

BIOBEHAVIORAL SYSTEMS

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23 January 2007

FREEDOM OF INFORMATION REQUEST

Elias A. Zerhouni, M.D.
Director
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

Dear Dr. Zerhouni,

This is a request for information under the Freedom of Information Act.

On 15 December 2006, I emailed a request to Dr. Fauci on information concerning the controls for personal genital hygiene in the recent NIH report that circumcision reduces HIV about 50-60 percent. His office referred me to Dr. Ronald Gray, Principle Investigator of the research project that reported these findings.

My email letter to him of 4 January 2007 was promptly responded to on the same day with the following reply "We did promote genital hygiene both for intervention and control arm participants, but we did not provide Medwipes." He referred me to Professor Taha for further information but forgot to include her email address. I replied on 4 January 2007 requesting Professor Taha's email address, which he provided on 5 January 2007 with no further comment. As of this date of 23 January 2007 I have not heard from Professor Taha.

I had requested from Dr. Gray the following information:

1. Protocol that details the controls for personal genital hygiene.
2. The appropriate most cost-effective biocide that would be used in the Medwipes.
3. Whether cultures were conducted prior to and after circumcision (6 months and one year) to determine levels of HIV. Similarly for the use of Medwipes when the study is conducted.

The only answer that I received from Dr. Gray was that Medwipes were not used and the statement "I believe it is an important intervention that needs to be rigorously evaluated".

My intention with these letters of concern is to avoid the potentially worst world-wide medical blunder of the 21st Century, if it was demonstrated the use of Medwipes on a daily basis and immediately before intercourse, would accomplish the same effects as circumcision.

It is alarming to read in a *New York Times* report on this circumcision study the following:

Outside Muslim regions, circumcision is spotty. In South Africa, for example, the Xhosa people circumcise teen-age boys, while Zulus, whose traditional homeland abuts theirs, do not. AIDS is common in member of both tribes. and

They were given safe sex advice "although many presumably did not take it" and retested regularly. and

Uncircumcised men are thought to be more susceptible to AIDS because the underside of the foreskin is rich in Langerhans, cells, which attach easily to the virus. The foreskin may also suffer small tears during intercourse, making it more susceptible to infection (an unsubstantiated hypothesis that needs verification). (NYT, Circumcision Reduces Risk of AIDS, Study Finds, 13 Dec 05).

An explanation is needed why Zulus, who do not circumcise their teen-age boys, have the same infection rate as the Xhosa people who do circumcise.

The rush to judgment by the NIH and the *New York Times Magazine* to claim effectiveness of circumcision in reducing HIV infection has mislead the nation and the world. "But we must not let our hope for a thunderbolt prevent us from racing ahead with circumcision now" (NYTM: A Real-World AIDS Vaccine? (14 Jan 07).

I am concerned that modern medicine has forgotten it own history with respect to the role that personal hygiene has in the prevention of disease. A short biosketch of Ignac Fulop Semmelweis is attached, who in 1844 and 1848 virtually eliminated women dying in childbirth by having the physicians and students wash their hands in chlorinated lime before entering the maternity ward. "Under these procedures, the mortality rates in the first division dropped from 18.27 to 1.27 percent, and in March and August of 1848 no woman died in childbirth in his division."

The medical profession was hostile to his discovery. "At a conference of German physicians and natural scientists, most of the speakers--including the pathologist Rudolf Virchow--rejected his doctrine. The years of controversy gradually undermined his spirit. In 1865 he suffered a breakdown and was taken to a mental hospital, where he died (Encyclopaedia Britannica Article, attached).

In America, circumcision and clitoridectomy was the nineteenth century answer to masturbation where the superintendent of the Massachusetts Lunatic Asylum stated in his 1848 annual report that 32 percent of admissions were for "self-pollution" and in 1889 Joseph Jones, M.D. a former president of the Louisiana State Board of Health and a medical professor stated that "hopeless insanity" was one of the many consequences of masturbation and that the child of a masturbator was liable to hereditary insanity (Duffy, 1963). These medical views on the dangers of masturbation are rooted in ancient Judeo-Christian teachings (Prescott, 1989). (<http://www.montagunocircpetition.org/>)

Surgery is a measure of last resort not the first resort. Behavior has always been the first line of defense against ill health and disease. Sanitary engineers have done more for the public health of a nation than all of modern medicine combined. Clean water, clean air, clean earth, clean behaviors are indispensable for the development of a healthy organism. Toxic environments produce toxic organisms.

Modern medicine has made many errors in the past and the NIH should not be lead to repeat those errors, as it appears that you are on the brink of doing so. It is difficult to contemplate the medical profession embarking on a surgical path of millions of circumcisions with the massive supporting health infrastructure that will be required when simple acts of personal genital hygiene would suffice.

I will look forward to receiving the information requested and trust that this analysis will prompt a more careful view of circumcision being, in part, a solution to HIV-AIDS. I trust that you will communicate these concerns to Dr. Fauci and Dr Gray.

Sincerely,

James W. Prescott, Ph.D.
Director

Duffy, J (1963). Masturbation and Clitoridectomy. *The Journal of the American Medical Association*. Vol 186, pp. 246-248.

Prescott. J.W. (1989). Genital Pain vs. Genital Pleasure: Why the One and Not The Other? *The Truth Seeker*. July/August pp. 1421. <http://www.montagunocircpetition.org/>

P.S. Since this letter was written, it was reported by Lawrence Altman, International Herald Tribune , that studies of microbicides were terminated because evidence of failure. He reported:

Family Health International of Research Triangle Park, North Carolina, conducted the second trial involving 1,700 participants in Nigeria. The study found neither a benefit in preventing HIV infection nor an increased risk of developing it.

So, given the adverse findings in the Conrad trial, "the responsible course of action was to halt our study," said Dr. Vera Halpern, the principal investigator of the Family Health International trial. <http://www.iht.com/articles/2007/02/01/news/aids.php>

February 1, 2007.

Ignaz Philipp Semmelweis

Encyclopædia Britannica Article (German)ä

born July 1, 1818, Buda, Hungary, Austrian Empire [now Budapest, Hung.]
died August 13, 1865, Vienna, Austria

Hungarian Ignác Fülöp Semmelweis German-Hungarian physician who discovered the cause of puerperal ("childbed") fever and introduced antiseptics into medical practice.

Educated at the universities of Pest and Vienna, Semmelweis received his doctor's degree from Vienna in 1844 and was appointed assistant at the obstetric clinic in Vienna. He soon became involved in the problem of puerperal infection, the scourge of maternity hospitals throughout Europe. Although most women delivered at home, those who had to seek hospitalization because of poverty, illegitimacy, or obstetrical complications faced mortality rates ranging as high as 25-30 percent. Some thought that the infection was induced by overcrowding, poor ventilation, the onset of lactation, or miasma. Semmelweis proceeded to investigate its cause over the strong objections of his chief, who, like other continental physicians, had reconciled himself to the idea that the disease was unpreventable.

Semmelweis observed that, among women in the first division of the clinic, the death rate from childbed fever was two or three times as high as among those in the second division, although the two divisions were identical with the exception that students were taught in the first and midwives in the second. He put forward the thesis that perhaps the students carried something to the patients they examined during labour. The death of a friend from a wound infection incurred during the examination of a woman who died of puerperal infection and the similarity of the findings in the two cases gave support to his reasoning. He concluded that students who came directly from the dissecting room to the maternity ward carried the infection from mothers

who had died of the disease to healthy mothers. **He ordered the students to wash their hands in a solution of chlorinated lime before each examination.**

Under these procedures, the mortality rates in the first division dropped from 18.27 to 1.27 percent, and in March and August of 1848 no woman died in childbirth in his division. The younger medical men in Vienna recognized the significance of Semmelweis' discovery and gave him all possible assistance. His superior, on the other hand, was critical—not because he wanted to oppose him but because he failed to understand him.

In the year 1848 a liberal political revolution swept Europe, and Semmelweis took part in the events in Vienna. After the revolution had been put down, Semmelweis found that his political activities had increased the obstacles to his professional work. In 1849 he was dropped from his post at the clinic. He then applied for a teaching post at the university in midwifery but was turned down. Soon after that, he gave a successful lecture at the Medical Society of Vienna entitled "The Origin of Puerperal Fever." At the same time, he applied once more for the teaching post, but, although he received it, there were restrictions attached to it that he considered humiliating. He left Vienna and returned to Pest in 1850.

He worked for the next six years at the St. Rochus Hospital in Pest. An epidemic of puerperal fever had broken out in the obstetrics department, and, at his request, Semmelweis was put in charge of the department. His measures promptly reduced the mortality rate, and in his years there it averaged only 0.85 percent. In Prague and Vienna, meantime, the rate was still from 10 to 15 percent.

In 1855 he was appointed professor of obstetrics at the University of Pest. He married, had five children, and developed his private practice. His ideas were accepted in Hungary, and the government addressed a circular to all district authorities ordering the introduction of the prophylactic methods of Semmelweis. In 1857 he declined the chair of obstetrics at the University of Zürich. Vienna remained hostile toward him, and the editor of the Wiener Medizinische Wochenschrift wrote that it was time to stop the nonsense about the chlorine hand wash.

In 1861 Semmelweis published his principal work, *Die Ätiologie, der Begriff und die Prophylaxis des Kindbettfiebers* ("Etiology, Understanding and Preventing of Childbed Fever"). He sent it to all the prominent obstetricians and medical societies abroad, but the general reaction was adverse. The weight of authority stood against his teachings. He addressed several open letters to professors of medicine in other countries, but to little effect. **At a conference of German physicians and natural scientists, most of the speakers—including the pathologist Rudolf Virchow—rejected his doctrine. The years of controversy gradually undermined his spirit. In 1865 he suffered a breakdown and was taken to a mental hospital, where he died.** Ironically, his illness and death were caused by the infection of a wound on his right hand, apparently the result of an operation he had performed before being taken ill. He died of the same disease against which he had struggled all his professional life.

Semmelweis' doctrine was subsequently accepted by medical science. His influence on the development of knowledge and control of infection was hailed by Joseph Lister, the father of modern antisepsis: "I think with the greatest admiration of him and his achievement and it fills me with joy that at last he is given the respect due to him."

Imre Zoltán



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, MD 20892

February 12, 2007

James Prescott
1140-17 Savannah Road
Lewes, DE 19958

Re: FOI Case No. 33498

Dear Mr. Prescott:

This acknowledges your January 23, 2007, Freedom of Information Act (FOIA) request addressed to Dr. Elias A Zerhouni, Director of the National Institute of Health, which was forwarded to the National Institute of Allergy and Infectious Diseases (NIAID) Freedom of Information Office. You requested a copy of Trial of Male Circumcision to Reduce HIV Incidence Protocol. You are specifically interested in:

1. The protocol that details the controls for personal genital hygiene.
2. The appropriate most cost-effective biocide that would be used in the Medwipes
3. Whether cultures were conducted prior to and after circumcision (6 months and one year) to determine levels of HIV. Similarly for the use of Medwipes when the study is conducted.

We have queried the NIAID Division of Acquired Immunodeficiency Syndrome. If any documents responsive to your request are located, they will be reviewed for releasability. We will do everything possible to comply with your request in a timely manner. Please feel free to call me on (301) 451-5109 for additional information or to inquire about the status of your request.

Provisions of the FOIA allow us to recover part of the cost of complying with your request. We shall charge you for records in accordance with the Department of Health and Human Services FOIA regulations as they apply to individual requesters; i.e., you will be charged for duplication at 10-cents per page although the first 100 pages are free; 2 hours of search time are free and thereafter search time is charged at the hourly rate (\$20.00, \$40.00 and \$72.00) of the searcher; there is no charge for review time. If there are any fees associated with processing this request, you will be sent an invoice with our final response.

Sincerely,

Susan Boyle
Freedom of Information Coordinator (Acting)
National Institute of Allergy and Infectious Diseases

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15 February 2007

Ms Susan Boyle
Freedom of Information Coordinator
National Institute of Allergy and Infectious Diseases
6610 Rockledge Drive, MSC 6605
Bethesda, MD 20892

FOIA Case No 33498

12 February 2007

Dear Ms Boyle,

I am withdrawing my request for information under the FOIA, as I was not aware that such requests carry charges. My letter to Dr. Zerhouni was a simple request for information, which has been denied me, as a concerned health professional.

My letter to Dr. Zerhouni stands on its merit without the burdensome characteristics of the FOIA. The refusal to answer a simple inquiry as to what the most effective microbiocide agent to control for HIV infections has been unconscionably withheld from me. Neither Dr. Fauci nor Dr. Gray responded to such a simple request. The answer is that there is no microbiocide agent, as the recent report by Lawrence K. Altman "Safety concerns halt trials of HIV microbiocide" (February 1, 2007) International Herald Tribune has documented.

Dr. Zerhouni, Fauci and Gray certainly must be aware of these results and their refusal to provide this information to a concerned health professional can only be considered an obstruction of science. My letter to Dr. Zerhouni with attachments is posted at <http://www.violence.de/politics.shtml> --scroll to bottom of page.

I am requesting that Dr. Zerhouni provide me with the information requested, as I am trying to avert what could be the biomedical blunder of the 21st century.

Sincerely,

James W. Prescott, Ph.D.
Director

cc: Dr. Zerhouni

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13 March 2007

Lawrence K. Altman, M.D.
Medical Columnist
The New York Times
229 West 43rd Street
New York, NY 10036

Dear Dr. Altman,

As a health professional, I am concerned about the failure of the NIH to acknowledge its failure to control for personal genital hygiene in its studies on the effects of circumcision to control for HIV infection and its recommendation that circumcision is an effective intervention to control for the spread of HIV infections.

My request for information on the exact controls for personal genital hygiene that were utilized in these studies has been denied and what would be the most effective microbicide to be used in Medwipes that could be distributed along with condoms was not responded to. The history of these communications is summarized in my letter to Dr. Zerhouni of 23 January 2007, which has not been answered. The NIH has not acknowledged your report of 1 February 2007 that a study of microbicide was terminated because of evidence of failure (enclosed).

I am alarmed that the NIH would permit misleading information on the effects of circumcision to control the spread of HIV infection be permitted to circulate in the press including *The New York Times* given the lack of controls and the future availability of effective microbicide (see enclosures).

The NIH Microbicide Trials Network (MTN) is holding a conference on these issues (March 27-29, 2007) at the Marriott Wardman Park in Washington, DC, which I hope you will attend to bring the latest information and balance on the role of microbicide v circumcision to world attention. Any information that you can obtain with respect to controls for personal genital hygiene utilized in these HIV studies would be appreciated.

The lessons learned from Ignaz Philipp Semmelweis, a German-Hungarian physician (1818-1865), that failure of personal hygiene (not washing one's hands) was the cause of high maternal childbirth deaths has apparently been lost on the NIH investigators, attached). As I have pointed out in my letter to Dr. Zerhouni, circumcision--a surgical procedure--to control for infectious disease is absurd as its claim to cure the ills of masturbation.

As George Santayana has reminded us in *The Life of Reason* (1905) "Those who cannot remember the past are condemned to repeat it."

Perhaps, with your assistance, the greatest medical blunder of the 21st century--circumcision to control for an infectious disease-- can be avoided.

Sincerely,

James W. Prescott, Ph.D.
Director

<http://www.app.com/apps/pbcs.dll/article?AID=/20070305/LIFE11/70305027>
http://www.redorbit.com/news/health/854802/matteks_epivaginal_excel_in_microbicide_hiv_research_study/index.html?source=r_health#