same virus that was picked up "naturally" in a sexual encounter. I believed very strongly that in order to pinpoint the initial "introduction" of the AIDS virus into gay men, it was essential to study carefully the epidemiological profile of the very earliest cases.⁷⁰

Dr. Cantwell's book demonstrates the importance of first isolating and reaching consensus on *Elements*. His work was dismissed due to its speculative claims about contamination being intentional. As a result, there's no indication that his potentially valuable epidemiological observations, as one of the earliest diagnosticians of the condition, were ever evaluated.

January 1982

The FDA and WHO discuss 3 chimpanzee-plasma-derived Hepatitis-B vaccines from NYBC, FDA and the WHO:²⁵

Less purified preparations have also been suggested for vaccine use, which would enable hepatitis B vaccines to be made inexpensively and to include other potential antigenic specificities that might contribute to immunity. [Citations to Prince's B-Vax papers]

Aqueous Polypeptide Vaccine [FDA]

HBsAg, subtype adw, was obtained from the plasma of a chimpanzee chronic carrier...

Micellar Polypeptide Vaccine [WHO]

A micellar preparation of the polypeptide vaccine (micellar polypeptide vaccine) was also prepared [Skelly et al, 1979]

The *Skelly et al, 1979* citation refers to a WHO paper:

Hepatitis B surface antigen

The purification of HBs 20 to 25 nm particles from plasma obtained from a persistently infected chimpanzee¹⁵

July 1982

AIDS cases rose from 5 in June 1981 to 514 in July 1982.⁷¹ In San Francisco, 6 of 10 were cohort participants.⁷² Some blamed a government plot.⁷³

September 3, 1982

The CDC published:

Current Trends Hepatitis B Virus Vaccine Safety: Report of an Inter-Agency Group

HBV vaccine licensed in the United States is prepared from human plasma containing hepatitis surface antigen (HBsAg)... Beginning in 1978, a disease or group of diseases was recognized, manifested by Kaposi's sarcoma and opportunistic infections, associated with a specific defect in cell-mediated immunity. This group of clinical entities, along with its specific immune deficiency, is now called acquired immune deficiency syndrome (AIDS)... In three vaccine-placebo trials (two among homosexual men between 1978 and 1980 (3,4) and one among hospital employees in 1981), 549, 714, and 664 persons, respectively, received vaccine, and equal numbers received placebo.... However, lots used in early studies may have been produced before the occurrence of AIDS.³⁰

November 12, 1982

NYBC responded to concerns by pointing to a lack of AIDS in medical personnel. There's no mention of medical personnel receiving a different vaccine lot. NYBC claimed early AIDS cases were not trial participants in the phase 3 trial using the Merck vaccine. There's no mention of the two clinical trials of NYBC's own B-Vax (Fig 2,3). They did not comment on claims that the earliest cases like Ken Horne contracted AIDS in New York bathhouses before the phase 3 trial when NYBC was reportedly inoculating patrons.⁷⁴

There are no cases among persons in other groups who have gotten vaccine in immunogenicity or efficacy studies, such as medical personnel and dialysis patients.... None of the patients with Kaposi's sarcoma were participants in the hepatitis B vaccine trial. Therefore, we

do not think that the epidemic is caused by or related to the vaccine.... We expect that some patients with acquired immune deficiency and Kaposi's sarcoma have received the vaccine because they are in the group known to be affected.⁷⁵

However, another NYBC colleague wrote:

The total number of deaths identified in the cohort for the years 1978-1988 was 998... This study illustrates the enormous toll the AIDS epidemic has taken on a cohort of homosexual men in New York City.⁷⁶

November 15, 1982

From the Proceedings of the WHO International Symposium in Athens, Greece.⁵

A NEW HEPATITIS B VACCINE CONTAINING HBeAg IN ADDITION TO HBsAg... Chimpanzee plasma containing HBeAg and HBsAg... Four lots have passed chimpanzee safety tests; two of them have been tested in clinical trials.

Throughout the entire two years of the trial in homosexual men he told us over and over again at monthly meetings, that the study was a disaster.

The Hepatitis B vaccine... Much controversy still exists regarding the safety against possible new or unknown syndromes... certain risks remain ; ... possible presence of other ... theoretical (e.g., Acquired Immune Deficiency Syndrome) viral agents that might have coinfecting the donors of plasma from which the vaccine HBsAg was isolated.

The importance of broad-spectrum inactivation of all possible agents in human blood was recently called to attention by the current epidemic of acquired immunodeficiency syndrome that is presenting as Pneumocystis pneumonia and Kaposi's sarcoma. Epidemiologic data,

indicating transmission by human interpersonal contact or transfer by human blood Factor VIII, strongly suggest that the acquired immunodeficiency is caused by a virus of man that may be present in blood.⁵

Merck and NYBC had filed a trio of patents, 4,118,477; -478; -479^{29,35,36}, stating “the chimpanzee offers the practical advantage”, but now Merck’s patent Appl No 577,483⁷⁷ was abandoned, filing a revision that now identified the antigen source to ‘human’: “The starting material for the purified hepatitis B surface antigen (HBsAg) of the present invention is human biological fluid containing hepatitis B surface antigen”.³⁷ NYBC also filed an updated patent using the term “human blood plasma”,⁷⁸ and the next mention of this vaccine used species-agnostic language.⁷⁹ NYBC’s updated trial documents now claimed medical personnel received the same Lot 751 as gay men³⁸, not Lot 761 as reported during the trial²². Merck used the term “human plasma” when referring to Lot 751, but without expressly stating it was the starting material:

Infected human plasma, as shown in Figure 34-1. contains normal plasma constituents, 20 my diameter particles of HBsAg in spherical and tubular form, and 42 mm Dane particles that are the infectious virus. The vaccine is prepared from surface antigen that has been purified to remove extraneous materials and treated to destroy the infectivity of any retained virus particles.⁵⁹

January 1983

One of the manufacturers of plasma-derived products wrote in an internal memo:

There is strong evidence to suggest that AIDS is passed on to other people through . . . plasma products.³¹

February 1983

While the Lancet reported “Many fear that the AIDS agent could be included in the vaccine and be spread by it”⁴, the FDA stated:

THE RECENTLY licensed subunit hepatitis B vaccine (HEPATAVAX-B) is unique among vaccines in that it is manufactured solely from human plasma... The etiology of AIDS is unknown... suggested causes include exposures to antigenic substances, opiates, nitrite inhalants, or chemotherapeutic agents to which homosexual males may be exposed during treatments for various disorders.... The recent discovery of several documented cases of AIDS in heterosexual hemophilic patients, although in no way proved to be related to the lifesaving blood-derived clotting factor concentrates that they receive, has raised questions regarding the safety of plasma donated for Hepatitis B vaccine manufacture by persons with chronic hepatitis B who may have unrecognized or early AIDS... Although never documented to be transmitted by blood... since AIDS occurs among certain high-risk groups receiving the vaccine, it is inevitable that cases of AIDS will occur in vaccine recipients unrelated to the vaccine itself.... It is clear at this point that the known risk of hepatitis B for persons in high-risk groups far exceeds the risks of vaccine-induced infection by a theoretical transmissible agent that would have to survive the purification and inactivation procedures applied to the licensed hepatitis B vaccine. The recommendations of the Immunization Practices Advisory Committee have recently been reaffirmed; all persons at high risk for hepatitis B should receive hepatitis B vaccine.³²

1984

The CDC report mentioned in reference to Fig 1d stated:

Current Trends Hepatitis B Vaccine: Evidence Confirming Lack of AIDS Transmission

In addition, the rate of AIDS for HB vaccine recipients in CDC vaccine trials among homosexually active men in Denver and San Francisco does not differ from that for men screened for possible participation in the trials but who received no HB vaccine because they were found immune to HB.⁴³

I filed a FOIA for the data behind the charts and anything related to the trial. The CDC replied “no records”. To my pending appeal the director replied “your appeal falls under ‘unusual circumstances’ in that our office will need to consult with another office or agency that has substantial interest in the determination of the appeal.”

The CDC director told the New York Times:⁸⁰

It is clear, absolutely clear, that this vaccine is safe. It does not contain the AIDS virus, and even if it did, the data demonstrate that the virus would be killed by inactivation steps used in the manufacturing process.

Later that year, Dr. Alfred Prince from the New York Blood Center (NYBC) to the *World Health Organization Regional Office for Africa* and the *Organisation of African Unity*, held in France:²⁶

In the interests of 'safety', prohibition has apparently, as a consequence, found its way into the recommended requirements in the European Pharmacopoeia.

The failure of the Merck, Sharpe, and Dohme vaccine to protect renal dialysis patients... suggests that one or more of the relatively harsh purification steps employed in preparing the Merck vaccine (i.e., pepsin-hydrochloride or urea treatment) may have impaired its immunogenicity.

It [NYBC's vaccine] entails accepting theoretical, albeit so far unproven, dangers due to the inclusion of host antigenic components... The vaccines produced so far appear to be entirely safe. More than 8 million

doses have been administered without a single report of any serious adverse reaction, or inadvertent transmission of hepatitis or of the recently described AIDS syndrome... Thus, after a manufacturer has shown his ability to produce safe lots consistently, this test [checking each lot for infectious viruses] can probably be dispensed with if the manufacturing protocol includes steps giving an acceptable aggregate process efficacy.²⁶

End

At this juncture, researchers discovered that archived blood samples from chimpanzees used in hepatitis vaccine development tested positive for HIV.⁵² Notably, I found no further references to chimpanzee-derived vaccines in any publicly accessible documents after this was revealed.

Question: Was it ever determined why some gay men developed Kaposi Sarcoma⁸¹ and immune-system collapse without HIV?⁸²

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