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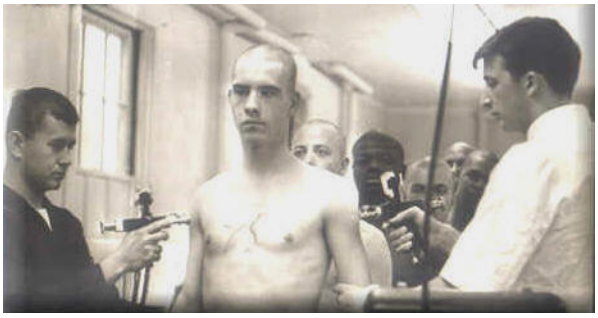
Hepatitis C from

JET GUN INJECTIONS

Boot Camp, Paris Island 1968



The study ended early because the protector cap needle-free injector (**PCNFI**) **failed to prevent contamination in the first batch tested (8.2% failure rate).**

Vaccine. 2008 Mar 4;26(10):1344-52. Epub 2008 Jan 18. Links

Preventing contamination between injections with multiple-use nozzle needle-free injectors: a safety trial.

Kelly K, Loskutov A, Zehrung D, Puaa K, LaBarre P, Muller N, Guiqiang W, Ding HG, Hu D, Blackwelder WC.

PATH, 1455 NW Leary Way, Seattle, WA 98107, USA. kkelly@path.org

Multiple-use nozzle jet injectors (MUNJIs), a type of needle-free injector, use a high-pressure stream to penetrate skin and deliver medicament. Concerns for their potential to transmit blood borne pathogens led to development of a hybrid MUNJI for use in mass immunizations. The HSI-500, referred to here as a protector cap needle-free injector (PCNFI), utilizes a disposable cap as a shield between the reusable injector nozzle and the skin to reduce the risk of contamination. This study aimed to determine the presence of hepatitis B virus (HBV) contamination in post-injection ("next person") samples immediately following injection in HBV-carrier adults. Tolerability and pain were also assessed. **The study ended early because the PCNFI failed to prevent contamination in the first batch tested (8.2% failure rate).** The injections were very well tolerated, with most followed by no bleeding (81.2%) or mild bleeding (7.8%). 55.2% of participants experienced no pain while 42.3% experienced mild pain following injection.

PMID: 18272265 [PubMed - indexed for MEDLINE]

Hepatitis C is a result of receiving immunizations in service

by means of a multi-use jet gun injector.
CONCLUSION OF LAW
Hepatitis C was incurred in service. 38 U.S.C.A. § 1131 (West 2002); 38 C.F.R. § 3.102, 3.303 (2005).
ADD TO YOUR CLAIM!

Vaccine Weekly
August 03, 2001
by N.R. Saltmarsh, staff medical writer -

Jet Injectors Capable of Transmitting Blood-Borne Pathogens

Jet injectors may be ideal for mass immunization programs but not until design refinements eliminate their capacity to transmit blood-borne infections, say researchers working in England.

The injectors, which are needleless systems that penetrate skin with high-pressure fluid, have potential advantages over needles and syringes, but P.N. Hoffman and associates at the Laboratory of Hospital Infection, London, sought to determine whether they might have a major disadvantage as well.

They used a highly sensitive enzyme-linked immunosorbent assay (ELISA) to detect whether small amounts of blood and fluid remained in the jet injector after injecting inert buffer into calves.

All four injectors tested - two with reusable heads and direct skin contact, one with single-use injector heads, and one with an injector head that discharged at a distance from the skin - contained at least 10 pl of blood, enough to transmit hepatitis B infection, reported Hoffman and coworkers ("A model to assess the infection potential of jet injectors used in mass immunization," Vaccine, July 2001;19(28-29):4020-4027).

"The source of the contamination was consistent with contamination by efflux of injected fluid and blood from the pressurized pocket in tissue that is formed during injection," reported Hoffman and coauthors. "This insight should inform the design of safe jet injectors."

For more information about this study contact P.N. Hoffman, Laboratory of Hospital Infection, Central Public Health Laboratory, 61 Colindale Ave., London NW9 5HT, UK.

Key points reported in this study include: * Needleless jet injector systems are potentially beneficial for mass immunization programs, but they may transfer blood-borne viruses * Researchers used a highly sensitive ELISA to evaluate whether small volumes of blood remained in the jet injectors after injecting calves with a buffer solution * All four injector models tested transmitted more than 10 pl of blood, the minimum amount required for hepatitis B transmission, and the quality of the blood was consistent with efflux from the pressurized pocket created by the jet injector

This article was prepared by Vaccine Weekly editors from staff and other reports.

Follow up
http://cphl.phls.org.uk/divisions/nsi/lhi/highlights.htm (if this link no longer works, click here

transmission of hepatitis c by jet gun injections exists)

The Central Public Health Laboratory (CPHL) is the national reference centre for medical microbiology in the UK. CPHL provides specialist expertise and advice to the Regional PHLS laboratories, NHS hospital laboratories, consultants in communicable disease control, community and hospital physicians, environmental health officers, government and industry.

Public Health Highlights

Interventions LHI in their reflective practitioner role receive many requests for advice on the prevention and control of infection and outbreaks. These cover infection control in hospitals and other, wider aspects of healthcare. One example of this was recently generated in the Infection Control Unit and concerns the transmission of blood borne infectious agents by jet injectors. These injectors use a high-pressure focussed jet of fluid to provide a needleless mechanism for penetrating skin. They have great potential in mass immunisation campaigns in areas of limited resources and allow high immunisation delivery rates. They would eliminate many logistical problems such as the shipping of single-use syringes and needles, accidental contaminated needlestick injuries to immunisation staff, and the burden of safe disposal of sharps clinical waste.

At the request of the World Health Organization, we developed a laboratory model of jet injection safety that could test the capacity of jet injectors to transmit blood between injection recipients. Hepatitis B is thought transmissible in volumes of blood as low as 10 picolitres, so a novel immunoassay (developed in conjunction with Kings College, University of London) was used that could detect these extremely low levels. Results from the use of this model indicated jet injectors can regularly transmit relevant volumes of blood. Use of this model under field conditions in Brazil (in conjunction with WHO and the Brazilian Ministry of Health) confirmed the laboratory model as valid.

As a result of this work, WHO and other major users of jet injectors have reconsidered their use. A more positive outcome of this work has been an understanding of previously unsuspected contamination mechanisms, which is enabling design of new generations of jet injector whose safety can be assessed in our model. View Study

Paris Island Air Force inspection

Jet injector nozzles were frequently contaminated with blood

click here Vaccines in the Military Department of Defense- Wide review of Vaccine Policies and Procedures
Read excerpt- Page 60 in particular says, "Of note is that the **AFEB made a site visit to the MTF at Parris Island** and directly observed high volume recruit immunization using jet injectors. It was **noted that jet injector nozzles were frequently contaminated with blood,** yet sterilization practices were frequently inadequate or not followed." View complete report at
http://www.ha.osd.mil/afeb/reports/vaccines.pdf

Military discontinues the use of jet guns for mass immunization of military troops

U.S. Department of Defense (DoD) needle-free injection policy chronology

- (1997-11-20) Ped-O-Jet® manufacturer (Keystone Industries, Cherry Hill, NJ) notifies Defense Supply Center Philadelphia (DSCP) (Defense Logistics Agency) of intent to withdraw as device supplier over liability concern for bloodborne disease transmission from multiple-use-nozzle design.

- (1997-12-05) DoD Medical Materiel Quality Control Program (MMQCP) issues withdrawal of automatic jet hypodermic injection units (MMQC-97-1169).

- (1997-12-07) DSCP issues Medical Products Quality Control System (MPQCS) device alert (DSCP 970147) as "cautionary measure", while noting the absence of bloodborne disease transmission case reports over 35 years of military use (followup MMQC-98-1019 dated 1998-Jan-30).

- (1998-01-09) Armed Forces Epidemiological Board (AFEB) concurs with withdrawal of Ped-O-Jet® for "routine immunization", but availability for "public health emergency". AFEB recommends use of "newer technology" devices with disposable parts for skin contact.

- (1998-04-20) Navy Bureau of Medicine and Surgery updates via BUMED notice 6230 its *Immunization Requirements And Recommendations* document (3.6Mb .pdf) prohibiting jet injector use until otherwise directed.

- (1998-04-28) AFEB recommends DoD formulate new needle-free injector specifications and support device research and development.

- (1998-07-09) Letter from Dr. Sue Bailey, Assistant Secretary of Defense, Health Affairs, to United States Representative Alan B. Mollohan (D-WV), explaining DoD policy on jet injectors in response to the concerns of a constituent of the Congressman.

- (1998-1999) Manufacturer discontinuation of large multi-dose vials for yellow fever, meningococcal, and tetanus-diphtheria vaccines because of military withdrawal of Ped-O-Jets® capable of using them (MMQC-99-1248 dated 1998-Nov-03 and MMQC-99-1251 dated 1999-Aug-12).

- (1998-11-25) Navy Bureau of Medicine and Surgery authorizes military use of new disposable-cartridge jet injector (Preventive Medicine Directorate).

- Current DoD policies and information available at the Military Immunization Information Source http://www.cdc.gov/nip/dev/jetinject.htm

U.S. Department of Defense (DoD)

FDA Enforcement Report

The FDA Enforcement Report is published weekly by the Food and Drug Administration, U.S. Public Health Service, Department of Health and Human Services. It contains information on actions taken in connection with agency regulatory activities. Snap shot as of 9/18/08
http://www.fda.gov/bbs/topics/ENFORCE/ENF00058.html

Product: **Vernitron Majestic Table Top Sterilizers, Models 8080,**
V8000, or R816 a table top steam autoclave with an
8" x 8" x 16" chamber. Recall #Z-738/740-0.

Code:
All of the above model numbers manufactured prior to 1985. **(note: these autoclaves were used to sterilize the Ped-o-Jet Jetguns used by the military. Sterilization could not be guaranteed.)**

Manufacturer:
Vernitron Better Built Corporation (OOB), Carlstadt, New Jersey.

Recalled by:
Vernitron Medical Products, also known as Ped-O-Jet International, Dayton, New Jersey, by letter February 26, 1990. Firm-initiated field correction ongoing.

Distribution:
Nationwide, Canada, Korea.

Quantity:
Firm estimates fewer than 100 uncorrected units remain on market.

Reason:
The locking hub may detach from the unit at high pressure as a projectile and may also **cause a compromise of sterility of the contents of the sterilizer.**

CDC- MMWR Recommendations and Reports

January 28, 1994 / 43(RR01);1-38

General Recommendations on Immunization Recommendations of the Advisory Committee on Immunization Practices (ACIP)

The following CDC staff members prepared this report:* John C. Watson, MD, MPH Charles W. LeBaron, MD Sonja S. Hutchins, MD, MPH Stephen C. Hadler, MD Walter W. Williams, MD, MPH National Immunization Program, CDC

Jet Injectors

Jet injectors that use the same nozzle tip to vaccinate more than one person (multiple-use nozzle jet injectors) have been used worldwide since 1952 to administer vaccines when many persons must be vaccinated with the same vaccine within a short time period. These jet injectors have been generally considered safe and effective for delivering vaccine if used properly by trained personnel; the safety and efficacy of vaccine administered by these jet injectors are considered comparable to vaccine administered by needle and syringe.

The multiple-use nozzle jet injector most widely used in the United States (Ped-o-Jet) has never been implicated in transmission of bloodborne diseases. However, the report of an outbreak of hepatitis B virus (HBV) transmission following use of one type of multiple-use nozzle jet injector in a weight loss clinic and laboratory studies in which blood contamination of jet injectors has been simulated have caused concern that the use of multiple-use nozzle jet injectors may pose a potential hazard of bloodborne-disease transmission to vaccine recipients (10). **This potential risk for disease transmission would exist if the jet injector nozzle became contaminated with blood during an injection and was not properly cleaned and disinfected before subsequent injections.** The potential risk of bloodborne-disease transmission would be greater when vaccinating persons at increased risk for bloodborne diseases such as HBV or human immunodeficiency virus (HIV) infection because of behavioral or other risk factors (11,12).

Multiple-use nozzle jet injectors can be used in certain situations in which large numbers of persons must be rapidly vaccinated with the same vaccine, the use of needles and syringes is not practical, and state and/or local health authorities judge that the public health benefit from the use of the jet injector outweighs the small potential risk of bloodborne-disease transmission. This potential risk can be minimized by training health-care workers before the vaccine campaign on the proper use of jet injectors and by changing the injector tip or removing the jet injector from use if there is evidence of contamination with blood or other body fluid. In addition, mathematical and animal models suggest that the potential risk for bloodborne-disease transmission can be substantially reduced by swabbing the stationary injector tip with alcohol or acetone after each injection. It is advisable to consult sources experienced in the use of jet injectors (e.g., state or local health departments) before beginning a vaccination program in which these injectors will be used. Manufacturer's directions for use and maintenance of the jet injector devices should be followed closely.

Newer models of jet injectors that employ single-use disposable nozzle tips should not pose a potential risk of bloodborne disease transmission if used appropriately.

(((Thanks Roger))))

This reads as a ***tacit admission, problems existed with the jet injectors.*** .

NOVEMBER 1998
http://www-nehc.med.navy.mil/prevmed/epi/BUMED25NOV98.txt

SUBJ/**MEDICAL JET INJECTOR USE FOR IMMUNIZATIONS, UPDATE//**
REF/A/DOC/BUMEDNOTE 6230/20APR98//

REF/B/MSG/NAVMEDLOGCOM FORT DETRICK MD/081300ZDEC97/NOTAL//

NARR/REF A IS BUMED **IMMUNIZATION REQUIREMENTS AND RECOMMENDATIONS NOTICE**. REF B IS NAVMEDLOGCOM **DRUG RECALL** NUMBER 97-75, DOD-MMQC-97-1169

AUTOMATIC JET HYPODERMIC INJECTION UNITS/WITHDRAWAL (DPSC 970147).//
POC/MCBRIDE/CDR,MC,USN/MED-24B/WASHINGTON DC/TEL:COM (202)762-3495
/TEL:DSN: 762-3495//

RMKS/1. THIS MESSAGE HAS BEEN COORDINATED WITH THE COMMANDANT OF THE MARINE CORPS (CMC). THE COMMANDANT HAS AUTHORIZED TRANSMISSION TO MARINE CORPS ACTIVITIES.

2. PURPOSE: UPDATE GUIDANCE IN REFS A AND B ON USING COMMERCIAL JET INJECTORS FOR ADMINISTERING IMMUNIZATIONS.

3. BACKGROUND: SINCE ISSUING REFS A AND B, SEVERAL ACTIVITIES EXPRESSED INTEREST IN USING A NEW TRANSCUTANEOUS, CO2 POWERED IMMUNIZATION DEVICE MANUFACTURED BY BIOJECT, INC. THIS DEVICE, MARKETED AS "BIOJECTOR 2000 INJECTION MANAGEMENT SYSTEM", IS THE ONLY FOOD AND DRUG ADMINISTRATION (FDA) LICENSED HYPODERMIC JET INJECTOR. **IT AVOIDS RISKS OF BLOOD-BORNE PATHOGEN TRANSMISSION AND NEEDLE-STICK INJURY ASSOCIATED WITH PREVIOUSLY USED JET INJECTOR GUNS.**

4. GUIDANCE:

A. BIOJECTOR 2000 INJECTION MANAGEMENT SYSTEM IS AUTHORIZED FOR USE IN NAVY AND MARINE CORPS ACTIVITES FOR IMMUNIZATION ADMINISTRATION TO SERVICE MEMBERS AND OTHER BENEFICIARIES. AT THIS TIME, NO OTHER HYPODERMIC JET INJECTOR SYSTEM IS FDA APPROVED-THIS IS REQUIRED PRIOR TO CONSIDERATION FOR BUMED AUTHORIZATION.

B. USE OF HYPODERMIC JET INJECTOR APPARATUS LISTED IN REF B REMAINS UNAUTHORIZED.

C. WITH BIOJECTOR 2000, ESTIMATED COST PER INJECTION AND MECHANICS OF PREPARATION FOR EACH INJECTION MAY LIMIT COST AND PAGE 03 RUENMED3162 UNCLAS EFFICIENCY BENEFITS. HOWEVER, THESE **CONCERNS MAY BE OFFSET BY SAFETY ENHANCEMENT THROUGH AVOIDANCE OF BLOOD-BORNE PATHOGEN EXPOSURE AND ELIMINATION OF POSSIBLE NEEDLE-STICK INJURY** TO BOTH PATIENTS AND THOSE ADMINISTERING IMMUNIZATIONS. ALSO, SHARPS DISPOSAL IS

NOT NECESSARY.

5. POINTS OF CONTACT:
A. PROCUREMENT: NAVMEDLOGCOM, FORT DETRICK, MD-LT
WILLIAMS, TEL: (301)619-3086; DSN 343-3086 OR HM1
SPICER, TEL: (301)619-7118; DSN 343-7118.
B. BUMED-24: CDR MCBRIDE, (AS ABOVE)
EMAIL: WZMCBRIDE@US.MED.NAVY.MIL.//

RTAUZYUW RUENMED3162 3291800-UUUU--RUCOFAE.
ZNR UUUUU
RUCKMEA T CG II MEF
RUWICBD T CG FIRST FSSG
RUWICBE T CG I MEF

R 251800Z NOV 98 ZYB PSN 895734I36
FM BUMED WASHINGTON DC//24//
TO AIG SEVEN SEVEN EIGHT THREE
AIG SIX NINE FOUR SEVEN
INFO AIG ONE THREE SEVEN SEVEN SIX
BT
UNCLAS //N06230//
MSGID/GENADMIN/BUMED//

Potential for cross-contamination from use of a needleless injector._

CONCLUSION: This study demonstrated that needleless injectors become contaminated during in vitro use and direct contact with contaminated surfaces and that **needless injectors carry over the contamination to subsequent sites of release.** The replacement of the injector's rubber cap with a new one after initial discharge or the removal of an exposed rubber cap and immersion of the head of the injector in 2% glutaraldehyde followed by a rinse of the head in sterile water, as recommended by one injector manufacturer, can minimize or eliminate the carryover. View

Safety Testing of Needle Free, Jet Injection Devices to Detect Contamination with Blood and Other Tissue Fluids

JAMES M. SWEAT[a,b], et.al

"Five different procedures were used to administer injections to calves and pigs: (1) following compliance protocol (device nozzle is swabbed with alcohol between vaccinates)",....."It was interesting to note that the amount of backsplash resulting from injection using a disposable plastic nozzle was slightly less than that from the metal type"....."If albumin is detected in test samples (at more than 10 pL/mL), the conclusion is that the device is responsible for transmitting volumes of blood sufficient to contain pathogenic agents." View study

June 2003 excerpts from Federal Laboratory Community online paper

"The challenge was to solve the pathogen transfer problem while retaining the advantages of the needle-free injector system.

The technology transfer of a Russian-designed protector cap was the missing link needed to improve the safety found in this needle-free injector system. This protector cap provides three separate challenges to any pathogen transfer between patients. Each cap is packaged in a sterile container and exposed only immediately before injection. The cap is then disposed of after each use in a biohazard bag."
http://www.federallabs.org/ContentObjects/News/NewsLink/NewsLinkJune2003.pdf

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SHDEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH ADMINISTRATION,
FOOD AND DRUG ADMINISTRATION

GENERAL HOSPITAL & PERSONAL USE DEVICES PANEL

OPEN SESSION

Monday, August 2, 1999

Jet Guns were always cleaned between injections of the Military troops!

Quote: It = jet gun injectors

MR. HARRINGTON: Not necessarily. It was used by the Army for 35 years and it was always wiped. Never had an issue. Good tracking system. And there's nothing recorded in the world that says that it wasn't wiped. It's in a study that was presented using a method that isn't approved, it was not wiped and it said oh, we can contaminate 31 out of 100...

....What I'm saying to you is we believe that there are situations--the U.S. military for 35 years used the product appropriately. There was never an indicated transmission of hepatitis. Certainly they follow cases of hepatitis in the U.S. military.

PREVENTION AND CONTROL OF HEPATITIS B IN CENTRAL AND EASTERN EUROPE AND THE NEWLY INDEPENDENT STATES Click here jet gun injectors with a design fault that allowed blood to remain inside the equipment

Cost of tetanus toxoid injection using a jet-injector (Imule) in collective immunization in Senegal: comparison with injection using a syringe and resterilizable needle]

Needle-less jet injectors were developed by the US army after World War II. Their principal use, however, has been in the administration of lyophilized vaccines from multidose vials to at-risk populations in developing countries. In 1983, a hepatitis B epidemic occurred among customers of a beauty clinic in California (USA) following the use of jet-injectors, demonstrating a clear risk of cross-contamination associated with this technique. **As a result, the WHO and UNICEF stopped recommending jet-injectors for collective immunizations in developing countries** View study

Breaches in safe-injection practices CDC recommendations. How many were not practiced on you?
...Fourteen patients reported breaches in safe-injection practices by the practitioner, including **1) failure to practice hand hygiene, 2) failure to prepare the skin with an antiseptic, 3) failure to wipe vials with alcohol before injection, and 4) failure to wear gloves.** Of 11 patients who could recall, all reported use of a new needle; however, **nine patients reported use of a multidose vial.**

BOX. Infection-control and safe-injection practices

Injections

- Inject only substances approved by the Food and Drug Administration.*
- Use a sterile, single-use, disposable needle and syringe for each patient and discard intact in an appropriate sharps container after use.
- Use single-dose medication vials, prefilled syringes, and ampules when possible.
- Do not administer medications from single-dose vials to multiple patients or combine leftover contents for later use.
- If multiple-dose vials are used, restrict them to a centralized medication area or for single-patient use. Never reenter a vial with a needle or syringe used on one patient if that vial will be used to withdraw medication for another patient. Store vials in accordance with manufacturer's recommendations and discard if sterility is compromised.
- Do not use bags or bottles of intravenous solution as a common source of supply for multiple patients.
- Use aseptic techniques to avoid contamination of sterile injection equipment and medications.

Patient-care equipment

- Handle patient-care equipment, including medications that might be contaminated with blood or body fluids, in a manner that prevents skin and mucous membrane exposures, contamination of clothing, and transfer of microorganisms to other patients and surfaces.
- Evaluate equipment and devices for potential cross-contamination of blood and body fluids. Establish procedures for safe handling during and after use, including cleaning and disinfection or sterilization as indicated.

Work environment

- Dispose of used syringes and needles at the point of use in a sharps container that is puncture-resistant and leakproof and that can be sealed before completely full.
- Maintain physical separation between clean and contaminated equipment and supplies.
- Clean and disinfect equipment and surfaces after use in accordance with recommended guidelines.

Hand hygiene and gloves

- Perform proper hand hygiene (e.g., hand washing with soap and water or use of an alcohol-based hand rub) before preparing and administering an injection, before and after donning gloves, and between patients.
- Wear gloves for procedures that might involve contact with blood and change gloves between patients.

* Center for Drug Evaluation and Research, Food and Drug Administration. Index to drug-specific information. Available at http://www.fda.gov/cder/drug/drugsafety/drugindex.htm.

Jet injectors may transmit blood-borne infections

"Considering That in similar situations there is a **theoretical risk of transmission as high as 1 per 388"...** " conclusion can be reached that jet injectors can be safely used in the medical practice if they are protected by the sterile anticontaminant disposable device" View study

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An outbreak of hepatitis B associated with jet injections in a weight reduction clinic. None of the 22 persons who had received injections only by syringe experienced hepatitis B virus infection. Stopping the use of the jet injectors on July 2, 1985, at clinic 1, was associated with the termination of this outbreak. This investigation **demonstrated that jet injectors can become contaminated with hepatitis B virus and then may be vehicles for its transmission.** View study

INFO: Potential for Cross-Contamination From Use of a Needleless Injector.

The in vitro fluorescein indicator tests conducted in this study clearly show that needleless injectors become contaminated on use. The contact of the injector's discharge orifice, head, and rubber cap with surfaces simulating body tissues and fluids during the in vitro tests generally **resulted in the contamination of these 3 sites on the device.** View study

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Virus transmission by subcutaneous jet injection.

The **virus infection was transmitted by subcutaneous jet injection in 16 cases out of 49**. Other routes of cross-infection were ruled out. Before using the jet injector as a harmless instrument for mass subcutaneous injection, further experiments on the risks of virus transmission should be performed View study

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P*ossible infectious causes in 651 patients with acute viral hepatitis during a 10-year period (1976-1985).*

Six hundred and fifty-one patients with acute viral hepatitis were identified serologically between January 1976 and December 1985. Of these, 109 (17%) had hepatitis A, 135 (21%) had hepatitis B, and **407 (62%) had hepatitis non-A, non-B.**.."For hepatitis non-A, non-B, the most important infectious cause was medical procedures (65%)"... These data suggest that hepatitis non-A, non-B can be a kind of nosocomial disease. View study

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JUL 9, 1998 THE ASSISTANT SECRETARY OF DEFENSE WASHINGTON, D.C. 20301-1200 HEALTH AFFAIRS

Dr Sue Bailey: " However, there is concern that use of jet injectors may pose a potential risk for translating bloodborne infections to vaccine recipients. **Laboratory studies in Brazil and the United Kingdom suggest that bloodborne transmission theoretically could occur with use of jet injectors...**...a DoD Medical Quality Assurance System Device Alert on December 9, 1997, recommended that use of all jet injectors be discontinued. This action was taken in response to a letter from Ped-O-Jet International, the manufacturer of the jet injector product most commonly used in DoD. The manufacturer notified us that they were discontinuing producing and servicing their product... they "strongly urged the Armed Forces to discontinue use of the product" until studies conclude that no risk is present for bloodborne disease transmission. View study

National Immunization Program Centers for Disease Control

"To date, the transmission of the hepatitis C virus by "air gun" vaccination has not been documented. However, **in theory, it is entirely possible that the virus can be transmitted in this fashion.** The transmission of the hepatitis B virus (which is also transmitted by blood exposure) by this type of instrument has been documented in a very small number of cases. The hepatitis C virus can be transmitted by the use of an unsterilized needle by more than one person. It is possible that you were exposed to the hepatitis C virus in either of the instances you mention.
Suzanne Johnson-DeLeon, M.P.H.
Bilingual Health Educator
National Immunization Program
Centers for Disease Control

World Health Organization Statements on Jet Gun Injection and Transmission of Blood Born Pathogens

....the metal cap was found to be **contaminated after 1 in 7 injections** View study

note: Iatrogenic = hepatitis

Iatrogenic contamination of multidose vials in simulated use. A reassessment of current patient injection technique.

Arch Dermatol. 1990 Nov;126(11):1441-4.
PMID: 2173497; UI: 91053223.

Contamination susceptibility of three needleless and one standard needle injection systems.

Can J Anaesth. 1999 Mar;46(3):290-3.
PMID: 10210058; UI: 99224764.

Fluid mechanics analysis of a spring-loaded jet injector.

IEEE Trans Biomed Eng. 1999 Feb;46(2):235-42.
PMID: 9932345; UI: 99131137.

ABSTRACT:
A syringe jet injector is a device designed to administer a drug quickly and painlessly through the skin. Though syringe jet injectors have been in use for almost 50 years, current designs still suffer from inconsistent performance. To better understand the fluid mechanics of jet injection and gain insight into how the design might influence performance, two theoretical analyses to determine the fluid pressure profile at the exit orifice were conducted. The first was a continuum analysis assuming static incompressibility.

Results demonstrated that the **maximum jet pressure was highly sensitive to the spring constant,** initial piston velocity, and piston cross-sectional area while the time to achieve the maximum pressure was most sensitive to the injection chamber length, initial piston velocity, bulk modulus of the injectant, and the

piston cross-sectional area. The second analysis was a shock wave analysis. Results demonstrated a stepwise pressure-time plot that was similar in magnitude to that for the continuum analysis assuming static incompressibility. Results from these two investigations are useful for design modification of the **jet injector to achieve desired pressure-time profiles at the orifice.** Control of pressure-time profiles may help to achieve a more consistent and effective injection process.

NLM PUBMED CIT. ID: 9932345

SOURCE: IEEE Trans Biomed Eng 1999 Feb;46(2):235-42

More Studies

Evaluation of the insulin jet injector as a potential source of infection.
Am J Infect Control. 1989 Oct;17(5):258-63.
PMID: 2683885; UI: 90054504.

Position statement on jet injectors.
Diabetes Care. 1988 Jul-Aug;11(7):600-1. No abstract available.
PMID: 3060330; UI: 89078140.

Jet injectors and infection.
Public Health. 1987 May;101(3):147-9. No abstract available.
PMID: 3588820; UI: 87232503.

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{Dunne1954} Dunne B, Cassen B. Some phenomena associated with supersonic liquid jets. J Appl Physics, May 1954;25:569-572.
{Carpenter1965} Carpenter CL, Jolly HW Jr, Reed RJ. Dermojet histopathological artifacts. Arch Dermatol 1965;92:304.

{Rey1965b} Rey M, Baylet R, Cantrelle P, Dauchy S, Diop Mar I, Guerin M. Vaccination contre la rougeole en mileu rural sénégalais par un vaccin vivant suratténué (Schwarz) au moyen d'un injecteur sans aiguille (Dermojet). Possibilités d'association avec le vaccine [Vaccination against measles in a rural Senegalese environment with overattenuated live vaccine (Schwarz) by means of an injector without a needle (Dermojet). Possibilities of interaction with vaccine]. Bull Société Médicale d'Afrique Noire de Langue Française. 1965;10(3):392-406.

{Lenz1966} Lenz TR. Foreign body granuloma caused by jet injection of tetanus toxoid. Rocky Mountain Med J 1966;63:48.
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[Lukin1997 tested transmissibility of virulent “Trinidad” strain of Venezuelan Equine Encephalitis virus in lab animals - guinea pigs, rabbits, and monkeys using stock and modified BI-19, BI-1M and BI-3 jet injector models. Following a total of 534 injections into infected animals followed by 534 injections into a paired uninfected one, 15 (2.8%) uninfected injection recipients became infected with VEE. Transmission did not occur at virus concentrations in donor rabbits of 4.5IgDL50/mL and dose volumes of 0.1 to 0.2 mL, but did occur when dose volumes were 0.5 mL. At virus concentrations of 6.0IgDL50/mL in the donor animal, transmission occured regardless of volume injected. **Modification of the devices BI-19 and BI-1M with “rubber caps” and BI-3 injector with a changed angle of jet penetration resulted in no transmisson of infection, even with concentrations up to 7.0IgDL50/mL and volumes up to 1.0 mL.]**

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PATH is a nonprofit, nongovernmental, international organization. PATH's mission is to improve health.....

Health Need: With the advent of the AIDS epidemic, and a clearer understanding of the transmission of hepatitis B and other bloodborne diseases through the use of unsafe needles worldwide, safe-injection technologies have become a high priority for international health agencies. Reuse of contaminated syringes, needlestick injuries among health workers, and threats to the community from improperly disposed of and contaminated sharps waste are serious health risks. Multi-dose jet injectors, although credited with decades of use in the field, are **no longer used due to evidence of cross-contamination between injections**. The availability of a safe and contamination-free multi-dose jet injector would have great beneficial impact on public health worldwide

Technology: Under the HealthTech program, PATH has partnered with Felton International, Inc., of Kansas, and MedEquipment of Voronezh, Russia, in the evaluation, testing, and design refinement of a multi-dose jet injector developed and manufactured by MedEquipment. This is a high-workload injector (designated BI-100), intended for use in mass immunization campaigns. **The injector utilizes disposable protector caps that prevent retrograde passage of infectious material to the jet-injector nozzle.** This is a novel and effective approach to eliminating cross contamination between injections, while maintaining a high rate of vaccine delivery to multiple patients

http://www.path.org/files/htup-JetInjector.pdf+safety+of+multi-dose+jet+injection&hl=en&ie=UTF-8

August 2003, one regional office issued a rating decision granting service connection for hepatitis C virus (HCV) infection as the result of immunization with a “jet air gun.” The VA has counteracted by saying the statements made by three members during veterans lobbie trip to DC. misleading statement, incorrectly ascribed to Lawrence Deyton MSPH, MD Chief Consultant, Public Health Strategic Health Care Group, US Department of Veterans Affairs, Washington,†DC is posted on the Internet (http://www.hcvets.com/). On this site, the following is incorrectly ascribed to Dr. Deyton: "Anyone who had inoculations with the jet injector were [sic] at risk of having hepatitis C and should be tested."

http://www.hepatitis.va.gov/vahep?page=scpl-00-01

DEPARTMENT OF VETERANS AFFAIRS
Veterans Benefits Administration Washington, D.C. 20420

June 29, 2004

Director (00/21) In Reply Refer To: 211
All VA Regional Offices Fast Letter 04-13

SUBJ: Relationship Between Immunization with Jet Injectors and Hepatitis C Infection as it Relates to Service Connection

BACKGROUND: In August 2003, one regional office issued a rating decision granting service connection for hepatitis C virus (HCV) infection as the result of immunization with a “jet air gun.” A misleading statement, incorrectly ascribed to Lawrence Deyton MSPH, MD Chief Consultant, Public Health Strategic Health Care Group, US Department of Veterans Affairs, Washington,†DC is posted on the Internet (http://www.hcvets.com/). On this site, the following is incorrectly ascribed to Dr. Deyton: "Anyone who had inoculations with the jet injector were [sic] at risk of having hepatitis C and should be tested."

KEY POINTS:
• HCV is spread primarily by contact with blood and blood products. The highest prevalence of HCV infection is among those with repeated, direct percutaneous (through the skin) exposures to blood (e.g., injection drug users, recipients of blood transfusions before screening of the blood supply began in 1992, and people with hemophilia who were treated with clotting factor concentrates before 1987).

• Since the 1990’s, injection drug use has been the principal mode of transmission of HCV. Because of screening procedures, HCV is now only rarely transmitted by blood product transfusion or organ transplant. Clotting factor concentrates are processed in such a way that the virus is inactivated; these viral inactivation procedures have virtually eliminated clotting factor concentrates as a source for HCV.

• Population studies suggest HCV can be sexually transmitted. However, the chance for sexual transmission of hepatitis C is well below comparable rates for HIV/AIDS or hepatitis B infection. Researchers studied five groups of

monogamous couples, in which only one was infected with HCV. Less than five percent of the uninfected partners became infected with HCV during the time periods studied.

• Occupational exposure to HCV may occur in the health care setting through accidental needle sticks. A veteran may have been exposed to HCV during the course of his or her duties as a military corpsman, a medical worker, or as a consequence of being a combat veteran.

• When needles (and other objects that puncture the skin) are contaminated with HCV infected blood and are then used by others, HCV can be transmitted. HCV can potentially be transmitted with reuse of needles for tattoos, body piercing, and acupuncture.

• The hepatitis B virus is heartier and more readily transmitted than hepatitis C. While there is at least one case report of hepatitis B being transmitted by an airgun injection, thus far, there have been no case reports of HCV being transmitted by an airgun transmission.

• The source of infection is unknown in about 10 percent of acute HCV cases and in 30 percent of chronic HCV cases. These infections may have come from blood-contaminated cuts or wounds, contaminated medical equipment or multi-dose vials of medications.

CONCLUSION:
The large majority of HCV infections can be accounted for by known modes of transmission, primarily transfusion of blood products before 1992, and injection drug use. Despite the lack of any scientific evidence to document transmission of HCV with airgun injectors, it is biologically plausible. It is essential that the report upon which the determination of service connection is made includes a full discussion of all modes of transmission, and a rationale as to why the examiner believes the airgun was the source of the veteran's hepatitis C.

/s/
Carolyn F. Hunt
Acting Director
Compensation and Pension Service

FOR IMMEDIATE RELEASE
Contact: Press Office, 540-248-7324
by Staff

February 28, 2005

Plan Backfires- VBA Fast Letter Boost Claims

BUSH ADMINISTRATION FIGHTS AGAINST SERVICE CONNECTED DISABILITY FOR VETS WITH HEPATITIS C

Top Guns with the Department of Veterans Affairs (VA) are going on the offensive to prevent veterans from getting service connected disability for HEPATITIS C transmitted by airgun shots before, during, and after the Vietnam War.

Three decades after the end of the war, hundreds of thousands of brave men and women who served their country are dying, and the Bush Administration is fighting their attempts to get pensions and adequate VA medical treatment. An estimated 95% of all claims are denied, despite reliable scientific evidence.

In April 2002, a delegation of members representing the HEPATITIS C Movement for Awareness (HMA) and HCVets.com, a HEPATITIS C military claims support organization for families, went to Washington DC on a mission to educate representative concerning HEPATITIS C related issues.

The delegation had appointments with Congressional and Veterans Affairs representatives. One of these meetings was with Lawrence Deyton MSPH, MD Chief Consultant, Public Health Strategic Health Care Group, for the VA.. Members met specifically with Dr. Deyton to expressed concern regarding transmission methods for the HEPATITIS C virus listed by the VA, and the need to reform qualifications for testing Veterans. Those attending the VA will not get tested because they did not use drugs or become an alcoholic, risk factors used to qualify patients for testing. Members requested Dr. Deyton include reused needles, vials, syringes and airguns in this determination to test Veterans.

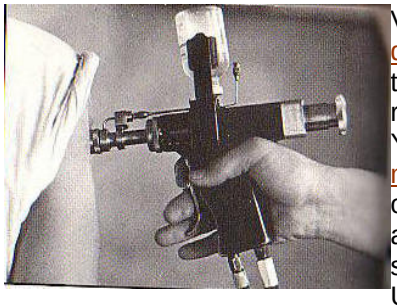
Dr. Deyton acknowledged these risks, stating "his hands were tied". He stated, "Anyone receiving airgun injections, should get tested for HEPATITIS C." Deyton did not just say "Veterans", says Ed Wendt, Vietnam era Veteran, transplant survivor and HMA's Government Relations Director. Quoting members who attended the meeting, Deyton implied "everyone" receiving shots administered by the now defunct style airguns, should be tested.

HMA published Dr. Deyton's quote in an upcoming newsletter which resulted in a Veteran service connected for HEPATITIS C at the regional VA level. The decision was based on that quote, plus other evidence submitted that demonstrated the products used to sanitize & disinfect medical and dental equipment, did not kill the HEPATITIS C virus.

In order to counteract the decision and avoid accountability for the 2 plus million service related infections, the Department of Veterans Affairs Veterans Benefits Administration, in charge of the regional office that approved the claim, issued a "Fast Track" letter, a sort of report, to all regional offices, calling Dr. Deyton's quote, a misquote. But, Wendt, says, "we did not misquote Dr. Deyton as the allegations suggest in the VBA Fast letter." "Members were very clear on what

they heard." Further quotes were made by Dr. Deyton to the Kansas City Star's investigative report Mike McGraw. Dr. Deyton is quoted as saying, "it's possible the devices could transmit HEPATITIS C: Deyton continues, "I am sure that, with the right degree of misuse, the devices could become contaminated."

In the Fast Track letter, Carolyn F. Hunt, Acting Director, for Compensation and Pension Service states: "..needles (and other objects that puncture the skin) are contaminated with HCV infected blood and are then used by others, HCV can be transmitted. HCV can potentially be transmitted with reuse of needles for tattoos, body piercing, and acupuncture.", ".....infections may have come from blood-contaminated cuts or wounds, contaminated medical equipment or multi-dose vials of medications."



Vaccinations were routinely given with multi-dose vials and reused needles. Injection give by the airguns included HEPATITIS B vaccine; responsible for the outbreak of AIDS in New York City, in which an astounding 64% of the men who got the vaccine developed AIDS and other blood-borne viruses. Access is not available for testing stored patients blood samples for HEPATITIS C infection rate The U.S. Department of Justice is keeping this information "classified" and "unavailable" for public research and investigation..

Ms. Hunt also states, "Blood-contaminated cuts or wounds can spread HEPATITIS C". "This statement speaks volumes", says Harry Hooks, Vietnam combat Veteran and manager of HCVets.com. "Airplane and auto mechanics, or others at risk for cuts, that shared rags to wipe the wound, could be at risk. HEPATITIS C lives for weeks after the blood has dried. It can be reconstituted and transmit to others."

In the letter, Ms. Hunt continues to say "It is essential that the report upon which the determination of service connection is made includes a full discussion of all modes of transmission, and a rationale as to why the examiner believes the airgun was the source of the veteran's HEPATITIS C."

But Hooks says, "Veteran's submitted convincing scientific studies, military reports and physicians letters in support with their claims, showing the only risk for their HEPATITIS C infection was the service." Evidence submitted, such as the "Vaccines in the Military:" A Department of Defense-Wide Review of Vaccine Policy and practice; an Infectious Diseases Control Subcommittee of the Armed forces Epidemiological Board review presented in August 1999. Page 61 discusses the Paris Island Air Force inspection in which inspectors indirectly observing high volume recruit immunization using jet injectors. It was noted "jet injector nozzles were frequently contaminated with blood, yet sterilization practices were frequently inadequate or not followed." The complete report can be viewed here

Military Veterans also submitted government testimony in support of their claims. Such as the statement by Robert Harrington, owner of the company PED-O-JET, maker of the military airguns used on the troops. During a meeting with the FDA, VA and others, he states "if the gun was not wiped off, it could contaminated 31 out of 100 patients."
Despite their efforts, the claims are denied.

"All people that served in the military know the airguns were not wiped off for military application", says Hooks.

"The VA would prefer if veterans evidence was not included", Hooks continues,

"according to correspondence with a Pittsburgh VA, the VA has a staff of medical personnel to review information and provide judgment based on their training and research. The problem is, say's Hooks, "to the best of my knowledge, no one's training these adjustors about HEPATITIS C transmission. I think the denial rate for VA claims proves that."

"One thing is very clear", says Tricia Lupole, National Director for HMA, "It's the VA lacking rationale, the VA denied service connection to one Veteran shot in the chest in Vietnam in 1968 and transfused. He died from HEPATITIS C liver cancer in 2003. Another patient was hospitalized with HEPATITIS during military service and the VA claims his HEPATITIS C is not service connected. Yet another, denied because he fell within the group that, according to the VA, has "no clue" how the virus was transmitted; virtually ignoring every statement Ms. Hunt made.

A claim recently denied, would not acknowledge the fact the Veteran found a buddy stationed with him during most of his service. The buddy also has the same strain of HEPATITIS C. The virus has many different types of strains, called genotypes. There are 6 different genotypes and over 50 subtypes within those strains. The state and federal court system use a test to determine "same source" infection when exposure to the virus occurs though hospital neglect, meaning that science can tell if people were infected by the same source. But, the VA will not run this test or accept any evidence to support it. We're not going to let the VA get away with this."

Lupole says, "Despite the attempts to portray HCVets.com an unreliable source, the letter works to the Veterans advantage because it acknowledges possible ways for transmitting the virus previously denied by the VA claim adjusters. Claims that are pending or previously denied, should consider this as critical evidence to include.

More information on service related transmission methods for the HEPATITIS C virus can be found at http://hcvets.com

http://hcvets.com/data/transmission_methods/SterilantsDisinfectants.htm evidence submitted that demonstrated the products used to sanitize & disinfect medical and dental equipment, did not kill the HEPATITIS C virus.

http://www.march-on-dc.com/National/News/2005/02/data/JobRelatedInfection.htm